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Improving the usability of intravenous medication labels to support safe medication delivery

David T. Bauer^a and Stephanie Guerlain^a

David T. Bauer: dtb5f@virginia.edu; Stephanie Guerlain: guerlain@virginia.edu

^aDepartment of Systems and Information Engineering, University of Virginia, Charlottesville, VA, 151 Engineer's Way, PO Box 400747, Charlottesville, VA 22904-4747, United States of America

Abstract

Medication label design is frequently a contributing factor to medication errors. Design regulations and recommendations have been predominantly aimed at manufacturers' product labels. Pharmacy-generated labels have received less scrutiny despite being an integral artifact throughout the medication use process. This article is an account of our efforts to improve the design of a hospital's intravenous (IV) medication labels. Our analysis revealed a set of interrelated processes and stakeholders that restrict the range of feasible label designs. The technological and system constraints likely vary among hospitals and represent significant barriers to developing and implementing specific design standards. We propose both an ideal IV label design and one that adheres to the current constraints of the hospital under study.

Keywords

Medication labels; label design; medication errors; hospital pharmacy

1. Introduction

Poorly designed medication labels pose a threat to patient safety by contributing to medication errors. Nearly one-third of the medication errors reported to the United States Pharmacopeia (USP) from June 1996 to May 1997 cited labeling or packaging issues (United States Pharmacopeia, 1998). Clutter, poor readability, poor use of color, and lack of differentiation between similarly-named drugs are among the labeling concerns reported to USP. In a self-reported survey, anesthesiologists cited the misidentification of a syringe and the misidentification of a drug ampoule or vial as a contributing factor in 70.4% and 46.8% of medication errors they experienced, respectively (Orser, Chen, & Yee, 2001).

Label design recommendations and research have been primarily focused on outpatient medication use and manufacturers' labels and supplementary materials. In a comprehensive review of prescription drug label research, Shrank, Avorn, Rolon and Shekelle (2007)

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Corresponding author: Stephanie Guerlain, Phone: +1 434 924 4438, Fax: +1 434 982 2972.

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Relevance to industry

Hospitals are tasked with creating customized medication labels with minimal guidance. Our process, findings, and proposed labels provide insight for similar investigations at other institutions.

included six types of patient-oriented labels: consumer medication information, container labels, direct-to-consumer advertising, package inserts, patient education materials, and over-the-counter labels. Cohen (2006) discussed the use of color, typeface, contrast, and expressions of concentration and strength with regard to provider interactions with labels, but the recommendations are primarily aimed at pharmaceutical companies and regulatory bodies.

Pharmacy-generated labels for inpatient care have a different user population and task structure. These labels support a variety of health care providers with diverse information requirements who work in often fast-paced, interruptive, and stressful environments. Furthermore, intravenous administration is error-prone and dangerous (Nicholas & Agius, 2005; Taxis & Barber, 2003). In a study of 10 hospital wards, Taxis and Barber (2003) identified 249 errors in 430 intravenous medication administrations. Little guidance is available for designing labels to best support this work. The applicability of recommendations from research on other types of labels is unclear due to the key differences in the context of use. Intravenous (IV) medications labels are particularly important because of the similar appearance of many drugs and doses.

We became involved in a project to redesign IV labels as a result of a patient safety officer wondering whether the IV labels at her hospital may be a contributing factor to reported adverse events. She therefore contacted the second author to determine if, from a human factors perspective, the labels could be improved. Several design issues were immediately apparent, and others emerged through a detailed analysis of the medication use system. In the course of this investigation we discovered that the label design was constrained by several interrelated processes. Stakeholders at each of the stages of medication ordering, preparation, distribution, and administration have different information needs and, as a result, the labels contain an overabundance of data trying to simultaneously fulfill these needs. This article chronicles our efforts and illustrates the challenges we faced and lessons learned. In addition, we present an ideal label design and one that is feasible under the constraints of the particular setting under study.

2. Methods

Our interdisciplinary team included two human factors engineers, two information systems analysts, a pharmacist, and a member of the Quality and Performance Improvement Department. We first performed a heuristic analysis of the IV labels that focused on the visual design and placement of information. An analysis of the stakeholders and the medication delivery system followed, which included interviews with key personnel and observations of the process. Additionally, we determined requirements imposed by law, The Joint Commission, and the hospital. The Joint Commission is a not-for-profit organization that accredits and certifies health care organizations that maintain a high level of quality and safety performance. Using this information, we began an iterative design phase in which we sought feedback from various stakeholders.

Our analysis included two types of IV medications: continuous IV (CIV) infusions and IV piggybacks (IVPB). CIVs are fluids with or without added medications delivered continuously into a vein. IVPB medications are infused over shorter periods of time on an intermittent schedule, such as once every six or eight hours.

Along the course of the redesign, we discovered many interrelated processes that affect the content and use of the label. For example, much of the information on the label depends on how the physician types the order into the computer. As a result, individual fields (e.g., the drug name) are not flagged as such and cannot be printed in a particular location or

contrasting font. Since both nurses and pharmacists use the same label but for different purposes, information required by pharmacists ends up intermixed with information that nurses need for administering the order, and each of these stakeholders must search for the information that is relevant to his or her tasks. Finally, there were many technical constraints imposed by the computerized provider order entry (CPOE) system in use that restricted what could be done, such as the inability to use mixed-case or different size fonts. We therefore decided to deliver two designs: 1) an “ideal” label, that ignored these technical constraints (with the idea that technology changes and this would inform future implementations) and 2) the “feasible” label, which was an adaptation of the ideal label that took into account the current technical constraints.

3. Results

3.1 Initial evaluation

Fig. 1 is a replication of a CIV label in use at the time of our study, and Fig. 2 is an example of an IVPB label. Before administering medications, nurses should verify the five rights: right patient, right drug, right dose, right route, and right time. For example, Fig. 1 is a label for 125 milligrams (mg) of Diltiazem diluted in 100 milliliters (ml) of 5 % dextrose to be delivered continuously through an IV line at a rate of 5 mg per hour until the physician discontinues the order. Note that the correct concentration is 1.25 mg/ml, not 1 mg/ml as listed on the label. We did not discover the source of this error. Fig. 2 is a label for 1,000 mg of Vancomycin diluted in 250 ml of 0.9 % sodium chloride to be delivered as an IVPB over 60 minutes daily at 1 a.m., 9 a.m., and 5 p.m. with the initial dose starting at 5 p.m.

We identified several issues with these labels:

1. Poor background contrast was a primary issue (the contrast in Fig. 1 and Fig. 2 is much better than the original labels). The black ink often appeared grey, particularly when the printer toner was low.
2. Medication information was not presented in a consistent location on the IVPB label.
3. Information that pertained only to pharmacy was intermixed with information relevant for administration.
4. Readability was poor due to the use of all upper case letters, ineffective bold text, and, in the IVPB, the block text format. Additionally, the labels used fixed-width letter spacing.
5. Labels contained too much information, and the text format reduced the available space.

3.2 Stakeholders and medication use process analysis

Our next steps were identifying stakeholders and analyzing the medication use process. Registered nurses (RNs), certified pharmacy technicians (CPhTs), registered pharmacists (RPhs), physicians, and pharmacy messengers are the providers most commonly involved in the process. Other providers may fill the same role as these individuals. For example, licensed practical nurses may administer medications instead of an RN in some states. Also, advanced practice nurses and physician assistants may order medications in addition to physicians. For simplicity in describing the system, we do not list these groups as separate stakeholders.

The following steps describe the basic process flow for a physician ordering a new CIV from the central pharmacy for an adult patient (see Fig. 3). The process varies somewhat for

scenarios involving IVPBs, pediatric patients, and medications located on the unit. See Aspden, Wolcott, Bootman, & Cronenwett (2006) for a more detailed description.

Physicians initiate the medication use process by determining the appropriate medication order and entering it in the CPOE system. The order prints both on the unit where the patient is located and in the central pharmacy, which alerts the patient's nurse and the pharmacy that an order has been entered.

The nurse then schedules the delivery time electronically. Meanwhile, a pharmacist verifies the order but waits for the scheduled request from the nurse before proceeding. Once the order has been verified and scheduled, two labels are printed in the pharmacy. One is saved as the hard copy of the order, and the other is eventually placed on the CIV bag. Next, a CPhT prepares the medication, which a pharmacist then verifies. The CPhT labels the bag and then either temporarily stores it in the pharmacy or has it delivered to the unit.

CIVs are delivered either via a messenger at a scheduled time during the day, or through the pneumatic tube system if it is needed at other times. Certain medications that should not be jostled extensively are never sent through the tube system. Upon delivery, a nurse, health unit coordinator, or patient care assistant stores the medication in a medication drawer or refrigerator. At the proper time, the administering nurse retrieves the medication, hangs the CIV, records the time on the label, and initials the label. For some medications, a second nurse verifies that the medication has been administered correctly. Nurses and physicians then monitor the patient and make necessary changes to the rate. When the CIV is close to empty or expired, the nurse can schedule another bag in the information system, repeating this process until the physician discontinues the order.

Providers rely on the CIV label throughout the process. In the pharmacy, an extra copy of the label is printed to serve as a written order, which pharmacists use in lieu of the electronic information system to verify patient and medication information. The order copy of the label also serves as a communication mechanism between pharmacists and CPhTs. Pharmacists initial the order after they verify it, CPhTs initial the order and list the time of compounding when they fill the order, and pharmacists initial again after reviewing the completed order. Additionally, when labels print in the pharmacy, they form a queue indicating the sequence in which they were received.

The way physicians enter the order can impact the preparation of the IV in the pharmacy. In some cases, physicians are able to enter the administration schedule or even the entire order as free text, and the order of information on the label is determined by their entry. Physicians do not always include all the relevant information on the order, such as the patient's weight; therefore, it does not appear on the written order in the pharmacy. Pharmacists then have to call the ordering physician or look for the missing data in the electronic record.

Furthermore, the unit and room number on the label indicate the delivery location. Once the CIV is on the unit, the patient name and instructions for storage (e.g., refrigerate) inform nurses where to store the CIV. Nurses again use the label to identify the correct medication when the time comes to administer the CIV, and they use the information on the label to double-check that the patient, drug, dose, route, and time are correct.

Table 1 lists the information requirements at each stage in the process, as well as the regulatory, legal, and institutional requirements. These requirements do not necessarily reflect information that must appear on the medication label if it is available from other sources. The data that are included must be presented amid a variety of constraints.

3.3 Constraints

The design of hospital information systems impose a number of constraints on IV label design. Font characteristics are severely restricted at the institution studied. Mixed case lettering and proportional letter spacing are not possible, and the font can only be one size. While bolding is possible, it can only be for certain locations on the label and not particular words. The printers only print in black and white and require that the toner be changed periodically, which often results in faded ink on the labels.

In the CPOE system, IVPBs are ordered in the same manner as other types of medications, but CIVs are ordered through a separate sequence, called the IV pathway. This pathway allows each additive to be billed and enables prescribers to make changes to orders without having to create a new order. A major limitation to the IV pathway is that there is no way to schedule times for multiple doses, which is the primary reason IVPBs are ordered through the medication pathway. The two types of orders produce different types of labels. Ideally, CIVs and IVPBs would have a consistent design, but the label would have to contain information only for the pharmacy (i.e., irrelevant to nurses) because the medication pathway does not support different designs for the label that goes on the medication and the label used in the pharmacy.

We also identified several physical and environmental constraints. The maximum label size is 3¼ inches × 4 inches, as it must fit onto the smallest IV bag. Choices of paper and ink are important for storage. Ink can smear and the label can become unglued in the refrigerator. On the other hand, labels that are well-suited for refrigeration can be troublesome due to the heat of a laser printer. Nurses administer medications in a variety of environments that may be dark or bright. For instance, at one point white labels were used at the hospital, and the light from windows made reading the text on a hanging IV difficult.

An additional constraint we faced is that a year's supply of labels are purchased at one time and had just been ordered before we began the analysis. This had to be figured into the cost of changing the label background color. Finances also played a role in the software issues. Updates to the information system were available that would have ameliorated many of the design constraints. The hospital stopped updating the software because they were in the early stages of implementing a new information system; however, at the time of our study, the inpatient medication process would not be changed for at least two years.

3.4 Label redesign

The proposed ideal label (Fig. 4) was designed without consideration of the identified technical constraints, with the assumption that the technology will be changing with the implementation of a new electronic record system. A second, feasible label (Fig. 5) was then designed that would work with the current technology. For the ideal label, the font formats follow the ISMP guidelines (Institute of Safe Medication Practices, 2009), which recommend a bold, 12 point, sans-serif font for the patient name, generic drug name, and dose (we added route to this list). The other patient identifiers, drug concentration, and expiration date are in 10 point serif font (Times New Roman). Brand names are listed in all upper case letters as ISMP recommends. While not depicted here, the design also makes use of tall-man lettering (e.g., VinBLAS^tine and VinCRIS^tine), which can potentially reduce drug confusion errors (Filik, Purdy, Gale, & Gerrett, 2006).

The ISMP sample label also includes a medication bar code, which is not used at the institution. In addition, ISMP recommends a 250-character comment field, but the location of such a field in their sample label is unclear. Due to the limited size of the label, adding a field of this length is not trivial, particularly for hospitals that use bar-coding.

The grey shading subtly divides the patient and drug information. The placement of the patient location on the label was chosen to discourage the use of room number for patient identification in concordance with The Joint Commission's national patient safety goals (The Joint Commission, 2009). Additionally, patient location and approximate administration time are the information needed for dispensing the medication from the pharmacy, and the positioning below the shaded area makes them easy to find.

Drug calculations can be difficult for some nurses (O'Shea, 1999). To calculate the infusion rates, the prescribed rate of the drug is multiplied by the patient's weight, if necessary, and then this quantity is divided by the concentration. The placement of these data on the new label reflects the relationships among these quantities and reminds nurses how to set up the equation. The old label included the prescribed rate of the drug, but it usually did not contain the infusion rate. This omission is acceptable because the IV infusion pumps automatically calculate the infusion rate based on the other inputs; however, nurse are supposed to do the calculation by hand as a double-check. The numbers used in the calculation are difficult to find on the old label, which complicates the task. We have included the initial infusion rate on the label and organized the data necessary for the calculation to better support this task.

The feasible label (Figure 5) represents the best design with consideration for the constraints in place. This label does not make use of the mixed-case lettering, different font sizes, colored font, or gray background shading. Spacing between lines is used to break up the text because the font characteristics cannot vary. Also, the allergies are indented since color is not available.

4. Discussion

An analysis of the medication use process guided our development of the "ideal" medication label for facilitating safe IV therapy. The label groups related information and emphasizes the patient name, medication name, dose and route. We also incorporated ISMP's recommendations for IVPB labels in our design. ISMP provides a sample label containing the minimum recommended content on their website (Institute for Safe Medication Practices, 2009). We incorporated additional content due to legal, regulatory, and internal requirements, including allergies, age, sex, weight, initial rate, concentration, duration, date prepared, comments, a refrigerate flag, and a blank field where the nurse can record the administration time. Providing all of this information, in readable font sizes, while preserving white space was challenging. Including a comment field of 250 characters was particularly problematic. Additional design improvements may be possible, such as expanding the use of color. This represents an area of future work along with user testing of different design alternatives.

Human performance in complex systems is influenced by the environment, artifacts, policies, procedures, and other system components. At the institution under study, the medication use process is intricate, and IV labels support several tasks. The multiple providers who perform these tasks have different information needs, which caused the original label to be inundated with data. The most effective modification would be to remove the information not relevant to nurses from the label on the bag; however, the information system does not allow two different labels to print for IVPBs, which is necessary for the pharmacy in the current system. The IV pathway does contain this functionality, but utilizing it would result in IVPBs and CIVs having inconsistent designs. Furthermore, the current software only supports printing in one font with uppercase, equally-spaced, black letters of a single point size. These restrictions led us to develop a second, "feasible" label design that adhered to the current system constraints, albeit with some programming changes.

The design of labels can either help convey or obscure task-critical information, including safety checks at the time of administration. Increased cognizance of medication safety has given rise to the renowned five rights of medication safety. The five rights represent the desired outcomes of the medication use process, but are often misconstrued as a means for individuals to reduce medication errors (Cohen & Smetzer, 2007). When viewed in this regard, the five rights place disproportionate responsibility for medication safety on nurses. Redesigning the medication use system to make tasks easier is a better approach than simply demanding improved performance from individuals. When making such design changes, a broader analysis should include comparing how such information is labeled on the IV bag as compared to the patient's wristband, the IV pump confirmation screen once programmed, and on the patient treatment plan since, in order to verify the five rights, these five factors need to be compared across all of these artifacts by the nurse at the bedside.

The medication delivery system is complex and contains many potential sources of errors and opportunities for improvement. We recognized and documented several other potential system flaws, but they are beyond the scope of this publication. Ackroyd-Stolarz, Hartnell, and MacKinnon (2005) and Cohen (2006) discuss many of these issues and strategies for improving the medication use system. In this study, we limited our analysis to IV labels for inpatient use. Most design elements should translate to other types of medications, but there will likely be other requirements and constraints to consider. Additionally, many of our constraints stemmed from the hospital's information system and policies. One reason we did not formally test our designs is because a new system was being implemented and would have new capabilities and limitations. Technological differences are the motivation for creating ideal designs in addition to feasible ones. Other institutions should develop the label design requirements based on analyses of their medication use process and system constraints.

5. Conclusion

Label design is known to affect the likelihood of making errors when administering medications (United States Pharmacopeia, 1998; Orser et al., 2001). Current recommendations and requirements for medication label design were found insufficient to aid in designing pharmacy-generated IV labels. A human factors analysis of medication labels at the institution under study, along with a stakeholder and task analysis, led to a proposed ideal label that had to then be adjusted to create a feasible label given software and process constraints in place. Software vendors need to become aware of label design considerations so that pharmacies can generate labels that follow good human factors guidelines and provide information to the stakeholders involved in all phases of medication use, including ordering, verifying, scheduling, preparing, delivering, storing, retrieving, and finally, administration.

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754 **EXP 1800 03/01**
243404 02/28/05 17:33 SICU
DOE, JOHN Q. 22 M 5191A
ALLERGIES: OXYCODONE

IV LINE. 5% DEXTROSE 100 ML

DILTIAZEM 125MG (FINAL CONC:
1MG/ML; FINAL VOLUME:

FOR APPROX 18:00 02/28/05

RATE: BEGIN AT 5 MG/H
CONTINUE UNTIL DC'D
SEND TO PT CARE UNIT
SCHEDULED BY:
JOHNSON, BETSY RN
KRGH

Figure 1.
Continuous IV label

0034 **EXP 0800 08/14**
243404 08/12/05 07:58 NNICU
DOE, JASON J. OD M 2150
****NEW STERILE PRODUCT ORDER****
TREATMENT OF DOCUMENTED OR
SUSPECTED SERIOUS INFECTION
DUE TO B-LACTAM RESISTANT GRAM
(+) ORGANISM...VANCOMYCIN
1000MG IVPB, 0.9% SODIUM
CHLORIDE....250ML, INFUSE OVER
60 MINUTES, DAILY AT, 17:00HRS,
01:00HRS, 09:00HRS, (08/12/04
17:00-..), (6800), (# 498).
REFRIGERATE
JOHNSON, JAMES MD
ALLERGIES: NONE KNOWN

Figure 2.
IVPB label

Figure 3.
The medication use process in the particular setting under study

Doe, John Q.		IV LINE	
22 M MR: 2434004		hung by: _____	
Allergies: Oxycodone		date/time: _____	
diltiazem		125	mg
(CARDIZEM)			
In 5% dextrose		100	ml
Initial flow: 4 ml/hr	med rate:	5 mg/hr	wt: 102 kg
Cont until DC'd	conc:	1.25 mg/ml	
For Approx: 12:00 01/02/09		STICU 7191C	
Comments: (e.g. Precautions, PT consent info, Reason for use, etc)			
Refrigerate	<i>(EXP STAMP)</i>	Prepared: 01/02/09	

Figure 4.
Proposed ideal label

DOE, JOHN Q.
22 M MR: 2434004 WT:102 KG
ALLERGIES: OXYCODONE

DILTIAZEM (CARDIZEM) 125 MG

IV LINE 5% DEXTROSE 100 ML
CONC: 1.25 MG/ML

INITIAL RATE: 5 MG/H CONTINUE UNTIL DC'D
FOR APPROX 12:00 01/02/09 STICU 7191C

COMMENTS:

HUNG BY: _____ DATE/TIME: _____

Prepared: 01/02/09 (EXP STAMP)
REFRIGERATE

Figure 5.
Proposed feasible label

IV information requirements

Table 1

Information	Regulatory requirement			Tasks requirements					
	Legal	JC	Internal	Order	Verify	Prep	Delivery	Storage	Admin
Patient name	•	•	•	•	•	•	•	•	•
MR #			•	•	•				•
Age		• ¹	•	•	•				•
Sex		• ¹	•	•	•				•
Weight			•	•	•				•
Location		•	•	•		•			
Medication name	•	•	•	•	•	•			•
Medication dose	•	•	•	•	•	•			•
Diluent & volume	•	•	•	•	•	•			•
Initial rate	•	•	•	•	•				•
Duration		•	•	•	•				•
Schedule		•	•	•	•				•
Brand name			•	•	•	•			•
Date prepared		•	•		•	•			
Date/time of order		• ²	•		•	•			
Type of order (e.g. new, replacement, IVPB)			•	•	•				
Reason for use or MD/Pt consent		• ²	•	•	•				•
Other monitoring/ cautionary info (e.g. cytotoxic drug warning)	•	•	•	•	•	•			•
Expiration date and time	•	•	•		•	•			•
Name of prescriber and contact			•		•				
Name of scheduler					•				
Allergies		• ¹	•	•	•				•
Refrigerate or non refrigerate flag	•	•	•			•		•	

JC: Joint Commission

¹ Must be readily accessible to pharmacist

² Required to be on order, not necessarily on the label

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