Recommendations for the Implementation of Joint Commission Guidelines for Labeling Medications

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PREAMBLE

THE membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such they represent a valid broad expert constituency of the subject matter under consideration for standards production.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

METHODOLOGY

SIR produces its Standards of Practice documents using the following process. The Standards of Practice Committee members conceptualize standards documents of relevance and timeliness. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned dependent upon the magnitude of the project.

An in-depth literature search is performed using electronic medical literature databases. Then a critical review of peer-reviewed articles is performed with regards to the study methodology, results, and conclusions. The qualitative weight of these articles is used to write the document such that it contains evidence-based data with respect to content.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members using a Modified Delphi Consensus Method (Appendix A) (1,2). For purposes of these documents consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members, either by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee, and appropriate revisions made to create the finished stan-

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dards document. Prior to its publication the document is endorsed by the SIR Executive Council.

INTRODUCTION

In January 2006, the United States Pharmacopeia stated that "...medication errors occurring in radiological services produced the highest percentage of harm—seven times higher than all medication errors studied in the 2000–2004 reporting period" (3). The United States Pharmacopeia went on to describe errors occurring in the radiology department, cardiac catheterization laboratory, and nuclear medicine as "hidden risks for patients" and recommended that the issue of medication error "... must be addressed for patient safety and quality of care" (3). While the methods of compiling and analyzing these data were later called into question, the public was left believing that significant medication errors occur with greater frequency in radiology departments when compared with the hospital as a whole.

This review summarizes our analysis of the problem, and makes specific recommendations applicable to interventional radiology. These recommendations are guided by the Joint Commission 2007 National Patient Safety Goals (NPSGs). Specifically, Goal 3D requires that hospitals "Label all medications, medication containers (eg, syringes, medicine cups, basins), or other solutions on and off the sterile field in perioperative and other procedural settings" (4). The Joint Commission's guidelines are very clear on this topic, and have been reproduced verbatim in this text. This article is an attempt to help the practitioner apply the Joint Commission guidelines to the daily best practices of interventional radiology.

DEFINITIONS

The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as ". . . . . any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use" (5).

A more practical definition for medication errors for interventional radiology should also include the administration of a substance (or dosage of a substance) not intended for use in a particular patient. This also applies to the administration of a medication intended for a different patient, administration of a medication to which the patient has a known allergy, or enteral or parenteral administration of a substance not intended for internal use. It is important to realize that medication errors may or may not produce an adverse reaction.

BACKGROUND

Interventional radiologists understand that their subspecialty has evolved through many means, including laboratory research, clinical experience, and the use of novel devices and medications in an off-label fashion. As such, the procedure table in the interventional radiology suite may include standard components such as skin cleansers, saline flush, local anesthetics, and iodinated contrast agents. However, it is not unusual to find other drugs such as gadolinium contrast agents and carbon dioxide. Embolization tables may include injectable agents such as polyvinyl alcohol, embolic spheres, embolic coils, absorbable gelatin sponge, several concentrations of ethanol or other sclerosing agents, and different glue preparations. Thrombolytic agents are also commonplace in the interventional radiology suite. Unlabeled, many of these substances may be mistaken for one another, with potentially catastrophic consequences.

A recent article (6) written to illustrate mortality as a result of injection of unlabeled substances details selected case reports of deaths in the operating room and cardiac catheterization laboratory. In each case, the common preventable factor is physician injection of a hazardous substance stored in an unlabeled container on the sterile field.

While database searches returned more than 4,000 articles pertaining to medication errors, there are, understandably, few prospective randomized clinical trials addressing their prevention. Many case reports deal with medication errors involving a single medication or a specific scenario (7). Many advocate the use of computerized pharmacopeias and automated dispensing systems to reduce errors (8,9). Several organizations sponsor Web pages with suggestions on reducing medication errors (5,7,9).

To provide some guidance for the interventional radiologist regarding this high-profile and medically important issue, recommendations from several sources (5–15) have been compiled into recommendations applicable to interventional radiology. The SIR Safety and Health Committee believes that the lack of relevant literature does not limit the importance of these guidelines.

The Joint Commission has issued clarifications of various points regarding interpretation of the NPSGs. These include the following statements: NPSG Goal 3D "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" (4). In addition, NPSG Goal 3D applies to all "perioperative and other procedural settings" (4).

These clarifications make plain that the guidelines given must be applied to all procedures performed by interventional radiologists, regardless of where in the hospital they are performed, and to all procedural settings, not just intraprocedural administration of medications. All quotations given in the Guidelines in this statement are from Joint Commission guidance documents.

JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS REQUIREMENTS PERTAINING TO MEDICATION LABELING (2007 NPSG REQUIREMENT 3D)

The Joint Commission has published its expectations for implementation of the NPSGs. The Joint Commission's expectations for implementation of Goal 3D (labeling of medications, medication containers and solutions on and off the sterile field) are given here verbatim

from the Joint Commission guidelines and are also available online at the Joint Commission's web site (4):

1. Medications and solutions both on and off the sterile field are labeled even if there is only one medication being used.
2. Labeling occurs when any medication or solution is transferred from the original packaging to another container.
3. Labels 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.
4. All labels are verified both verbally and visually by two qualified individuals when the person preparing the medication is not the person administering the medication.
5. No more than one medication or solution is labeled at one time.
6. Any medications or solutions found unlabeled are immediately discarded.
7. All original containers from medications or solutions remain available for reference in the perioperative/procedural area until the conclusion of the procedure.
8. All labeled containers on the sterile field are discarded at the conclusion of the procedure.
9. At shift change or break relief, all medications and solutions both on and off the sterile field and their labels are reviewed by entering and exiting personnel.

SIR GUIDELINES

The following represent our attempt to apply Joint Commission requirements to the everyday best practices of interventional radiology. The reader should understand that, although many of these may seem onerous, the Joint Commission is very clear that each of these apply directly to interventional radiology, and there is no instance when these requirements do not apply.

1. All solution containers and syringes must be labeled. This includes contrast material loaded into power injectors (4). The label must include the following elements as directed by the Joint Commission: "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 [intravenous] admixtures. In most cases of medications and solutions in the procedural setting, only the drug name and strength (concentration) will be needed" (4). Prelabeling empty containers or syringes 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" (4).

   Note that the only exception to the labeling requirement is that stated by the Joint Commission: "If during the perioperative or periprocedural process, a solution or medication (either in the sterile field or out) is poured, drawn into a syringe, or otherwise used from it's [sic] original container and immediately administered or disposed of in some fashion, labeling is not required. 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" (4).

   SIR is well aware that existing methods of distinguishing between syringes containing flush solution and syringes containing contrast material (use of different-sized syringes and/or syringes with different-colored plungers) have worked well for decades, and that a simple method exists for determining whether a syringe contains contrast material (ie, fluoros-copy of the syringe). The Society is also aware that the requirement for labeling syringes at the time they are filled is onerous when applied to syringes used for hand injection of flush solution and contrast material during interventional procedures. The Society is further aware that labeling the contents of a power injector is of minimal value if only nonionic iodinated contrast agents are used in the power injector. Nonetheless, unless and until the Joint Commission changes its expectations for NPSG Goal 3D, the Society is unable to recommend that these procedures be dispensed with.
2. Label syringes and containers containing medications on the procedure table using sterile labels and a sterile marking pen or preprinted labels. It is understood that this may be time-consuming and pose at least a minor inconvenience. Most commercially available procedure packs come with preprinted labels for lidocaine and flush and contrast agents. Different concentrations of local anesthetics and contrast agents should be labeled (as detailed earlier). When using more than one contrast agent (ie, gadolinium vs iodinated contrast agents), syringes containing them should each have individual labels. The radiologist should consider labeling syringes containing carbon dioxide to prevent inadvertent injection of room air. Medications should be drawn up one at a time in appropriately labeled syringes. Verify the medication visually and verbally by reading product name, strength, dosage, and expiration date from the original containers. The Joint Commission states that drugs should be drawn up by the person administering the medication or by two other individuals. To comply with this requirement, it may be easiest for the physician to draw up and label medications (eg, lidocaine, contrast agent, thrombolytic agent) immediately before starting the case. Drug manufacturers may assist in this enterprise by providing sterile preprinted labels with their medications. Manufacturers of sterile angiography packs may assist by providing sterile preprinted labels, as well as additional blank labels in the trays.
3. Remove skin preparation substances (eg, povidone iodine, alcohol, chlorhexidine) from the table as soon as the patient is prepared and draped, or use a second table for patient preparation materials. This eliminates the possibility of accidental parenteral administration of these materials.

4. Avoid storing similar appearing medications in the same area to reduce medication misadministration. All medications should be prominently labeled.
5. Encourage the use of single-use vials to avoid improper handling practices.
6. Label each syringe containing a drug used for sedation in accordance with Joint Commission requirements. Encourage nurses to repeat (ie, verify) physicians' verbal orders before administering medications. In general, the routine placement of syringes containing agents for sedation on the procedure table is cautioned against, as this introduces another opportunity for a preventable adverse event. On those occasions when the operator must administer these agents, syringes containing these drugs should be labeled as described earlier and removed from the procedure tray as soon as possible after use.
7. Do not use unlabeled medications. Discard them immediately. (This includes solutions at the nurse's station.)
8. All original containers from medications or solutions must remain available for reference in the perioperative area until the conclusion of the procedure (4).
9. All labeled containers on the sterile field must be discarded at the conclusion of the procedure (4).
10. Encourage uniformity throughout the entire radiology department. This will help prevent errors from occurring when physicians or nurses unfamiliar with the procedure are participating.
11. Encourage physicians, nurses, and technologists to review the patient's list of medications and allergies.
12. Establish a working dialogue with supporting pharmacies to facilitate reporting, remediation, and prevention of medication errors.
13. Encourage an environment of teamwork and communication among physicians, nurses, and technologists.

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APPENDIX A: CONSENSUS METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the SIR HI-IQ^{IM} System national database.

Consensus on statements in this document was obtained utilizing a modified Delphi technique (1,2).

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SIR DISCLAIMER

The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.