

Medication Safety: Just a Label Away

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What do consumers rely on when they go to a grocery store to buy a product? Typically, it is the product's label. Reading the label is how a person determines the container's contents and how he or she ensures the safety of the product for use. Medication labels are no different. Pharmaceutical companies label medication containers so the consumer, in this case the patient, safely receives the appropriate product. The nurse's role is to ensure that a secure process is in place to facilitate error-free medication administration in the health care setting.

Nurses recognize that safe medication practices are essential to the provision of quality patient care. One of the earliest lessons for nursing students addresses the "five rights" of safe medication administration:

- right patient,
- right medication,

- right dose,
- right time, and
- right route.

Proper container labeling is integral to a nurse's compliance with these five rights.

ERROR STATISTICS

In a 1998 report from the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, medical errors were identified as one of the four major issues that needed to be addressed to improve the quality of the nation's health care.¹ In 1999, the Institute of Medicine (IOM) published a report titled *To Err is Human—Building a Safer Health System* in which medical errors were defined as

the failure of a planned action to be completed as intended . . . or the use of a wrong plan to achieve an aim.^{2(p28)}

The OR was specifically identified as a department in which a high likelihood exists for medical errors to occur, and these could result in serious consequences. The IOM's report concluded that errors are seldom the result of recklessness. More often, they are caused by faulty processes or conditions that may lead health care workers either to make mistakes or to fail to prevent mistakes from happening. Health care institutions were encouraged to make safety a high priority by developing processes and providing necessary supplies that would help prevent medical errors.³

In a 2006 report, the IOM's Board on Health Care Services revealed that medication errors were the most common medical error, causing harm to approximately 1.5 million people every year.⁴ A medication error was defined as "any

ABSTRACT

IN PERIOPERATIVE SETTINGS, medications are removed from manufacturers' identifying containers; therefore, scrub personnel should label medications placed on the sterile field.

COMPLIANCE WITH MEDICATION labeling practices with the use of both blank and preprinted labels was tested in the OR at a Houston, Texas, hospital.

SCRUB PERSONNEL WERE more likely to label medications and medication-delivery devices when preprinted medication labels were provided.

DATA OBTAINED FROM this project influenced the hospital's management team to supply preprinted labels for all procedures to improve safety for surgical patients. *AORN J* 86 (October 2007) 618-625. © AORN, Inc, 2007.

error occurring in the medication use process."^{4(p37)} The report implied that all medication errors are preventable. According to the IOM's findings, an average of one medication error occurs per patient per day. Approximately 400,000 preventable, medication-related injuries occur in hospitals each year. The remaining 1.1 million medication errors occur outside of hospitals. The report states that most medication errors occur at the prescription or administration stage.⁴

PURPOSE OF THE PROJECT

Because of the high medication error rates reported in hospitals, it is desirable to identify and implement the best methods of promoting medication labeling in the perioperative setting. Doing so will reduce the possibility that a medication error will occur. The purpose of a quality improvement project conducted at one metropolitan Houston, Texas, hospital was to determine whether the provision of preprinted medication labels placed on the sterile field would improve the practice of labeling medications in perioperative settings. Preprinted labels were provided for use in randomly chosen surgical procedures, while blank labels (ie, the standard of care in the facility) were provided for other procedures. Perioperative personnel's compliance rates with the labeling of medications were tracked, and the compliance rates were compared between groups using preprinted versus blank labels.

REVIEW OF LITERATURE

A review of the literature identified medication labeling as one of the biggest issues for medication safety. In a 2002 report from the Agency for Healthcare Research and Quality, it was estimated that approximately 7,000 people die each year from medication errors.⁵ Although many of these injuries and deaths likely have gone unreported, some have made news headlines. The following events, which occurred many years apart, show that even though medication safety has been studied, discussed, and mandated, errors continue to occur, and existing systems and procedures are not infallible.

A report published in *Hospital Pharmacy* in 1989 relates the story of a man who was un-

dergoing a procedure to remove a cancerous tumor from his eye. This patient died when glutaraldehyde, a substance that was intended to preserve the tissue specimen, was injected intrathecally. The glutaraldehyde was mistaken for spinal fluid which had been removed from the patient to decrease pressure in his brain. Both of these fluids were stored in unlabeled containers on the sterile field.⁶

An article printed in 1998 told the story of a young boy who received an injection of adrenaline from his surgeon, who thought it was lidocaine. As a result of this mistake, the child died. In this particular instance, the two medications had been prepared according to hospital procedure. The adrenaline was poured into a plastic cup on the sterile field and the lidocaine was poured into a metal cup. Although the staff members who were involved had exercised care in preparing the medications, neither of the cups had been labeled.⁷

In an alert published in 2004, the Institute for Safe Medication Practices (ISMP) reported that a woman was injected with chlorhexidine, an antiseptic skin preparation solution, instead of contrast media during a radiological procedure. Both solutions were clear and had been placed on the same table in unlabeled containers during the procedure. As a result of this error, the woman died.⁶

THE COST OF MEDICATION ERRORS. The personal costs of medication errors for patients may include suffering, the need for additional treatment, loss of income, and death. Family members also experience emotional trauma as a result of seeing a loved one suffer. For the estimated 1.5 million people who are injured by medication errors each year, health care facilities incur a conservative estimate of \$3.5 billion in additional expenses while treating their injuries. If this dollar amount were extended to lost wages, lost productivity, and other additional expenses, the costs associated with medication errors might increase to as much as \$29 billion.⁸

In addition to the financial costs involved in medication errors, there are substantial costs to the reputation of the health care profession and its members. Every time a medication error occurs, whether it is reported by the media or whether the information simply is spread by

word of mouth, the public loses confidence in the quality of health care that is provided. A poll conducted by the American Society of Health-System Pharmacists in 1999 found that 61% of those surveyed were “very concerned” about being given the wrong medicine. The survey also indicated that 58% of respondents were very concerned about being given two or more medicines that would negatively react with one another, and 56% expressed concern that they would experience complications from a medical procedure.¹

RECOMMENDATIONS FOR MEDICATION LABELING. In 2004, the ISMP’s *Medication Safety Self Assessment of OR Practices*⁹ showed that 41% of surveyed staff members always labeled containers on the sterile field, 18% did not label at all, and 42% labeled inconsistently. Even though these data reflect a 30% improvement from a similar survey done in 2000, it is concerning that such a small percentage of health care personnel practice proper labeling of medications in an environment where patients rely solely on these clinicians to protect them from harm.⁶

The ISMP recommends that

- safe labeling policies and procedures be implemented in the perioperative setting,
- labels be provided and required on all containers and syringes, and
- each medication be labeled properly when it is added to the sterile field and before any other medication is dispensed (Figure 1).⁶

Also included in these recommendations is that any medication found in an unlabeled container or device be discarded immediately because the contents of the container cannot be verified without a label.⁶

In 2006, the Joint Commission added a new National Patient Safety Goal in which health care workers are instructed to

*label all medication, medication containers (eg, syringes, medicine cups, basins) or other solutions on and off the sterile field in perioperative and other procedural settings.*¹⁰

This goal was initiated to address an identified risk in the process of medication administration. When medications are placed in unlabeled containers they are rendered unidentifiable



Figure 1 • Appropriately hand-labeled medication cup and syringe into which medication can be dispensed.



Figure 2 • Unlabeled medications are unidentifiable.

(Figure 2).¹⁰ The Joint Commission added specific requirements to this goal in 2007, stating that all labels should include the medication’s name; strength; amount; and expiration date (ie, when a medication is not used within 24 hours) or expiration time (ie, when the medication expires in less than 24 hours). Additional process expectations were added to this guideline, including the recommendation that “no more than one medication or solution is labeled at one time.”¹¹ Labeling is not required, however, if a medication is removed from its original container and immediately administered by the individual who removed it.¹¹

In response to a growing concern about medication safety, AORN developed a guidance statement titled “Safe medication practices in perioperative settings across the life span,” which states that constraints should be

implemented that make it difficult to commit medication errors.¹² Another recommendation in this guideline is that all medications, including chemicals and reagents, should be labeled on and off the sterile field. All containers and delivery devices should be labeled, even if only one medication is involved, when that medication has been removed from its original packaging.¹²

SAFETY IN THE PERIOPERATIVE ENVIRONMENT

Medication safety in the perioperative setting is an essential element in the provision of quality patient care. The administration of medications in the OR is a unique process, which involves the removal of the medication from the manufacturer's packaging. Often, the person administering the medication is not the person who prepared it. In fact as many as three individuals can be involved before the patient receives the medication:

- the circulating nurse,
- the scrub person, and
- the physician.

Even though all three individuals are part of the same OR team, their roles and tasks often occur at different stages and locations during the intraoperative period. For example, to prepare a local injection, the circulating nurse typically draws up the medication from a vial at a workstation. When he or she has transferred the medication to the sterile field, the circulating nurse moves on to other tasks and responsibilities. At some point during the procedure, the scrub person will prepare the delivery device (eg, the syringe) so that it is available when the surgeon is ready to administer the medication. With each additional person involved in the process, the risk of medication error increases unless processes are in place to protect the patient.

AN INVESTIGATION AT ONE FACILITY

In an investigation of the ORs in one metropolitan Houston, Texas, hospital, the processes of labeling medications that were placed on the sterile field during surgical procedures was observed, and this observation revealed inconsistencies in the medication labeling practices of scrub personnel. At times, the medicine cup would be labeled but the injection syringe would not be labeled. At other times, neither

the container nor delivery device would be labeled. The saline basin and bulb syringe consistently were not being labeled. One reason for this was that often the time allotted to prepare medications was limited or the scrub person was rushed because of other duties (eg, turning over the room between procedures, counting large instrument sets, responding to surgeon demands). These other duties often took priority over labeling medications. Staff members commonly relied on physical devices, such as basins and medicine cups, to distinguish the different medications on the sterile field. To date, no medication errors have been reported in this hospital's ORs; however, it was felt that a safe system of labeling medications on the sterile field was essential to guarantee medication safety for all patients and to be in compliance with AORN's guidelines and the Joint Commission's requirements.

METHOD

The primary investigator for this descriptive clinical investigation was an RN first assistant and clinical educator with 30 years of OR experience. The facility is a 216-bed community hospital with nine surgical suites that is part of a 16-hospital system. Data were collected during a three-month period, and a convenience sampling technique was used. Eligibility criteria included all surgical procedures in which the patients were undergoing general anesthesia on the designated data collection days. These days were determined by the availability of the primary investigator. Data were collected by the primary investigator with the assistance of several perioperative nurses who had been trained in data collection methods.

The eligible scheduled procedures were randomly assigned to receive preprinted medication labels or blank labels. Blank labels were to be filled in by the perioperative scrub person who was assigned to each procedure. Scrub personnel were either certified surgical technologists or RNs, depending on the scheduling of staff members each day. A systematic, randomized approach was used, which incorporated slips of paper on which the surgical suite numbers were written. These were placed into a container. The slips listed all of the OR suites

that were scheduled for use on a particular day. Each day, half of the scheduled ORs were randomly assigned to receive preprinted labels. All ORs received blank labels as a part of the custom packs that are used during every procedure, thus representing the standard of practice in the facility. The packages of preprinted labels were discreetly placed on the appropriate case carts with a memo requesting they be opened on the sterile field (Figure 3).

Data were collected by the primary investigator's direct observation. The circulating RN intentionally was not included in the data collection process so that he or she would not prompt the scrub person to label the medications. This was done to avoid influencing the data. After commencement of the procedure, the investigator observed the back table to assess whether and how all medications on the sterile field, including solutions and reagents such as normal saline, had been labeled (Figure 4).

ANALYSIS

Statistical analysis included descriptive statistics and chi-square analysis. Data were recorded into Chekker, a computerized data collection system developed by the Memorial Hermann Healthcare System's Information Systems Department, Houston, Texas. Data were then input into a computerized spreadsheet and analyzed using SPSS 10.0 statistical software.¹³

RESULTS

Data from 128 procedures were collected and analyzed. In one procedure, no medications were placed on the field, so no data were collected during this procedure. Of the remaining 127 procedures in which medications were used, only blank labels were provided for 55 procedures (43.31%) and preprinted labels were provided for 72 procedures (56.69%).

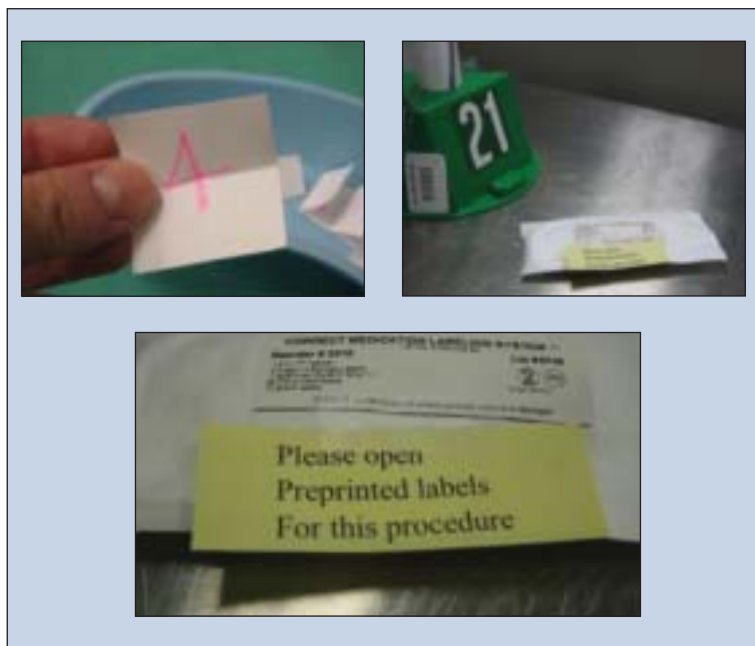


Figure 3 • Random assignment of labels to specific ORs (*top left*). Provision of preprinted labels (*top right*). Instructions for use of preprinted labels (*bottom*).



Figure 4 • Data collection during a surgical procedure.

Data were collected until the minimum number of data points needed for statistical validity had been reached. Medications were labeled for transfer to the sterile field in 75 of the 127 total procedures (59.05%). Medications were not labeled in 52 of the 127 procedures (40.95%). When blank labels were provided, medications transferred to the sterile field were labeled in only 22 of the 55 procedures (40.00%). When preprinted labels were provided on the field, medications were labeled in 53 of the 72 procedures (73.61%). According to

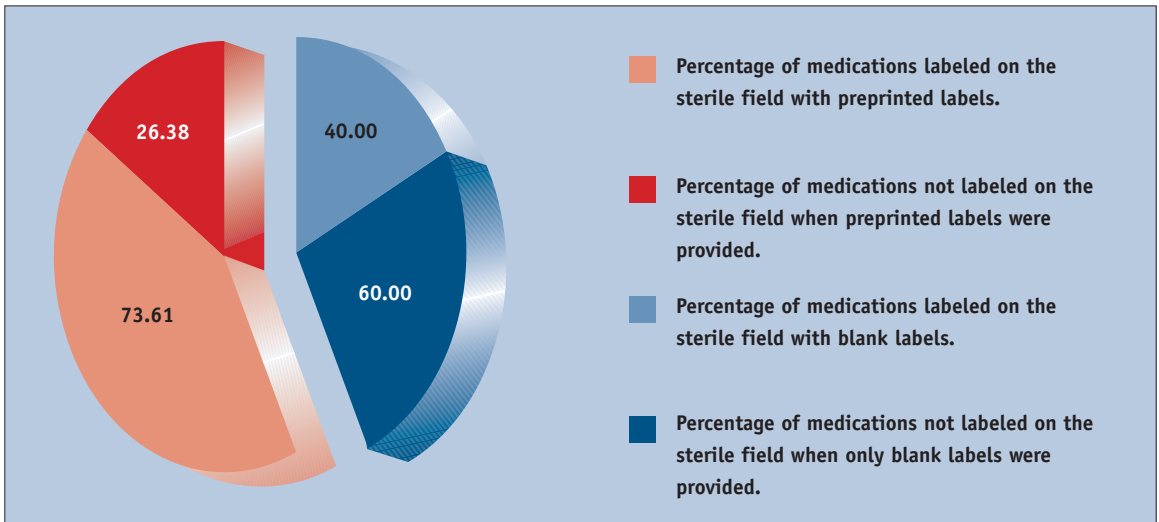


Figure 5 • Comparison of labeling of medications using preprinted labels versus hand-written labels.

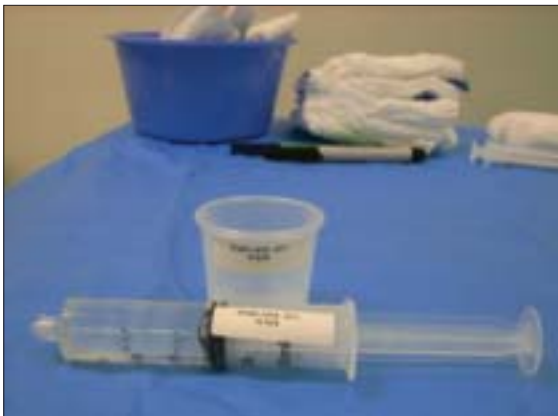


Figure 6 • Labeling of medication with preprinted labels.

these data, investigators determined that scrub personnel were more likely to label the medications when preprinted labels were provided (Figure 5).

DISCUSSION

Using the data obtained from this project, the management team met to discuss how to best address the inconsistent labeling practices in this facility and to implement an improved labeling system. The management team developed a plan to create a list of medications frequently administered on the sterile field. Surgeon preference cards were used to gather this information, and a list of 38 frequently used medications were identified for inclusion in

the labeling kit. It was necessary to create multiple labels for certain common medications to allow OR personnel to label both the containers and the delivery devices (Figure 6). It was impractical, however, to create labels for every commercially available medication, so several blank labels also were included in the kit for infrequently used medications.

Hospital managers decided to purchase custom-designed preprinted labeling kits. Waterproof label marking pens also were included in these kits because skin markers included in the hospital’s procedure packs smear when wet. The intent of providing these kits is that scrub personnel will open a label kit for every procedure in which medications are placed on the sterile field. As a follow up, quarterly audits will be performed to determine whether staff members are in compliance with the new labeling system. Audit data were not available at the time this article was written.

LIMITATIONS OF THE PROJECT

The main limitation in this investigation was the inability to maintain a blind research design. As the data collection continued, staff members began to question why preprinted labels sometimes were provided when blank labels always were available in the sterile procedure packs. To maintain the ethical principal of veracity, when staff members asked, they

were told that the preprinted labels were part of an investigative project. This may have compromised the results to some degree. Additionally, to maintain patient safety, the investigator determined that it was necessary to point out to noncompliant scrub personnel that they should label the medications properly.

CLINICAL IMPLICATIONS

In recent years, medication-related errors have been studied extensively. They are the most common type of medical errors, affecting a substantial number of patients. They also account for a sizable increase in health care costs. This qualitative improvement project demonstrated that supplying preprinted medication labels facilitated the identification of medications on the surgical field and encouraged staff members to label all patient medications in use. A prospective, randomized, comparative approach provided strong supportive data for a practice change, which, it is hoped, will result in improved safety for surgical patients. — ■■■ —

Editor's note: Chekker is a registered trademark of the Memorial Hermann Healthcare System, Houston, TX.

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