

National Patient Safety Goals®

**Effective January 2024 for the Ambulatory Health Care Program**

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| Introduction to the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery TM |
| The Universal Protocol applies to all surgical and nonsurgical invasive procedures. Evidence indicates that procedures that place the patient at the most risk include those that involve general anesthesia or deep sedation, although other procedures may also affect patient safety. Organizations can enhance safety by correctly identifying the patient, the appropriate procedure, and the correct site of the procedure.  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.  The Universal Protocol is implemented most successfully in organizations with a culture that promotes teamwork and where all individuals feel empowered to protect patient safety. An organization should consider its culture when designing processes to meet the Universal Protocol. In some organizations, it may be necessary to be more prescriptive on certain elements of the Universal Protocol or to create processes that are not specifically addressed within these requirements. |

Organizations should identify the timing and location of the pre-procedure verification and site marking based on what works best for their own unique circumstances. The frequency and scope of the pre-procedure verification will depend on the type and complexity of the procedure. The three components of the Universal Protocol are not necessarily presented in chronological order (although the pre-procedure verification and site marking precede the final verification in the time-out). Pre-procedure verification, site marking, and the time- out procedures should be as consistent as possible throughout the organization.

Note: Site marking is not required when the individual doing the procedure is continuously with the patient from the time of the decision to do the procedure through to the performance of the procedure.

**UP.01.01.01**

Conduct a pre-procedure verification process.

**--Rationale for UP.01.01.01--**

Organizations should always make sure that any procedure is what the patient needs and is performed on the right person. The frequency and scope of the verification process will depend on the type and complexity of the procedure.

The pre-procedure verification is an ongoing process of information gathering and confirmation. The purpose of the pre-procedure verification process is to make sure that all relevant documents and related information or equipment are as follows:  
- Available prior to the start of the procedure

- Correctly identified, labeled, and matched to the patient’s identifiers  
- Reviewed and are consistent with the patient’s expectations and with the team’s understanding of the intended patient, procedure, and site

Pre-procedure verification may occur at more than one time and place before the procedure. It is up to the organization to decide when this information is collected and by which team member, but it is best to do it when the patient can be involved. Possibilities include the following:  
- When the procedure is scheduled

- At the time of preadmission testing and assessment  
- At the time of admission or entry into the facility for a procedure  
- Before the patient leaves the pre-procedure area or enters the procedure room

Missing information or discrepancies are addressed before starting the procedure.

**Element(s) of Performance for UP.01.01.01**

1. Implement a pre-procedure process to verify the correct procedure, for the correct patient, at the correct site.

Note: The patient is involved in the verification process when possible.

1. Identify the items that must be available for the procedure and use a standardized list to verify their availability. At a minimum, these items include the following:  
   - Relevant documentation (for example, history and physical, signed procedure consent form, nursing assessment, and pre-anesthesia assessment)  
   - Labeled diagnostic and radiology test results (for example, radiology images and scans, or pathology and biopsy reports) that are properly displayed  
   - Any required blood products, implants, devices, and/or special equipment for the procedure  
   Note: The expectation of this element of performance is that the standardized list is available and is used consistently during the pre-procedure verification. It is not necessary to document that the standardized list was used for each patient.

Introduction to UP.01.02.01

Wrong-site surgery should never happen, yet it is an ongoing problem in health care that compromises patient safety. Marking the procedure site is one way to protect patients; patient safety is enhanced when a consistent marking process is used throughout the organization. Site marking is done to prevent errors when there is more than one possible location for a procedure. Examples include different limbs, fingers and toes, lesions, level of the spine, and organs. In cases where bilateral structures are removed (such as tonsils or ovaries) the site does not need to be marked.

**UP.01.02.01**

Mark the procedure site.

**Element(s) of Performance for UP.01.02.01**

1. Identify those procedures that require marking of the incision or insertion site. At a minimum, sites are marked when there is more than one possible location for the procedure and when performing the procedure in a different location would negatively affect quality or safety.  
   Note: For spinal procedures, in addition to preoperative skin marking of the general spinal region, special intraoperative imaging techniques may be used for locating and marking the exact vertebral level.
2. Mark the procedure site before the procedure is performed and, if possible, with the patient involved.
3. The procedure site is marked by a licensed practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed. In limited circumstances, the licensed practitioner may delegate site marking to an individual who is permitted by the organization to participate in the procedure and has the following qualifications:  
   - An individual in a medical postgraduate education program who is being supervised by the licensed practitioner performing the procedure; who is familiar with the patient; and who will be present when the procedure is performed  
   - A licensed individual who performs duties requiring a collaborative agreement or supervisory agreement with the licensed practitioner performing the procedure (that is, an advanced practice registered nurse [APRN] or physician assistant [PA]); who is familiar with the patient; and who will be present when the procedure is performed.  
   Note: The organization’s leaders define the limited circumstances (if any) in which site marking may be delegated to an individual meeting these qualifications.
4. The method of marking the site and the type of mark is unambiguous and is used consistently throughout the organization.  
   Note: The mark is made at or near the procedure site and is sufficiently permanent to be visible after skin preparation and draping. Adhesive markers are not the sole means of marking the site.
5. A written, alternative process is in place for patients who refuse site marking or when it is technically or anatomically impossible or impractical to mark the site (for example, mucosal surfaces or perineum). Note: Examples of other situations that involve alternative processes include:  
   - Minimal access procedures treating a lateralized internal organ, whether percutaneous or through a natural orifice

- Teeth  
- Premature infants, for whom the mark may cause a permanent tattoo

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**UP.01.03.01**

A time-out is performed before the procedure.

**--Rationale for UP.01.03.01--**

The purpose of the time-out is to conduct a final assessment that the correct patient, site, and procedure are identified. This requirement focuses on those minimum features of the time-out. Some believe that it is important to conduct the time-out before anesthesia for several reasons, including involvement of the patient. An organization may conduct the time-out before anesthesia or may add another time-out at that time. During a time-out, activities are suspended to the extent possible so that team members can focus on active confirmation of the patient, site, and procedure.

A designated member of the team initiates the time-out and it includes active communication among all relevant members of the procedure team. The procedure is not started until all questions or concerns are resolved. The time-out is most effective when it is conducted consistently across the organization.

**Element(s) of Performance for UP.01.03.01**

1. Conduct a time-out immediately before starting the invasive procedure or making the incision.
2. The time-out has the following characteristics:  
   - It is standardized, as defined by the organization.  
   - It is initiated by a designated member of the team.  
   - It involves the immediate members of the procedure team, including the individual performing the procedure, the anesthesia providers, the circulating nurse, the operating room technician, and other active participants who will be participating in the procedure from the beginning.  
   Note: For organizations providing telehealth surgical services: Based on current UP requirements, telehealth staff who are physically present in the operating room and participating in a surgical procedure are actively involved in the time-out.
3. When two or more procedures are being performed on the same patient, and the person performing the procedure changes, perform a time-out before each procedure is initiated.
4. During the time-out, the team members agree, at a minimum, on the following: - Correct patient identity  
   - The correct site  
   - The procedure to be done

Note: For organizations providing telehealth surgical services: Based on current UP requirements, telehealth staff who are physically present in the operating room and participating in a surgical procedure are actively involved in the time-out.

5. Document the completion of the time-out.  
Note: The organization determines the amount and type of documentation.