Quality Improvement Guidelines for Preventing Wrong Site, Wrong Procedure, and Wrong Person Errors: Application of the Joint Commission "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" to the Practice of Interventional Radiology

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Abbreviation: WS = wrong site

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, Fairfax, VA 22033.

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METHODOLOGY

SIR produces its Standards of Practice documents using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. Certain documents are conceptualized by the Safety and Health Committee. 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. Ordinarily, the qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds. However, an evidence table is not relevant to this guideline

When the evidence of literature is weak, conflicting, or contradictory, con-

sensus 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 Safety and Health Committee members and then by Standards of Practice Committee members, either by telephone conference calling or face-to-face meeting. The finalized draft from the Standards of Practice 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 standards document. Prior to its publication the document is endorsed by the SIR Executive Council.

INTRODUCTION

The purpose of this document is to provide guidelines for a safe, accurate, and consistent process for verifying the interventional procedural treatment site. This material is intended as a supplement to the existing Joint Commission guideline, "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" (referred heretofore as the Universal Protocol), adopted by the Joint Commission on July 18, 2003, and subsequently updated (3). This document is available at *http://www.jointcommission.org/PatientSafety/UniversalProtocol/*. The contents of this document are intended to assist interventional radiologists in developing a standard operating procedure for clinical application of the Joint Commission guideline.

Preventing wrong site, wrong procedure, and wrong person surgery errors requires a reliable system of procuring clinical information/prior imaging, procedure planning, and dissemination of information. The Joint Commission refers to this process as the "preoperative verification process" (3). Several features unique to interventional radiology will be discussed later in this report.

The Joint Commission document defines preoperative skin marking as a step in the process of preventing wrong site (WS) errors (3). Skin marking is necessary for only a limited number of the procedures interventional radiologists perform, because for most interventional radiology procedures, (i) side is irrelevant for the procedure or (ii) imaging guidance is an inherent part of the procedure. This document attempts to delineate the process for determining those procedures for which site marking is required.

Prevention of WS errors should be part of a patient identification system that also prevents wrong person and wrong procedure errors. Active communication and collaboration are expected among all perioperative/procedural team members. This communication and collaboration must also include the patient. The process should culminate in a team discussion in the procedure room immediately before the start the procedure. This step is referred to as the "time out" (3). Even if a procedure is exempt from the requirement for skin marking, the remainder of the time out process must still be performed as outlined in the Universal Protocol. This policy may not apply in emergent, life-threatening clinical situations at the discretion of the responsible physician.

Interventional radiology imaging equipment can lead to left/right errors. The interventional radiologist is also responsible for making certain that images are correctly labeled before being sent to a Picture Archiving and Communication System or other permanent storage medium in order to prevent future WS errors.

DEFINITIONS

The following definitions are taken verbatim from the Joint Commission Web site.

Marking the Operative Site

"Marking the site is required for procedures involving right/left distinction, multiple structures (such as fingers and toes), or levels (as in spinal procedures). Site marking is not required (nor is it prohibited) for other procedures. These may include midline sternotomy, Cesarean section, laparotomy and laparoscopy, cardiac catheterization and other interventional procedures for which the site of insertion is not predetermined. For those procedures in which site marking is not required, the other requirements for preventing wrong site, wrong procedure, wrong person surgery still apply" (4).

Time Out

"To conduct a final verification of the correct patient, procedure, site and, as applicable, implants. Active communication among all members of the surgical/procedure team, consistently initiated by a designated member of the team, conducted in a 'fail-safe' mode, that is, the procedure is not started until any questions or concerns are resolved" (3).

Invasive Procedure

"The universal protocol should be applicable or adaptable to. . . invasive procedures that expose patients to harm, including procedures done in settings other than the operating room" (3). "Certain routine 'minor' procedures such as venipuncture, peripheral [intravenous catheter] placement, insertion of [nasogastric] tube, or Foley catheter insertion are not within the scope of the protocol" (4).

Sentinel Event

"A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, 'or the risk thereof' includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called 'sentinel' because they signal the need for immediate investigation and response" (3).

UNIVERSAL PROTOCOL

"In July 2003, The Joint Commission Board of Commissioners approved the

Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery. The Universal Protocol was created to address the continuing occurrence of these tragic medical errors in Joint Commission accredited organizations. The Universal Protocol became effective July 1, 2004, for all accredited hospitals, ambulatory care and office-based surgery facilities. The Universal Protocol drew upon, and expanded and integrated, a series of requirements under The Joint Commission's 2003 and 2004 National Patient Safety Goals. It is applicable to all operative and other invasive procedures. The principal components of the Universal Protocol include: (i) the pre-operative verification process; (ii) marking of the operative site; (iii) taking a 'time out' immediately before starting the procedure; and (iv) adaptation of the requirements to non–operating room settings, including bedside procedures" (3).

These guidelines are written to be used in quality improvement programs to assure all procedures are performed on the correct patient and at the correct site. The most important processes for achieving these goals are planning/evaluation, preprocedure marking, and intraprocedural/time out stages. The outcome measures or indicators for these processes are (i) appropriate information acquired to plan appropriate site and side obtained before the procedure when possible, (ii) frequency of marking of site before the procedure when indicated, (iii) confirming that a time out occurred, and (iv) incidence of WS errors. Outcome measures are assigned threshold levels at the institution.

Practicing physicians should strive to achieve a perfect process (eg, 100% marking of site when indicated). In practice all physicians will fall short of this ideal to a variable extent. When measures such as indications, or success rates, fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold, a review should be performed to determine causes and to implement changes, if necessary. Each institution/hospital should define thresholds as needed for the process steps, defined in detail later in these guidelines, to meet its own quality improvement program needs. Therefore, indicator thresholds may be used locally to assess the efficacy of ongoing quality improvement programs. For example, if the incidence of procedures for which a time out is not performed is one measure of quality in preventing WS errors, then values in excess of a threshold should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the missed step.

WS errors are a sentinel event (3), so the threshold for these events should be zero and any such events should be reviewed carefully using root cause analysis. Individual complications or a breach in the standard of practice may also be associated with the subsequent development of a WS event (5). Therefore, all such events, as well as "close calls" should be subject to peer review. Patterns of complications that could lead to a WS error should be addressed.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. WS errors involving an invasive procedure are major complications. Placement of a central catheter on the less desirable side is not a major complication unless there are clinical issues indicating one side should be used. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; Appendix B).

Implementing the Universal Protocol

The application of the Universal Protocol for patient identification is indicated for all invasive procedures. (The Joint Commission's specific expectations for implementation of the Universal Protocol are available on their Web site [6].) Within the group of procedures subject to the Universal Protocol are a subset of procedures for which skin marking is required and a subset of procedures for which skin marking is not necessary. This portion of the guideline attempts to clarify certain issues that may arise during implementation of the Universal Protocol. All quotations in this section are taken from the Joint Commission Web site.

Time Out Process

The purpose of the time out is "to conduct a final verification of the correct patient, procedure, site and, as applicable, implants" (3). "The 'time out,' or immediate preoperative pause, must occur in the location where the procedure is to be done (for example, when the patient is on the operating table). Given this restriction, the 'time out' may precede induction of anesthesia or may occur after the patient is anesthetized (participation by the patient is not expected) but just before starting the procedure" (4). "The 'time out' must involve the entire surgical team. At a minimum, this includes active participation by the surgeon, anesthesia provider, and circulating nurse. Participation by the other members of the team, as appropriate to their involvement in the procedure, is also encouraged. In particular, there should be no barrier to anyone speaking up if there is concern about a possible error. To include some members of the team but not others sends the wrong message" (4).

For interventional radiology, this means that the time out should be performed after the patient is placed on the procedure table, regardless of whether this is in the interventional fluoroscopy suite, the computed tomography (CT) scanner, an ultrasound (US) room, or at the bedside. All personnel involved in the procedure should also be involved in the time out. The time out must be performed before the invasive procedure is started.

Procedures for Which the Site/Side Must Be Marked on the Skin

The correct site must be marked for all invasive procedures involving "(i) right/left distinction based on external landmarks, history, or prior studies; or (ii) multiple structures (fingers, toes) or levels (spine)" (3). If both the left and right side will be sites for intervention, both must be marked. For

spine procedures, the general region may be marked, but the exact level should be determined with intraprocedural imaging (3).

For interventional radiology, the side or individual structure may be known, in which case it should be marked on the skin. Alternatively, the lesion may be identified during intraprocedural imaging, in which case it cannot be marked on the skin. This situation would normally be exempted based on the continuous presence exemption (as described later).

There are situations in which site marking is required by the Joint Commission, but implementation of this requirement is difficult or impossible. For example, if angioplasty of the right renal artery is planned, theoretically the skin over the right kidney should be marked. However, after the patient is draped, this mark will not be visible. In these situations, the Joint Commission recommends "marking the skin at or near the proposed incision/insertion site to indicate the correct side of the proposed procedure, even when the proposed incision/insertion site is in the midline or through a natural body orifice. This mark, as for other site marks, must be positioned to be visible after the patient is prepped and draped unless it is technically or anatomically impossible or impractical to do so" (4). This would require a skin mark on the groin indicating which renal artery is to undergo angioplasty. This is a potential source of confusion because it may be seen as an indication of which common femoral artery should be punctured. The Joint Commission advises that, "in such technically difficult cases, an alternative method for visually identifying the correct side should be used (eg, a temporary unique wrist band or other similar device)" (4). Unfortunately, such an alternative method is unlikely to be visible through the sterile drapes. In these cases, the Society of Interventional Radiology recommends that the side of intervention be confirmed in the manner traditionally used by interventional radiologists: appropriate intraprocedural imaging. This is consistent with the Joint Commission's requirement that spinal levels be confirmed with imaging at the time of the intervention.

Situations Excluded from the Skin Marking Requirement

Site marking is not required (nor is it prohibited) for procedures other than those described earlier in this report. "These may include mid-line sternotomy, Cesarean section, laparotomy and laparoscopy, cardiac catheterization and other interventional procedures for which the site of insertion is not predetermined. For those procedures in which site marking is not required, the other requirements for preventing wrong site, wrong procedure, wrong person surgery still apply" (4).

Situations with right/left distinction in which intraprocedural imaging is used to provide confirmation of the correct side may also be exempt from the marking requirement. The Joint Commission requires site marking when there is "right/left distinction based on external landmarks, history, or prior studies" (emphasis added) (4). Situations in which right/left distinction is determined or confirmed with intraprocedural imaging before the intervention (the case in virtually all interventional procedures) do not fall within this requirement. This interpretation is consistent with New York State Surgical and Invasive Procedure Protocol (exception E7) (7). When both left- and right-sided structures are known to be abnormal (eg, bilateral hydronephrosis), the Society of Interventional Radiology recommends that skin marking be performed even if intraprocedural imaging is employed.

It is the opinion of the Society of Interventional Radiology that, in procedures in which vascular access is simply a means to provide a route of access to perform a procedure or to provide central venous access, skin marking at the vascular access site is not needed. This is consistent with the Joint Commission guidance cited earlier in this report regarding cardiac catheterization. Placement of central venous catheters is a special clinical situation in which side marking is not required, but in which it is good clinical practice to investigate if there is a preferred side.

In addition to the exemptions noted earlier, the Joint Commission specifically notes that "skin marking is not mandatory if the practitioner performing the procedure remains with the patient continuously from the time the decision is made to do the procedure and consent is obtained from the patient up to the time of the procedure itself" (3). Finally, the patient always has the right to refuse skin marking (4).

Method for Performing Skin Marking

The Protocol states, "The person performing the procedure should do the site marking." The word "should" is in contrast to the more definitive term "must," which is used elsewhere in the Protocol. It recognizes the need for flexibility to accommodate the logistical and procedural realities of the full range of surgical facilities. When it is not feasible for the person performing the procedure to mark the site, another member of the surgical team who is fully informed about the patient and the intended procedure must do the marking. In this context, the preoperative registered nurse is considered a member of the surgical team. Any delegation of responsibility for marking the surgical site must be consistent with applicable law and regulations (we are advised that some states may prohibit nurses from marking the surgical site). The organization must ensure that whenever the responsibility for site marking is delegated to someone other than the person who will be doing the procedure, the safety of the patient will not be compromised. Note that while the Protocol requires that the patient be involved in the process, it is not expected, or even recommended, that the patient mark his/her own surgical site (4).

"The [Universal] Protocol does not specify the type of mark—that is left to the organization to decide—but whatever the decision on this, the mark must be unambiguous and the process should be consistent throughout the organization. Consideration should be given to aligning the site marking procedures with those of other surgical facilities in the same geographic area, since surgeons are frequently on multiple medical staffs. Use of 'X' is discouraged since this may be ambiguous: does 'X' mean 'operate here' or 'do not operate here'? A line indicating the intended site of incision, the

surgeon's initials, or the word 'yes' are all preferable ways to mark the site" (4).

"A marker that is sufficiently permanent to remain visible and will not wash off when the site is prepped may be used for marking the site" (4). "Under the Universal Protocol, adhesive site markers are permitted as an adjunct to directly marking the skin. While the Protocol does not explicitly prohibit the use of adhesive markers, it does state, 'Adhesive site markers should not be used as the sole means of marking the site.' This means that when site marking is required, it must be done by directly marking the skin" (4).

"Site marking should be done prior to moving the patient into the room where the procedure will be done. Part of the requirement is that the site marking be done 'with the involvement of the patient.' For this to be done in a meaningful way, it should happen before the patient is significantly sedated. Participation may be precluded by a disease state or heavy sedation. However, sedation by itself does not necessarily prevent the patient from participating in the site marking process. The patient's capacity to participate must be based on an individual assessment" (4).

"In cases of non-speaking, comatose, or incompetent patients, or children, the 'patient involvement' in the site marking process should be handled in the same way that you handle the informed consent process. Whoever has authority to provide informed consent for the patient to undergo the procedure would, as appropriate, participate in the site marking process" (4).

Clinical Emergency

"None of these precautions should interfere with the timely care of the patient in an emergency situation. In most of these cases, when invasive procedures are performed under emergency or urgent conditions, the practitioner performing the procedure will be in continuous attendance of the patient from the point of decision to do the procedure. Under those circumstances, marking the site would not be necessary, although the 'time-out' to verify the correct patient, procedure, and site would still be appropriate (unless it was such an emergency that even the time out would add more risk than benefit)" (4).

PROCEDURE

The purpose of this Guideline is to provide an outline for the implementation of the Universal Protocol for prevention of WS errors in an interventional radiology practice. One must first be familiar with the expectations for implementation of the Universal Protocol outlined by the Joint Commission (6). In addition, there are several steps in the process that benefit from elaboration and specification in regards to interventional radiology. The source of WS errors in interventional radiology can be divided into planning/evaluation (ie, preprocedure verification), preprocedure marking, and intraprocedural "time-out" (3) stages. The postprocedure stage is also important to prevent future errors in the same patient.

Planning/Evaluation

Errors can be caused by omission or commission. Controlling WS errors at this stage should focus on preventing scheduling errors because these can easily be perpetuated in subsequent stages (eg, patient is scheduled for a right nephrostomy when they really need a left nephrostomy). This planning/evaluation stage is also important in avoiding a missed opportunity to order outside radiologic studies or copies of operative reports that may be helpful in preventing WS errors in later stages (see "3" below). Informed consent is often done in advance, which adds another opportunity for the patient to participate in the planning of the procedure. There is substantial evidence that active early involvement of patients in the planning of their procedures prevents many WS errors (8). During the consent process, the patient and the patient's family should understand that the site of skin entry and the site of treatment may be different.

If possible, indicate the side and site at the time of procedure scheduling (often indicated by a referring physician) or preprocedural evaluation in the interventional radiology clinic. Scheduling should be performed by a health care professional familiar with interventional radiology procedures whenever possible.

Make sure all potentially necessary images and/or reports are requested so they are available at the time of procedure. If beneficial, mark or annotate the region of interest on the films/images. Appropriate physician-to-physician communication should be the norm.

Preprocedural Marking

Preprocedural marking is only rarely required in interventional radiology procedures. More importantly, in the immediate preprocedural period, information from many different sources should be collected. The interventional radiologist or designee are responsible for insuring that the correct structure and side are identified on previous studies. This identification process may require marking a film (or Picture Archiving and Communication System image) with the intended site of treatment.

Patient marking is necessary only when direct puncture into the area of interest is done based on external landmarks (rather than intraprocedural imaging) and there is a possibility for left/right or level errors (see Indications section).

Time Out

The time out is fully described on the Joint Commission Web site (3), but errors unique to interventional radiology can occur when preprocedural information is not conveyed to the staff and physicians performing the procedure. For example, a patient with multiple lesions on a planning magnetic resonance (MR) angiogram or CT angiogram could undergo a different procedure in the absence of appropriate communication.

Intraprocedural errors can also occur as a result of patient positioning (prone versus supine) and patient orientation in the room. These errors may not be immediately recognized by the interventional radiologist because of patient draping that masks the anatomy. Site marking will prevent this

error, but the time out should include a review of the patient's orientation.

Imaging equipment (eg, fluoroscopy, US, CT, MR, or other) that does not insure correct orientation or labeling of the images could potentially lead to errors. The interventional radiologist should be aware of this issue, and use the time out to confirm correspondence between the image guidance system image and the patient orientation (eg, the apparent left side of the patient in the image on the screen corresponds to the patient's left side).

Manual entry of patient information into the imaging equipment may lead to misidentification of the images as belonging to the wrong patient. The time out process should include a step to confirm that the correct patient's information is displayed on the image monitor before the procedure is started.

Postprocedure

Make certain that all permanent images are correctly labeled regarding patient and side before archiving. A regular program of equipment maintenance and quality assurance is recommended.

Success Rates

There is no literature evidence to determine an acceptable success rate in executing these steps. Success rates should approach 100%, but will have to be locally determined and monitored.

Complications

In 1998, the Joint Commission received 15 reports of wrong site, wrong person, or wrong procedure surgery. In a Sentinel Event Alert issued in December 2001, 150 such instances were reported, 41% of which were related to orthopedic or podiatric surgery (9). The Joint Commission identified emergency procedures, unusual physical characteristics of the patient, time pressures, multiple surgeons, and multiple procedures on the same patient as risk factors. In a survey of orthopedic surgeons, of an estimated 6,700,000 surgical procedures, 242 were performed at the wrong site, for an incidence of one in 27,686 procedures (10). An analysis of insurance claims and malpractice claims suggest that the incidence appears to be one in 112,994 for surgery in general (11). It is recommended that there be a zero threshold for this type of error and a quality improvement initiative with peer review be undertaken when one of these events is identified (8).

Estimating the frequency of WS errors in interventional radiology is essentially impossible. Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising thousand of patients, and for procedures far removed from an interventional radiology practice. No reliable data exist for interventional radiology procedures.

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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™ System national database.

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

APPENDIX B: SOCIETY OF INTERVENTIONAL RADIOLOGY STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. No therapy, no consequence
B. Nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (<48 hours)
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).
E. Permanent adverse sequelae
F. Death.

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