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Experience with the use of the Codonics Safe Label System™ to improve labelling compliance of anaesthesia drugs

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SUMMARY

The Codonics Safe Labeling System™ (http://www.codonics.com/Products/SLS/flash/) is a piece of equipment that is able to barcode scan medications, read aloud the medication and the concentration and print a label of the appropriate concentration in the appropriate colour code. We decided to test this system in our facility to identify risks, benefits and usability. Our project comprised a baseline survey (25 anaesthesia cases during which 212 syringes were prepared from 223 drugs), an observational study (47 cases with 330 syringes prepared) and a user acceptability survey. The baseline compliance with all labelling requirements was 58%. In the observational study the compliance using the Codonics system was 98.6% versus 63.8% with conventional labelling. In the user acceptability survey the majority agreed the Codonics machine was easy to use, more legible and adhered with better security than the conventional preprinted label. However, most were neutral when asked about the likelihood of flexibility and customisation and were dissatisfied with the increased workload. Our findings suggest that the Codonics labelling machine is user-friendly and it improved syringe labelling compliance in our study. However, staff need to be willing to follow proper labelling workflow rather than batch label during preparation. Future syringe labelling equipment developers need to concentrate on user interface issues to reduce human factor and workflow problems. Support logistics are also an important consideration prior to implementation of any new labelling system.

Key Words: anaesthesia, drug administration, syringe labelling, compliance

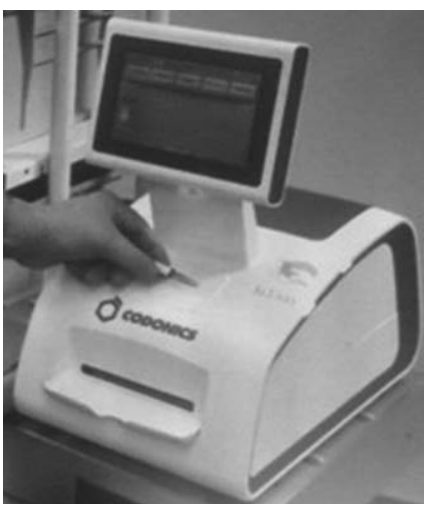

FIGURE 1: Codonics Safe Label System.

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The Codonics Safe Labeling System™ is a piece of equipment that is able to scan barcode medications, read aloud the medication and the concentration and print a label of the appropriate concentration in the appropriate colour code (Figure 1). An additional feature is read back. Once the syringe is labelled, the rescan of the label enables a visual and audio check just prior to administration. We decided to test this system in our facility to identify risks, benefits and usability. Our project comprised a baseline survey, an observational study and a user acceptability survey.

METHODS

The National University Hospital is an 1100 bed academic medical centre of the National University Health System in Singapore. There are 24 operating rooms and about 30,000 operations a year are performed in the operating room suites. The anaesthesia department has 37 specialists and 60 residents.

The anaesthesia department in 2012 (at the time of the study) already had used a medication safety program that included regular standardising and sorting of medications to remove less-often used drugs from the anaesthesia drug trolley, and

regular organisation of the drug drawers to facilitate identification of the correct drug. There is also a hospital electronic, anonymous reporting system and an audit form for reporting of any incidents including medication errors and near-misses for every anaesthesia case. There are pre-prepared drug labels that anaesthesiologists may use to stick on syringes, which in this paper we will refer to as conventional labelling. If the specific drug used did not have a pre-prepared label then blank beige adhesive tape could be used with a marker pen to write the name and other information of the medication on the adhesive tape.

Labelling compliance included that described by the Joint Commission Standards[1] and the American Society of Anesthesiologists[2].

According to Joint Commission Standards Standard MMU.5.2, labelling compliance is defined as 'when a medication is removed from its original packaging or prepared and dispensed in a different form/container – and *not immediately administered* – the medication *must be labelled* with the *name* of medication, the *dosage*/*concentration* of the medication, the date of *preparation*, and the time of *expiration*' (emphasis added). The American Society of Anesthesiologists standard colour code, legibility and security (i.e. adequate stickiness of labels) on syringes were also considered in labelling compliance assessment in our study.

In anaesthesia the dose often depends on the response of the patient and redosing may occur, hence the presence of the concentration on the label was audited and not the dose itself.

First, a baseline audit was done to determine the extent of any deficiencies in drug labelling in the general operating rooms. The second part of the study comprised a randomised study with 1) conventional labelling versus 2) the use of the Codonics machine, in order to determine if there was a difference in compliance or medication error rate. One operating room was selected for consistency of cases and ease of logistics. The operating theatre selected conducted cases only for obstetrics and gynaecology to facilitate the homogeneity of the data collected. The third part of the study was a user acceptability survey.

Participants were all members of the anaesthesia department. Ethics approval was obtained from the Singapore National Healthcare Group Ethics Review Board (Approval Number: 2012/00514). Patient consent was not required.

Baseline Audit

An observational study was conducted on the labelling compliance in the main operating theatre rooms by one consistent trained observer who stayed throughout the case to observe for medication errors and labelling practices. The observer was a medical physician who was allocated full-time to this project. She had undergone training for three months with the pharmacy department and in the operating room with an anaesthesiologist to understand preparation and administration of medications, audit of labelling compliance and common anaesthesia medication errors. She was observing as unobtrusively as possible.

Twenty-five cases in different operating rooms covering all specialties were observed.

Randomised Study

All anaesthesiologists in the department were given tutorials and hands-on training with the machine prior to the study. Sessions were repeated to ensure that everyone had been trained and attendance was recorded to ensure compliance. The machine was also placed in the recovery room area for a week to allow familiarisation with a trainer at hand to clarify any issues.

Data collection occurred over two months in 2012 in only one major operating room covering obstetric and gynaecological cases. Anaesthesiologists were assigned to this room by blinded rostering staff.

The labelling technique (i.e. labelling by conventional means or by use of the Codonics machine) was randomised daily. Randomisation was done by a blinded draw of paper slips with Codonics – case or conventional – on the slips and drawn by a third party who was not involved in the study. A trainer would then refresh anaesthesiologists' knowledge of the use of machine prior to the start of the anaesthetic.

Table 1
Categories of drugs used

Drug Category	Count	Percentage
Opioids	43	19%
Induction agents	41	18%
Vasopressors	34	15%
Antibiotics	23	10%
Muscle relaxants	21	9%
Others	20	9%
Anticholinergic agents	16	7%
Local anaesthetics	11	5%
Relaxant antagonists	7	3%
Heparin	3	1%
Protamine	2	1%
Vasopressor antagonists	2	1%
Total	223	100%

Table 2
Baseline conventional labelling compliance (Total syringes=190)

Subcategory	Number of compliant syringes	% compliance
Secure label	137	72.1
Colour code (ASA)	142	74.7
Legibility	164	86.3
Name	190	100
Concentration	145	76.3
Compliance to all categories	111	58.4

ASA=American Society of Anesthesiologists.

The observation was continuous by the same trained observer as in the baseline study, from the start to the end of the procedure, in order to audit labelling compliance and to detect near-misses and medication errors. Compliance was determined as before.

The Codonics machine is able to read data matrix barcodes only, so ampoules of drugs used for anaesthesia were checked to ensure that they had a compatible barcode, otherwise they were re-barcoded commercially. Each drug has a unique barcode and a library was set up to ensure that there were no duplications of the barcodes. The Codonics machine was on loan for the duration of the study.

User Acceptability Survey

This was designed with input from our university Human Factors Department. The survey questions are listed in Appendix 1 (online).

STATISTICS

Statistics were performed using IBM SPSS version 20 (IBM, Armonk, NY, USA). Based on baseline data, with the expectation that the labelling compliance would improve from 58% total compliance using conventional labelling to at least to 75% total compliance with the Codonics machine with 80% power and level of significance at 0.05, the sample size was calculated to be 81 syringes per arm for the randomised study. To give some allowance for data collection, a minimum of 100 samples for each arm was planned for the study in one major operating room. Chi square testing was used to assess differences in compliance for categorical variables. Differences were considered statistically significant if $P < 0.05$.

RESULTS

Baseline Study

A total of 25 anaesthesia cases were observed during which 212 syringes were prepared from 223 drugs (as some syringes had a combination of drugs (e.g. atropine and neostigmine, glycopyrrolate and neostigmine). The types of drug are described in Table 1.

Table 3
Cases observed and syringes prepared for the randomised study

	Number of cases observed	Number of syringes prepared	Number of syringes for labelling compliance study
Codonics	22	165	139
Conventional	25	165	116

Syringes were excluded if the drugs drawn were administered immediately as labelling is not required under these circumstances. The 223 drugs were placed in a total of 212 syringes (some had a mixture of drugs). From the total 212 syringes, 172 (81%) syringes were labelled, 36 (17%) of syringes were unlabelled and the observation was missed in 4 (2%) of the syringes. Out of 36 unlabelled syringes, 18 syringes were for immediate use (e.g. ondansetron). The syringes that did not require labelling and those not observed were excluded from the study. Hence, a total of 190 syringes were used to determine the labelling compliance as seen in Table 2.

Compliance in all categories of labelling was found to be only 58.4% (111 syringes out of 190, Table 2). Compliance for correct name was 100%. Individual category compliance ranged from 74.7% to 100% (Table 2). However, if the date of preparation and timing of expiration was included then the compliance was 0. There were no near-misses or medication errors detected by the observer or reported by anaesthesiologists.

The types of cases audited at baseline included cardiac, paediatric, gynaecology, general surgery and orthopaedic patients which is broadly representative of the case-mix in our main operating theatres.

Randomised Study

Data collection occurred over two months in 2012. Twelve primary anaesthesiologists and sixteen assisting anaesthesiologists (e.g. trainees) participated in this study. Consent was obtained from the participating anaesthesiologists. Only one anesthesiologist declined to participate and data were not collected for that day. The details of data collection are as shown in Table 3. None of the anaesthesiologists happened to be assigned more than once to the Codonics machine in the study.

A total of 366 drugs were prepared in 330 syringes. Combined drugs are prepared in one syringe and some drugs are excluded from the calculation as

they are administered by infusion or used directly from manufacturer's drug preparation. Out of 330 syringes, 75 syringes were for immediate use and did not need to be labelled according to Joint Commission Standards Standard MMU.5.2. Hence, a total of 255 syringes were used for determining the labelling compliance. The types and number of drugs used were also similar between the groups (Figure 2).

Labelling compliance in the conventional group was 63.8% (74 out of 116 syringes) and in the Codonics group was 98.6% (137 out of 139 syringes) (P <0.0001). If preparation date and time of expiration were included then the compliance in the control would be 0 for the Conventional group. Twelve syringes were not labelled at all in the Control group. Table 4 shows the compliance for subcategories of labelling categories.

The usage of the read back/scan back function of the Codonics machine is restricted by the limited space to keep the machine near the patient. Hence the observer noted that 25% of anaesthesiologists used this function and only for 14.9% of syringes.

There were no near-misses or medication errors reported in this part of the study, either by the observer or by anaesthesiologists.

User Acceptability Survey

A total of 39 anaesthesiologists and residents had hands-on experience with the Codonics machine during the baseline audit and randomised trial and answered the survey on user acceptability. The residents responding had at least six months anaesthesia experience. The survey questionnaires included both closed and open-ended questions.

Out of 39 respondents, 21 (55%) stated that demonstration was the most effective training method, three (8%) chose step-by-step written instructions, four (11%) suggested demonstration combined with a step-by-step instruction chart, eight (21%) did not respond to this question.

Concerning the perceived ease of learning, the majority of participants agreed it is easy to learn and to remember how to use the machine.

The majority agreed that with the Codonics machine it was easy to scan, prepare and print, was more legible and better adhered with security than the conventional preprinted labels in current practice. Most were neutral when asked about the likelihood of flexibility and customisation, ease of maintenance and how likely the machine was to prevent drug errors.

Most of the participants were dissatisfied with the increased workload and increased time of drug labelling. As a result, most of the staff preferred the conventional pre-printed labels though Codonics was more legible and adhered better. Out of 39 respondents, one (2.6%) strongly agreed and 15 (39.5%) agreed that Codonics would improve medication safety; while nine (23.7%) were neutral, 12 (31.6%) disagreed and one (2.6%) strongly disagreed with this statement. Sixteen (41%) agreed that the size, functionality and practicality of the Codonics system was suitable for their use while 11 (28%) and

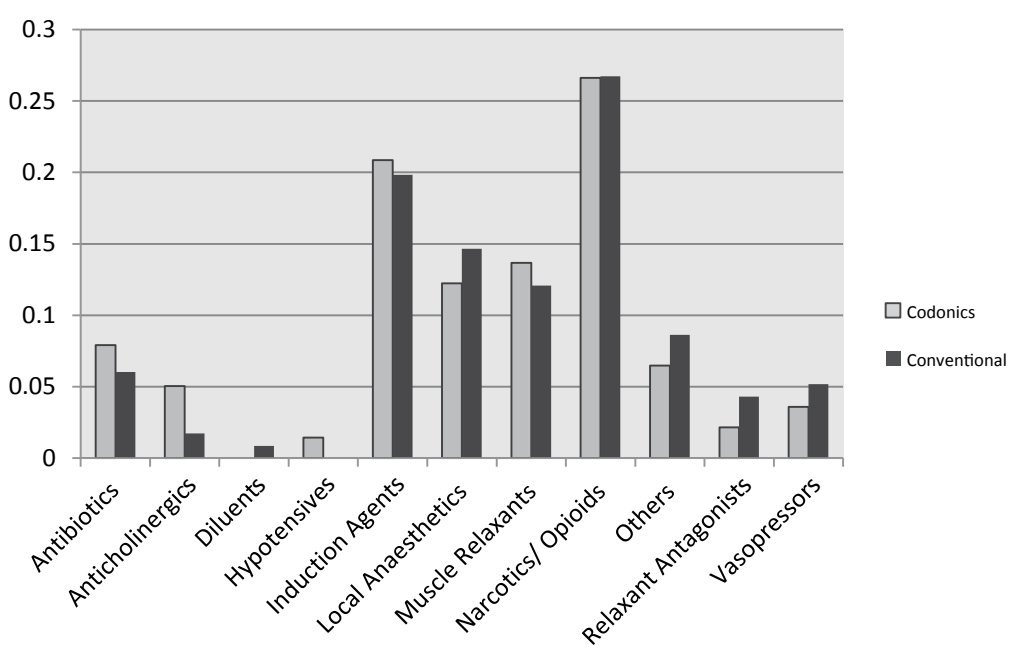

FIGURE 2: Type and number of drugs between groups.

Table 4
Labelling compliance for subcategories

Subcategories	Syringes Codonics count (%)	Syringes conventional count (%)
Security (stickiness)	138(99)	99(85)
Colour code	137(99)	103(85)
Legibility	138(99)	103(85)
Name of drug	138(99)	104(85)
Concentration	137(99)	78(67)
Preparer	133(97)	1(0)
Date and time of preparation	133(97)	2(0)
Date and time of expiration	133(97)	0

12 (31%) were neutral or found it unacceptable. As for the question on overall satisfaction, almost half of the participants (43.6%) were satisfied with the Codonics system while nine (23.1%), ten (25.6%) and three (7.7%) were neutral, found it frustrating or very frustrating respectively.

DISCUSSION

Medication safety is a special concern for anaesthesiologists as preparation, labelling and administration of numerous potent medications occur in rapid sessions often without another person to counter-check. The medication error rate is estimated to be as high as 1 in 203 anaesthesia cases[3,4] and may have serious morbidity in about 4.7% of errors or even lead to death in about 0.3% of errors[3]. Determination of the actual error rate is difficult as the voluntary reporting rate is low[5]. Drug preparation, including labelling and syringe swap, is one of the most common errors, accounting for 50.8% of the incidences[3,6]. Other common errors include that of omission and wrong dosage[7]. The cost of medication errors in anaesthesia worldwide was estimated at US$17.8 to 26.6 billion a year[3,6] and, despite increased awareness in the last 22 years, the frequency of medication errors in anaesthesia has not changed[7,8].

Drug errors have been found to be due to multiple system and human factors[9,10]. Syringe swap and misidentification of labels were common contributing factors and 84% of participants in a 687 anaesthesiologist practitioner survey agreed that improved standards for drug labels would reduce the incidence of errors[11].

Both improved manual labelling systems and technology-assisted (barcode and radiofrequency tag) labelling solutions have been explored[12]. An interesting manual system has been described; this system includes a reusable drug label on the cap of injectable medication to improve ease of access for reading the label and also for use as a label on the syringe[13].

Merry et al have developed a multimodal system for anaesthesia drug preparation, labelling and administration[14]. However, this system is not easily adopted in institutions that do not have enough resources to have pre-drawn syringes or have yet to have an end-to-end electronic medication system.

The Codonics system is user-friendly and does not require much training for use. However we did not extend the randomised study to the emergency or cardiac areas as this would be difficult to coordinate a full-time observer and to ensure consistency of cases. Some of the drug ampoules also required re-barcoding to be recognised by Codonics which incurred additional resources. As the rest of the hospital was already moving towards barcoding drug recognition the extension to anaesthesia is likely a matter of time.

We felt that instead of just data matrix recognition only, if the scanner software in Codonics was able to read a variety of barcodes it would have helped to facilitate the project without software re-engineering which delayed the onset of the project itself. However, an administrator must be at hand to update the barcodes in the system. Every time a new drug or a drug with a different barcode is introduced, the machine software will need to be updated with the changes in the barcodes.

The machine is about the size of a personal computer without any in-built battery power capability. It may be difficult to place it in a position convenient for scanning and read back immediately prior to drug administration. If the power supply needed to be disconnected, or was accidentally disconnected the machine would need to be restarted which takes about a minute and results in a loss of efficiency. Improvement in equipment design and interface, e.g. battery backup and a wireless scanner, could perhaps improve ease of use.

No difference in error rate was reported, however this was not the aim of our study. Our error rate, as estimated by an ongoing audit programme, is about 0.03% and so an estimated 7000 cases in each arm would be required to detect a difference in error rate. Observational studies have been found to be more accurate than incident reporting[5], and in our study both methods were used, neither of which yielded any medication errors during that period for the cases under study. Nevertheless, it is possible the Codonics system could have prevented serious medication errors previously recorded in our department as some

involved syringe swaps (e.g. atracurium instead of midazolam, suxamethonium instead of fentanyl and vasopressin instead of heparin). Other cases such as double dose of drugs (e.g. paracetamol) would not have been prevented by the Codonics system.

We have also observed that the appropriate workflow needs to be followed in order for the Codonics machine to prevent drug error. The ampoule has to be picked and scanned followed by application of the label and rescanning on administration. If staff do not follow the workflow (e.g. preparing drugs by batch, scanning ampoules first and generating a number of labels prior to labelling) then medication errors may not be prevented. This is one trade-off between efficiency and patient safety that staff may have to consider. Sterile medications (e.g. for intrathecal injections) would also require an alternative means to ensure appropriate labelling as the labels from the Codonics machine produced are not sterile.

User feedback included concerns with printing time and request for a few different size labels to be made available in the machine, which is currently not possible.

A potential limitation of the study included the presence of an observer in the room, which may alter behaviour. There is a possibility of the Hawthorne effect. The first baseline audit showed a compliance of 58.4% and the next conventional measurement in the randomised study showed a compliance of 63.8%. It is possible that the staff became more conscious that there was a project to improve labelling in the department and hence consciously improved. Furthermore, the first baseline was done with a wide variety of cases and the second conventional labelling with more restricted types of cases in one operating room. This could also have affected the slight difference in results.

The same observer was present for both the Codonics and conventional groups and hence the presence of the observer should have had an equal effect in the randomised study and should not have biased the result.

Although the rosterers were blinded, none of the anaesthesiologists happened to be assigned to the Codonics machine more than once during the study, which helped to minimise any learning effects. Another limitation of the study was that these observations were done on elective cases only.

The bid to harness technology to improve patient safety has been a focus of healthcare organisations but certainly new gaps and unintended consequences can be an issue[15]. Woods and Dekker elaborated on these issues with clarity, appropriately emphasising the importance in observing how technology, work and people interface in the designing, developing and implementing of technology. There is a misconception that technology is an easy and straightforward substitution for human inadequacies – the substitution myth. This is a gross oversimplification and the addition of a machine redefines the human's role and human/work relationships as well. A resettling of humans into the new practice is often needed, altering the situations and conditions of the people engaged in the task and altering the paths to failure. Woods and Dekker mention that new roles emerge, and in our case, a new role would be someone who is needed to update the drugs into the drug library of the machine. The level of understanding of the work also changes, other than just placing a label on a syringe, anaesthesiologists have to learn to operate and understand how to operate a new machine[16].

Although the compliance with proper labelling improved significantly, the feedback survey is equivocal. Even the perceived simple introduction of barcode scanning prior to administration for a verbal and visual check will require more improvements in order for anaesthesiologists to be able to use this part of the process effectively rather than as an awkward adaptation to work around the technology.

Usability testing early on is critical; as we found in this project, post-release change requests are often slow and costly and users are often not willing or able to wait for changes. This would lead to a loss of momentum and goodwill of the users and resistance to change[17].

Other human factors to be considered include the issues of potential lack of flexibility of technology, the need to have provisions of manual backup, a false sense of security due to loss of human vigilance and over-reliance on technology[18].

CONCLUSION

The Codonics labelling machine is user-friendly and improved syringe labelling compliance in our study. However, staff need to be willing to follow proper labelling workflow rather than batch label during preparation. Future syringe-labelling equipment developers need to concentrate on user-interface issues to reduce human factor and workflow problems. Support logistics are also an important consideration prior to implementation of any new labelling system.

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