IV Product Labeling: Practices to Improve Patient Safety

In the typical, high-volume pharmacy work environment, similarly labeled IV products are stored in and dispensed from the same areas. While you may think, “How could anyone possibly confuse one distinctly labeled drug for another?”, in a busy and often-cluttered pharmacy, product identification errors can occur and result in medication administration errors on the nursing units.

Drug manufacturers have taken numerous steps to distinguish IV products from one another. However, there are only so many sizes, shapes, colors, and warning messages that can be used to differentiate drug products, and it will only be so long before a pharmacist or nurse confuses one red label, for instance, for another. In the health care environment, where proper identification is critical, steps must be taken to reduce the potential for error, and many of these safety measures begin in the pharmacy.

Purchasing Considerations: The difference in IV product labels is not always obvious to us when we order medications from wholesalers. Often, it is not until a product is about to be stocked on the shelf that someone says, “This looks a lot like another product in our inventory.” Many IV product-labeling variables make it challenging to predict the potentially dangerous situations that could arise. However, there are several actions you can take to minimize your risk.

Formulary control and standardization are crucial. First, limit the number of concentrations you stock for any drug, as the fewer the concentrations available, the fewer the opportunities for picking the wrong concentration will be.

In addition, IV product purchases are typically driven by established contracts, but consider purchasing off-contract if a certain manufacturer’s labeling consistently presents opportunities for error. It may be worth spending a few extra dollars to avoid a problem as significant as a medication error.

Stocking Considerations in the Pharmacy: When stocking IV products in the pharmacy, your staff needs to have labeling concerns on their radar. For instance, if a technician notices that a manufacturer’s new magnesium sulfate 4g bags look a lot like another product you stock, they should immediately notify management so if a technician notices that a manufacturer’s new magnesium sulfate 4-g bags look a lot like another product you stock, they should immediately notify management so that they can take action to prevent errors.

In addition, look-alike, sound-alike products should not be stocked in close proximity to one another – neither in the pharmacy nor on the nursing unit. Consider going as far as to stock products at risk for misidentification across the room from each other.

Stocking Considerations on the Nursing Unit: Just as in the pharmacy, effective stocking practices on the nursing unit can prevent medication errors. If your institution utilizes automated dispensing cabinets (ADCs), consider stocking one line item per drawer or using locked, lidded cubes within each cabinet drawer. This practice further limits nurses’ access to medications and reduces the potential for selecting the wrong drug or concentration. If you are unable to stock medications in this manner, avoid storing look-alike, sound-alike drugs or multiple concentrations of a drug in one drawer. Your goal is to make it easy for nurses to make the right selection.

Of course, in order for any of these error-prevention techniques to be effective, pharmacy must ensure the cabinet drawers are stocked accurately in the first place. Remember that any point in your process that relies on human accuracy is error-prone, so establish double-checks at those points in your medication management process – even when putting unused medications back into pharmacy’s inventory – to prevent errors. Technology, such as robot-driven replenishment and bar code reconciliation during ADC stocking, can further ensure accuracy.

Label Design: For IV drugs compounded in your pharmacy, follow ISMP’s recommendations in establishing your labeling standards. Put thought into how information will be expressed on your labels and where the labels will be placed on the bag. In developing your label template, ask yourself the following:

- Is there enough white space on the label to promote readability?
- Is the font big enough?
- Are the colors used helpful in communicating vital information?
- Ask your staff members to review the template and several sample labels. Gathering input from multiple parties is vital; if a label is confusing to somebody, it could be confusing to everybody. To ensure patient safety, be sure the template you develop is interpreted the same way by a number of people.

Color Coding: Helpful or Harmful?: Because there are only so many options to choose from, the color-coding of IV medication labels can be problematic. You can take great pains to distinguish medications or drug classes from each other, but a manufacturer’s introduction of new color-coded labeling can negate any differentiation you may have achieved and present new opportunities for error.
Furthermore, color-coding can increase one’s confidence in selecting medications to the point that he or she will no longer read the label information to make a distinction between products. If you are used to always selecting a morphine bag with a green label, you may easily reach for a bag of hydromorphone labeled with a similar color. All too often, we assume the same color means the same drug.

This type of human error related to color-coded labels is largely unavoidable. However, by stressing the importance of the careful reading of label information, you can encourage staff to reduce their reliance on color for drug identification. Make sure the potential dangers of color-coding are on your institution’s radar, through continuous education and training, in order to decrease these risks.

Your training curriculum should stress the simple human factors that can lead to wrong item selection and demonstrate how colors often make items look alike. Using side-by-side pictures of look-alike products always gets people’s attention. The goal of training is to communicate to staff the necessity of reading the label on the package itself as a standard procedure and self-check. Staff should never rely on visual identification alone, nor on bin labeling to identify drugs or fluids. Training should also underscore the importance of – and the processes for – reporting look-alike products, near misses, and errors due to look-alike and label-misreading issues.

**Tall-Man Lettering:** Tall-man lettering is another tool for increasing the safety of your IV medication labels. Many manufacturers currently use tall-man lettering to distinguish products from one another, however, because few industry standards have been established, manufacturers do not always use tall-man lettering consistently. While the FDA has a published list of accepted tall-man lettering for a limited number of drugs, some manufacturers have extended that list and made up their own treatments, which differ from company to company. This inconsistency can lead to errors. Furthermore, if tall-man lettering is present on every label, eventually it will stop catching people’s eyes. So restrict tall-man lettering within your internal systems to those drugs on the FDA list to avoid so-called alert fatigue.

**Over-Wraps:** Several types of over-wraps are available for IV products – and not surprisingly, some are better at ensuring patient safety than others. Semi-opaque, plastic over-wraps can make it difficult to read drug label information – imagine trying to read through wax paper – and present opportunities for human error. Mylar over-wraps affixed with clearly printed, white paper labels are much easier on the pharmacist’s and nurse’s eye.

**Warning Labels:** The judicious use of special warning labels can prevent errors in the pharmacy and on the nursing units. However, warning labels should be used sparingly to avoid cluttering your drug labels and increasing the opportunity for alert fatigue, which can dilute the importance of necessary warning labels. Instead of developing a wide array of warning labels, spend more time making sure the drug information itself is presented clearly.

I would caution strongly against using warning labels in an effort to improve drug selection, as this could have the reverse effect of increasing look-alike errors. Rather, alternative safety measures, such as reducing stocked items, should be implemented to improve drug identification. Warning labels are more useful in identifying how certain drugs must be handled, for example using “Chemotherapy” labels.

**Failure Mode Effects Analysis:** Conducting a failure mode effects analysis (FMEA) can aid in identifying opportunities for labeling-related errors in your medication management process. First, gain a better understanding of what your medication-use environment looks like. For instance, observe your compounding personnel in the cleanroom. Watch them label products, and ask yourself where something could go wrong. Watch your staff stock and pick inventory, and then determine at which points they are likely to make mistakes. By tracing every process, you can identify all of the opportunities for human errors – namely any time a person has to make a decision.

In conducting your FMEA, keep your eye and mind on the following:
- Drug containers of the same or similar shape
- Drugs that are labeled with similar colors
- Drugs from the same therapeutic class
- Different dosage forms and sizes for the same drug
- Look-alike, sound-alike drugs
- Clutter in the storage and dispensing areas
- The potential for drugs to fall from one bin into another
- Staff members charged with multiple, simultaneous duties, i.e. stocking new inventory and restocking returned inventory
- The effects of high-volume periods on the pharmacy staff
- Workflow where multiple products occupy the same work space

There is a veritable laundry list of things to look out for, so be vigilant when conducting your FMEA.

**The Solution:** The FDA, USP, ASHP, and the pharmaceutical industry have all exhibited interest in addressing these IV drug labeling issues. Of course, in dealing with organizations of their size, matters often become complex. While everyone is interested in doing the right thing, we do not yet know what the “right thing” is, and drug manufacturers are hesitant to make changes to their packaging and labeling processes until the FDA establishes the standards. A deliberative process is needed to determine the standards for the labeling of IV drug products. Rather than just one resolution, we will likely need a number of solutions for label safety – solutions that can work in a variety of atmospheres, since what works in one care environment may be problematic in another.

That said, consistency is the key to safer labeling. While each drug manufacturer seems intent on improving patient safety, their disparate efforts in doing so yield results that can cause confusion between products, for example, the total volume or concentration of a drug may be expressed differently from manufacturer to manufacturer. Manufacturers and the FDA have a tremendous opportunity to conduct an extensive human factors study to determine how the limited number of options available can create variability and/or consistency – and therefore, opportunities for improvement – in health care professionals’ interpretation of IV drug labeling.

It is only human to make errors, and in the complex atmosphere of health care, mistakes are all too easy to make. However, if given the necessary information, the FDA and pharmaceutical manufacturers – as well as caregivers – stand to positively impact patient safety through appropriate IV drug labeling techniques.

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