Enhancing Pharmacy Labeling with Color to Improve Patient Safety
Overview

Medication errors remain a major problem despite the attention, process changes and technology solutions that have been focused on eliminating them since To Err is Human: Building a Safer Health System was published. The landmark Institute of Medicine (IOM) report was released in 1999 and concluded between 44,000 and 98,000 people die each year in the U.S. as the result of preventable medical errors. In 2010 there were more than 1 million serious medication errors alone in the U.S., costing the country an estimated $7.5 billion.¹

These errors occurred despite $30 billion that was invested in technology systems to prevent them.² Packaging and labeling issues were cited as the primary cause of 33 percent of medication errors, and 30 percent of resulting fatalities, in research published by U.S. Pharmacopeia (USP).³ Various processes for Five Rights checks, medication labeling verification, bar code medication administration systems and other technologies and processes are helpful for preventing errors, but none are 100 percent effective.

There is no single process or technology that will prevent all medication errors – if there was every pharmacy and hospital would have implemented it already. Instead, healthcare professionals need to bring multiple process improvements and technology enhancements together to weave the patient safety net.

The selective use of color on medication labeling can be a valuable resource for protecting patient safety. When used appropriately, color can enhance processes to add clarity to medication dispensing and administration operations. While there is little research-based evidence on the direct benefit of color labeling, researchers, policy makers, pharmacists and nurses alike have expressed the benefits of color-enhanced medication labels.

This white paper describes different ways color is being used to support pharmacy labeling operations, how it contributes to patient safety, the limitations and dangers associated with color labeling, and presents supporting information from users, researchers and healthcare organizations.

“‘As more medications are approved and become available to Americans, the opportunity for potentially dangerous or even deadly errors due to drug mix-ups from look alike or sound alike names becomes increasingly high.’”

Diane Cousins, R.Ph
U.S. Pharmacopeia

Pharmacy Labeling with Color
The Persistent Patient Safety Problem

The *To Err is Human* report remains widely cited and influential – in part because subsequent studies haven’t refuted the key findings. Preventable medication errors remain a large-scale problem. For example, in 2010 the *New England Journal of Medicine* published a six-year study of 10 North Carolina hospitals that concluded: “We found that harms remain common, with little evidence of widespread improvement…. In conclusion, harm to patients resulting from medical care was common in North Carolina, and the rate of harm did not appear to decrease significantly during a 6-year period ending in December 2007, despite substantial national attention and allocation of resources to improve the safety of care.”

Medication labeling and dispensing errors remain a persistent source of adverse drug events (ADE) and other patient safety problems. Labeling errors were attributed to 4 percent of hospital dispensing errors in one study and up to 58 percent of dispensing errors at community pharmacies that used manual dispensing systems. A simulation found that CPOE systems missed one half of routine medication orders on average, including one third of potentially fatal orders. Dosage errors, look-alike/sound-alike (LASA) medications, administration to the wrong patient and illegible orders also all contribute to ADEs.

These problems have never been easy to eradicate, and the growing complexity of pharmacy labeling requirements is likely to make it harder. When regulations change, the change almost always requires more information on a label, not less. Meanwhile pills, syringes, vials and other containers are not getting larger, which often means fonts get smaller. With potential new requirements for drug packaging and labeling, pedigree information, unit-of-use bar coding and new compounding regulations all in the works, pharmacies will need to find new ways to effectively communicate critical medication safety information.

Using color on pharmacy labels can help solve some of these challenges. Carefully applied color can help prevent drug mix-ups, wrong-patient administration, dosage errors and legibility problems – without having to introduce color coding, and regardless of whether CPOE, bar code medication administration or other automated systems are in place. The keys are to use color selectively and effectively, as the following sections outline.
Understanding Roles and Uses for Color

There truly is a spectrum of meanings associated with the word “color.” When considering how color can be used in pharmacy labeling, it is important to be precise in how the term is applied, because the safety and effectiveness of different color processes varies. The U.S. Food and Drug Administration’s Center for Drug Evaluation and Research (CDER) offers the following useful definitions for healthcare color use:

- **Color matching** – application of color to match one item to another—used in the medical device area.
- **Color differentiation** – use of color to enhance features on a label, labeling and packaging to distinguish or differentiate one item or product strength from another.
- **Color coding** – systematic application of color to aid in identifying, differentiating or classifying a drug generally within the same pharmacological class.
- **Color branding** – use of color to differentiate drugs within the same pharmacological class that is managed by a single sponsor.

Most of the ways hospital pharmacies effectively use color labeling today relate to color differentiation, which is commonly referred to as color enhancement. Examples include highlighting the drug dosage with a yellow background field, and printing warnings in red type. While there is strong support for these and other uses of color enhancement, there is widespread concern about color coding.

In testimony before the FDA, Dr. Michael Cohen, president of the Institute for Safe Medication Practices (ISMP), highlighted the differences between color coding and color differentiation, and issued the following recommendations:

- Color can be used successfully to differentiate products, to draw attention to important information or to enhance recognition of unique letter characters.
- Reserve color coding for only high alert drugs such as insulin, neuromuscular blockers, and concentrated electrolytes but only after testing and feedback about prototypes.
- The use of color may be effective, but only when it’s one of several different variables.
Besides the ISMP, the American Medical Association (AMA), American Society for Health-System Pharmacists (ASHP) and other leading organizations have all voiced concerns about over-reliance on color coding. A common concern is that practitioners will rely on color as the primary method for identifying a drug, and will forgo the recommended three readings of the drug label. The chance for confusing a color and its meaning rises along with the more colors that are used. Color can also be inconsistent – color can fade if improper label material or a low-quality printer are used, which could cause the intended color to be misinterpreted for another, opening an avenue for errors.

In a June 2010 FDA workshop on how to design packaging to minimize medication errors, Pfizer’s vice president of packaging services gave the following testimony:

“We found color to be very, very important in laying out what things should look like, particularly where we have one product that might have five different strengths, all in the same container closure system size. Use of color to help differentiate within that particular product across the various strengths is very helpful. However, it doesn’t necessarily mean that you need to have six colors on each label. You can do it with as few as two colors, which is the option that we’re pursuing.”

**Color Enhancement Use Cases**

The quote from Pfizer touches on several key points related to color labeling – that color can be very helpful for differentiation, it should be used selectively, and the number of colors should be limited. It is important to keep those principles in mind when considering and prioritizing the dozens of potential use cases for color in pharmacy labeling.

Pharmacy printers and label media available today enable organizations to apply color anywhere on the label, and apply legible labels to practically anything, including bottles, syringes, vials and IV bags, even those that experience condensation and refrigerated storage. However, there are major differences between how color could be used and how it should be used, as the comments and process recommendations regarding color coding and color enhancement illustrate.
Color is best used selectively, which helps prevent organizations from using too much or too many colors, and avoid the confusion that results. Overuse of color can lessen its impact. To prioritize how color should be used, consider using it to support labels or processes where confusion or errors are persistent. For example, if nurses say dosage is difficult to find on a label or is difficult to read because of small type, dosage could be highlighted. If caregiver exposure to toxic materials is a concern, color highlighting or graphics might be used to emphasize warnings and safe-handling instructions.

Today color is most commonly used on pharmacy labels to highlight some of the following elements: drug name, dosage, patient name, dispensing instructions or warnings, though not all of these elements are typically highlighted on the same label.

Because color labels support and are complementary to other processes and systems (e.g. CPOE, bar code medication administration), color can easily be incorporated as an added safeguard. Here is a brief overview of how colored text or highlighting can be used to reduce errors and enhance common processes.

- **Highlight drug names** – makes the medication easily identifiable. Selective use of color can be especially useful for LASA differentiation.

- **Identify custom concentrations** – the ISMP has recommended using a different color pharmacy label to distinguish a custom concentration of patient controlled analgesia (PCA) to be dispensed from a programmable pump.11

- **Highlight dosages & concentrations** – as one of the most important elements to be verified before administration, dosage/concentration deserves special treatment. Dosage errors were identified as the leading cause of medication-related ADE identified in multiple studies, accounting for up to 58.3 percent of errors.12 Some facilities use color to differentiate between adult and pediatric versions of a medication to help prevent accidental overdose.

- **Consolidate auxiliary labels** – Color fields and colored text on the primary label can reduce the need to apply auxiliary labels (e.g. expiration date, refrigerated storage, etc.). This process saves pharmacists the step of applying additional labels, eliminates the chance they will be forgotten, and saves the cost and effort of maintaining multiple auxiliary label stocks.
• **Identify toxic materials** – protect pharmacists, nurses and other staff by marking toxic materials used in chemotherapy and nuclear medicine with color warning symbols and/or highlighting warnings at the bulk, intermediate and unit-of-use levels.

• **Emphasize delivery method** – this can be especially useful for syringes, which can be injected directly or into an IV bag. Highlighting is a space effective way to emphasize important information on space-constrained syringe and vial labels.

• **Highlight patient name** – to supplement procedures to prevent wrong-patient administration.

• **Communicate special administration instructions** – use color selectively if medication for a specific patient is to be administered in a non-standard way.

• **Highlight special storage, handling or disposal requirements** – help ensure proper storage, reduce waste and prevent exposure to dangerous materials by highlighting special requirements or applying color graphic symbols.

There are many possible variations of these uses, and other helpful ways that color can be applied. Organizations typically introduce color in response to a specific problem or process improvement initiative. For example, labels may be redesigned after nurses expressed concern over a specific look-alike/sound-alike pair, or after an analysis revealed an inordinate amount of near misses for dosage errors. The following cases illustrate how color labels were successfully introduced in response to actual pharmacy and hospital challenges.

**User Perspectives**

Kenneth Latta, BS, RPh is a consultant for pharmacy labeling and works at Duke Compounding Facility, which is part of the Duke University Health System. The organization has been using color on pharmacy labels for many years, and credits color enhancement and other label format changes designed to increase legibility with reducing the monthly medication error average from 1.5 to zero. “I think you’ll find the use of color for label differentiation is key,” Latta said. “Color allows for the differentiation of packets of information on the label.”
Cook Children’s Medical Center

Cook Children’s Medical Center in Texas selectively uses color in its compounding practices. The primary application is to highlight the names of high-risk narcotics, especially those for use in NICU, where the risk of overdose is highest.

“Color is great when it is used to highlight concentrations,” said Jason Evans, clinical pharmacist at Cook Children’s Medical Center’s. “The biggest benefit is that it gives us an easy way to make labels stand out and make each label different enough so the person administering the medication has to stop and look at what they’re handling.”

Evans considers color highlighting an important safeguard even though the medical center has a bar code medication administration system. While it is relatively easy for Evans to redesign labels to include color, not all labels carry it, to maintain the impact. The hospital is considering expanding the use of color from narcotics to chemotherapy drugs and to highlight products that require immediate refrigeration after compounding.

“Color is a way to make labels attractive while conveying important information quickly,” Evans said. “Our nurses loved it when we added color, because they felt it helped differentiate products.”

Billings Clinic

Billings Clinic in Billings, Montana, used color to reduce its need for auxiliary labels. Now when a pharmacist prints a primary label, the use-by date and any special storage or handling instructions are automatically included in a color field. Pharmacists previously had to apply these and other labels separately.

“We’ve had a lot of positive feedback. Our pharmacists and technicians both like having the auxiliary label information right on the main label because it saves them time,” said Kyle Townsend, clinical manager of pharmacy services at Billings Clinic. “Plus it’s safer. With the information all on one label that is generated from our system, there is no chance the auxiliary label information won’t be applied.”
Billings Clinic now prints the beyond-use date for each medication in red on the primary label. Hazardous materials and those that require refrigerated storage also include color text. All IV bag labels include color labels, with the drug dose printed in blue, route, frequency and rate in green. Stat orders are denoted in bold red type.

“Judicious use of color is very important. Color is more for the areas that you really want to stand out. Therefore we thought it was appropriate to use color on our labels. It’s also a huge time-saver for our staff. Applying auxiliary stickers is a mundane process,” said Townsend.

“Just from the time it saves, plus the security I get from knowing the auxiliary information will be on there, and the fact that color just pops out for the nurse who administers the medication – to me that’s worth the investment in color printing right there.”

**Hartley Medical Center Pharmacy**

Hartley Medical Center Pharmacy is an independent pharmacy in California that provides compounding services to multiple hospitals. It helps its customers easily identify and handle orders by using color on labels to highlight the patient name as well as storage (e.g. refrigerate, room temperature) instructions. Hartley Medical Center Pharmacy also applies highlighting only to select letters of LASA medications to help differentiate one drug from another.

“Color makes it easier for us to make key information clear and legible while keeping space available on the label,” said William Stuart, RPh, Pharmacist in Charge, at Hartley Medical Center Pharmacy. “Color enhances our clients’ visual accuracy for those medications. They can easily identify the medication and the patient on the package.”

To prevent confusion, Hartley Medical Center Pharmacy strives not to abbreviate on its labels. This has been a challenge in the past, because some of the preparations it compounds contain seven different items. Color is a space-effective way to highlight important information, which helps avoid abbreviating by keeping more space available. Stuart also credits having color available on demand for helping the organization comply with California Board of Pharmacy regulations for font sizes.
Because Hartley Medical Center Pharmacy is an independent pharmacy in a competitive environment, Stuart values the professional, quality image the color labels convey to hospital clients.

“Ever since we changed the labels to include color we’ve had so many compliments from our customers,” said Stuart. “Color is just an awesome way to present yourself.”

Hartley Medical Center Pharmacy instituted color labeling to improve clarity and legibility, but sees other important benefits as well. “When you add color, you are optimizing technology to provide better care,” said Stuart. “By providing better care, you’ve decreased your risk. Whenever you reduce risk you will reduce cost, even if the cost savings aren’t seen right away.”

**Conclusion**

Color is not the silver bullet that will eliminate medication errors. Instead, it is one more asset that healthcare organizations can use in their systems and processes to protect patient safety. Color labeling is a convenient, low-risk option that can be used on a variety of materials in a variety of processes, from compounding to storage to administration to disposal. Color labeling is also a low-cost safeguard. It costs only pennies to add color to a label, while the average cost of an ADE has been measured from $2,013\textsuperscript{17} to more than $9,000.\textsuperscript{18} Of course, ADEs can cost much more. The mortality rate for patients who experienced an adverse drug event is 3.5 percent, which is more than three times higher than for those who did not (1.1 percent).\textsuperscript{19} Color labeling could pay for itself by preventing even one ADE or other medication error.

Keys to using color effectively in pharmacy labeling include applying color where it will make the most impact, and using color selectively. Another key is to produce labels with printers and media that are created specifically for pharmacy use to maintain color quality and avoid ambiguity. To learn more about label printing considerations, see Epson’s white paper *Technology Options for Color Healthcare Label & Wristband Printing.*
About Digi-Trax Corporation

Digi-Trax Corporation was founded in 1986 as a Value Added Reseller (VAR) and System Integrator (SI) of Automatic Data Capture (ADC) systems. Our primary focus has been to provide innovative solutions to the healthcare community. We are a complete solutions source for hardware, software, supplies and service. Digi-Trax’s Auto-ID/Data Collection applications include products for blood banking, cellular therapy, anesthesia, transfusion, laboratory, patient identification, pathology, and more. Digi-Trax is a member of Clinical Lab Management Association (CLMA), American Association of Blood Banking (AABB), and a registered manufacturer with the International Council for Commonality in Blood Banking Automation (ICCBBA). We have been consulting members to the International Society for Blood Transfusion (ISBT) and its ISBT Working Party on Automation and Data Processing (WPADP). We have also actively participated in the AABB, ISBT-128 Task Force that developed the ISBT-128 implementation guideline. We are active participants in the Americas Technical Advisory Group (ATAG), charged with the management of the US Consensus Standards for ISBT-128. Digi-Trax is also a member of ISBER (International Society of Biological and Educational Repositories) and the AATB (American Association of Tissue Banks).

About Epson

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