THE JOINT COMMISSION NATIONAL PATIENT SAFETY GOAL (NPSG) 3D requires that hospitals “label all medications, medication containers (e.g., syringes, medicine cups, basins), or other solutions on and off the sterile field in perioperative and other procedural settings.” It is incumbent upon pharmacy to become involved in achieving compliance with this goal and in establishing practices, policies, and procedures to do so.

At the University Community Hospital in Tampa, Florida, our pharmacy and nursing departments audit areas such as anesthesia, radiology, surgery, endoscopy, the cardiac cath lab, and the electrophysiology lab at least monthly to ensure the appropriate and complete labeling of products drawn up in syringes, poured into basins, or transferred to other containers. We had noticed that anesthesia, radiology, and surgery were consistently non-compliant with NPSG 3D; in some cases, the names of medications were absent, and in others, there were no labels at all on syringes or basins. Pharmacy was concerned that non-compliance with labeling medications, solutions, and solution containers would risk patient safety, so we reported it to the medication management committee in the fall of 2005. To remedy this problem and achieve Joint Commission compliance, we embarked on an initiative to assure that all medications, medication containers, and solutions are labeled on and off the sterile field.

The Improvement Process
Pharmacy met with nursing, physicians, and other health care professionals to research why products were not being labeled. They found that the present tools, such as blank labels, orange labels, and sterile pens, were not being utilized correctly. In addition, labels with the names of the medications were available in different colors and were utilized inconsistently in surgery, radiology, and other areas of the hospital. The work group determined that labeling needed to be as user-friendly and standardized as possible.

After collecting the baseline data identifying the areas for improvement, nursing and pharmacy created a non-sterile product label format that included:
- Patient name
- Date and time drawn up
- Initials of the person who drew up the medication
- Medication name

The University Community Hospital developed customized labels as part of their initiative to comply with NPSG 3D.
Concentration/strength
Dose
Expiration date, i.e. “Expires 12 hours from time drawn up”

The label was printed on standard blank labels 0.75 by 1.5 inch using a standard label printer. The chairman of the medication management committee then carried out hospital-wide education on NPSG 3D, including a PowerPoint presentation, written education, and verbal presentations at all of the medical and clinical staff meetings. As part of a separate initiative, materials management worked to create a sterile label kit that contained 20 blank labels and a sterile pen. This kit was distributed throughout the hospital to label products used in sterile procedures.

Despite these changes, the compliance problem continued. Pharmacy and nursing found that the staff was not using the new labels. Interviews with the staff identified the following reasons for noncompliance:

- Filling in the blanks took too much time. A study in the cath lab showed that the average time to fill all of the blank labels used on a cath lab patient was approximately 15 to 20 minutes.
- Staff wanted an easy and user-friendly process.
- Staff wanted a color-coded label.
- Staff wanted a label with as much information pre-printed as possible.
- For standard doses, staff wanted the concentration and dose pre-printed on the label.

The medication management committee reviewed these findings and customized their own wish list. It included:

- Standardizing the label format
- Standardizing the color of the label based on color-code guidelines approved by anesthesia as follows:
  - Yellow for induction
  - Orange for tranquilizers
  - Gray for local anesthetics
  - Violet for vasopressors
  - Fluorescent red for muscle relaxants
  - White for miscellaneous items
- Using tall-man lettering when possible
- Making the label size user-friendly
- Developing labels that could be used at multiple hospitals to improve the consistency of the process.

For more information, circle #72 on the Reader Service Card.

Form that beautifully follows function.

Look to R.C. Smith for assistance with compliance to USP-797 as well as creative ways to improve your pharmacy’s workflow.
To meet the 2006 National Patient Safety Goal 3D in all practice settings which states: All medications, medication containers (e.g., syringes, medicine cups, basins) or other solutions on and off the sterile field in perioperative and other procedural settings will be labeled.

Where is this applicable?
Any procedural setting in the hospital where medication or solutions are transferred from the original package to another container (syringe, cup, basin, etc.)

Responsible Parties:
- All patient care areas
- Medication includes any prescription medications, samples, herbas, vitamins, nutraceuticals, over-the-counter, vaccines, diagnostic and contrast agents, radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, intravenous solutions and any product designated by the FDA as a drug.
- Solution includes chemicals and reagents such as, but not limited to, formalin, saline, sterile water, Lugol’s solution, radiopaque dyes, glutaraldehyde, and chlorhexidine.

Labeling must include:
- Name of medication or solution, strength, date, and time
- Label one item at a time.
- Single items must also be labeled.
- Keep original containers of the medication or solution until the end of the procedure.
- Remember that containers and solutions brought in during the procedure for purposes of collecting specimens, harvesting organs, etc., must also be labeled.

If in doubt, throw it out:
- Never use an item if it is unlabeled or there is any doubt as to its identity.
- Discard any item that is over 12 hours old.
- USP < 797> regulates maximum time for sterile products to 12 hours.

Communication:
- Labels are verified verbally and visually by two qualified individuals.
- If at shift change or break relief, all medications and solutions on and off the sterile field and their labels are reviewed by entering and exiting personnel.

Why is this necessary?
- Fatal outcomes have been reported by other hospitals of wrong items injected due to unlabeled syringes or basins like formalin or chlorhexidine injected instead of intraspinal fluid or lidocaine.


Pharmacy and materials management met with a printing company, identified by Novation – our GPO – and the VHA, to develop labels that met these guidelines. We received approval for the project through Novation’s Value Analysis Team for Supplies. The Novation contract with the VHA enabled us to develop and implement these labels in a cost-effective manner. Pharmacy, nursing, and other health care professionals then worked to develop labels with as many filled-in blanks as possible. For example, a pre-printed propofol label contains the following information:
- Propofol
- 10mg/ml
- Expires four hours after time drawn up

The VHA’s Joint Commission preparation coordinators assisted in reviewing the labels to assure that the medication management committee was complying with Joint Commission standards and NPSG 3D. The staff was satisfied with the standardization, color-coding, and most of the information pre-printed on the label.

Compliance began to improve immediately. To reinforce compliance, the medical staff updated and approved the policy for labeling medications and solutions. Implementation of the new medication-specific labels took place in June 2006. Feedback from staff and physicians was continually obtained as the labels were modified to meet the needs of both staff and physicians.

Both the sterile and non-sterile labels are 0.75 by 1 inch and are ordered by each patient care unit as needed. Sterile label kits are stored in our supply Pyxis machines. Non-sterile labels are stored on rolls in designated holders. The nurse or health care professional labels each item as it is drawn up or poured into a container. The labeled products and containers are verified by two health care professionals.
Results
To ensure continued compliance, education and monitoring by the medication management committee and others is ongoing. Our staff performs walking rounds to ensure that items are labeled appropriately. We also quiz the staff to assure that they can verbalize the process, and we report the quiz results to our performance improvement committees on a regular basis.

Compliance has improved dramatically and is consistent, and education has successfully reinforced the need to utilize these labels. Based on the success of the program, these labels were shared with other hospitals in our system. We have also created practitioner-specific label kits and an educational poster (Recreated in Figure 1).

While the initial costs of the pre-printed labels were more than the cost of the blank ones, the improved patient safety and the ability to quickly turn around cases nullified the cost. That said, by standardizing the kits, the cost of the labels and the sterile label kits became much more affordable. Ultimately, the cath lab was able to decrease their labeling time from 15 to 20 minutes with the first label format to five minutes per case with the new labels. Sterile label kits have also been developed for MRI, CAT scan, and other specialty areas, including eye surgery. Our program was published in the June 2006 “VHA Southeast Bright Ideas” newsletter. All in all, because of careful, thorough planning and vigilant post-implementation monitoring, our program to meet the requirements of the Joint Commission NPSG 3D has been a success and addressed our primary goal of providing safe patient care.

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