



Enhanced Medication Labeling to Improve Patient Safety

Pharmacies have taken many steps to ensure their compounded sterile preparations (CSPs) meet all of their quality expectations prior to being dispensed. However, even with all of that checking, the risk of error remains – on the label.

Every pharmacist would doubtlessly agree that CSPs should be labeled in accordance with state board of pharmacy regulations, federal regulations, and applicable USP Chapters (i.e., <1> Injections and <797>). However, pharmacies can surpass these label requirements to ensure and enhance patient safety and reduce medication errors. Well-labeled preparations will allow pharmacy and nursing staff to properly identify and select the correct medication, dosage form, quantity, concentration, and strength when dispensing and administering CSPs.

In selecting any drug from the pharmacy shelf, there must be active human observation, regardless of whether a bar code scanner or automated delivery system is involved. Pharmacists, technicians, practitioners, and nurses all have a responsibility to read the label prior to release, picking, dispensing, and use. The amount of labels a person in any one of these areas might read in one day can be in the hundreds, but we should all, as professionals in the field, remember that this equates to hundreds of chances to make a mistake – or, if done right, to avoid one.

So what are pharmacies doing to make compounded medications safer through labeling? And what are some of the best practices your pharmacy can employ to improve or enhance your safety program for the labeling and dispensing of CSPs? Performing a failure modes and effects analysis (FMEA) to determine the points in the medication-use process at which an error might occur is a good start. It is not enough to rely on your complaint-handling and

If your pharmacy has not already deployed tall-man lettering, you should do so in order to **reduce medication errors** related to look-alike, sound-alike drugs.

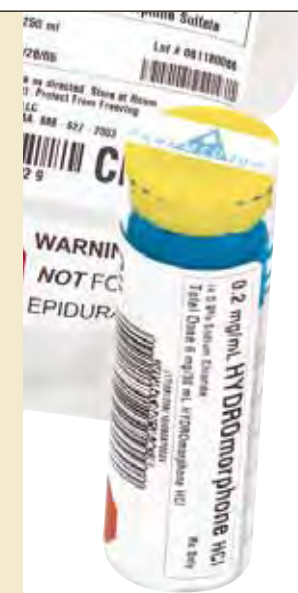


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adverse event system to react to issues as they arise. Being proactive and using FMEA can help to reduce medication errors across the board. FMEA requires input not only from pharmacy staff, but also from nurses and prescribers. As you perform your analysis, there are some basic questions you should ask.

Are Your Pharmacy Labels Clear?

Pharmacists are certainly clear about the information that must be on CSP labels when they are released from the compounding area to the dispensing area, where they receive their final prescription labeling prior to dispensing. Pharmacists check for the pharmaceutical name, generic or chemical names, the amounts or concentrations of each ingredient, the total volume, the lot

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Compounded Sterile Preparations

number, the beyond-use date, the route of administration, and any storage requirements. Many pharmacies employ bar codes that can contain all of this information and be verified through a simple bar code scan. However, it is important to remember the concept of human observation throughout your process, even with the use of automation.

For the sake of prominence, most state regulations require that the active ingredient of the CSP, its strength, and total volume be in a boldface font and larger than the rest of the label information. This allows for greater visibility

errors related to look-alike, sound-alike drugs.

Should You Use Color-Coding?

Despite what many may believe, and according to ISMP, there is no research to support that color-coding medications has reduced medication errors. In the past, it has been used to differentiate drug classes. However, that may serve to increase intra-class medication errors. Many industry experts recommend avoiding color-coding whenever possible.

Font color can have a positive impact on the prevention of medication errors, as it can reduce the potential for human error by drawing attention to certain items on a label that must be reviewed prior to dispensing. For example, different strengths or concentrations of the same drug may be labeled in different font colors and sizes or printed within a colored box on the label, allowing for better visual determination of the correct drug. Keep in mind, however, that the staff pulling, dispensing, and administering these medications may be colorblind.

Do Your CSPs Need Additional Labeling?

Auxiliary labeling on CSPs with special precautions – especially those identified by ISMP as high-alert medications – can warn users and prevent human error. When font color is not enough to differentiate a drug with a high potential for harm or one that is commonly picked from the shelf in error, a standout label should be used. Warning labels can be placed on bins and shelves where CSPs are stored as well as the immediate container to direct staff to take extra precautions.

What About the Use of Symbols and Watermarks?

Symbols may serve to distract staff during medication selection, and many industry publications have cautioned against their use. However, some symbols are widely accepted, such as those that are used to differentiate concentrations. If your pharmacy chooses to use symbols, be sure to test these during your FMEA exercises and consider all areas where they may not be effective in warning staff.

The use of watermarks on CSPs can be an additional means to differentiate medications. If you decide to employ watermarks in your labeling process, be sure they do not interfere with the visual inspection of all of the CSP label elements.

What Considerations Should Be Made if Bar Coding Is Used?

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) recommends using both bar codes and human readable medication labels. Bar codes can contain a wide variety of information, but should, at the very least, contain the lot number and beyond-use date for your CSPs. If you decide to use bar codes on your CSP labels, be sure to budget for the costs associated with bar code scanners and ensure the software and equipment used to generate and scan the bar codes is integrated with your hospital's information management systems, as well as validated and tested to ensure they work as intended. When implemented properly, bar coding can greatly reduce medication errors, and numerous system alerts can be implemented for high-alert and look-alike, sound-alike medications. In addition, bar codes can improve workflow efficiency with respect to medication tracking



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and positive identification of the medication, and thereby leaves less room for errors when medications are picked from pharmacy shelves or sent to the nursing units for dispensing.

Some CSPs, such as vials, may be too small for their labels to accommodate all of the desired information. At the very least, the label of the immediate container of the CSP must contain the drug name, route of administration, lot number, pharmacy name, strength, and total volume. Small volume parenterals should be placed in a container that is fully labeled and can accommodate the patient prescription label without covering the medication information label.

What Should You Do About Look-Alike, Sound-Alike Drugs?

Errors involving look-alike, sound-alike drugs have been reported to the Institute for Safe Medication Practices (ISMP) through the USP-ISMP Medication Errors Reporting Program (MERP). ISMP's list of confused drug names can be found at www.ismp.org/Tools/confuseddrugnames.pdf, and also includes the Joint Commission's list of drugs that accredited institutions must carry on its list of look-alike or sound-alike drugs. In August 2007, ISMP released a revised list of high-alert medications – those with high potential for patient harm when dispensed and used in error – available for download at www.ismp.org/Newsletters/acute/articles/20070809.pdf

How can pharmacies take action to address the drugs on these lists? Many have employed tall-man lettering to better differentiate drugs. Many labeling software applications offer tall-man lettering. If your pharmacy has not already deployed tall-man lettering, you should do so in order to reduce medication

and records compliance.

Some bar codes require less space on a label than others. Certain two-dimensional bar codes are only a few millimeters high and wide and can fit on even the tiniest of CSP labels. Keep in mind that some bar code readers can only decode black or blue ink and the label color itself can affect the reader's ability to scan the code. Decisions will need to be made about label colors if you are unable to scan codes against darker backgrounds. However, if significant changes to medication labels are made, communicate with practitioners outside of the pharmacy to avoid confusion and the potential for errors. Pharmacies should review, communicate, and roll out label changes systematically.

What are Some Good Resources to Review When Making These Decisions?

In January 2007, the Center for Drug Evaluation and Research (CDER) held a public meeting on "Improving Patient Safety by Enhancing the Container Labeling for Parenteral Infusion Products." You can view the many informative presentations at www.fda.gov/cder/meeting/parenteral/presentations.htm. This site also includes discussion of the pros and cons of making label changes and provides a comprehensive view of the USP Chapter <1>'s new label requirements for injections, effective in 2009.

Conclusion

Proper CSP labeling can have a positive impact on medication safety at your hospital. By approaching labeling decisions thoughtfully and systematically, your facility stands to improve patient safety and workflow efficiency and decrease errors in the pharmacy and throughout the care process. ■



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