

Evaluation of color-coded drug labeling to identify endovenous medicines

Avaliação da rotulagem com código de cores para identificação de medicamentos endovenosos
Evaluación de los etiquetados con código de colores para la identificación de medicamentos endovenosos

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ABSTRACT

Objective: To analyze the opinion of nursing professionals on the design, practicality of use and the usefulness of color-coded drug labeling in a pediatric intensive care unit. **Methods:** A cross-sectional study with 42 nursing professionals. A structured questionnaire was used based on a five-level Likert scale. To assess the proportions, a binomial test was used. **Results:** Concordance ratio >0.8 for all propositions related to design, practicality and most of the propositions related to error prevention. **Conclusion:** According to the opinion of the nursing team, the implemented technology has an adequate design, as well as being practical and useful in the prevention of medication errors in the population at the ICU.

Descriptors: Medication Errors; Patient Safety; Intensive Care Units; Drug Labeling; Technology.

RESUMO

Objetivo: Analisar a opinião dos profissionais de enfermagem sobre o *design*, a praticidade do uso e a utilidade da rotulagem com código de cores em uma unidade de terapia intensiva pediátrica. **Método:** Estudo transversal, realizado com 42 profissionais de enfermagem. Utilizou-se um questionário estruturado com base em uma escala Likert de cinco níveis. Para a análise das proporções, utilizou-se o teste binomial. **Resultados:** Houve proporção de concordância >0,8 para todas as proposições relacionadas ao *design*, à praticidade do uso e à maioria das proposições relacionadas à prevenção de erros. **Conclusão:** De acordo com a opinião da equipe de enfermagem, frente ao objeto de estudo, a tecnologia implementada tem *design* adequado, além de ser prática e útil na prevenção de erros de medicamentos em população atendida na UTI.

Descritores: Erros de Medicação; Segurança do Paciente; Unidades de Terapia Intensiva; Rotulagem de Medicamentos; Tecnologia.

RESUMEN

Objetivo: Analizar la opinión de los profesionales de Enfermería acerca del diseño, la practicidad del uso y la utilidad de los etiquetados con código de colores en una unidad de terapia intensiva pediátrica. **Método:** Estudio transversal, realizado con 42 profesionales de enfermería. Se utilizó un cuestionario estructurado basado en una escala Likert de cinco niveles. Para el análisis de las proporciones, se utilizó la prueba binomial. **Resultados:** Se encontró la proporción de concordancia >0,8 para todas las proposiciones relacionadas con el diseño, la practicidad del uso y la mayoría de las proposiciones relacionadas con la prevención de errores. **Conclusión:** Según la opinión del equipo de enfermería frente al objeto de estudio, la tecnología implementada tiene un diseño adecuado, además de ser práctica y útil en la prevención de errores de medicamentos en población atendida en la UTI.

Descriptorios: Errores de Medicación; Seguridad del Paciente; Unidades de Terapia Intensiva; Etiquetados de Medicamentos; Tecnología.

INTRODUCTION

Drug therapy is widely used in Intensive Care Units, and in a larger amount when compared to other hospitalization units. This is due to the nature of care provided, which is characterized by severe clinical conditions and complex interventions⁽¹⁾.

The drug administration process is prone to errors and there are several reasons for this adverse event to happen, which can be at any stage of the medication system and involves any of the numerous medications available, including those classified as high-alert medications⁽²⁾.

High-risk medications, also known as high-alert or potentially dangerous medications, are those with the highest potential for serious harm because they increase the length of hospital stay and recovery, expose patients to a greater number of procedures and therapies. In addition, they may cause more serious consequences for patients, such as death, in which an error is incurred in the course of its use⁽³⁻⁴⁾.

The numbers draw attention to this reality and warn of a health problem that can be avoided. Errors associated with the medication process can affect up to 947 of 1,000 patients per day in intensive care units and raise hospital costs by up to US\$2.8 million⁽⁵⁾. Previous studies have also shown that out of every five drugs given to patients, an error occurs⁽⁶⁻⁷⁾.

To reduce these complications, some health technologies have been conquering space in Nursing. The technology is present in all stages of care, considered both a process and a product⁽⁸⁾. The development and implementation of care technology in clinical practice can benefit the quality of the care provided and the occurrence of the smallest number of preventable errors.

One of these technologies corresponds to the use of adhesive labels to identify the devices that take the drugs to patients. It was developed by the International Society for Anaesthetic Pharmacology⁽⁹⁾. Different colors and shapes are used, considering the drug class, as well as the location of the text and the font-size. In 2008, the International Organization for Standardization (ISO) published standard ISO 26825, which refers to the standardization drug labels based on the method described. In 2013, the Australian Commission on Safety and Quality in Health Care published the recommendations to monitor the identification of drugs to be used in all Australian health services based on color-coded drug labeling⁽¹⁰⁾.

The standardization of color-coded labeling is used in intensive care units in Europe and has a major impact on improving patient safety and reducing medication errors⁽¹¹⁾.

In Brazil, high-alert drugs are identified according to the standardization established by the hospital, which may make it difficult to monitor potentially dangerous drugs. The use of color-coded labels is not widespread and there is no standard policy for labeling these drugs. In this light, scientific studies dealing with the use of these technologies must be developed to contribute to patient safety⁽¹²⁾.

OBJECTIVE

Analyze the opinion of nursing professionals on the design, practicality of use and the usefulness of color-coded drug labeling in a pediatric intensive care unit.

METHOD

Ethical aspects

The study was registered in the *Plataforma Brasil* (Brazil Platform: a national and unified database for scientific research) and submitted and approved by the Committee of Ethics in Research with Human Beings, *Hospital de Messejana Dr. Carlos Alberto Studart Gomes*.

Research design, place and period

This is a cross-sectional study, developed in a pediatric intensive care unit (ICU) of a tertiary referral hospital in pediatric cardiac surgeries in the state of Ceará. This unit has eight beds and a monthly average of 25 pediatric admissions for post-surgical treatment related to congenital heart diseases. Data collection occurred between January and March 2015.

Population, sample, inclusion and exclusion criteria

The study population corresponded to Nursing professionals working in the intensive care unit mentioned. For the sample, considering the staff of the unit, all nursing professionals of the pediatric postoperative ICU were chosen. For this, the following inclusion criteria were listed: holding a degree in Nursing and/or being a nurse; assisting the mentioned unit; and being available for data collection. The sample totaled 42 participants.

Study protocol

Color-coded labels were implemented at the study site in September 2014 and their development was based on the study proposed by Porat *et al.*⁽⁹⁾. The labels were created in three formats, to identify all the devices used in the administration of intravenous drugs such as infusion pumps, syringes and saline solution (Figures 1, 2 and 3). For the last two devices, the same label design was used.

The colors were defined according to the drug class, previously established by the American Society of Anesthesiology⁽¹³⁾ and by ISO 26825. As for the design, the background color of the labels was white, and the drug nomenclature was highlighted with the referring color to its drug class.

After making the labels, on-site trainings and lectures were conducted with the professionals for the proper use of and correct filling in the technology. The evaluation of the labeling system was carried out three months after the implementation of this technology.



Source: Adapted from the study by Porat *et al.* (2009)⁽⁹⁾.

Figure 1 – Example of label designed for the kits for each drug, size 5cm x 1.5cm, Times New Roman font

Patient: _____ Bed: _____

DOPAmine

Dilution: _____

Date: ____/____/____ Time: _____

Flow: _____ mL/hr Sig. _____

Source: Adapted from the study by Porat et al. (2009)⁽⁹⁾.

Figure 2 – Example of label designed for the kits for infusion pumps, size 8.5cm x 5cm, Times New Roman font

DOPAmine

Source: Adapted from the study by Porat et al. (2009)⁽⁹⁾.

Figure 3 – Example of label designed for the syringes and saline solutions for each drug, size 8.5cm x 2.5cm, Times New Roman font

Chart 1 - Standardized colors for the respective drug classes.

Drug Class	Examples	Standardized color
Induction Agents	Thiopental, Ketamine	Yellow
Tranquilizers	Dizepam, Midazolam	Orange
Muscle Relaxants	Vecuronium, Pancuronium	Fluorescent red
Narcotics	Fentanyl, Morphine	Blue
Narcotic Antagonists	Narcan/Naloxone	White and blue diagonal stripes
Vasopressors	Adrenaline, Dopamine	Violet
Hypotensive Agents	Nitroglycerin, Sodium nitrite	White and violet diagonal stripes
Local Anesthetics	Lidocaine	Gray
Anticholinergic Agents	Atropine<0	Green

Source: Adapted from the American Society for Testing and Materials (1994)⁽¹⁴⁾

A questionnaire addressing color-coded labeling technology was used. This instrument was derived from an adaptation of the questionnaire proposed by the Australian Commission on Safety and Quality in Health Care (2013)⁽¹⁰⁾.

The questionnaire consists of two parts: the first, containing the sociodemographic data of participants; the second, with 15 items referring to the evaluation of the color-coded labeling system implemented at the study place, to know the perception of professionals regarding the design, practicality of the use, and usefulness of this labeling system in the prevention of errors of medication administration in the population served at the ICU. A Likert scale was used to obtain the answers with five degrees of variation, considering grade 5 – totally disagree (TD) and the extreme opposite, grade 1 – fully agree (FA). The scores were of 1.0; 0.75; 0.5; 0.25 and 0, to fully agree, partially agree, indifferent, partially disagree and totally disagree, respectively.

The researchers conducted a pilot test with four collaborators, to verify the clarity and compression of the instrument items. The application of the questionnaire did not lead to modifications

or exclusions of items. The participants of the pilot test were excluded from the total sample.

The data collection instrument was distributed to professionals who agreed to participate and signed the Informed Consent Term. They answered the questionnaire individually, during working hours, returning it immediately to the researcher.

Results analysis and statistics

The data collected were typed into the Microsoft Excel for Mac® 2011 worksheet, summarized and presented descriptively by means of frequency distribution, absolute values, averages and standard deviation. A proportional analysis was performed using the binomial test. In this study, the proportion of nurses who considered the labeling system as adequate/practical/useful lower than 0.8 was considered as an alternative hypothesis.

RESULTS

The sample of this study was characterized by participants aged between 21 and 52, with a mean age of 32.33 years old (S.D. ± 7.88) and the median of 34 years old; 100% were female; 35.7% were nurses and 64.3% were licensed practical nurses. Regarding the time in the ICU, a median of 4 years (p<0.05) was obtained.

In this analysis, the agreement of the nursing team in front of the object of study is shown. The higher the score obtained from the p-value, the more favorable is the attitude of the subject regarding the usefulness of the color-coded drugs labeling on patient safety and vice versa.

The data in the table below refer to the analysis of the propositions from the instrument of data collection (Table 1).

In the analysis of the design-related propositions, the values of the items were significant, considering the proportion of the nursing team of the ICU under study was above 80% (p=0.9999), which makes this item appropriate.

Regarding the agreement of the propositions as for error prevention, the values were significant in most items (p=1), except in the proposition "Is it necessary to handle the drug label to identify an E-V line?" that obtained p value<0.0001. Although the value obtained for this proposition is not statistically significant (p<0.8), in clinical practice it indicates a positive sign since the use of color-coded labels facilitates visualization and reduces the time needed to differentiate intravenous lines. Thus, it is not necessary to handle the drug label to identify what is being infused, as is done on the labeling without color coding, which facilitates the monitoring of intravenous therapy.

The propositions regarding the practicality of use also presented an adequate evaluation. The values of the proportion among professionals were greater than 80% (p=1).

As for the time to label all drugs, by the patient's bed, participants were questioned about how long this task needed to be performed and a median of two minutes (IQ 0) was obtained. According to the nursing professionals' statements, the labeling system contributed positively to nursing care. It reduced the average time of performance for general tasks. The nursing team used a white-backed adhesive tape before using color-coded labeling, and they needed to write the drug nomenclature, dosage, date, time, and dilution for each drug prepared, thus demanding more time on general tasks.

Table 1 - Distribution of the results of the propositions referring to the perception of nursing professionals about the use of color-coded labeling at the study site. Fortaleza City, state of Ceará, Brazil, 2016 (n=42)

Propositions	Median	IQR	CI	P Value
Design				
Is the use of the drug nomenclature appropriate?	0.75	0.25	0.82 - 0.99	0.999
Are the dimensions of the label adequate?	1	0	0.89 - 1.0	1
Is the color coding in accordance with the drug class/action acceptable?	1	0	0.89 - 1.0	1
Is the text on labels readable?	1	0	0.89-1	1
Error prevention				
Is the capital letter used at the beginning of the drug nomenclature on labels helping to differentiate the names of similar drugs?	1	0	0.89-1	1
Was the place of the color used useful to identify the drug?	1	0	0.89-1	1
Was the standardization of red lettering on a white background in high-risk drugs with no color coding useful to help in their identification?	1	0	0.89 - 1	1
Is it necessary to handle the drug label to identify an E-V line?	0	0.25	0 - 0.10	<0.0001
Practicality of use				
Are the labels long-lasting throughout their use?	1	0	0.89-1	1
Does it make the identification of E-V lines, infusion pumps and saline solution pouches easier?	1	0	0.89-1	1
Is it more helpful to have pre-printed labels rather than handwritten labels?	1	0	0.89 - 1	1
Does the range of labels available cover most drugs administered through continuous infusion at the ICU?	1	0	0.89 - 1	1

Note: *binomial test; IQR – interquartile range; CI – confidence interval at 95%.

In general analysis, there was positive agreement in all the propositions related to the design and practicality of use. Most of the propositions related to error prevention indicated that color-coded labeling is a good tool for monitoring intravenous drug therapies.

DISCUSSION

The occurrence of iatrogenic events in care endangers the lives of patients at received the attention of nurses in the search for care that ensure the lesser risks possible⁽¹⁵⁾. Health care, free from risks and failures to patients, is a goal to be achieved by health professionals and a commitment to professional training⁽¹⁶⁾.

The design of the labels implemented in care was evaluated to check if its presentation was clear and easy to understand. The suitability of label size and color choice was checked. Each of these items was considered adequate by nursing professionals. Although all design items have achieved a satisfactory response, a study that also evaluated the relevance of label templates, based on the same proposal, demonstrated that there were problems with the design, especially in relation to the selected colors, because the color of the drug label identified a category of drugs but did not necessarily identify a specific drug⁽¹⁷⁾.

Drug incidents occur independently of the route of administration. Nonetheless, the intravenous route exposes patients to a higher risk⁽¹⁸⁾. A Spanish study found that 50% of medication errors occurred when using the IV route⁽¹⁹⁾. In a hospital in Australia, 293 incidents with patients were reported, 24% of which were drug-related and 35% related to the IV⁽²⁰⁾.

During the analysis of nursing professionals' opinions on the causal factors of errors in medication administration it was found that administering drugs in the wrong route was present in 17% of the answers⁽²¹⁾. Recognize that medication errors are frequent

and identify their patterns and causes in the daily practice of child care are only the first step to reduce their occurrence risks⁽²²⁾.

Regarding error prevention, participants consider color-coded labeling adequate in detecting failures in the administration and monitoring of continuous infusion medicines, preventing errors in the process. Another study with a similar research design obtained 93% of favorable results of the Nursing team when finding that there was improvement to identify the drug administration errors using this technology. According to the findings, this labeling system facilitates the orientation and identification of errors in drug administration in wrong routes⁽⁹⁾.

This fact can be justified due to the expectation to guarantee the best result within the clinical conditions and the severity of patients in intensive care units, with the lowest possible complication rates resulting from the procedures performed⁽²³⁻²⁴⁾. Technologies able to innovate care will always find receptivity by professionals, as well as an environment conducive to their application in the network of health care⁽²⁵⁾.

Regarding the practicality of use of color-coded labels in continuous infusion medicines, the participants considered this technology useful, making the work of nursing professionals easier for its application. In accordance with these findings, one study emphasized the accuracy and speed of drug delivery due to color-coded labeling in simulated situations of high stress, compared to simple labels made of white tape or simply paper. The group that used white labels failed to distinguish different drug groups, especially in critical situations⁽²⁶⁾.

Contributions to the Nursing, Health or Public Policy fields

The evaluation of a technology is of utmost importance to test its quality and suitability for the purpose for which it is intended. Today, there is a growing need to use instruments produced and

tested with scientific rigor, to provide a better quality of Nursing performance in the different care settings.

Study limitations

The results found in this study should be considered with caution, considering the limited number of the sample used. It may not correspond to the generalization of the data obtained.

CONCLUSION

Research identified that nursing professionals agree on the relevance of the use of color-coded drug labeling system. This technology was considered adequate in relation to the design and the practicality of use. Moreover, it is useful to prevent drug administration errors in the population served at the ICU.

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