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Label Design Affects Medication Safety in an Operating Room Crisis: A Controlled Simulation Study

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Objective: Several factors contribute to medication errors in clinical practice settings, including the design of medication labels. The objective of this study was to quantify the impact of label design on medication safety in a realistic, high-stress clinical situation.

Methods: Ninety-six anesthesia trainee participants were randomly assigned to either the redesigned or the current label condition. Participants were blinded to the study's focus on medication label design and their assigned label condition. Each participant was the sole anesthesia provider in a simulated operating room scenario involving an unexpected vascular injury. The surgeon asked the participant to administer hetastarch to the simulated patient because of hemodynamic instability. The fluid drawer of the anesthesia cart contained three 500-ml intravenous bags of hetastarch and one 500-ml intravenous bag of lidocaine. We hypothesized that redesigned labels would help participants correctly select hetastarch from the cart. If the participants incorrectly selected lidocaine from the cart, we hypothesized that the redesigned labels would help participants detect the lidocaine before administration.

Results: The percentage of participants who correctly selected hetastarch from the cart was significantly higher for the redesigned labels than the current labels (63% versus 40%; odds ratio, 2.61 [95% confidence interval, 1.1–6.1]; $P = 0.03$). Of the participants who incorrectly selected lidocaine from the cart, the percentage who detected the lidocaine before administration did not differ by label condition.

Conclusions: The redesigned labels helped participants correctly select hetastarch from the cart, thus preventing some potentially catastrophic medication errors from reaching the simulated patient.

Key Words: medication safety, medication error, medication label design, human factors, simulation, patient safety

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The Institute of Medicine (IOM) estimated that, on average, a hospital patient is subject to at least 1 medication error per day.[1] A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a health care professional, patient, or consumer.[2] The IOM cited several factors that contribute to medication errors, including the design of medication labels. According to the IOM, labeling and packaging account for 33% of medication errors, including 30% of fatalities.

Various medication safety organizations have published recommendations on the design of optimal medication labels.[3–9] The recommendations are based on subject matter expertise and sound human-centered design principles, but there is minimal evidence to support their adoption.[10,11] Moreover, the limited label design research has 2 noteworthy limitations—the study environments did not capture the complexity of real clinical practice settings and/or the study tasks did not represent the actual tasks that occur during the medication use process.[12–21] These limitations affect the generalizability of the results to the clinical environment. Concerns about the generalizability of existing evidence emphasize the need for a new approach to evaluate medication safety strategies that accounts for the complexity of real clinical practice settings.[22]

High-fidelity clinical simulation is the closest approximation to a real clinical practice setting that can be used to study the impact of label design on medication safety without endangering patients. A recent label design study leveraged clinical simulation to address concerns about the generalizability of existing evidence.[23] The previous study used an interview method to collect providers' subjective impressions about the medication labels after the simulation, whereas our study measured the objective effects of label design on provider performance during the simulation. The specific objective of our study was to quantify the impact of label design on performance of a medication administration task in a realistic, high-stress clinical situation.

To quantify the impact of label design on medication safety, we compared the performance of 2 groups of providers who were randomly assigned to administer medications with either existing medication labels or redesigned labels. The redesigned labels incorporated published design recommendations from medication safety organizations and findings from the existing literature. The redesigned labels incorporated 3 changes focused on reducing visual clutter and enhancing the visual cues needed to detect differences between medications. First, the redesigned labels were printed on opaque, white adhesive paper labels to improve legibility. The National Patient Safety Agency recommends the use of matt materials on infusion bags and paper labeling on ampoules to improve legibility on clear medication containers.[9] A study investigating ampoule label design found that nurses took significantly less time to identify important medication information from opaque, white labels as compared with clear labels.[19] Second, the redesigned labels used inverted text (e.g., white text on a dark background) to highlight key medication information. The National Patient Safety Agency recommends the use of inverted text to draw the eye to key information on the label.[9] A study investigating different typographical strategies for medication names found that nurses made the fewest selection errors

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when the medication name contained inverted text compared with other typographical strategies (i.e., tall man lettering, all lowercase, and bold text).[16] Finally, the redesigned labels distributed information across a front and back panel to reduce visual clutter and highlight key information on the front panel. The National Patient Safety Agency recommends creating a front panel that features only key information (i.e., drug name, strength, administration route[s], and warning) with subsequent information shown on the back panel.[9] The National Coordinating Council for Medication Error Reporting and Prevention recommends the printing of the drug name and the strength on both sides of intravenous (IV) bags.[8]

The specific medications and simulation scenario used in this study replicated the circumstances of a close call involving a 500-ml IV bag of lidocaine that could have been substituted for a 500-ml IV bag of hetastarch because of look-alike packaging.[24] The lidocaine IV bag was incorrectly stocked in the fluid drawer of an anesthesia cart with hetastarch IV bags. According to the Safety Assessment Code Matrix of the Veterans Administration (VA), a mix-up between lidocaine and hetastarch would be classified as a "catastrophic" event because it has the potential to result in patient death or major permanent loss of function.[25] We hypothesized that the redesigned labels would help participants correctly select hetastarch from an anesthesia cart that was also "incorrectly stocked" with lidocaine. If the participants incorrectly selected lidocaine from the cart, we hypothesized that the redesigned labels would help participants detect the lidocaine before administration.

METHODS

Institutional review boards at the VA Pittsburgh Healthcare System and the University of Pittsburgh reviewed and approved the research protocol before recruitment of participants.

Participants

Participants were recruited from a population of 99 anesthesia trainees from the Department of Anesthesiology Residency Program at the University of Pittsburgh School of Medicine and the Nurse Anesthesia Program at the University of Pittsburgh School of Nursing who were enrolled in the Anesthesia Crisis Leadership Training course. The course occurred between March and May 2013. During recruitment, the participants were informed that they would be taking part in a study investigating how the "design of the medical environment" affects provider performance but were blinded to the study's focus on medication label design and their assigned label condition. The participants were informed that they would be participating in an operating room crisis scenario but had no prior information regarding the specifics of the scenario. All participants provided written informed consent.

Ninety-six anesthesia trainees volunteered to participate in the study. All participants had prior experience in the simulated environment. Stratified random sampling was used to control for the participants' experience level across the 2 conditions. Specifically, the participants were grouped into 7 strata based on their profession and education level—(1) postgraduate year 4 (PGY-4) anesthesia residents, (2) PGY-3 residents, (3) PGY-2 residents, (4) fall 2013 graduating student registered nurse anesthetists (fall 2013 SRNAs), (5) spring 2014 SRNAs, (6) fall 2014 SRNAs, and (7) spring 2015 SRNAs. Then, participants within each strata were randomly assigned to a label condition by placing folded sheets of paper containing participant names into 2 different piles representing the 2 label conditions.

Before conducting the analysis, 3 of the coinvestigators who were not present for the data collection conducted an independent blind review of 10 cases in which an unexpected event occurred. Seven cases were excluded from the analysis because the unexpected event could have introduced confounding variables that affected the outcome measures of interest. For example, 1 case was removed by consensus because an investigator accidently stocked the fluid drawer with 2 IV bags of lidocaine. The normal study procedure was to stock the fluid drawer with 1 IV bag of lidocaine.

Data from 89 participants were used in the analyses—44 anesthesia residents and 45 SRNAs. Table 1 provides the demographic breakdown of the 89 participants across the 2 label conditions.

Settings

The study took place in a simulated operating room at the University of Pittsburgh's Peter M. Winter Institute for Simulation Education and Research.

Labels

The current label condition used 500-ml IV bags of lidocaine and hetastarch manufactured by B. Braun Medical Inc (Bethlehem, PA)—the labels involved in the close call that prompted this study (Fig. 1).[24]

The redesigned labels incorporated the 3 design recommendations under investigation and were developed using an iterative design process with feedback from pharmacists, anesthesiologists, and nurse anesthetist end users. The redesigned labels contained all of the same information as the current labels. The redesigned labels were printed on adhesive labels using a photo quality printer and affixed to unlabeled 500-ml IV bags (Fig. 2).

Measures

Medication safety was evaluated by measuring (1) the frequency of correct medication selections from the cart and (2) the frequency of correct medication administrations to the simulated patient.

A correct medication selection was recorded when a participant selected hetastarch from the anesthesia cart. A video camera pointing directly into the cart was used to determine which medication the participant selected. Instances of correct medication selection were recorded in real time during the simulation by an investigator in the observation room and confirmed by the principal investigator through video review after the simulation.

A correct medication administration was recorded when a participant administered hetastarch to the simulated patient. The action of hanging the IV bag on the pole and releasing their hands from the bag was considered simulated administration. Instances of correct medication administration were recorded for the subset of participants who incorrectly selected lidocaine from the cart. A participant who incorrectly selected lidocaine from the cart could correctly administer hetastarch if they detected the lidocaine before administering it to the simulated patient. Instances of correct medication administration were recorded in real time during the simulation by investigators in the observation room and confirmed by the confederates in the simulation.

Research Design

A randomized controlled between-subjects design was used to compare the participants in the current label condition with the participants in the redesigned label condition on (1) the frequency of correct medication selections and (2) the frequency of correct medication administrations.

TABLE 1. Demographic Breakdown by Label Condition

	Redesigned	Current
No. anesthesia residents	23	21
No. SRNAs	23	22
Age, mean (SD), y	30.52 (3.59)	29.63 (3.02)
Experience administering medications, mean (SD), mo	51.20 (40.65)	51.21 (36.69)
Experience as anesthesia providers, mean (SD), mo	17.73 (10.67)	18.42 (13.21)

Procedure

Before each experimental trial, the anesthesia cart was stocked with the same products. The top of the anesthesia cart was stocked with labeled syringes of anesthetic medications (etomidate, succinylcholine, rocuronium) and emergency vasoactive medications (phenylephrine, epinephrine, atropine). The medication drawer (top drawer of the cart) was stocked with vials and ampoules of reserve anesthesia medications. The fluid drawer (bottom drawer of the cart) was stocked with IV bags of normal saline in the back 2 quadrants and IV tubing in the front left quadrant. The front right quadrant contained two 500-ml IV bags of hetastarch lying side by side on the bottom, one 500-ml IV bag of lidocaine on top of the 2 IV bags of hetastarch, and one 500-ml IV bag of hetastarch directly on top of the 1 IV bag of lidocaine. Normally, 500-ml IV bags of lidocaine would not be stocked in the fluid drawer of an anesthesia cart found in an operating room. The lidocaine bag was "incorrectly stocked" with the hetastarch in this scenario to replicate the circumstances of the close call that prompted this study. All IV bags were placed in the cart with the labels facing up. The IV bags were each placed in their normal clear outer wrap to increase the realism of the task (Fig. 3). Aside from the "incorrectly stocked" IV bag of lidocaine, the anesthesia cart was stocked with the same products as an anesthesia cart found in an actual operating room.

Upon entering the room, the participant was oriented to the simulation environment. Next, he or she was provided the rules of engagement for the scenario. The participant was told that fluid administration would comprise removal of the IV bag from the outer wrap and hanging it on the pole. Because of a limited supply of medication, the participant was told not to "spike" the fluids and that hanging the IV bag on the pole is equivalent to administration. The participant was accustomed to this procedure for simulating medication administration through involvement in other simulation courses.

The participant engaged in an operating room crisis scenario as the sole anesthesia provider in the room with 2 confederates—1 surgeon and 1 circulating nurse. The participant was given a typed report describing the patient's history of trauma and his refusal to accept blood products based on religious belief. The participant was given time to ask clarifying questions about the patient report before starting the scenario.

One minute into the scenario, the surgeon exclaimed in a panicked voice that there was a vascular injury and began suctioning a large volume of blood from the simulated patient. The surgeon immediately requested that the participant administer hetastarch to the patient because of hemodynamic instability. A 500-ml IV bag of hetastarch was on top in the fourth quadrant of the fluid drawer. One minute after the participant administered the first IV bag of hetastarch, the surgeon requested that the participant administer a second bag of hetastarch. Because a 500-ml IV bag of lidocaine was now on top in the fluid drawer, the participants' medication selection and administration were measured at this point in the scenario. If the participant administered a second bag of hetastarch, the simulated patient was programmed to stabilize hemodynamically. The surgeon told the participant that he had control of the bleeding, and the scenario ended. If

FIGURE 1. B. Braun Hespan and lidocaine labels.

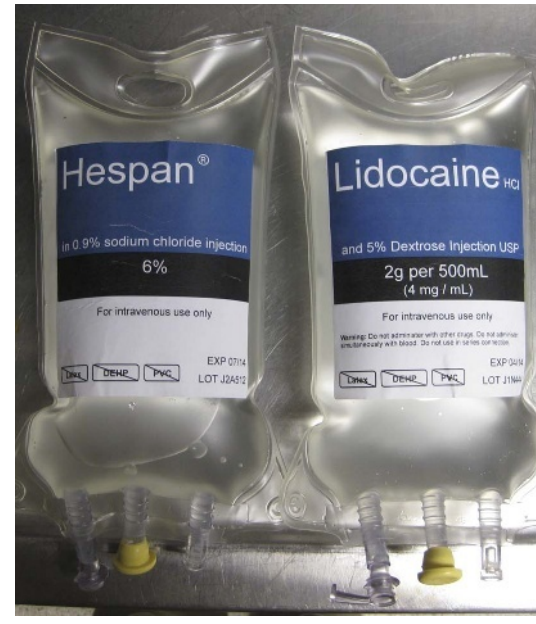

FIGURE 2. Redesigned labels affixed to unlabeled 500-ml IV bags. The redesigned labels were opaque, white 2-sided medication labels with inverted text highlighting key medication information.

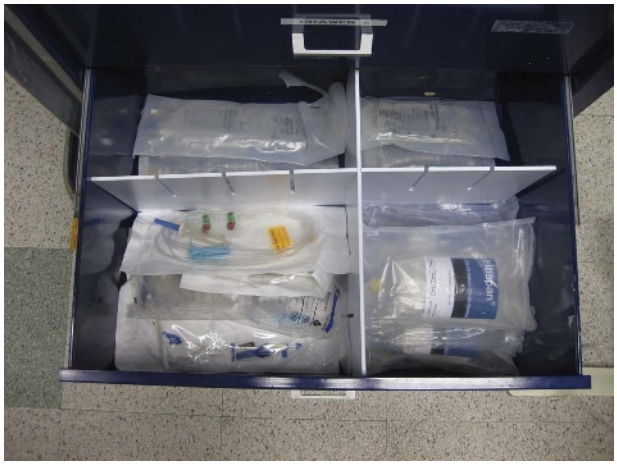

FIGURE 3. Contents of the fluid drawer at the beginning of each scenario.

the participant administered lidocaine, the simulated patient was programmed to respond with increasing hemodynamic instability. The surgeon told the participant that he had control of the bleeding, but the scenario was allowed to continue for 1 minute to provide an opportunity for the participant to address the patient's hemodynamic instability and potentially recognize the medication error.

After the scenario, the participants completed a demographic survey to capture their age, months of experience administering medications, and months of experience as anesthesia providers (Table 1). The participants were also asked to "report every IV fluid or infusion that they saw during the execution of the scenario" to determine whether they noticed the lidocaine bag. Only 1 participant who administered lidocaine to the simulated patient reported seeing the lidocaine bag but said, "I administered it anyway because it was simulation." Data from that participant were excluded before analysis per the exclusion procedure described above. No other participants who administered lidocaine to the simulated patient reported seeing the lidocaine bag.

Statistical Analysis

Data were analyzed using the SPSS software version 19 (IBM Corporation, Armonk, NY). Two-tailed χ^2 tests of independence were used to indicate whether label design was associated with medication safety. We considered $P \leq 0.05$ to be a statistically significant association between the 2 variables. Phi (Φ) coefficients were calculated to evaluate the degree of association between the variables. Finally, odds ratios and 95% confidence intervals were calculated to compare the odds of selecting and administering the correct medication given the label condition.

RESULTS

Medication Selection

We compared the frequency of correct medication selections by label condition to determine whether the 2 variables were associated (Table 2). A χ^2 test of independence indicated that correct medication selections from the cart were associated with label condition, χ^2 (N = 89) = 4.92, $P = 0.03$, $\Phi = -0.24$. The percentage of participants who correctly selected hetastarch from the cart was significantly higher for the redesigned label condition (63%) compared with the current label condition (40%). The odds of selecting the correct medication with the redesigned labels were 2.61 times greater than the odds of selecting the correct medication with the current labels; odds ratio, 2.61; 95% confidence interval, 1.1–6.1.

TABLE 2. Medication Selection by Label Condition

	Selection, n (%)		
Label Condition	**Correct**	**Incorrect**	**Total**
Redesigned	29 (63)	17 (37)	46
Current	17 (40)	26 (60)	43
Total	46 (52)	43 (48)	89

Medication Administration

Only the 43 participants who incorrectly selected lidocaine from the cart could possibly administer lidocaine to the patient. Therefore, we used the subset of 43 participants who incorrectly selected lidocaine to compare the frequency of correct medication administrations by label condition to determine whether the 2 variables were associated (Table 3). A χ^2 test of independence indicated no association between correct hetastarch administrations and label condition for the subset of participants who incorrectly selected lidocaine from the cart, χ^2_1 (N = 43) = 0.21, $P = 0.65$, $\Phi = 0.07$.

DISCUSSION

We hypothesized that redesigned labels would help participants correctly select hetastarch from a cart that was also "incorrectly stocked" with lidocaine. The percentage of participants who correctly selected hetastarch from the cart was significantly higher for the redesigned label condition compared with the current label condition. Because all of the participants who selected hetastarch from the cart went on to administer hetastarch to the simulated patient, the redesigned label prevented some potentially catastrophic medication errors from reaching the simulated patient.

If the participants incorrectly selected lidocaine from the cart, we hypothesized that the redesigned labels would help participants detect the lidocaine before administering it to the simulated patient. Given that 43 participants incorrectly selected lidocaine from the cart, this study was underpowered to detect a statistically significant difference in correct medication administrations across label condition. This study should be replicated with a larger sample size to determine whether a statistically significant difference exists on this measure.

The results of this study provide additional evidence to support the use of opaque, white medication labels and the use of inverted text for highlighting key medication information on the label. The results also provide initial evidence to support the use of 2-sided labels on IV bags. Because the redesigned labels incorporated all 3 recommendations, the relative impact of the individual label design changes on medication safety cannot be determined. Future research should continue to evaluate published label design

TABLE 3. Medication Administration by Label Condition

	Administration, n %		
Label Condition	**Correct**	**Incorrect**	**Total**
Redesigned	6 (35)	11 (65)	17
Current	11 (42)	15 (58)	26
Total	17 (40)	26 (60)	43

recommendations with the goal of providing empirical evidence to support the adoption of those recommendations that show a measurable improvement on medication safety.

Limitations

This was an unfunded, single-site study with some practical limitations. First, the convenience sample included only anesthesia trainees and did not include any experienced anesthesia providers. This sample might not be representative of the larger population of anesthesia providers in the United States. Second, our simulated environment resembled, but was not identical to, an actual operating room setting. Although the anesthesiologists who observed this study indicated that the participants' behavior in this study closely resembled that of the real-world environment, the participants may have applied less caution in the simulated environment. Third, the simulated task was highly realistic but did not exactly replicate the task of administering IV fluids. Because cost restrictions limited the supply of medication for the study, the participants were told not to "spike" the IV bags. Although the participants in this study were accustomed to this medication conservation procedure from previous experiences in simulation, the final step of spiking the IV bag may have provided another critical opportunity to detect the incorrect medication before administering it to the simulated patient.

Because the objective of this study was to quantify the impact of label design on medication safety, it is important to note that the study limitations would have affected both label conditions equally. Therefore, the study limitations cannot explain the statistically significant difference found between label conditions on the number of correct medication selections.

The study limitations may have resulted in higher numbers of incorrect medication selections and incorrect medication administrations overall. Therefore, the total number of errors reported in the tables should not be used to approximate "real-world" error rates. However, the probability of a potentially catastrophic mix-up between hetastarch and lidocaine cannot be classified as a "remote" event (i.e., may happen sometime in 5-30 y) according to the VA's Safety Assessment Code Matrix.[25] Besides the June 2012 close call that prompted this study, there was a March 2014 disclosure of a perioperative death of a patient because of an incorrect administration of lidocaine instead of hetastarch.[26] Both events involved IV bags of lidocaine that were incorrectly stocked with IV bags of hetastarch in the anesthesia cart. Future research should investigate whether label design can prevent errors that occur earlier in the medication-use process, such as stocking errors.

CONCLUSIONS

Medication errors occur within a complex, multifaceted, and multidisciplinary clinical environment. Several factors contribute to medication errors in clinical practice settings, including the design of medication labels. Medication safety organizations have published recommendations on the design of optimal medication labels, but there is minimal evidence that their adoption will improve medication safety in real clinical practice settings. Concerns about the generalizability of existing evidence make it possible to argue that label design changes may not improve medication safety.[27] This study leveraged clinical simulation as a test bed to measure the effects of label design on provider performance of a medication administration task in a realistic, high-stress clinical situation. The results of this study provided support for the adoption of opaque, white 2-sided medication labels on IV bags and the use of inverted text for highlighting key medication information on the label.

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