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Integration of the Codonics Safe Label System® and the Omnicell XT® Anesthesia Workstation into Pediatric Anesthesia Practice: Utilizing Technology to Increase Medication Labeling Compliance and Decrease Medication Discrepancies While Maintaining User Acceptability

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Abstract

Background: Perioperative medication errors are recognized as a source of patient morbidity and mortality. Medication management systems with built-in scanning and label-printing functions that integrate with medication-dispensing cabinets have the potential to decrease medication administration errors by improving compliance with medication labeling. Whether these management systems will also improve periodic automatic replacement (PAR) inventory control and be accepted by users is unknown. We hypothesized that implementation of the Codonics Safe Label System®, an automated labeling system (ALS), would increase compliance with labeling guidelines and improve PAR inventory control by decreasing medication discrepancies while maintaining user acceptability in the OR. **Methods:** We audited a cohort of anesthesia workstations and electronic anesthesia records for 2 months to compare dispensed and administered medications and establish a discrepancy baseline. We also observed a convenience sample of syringes to evaluate labeling compliance. Post-implementation of the ALS, we repeated the audit. Finally, an anonymous survey was distributed electronically to providers to assess user acceptability. **Results:** Pre-implementation the average daily medication discrepancy rate was 9.7%, decreasing to 6.1% post-implementation ($\chi^2_1 = 43.9$; $P < .0001$). Pre-implementation 330 of 696 syringes (47.4%) were either missing a label or labeling elements. After implementation, 100% of all syringes received a label with the complete required labeling information ($P < .0001$). All respondents agreed or strongly agreed that the system was easy to use, accurate, met their needs, printed labels quickly, improved safety and efficiency, and was recommendable. **Conclusion:** The ALS significantly increased the rate of best-practice-compliant medication labeling while reducing medication inventory discrepancies. The system was highly accepted by providers.

Keywords

medicaiton safety, information systems and technology, medication errors, medication process, materials management/central supply

Introduction

In an era of increasing healthcare costs and decreasing reimbursement, healthcare organizations will thrive only by providing the safest care at the highest quality, with the most value to their patients.[1] One method of improving operational management in a healthcare organization is to improve patient safety and inventory control wherever possible. A potential target of opportunity is the operating room (OR) and, more specifically, the drugs administered by anesthesiologists. Anesthesiologists are unique in that they prepare, label, and administer their own medications without pharmacy oversight. This practice can result in potential medication error and patient harm.

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Perioperative medication errors are well recognized as a significant source of patient morbidity and, rarely, mortality.[2-6] In fact, a study by Nanji et al found that one in 20 medication administrations perioperatively resulted in a medication error and/or adverse drug event.[2] Integrated medication management systems that have built-in scanning and label-printing functions, as well as interoperability with automated medication-dispensing cabinets such as the Omnicell XT® anesthesia workstation (AWS; Omnicell, Mountain View, CA), have the potential to decrease medication administration errors by improving drug labeling compliance with standards recommended by the American Society of Anesthesiologists (ASA), The Joint Commission (TJC), the American Society for Testing and Materials (ASTM), and the International Organization for Standardization (ISO).[7-9] Whether these management systems will also improve pharmacy periodic automatic replacement (PAR) level inventory control by providing more accurate information on when drug replenishment in each anesthetizing location is required is unknown. Further, because integration of new technology into the workplace can be burdensome to providers and will be successful only if accepted by the users, it is important that workflow considerations be evaluated when implementing any new technology.

We hypothesized that implementation of the Codonics Safe Label System® (Codonics, Cleveland, OH), an automated labeling system (ALS), would increase compliance with best practice drug labeling guidelines and improve pharmacy PAR inventory control by decreasing medication discrepancies while maintaining user acceptability in the operating rooms (ORs).

Methods

Setting

This study, determined to be non-human subject research by the Colorado Multiple Institutional Review Board, was a single-center, prospective quality improvement evaluation designed to measure medication discrepancies before and after implementation of the ALS. Investigators also used convenience sampling to measure the frequency of missed labeling before and after implementation and collected user acceptability data by electronic survey. Our institution is a free-standing quaternary, academic, children's hospital that has 14 sterile ORs, 2 cardiovascular ORs, and 9 non-sterile procedure rooms. These rooms are staffed by a variety of care team models that consist of anesthesia providers, including attending anesthesiologist-supervised anesthesia residents and fellows, certified registered nurse anesthetists (CRNAs), and certified anesthesia assistants (CAAs), as well as non-supervising, solo practicing attending anesthesiologists.

During the months of November to December 2015, we audited a cohort of AWSs and the electronic health record (Epic® systems version 2014, Verona, WI) to establish a medication discrepancy baseline. We compared what medications were removed from the AWS to what medications were administered, as documented in the anesthesia information management system (AIMS). A discrepancy existed if a provider documented a medication in the AIMS but failed to decrement the medication from the AWS, implying that the AWS par levels would now be inaccurate. Additionally, during this time, we analyzed a convenience sample of syringes to evaluate compliance with best practice label elements as determined by ASA, TJC, ASTM, and ISO. Syringes were considered compliant if they included self-adhesive, color-coded labels that contained the drug name, concentration, diluent, date and time prepared, and preparer's name or hospital identification number. No provider or patient information was recorded. All providers had access to commonly used medications and blank labels in every OR. These commonly used color-coded, adhesive, medication labels had pre-printed drug names and concentrations and included a space to record date, time, and identification of the provider preparing the medication. Ideally, these labels could meet all best practice requirements if completed by the anesthesia providers.

During the "go-live" of the ALS, 2 days of hands-on training was available to all anesthesia providers with opportunity to comment and ask questions. Because not all providers work every day and due to vacations, sick leave, etc, not all providers had the opportunity to participate in hands-on training prior to use. After the installation of the ALS in 4 highly utilized operating rooms, we re-audited the AWSs and the AIMS between April and July 2016 to evaluate post-intervention discrepancy rates. Similarly, a convenience sample of syringes was taken to evaluate labeling compliance. Finally, an anonymous survey was distributed electronically to all providers who used this technology to assess user acceptability. Four operating rooms were used because 4 ALSs were provided for trial by Codonics. The 4 operating rooms were chosen based on their high caseloads and case types. One location is used primarily as an endoscopy suite including gastroenterology and pulmonology procedures. One location is used primarily for otolaryngology procedures including myringotomy tubes, adenotonsillectomy, etc. One location is used primarily for general pediatric surgery cases and urgent or emergent cases. One location is used primarily for orthopedic surgery including larger cases like posterior spine fusions.

The ALS mounts to the right side of the AWS (Figure 1). It consists of a barcode scanner and printer that networks to the AWS, allowing single user login to both systems. After login, the patient is selected from the AWS menu, linking the medication to the correct patient. When an anesthesia provider removes a medication vial or pre-filled syringe from the AWS and the medication's barcode is scanned into the ALS, an auditory read-back of the scanned medication is given and the device prints a label within 6 seconds. The

Figure 1. The Codonics Safe Label System®: (a) mounted to the right side of the Omnicell XT® anesthesia workstation, (b) an automated medication-dispensing cabinet, and (c) is shown.

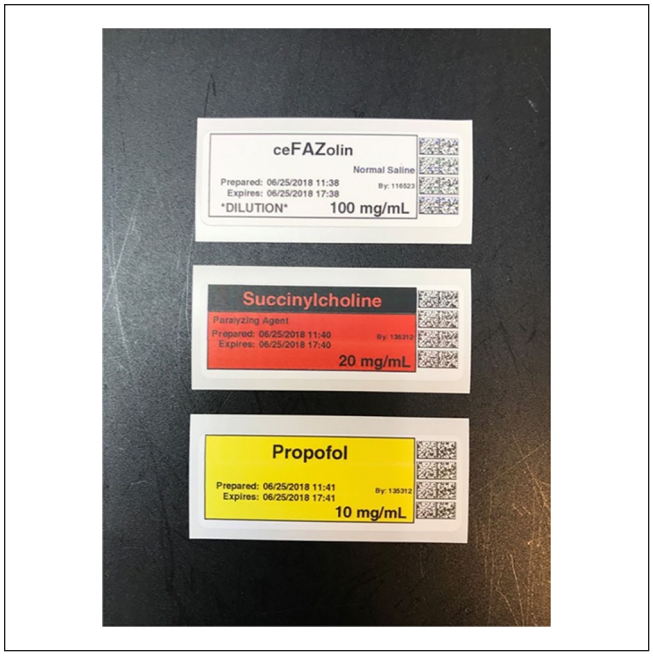

Figure 2. The Codonics Safe Label System® prints labels that are compliant with standards recommended by the American Society of Anesthesiologists (ASA), The Joint Commission (TJC), the American Society for Testing and Materials (ASTM), and the International Organization for Standardization (ISO).[7-9] The printed color coded, adhesive labels include medication name, diluent, concentration, expiration date/time, preparer, and a barcode. Examples of an antibiotic (cefazolin) white label (top), a neuromuscular blocking agent (succinylcholine) red label (middle), and a general anesthetic (propofol) yellow label (bottom) are shown.

printed label includes medication name, diluent, concentration, expiration date/time, preparer, and a barcode (Figure 2). Scanning the medication also decrements the medication/vial count from the AWS and reconciles inventory stock for the pharmacy. While the label is being printed, the provider draws the medication into a syringe if necessary and then affixes the label to the syringe.

Outcome Measures

The primary outcome measure was a decrease in medication discrepancies. The secondary outcome measure was an increase in medication labeling adherence rates. The tertiary outcome measure was user acceptability with the ALS compared with the previous process. Medication discrepancies were captured by comparing the medications assigned to the patient as documented in the AWS to the documentation of administration in the AIMS. Investigators audited daily missed-labeling rates in the OR by looking at syringes with medication drawn into them. The rate was calculated as the number of missed labels divided by the total number of syringes measured that day. Each audited label was reviewed for presence of the label, the name of the drug, the concentration of the drug, the date and time the drug was drawn into the syringe, and the identification of the provider who drew the medication into the syringe. Measures of user acceptability were collected by distributing a survey asking anesthesia providers to rate the acceptability and usability of the system on a Likert scale (1-5, 5 being the most acceptable). The survey (Appendix) was administered after implementation of the ALS to all providers whether or not they had training in its use prior to implementation.

Data Collection and Statistical Analysis

Data collection and storage were managed by using REDCap® (https://redcap.vanderbilt.edu) electronic data capture tools. Labeling data were collected by convenience sampling of all of the ORs Monday through Friday before case starts until the adequate number of syringes had been sampled in each phase of the study. Study investigators recorded whether necessary compliance information was present on syringes containing medication. Post-implementation, study investigators verified that the system was in fact labeling with the necessary information.

Data were summarized as mean plus standard deviation or percentage distribution as appropriate. Frequencies were calculated for categorical outcomes and presented with Wilson 95% confidence intervals. Likert scores for user acceptability of the intervention were summarized as medians with interquartile ranges. Scores were compared between 2 groups, those who received training in ALS and those who did not. Chi squared test was used to compare the rate of missed labels between time periods. A *t*-test was used to compare the mean daily medication discrepancy rate between time periods. *P* values of $<.05$ were considered statistically significant, and all analyses were carried out with SAS software version 9.1 (SAS Institute, Cary, NC).

Results

Medication administration data were collected from 1014 patients in the pre-intervention group and 958 patients in the post-intervention group. Before implementation of the ALS, the average daily discrepancy (medications documented in the AIMS as given but not assigned to the patient in the AWS) was 9.7% (538 of 5527), whereas after implementation, the discrepancy rate decreased to 6.1% (287 of 4672). The estimated 37% reduction (3.6% decline; 95% CI, 2.6%-4.6%) in medication discrepancies was statistically significant ($\chi^2_1 = 43.9$; $P < .0001$).

Before implementation of the ALS, 330 of the 696 syringes audited (47.4%; 95% CI, 43.7%-51.1%) were missing either a label and/or one or more required label information elements. Eight percent of the syringes used were missing a label, 13% were missing the drug name, 42% were missing the concentration, 50% were missing the date prepared, 39% were missing the time of preparation, and 8% were missing the identification of the preparer. After implementation, a total of 433 syringes were audited, and 100% had a label and all required labeling information. The differences in proportions pre- and post-implementation were statistically significant for all 6 required label elements (all $P < .0001$; Figure 3).

A total of 72 out of 85 (84%) anesthesia providers participated in the anonymous user acceptability survey, of whom 40 (56%) received training in the use of the ALS before its implementation, 28 (39%) did not, and 4 (5%) could not remember. All respondents either agreed or strongly agreed that the system was easy to use (77%), accurate (75%), met their needs (84%), printed labels quickly (73%), improved safety and efficiency (68%), and worthy of recommending to others (70%). User acceptability did not differ based on whether the provider received or did not receive formal training in the system.

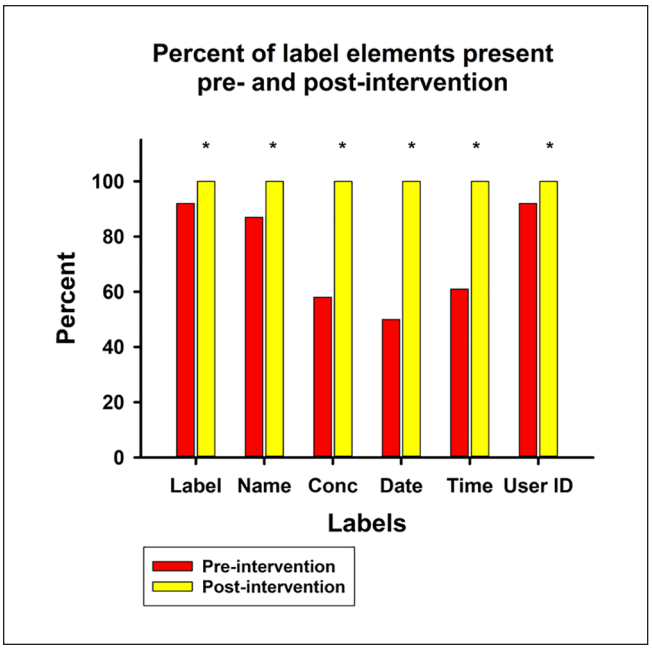

Figure 3. The percent of label elements present pre- (red bars) and post-implementation (yellow bars) of the Codonics Safe Label System® are presented. The required elements included presence or absence of a label, the drug's name, concentration (conc), date and time the drug was prepared, and by whom (user ID). The differences in proportions pre- and post-implementation were statistically significant for all 6 elements (all $P < .0001$) (*).

Discussion

Implementation of the ALS integrated medication management system with built-in scanning and label-printing functions dramatically improved drug labeling compliance with standards recommended by the American Society of Anesthesiologists (ASA), The Joint Commission (TJC), the American Society for Testing and Materials (ASTM), and the International Organization for Standardization (ISO) to 100%.[7-9] Further, because this labeling system is coupled to the automated medication-dispensing cabinets within each anesthetizing location, it decreased medication inventory discrepancy rates by 37% which has important implications to the pharmacy's PAR inventory management systems. Finally, implementation of this new technology was not disruptive to workflow and was widely accepted and easy to use by myriad anesthesia providers confirming its value in the intraoperative period.[10,11]

Ultimately, patient safety considerations are paramount. The unique practice by anesthesiologists of preparing, labeling, and administering medications without pharmacy oversight can potentially contribute to significant medication error. Indeed, perioperative medication administration errors are an ever-present concern and a significant source of patient morbidity and, rarely, mortality.[2,3] As anesthesiologists, we have all made, or know of colleagues who have made, anesthetic drug administration errors.[4,12,13] Indeed, prior to implementing the ALS in our institution, the error rate of either no drug labels or labels missing one or more essential elements was almost 50%. Our study, like previous ones, demonstrated that use of the ALS has the potential to minimize or prevent many, if not all, of these errors.[10,11]

The drugs that anesthesia providers prepare are often supplied in look-alike glass ampules or bottles that can be easily misread or mislabeled in the fast-paced, noisy, tumultuous environment of the OR. A major safety function of the ALS is the auditory, double-check, read-back that occurs when the device scans the selected drug's barcode. This auditory read-back ensures that the drug ampule selected is the intended medication and allows the provider to confirm the correct drug and drug concentration while affixing the label to a syringe prior to administration. Indeed, this feature would likely prevent a common medication error in our practice that occurs when look-alike drug ampules are stocked or

mis-stocked in the OR medication dispensing cabinets. Though some surgeons and anesthesia providers did complain about the sound volume of this read-back, we thought this function important enough to require it in all anesthetizing locations regardless of the noise it produces.

Key elements of best practice include label content (the drug's name, concentration, volume), font (size, use of additional emphasis for the initial or distinctive syllable of similar drug names), contrasting background, color, barcoding, and adhesive label that allows the user to write additional information with a pen or marker.[8,9] The label should also provide information on who prepared the drug and the drug's expiration date and time. We found that the ALS produced labels that were compliant with these best practices and improved label compliance by all anesthesia providers, results that are consistent with those of other research with this technology.[10,11] Of note, the surveyed providers commented very positively on the fact that the labels were also highly adherent, water resistant, and properly color coded.

To successfully improve process performance, we focused on 2 elements, namely, the change had to improve results and second it had to add value to the practitioner's workflow. At our hospital, the ALS did both: it improved the quality of drug labeling by producing labels with all the required ASTM, ISO, and TJC best practice elements; was adopted by all anesthesia providers; and improved productivity by reducing the time required to produce and affix accurate and compliant drug labels.

Nevertheless, we believe that medication errors can still occur with the use of the ALS, and that some errors may be avoidable in the future. In current, typical anesthesia workflow practice, multiple drugs are prepared before the induction of anesthesia and placed on or in a locked drawer in the AWS. Because of the many syringes available, even when properly labeled, the anesthesiologist may accidentally pick up the wrong syringe and administer the wrong drug at the wrong time. This error can potentially be prevented by coupling the barcode printed on the ALS generated drug label with a bar code reader on the electronic anesthesia information management system (AIMS). Ideally, this integrated system would scan, identify, read aloud, and record within the AIMS, the drug being administered as it was being administered and would prevent the wrong drug being given at the wrong time.

Errors in PAR levels in the AWS can pose a significant threat to patient safety because many of the medications used by anesthesiologists can be lifesaving and must be immediately available. Inaccurate PAR levels can lead the pharmacy to falsely believe adequate amounts of medications are available, potentially resulting in missing medications vital to timely patient resuscitation efforts. In our current study, we significantly decreased inventory errors within the automated dispensing cabinets but did not eliminate it. An obvious question is "why is there still a 6.1% discrepancy?" We believe this is due to the fact that certain meds are drawn up and administered immediately (ie, ondansetron) without being scanned. Put simply, some users bypass the system. We can do our best to utilize technology, however, there will always be some human element requiring one to do the right thing. Further investigation to improve inventory control and PAR level restocking is an area for future investigation.

This study has the expected limitations of a pilot study, as it did not cover all anesthetizing locations within our children's hospital. Further, the study ran over a limited timeframe and the results may have improved, or there could be a decrease in adoption over time. A simple convenience sample of labeled syringes may pose a limitation, as we were not available to evaluate every syringe at all times. Ideally, we would have conducted a study using direct observation during the entire case. Regardless, even a modest improvement in labeling compliance would likely have been seen. Our academic institution poses a limitation as we have trainees, CRNAs, CAAs, and attending anesthesiologists in the OR at any given time, therefore our findings may not be generalizable to differing hospital settings. Another limitation may be that the verbiage of the survey questions was positive, however, there were obviously opportunities to give low scores for any of the questions asked. We found that the institution of the ALS integrated medication management systems with built-in scanning, and label printing functions significantly decreased medication discrepancies, increased labeling compliance with best practice, and was widely accepted and easy to use by a myriad of anesthesia providers. Our results ultimately resulted in the hospital purchasing ALSs for all anesthetizing locations at our institution.

Conclusion

In conclusion, we found that The Codonics Safe Label System® coupled to the Omnicell XT® automated medication-dispensing cabinet significantly increased the rate of best-practice-compliant medication labeling while reducing medication inventory PAR discrepancies. The system was easy to use, did not interfere with operating/procedure room work flow, and was highly accepted by all members of the anesthesia care team.

Appendix

User Satisfaction Survey
System Easy to Login
Vial Scanning Accurate
Label Printing Speed Appropriate
Met My Needs As Clinician
Confirmation Improved Safety and Preparation
Preset Dilutions Were An Improvement
System Improved Efficiency
I Would Recommend This Product

Declaration of Conflicting Interests

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