“Smart Labels”: Improving Syringe Labeling Compliance and Patient Safety in the Operating Room

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Introduction

The preparation and labeling of medications for anesthesia is a time consuming, multi-step and error-prone process [1,2] . The Joint Commission (JC) and ASA have specific requirements for labeling medications as a means of mitigating this problem; however 17% of hospitals receive a citation for improper labeling of medication and solutions[3] .

This study evaluated a novel, barcode based solution (SmartLabels) that may provide a systems-level solution to ensure 100% compliance with JC and ASA medication labeling requirements and may improve patient safety and clinician communication.

Methods

Baseline compliance with ASA and JC requirements were evaluated over a one month period at two large academic medical centers. Syringes were assessed for the following elements (according to hospital policy): drug name, concentration, date of preparation, time of preparation, and clinician initials or if it was a pre-filled syringe. Subsequently, at one institution SmartLabels was installed in 5 ORs. The new system produces JC and ASA complaint syringe labels on demand at the point of care while providing closed-loop audio and visual feedback to the clinician simply by scanning the FDA mandated drug vial barcode.

Results

The baseline study evaluated 1565 syringes. Of the 1090 syringes, 43.6% (n=681) were pre-filled by the pharmacy or a 3 rd party vendor and 56.4% (n=884) of syringes were prepared by the clinician. 33.7% (n=527) of the syringes were prepared by the clinician and met JC requirements, 2.9% (n=45) of syringes had no label, 16.5% (n=258) had only the drug name, 3.6% (n=56) had only the drug name and concentration but no expiration when the drug expired in less then 24 hours

The study then evaluated 340 syringes in 5 ORs with SmartLabels installed. 41% (n=139) were pre-filled. 59% (n=201) were prepared by the clinician and 100% (n=201) of these were fully compliant with JC/ASA requirements.

Discussion

Less then half of the syringes prepared by the clinicians in the baseline audit met JC requirements. Implementation of this new system improved compliance to 100% immediately and with minimal training.

Clinicians were very accepting of the new system into their workflow, citing the ease of use and utility of the safety features, such as the audio & visual read-back provided by the system. The safety features of the system may decrease drug administration errors and has improved compliance with JC standards.

Additionally, this system exceeds the minimum JC requirements providing date and time of preparation and expiration for all medications (figure 3). Furthermore, all the labels are color coded according to the ASA's guidelines for labeling of pharmaceuticals, and carry a 2D barcode of all essential information that can be integrated with an AIMS.

Table 1: Joint Commission NPSG.03.04.01 (July 1, 2009)

Rationale

Medications or other solutions in unlabeled containers are unidentifiable. Errors, sometimes tragic, have resulted from medications and other solutions removed from their original containers and placed into unlabeled containers. This unsafe practice neglects basic principles of medication management safety yet has been routine in many organizations. The labeling of all medications, medication containers, and solutions is a risk reduction activity consistent with safe medication practices. This practice addresses a recognized risk point in the safe administration of medications in perioperative and other procedural settings.

Elements of Performance

Medications and solutions both on and off the sterile field are labeled even if there is only one medication being used.

1. Labeling occurs when any medication or solution is transferred from the original packaging to another container.
2. Medication or solution labels include the **medication name, strength, amount** (if not apparent from the container), **expiration date when not used within 24 hours, and expiration time when expiration occurs in less than 24 hours**.
3. All medication or solution labels are verified both verbally and visually by two qualified individuals whenever the person preparing the medication or solution is not the person who will be administering it.
4. No more than one medication or solution is labeled at one time.
5. Any medications or solutions found unlabeled are immediately discarded.
6. All original containers from medications or solutions remain available for reference in the perioperative or procedural area until the conclusion of the procedure.
7. All labeled containers on the sterile field are discarded at the conclusion of the procedure.

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Introduction

In the delivery of anesthesia, the process of labeling medications has been shown to be a time consuming, error prone, and multi step process[1,2]. In effort to mitigate risk, the American Society of Anesthesiology has developed a statement of labeling of pharmaceutical for use in anesthesiology, making recommendations for label content, font, background contrast, color, and bar coding.

Figure 1: Setup of our “Smart Label” Solution

Additionally, The Joint Commission (JC) has developed National Patient Safety Goals (NPSG) that outline elements of performance that hospitals are expected to adhere to. However, 17% of hospitals do receive a citation for improper labeling of medications and solutions from the Joint Commission.

In an effort to help reduce error and maintain best practice standards for drug labeling, a multidisciplinary team developed a point of care syringe labeling solution that has been previously reported.[4] The device contains a barcode scanner that reads the FDA mandated barcode on vials used to decode the vial and produce a full color waterproof label.

This study evaluated baseline compliance with the 2009 JC NPSG 03.04.01 standard at two tertiary care centers. The impact of implementation of the new system was also evaluated.

Methods

Baseline compliance was evaluated at two large tertiary health care centers in the United States. All observations were made by one trained individual at each site. Effort was made to try and prevent the anesthesiologists from knowing that labeling compliance was being monitored and random rooms were selected on random days in effort to achieve as accurate of baseline compliance as possible.

Compliance with the automated labeling solution, “Smart Labels” was evaluated at only one of the previous sites, with observations being made by the same user. The “Smart Labels” device was implemented into 5 Ors on busy vascular and thoracic services. All users were provided with in-service training and the devices were supported 24-7 by an on call OR engineering team.

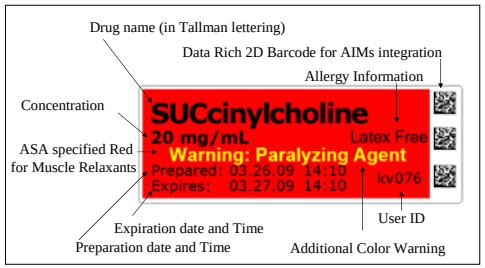


Figure 2: Breakdown of the content of the Smart Labels

Results

Table 2: Breakdown of drugs assessed in the initial compliance for each site and the total. The number of prefilled syringes are showed in parentheses.

	Hospital 1 %of Syringes (% Prefilled)	Hospital 2 % of Syringes (% Prefilled)	Total % of Syringes (% Prefilled)
Premedication	5% (0%)	1.3% (0%)	3.9 (0%)
Narcotic Agents	8.3% (0%)	13.5% (0%)	9.9 (0%)
Induction Drug	12.8% (5%)	11.6% (0.4%)	12.4 (3.6%)
Muscle Relaxant	23.3% (10.7%)	25.3% (12.6%)	23.9 (11.3%)
Vasopressors	25.4% (24.8%)	24.8% (24.2%)	25.2 (24.6%)
Anticholinergics	16.8% (0.4%)	1.3% (0%)	12.1 (0.3%)
Other	8.3% (4%)	22.3% (3.2%)	12.6 (3.8%)
Total	**100.0 (44.9)**	**100.0 (40.4%)**	**100.0 (43.6%)**

A total of 1197 syringes were analyzed between the two sites for baseline compliance in 170 OR cases as presented in Table 2. These syringes were compared against 2009 Joint Commission Standard MM.4.30.01 for compliance and the compliance is presented in Figure 2.

Syringes that were prepared by a third party vendor were classified as “Prefilled”. Those syringes meeting JC requirements were labeled at JC Compliant. All Compliant syringes are shown with angled stripes in Figure 2. Syringes there were missing a label were designated “No Elements” and those with only a name were designated “Name Only”. Since Propofol expires in less then 24hrs of preparation it requires that the expiration time be noted on the label. Syringes missing this are designed “Propofol without Expiration.”

An additional 48 cases, were analyzed that utilized the “Smart Labels” system, looking at 340 syringes. Compliance in these cases were found to be 100% compliant with JC standards with minimal workflow disruption.

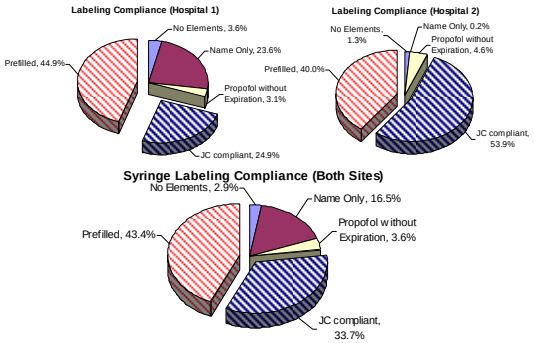
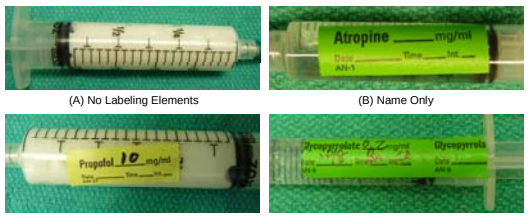


Figure 3: Baseline syringe labeling compliance breakdown



(A) No Labeling Elements (B) Name Only

(C) Propofol without Expiration (B) JC Compliant

Figure 4: Examples of syringe labeling compliance categories

Table 3: Joint Commission Standard NPSG.03.04.01: (2010 JC Standard)

Elements of Performance for NPSG.0..04.01

1. In perioperative and other procedural settings both on and off the sterile field, label medications and solutions that are not immediately administered. This applies even if there is only one medication being used.
2. In perioperative and other procedural settings both on and off the sterile field, labeling occurs when any medication or solution is transferred from the original packaging to another container.
3. In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the following:
   - **Medication name**
   - **Strength**
   - **Quantity**
   - **Diluent and volume (if not apparent from the container)**
   - **Preparation date**
   - **Expiration date when not used within 24 hours**
   - **Expiration time when expiration occurs in less than 24 hours**
4. Verify all medication or solution labels both verbally and visually. Verification is done by two individuals qualified to participate in the procedure whenever the person preparing the medication or solution is not the person who will be administering it.
5. Label each medication or solution as soon as it is prepared, unless it is immediately administered.
6. Immediately discard any medication or solution found unlabeled.
7. Remove all labeled containers on the sterile field and discard their contents at the conclusion of the procedure. Note: This does not apply to multiuse vials that are handled according to infection control practices.
8. All medications and solutions both on and off the sterile field and their labels are reviewed by entering and exiting staff responsible for the management of medications.

Discussion

Figure 5: Smartlabels being used in an OR

Safe, high quality, error free care is the goal of anesthesiologists as they care for patients. Our study demonstrates that broad variability of current labeling compliance practice exists among hospitals. As an increasing number of required compliance elements are added, full compliance with the national standards will become increasingly more difficult.

Innovative, user-friendly systems such as the one studied here may help solve the compliance challenge without impeding workflow or adding time to the process. Increased compliance with labeling requirements may help eliminate drug errors in the operating room and further improve patient safety. However, many could argue that simply labeling name and concentration is simply enough; however, by providing this additional information it ensure that you are not using that propofol that accidentally didn’t get cleaned up from the previous day. Additionally from a best practices point of view, this information should be present to simply provide the best care possible.

Providing the best patient care at a minimal disruption to work flow was the main focus of this project. With increasing complex labeling requirements, this will likely take an increasing larger amount of an anesthesiologist's time. When looking at the JC’s National Patient Safety Goals for 2010 (NPSG.03.04.01), the requirements again increase. With current labeling practices, only 1 label in the baseline compliance would meet the these new 2010 standards. However, with an automated labeling solution, such as the one developed for this study, not only does it meet the 2010 requirements, but provides other critical information for providing the best patient care.

References:

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