A System for Anesthesia Drug Administration Using Barcode Technology: The Codonics Safe Label System and Smart Anesthesia Manager™

Srdjan Jelacic, MD,* Andrew Bowdle, MD, PhD,* Bala G. Nair, PhD,† Dolly Kusulos, RPh,† Lynnette Bower, PharmD,† and Kei Togashi, MD*

BACKGROUND: Many anesthetic drug errors result from vial or syringe swaps. Scanning the barcodes on vials before drug preparation, creating syringe labels that include barcodes, and scanning the syringe label barcodes before drug administration may help to prevent errors. In contrast, making syringe labels by hand that comply with the recommendations of regulatory agencies and standards-setting bodies is tedious and time consuming. A computerized system that uses vial barcodes and generates barcoded syringe labels could address both safety issues and labeling recommendations.

METHODS: We measured compliance of syringe labels in multiple operating rooms (ORs) with the recommendations of regulatory agencies and standards-setting bodies before and after the introduction of the Codonics Safe Label System (SLS). The Codonics SLS was then combined with Smart Anesthesia Manager software to create an anesthesia barcode drug administration system, which allowed us to measure the rate of scanning syringe label barcodes at the time of drug administration in 2 cardiothoracic ORs before and after introducing a coffee card incentive. Twelve attending cardiothoracic anesthesiologists and the OR satellite pharmacy participated.

RESULTS: The use of the Codonics SLS drug labeling system resulted in >75% compliant syringe labels (95% confidence interval, 75%–98%). All syringe labels made using the Codonics SLS system were compliant. The average rate of scanning barcodes on syringe labels using Smart Anesthesia Manager was 25% (730 of 2976) over 13 weeks but increased to 58% (956 of 1645) over 8 weeks after introduction of a simple (coffee card) incentive ($P < 0.001$).

CONCLUSION: An anesthesia barcode drug administration system resulted in a moderate rate of scanning syringe label barcodes at the time of drug administration. Further, adaptation of the system will be required to achieve a higher utilization rate. (Anesth Analg 2014;XXX:00–00)

The adoption of technologies that improve quality of care and patient safety has accelerated in recent years due to pressures from government, insurance groups, and consumers. The process of implementing new technologies is challenging and dependent on a number of variables including organizational, technological, and individual factors.[1] One of those technologies that has the potential to reduce medication errors and improve patient safety is barcode medication administration (BCMA) technology.[2–4]

Hospitals are increasingly adopting the BCMA technology on nursing floors to improve safety, efficiency, and expand the use of the electronic health record as part of the Medicare Stage 2 "meaningful use" rules.[a] Although the specialty of anesthesiology is at the forefront of adopting new technologies to improve patient safety, little has been done to introduce BCMA technology in the operating room (OR) outside work published by Merry et al.[2,5–7] They developed a multimodal drug administration system that includes specific methods to organize the anesthesia workspace, prefilled syringes with colored and barcoded labels, and a computer system for identifying, recording, and confirming the syringe barcode with auditory and visual cues before drug administration. There is evidence that this system may reduce errors based on a subset analysis of users who used all the system features.[2]

The Safe Label System SLS 500i (Codonics Inc., Middleburg Heights, OH) is a new computerized drug labeling system designed for use at the anesthesia point-of-care. It scans the drug vial barcode and generates a compliant color-coded syringe label that is adaptable to the recommendations of regulatory agencies and standards-setting bodies (Methods and Table 1). The user can modify the syringe label contents to generate a label that is compliant with any labeling standards. Drug manufacturers have been required to include barcodes on drug vials in the United States by the Food and Drug Administration since 2004.[b] The Codonics SLS system recently received FDA 510(k) clearance.

From the *Department of Anesthesiology and Pain Medicine, Division of Cardiothoracic Anesthesiology; and †Pharmacy, University of Washington School of Medicine, Seattle, Washington.

Accepted for publication March 21, 2014.

The authors declare no conflicts of interest.

Preliminary data was presented as a poster at the 13th International Congress of Cardiothoracic and Vascular Anesthesia, Auckland, New Zealand on November 14th to 17th, 2012.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website (www.anesthesia-analgesia.org).

Reprints will not be available from the authors.

Address correspondence to Srdjan Jelacic, MD, Department of Anesthesiology and Pain Medicine, University of Washington School of Medicine, 1959 NE Pacific St., AA-117B, Box 356540, Seattle, WA 98195-6540. Address e-mail to sjelacic@uw.edu.

DOI: 10.1213/ANE.0000000000000256

[a] Centers for Medicare and Medicaid Service (CMS): Stage 2 Overview Tipsheet. Available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage2Overview_Tipsheet.pdf. Accessed January 22, 2014.

[b] Food and Drug Administration. Bar code label requirement for human drug products and biological products. Available at: http://www.gpo.gov/fdsys/pkg/FR-2004-02-26/pdf/04-4249.pdf. Accessed January 22, 2014.

Table 1. Summary of Syringe Label Content and Color Coding Guidelines

Label element	Regulation	Notes
Drug name	The Joint Commission NPSG.03.04.01[a] The Joint Commission standard MM.05.01.09[b] ACSQHC recommendations[c] USP <797>[d] CMS standard §416.48(a)[d]	
Strength or concentration	The Joint Commission NPSG.03.04.01 The Joint Commission standard MM.05.01.09 ACSQHC recommendations	
Quantity or amount	The Joint Commission NPSG.03.04.01 The Joint Commission standard MM.05.01.09 ACSQHC recommendations USP <797>	The Joint Commission standard MM.05.01.09 requires amount "if not apparent from the container"
Diluent	The Joint Commission NPSG.03.04.01 The Joint Commission standard MM.05.01.09	The Joint Commission standard MM.05.01.09 requires diluent "for all compounded IV admixtures and parenteral nutrition formulas"
Volume	The Joint Commission NPSG.03.04.01 ACSQHC recommendations	The Joint Commission NPSG.03.04.01 requires volume "if not apparent from container"
Expiration date[e]	The Joint Commission NPSG.03.04.01 The Joint Commission standard MM.05.01.09 CMS standard §416.48(a) USP <797>	The Joint Commission NPSG.03.04.01 and standard MM.05.01.09 require expiration date "when not used within 24 h"
Expiration time[f]	The Joint Commission NPSG.03.04.01 The Joint Commission standard MM.05.01.09 USP <797>	The Joint Commission NPSG.03.04.01 and standard MM.05.01.09 require expiration time "when expiration occurs in <24 h"
Preparation date	The Joint Commission standard MM.05.01.09 CMS standard §416.48(a)	
Preparation time	CMS standard §416.48(a)	
Preparer's initials	CMS standard §416.48(a) USP <797>	
Color coding	ISO 26825:2008[g] ASTM international D4774[h] ASA statement[i]	

[a]The Joint Commission. Hospital National Patient Safety Goals NPSG.03.04.01. Available at: http://www.jointcommission.org/assets/1/6/HAP_NPSG_Chapter_2014.pdf. Accessed January 22, 2014.

[b]The Joint Commission. Standard MM.05.01.09 for anesthesia drug labels is not freely available and can be purchased online at http://store.jcrinc.com.

[c]Australian Commission on Safety and Quality in Health Care. National Recommendations for User-applied Labeling of Injectable Medicines, Fluids and Lines. Available at: http://www.safetyandquality.gov.au/wp-content/uploads/2012/02/Labelling-Recommendations-2nd-edition-February-2012_PRESS.pdf. Accessed January 22, 2014.

[d]US Pharmacopeia. USP-NF General Chapter <797> Pharmaceutical Compounding - Sterile Preparations. Available at: http://www.usp.org/store/products-services/usp-compounding. Accessed on January 22, 2014.

[e]CMS addresses the labeling of medications for hospitals under standard §482.25(b)(3), but does not specifically address the operating room setting. CMS standard §416.48(a) addresses the labeling of medications for ambulatory surgery centers and specifically addresses the operating room setting.

[f]According to Joint Commission NPSG.03.04.01 requirement "the date and time are not necessary for short procedures, as defined by the hospital."

[g]The full version of the ISO standards is not freely available, but can be purchased online at ISO.org

[h]The full version of the ASTM D4774 standards is not freely available, but can be purchased online at ASTM.org (an abbreviated version of ASTM D4774 is freely available at: http://www.astm.org/Standards/D4774.htm; accessed January 22, 2014). Interestingly, while specifying label colors, the ASTM D4774 also states "the user may alternatively use black and white labels rather than these colored labels."

[i]American Society of Anesthesiologists. Statement on Labeling of Pharmaceuticals for Use in Anesthesiology. Available at: http://www.asahq.org/for-members/standards-guidelines-and-statements.aspx. Accessed January 22, 2014.

Several commercially available anesthesia information management systems (AIMS) are currently capable of scanning syringe label barcodes. However, to the best of our knowledge, none of the currently available AIMS are capable of scanning the drug vial barcode and generating a corresponding syringe label containing a barcode in the OR. A point-of-care BCMA system that is capable of scanning the barcodes on vials before drug preparation, creating syringe labels that include barcodes, and scanning the syringe label barcodes before drug administration would be necessary.

We created such a system by combining the commercially available Codonics SLS computerized drug labeling system and our in-house decision support software, Smart Anesthesia Manager (SAM).[8] Subsequently, we performed a study to measure compliance of syringe labels with the recommendations of regulatory agencies and standards-setting bodies before and after introduction of the system. In addition, we measured the rate of utilization of the syringe label barcode scanning at the time of drug administration. We also described a few of the human factors issues that were encountered when the new system was introduced into the anesthesia workflow.

METHODS

The study was conducted at a single academic center with 27 ORs and an OR satellite pharmacy. Our satellite pharmacy prepares about 50% of the drugs used in the ORs. The study was granted exempt status by our IRB and was conducted in 2 parts (Supplemental Digital Content Figure 1, http://links.lww.com/AA/A874, which illustrates the study timeline). The first part was an audit of syringe labels in multiple ORs to determine the level

Figure 1. The Codonics SLS drug labeling system mounted on the side of the anesthesia cart.

of compliance with the label color and selected content that was most clinically relevant to our practice setting. We selected the following labeling requirements of the Joint Commission (TJC) in order for the label to be considered compliant: (a) correct drug name, (b) concentration, (c) date and time of expiration when expiration occurs in <24 hours, and (d) color scheme per American Society of Anesthesiologists recommendations[c], which are based on International Organization for Standardization (ISO) 26825:2008[d] and American Society for Testing and Materials D4774 standards[e] (Supplemental Digital Content, Figure 2, http://links.lww.com/AA/A876, which illustrates standard background colors). It is important to understand that there is no single universally accepted standard for syringe label content and color because several regulatory agencies and standards-setting bodies, including TJC, Centers for Medicare and Medicaid Services, US Pharmacopeial Convention, ISO, American Society for Testing and Materials, American Society of Anesthesiologists and Australian Commission on Safety and Quality in Health Care (Table 1) have published guidelines. In the United States, TJC label content requirements are the most relevant because member hospitals can be sanctioned if syringe labels do not meet

[c]American Society of Anesthesiologists. Statement on Labeling of Pharmaceuticals for Use in Anesthesiology. Available at: http://www.asahq.org/for-members/standards-guidelines-and-statements.aspx. Accessed January 22, 2014.

[d]The ISO 26825:2008 standards are not freely available, but can be purchased online at ISO.org.

[e]The full version of the ASTM D4774 standards is not freely available, but can be purchased online at ASTM.org (an abbreviated version of ASTM D4774 is freely available at: http://www.astm.org/Standards/D4774.htm; accessed January 22, 2014).

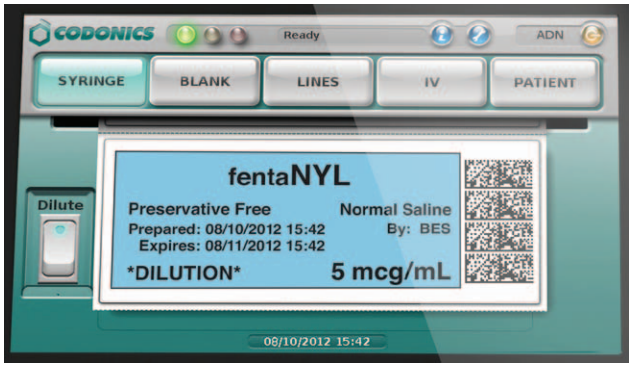

Figure 2. An example of Codonics SLS screen displaying all the compliant label elements, following a fentanyl vial scan.

TJC specifications. In addition, we recorded whether the syringe was prepared by the anesthesia provider or the pharmacy, whether the label was legible, and whether it contained abbreviations. The time period of the syringe audits was 5 weeks. The investigator auditing syringe labels examined all the syringes in a given OR before the first case of the day while the anesthesia provider was away from the OR, preparing the patient. The anesthesia providers were not aware that the audit was being conducted. The investigators entered ORs as they became available and examined each syringe found on the top of the anesthesia cart. We did not collect any patient or provider identifiers. Commercially boxed, prefilled emergency drug syringes (epinephrine and atropine) were excluded from the audit.

In the second part of the study, we introduced the Codonics SLS drug labeling system (software version 1.2.1, Codonics Inc., Middleburg Heights, OH) in 2 cardiothoracic ORs and the OR satellite pharmacy. The Codonics SLS drug labeling system in the satellite pharmacy was used to make labels for those drugs that are traditionally drawn and labeled by the pharmacy, which included lidocaine, succinylcholine, epinephrine, ephedrine, phenylephrine, heparin, and calcium chloride syringes. The anesthesia providers were urged to exchange the traditional pharmacy prefilled and labeled syringes for the ones containing Codonics SLS labels for each case in the 2 cardiothoracic ORs. The Codonics SLS units in the 2 ORs were mounted on the side of anesthesia carts (Fig. 1) to optimize the drug preparation workflow and clear the space on top of the anesthesia cart. To create a syringe label, anesthesia providers scanned their identification barcode to "log in" (only necessary to perform once per day while using the unit) and then scanned the drug vial. Before printing a syringe label, auditory feedback confirmed the drug name and concentration while the name of the drug and concentration were displayed on the Codonics SLS screen with the appropriate color background corresponding to the drug as per American Society of Anesthesiologists recommendations (Fig. 2). The Codonics SLS unit printed labels in 14 seconds (the current software version requires only 7 seconds), which was usually the time needed to draw the drug into a syringe. Printed labels bearing the color scheme per American Society of Anesthesiologists recommendations contained the name of the drug, concentration, date/time of preparation, expiration date/time, and the preparer's initials

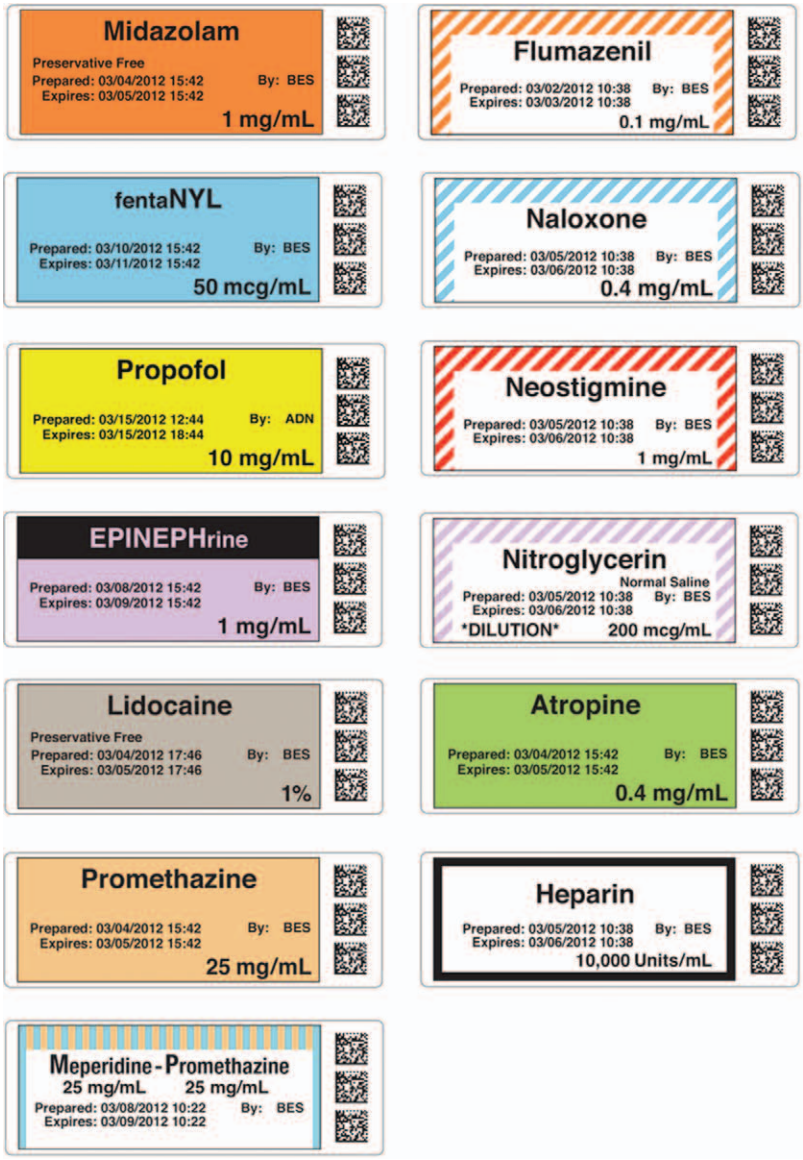

Figure 3. Examples of syringe labels made by the Codonics SLS drug labeling system. Note that the generic name of the drug, the concentration, the initials of the preparer, the date and time of preparation, the date and time of expiration, and a 2D barcode are applied to an appropriately colored label. Also, note that expiration times that comply with USP <797> will vary depending on the conditions under which the drugs are prepared. The expiration time of 24 hours after preparation in these examples would not apply to typical anesthesia provider-prepared syringes.

(Fig. 3). Subsequent reference to these labels in this article will describe them simply as "compliant" labels. Although the Codonics SLS drug labeling system has multiple features, the only other feature used in the study was the dilution feature for making vasopressin labels.[f] Cardiothoracic anesthesiology faculty and residents on their cardiothoracic anesthesia rotation were given a brief training tutorial on using the Codonics SLS units.

After the introduction of Codonics SLS units, a repeat syringe audit was performed in the 2 cardiothoracic ORs to measure the level of compliance with selected label elements and color scheme per American Society of Anesthesiologists recommendations. The syringe audit was conducted in the same manner as the audit before the introduction of Codonics SLS units except for the longer time period (7 weeks) and being limited to 2 cardiothoracic ORs.

Anesthesia providers were urged to scan the barcode of each syringe immediately before administration. Because the AIMS in our institution does not have built-in support for scanning Codonics SLS syringe label barcodes, we used an off-the-shelf barcode scanner and our own software, SAM.[8] SAM was developed at our institution to work in conjunction with our AIMS (Merge AIMS, Merge Healthcare Inc., Hartland, WI) to perform a variety of tasks that are not provided by the AIMS software alone.[9,10] For this study, SAM was programmed to detect Codonics SLS syringe label barcodes and to provide auditory[g] and visual feedback of the drug name.[6] SAM "speaks" the name of the drug, and displays a "pop-up" window on the screen of the AIMS with the drug name, the time of administration, and

[f]To make a dilution label, the provider first pressed the "dilute" button on the main touchscreen to turn the dilution function on. Next, the drug vial barcode was scanned. After the drug name was confirmed with auditory feedback, the dilution screen presented the provider with common dilution concentrations and diluent options. After the provider selected appropriate dilution concentration and diluent for the drug, the label was printed.

[g]A.F. Merry and C.S. Webster were the first to use a recorded voice to announce the drug name following scanning the barcode on the syringe in the anesthesia workplace.

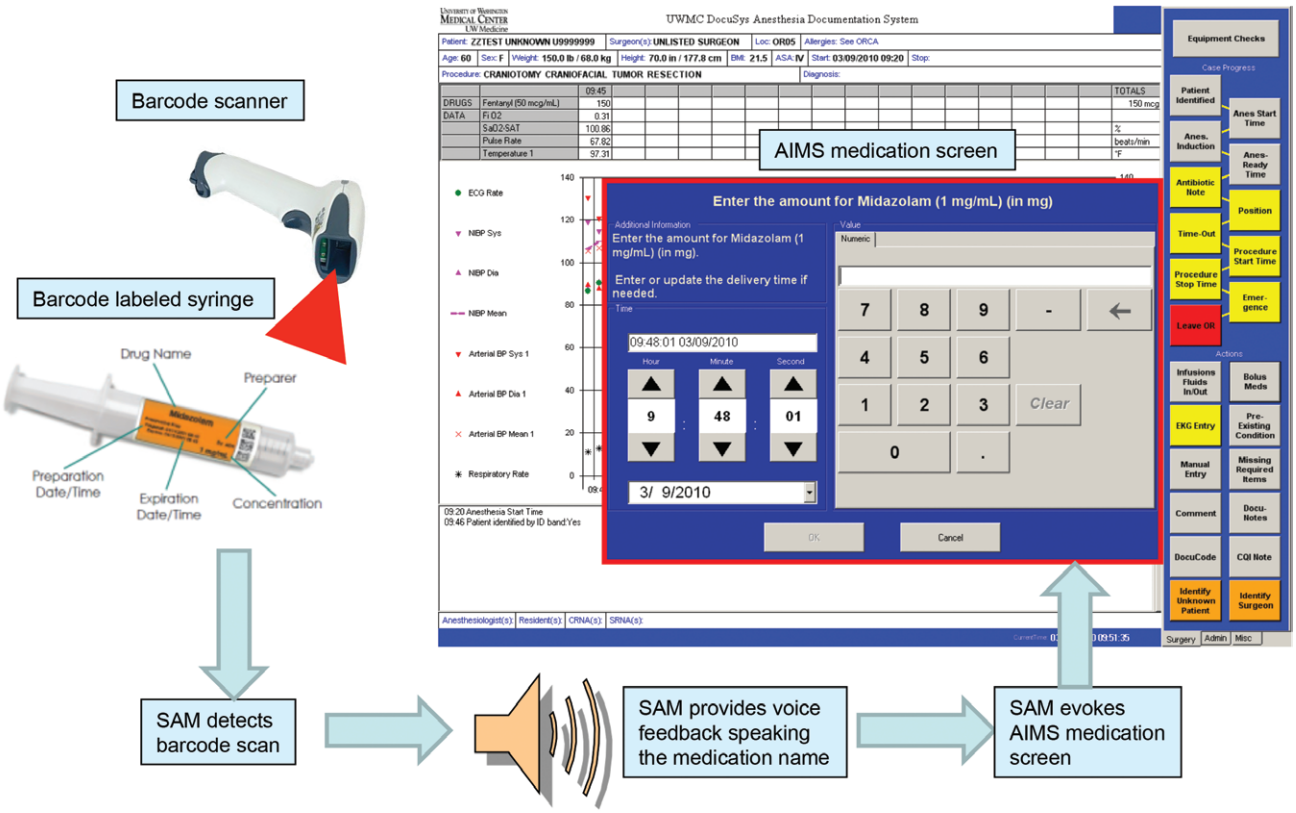

Figure 4. The workflow in Smart Anesthesia Manager (SAM) for barcode identification of a syringe with a Codonics Safe Label System (SLS) label. The dose of the drug is manually entered onto the touch screen of the Anesthesia Information Management System (AIMS) display. The time of scanning the drug appears in the medication administration time field by default; however, this time can be adjusted if necessary.

a provision allowing the dose of the drug to be entered into the anesthesia record. The workflow of drug administration with syringes bearing Codonics SLS labels containing barcodes is shown in Figure 4 and in the Supplemental Digital Content 3, video, http://links.lww.com/AA/A875. An internal computer log was kept of all drug administrations and syringe barcode scans.

After the introduction of the system, we prospectively measured the use of the SAM drug scanning system in the 2 cardiothoracic ORs. The AIMS and SAM databases were interrogated to determine the bolus drugs given during a case. For each bolus drug, the presence or absence of a corresponding barcode scan in the SAM audit logs was verified. A drug administration was deemed to be successfully scanned if a documented drug in the AIMS record had a corresponding entry in audit logs, indicating that the anesthesia provider scanned the drug barcode at the time of administration. If the time stamp of the barcode scan was later than the drug administration time entered in the AIMS by the provider, this was not considered a successfully scanned drug administration because barcode scanning is intended to occur immediately before drug administration, not after administration. The overall rate of scanning was computed by dividing the number of successfully scanned barcoded drugs by the total number of bolus drugs. The rate of scanning was determined for each attending anesthesiologist. Syringes prepared by drawing the drug from an infusion bag could not be barcoded and were therefore excluded from the utilization calculation. Utilization reports were generated weekly and e-mailed to the anesthesia faculty to provide performance feedback.

After 13 weeks using the Codonics SLS and the SAM barcode scanner, we found that the rate of scanning the syringe barcode at the time of drug administration was disappointingly low. Therefore, we offered an incentive, in the form of coffee gift cards in the amounts of $100, $50, and $25 for the attending anesthesiologists with the 3 highest cumulative rates of barcode scanning (excluding the 2 coauthors, SJ and AB) after an additional 8 weeks of data collection.

Data and Statistical Analysis

Continuous, discrete, and categorical data were described as the mean, range, and standard deviation (SD) where appropriate. To account for clustering effects within each surgical case and anesthesiologist, we chose a generalized estimated equation logit model using the exchangeable (equal) correlation structure, specifying anesthesiologist as the unit of clustering.[11] This approach provides standard errors for parameter estimates, which account for clustering and from which appropriate confidence intervals (CIs) and significance tests can be computed. CIs are provided for estimates of percent compliance with labeling standards. However, testing was not performed to compare the rates of compliant labels before and after the introduction of the Codonics SLS system because the sampling frame was not comparable at the 2 times. Hypothesis testing was performed to compare the rate of scanning of syringe barcodes before and after the coffee card incentive since the same

ORs and providers were involved in the 2 time periods. The overall pre-post comparison was tested, and since that was significant, further pre-post analyses were conducted within each of the 12 providers. All *P* values are reported uncorrected for multiple comparisons. *P* values ≤0.001 were considered statistically significant with correction. All statistical comparisons were performed using STATA version 11.0 (StataCorp LP, College Station, TX).

RESULTS

Use of the Codonics SLS drug labeling system in 2 cardiothoracic ORs and the satellite pharmacy resulted in >75% compliant syringe labels (95% CI, 75%–98%). All syringe labels made using the Codonics SLS system were compliant. Before the introduction of the Codonics SLS drug labeling system, we audited 327 syringes that were prepared by either the satellite pharmacy or anesthesia providers in multiple ORs. The anesthesia providers prepared 127 (39%) syringes, while the satellite pharmacy prepared 200 (61%) syringes. Twelve percent (n = 15) of anesthesia provider-prepared syringes were without a label. Of the 15 unlabeled syringes, 13 contained propofol while 2 had a drug vial taped to the syringe. Of the remaining 112 syringes with labels prepared by anesthesia providers, 21% (n = 24) were missing drug concentration, 41% (n = 46) were missing expiration date and time, 7% (n = 8) had incorrect label color, 4% (n = 4) were illegible, and 1% (n = 1) used abbreviations (Fig. 5). Fourteen percent had at least 2 label elements missing (Fig. 6). There were only 46 syringes (36%) prepared by clinicians that were compliant. Of the 200 syringes prepared by the satellite pharmacy, all were compliant except 3% (n = 6) that had incorrect label color (all were lidocaine syringes with white labels instead of the recommended gray labels, which were out of stock).

After the introduction of the Codonics SLS drug labeling system in 2 cardiothoracic ORs and the OR satellite pharmacy, a repeat audit found 312 syringes, of which 101 (32%) had been prepared by anesthesia providers, and 211 (68%) by the satellite pharmacy. All these syringes had a label. All the syringe labels prepared by the satellite pharmacy and 93% of the syringe labels prepared by the anesthesia providers were compliant. Anesthesia providers prepared 88% (89 of 101) of the syringe labels using the Codonics SLS system, which were all compliant. Twelve percent (12 of 101) of the syringe labels prepared by anesthesia providers were still made by hand, of which only 42% (5 of 12) were compliant. Of 12 syringe labels manually prepared by anesthesia providers, 50% (n = 6) were missing drug concentration, 17% (n = 2) were missing expiration date and time, and 8% (n = 1) had incorrect label color. Seventeen percent (n = 2) of syringe labels manually prepared by anesthesia providers had at least 2 label elements missing. None of the syringe labels prepared by anesthesia providers were illegible or used abbreviations. The OR satellite pharmacy prepared all the syringe labels using Codonics SLS system. Anesthesia providers exchanged 91% (192 of 211) of the usual pharmacy prefilled syringes containing traditional labels for the special pharmacy prefilled syringes containing Codonics SLS labels for the use in this study.

The average rate of scanning barcodes on syringe labels using SAM was 25% (730 drugs scanned out of 2976 drug administrations) over 13 weeks but increased to 58% (956 drugs scanned out of 1645 drug administrations) over the subsequent 8 weeks (P < 0.001) after introduction of a simple (coffee card) incentive (Figs. 7, 8 and 9). Nine anesthesia faculty members had significant differences in their rate of barcode scanning at the time of drug administration after the incentive (Fig. 7). There were relatively

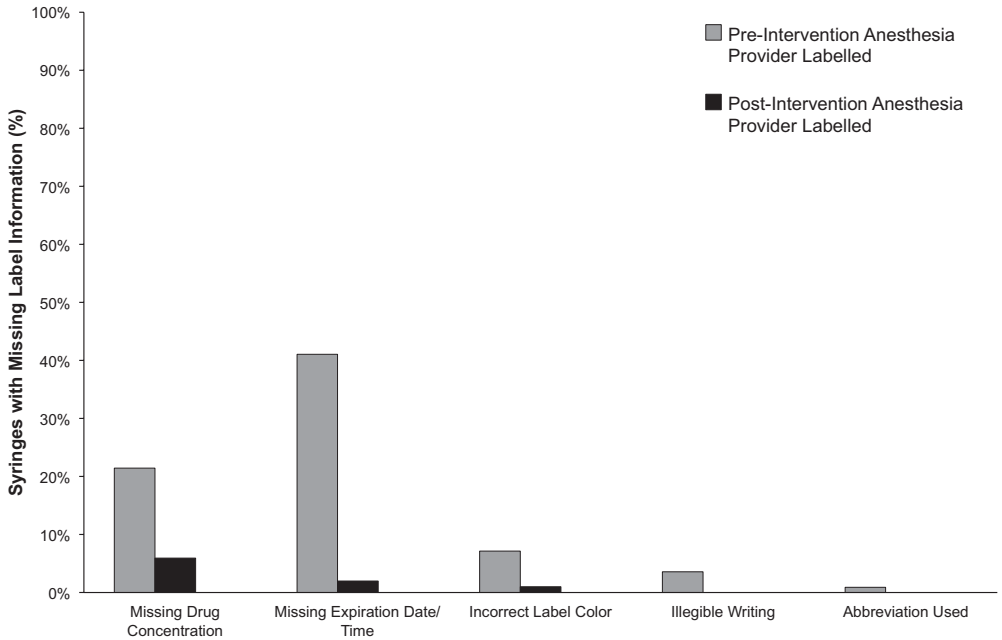

Figure 5. The percentage of anesthesia provider-prepared syringes with missing label elements before and after introduction of the Codonics SLS system. The syringes with missing elements following introduction of the Codonics SLS system had handmade labels that were not made with the Codonics SLS system.

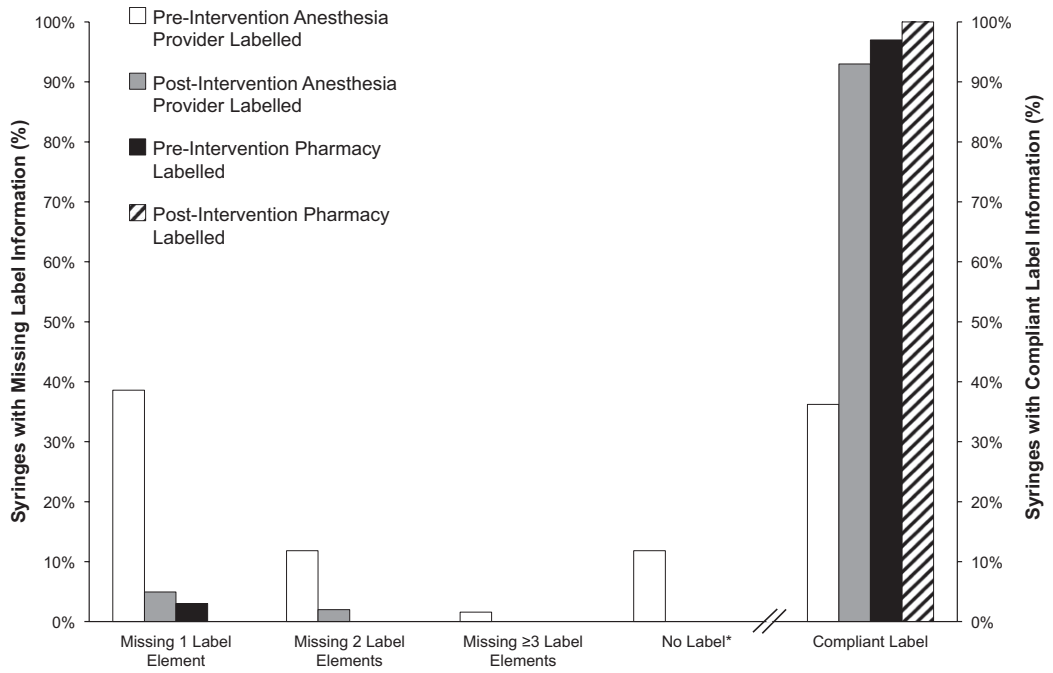

Figure 6. The percentage of syringes with various numbers of missing label elements, as prepared by anesthesia providers or the operating room satellite pharmacy, before and after the introduction of the Codonics SLS system in both the operating room and the pharmacy. Syringes that were prepared by anesthesia providers that were not compliant, following introduction of the Codonics SLS system were made by hand, not with the Codonics SLS system. The missing label elements and no label category data are represented by the left-sided vertical axis while the compliant label category data is represented by the right-sided vertical axis as indicated by the horizontal axis break mark. *Syringes without labels were not included in the "missing label elements" categories.

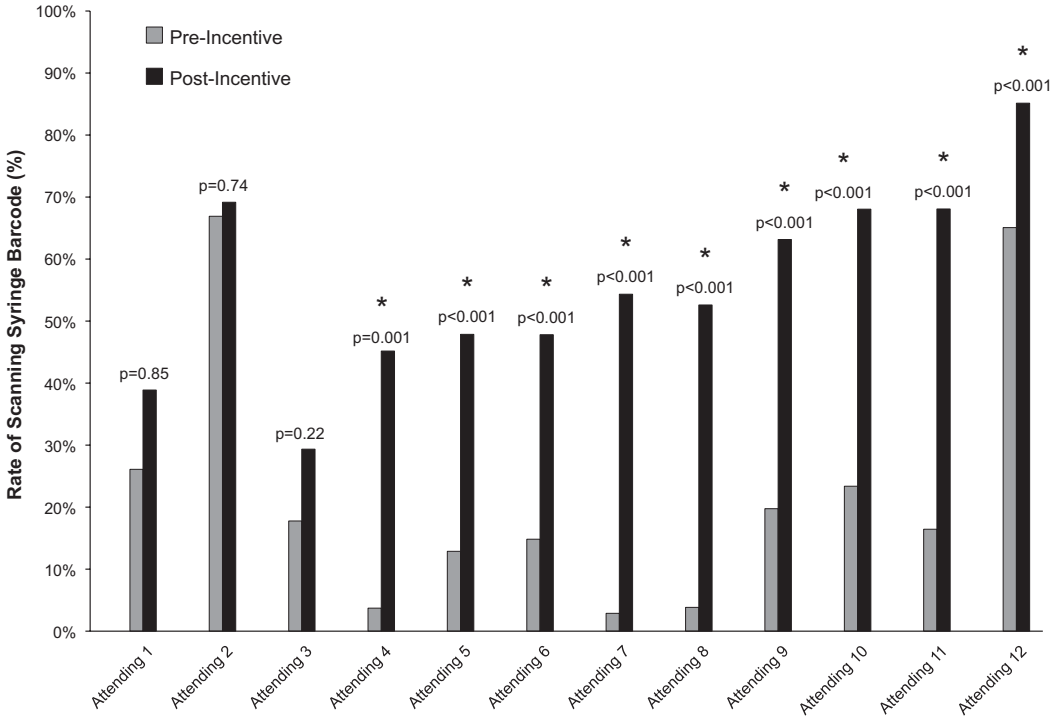

Figure 7. The percentage of bolus drugs that were entered with the SAM barcode scanners at the time of administration for each of 12 attending anesthesiologists, for the first 13 weeks of the study (preincentive) and for the subsequent 8 weeks following an simple incentive consisting of a contest with coffee gift card awards for the top 3 performers (postincentive). Following the simple incentive, 9 anesthesia faculty had significant differences in their rate of barcode scanning at the time of drug administration. Attendings 1 and 2 reported technical issues and infrequent presence in 2 cardiothoracic ORs as reasons for low rate of syringe barcode scanning. Attending 10 already had relatively high rate of barcode scanning before the incentive. Asterisk above the *P* value indicates statistically significant difference. All *P* values are reported uncorrected for multiple comparisons. The *P* value ≤ 0.001 is significant with correction.

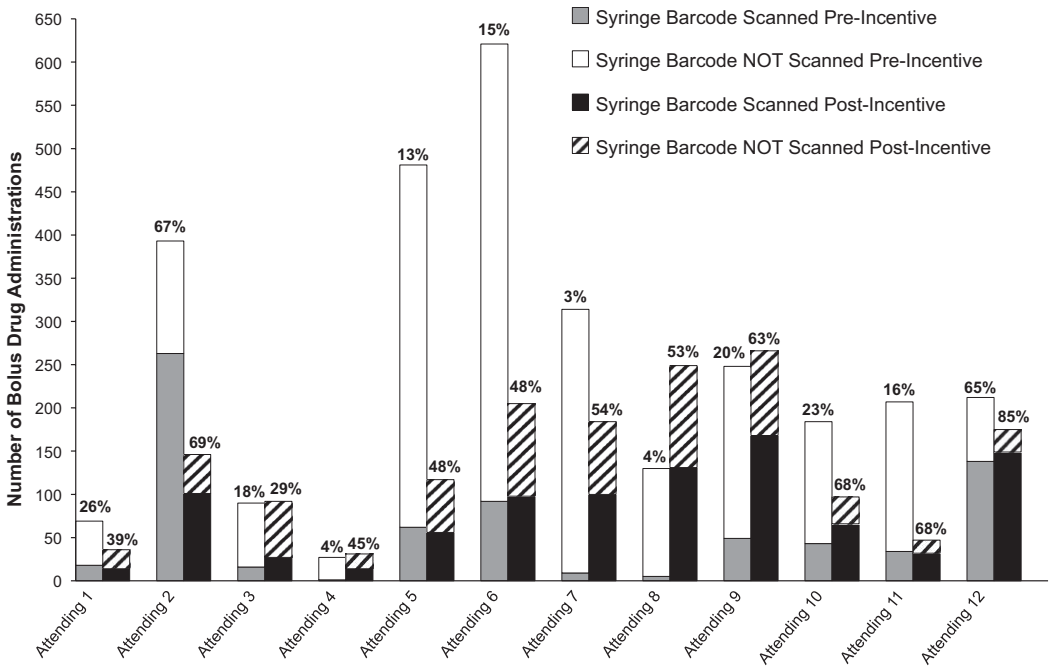

Figure 8. The number of bolus drugs that were scanned (light gray and black) or were not scanned (white and striped) at the time of administration, before (left hand column) and after (right hand column) intervention of a coffee gift card contest are shown for each of the 12 attending anesthesiologists. The percentage of bolus drugs that were scanned is shown at the top of each column.

high and low performing attending physicians before and after the incentive. Before the coffee card incentive, 9% (65 of 730) of syringe barcode scans in the SAM database occurred after the drug administration time was recorded in the AIMS database, based on the time stamp of the barcode scan and the time of administration entered by the provider, and were not counted as successful scans in the rates reported above. Similarly, 10% (96 of 956) of syringe barcode scans after the coffee card incentive occurred after the drug administration time was recorded in the AIMS database and were not counted as successful scans in the rates reported above.

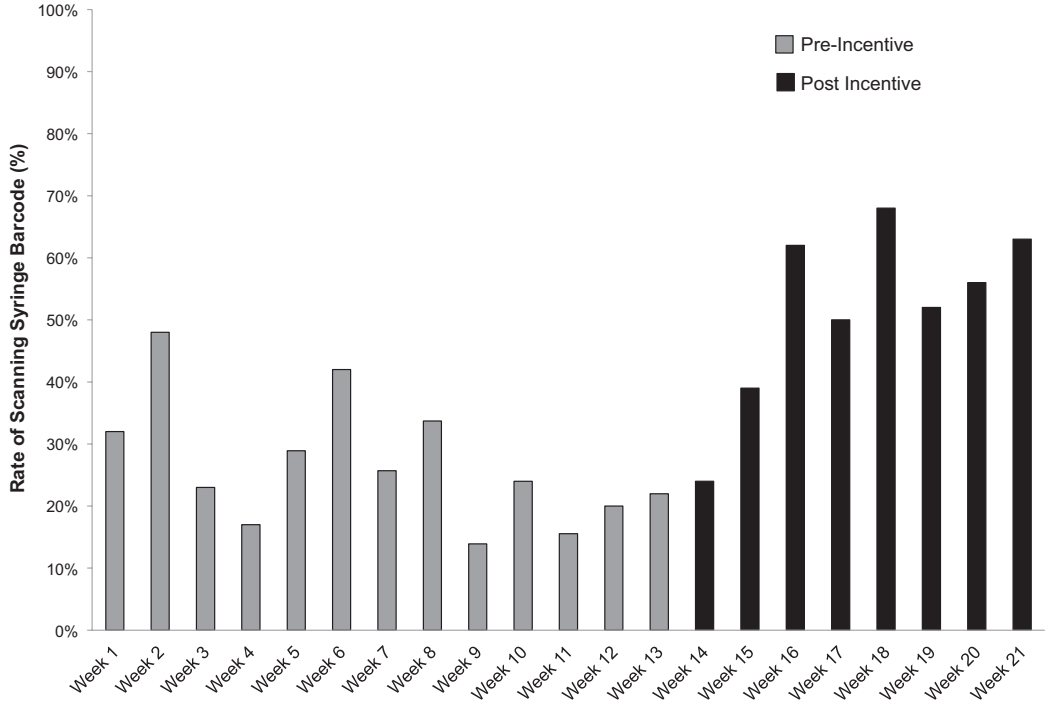

Figure 9. The rates of scanning syringe label barcodes at the time of drug administration on a weekly basis during 13-week preincentive and 8-week postincentive period.

Table 2. Issues Encountered with Codonics SLS Units During the Study

No. instances	Issue
7	Drug NDC was not found in the formulary (fentanyl, rocuronium, midazolam, and propofol)[a]
2	Printer ink cartridge empty
3	Paper jam
3	Printer paper roll ran out
2	System stopped responding and required reboot

NDC = national drug code, which is specific to drug manufacturer, drug strength, and package; SLS = Safe Label System.

[a]Fentanyl, rocuronium, midazolam and propofol NDC were in the Codonics formulary when the study began, but changes in drug manufacturer or packaging during the study required new NDCs to be entered. Therefore, regular routine maintenance of the Codonics formulary is necessary.

Technical issues that interfered with normal function of the Codonics system were tracked and are shown in Table 2.

DISCUSSION

Compliance of syringe labels prepared by anesthesia providers with the previously described recommendations from various regulatory agencies and standards-setting bodies (Table 1) has not been well studied. Our preintervention syringe audit demonstrated poor compliance, consistent with 2 previous reports.[12,13] The use of the Codonics SLS drug labeling system resulted in complete compliance with labeling requirements when used by the anesthesia provider; the only labeling failures pertained to labels that were made by hand. The most likely reason for using hand labeling after introduction of the Codonics SLS system was technical issues we encountered with the system during the study (Table 2), although we did not specifically track the reasons for not using the Codonics SLS system. In addition, restriction of the second part of the syringe audit to the subset of the anesthesia providers and cardiothoracic ORs (because only 3 Codonics SLS units were available to us) may have introduced a selection bias. There are no prospective randomized studies showing that drug labeling practices directly reduce drug administration errors. However, human factors research suggests that strategic use of labels may reduce errors.[14]

While scientific validation of the labeling recommendations of the regulatory agencies and standards-setting bodies listed in Table 1 would be desirable, it is important to understand that hospitals may be held accountable for meeting certain regulatory requirements, even in the absence of scientific validation. For example, many American hospitals are subject to the requirements of TJC, whose syringe labeling recommendations are shown in Table 1. Hospitals are likely to expect their anesthesia providers to take a shared interest in meeting the necessary requirements.

Establishing the appropriate date and time of expiration for syringes prepared by anesthesia providers warrants further discussion. TJC standards do not require a date and time of expiration unless the expiration occurs before 24 hours from preparation. The Food and Drug Administration "package insert" for propofol states that propofol has a 6- or 12-hour[h] expiration time after being drawn up into a syringe. However, the United States Pharmacopeia [USP] Chapter <797> (standards for compounding sterile solutions)[i] states that drugs prepared outside an ISO Class 5 environment,[j] such as an OR, should be administered within 1 hour. Interestingly, only 65% of hospital pharmacies use USP <797> compliant cleanrooms according to a recent survey.[15] Nevertheless, any organization wishing to be in compliance with USP <797> with respect to a 1-hour expiration of provider-prepared syringes would require a robust method for applying the date and time of expiration.

Route of administration is not addressed by any of the labeling recommendations in Table 1. Color labeling standards have been proposed to designate the intended route of administration (e.g., blue for IV and yellow for neuraxial);[k] however, to the best of our knowledge, these have not been reconciled with the internationally accepted syringe label colors pertaining to drug class. Confusion between neuraxial and IV injections ports is a potentially very serious route of administration error in anesthesia practice. There has been an effort to develop unique syringe connectors that would prevent a syringe containing a drug intended for the neuraxis to be connected to an IV port and vice versa.[16,17]

There are other possible methods for producing barcoded labels for syringes. Vials can be provided with peel-off or "flag" labels that can be transferred to the syringe. Preparation and expiration date/time and name of the preparer would have to be added by hand. The main disadvantage of this approach is that commercial drug vials are not usually available with flag labels, requiring the end-user to produce and add the labels. Another approach is to use commercially prefilled syringes with compliant labels. The main disadvantages for prefilled syringes are higher cost (Supplemental Digital Content 4, Table, http://links.lww.com/AA/A877, which compares the cost of drug vial acquisition at our institution and commercially available prefilled syringes) and limited availability. Finally, traditional anesthesia drug labels, usually supplied in rolls, could include a barcode; all other information except for the name of the drug would have to be entered by hand. The

[h]Advice contained in package inserts regarding expiration times for propofol is not entirely consistent. Expiration times of both 6 and 12 hours may be found in these documents. We reviewed current FDA approved package inserts for propofol found on a US government website: http://dailymed.nlm.nih.gov/dailymed/search.cfm?startswith=propofol&x=14&y=11. Applicable package inserts included those from AstraZeneca Pharmaceuticals, Fresenius Kabi USA, and APP Pharmaceuticals. AstraZeneca's package insert (dated "Rev 08/05") recommends propofol that has been drawn from a vial into a syringe should be discarded within 6 hours, whereas vials used for continuous infusion should be discarded within 12 hours. Fresenius Kabi USA does not make any distinction between propofol drawn into syringes and propofol vials used for continuous infusion, stating that both should be used within 12 hours (April 2013, pertaining to their product that does include an antimicrobial retardant). A "Health Care Provider Letter" issued by APP Pharmaceuticals (June 19, 2012) regarding Fresenius Propoven 1%, which does not contain any anti-microbial retardant, states that Fresenius Propoven 1% should be discarded within 6 hours of being drawn into a syringe, and that "propofol 1% used for IV infusion" should be discarded within 12 hours, along with the infusion system.

[i]US Pharmacopeia. USP-NF General Chapter <797> Pharmaceutical Compounding - Sterile Preparations. Available at: http://www.usp.org/store/products-services/usp-compounding. Accessed on January 22, 2014.

[j]The air in an ISO Class 5 environment must contain no more than 100 particles per cubic foot (3520 particles/m^3) and typically requires a "biological safety cabinet" or "clean room" in which the air is filtered.

[k]Australian Commission on Safety and Quality in Health Care. National Recommendations for User-applied Labeling of Injectable Medicines, Fluids and Lines. Available at: http://www.safetyandquality.gov.au/wp-content/uploads/2012/02/Labelling-Recommendations-2nd-edition-February-2012_PRESS.pdf. Accessed July 22, 2014.

main disadvantage of traditional anesthesia drug labels is that the label is not physically associated with the vial, so vial swap or label swap errors can still occur.

We deliberately did not attempt to determine whether our system actually prevented errors. Measuring the incidence of drug administration error is difficult and requires a very large number of drug administrations to obtain adequate statistical power. Two previous studies of anesthetic drug error found that 30% of drug errors typically involved the misidentification of a drug vial or a syringe, either due to mislabeling or to a "swap" (correct label that is not read or is misread).[18,19] Prevention of these types of errors may be possible by scanning the vial barcode, generating a corresponding syringe label containing a barcode, and then scanning the barcode on the syringe label immediately before drug administration. The evidence that scanning the barcode of a syringe just before drug administration reduces errors is not extensive.[3,4] Several studies found significant reduction in drug administration errors after implementation of barcode technology in the intensive care units and hospital wards.[20–23] Merry et al.[2] conducted a prospective randomized trial of a comprehensive anesthesia drug safety system that included scanning the barcodes of syringes before drug administration but did not find a statistically significant difference between the rate of drug administration error when the drug safety system was used compared with that of conventional practice. However, they did note that the rate of error was lower when anesthesia providers consistently scanned the drug barcode before administration and kept the voice prompt active (6.0% vs 9.7%; $P = 0.004$). Unfortunately, the compliance with these 2 features was only 18%. Other studies of drug errors after the implementation of BCMA in the intensive care unit and hospital wards did not find reduction in errors,[24,25] and some have identified unintended adverse consequences of barcode technology.[26–28] A consensus group convened by the Anesthesia Patient Safety Foundation has recommended the use of barcode scanners in anesthesia practice.[29] However, the results of our study and the study by Merry et al. suggest that consistent system use is a major obstacle to successfully implementing systems designed to improve safety, and that the ultimate effectiveness of such systems cannot be conclusively assessed without finding measures to insure a high level of use. In addition, unintended consequences and workarounds will have to be addressed and eliminated.

Convincing anesthesia providers to alter their work habits will generally require deliberate effort. Systems designed to improve safety will be accepted more readily and implemented more easily if they also improve efficiency. Recommended procedures are more likely to be followed if the staff members find that their job is made easier or more satisfying.[30–32] Our syringe audit showed that our staff quickly adopted the routine use of the Codonics SLS drug labeling system, resulting in a high level of syringe labeling compliance. However, consistent use of scanning the barcode on the syringe at the time of drug administration was more difficult to achieve. Interviews with staff did not reveal any objection to the rationale for scanning the barcode or major problems with the process itself. The reasons for the low rate of barcode scanning appeared to be difficulty remembering to use the new process or lack of motivation. Belief that barcode scanning is not necessary, helpful, useful, or that it does not promote safety may be detractors.

Improving the drug preparation and administration workflow is an important consideration when implementing BCMA technology. The Codonics units were mounted on the left side of the anesthesia cart, which is next to the syringe preparation area without impacting the amount of space on top of the anesthesia cart. The Codonics software version used in the study required 14 seconds to print the labels (the current software version takes only 7 seconds). Although we did not measure the time required to draw a drug into a syringe, 14 seconds is sufficiently fast in our experience that the steps necessary to draw a drug into a syringe can be completed while the label is printing. Fraind et al.[33] described 27 different steps in the process of IV bolus drug preparation including 2 steps for labeling a syringe (obtaining and attaching the label to the syringe). The new process using the Codonics units would replace the step of "obtaining a label" with scanning the vial and printing a label. However, the steps outlined by Fraind et al.[33] do not include locating the drug label roll, peeling off the label and writing additional information on a label, which would have to be added to their list to produce compliant labels. Those additional tasks would not be necessary with the Codonics unit, because all the required information is printed automatically, therefore improving the workflow of drug preparation.

Fraind et al.[33] also documented 14 steps in the process of administering an IV drug. Scanning the syringe with a barcode scanner would add another step to their list. However, the current drug documentation process using the AIMS at our institution without barcode scanning consists of 4 steps including selecting the drug menu on the main screen, scrolling through the list of drugs, selecting the drug, and entering the dose. Scanning the bar code with SAM actually shortens this process to 2 steps, scanning the barcode and entering the drug dose, because the drug entry screen is automatically brought up on the AIMS screen when the syringe bar code is identified.

Because some anesthesiologists and surgeons did not like the voice prompt that is intended to occur when a syringe label is scanned, staff members sometimes muted the sound on the workstation that is used for the AIMS. We believe that the voice prompt is important, because it enables the anesthesia provider to scan and administer the drug without constantly looking at the AIMS display screen. Without a voice prompt, wrong drug errors may go unrecognized if the anesthesia provider does not look at the display screen before administering the drug. Merry et al.[2] also found that the voice prompt of the barcode scanner system was frequently disabled during their prospective evaluation of their multimodal drug safety system. Interestingly, while voice prompts have been widely used in airplane cockpits and for certain medical applications such as defibrillators, there are apparently no studies of voice prompts in the ORs. However, Botney and Gaba[34] have discussed auditory prompts in general. There is evidence that alarms using voice are more effective than traditional alarms using sounds.[35]

To further improve the rate of syringe label barcode scanning, we tried a simple intervention that consisted of a

contest in which we offered coffee cards to the attending staff with the highest rate of scanning syringe labels. The intervention was immediately and dramatically effective. While this approach of using an incentive may be useful, clearly a more sustainable approach is needed that will result in consistent use of bar coding at a rate of >90%. We can envision 2 alternative approaches that could be used, both of which would require alteration of our AIMS software. The first approach would be to make scanning the barcodes mandatory; drug menus would not be accessible without scanning a barcode. On rare occasions when a barcode was not available for a drug, open text entry could serve as a backup method of recording the drug in the record. The second approach would be to make the drug menus more difficult to access except by scanning a barcode; drug menus could be accessed from the AIMS screen manually but would be "buried" under several layers of selection keys, making barcoding a much easier method of entering a drug into the record.

Introduction of any new technology into clinical practice has the potential for causing unintended consequences. We were not aware of any particular unintended consequences during this study. Hypothetically, taking the time to make a syringe label could result in a delay in therapy during an emergency. However, it should be noted that TJC and other agencies allow for omitting the syringe label for a drug that is going to be administered immediately by the provider who has prepared the syringe. We did encounter 7 drug vials with barcodes that were not included in our Codonics barcode formulary and other minor systems issues (Table 2). Technical failures can affect the success of an otherwise well-conceived system. The barcode formulary does need to be maintained and updated regularly, because drug products are constantly changing. A backup method for producing compliant labels by hand should be immediately available during use of the Codonics system, because occasional failures are possible with any equipment.

A major limitation of our study is that we did not observe the staff to determine whether the syringe barcodes were scanned before or after drug administration. Some drugs were probably administered before scanning the barcode on the syringe while the anesthesia provider did not record the correct time of administration, in which case the barcode scan time stamp would be recorded as the time of administration. This is clearly a critical issue because only scanning the barcodes before drug administration provides an opportunity to avoid a syringe swap type of error. Studies with direct observation are needed to determine the true rate of appropriate scanning before drug administration; however, such studies are logistically difficult and expensive.

In conclusion, the anesthesia barcode drug administration system that we have described, consisting of the Codonics SLS drug labeling system and the SAM, could be used to achieve compliance with a set of syringe labeling requirements and to identify the drug by scanning the barcode at the time of drug administration. Obtaining high levels of compliance with scanning syringe label barcodes will probably require configuring the AIMS so that scanning the barcode on the syringe is much more convenient than entering drugs from a menu, or so that scanning the barcode is mandatory. Strong support from departmental leadership for safety initiatives may also be helpful. Testing the hypothesis that using barcode scanners to identify drug vials and syringes will actually reduce drug administration errors will require a large prospective randomized trial in which there is a high level of compliance with the prescribed use of the barcode scanners.

DISCLOSURES:

Name: Srdjan Jelacic, MD.
Contribution: This author helped design and conduct the study, collect the study data, analyze the data, wrote the manuscript, is the primary author of the manuscript, and is the author responsible for archiving the study files.
Attestation: Srdjan Jelacic has seen the original study data and approved the final manuscript.
Name: Andrew Bowdle, MD PhD.
Contribution: This author helped design and conduct the study, collect the study data, analyze the data, and wrote the manuscript.
Attestation: Andrew Bowdle has seen the original study data and approved the final manuscript.
Name: Bala G. Nair, PhD.
Contribution: This author helped design and conduct the study, collect the study data, analyze the data, and wrote the manuscript.
Attestation: Bala G. Nair has seen the original study data and approved the final manuscript.
Name: Dolly Kusulos, RPh.
Contribution: This author helped design and conduct the study and write the manuscript.
Attestation: Dolly Kusulos reviewed the analysis of the data and approved the final manuscript.
Name: Lynnette Bower, PharmD.
Contribution: This author helped design and conduct the study and write the manuscript.
Attestation: Lynnette Bower reviewed the analysis of the data and approved the final manuscript.
Name: Kei Togashi, MD.
Contribution: This author helped analyze the data and write the manuscript.
Attestation: Kei Togashi has seen the original study data and approved the final manuscript.
This manuscript was handled by: Sorin J. Brull, MD, FCARCSI (Hon).

ACKNOWLEDGMENTS

We would like to acknowledge Codonics Inc. (Middleburg Heights, OH), which provided Safe Label System units for our study. Codonics Inc., did not have any involvement in the design, study conduct, data collection or analysis, or manuscript preparation.

REFERENCES

1. Karsh BT. Beyond usability: designing effective technology implementation systems to promote patient safety. Qual Saf Health Care 2004;13:388–94
2. Merry AF, Webster CS, Hannam J, Mitchell SJ, Henderson R, Reid P, Edwards KE, Jardim A, Pak N, Cooper J, Hopley L, Frampton C, Short TG. Multimodal system designed to reduce errors in recording and administration of drugs in anaesthesia: prospective randomised clinical evaluation. BMJ 2011;343:d5543
3. Cescon DW, Etchells E. Barcoded medication administration: a last line of defense. JAMA 2008;299:2200–2
4. Young J, Slebodnik M, Sands L. Bar code technology and medication administration error. J Patient Saf 2010;6:115–20

5. Merry AF, Webster CS, Connell H. A new infusion syringe label system designed to reduce task complexity during drug preparation. Anaesthesia 2007;62:486–91
6. Webster CS, Merry AF, Gander PH, Mann NK. A prospective, randomised clinical evaluation of a new safety-orientated injectable drug administration system in comparison with conventional methods. Anaesthesia 2004;59:80–7
7. Webster CS, Larsson L, Frampton CM, Weller J, McKenzie A, Cumin D, Merry AF. Clinical assessment of a new anaesthetic drug administration system: a prospective, controlled, longitudinal incident monitoring study. Anaesthesia 2010;65:490–9
8. Nair BG, Newman SF, Peterson GN, Schwid HA. Smart Anesthesia Manager™ (SAM)–a real-time decision support system for anesthesia care during surgery. IEEE Trans Biomed Eng 2013;60:207–10
9. Nair BG, Newman SF, Peterson GN, Wu WY, Schwid HA. Feedback mechanisms including real-time electronic alerts to achieve near 100% timely prophylactic antibiotic administration in surgical cases. Anesth Analg 2010;111:1293–300
10. Nair BG, Peterson GN, Neradilek MB, Newman SF, Huang EY, Schwid HA. Reducing wastage of inhalation anesthetics using real-time decision support to notify of excessive fresh gas flow. Anesthesiology 2013;118:874–84
11. Liang KY, Zeger SL. Longitudinal data analysis using generalized linear models. Biometrika 1986;73:13–22.
12. Le CP, Kalarickal P, Moore A, Primeaux P. Syringe Labeling Compliance in an Academic Medical Center. Chicago; The Anesthesiology 2011 Annual Meeting, A114
13. Vernest KA, Nanji KC, Sims NM, Driscoll WD, Levine WC. "Smart Labels": Improving Syringe Labeling Compliance and Patient Safety in the Operating Room. New Orleans; The Anesthesiology 2009 Annual Meeting, A609
14. Jensen LS, Merry AF, Webster CS, Weller J, Larsson L. Evidence-based strategies for preventing drug administration errors during anaesthesia. Anaesthesia 2004;59:493–504
15. Pedersen CA, Schneider PJ, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: dispensing and administration–2011. Am J Health Syst Pharm 2012; 69:768–85
16. Bell D. Recurrent wrong-route drug error - a professional shame. Anaesthesia 2007;62:541–5
17. Block M, Horn RJ, Schlesinger MD. Reducing risk of epidural-intravenous misconnections. APSF Newsletter 2012;26:63–6
18. Bowdle TA, Kruger C, Grieve R, Emmens D, Merry AF. Anesthesia drug administration errors in a university hospital. Anesthesiology 2003;99:A1358
19. Webster CS, Merry AF, Larsson L, McGrath KA, Weller J. The frequency and nature of drug administration error during anaesthesia. Anaesth Intensive Care 2001;29:494–500
20. Paoletti RD, Suess TM, Lesko MG, Feroli AA, Kennel JA, Mahler JM, Sauders T. Using bar-code technology and medication observation methodology for safer medication administration. Am J Health Syst Pharm 2007;64:536–43
21. Poon EG, Keohane CA, Yoon CS, Ditmore M, Bane A, Levtzion-Korach O, Moniz T, Rothschild JM, Kachalia AB, Hayes J, Churchill WW, Lipsitz S, Whittemore AD, Bates DW, Gandhi TK. Effect of bar-code technology on the safety of medication administration. N Engl J Med 2010;362:1698–707
22. DeYoung JL, Vanderkooi ME, Barletta JF. Effect of bar-code-assisted medication administration on medication error rates in an adult medical intensive care unit. Am J Health Syst Pharm 2009;66:1110–5
23. Franklin BD, O'Grady K, Donyai P, Jacklin A, Barber N. The impact of a closed-loop electronic prescribing and administration system on prescribing errors, administration errors and staff time: a before-and-after study. Qual Saf Health Care 2007;16:279–84
24. Helmons PJ, Wargel LN, Daniels CE. Effect of bar-code-assisted medication administration on medication administration errors and accuracy in multiple patient care areas. Am J Health Syst Pharm 2009;66:1202–10
25. Morriss FH Jr, Abramowitz PW, Nelson SP, Milavetz G, Michael SL, Gordon SN, Pendergast JF, Cook EF. Effectiveness of a bar-code medication administration system in reducing preventable adverse drug events in a neonatal intensive care unit: a prospective cohort study. J Pediatr 2009;154:363–8, 368.e1
26. McDonald CJ. Computerization can create safety hazards: a bar-coding near miss. Ann Intern Med 2006;144:510–6
27. Cochran GL, Jones KJ, Brockman J, Skinner A, Hicks RW. Errors prevented by and associated with bar-code medication administration systems. Jt Comm J Qual Patient Saf 2007;33: 293–301, 245
28. Patterson ES, Cook RI, Render ML. Improving patient safety by identifying side effects from introducing bar coding in medication administration. J Am Med Inform Assoc 2002;9:540–53
29. Eichhorn JH. APSF hosts medication safety conference. APSF Newsl 2010;25:1–20
30. Kennerly J, Jenkins A, Lewis AN, Eckel SF. Implementing smart pumps for epidural infusions in an academic medical center. Am J Health Syst Pharm 2012;69:607–11
31. Bailey PL, Glance LG, Eaton MP, Parshall B, McIntosh S. A survey of the use of ultrasound during central venous catheterization. Anesth Analg 2007;104:491–7
32. Egger Halbeis CB, Epstein RH, Macario A, Pearl RG, Grunwald Z. Adoption of anesthesia information management systems by academic departments in the United States. Anesth Analg 2008;107:1323–9
33. Fraind DB, Slagle JM, Tubbesing VA, Hughes SA, Weinger MB. Reengineering intravenous drug and fluid administration processes in the operating room: step one: task analysis of existing processes. Anesthesiology 2002;97:139–47
34. Botney R, Gaba DM. Human factors issues in monitoring. In: Hines RL, Blitt CD, eds. Monitoring in Anesthesia and Critical Care Medicine. 3rd ed. New York, NY: Churchill Livingstone, 1994:42–4
35. Edworthy J, Hellier E. Alarms and human behaviour: implications for medical alarms. Br J Anaesth 2006;97:12–7