Standards FAQ Details

NPSG (AMCAH / Critical Access Hospitals)

Labeling in Procedural Area - NPSG - Goal 3 - 03.04.01
Revised | March 26, 2010

Procedures outside of the OR

Q. Does NPSG.03.04.01 apply only in the operating room?

A. NPSG.03.04.01 applies to any surgical or other procedural setting and includes pre-, intra-, and post-operative/procedural components. Consequently, it applies not only to the surgical suite but also to prep areas, pre-op holding, and PACU. It also applies to medications used by anesthesia providers. In fact, it applies to all procedural areas that use medications or solutions including, but not limited to, radiology and other imaging services, endoscopy units, dental services, and patient care units where “bedside” procedures are done.

Immediate use of a medication or solution

Q. Is there an exception to the labeling requirement for immediate use?

A. If during the peri-operative or peri-procedural process, a solution or medication (either in the sterile field or out) is poured, drawn into a syringe, or otherwise used from its original container and immediately administered or disposed of labeling is not required. “Immediate administration” means with no intervening steps or functions prior to administration. However, if the medication or solution that has been removed from its original container will be used over the course of a procedure, for instance—prep solutions, normal saline used to rinse cardiac valves, local anesthetics, clotting agents, etc.—the receiving container must be labeled. Please also see MM.05.01.09.

This is also relevant to anesthesia services. If the anesthesia provider prepares a medication, immediately administers the medication, and the syringe or container is disposed of after the medication is administered, labeling the syringe or other container is not required. However, if the medication is prepared and slowly administered over the course of a procedure, if the medication is prepared by a staff member other than the administering provider, if the medication is prepared in bulk for the day’s cases, or if the provider preparing the medication participates in another function prior to administration, the syringe or other container must be labeled.

If more than one medication is prepared, each would need to be labeled. Preparing two medications at the same time does not meet the above-stated definition of immediate use; therefore each would have to be labeled.
Content of the label

Q. When labeling medications and solutions in the context of NPSG.03.04.01, what information must be on the label?

A. The labeling expectations for this safety goal are consistent with the requirements of standard MM.05.01.09, which state the label must include:

- Drug name, strength, amount (if not apparent from the container)
- Expiration date when not used within 24 hours (this would be rare for procedures)
- Expiration time if less than 24 hours (applies to only a few drugs)
- Date prepared and the diluent for all compounded IV admixtures

In most cases of medications and solutions in the procedural setting, only the drug name, strength (concentration), and amount will be needed.

Pre-filled syringes

Q. We have discovered that pre-sterilized, pre-labeled syringes are now commercially available. Is this acceptable?

A. It is acceptable to purchase and use pre-filled, pre-labeled syringes such as on procedure trays. However, pre-labeling medication and solution containers is not acceptable. The label should be prepared and applied at the time the medication or solution is prepared. Applying the label immediately before drawing up the medication is acceptable and may make the process of checking the label against the original container more efficient. Engraving basins for use only with sterile saline or other routine solutions also carries risk of pouring a solution into a basin that is pre-labeled for a different solution; this approach is not considered acceptable.

Pre-labeled syringes

Q. It has been our practice to pre-label syringes for anesthesia medications for the anesthesia cart in the trauma room as a means of reducing the time it takes to prepare needed medications when faced with an emergency situation. Is this acceptable?

A. The basis of the current Joint Commission position prohibiting the pre-labeling of empty syringes is the established medication management principle that labeling is part of the medication preparation process and should be done at the same time the medication is prepared.
(drawn up into the syringe). The safest approach is to use manufacturer-prepared pre-filled, pre-labeled syringes. Pharmacy-prepared pre-filled, pre-labeled syringes would also be a safe approach but may not be practical for anesthesia services.

Prelabeling of Syringes

Q. Is it acceptable to "label" a syringe by taping the vial (from which the medication was drawn up) to the syringe?

A. No; it is not acceptable to label a syringe by taping the vial to the syringe. The label should include the drug name, strength, amount (if not apparent from the container), expiration date when not used within 24 hours and expiration time when expiration occurs in less than 24 hours.

Pharmacist-prepared medications and solutions

Q. We have a pharmacist assigned to the OR to assist in the preparation of medications and solutions. Do syringes prepared or mixed by the Operating Room Pharmacist require another individual to verify the labeling of the syringes?

A. Medications prepared and labeled by a pharmacist would not require a second person verification. One of the reasons for this NPSG requirement is that in procedural settings, the usual processes for preparing and dispensing medications often are not followed. Involving the pharmacists gets it back to the “usual processes” and their attendant safeguards.