



## The Universal Protocol Facts

The Universal Protocol, created to address the continuing occurrence of wrong site, wrong procedure and wrong person surgery<sup>1</sup>, is a part of the 2014 Joint Commission (JC) National Patient Safety Goals.

The three principal components of the Universal Protocol include:

- Conducting a pre-procedure verification process<sup>1</sup>
- Marking the procedure site<sup>1</sup>
- Performing a time out immediately before starting the procedure<sup>1</sup>

The Universal Protocol is based on the following principles:

- Wrong-person, wrong-site, and wrong-procedure surgery can and must be prevented.
- A robust approach using multiple, complementary strategies is necessary to achieve the goal of always conducting the correct procedure on the correct person, at the correct site.
- Active involvement and use of effective methods to improve communication among all members of the procedure team are important for success.
- To the extent possible, the patient and, as needed, the family are involved in the process.
- Consistent implementation of a standardized protocol is most effective in achieving safety.<sup>2(p 13)</sup>

In 2003, The JC Board of Commissioners originally approved the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™ and it became effective July 1, 2004 for all accredited hospitals and ambulatory care and office-based surgery facilities.<sup>1</sup> In July 2008, an updated Universal Protocol was approved by the Board, effective January 1, 2009. In 2010, The Universal Protocol was revised to address patient safety issues and allow organizations flexibility in applying the requirements.<sup>1</sup>



## The Universal Protocol Frequently Asked Questions

### **Q. What procedures fall within the scope of the Universal Protocol?**

A. The Universal Protocol is not limited to operating rooms; it is relevant to all settings where operative and invasive procedures are performed.

The overall purpose of the Universal Protocol is to improve patient safety and prevent procedural errors. Each organization is expected to clearly define for itself which procedures will fall within the Universal Protocol. All health care workers involved in operative and other invasive procedures should know the procedures on which the Universal Protocol must be used.

### **Q. Is the Universal Protocol a requirement or a recommendation?**

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

### **Q. Is a pre-procedure verification checklist now required?**

A. Beginning in 2009, a pre-procedure verification checklist is required for all JC accredited organizations. 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 before the start of the procedure and have been accurately matched to the patient. Surveyors will evaluate the consistency with which the pre-procedure verification process is performed inclusive of the required components.

### **Q. What are the expectations for procedures being performed outside of the OR or at other designated procedure areas?**

A. For procedures not being performed in operative or at other designated 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 JC for invasive, high-risk, diagnostic or therapeutic procedures performed in an office, procedural area, emergency department, or at the bedside.<sup>3</sup>

### **Q. What about dental procedures where there have been several cases of extraction of the wrong teeth?**

A. According to the Universal Protocol, each health care organization should have an alternative process to address situations when it is technically or anatomically impossible or impractical to mark the site. An example is a process in place to use a dental radiograph or dental diagram to mark the site of the tooth or teeth.<sup>4</sup>

### **Q. Must all procedures be marked? Are there any exceptions?**

A. The overall purpose of the Universal Protocol is to improve patient safety by preventing procedural errors. Health care organization personnel should identify those procedures that require marking of the incision or insertion site. Personnel at each organization are expected to clearly define which procedures will fall outside the requirements for site marking, and all health care workers involved in operative and other invasive procedures should know these procedures and the processes for their management.



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

A. In those states where PAs or Advance Practice Registered Nurses (APRN) 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 practitioners, it is the administrators at 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 on the practitioner's scope of practice in the given state and within the organization, as well as his or her individual job description and competency requirements.

**Q. Can physicians who are residents perform the site marking?**

A. An organization may consider allowing residents to perform site marking only if the resident:

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

It is the responsibility of personnel at each organization 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 on the practitioner's scope of practice in the given state and within the organization, as well as his or her individual job description and competency requirements.

**Q. What if the patient refuses site marking?**

A. The patient always has the right to refuse. This situation should be handled the same way as any other patient refusal of care, treatment, or services. Personnel are responsible to provide the patient with information about why site marking is appropriate and desirable and the implications of refusing the site marking so that the patient can make an informed decision. The Universal Protocol does not require that the procedure be cancelled because the patient refuses site marking. Organization policy should describe the related procedural and documentation requirements.

**Q. What is the procedure for marking spinal surgery cases?**

A. Documentation, the use of diagrams, and site marking to indicate anterior or posterior, and general level of the planned procedure (eg, cervical, thoracic, lumbar, or rib number) are ways to identify a spinal surgical site.<sup>3</sup> Special intraoperative imaging techniques also may be used for locating and marking the exact vertebral level.<sup>3</sup>

**Q. Who should mark the surgical site?**

A. The Universal Protocol 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.<sup>2</sup> These providers must be involved directly in the procedure and will be present during the procedure.

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

A. 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, it is not permissible to conduct the time out without him or her present.



**Q. Are there situations when more than a single time out should be conducted (eg, when there are two separate procedures)?**

A. Examples of situations that may require two time out processes include when hospital policy or a law or regulation requires two separate consents, (eg Cesarean delivery followed by a tubal ligation); the performance of a spinal or regional block by the anesthesia professional before a general or orthopedic surgery; when the second procedure involves a new surgical team (eg a first team performs a mastectomy and a second team performs reconstructive surgery); and when a patient is repositioned (eg, supine to prone).<sup>3</sup> Two separate time out processes should occur for these situations. Each organization may define when more than one time out must be performed.

**Editor's note:** *the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery is a trademark of the Joint Commission, Oakbrook Terrace, IL.*

**References**

1. Facts about the Universal Protocol. The Joint Commission  
[http://www.jointcommission.org/assets/1/18/Universal\\_Protocol.pdf](http://www.jointcommission.org/assets/1/18/Universal_Protocol.pdf). Accessed July 17, 2014.
2. Critical Access Hospital: 2014 National Patient Safety Goals. The Joint Commission.  
[http://www.jointcommission.org/assets/1/6/CAH\\_NPSG\\_Chapter\\_2014.pdf](http://www.jointcommission.org/assets/1/6/CAH_NPSG_Chapter_2014.pdf). Accessed July 17, 2014.
3. Farris M, Anderson C, Doty S, Myers C, Johnson K, Prasad S. Institute for Clinical Systems Improvement. Non-OR Procedural Safety. Updated September 2012.  
[https://www.icsi.org/\\_asset/1hht9h/NonOR.pdf](https://www.icsi.org/_asset/1hht9h/NonOR.pdf) Accessed July 17, 2014.
4. Card R, Sawyer M, Degnan B, et al. Institute for Clinical Systems Improvement. Perioperative Protocol. Updated March 2014. [https://www.icsi.org/\\_asset/0c2xkr/Periop.pdf](https://www.icsi.org/_asset/0c2xkr/Periop.pdf). Accessed July 17, 2014.