



## **\$\$\$- : 5 Eg for the Revised Universal Protocol:**

### **Statement of the Problem:**

Wrong site, wrong procedure and wrong person surgeries are sentinel events (an unexpected occurrence involving death or serious physical or psychological injury) that The Joint Commission tracks through its voluntarily reported Sentinel Event Database. Launching the Joint Commission's Universal Protocol in July 2004 was followed by a sustained increase (not decrease) in the number of reported cases of wrong site surgery in the United States. The occurrence of these particular events – as reported to The Joint Commission - persists as a problem at the current rate of 8-10 new cases per month and remains the most frequently reported sentinel event in the database. Similarly, persistence of this patient safety problem is well recognized in those individual states with mandatory reporting systems for medical errors that include wrong site surgery.

### **Persistence of the Problem**

This trend could be construed simply as a reflection of expanded reporting, but the fact remains that the apparent incidence and frequency of this problem is not decreasing. These infrequent, though not rare, occurrences provide an important opportunity for better understanding the complexities involved in achieving organizational and professional cultural change that may also be relevant to resolution of other patient safety issues beyond those focused on performance of correct surgery.

Recognizing the significance of this persistent problem, The Joint Commission convened a second Wrong Site Surgery Summit where over 50 organizations participated in February 2007. This follow-up Summit sought to objectively review experience to date with the Universal Protocol, to examine the barriers to achieving consistent compliance with the Universal Protocol, and to explore other potential strategies for eliminating wrong site surgery.

Examples of salient discussion points and consensus at the 2007 Universal Protocol Summit:

- The three primary components for the Universal Protocol (procedure verification, site marking, time-out) are effective if properly implemented and consistently followed.
- Further refinements to and elaboration of the Universal Protocol to make it more directive (i.e., prescriptive) would be beneficial for improving success of the protocol.
- Re-emphasis is still needed that the Universal Protocol applies to all types of procedures in all types of procedure areas.
- A general misperception exists that time pressures are a hindrance to compliance with the Universal Protocol but there are no data to support the assertion.
- Effective organization management of this issue requires local ownership of changes in relevant policies and procedures, along with active engagement by the CEO and the Board.
- A “stop-the-line” mentality should be encouraged given the complexity of multiple systems and processes active in operative/procedural environments.
- Autonomous performance should be discouraged, and inter-disciplinary team performance with mutual accountability should be encouraged.
- Confirmation bias and behavioral automaticity in the use of checklists are barriers to improvement processes and should be recognized as such.
- Effective methods of direct observation and measurability of success are still required that are effective across settings and institutions.
- Cultural transformation occurs over years and/or decades (generations).

Revisions to the Universal Protocol were developed, vetted and approved utilizing the same processes as for the National Patient Safety Goals program. The revised Universal Protocol was released to the field in June 2008. Feedback since this release provided information for the following clarifications, which provided in the format of Frequently Asked Questions (FAQs).

**Is the "Universal Protocol" a requirement or just advice to be considered?**

Effective July 1, 2004, compliance with the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery is required for all Joint Commission accredited organizations, to the extent that these requirements are relevant to the services provided by the organization.

**What procedures fall within the scope of the Universal Protocol?**

The Protocol is not limited to operating rooms; it is relevant to all settings where procedures are performed. The Protocol and its implementation guidelines apply to all operative and other invasive procedures that expose patients to more than minimal risk. The Joint Commission's glossary defines invasive procedures as involving "the puncture or incision of the skin, insertion of an instrument, or insertion of foreign material into the body. Invasive procedures may be performed for diagnostic or treatment-related purposes."

While The Joint Commission does not specifically define the term minimal risk, certain routine "minor" procedures such as venipuncture, peripheral intravenous line placement, insertion of a naso-gastric tube or urinary bladder catheter are not within the scope of the Protocol. However, examples of procedures such as PICC line and all central line insertion, chest tube insertion and other similar types of common procedures are included. Please note that procedures specifically excluded from the Universal Protocol are electroconvulsive therapy (ECT), closed reduction, radiation oncology, lithotripsy and performance of dialysis (excluding insertion of dialysis catheters).

The overall purpose of the Universal Protocol is to improve patient safety and prevent procedural errors. Based upon the statements of the preceding paragraphs, and with a focus on safety, each organization is expected to clearly define for itself which procedures will fall within the Protocol. All healthcare workers involved in operative and other invasive procedures should know for which procedures the Protocol must be utilized.

**Pre-procedure Verification FAQs:**

**Is a pre-procedure verification checklist now required?**

Beginning 2009, a pre-procedure verification checklist is required. The intent of the requirement is to ensure that all relevant documents are available and have been reviewed, as well as ensuring blood products, implants and special equipment are available prior to the start of the procedure and accurately matched to the patient. Surveyors will evaluate the consistency with which the pre-procedure verification process is performed inclusive of the required components.

**Our pre-procedure area is not physically near the procedure area and is staffed by a peri-operative/recovery room team. The team preparing the patient in the pre-procedure area would not know what blood products, implants, devices or special equipment is needed in the procedure room. What are the expectations? Can this piece be verified in the procedure room rather than the pre-procedural area and still be compliant with the requirement?**

The intent of the requirement is to verify all required elements are ready prior to moving the patient into the operating or procedure room. While considering this intent, it is recognized that verification of all the items required in UP.01.01.01 EP 1 may create some logistical challenges, and may require new processes to be developed. If staff in the pre-procedure area do not have access to the needed elements in the procedure area, the organization would be expected to implement a process of communication between the two areas ensuring the required elements are available and ready for use. In those unusual circumstances when this verification cannot be performed during the pre-op verification process, the

confirmation may be done at the “time-out”. Please note that this approach should be based upon analysis of individual circumstances, and should not be routine practice.

**What are the expectations for procedures being performed outside of the operating room or at designated procedure areas?**

For procedures not being performed in operative or procedural areas, the verification processes and use of checklists is still required. The specific elements of the checklists and the specific processes for managing these situations is delineated by the organization.

**Site Marking FAQs:**

**Who should mark the site?**

The Protocol clearly states the site marking is performed by the licensed independent practitioner or other provider who is privileged or permitted by the organization to perform the intended surgical or non-surgical invasive procedure. These providers must be involved directly in the procedure and will be present during the procedure. The word “should” has been eliminated from the Universal Protocol, but the intent of the requirement has not changed. The language has become more definitive in 2009 in an effort to reinforce the current interpretation which is that the person privileged/permitted to perform the procedure and who will be actively involved in and present during the procedure performs the site marking.

**Can physician assistants (PAs) or nurses mark the site?**

In those states where PAs or Advance Practice RNs are considered as licensed independent practitioners, and are privileged/permitted to perform the actual procedure, the PAs and APRNs who are actively involved in and present during the procedure may mark the site.

For other situations where state regulations do not exist or cover these types of practitioneres, it is each organization’s responsibility to develop policies and/or procedures where individuals who are not licensed independent practitioners may perform site marking. This must be based upon the scope of practice in the given state and within the organization, as well as considering individual job descriptions and competencies.

**Can resident trainees (residents) perform the site marking?**

An organization may consider allowing residents to perform site marking if all of the following are true:

- The resident is considered to be a licensed independent practitioners, as determined by state law or regulation and the organization's medical staff by-laws
- The resident is privileged or permitted to perform the surgical or non-surgical invasive procedure
- The resident will be present during the procedure and actively involved

It is each organization’s responsibility to develop policies and/or procedures for other situations where individuals who are not licensed independent practitioners and trainees may perform site marking. This must be based upon the scope of practice in the given state and within the organization, as well as considering individual job descriptions and competencies.

**Must all procedures be marked? Are there any exceptions?**

The overall purpose of the Universal Protocol is to improve patient safety by preventing procedural errors. As historically stated for the Universal Protocol, midline, single organ procedures, as well as endoscopies

without intended laterality, do not require site marking - they are exempt. Also, site marking is not required before procedures in which there is no predetermined site of insertion such as cardiac catheterization and other interventional procedures. All other procedures are required to be marked.

Please note, however, that for those procedures in which site marking is not required, the other requirements of the Universal Protocol still apply. Based upon these statements, and with a focus on procedure safety, each organization is expected to clearly define for itself which procedures will fall outside the requirements for site marking and all healthcare workers involved in operative and other invasive procedures should know these procedures and the processes for their management.

### **Time Out FAQs:**

**UP.01.03.01 EP 1 states, “The time-out is conducted prior to starting the procedure and, ideally, prior to the introduction of the anesthesia process (including general/regional anesthesia, local anesthesia, and spinal anesthesia), unless contraindicated.” What does the word “ideally” mean?**

This statement was developed as a result of recognizing that wrong anesthesia procedures occur (e.g. wrong site regional anesthesia). Human factors literature would suggest that performing a time-out just prior to the incision or commencing the procedure is optimal. However, the reality is that this is not always possible due to logistical constraints related to the procedure or patients’ needs, as well as the concerns regarding wrong anesthesia procedures. Each organization defines under which situations the time-out is required to be performed prior to anesthesia or when it is preferable to do so immediately prior to the procedure/incision; or when flexibility may be considered while still focusing on the prevention of wrong-site or wrong-procedure surgery.

**Sometimes our surgeons are running multiple rooms. We are preparing, positioning and anesthetizing one patient while the surgeon finishes the previous case. In this situation, is it okay for the rest of the team to conduct the time-out without the surgeon?**

The ultimate goal of the Universal Protocol is to increase patient safety. In recognition of the critical role of the surgeon, or individual performing procedures, as part of the procedure team, it is not allowable to conduct the time-out without him or her present.

**Are there situations, such as when there are two separate procedures, when we should conduct more than a single time-out?**

Whenever there is more than one procedure being performed by separate procedure teams, there needs to be a time-out prior to each team commencing their procedure. This does not apply to those situations where the same team is performing multiple components during a single procedure. For example, a first team performs a mastectomy and a second team performs reconstructive surgery. Another example would be the performance of a spinal or regional block by anesthesia prior to a general or orthopedic surgery.

A specific situation requiring two time-outs is when hospital policy or law/regulation requires two separate consents, such as for a Cesarean section and a tubal ligation. Two separate time-outs should occur for these situations.

In all other circumstances, each organization may define when more than one time-out must be performed.

### **Potential Barriers and Risks for Unintended Consequences**

In considering how best to implement changes related to the Universal Protocol, the following issues are recognized:

- Failure to recognize risks in procedural settings other than the operating room.
- Lack of “agreement” by the procedure team and individuals performing the procedures surgeon regarding a standardized approach and the difficulty for changing local culture.
- Reluctance of nurses and other staff to question the individuals performing the procedures when a possible error is identified.
- Inadequate human resources and knowledge for facilitating processes to be challenged.
- “Automatic” behavior during the time-out process (“going through the motions” but without meaningful communication).
- Inconsistency of Universal Protocol procedures among several hospitals within a geographic area, staffed by the same surgeons operating at more than one of the hospitals.
- Permanent tattooing of immature skin (premature infants).
- Perception of increased workload by staff and decreased efficiencies.