

The Evolution of Universal Protocol in Interventional Radiology

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ABSTRACT: Interventional Radiology (IR) encompasses a wide range of procedures which can pose challenges to site verification unlike those in the operating room. At Children's Hospital of Boston, an incident occurred during an IR procedure which demonstrated that the hospital-wide site verification process did not include issues specific to IR. Our facility responded to this incident by analyzing the process, identifying the complexity of the factors that may have contributed, and implementing an improved site verification process in the radiology area. This report describes our clinical experience on developing a safe and effective means of verifying procedural site and implementing Universal Protocol in IR. (*J Radiol Nurs* 2006;25:106-115.)

CASE REPORT

Since 2003 the Interventional Radiology (IR) Department at Children's Hospital, Boston has been using a tool to document Universal Protocol (UP) which confirms patient identification and verifies the anatomic site of procedure (JCAHO, 2003a, 2003b). In October 2004, a patient underwent two consecutive procedures in IR. Despite the use of this tool, during the second procedure, the wrong side was tapped. The following case study describes the sequence of events that lead to this sentinel event and the subsequent steps that were taken to prevent the occurrence of a similar event.

The patient was a 10-year-old child with an extensive malformation of the lymphatic system resulting in lymphedema of the right lower extremity and pelvis. In 1999, a fenestration of the pelvic lymphatic malforma-

tion was performed with improvement. In July 2004, the patient developed significant chylous ascites and right pleural effusion. Several procedures were performed to control the leakage of chylous fluid into the abdomen and pleura.

The patient returned in October 2004 for continued treatment to manage her persistent progressive chylous ascites and pleural effusion. A Computerized Tomography (CT) guided lymphatic embolization of the malformation was scheduled. Upon arrival in IR the patient was sent for a chest x-ray to determine the extent of the pleural effusion. After review of the chest x-ray, both the anesthesiologist and the interventional radiologist obtained separate informed consents. Although it was not previously scheduled, the interventional radiologist added a right thoracentesis to the informed consent after review of the chest x-ray. The patient's parents consented to have a "percutaneous lymphangiogram, probable lymphatic embolization, right thoracentesis" under general anesthesia.

The patient entered the CT suite accompanied by the parents before the procedure. The Surgical Site Verification checklist and "Time-Out" procedure were completed with the patient and parents, as well as the participating attending interventional radiologist, attending anesthesiologist, radiology technologist, and radiology nurses. A "time-out" was done for the lymphangiogram and embolization. After the time-out procedure, the interventional radiologist indicated that he would use CT imaging to further delineate the area of pleural effusion. The site of the lymphangiogram was marked, however, the interventional radiologist elected

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1546-0843/\$32.00

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doi: 10.1016/j.jradnu.2006.08.003

to review the CT imaging before marking the intended site of thoracentesis. The patient was then placed under general anesthesia and positioned prone, feet first into the CT scanner and prepped and draped for the lymphangiogram and embolization.

The lymphangiogram and embolization attempts were completed after 3 h and the interventional radiologist then moved to complete the right thoracentesis. The site was prepped and draped by the interventional radiologist and subsequently the thoracentesis was attempted by aspirating the pleural effusion at the high mid axillary line. Despite several attempts, the thoracentesis only yielded approximately 1 cc of chylous fluid.

The patient tolerated the procedures well and was extubated in the CT suite without complications and was transported to the Postanesthesia Care Unit (PACU). During the handoff between the radiology nurse and PACU nurse, the PACU nurse recognized that the dressing for the thoracentesis was on the left side of the chest and that the intended procedure was to have been a right thoracentesis. The interventional radiologist was notified that the informed consent was for a right thoracentesis and yet the left side was accessed. The radiologist immediately recognized the error, evaluated the patient, and notified the parents. A chest x-ray was obtained and showed no evidence of pneumothorax or lung injury. The patient was hospitalized overnight as had been planned and had an unremarkable recovery.

THE HOSPITAL RESPONSE

The above event was immediately reported to the hospital's Program for Patient Safety & Quality (PPSQ), the Chief of the Radiology Department and to the appropriate nurse and technologist supervisors. The hospital PPSQ office determined that the event was indeed a "sentinel event" and therefore reported to the State Department of Public Health, the State Board of Registration in Medicine as well as the Joint Commission on Accreditation of Health care Organizations (JCAHO).

The PPSQ in concert with the clinical team reviewed the event and completed a root cause analysis. As a result of this review, a plan of correction was devised. Immediate changes in policy and procedure were written, including a provision for multiple time-out procedures when more than one procedure is being performed at a session and the designation of one team member, the nurse, as responsible for ensuring that all time-outs occur. This policy and procedure provides for specifics for the radiology area as shown below (Figure 1).

A hospital-wide initiative was instituted to have all appropriate staff made competent in the new policy. The JCAHO refers to time-out and site verification as

UP for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery (Figure 2). The new revised UP implementation was overseen by PPSQ and the Hospital's multidisciplinary UP committee.

DEVELOPMENT OF A UP CHECKLIST

A site verification tool was already being used for all IR procedures before this event. Nonetheless, the above event occurred despite adherence to this tool. Immediately after this event, the hospital PPSQ coordinator together with the anesthesia and interventional staff (radiologists, nurses, technologists) met to scrutinize and revise this checklist. The revisions were made specifically with regard to the unique issues posed by IR. In addition, the checklist was revised so that procedural verification requires a second check. This checklist has subsequently been adopted hospital-wide to encompass all interventions in multiple disciplines (Figure 3).

JCAHO STANDARDS

The JCAHO introduced its sentinel event policy in 1995. This policy is designed to improve patient safety by examining the frequency and cause of sentinel events and to share "lessons learned". A sentinel event is defined as 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 (JCAHO, 2006). Such events are called "sentinel" because they signal the need for immediate investigation and response. Wrong site, wrong procedure, and wrong person surgery are sentinel events. Accredited organizations are expected to identify and respond to all sentinel events by conducting a root cause analysis, implementing improvements to reduce risk and subsequently monitor those improvements (JCAHO, 2006).

As of December 2005 there have been 3,548 sentinel events reports received by JCAHO since establishing its sentinel event policy in 1995. Of this number, 455 or 12.8% were wrong site surgery making it the third highest-ranking event (JCAHO, 2006). In response to these alarming statistics, the JCAHO issued Sentinel Event Alerts in August 1998 and again in December 2001 (JCAHO, 1998, 2001). In 2004, JCAHO National Patient Safety Goals included several goals that target these issues. Goal #1 is to improve accuracy of patient identification by using two patient identifiers and "time-out" procedure before invasive procedures. Goal #4 is to eliminate wrong site, wrong patient, and wrong procedure surgery, to use a preoperative verification process to confirm documents, and to implement a process to mark the surgical site and involve

Procedure for Radiology:

1. The IR physician completes a Provider Order Sheet/Requisition for a patient for whom an IR procedure has been requested, designating the procedure and laterality (right, left, bilateral) where appropriate, without abbreviations. Corroboration and verification of the operative site are required before beginning the preparation of the patient (preparation includes administration of sedation or anesthesia) or the procedure itself.
2. On the day of the procedure, the IR nurse, or IR technologist in the absence of a nurse, will verify preoperatively that the site and laterality is consistent with the Provider Order Sheet (or requisition), operative consent form, anesthesia consent form (if indicated), applicable imaging, and is confirmed with the patient, parent/guardian.
3. Just prior to beginning the procedure if the patient is undergoing sedation the IR nurse or the IR Tech will verify with the attending IR Physician patient identification, procedure and site/side using active communication.
4. The IR nurse or the IR Tech is responsible for initiating the "Time Out" process just prior to the procedure to include:
 - a. Correct patient per patient identification policy
 - b. The physician/physician designee is responsible for actively communicating the procedure/site/side
 - c. The patient position is identified
 - d. Imaging studies are available when applicable.
 - e. Special equipment and/or Implants are available when applicable.

Additional "Time Outs" are necessary for the following:

- More than one procedure on the same patient and there is a different attending performing each procedure.
- More than one procedure performed on the same patient, particularly when the procedures are on different sites/sides of the patient and when it is necessary to reposition the patient re-prep or re-drape.
- Or if any team member wants to conduct an additional "time out."

(Data from Children's Hospital, Boston, policy and procedure manual)

Figure 1. Except from Children's Hospital Boston Policy and Procedure Manual.

UP For Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™

Wrong site, wrong procedure, wrong person surgery can be prevented. This UP is intended to achieve that goal. It is based on the consensus of experts from the relevant clinical specialties and professional disciplines and is endorsed by more than 40 professional medical associations and organizations.

In developing this protocol, consensus was reached on the following principles:

- Wrong site, wrong procedure, wrong person surgery can and must be prevented.
- A robust approach—using multiple, complementary strategies—is necessary to achieve the goal of eliminating wrong site, wrong procedure, wrong person surgery.
- Active involvement and effective communication among all members of the surgical team is important for success.
- To the extent possible, the patient (or legally designated representative) should be involved in the process.
- Consistent implementation of a standardized approach using a universal, consensus-based protocol will be most effective.
- The protocol should be flexible enough to allow for implementation with appropriate adaptation when required to meet specific patient needs.
- A requirement for site marking should focus on cases involving right/left distinction, multiple structures (fingers, toes), or levels (spine).
- The UP should be applicable or adaptable to all operative and other invasive procedures that expose patients to harm, including procedures done in settings other than the operating room. In concert with these principles, the following steps, taken together, comprise the UP for eliminating wrong site, wrong procedure, wrong person surgery:

Figure 2. Joint Commission on Accreditation of Healthcare Organizations, Universal Protocol.

the patient/family. These goals are now encompassed in the UP and continue to be an ongoing priority for the JCAHO. Effective July 1, 2004, compliance with the *UP for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery* has been required by all JCAHO accredited facilities (Figure 1).

The JCAHO has a requirement for marking the operative or procedural site. Specifically, the site should be marked at or near the site of incision or puncture with the surgeon's initials. Initials or the word "yes" are the only acceptable markings as other marks may be considered confusing or ambiguous. The marking

- Pre-operative verification process
 - Purpose: To ensure that all of the relevant documents and studies are available prior to the start of the procedure and that they have been reviewed and are consistent with each other and with the patient's expectations and with the team's understanding of the intended patient, procedure, site and, as applicable, any implants. Missing information or discrepancies must be addressed before starting the procedure.

Process: An ongoing process of information gathering and verification, beginning with the determination to do the procedure, continuing through all settings and interventions involved in the preoperative preparation of the patient, up to and including the "time out" just before the start of the procedure.


- Marking the operative site
 - Purpose: To identify unambiguously the intended site of incision or insertion.
 - Process: For procedures involving right/left distinction, multiple structures (such as fingers and toes), or multiple levels (as in spinal procedures), the intended site must be marked such that the mark will be visible after the patient has been prepped and draped.
- "Time out" immediately before starting the procedure
 - Purpose: To conduct a final verification of the correct patient, procedure, site and, as applicable, implants.
 - Process: 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, i.e., the procedure is not started until any questions or concerns are resolved.

Figure 2. (Cont.).

process should be consistent throughout each organization. The person performing the procedure or designee must do the marking. The marking should take place with the patient/family involved, awake, and aware if possible. The final verification must take place during the time-out (JCAHO, 2004a, 2004b).

The time-out must occur immediately before the start of the procedure to conduct a final verification of the correct patient, procedure, and site and must

be conducted in the location of where the procedure will be done. It must involve the entire team, use active communication, and be documented. The documentation is to include correct patient identity, correct site and side, agreement on the procedure to be done, and correct patient position. If applicable, the time-out must include the availability of correct implants and any special equipment. (JCAHO, 2004a, 2004b).



Children's Hospital Boston
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USE PLATE OR PRINT

MR. NO. _____ DATE _____

PT. NAME _____

DATE OF BIRTH _____

TIME OUT AND SITE VERIFICATION CHECKLIST

Time Out and Site Verification should be done for all invasive procedures

Planned Procedure as written on consent: _____

*Document All Additional Procedures on the back of this form Right / Left / Bilateral Procedure Name

Record/Documentation Verification	N/A	MD initials	Verifier initials
1. ID band is on the Patient and confirmed with 2 methods of ID (name, medical record, # and DOB).			
2. The Anesthesia/Sedation Consent is completed and reviewed <small>✓ (place check in first column if not applicable)</small>			
3. The Medical and Surgical Consent is completed and reviewed <small>✓ (place check in first column if not applicable)</small>			
4. History and Physical completed within 30 days <small>✓ (place check in first column if not applicable)</small>			
5. Provider Order Sheet/Requisition (completed, signed, and consistent) <small>✓ (place check in first column if not applicable)</small>			
6. HCG result available <small>✓ (place check in first column if not applicable)</small>			
7. Invasive procedure is verified with patient, parent/guardian or transferring caregiver.			
8. The operative/procedural site/side is initialed (when indicated) per policy			
9. Time Out was completed immediately prior to incision/invasive procedure per Policy. <ul style="list-style-type: none"> • Patient ID • Procedure/Site/Side • Patient Position • Imaging Studies (when applicable) • Special Equipment(when applicable) • Implants (when applicable) 			

ALL INITIALS MUST BE VERIFIED PRIOR TO THE ONSET OF THE PROCEDURE

Verifier Signature _____ Initials _____ Date _____

Verifier Signature _____ Initials _____ Date _____

Physician Signature _____ Initials _____ Date _____

WHEN AN ASSOCIATE ATTENDING HAS BEEN ASSIGNED, ATTENDING TO ATTENDING COMMUNICATION HAS OCCURRED.	
Name of Associate Attending(s)	Attending Surgeon Signature

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Figure 3. Children's Hospital Boston Universal Protocol Checklist.

RISK FACTORS UNIQUE TO RADIOLOGY IDENTIFIED

Despite adherence to a site verification tool, there are a multitude of factors that can contribute to inadvertent wrong site procedures. IR is a rapidly expanding area of medicine that has evolved into increasingly complex areas to accommodate for new equipment and procedures. As a result, these locations may be modified and not necessarily ideal for the scheduled procedure. Each risk factor unique to IR will be addressed below.

Modification of preexisting space

The JCAHO identifies this modification of preexisting space as an additional risk factor (JCAHO 2001). This case study supports this claim. The CT suite at our institution was designed for imaging only. The room is small with total square footage of 440 sq ft. The clear dimension in the room without the equipment closet and entrance alcove is approximately 20 ft x 19 ft. Performing any interventional procedure under general anesthesia requires a relatively large

Additional Procedures:

Planned Procedure as written on consent: _____

*Document All Additional Procedures on the back of this form

	Right / Left / Bilateral	Procedure Name	
Record/Documentation Verification	N/A	MD initials	Verifier initials
Medical and Surgical Consent is completed and reviewed			
Invasive Procedure is verified with patient, parent, guardian, or transferring caregiver			
The operative/procedural site/side is initialed (when indicated) per policy			
Time Out was completed immediately prior to incision/ invasive procedure per Policy. (patient id, procedure, site/side, position, imaging studies, special equipment, and implants when applicable)			

Verifier Signature _____ Initials _____ Date _____

Physician Signature _____ Initials _____ Date _____

Planned Procedure as written on consent: _____

*Document All Additional Procedures on the back of this form

	Right / Left / Bilateral	Procedure Name	
Record/Documentation Verification	N/A	MD initials	Verifier initials
Medical and Surgical Consent is completed and reviewed			
Invasive Procedure is verified with patient, parent, guardian, or transferring caregiver			
The operative/procedural site/side is initialed (when indicated) per policy			
Time Out was completed immediately prior to incision/ invasive procedure per Policy. (patient id, procedure, site/side, position, imaging studies, special equipment, and implants when applicable)			

Verifier Signature _____ Initials _____ Date _____

Physician Signature _____ Initials _____ Date _____

Planned Procedure as written on consent: _____

*Document All Additional Procedures on the back of this form

	Right / Left / Bilateral	Procedure Name	
Record/Documentation Verification	N/A	MD initials	Verifier initials
Medical and Surgical Consent is completed and reviewed			
Invasive Procedure is verified with patient, parent, guardian, or transferring caregiver			
The operative/procedural site/side is initialed (when indicated) per policy			
Time Out was completed immediately prior to incision/ invasive procedure per Policy. (patient id, procedure, site/side, position, imaging studies, special equipment, and implants when applicable)			

Verifier Signature _____ Initials _____ Date _____

Physician Signature _____ Initials _____ Date _____

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Figure 3. (Cont.).

amount of equipment and machinery for the existing footprint. Figure 4 illustrates the positioning of all the equipment in this space. There are also a number of personnel involved. Typically, this includes the interventional radiologist, radiology nurse, radiology technician, radiology fellow, anesthesia attending, and anesthesia resident. During the imaging sequences, all members of the team exit the suite and remain in the

control room to minimize radiation exposure. This results in a crowded, potentially noisy control room.

Inconsistent positioning of the patient relative to anesthesia

In the radiology area, the patient's position on the procedural table is not consistent. In the operating room, the patient's head is almost universally

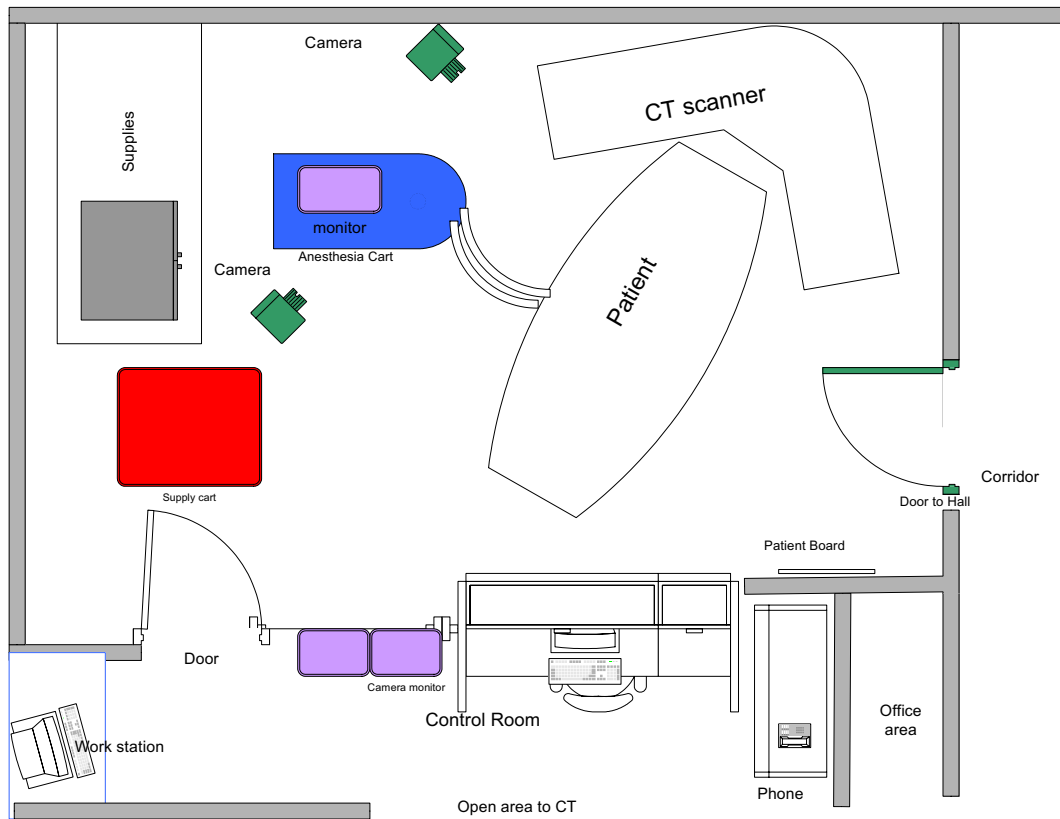


Figure 4. Footprint of CT suite in case study.

positioned near the anesthesia machine at the head of the bed. In fact, it is the standard of anesthesia care to position the head of the patient adjacent to the anesthesia machine and ventilator. In this way, with rare exception, all personnel in the operating room can easily identify position. In the IR suite, the patient position is dictated by the need for the operator to have physical access to the patient, although still having the area of interest positioned within the imaging field. For example, if the anesthesia machine is positioned at the top of an angiography table, a patient having a percutaneous procedure on the right kidney will be optimally positioned prone, with the feet toward the anesthesia machine, although a patient having a procedure on the left kidney is best positioned prone, with the head toward the anesthesia machine. Once the patient preparation and draping is complete, only the procedural site is visible, and it may be difficult for a newcomer in the procedure room to determine the patient’s orientation.

Orientation of images must be set to match the orientation of patient

The orientation of the displayed images is usually pre-selected to match routine diagnostic studies, rather than the actual patient orientation. In this case, where

the patient was in a “feet first prone” position, the images displayed during the procedure reflected the usual “head first supine” position.

Accurate marking of the procedural site

Marking the procedural site is a critical element in IR procedures. In the above case study, the thoracentesis site was not marked before the start of the lymphangiogram because the radiologist wanted to use CT imaging to mark the precise area of entry. This postponement was identified as a risk. Marking does not have to be in the exact location of intended puncture. The mark is done to identify laterality only. The exact site of the percutaneous needle puncture could have been determined after the patient was prepped and draped, with the radiologist’s initials verifying the correct side. It is important to understand that marking the site in advance does not commit the radiologist to that precise area of entry. Rather, it marks the general area. The initials, however, must be visible in the area that is to be prepped.

Multiple procedures at multiple patient sites

The JCAHO has recognized that multiple procedures performed on multiple parts of a patient are an additional risk factor (JCAHO, 2001). In the above case

study, a second time-out for the thoracentesis was not performed. A change in policy has now been made so that when more than one procedure is being performed during a session, all procedures must be reviewed for laterality during the initial time-out. The body part involved in the procedures must be initialized by the physician before beginning. Before beginning a subsequent procedure, a laterality check must be performed and the appropriate body part and procedure confirmed. During this case, there was a change of nurses and anesthesiologists. This second time-out ensures that all team members concur with the procedure to be performed. In addition, when a change of nurses, radiological technologists, or anesthesiologist occurs, handoff should include a review of the consent, the procedure that is ongoing, and the procedures that are planned.

Communication between team members encompassing different specialties

All members of the team, interventional radiologists, nurses, radiology technologists, and anesthesiologists must have a comprehensive understanding of the issues and participate in a shared effort to eliminate wrong site procedures in radiology. The JCAHO has identified incomplete or inaccurate communication among the surgical team as the leading root cause of wrong site surgery (JCAHO, 2004a, 2004b). Vigilance by all members of the team must occur to maintain the highest standards of patient safety. The attitude that the surgeon must never be questioned must be eliminated. A culture of open dialog where each team member's contribution is valued must be cultivated. Each team member must be empowered and encouraged to question and clarify the procedure to be performed. Missing information or any discrepancies must be resolved before the start of the procedure (Carayon, Schultz & Hundt, 2004). Additional time-outs can be conducted at any time by any member of the team.

EDUCATION AND IMPLEMENTATION

In reviewing the literature, it was noted that other institutions have found the implementation of the UP policy to be challenging and arduous (Brown, Riippa, & Shaneberger, 2001). At Children's Hospital both formal and informal education on UP occurred for all staff hospital-wide and special education was held for the staff in the IR area. At the start of the implementation process, some resistance occurred around the requirement of site marking and the time-out process. However, with additional reinforcement and education, all members of the team began to participate and buy into the process.

Children's Hospital policy changes now dictate that the nurse is the team member who is responsible for ini-

tiating the time-out. In some radiology procedures a nurse may not be present and then the radiology technologist is responsible. Time-out must be initiated just before the incision or invasive procedure to provide an opportunity to verify and clarify aspects of patient care. Nurses needed to feel comfortable to speak up at the start of the procedure as they ask for a time-out to be performed. Senior nurses began coaching less-experienced staff. Role-playing the process has been intricate in educating the staff. All team members present must actively participate in the time-out process by giving verbal agreement.

An additional time-out is required by the team if a patient has more than one procedure particularly when the procedure is on different sites or sides or if a patient is repositioned. It is important for nurses to document that an accurate time-out has been performed. At our facility a checklist has been devised to ensure that all elements of UP have been completed (Figure 3). This checklist has an area on the reverse side to document additional time-out procedures. UP documentation is audited monthly and additionally, live audits of the time-out process are observed for accuracy by designated staff who are not part of the actual process.

SUMMARY

Caring for patients in IR presents some unique challenges in procedural site verification. JCAHO has recommended strategies for reducing the risk of wrong site surgery including provisions for surgical site marking, taking a pause at the start of the procedure for a time-out, and developing a verification checklist to verify all pertinent documents before the procedure. A team approach to site verification is essential to ensure, develop, and implement safe patient care. At Children's Hospital in Boston, risk factors specific to radiology have been identified and strategies for reducing the risk of this sentinel event have been incorporated into hospital-wide policy and practice. This multidisciplinary process maximizes patient safety and further defines the JCAHO UP within the IR setting.

Acknowledgment

The authors wish to thank Eileen Sporing, Anne Micheli, Linda Connor, Jodi Manchester, Kevin Murphy, and Ahmad Alomari for their support and encouragement in the development of this article.

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