

Use of colour-coded labels for intravenous high-risk medications and lines to improve patient safety

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ABSTRACT

Problem: Labelling of high-risk drug infusions and lines is a well-recognised safety strategy to prevent medication errors. Although hospital wards characterised by multiple high-risk drug infusions use different types of labelling, little is known about the contribution of a colour-coded label (CCL) to patient safety.

Setting: A quality improvement programme audit at a tertiary care facility, the Hadassah University Medical Center Ein Kerem, Jerusalem, Israel.

Strategy for change: A CCL for intravenous (IV) high-risk medications and lines was designed to promote safer medication administration at the intensive care unit bedside and in other acute wards.

Methods: The purpose of the study was to compare a new CCL method (intervention) with the current labelling method (control). Laboratory simulation, imitating an intensive care unit, was designed. Safety of the medication treatment and overall duration of nurses' orientation with drugs and lines at the patient's bedside were measured.

Effects of change: The use of the new CCL improved proper identification of IV bags ($p < 0.0001$), reduced the time required for description of overall drugs and lines ($p = 0.04$), improved identification of errors at the treatment setting—drugs and lines ($p = 0.03$) and reduced the average performance time for overall tasks ($p < 0.0001$).

Lessons learnt: The use of CCLs for IV high-risk medications and lines can improve patient safety and improve medical staff efficiency.

Improving medication safety at the point of care is a major concern for hospital medical teams.¹ Intensive care units (ICUs) are particularly high-risk areas because of multiple high-risk drug infusions that are simultaneously infused.^{2,3} This complexity makes intravenous (IV) administration of drugs a high-risk situation. Errors frequently occur⁴ and can inflict serious harm to the patients' already fragile health.^{2,5,6}

Labelling of high-risk drug infusions and lines is a well-recognised safety strategy for the prevention of medication errors.^{2,3} A well-known field in which there is a colour-coded label (CCL) for high-risk medications is anaesthesiology. This method, implemented in the USA in 1994, only takes into account the labelling of syringes.^{7,8} In the ICU wards, there are no accepted standards for labelling high-risk IV medications and lines. There are limited data on the contribution of human factors principles and label design on patient safety.⁷ Furthermore, colour-coding has not been scientifically tested as a means to prevent medication errors.⁹

BACKGROUND AND SETTING

At the Hadassah University Medical Center, there was no standard policy for labelling high-risk IV medications. For years, nurses used a printed adhesive paper; with black print on a white background, applied to the syringe or the IV bag. The nurse was required to add the name of the drug, dosage, date and time, and sign for each IV drug preparation. Nurses in the ICUs and other acute care areas have implemented various methods that have helped them to identify and verify the right medication and lines at the patient's bedside.

OUTLINE OF THE PROBLEM

As a result of several drug infusion error reports, the Committee for Quality and Medication Safety (CQMS) at the Hadassah University Medical Center performed root cause analysis inquiries. These inquiries revealed the difficulties found by nurses and physicians in distinguishing between the many IV lines and medications given to the patient and the corresponding dangers. A need for a standard, comprehensive colour-coded labelling system for high-risk IV medications and lines was suggested to improve patient safety. Additionally, there are known problems related to colour code systems such as a limited variety of available discernible colours and identification of a medication within a pharmacological class.^{9,10} The CCL system was designed to answer these difficulties.

STRATEGIES FOR CHANGE AND IMPROVEMENT

The CQMS's first step was to define the list of high-risk IV drugs and lines requiring labelling. Twenty-three ICUs and other acute care areas at both Hadassah hospitals, Mount Scopus and Ein Kerem, sent the committee a list of the most frequently used drugs and lines. Line was defined as a pipe used for administering drugs, fluids or nutrition; keeping an IV open; or for drawing blood or taking other measurements—for example, central venous pressure. The committee found that most departments label three sites on the IV drug system: (1) IV bag or syringe, (2) IV line and (3) syringe pump. The label on the IV bag or syringe is a standard printed adhesive paper with black print on a white background. The nurse adds the name of the drug, dosage, date, hour and signature on each IV drug preparation. An adhesive bandage, with handwritten information written by the nurses, was used as the label on IV lines and syringe pumps.

Based on the data collected, a list of drugs and lines was prepared. The drugs were classified by their pharmacological class¹¹ and generic name.

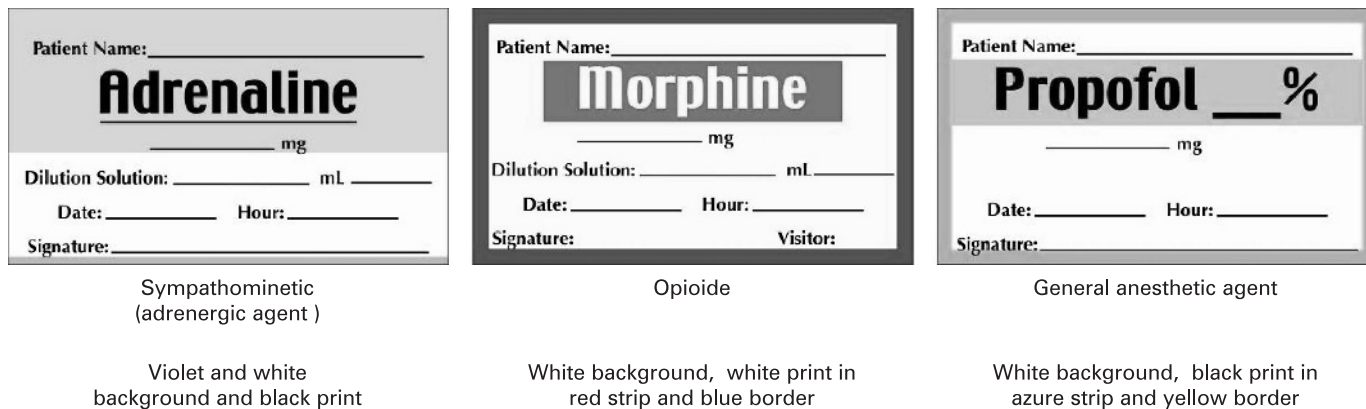


Figure 1 Examples of colour-coded labels for delivery of different pharmacological classes of IV medications.

The design of the labels took into account the international colour standards for anaesthetic drug labels¹² as well as diverse human factor engineering principles including font size, shape, colour and location of text.¹³ The latter was aimed at improving the drugs' name readability and the staffs' ability to recognise the drug at a glance. A contrasting background was used to accommodate those with red-green colour blindness. Other factors considered were easy readability under low illumination and from short distances—for example, across a patient's bed.

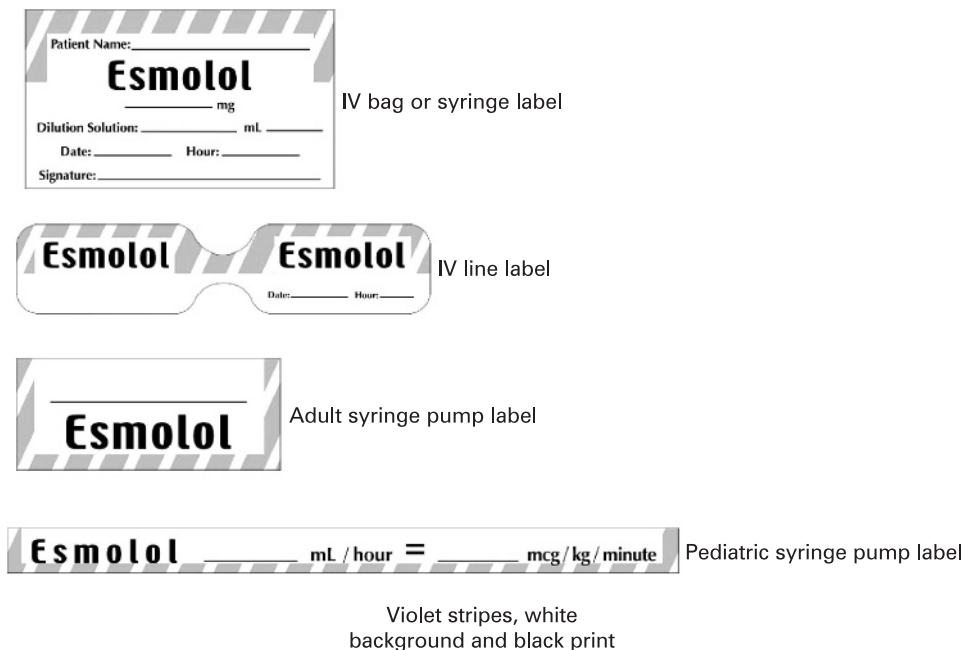
Within every pharmacological class, each drug had its individual colour and design (Addendum 1, fig 1). It was decided that the name of each drug would be printed on four different types of labels, one for each site on the IV drug system: (1) IV bag or syringe; (2) IV line; (3) syringe pump: adult and paediatric (fig 2). The labels for the IV bags and syringes also included a space to fill in the medication dosage and the name of the dilution solution and its volume. These details did not appear in the current method. Each label was measured to ensure a proper fit and appropriateness to the size of the device and that the bedside caregiver could easily read the label. Symbols, suggestive of the line's purpose, were also used in the

design of the lines' labels (fig 3). We created labels for 46 drugs, each having three or four stickers (bag or syringe; line; syringe pump: adult, paediatric if applicable). There were also labels to identify 19 different lines (eg, pulmonary artery, right atrium) for a total of 180 different labels. Each label type was supplied on a small wheel containing 100 labels. Guidelines were written, setting work standards for the labelling of high-risk drug infusions and lines at the patient's bedside for the two Hadassah hospitals.

The project costs included the labels' design (a one-time cost) and the printing of the labels. Each CCL is four to five times more expensive than the standard printed adhesive paper with black print on a white background.

Storage considerations needed to be taken into account when adopting this new method. The drug labels were stored next to each drug while the line labels were stored in a special device on the work surface in the medication room. This method can be implemented no matter where the medications are prepared, at the pharmacy or in the wards. This method is anticipated to only require minor modifications to be tailored to settings where pharmacists prepare IV medications and where medications, including IV medications, are bar-coded.

Figure 2 Examples of four types of labels for each drug.



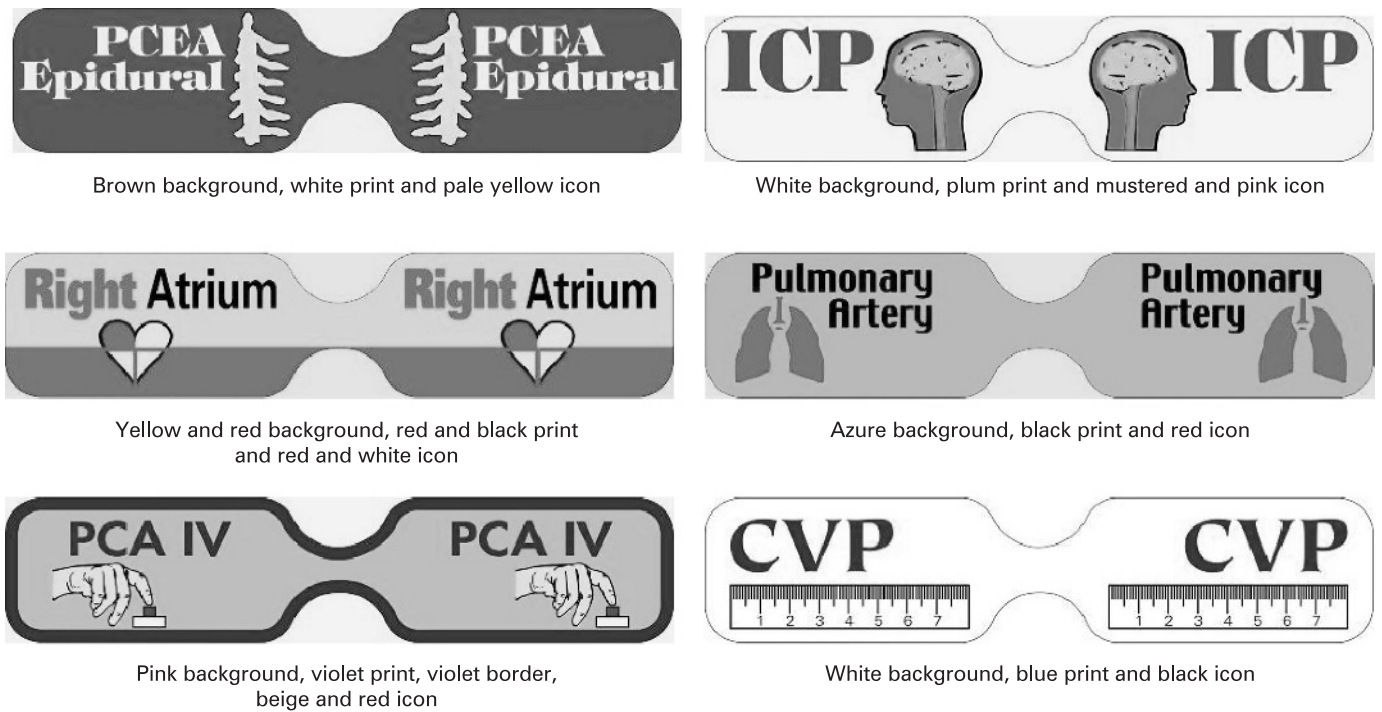


Figure 3 Examples of coloured labels for delivery of different types of lines.

METHODS

A laboratory simulation imitating an ICU was designed. Two identical intensive care beds with mannequins were set. Each “patient” was connected to several high-risk IV medications and lines. The difference between the two beds was in the use of the new CCL method for the “intervention bed” and the use of the current method in the “control bed”.

At the “control bed”, the label on the IV bag and syringe was a standard printed adhesive paper with black print on a white background (fig 4). When needed, the relevant details were handwritten by the participant, as they were accustomed to doing on the ward. Adhesive bandages were used to identify the medication in the syringe pump and line. Here too, drug details were added by hand. There were no labels for the lines as this was part of the new CCL method.

All of the labels on the IV system at the “intervention bed” were the new CCLs. The relevant details were written in by hand.

At both bedsides, the tasks were the same but the medications were different.

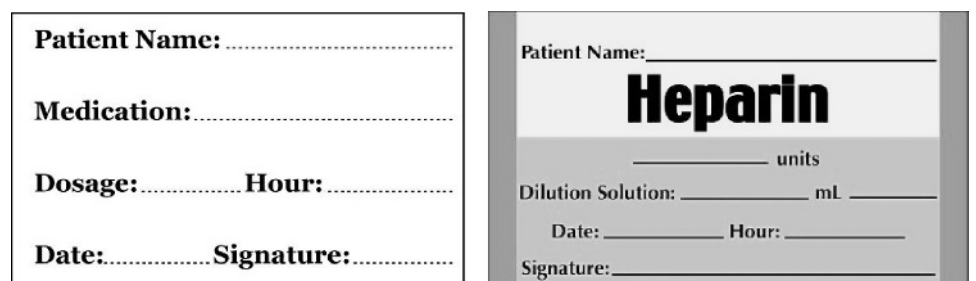
Nurses

Sixty-one nurses with a minimum of 2.5 years ICU experience participated in the study. Each participant was asked to perform six tasks at each of the two bedsides. Twenty-nine nurses began the study at the intervention bed, using the new method, and then continued to perform similar tasks at the control bed using the current method. The remaining 32 nurses began at the control bed, using the current method and then continued to perform similar tasks at the “intervention bed” using the new method. The nurses were randomly assigned to either of the two beds on an even/odd basis.

Measurements

The length of time it took to complete each task was measured by a stop watch. The examiner was the same individual for the entire study. Safety of the medication treatment and overall duration of orientation with drugs and lines by nurses at the patient’s bedside were measured by the following tasks:

Figure 4 Comparison between new coloured label and standard label printed on adhesive paper.



White background and black print

White and yellow background, black print and orange border

Table 1 Results of tasks performed

Task	Overall average control bed (SD) (minute:second)	Overall average intervention bed (SD) (minute:second)	p Value		
			Labelling method effect	Bed order effect	Labelling method × bed order interaction
Average time required to perform all tasks	00:28 (00:06)	00:25 (00:06)	<0.0001 (S)	0.33 (NS)	<0.0001 (S)
Syringe identification	00:06 (00:01)	00:07 (00:04)	0.029 (S)	0.54 (NS)	0.24 (NS)
Labelling of IV bag	01:20 (00:21)	01:07 (00:18)	<0.0001 (S)	0.25 (NS)	0.0002 (S)
Identification of syringe pump	00:05 (00:02)	00:05 (00:03)	0.93 (NS)	0.87 (NS)	0.062 (NS)
Identification of peripheral vein	00:10 (00:05)	00:11 (00:08)	0.73 (NS)	0.80 (NS)	0.0006 (S)
Description of all drugs and lines	00:50 (00:22)	00:45 (00:18)	0.04 (S)	0.69 (NS)	0.0001 (S)
Identification of an error in the treatment setting	00:17 (00:14)	00:15 (00:12)	0.4 (NS)	0.63 (NS)	0.03 (S)

NS, not significant; S, significant.

1. identification of a syringe: the length of time required to locate one syringe with a specific drug and dosage, among syringes with different drugs placed on a table.;
2. labelling an iv bag: the length of time required to label an iv bag containing a drug and its line and connect it to the patient;
3. identification of the syringe pump: the length of time required to identify one of the syringe pumps to change the required dosage of the medication;
4. identification of a peripheral vein: the length of time required to find a peripheral vein among other lines connected to the “patient”;
5. description of all drugs and lines: the length of time required to identify and describe every drug and line located within the patient’s immediate setting;
6. identification of error in the treatment setting: the length of time required to identify a labelling error, that is, a mismatch between syringe pump labelling and the labelling of its line.

At the end of every task set, the participant was asked to complete a questionnaire expressing a subjective opinion about the two methods. The purpose of the questionnaire was to allow for feedback from the participants, a quality indicator added to the quantitative data already collected.

Statistical methods

This study was a crossover within subjects designed trial. Therefore, a repeated-measures analysis of variance model was applied to analyse the tasks’ processing time. The model tests

the labelling method effect (within group effect: intervention method/control method), the bed order effect (between groups effect: which bed was first, intervention bed/control bed) and the interaction between them (estimates the link between bed order and the labelling method).

A p value of 5% or less (two-tailed) was considered statistically significant.

Analysis was done on the duration outcomes of each task and the average duration for all tasks related to three main factors: labelling method, bed order and the interaction between them.

RESULTS

Table 1 presents the average duration for each task, the standard deviation of both labelling methods and the statistical analysis in the cross-over design.

During the task sets, there were 15 cases where the participant found the labelling error before being asked. Hence, when this task was performed, the time performance was null. This situation was noted both at the control bed and at the intervention bed. These participants were excluded before analysis of the data for this task and the calculation of the average time performance for all tasks. Table 2 presents these outcomes.

In addition, we analysed the effect of several demographic variables, including age, sex, education, professional and ward seniority, and percent full-time position, on the outcome. Age was the only demographic variable found to be significant: the younger the participant, the less time it took to process the tasks.

Table 2 Results* of two specific tasks performed

Task	Overall average control bed (SD) (minute:second)	Overall average intervention bed (SD) (minute:second)	p Value		
			Labelling method effect	Bed order effect	Labelling method × bed order interaction
Average time required to perform all tasks	00:27 (00:05)	00:24 (00:07)	0.0003 (S)	0.01 (S)	<0.0001 (S)
Identification of an error in the treatment setting	00:20 (00:13)	00:15 (00:12)	0.045 (S)	0.43 (NS)	0.0012 (S)

*Excluding the 15 cases where the participants found the labelling error before being asked. NS, not significant; S, significant.

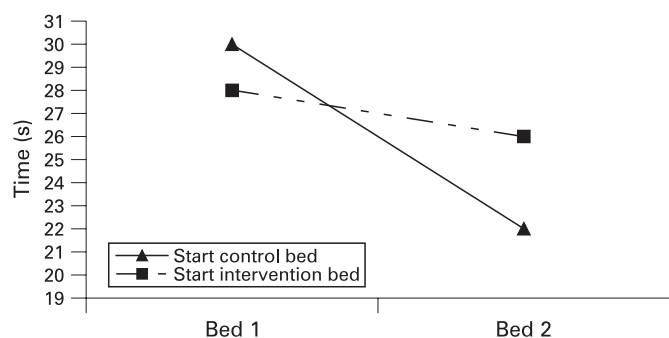


Figure 5 Average duration for all tasks in each bed.

Labelling method effect

Analysis of average performance time for all tasks, labelling bags tasks, description of all drugs and lines and error identification at the bedside were statistically significant (for the first two tasks, $p < 0.001$; and for the other two, $p < 0.05$), indicating the advantage of the new colour-coded labelling method at the intervention bed, as compared with the current method at the control bed (tables 1 and 2). Identification of the syringe was the only task that showed a statistically significant ($p < 0.05$) advantage effect in the control bed. In two tasks, identification of the peripheral vein and identification of the syringe pump, there was no statistically significant effect for either of the two methods.

Bed order and interaction

In most cases (in eight out of nine tasks; tables 1 and 2), there was no statistically significant effect of bed order on task performance. However, the interaction between labelling method and bed order showed a statistically significant effect in seven out of nine tasks.

As can be seen in table 1, considering the average time required to perform all tasks, the CCL method had a significant effect; bed order had no effect; and there was a significant interaction between labelling method and bed order. By observing figure 5, it can be seen that the first set of tasks, regardless of bed order, took more time to perform. The second set of tasks, regardless of bed order, took less time to perform. This can be explained by the learning effect; however, the difference in performance time between the first and second set of tasks was longer when the first set of tasks was performed on the control bed. Even though the second set of tasks, regardless of bed order, took less time to perform, when the second set of tasks was performed at the intervention bed, the time performance was much shorter. This can be explained by the fact that beyond the learning effect, the new CCL method is much more effective.

Questionnaires

Ninety-three percent (57/61) of the participants preferred the new CCL method. Seven percent (4/61) of the participants preferred the current method. Those that preferred the current method claimed—for example, that the labels had too many icons and colours or that the adhesive of the label was not strong enough.

LESSONS LEARNT

Our research findings show that the new CCL method is preferable to the current labelling method. The new method is

more visible and structured, thereby facilitating orientation and identification of errors at the patient's bedside. In addition, this method enables easier and faster labelling of drugs and lines.

The result in the “identification of a syringe” task showed a statistically significant advantage of the current method. This can be explained by the participants' comments in the questionnaires, which reflect their difficulties in familiarising themselves with the new labelling method—for example, written medication details (name and dosage) that do not exist in the current method.

Figure 5 illustrates the advantage of the new CCL method, with no connection to bed order during the trial. Even though there were some learning effects as the nurses moved from one bed to the other, these effects did not have a statistical effect on the results.

CONCLUSION

The purpose of developing this new drug and line labelling method was to improve patient safety and medical staff efficiency. Even though it would appear obvious that properly designed labels in a medical environment are more readable, improve patient safety and are easier to use, it was necessary to confirm this knowledge by an evidence-based study showing a conclusive reduced error rate. Such a study can provide support to administrative personnel for changing to a new method to reap documented evidence of patient safety and efficiency benefits despite some moderate cost increases. Because of the limited empirical literature regarding colour-coded labels and patient safety, additional research in the field is recommended.

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