

National Patient Safety Goals Effective January 2018

Ambulatory Health Care Accreditation Program

Goal 1

Improve the accuracy of patient identification.



NPSG.01.01.01

Use at least two patient identifiers when providing care, treatment, or services.

--Rationale for NPSG.01.01.01--

Wrong-patient errors occur in virtually all stages of diagnosis and treatment. The intent for this goal is two-fold: first, to reliably identify the individual as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual. Acceptable identifiers may be the individual's name, an assigned identification number, telephone number, or other person-specific identifier.




Elements of Performance for NPSG.01.01.01

1. Use at least two patient identifiers when administering medications, blood, or blood components; when collecting blood samples and other specimens for clinical testing; and when providing treatments or procedures. The patient's room number or physical location is not used as an identifier. (See also MM.05.01.09, EPs 8 and 11; NPSG.01.03.01, EP 1) 
2. Label containers used for blood and other specimens in the presence of the patient. (See also NPSG.01.03.01, EP 1) 

NPSG.01.03.01

Eliminate transfusion errors related to patient misidentification.

Elements of Performance for NPSG.01.03.01

1. Before initiating a blood or blood component transfusion: 
 - Match the blood or blood component to the order.
 - Match the patient to the blood or blood component.
 - Use a two-person verification process or a one-person verification process accompanied by automated identification technology, such as bar coding. (See also NPSG.01.01.01, EPs 1 and 2)
2. When using a two-person verification process, one individual conducting the identification verification is the qualified transfusionist who will administer the blood or blood component to the patient. 
3. When using a two-person verification process, the second individual conducting the identification verification is qualified to participate in the process, as determined by the organization. 

Goal 3

Improve the safety of using medications.

NPSG.03.04.01

Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings.









Note: Medication containers include syringes, medicine cups, and basins.

--Rationale for NPSG.03.04.01--

Medications or other solutions in unlabeled containers are unidentifiable. Errors, sometimes tragic, have resulted from medications and other solutions removed from their original containers and placed into unlabeled containers. This unsafe practice neglects basic principles of safe medication management, yet it is routine in many organizations.

The labeling of all medications, medication containers, and other solutions is a risk-reduction activity consistent with safe medication management. This practice addresses a recognized risk point in the administration of medications in perioperative and other procedural settings. Labels for medications and medication containers are also addressed at MM.05.01.09.

Elements of Performance for NPSG.03.04.01

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| <p>1. In perioperative and other procedural settings both on and off the sterile field, label medications and solutions that are not immediately administered. This applies even if there is only one medication being used.
Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process. Refer to NPSG.03.04.01, EP 5, for information on timing of labeling.</p> |  |
| <p>2. In perioperative and other procedural settings both on and off the sterile field, labeling occurs when any medication or solution is transferred from the original packaging to another container.</p> |  |
| <p>3. In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the following:
- Medication or solution name
- Strength
- Amount of medication or solution containing medication (if not apparent from the container)
- Diluent name and volume (if not apparent from the container)
- Expiration date when not used within 24 hours
- Expiration time when expiration occurs in less than 24 hours
Note: The date and time are not necessary for short procedures, as defined by the organization.</p> |  |
| <p>4. Verify all medication or solution labels both verbally and visually. Verification is done by two individuals qualified to participate in the procedure whenever the person preparing the medication or solution is not the person who will be administering it.</p> |  |
| <p>5. Label each medication or solution as soon as it is prepared, unless it is immediately administered.
Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.</p> |  |
| <p>6. Immediately discard any medication or solution found unlabeled.</p> |  |
| <p>7. Remove all labeled containers on the sterile field and discard their contents at the conclusion of the procedure.
Note: This does not apply to multiuse vials that are handled according to infection control practices.</p> |  |
| <p>8. All medications and solutions both on and off the sterile field and their labels are reviewed by entering and exiting staff responsible for the management of medications.</p> |  |

NPSG.03.05.01

Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

Note: This requirement applies only to organizations that provide anticoagulant therapy and/or long-term anticoagulation prophylaxis (for example, atrial fibrillation) where the clinical expectation is that the patient’s laboratory values for coagulation will remain outside normal values. This requirement does not apply to routine situations in which short-term prophylactic anticoagulation is used for venous thrombo-embolism prevention (for example, related to procedures or hospitalization) and the clinical expectation is that the patient’s laboratory values for coagulation will remain within, or close to, normal values.

--Rationale for NPSG.03.05.01--

Anticoagulation therapy can be used as therapeutic treatment for a number of conditions, the most common of which are atrial fibrillation, deep vein thrombosis, pulmonary embolism, and mechanical heart valve implant. However, it is important to note that anticoagulation medications are more likely than others to cause harm due to complex dosing, insufficient monitoring, and inconsistent patient compliance. This National Patient Safety Goal has great potential to positively impact the safety of patients on this class of medications and result in better outcomes.

To achieve better patient outcomes, patient education is a vital component of an anticoagulation therapy program. Effective anticoagulation patient education includes face-to-face interaction with a trained professional who works closely with patients to be sure that they understand the risks involved with anticoagulation therapy, the precautions they need to take, and the need for regular International Normalized Ratio (INR) monitoring. The use of standardized practices for anticoagulation therapy that include patient involvement can reduce the risk of adverse drug events associated with heparin (unfractionated), low molecular weight heparin, and warfarin.

Elements of Performance for NPSG.03.05.01

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| 2. Use approved protocols for the initiation and maintenance of anticoagulant therapy. | R <input type="checkbox"/> |
| 3. Before starting a patient on warfarin, assess the patient’s baseline coagulation status; for all patients receiving warfarin therapy, use a current International Normalized Ratio (INR) to adjust this therapy. The baseline status and current INR are documented in the clinical record.
Note: The patient’s baseline coagulation status can be assessed in a number of ways, including through a laboratory test or by identifying risk factors such as age, weight, bleeding tendency, and genetic factors. | R <input type="checkbox"/> |
| 7. Provide education regarding anticoagulant therapy to prescribers, staff, patients, and families. Patient/family education includes the following:
- The importance of follow-up monitoring
- Compliance
- Drug-food interactions
- The potential for adverse drug reactions and interactions | R <input type="checkbox"/> |
| 8. Evaluate anticoagulation safety practices, take action to improve practices, and measure the effectiveness of those actions in a time frame determined by the organization. | R <input type="checkbox"/> |

Introduction to Reconciling Medication Information

The large number of people receiving health care who take multiple medications and the complexity of managing those medications make medication reconciliation an important safety issue. In medication reconciliation, a clinician compares the medications a patient should be using (and is actually using) to the new medications that are ordered for the patient and resolves any discrepancies.

The Joint Commission recognizes that organizations face challenges with medication reconciliation. The best medication reconciliation requires a complete understanding of what the patient was prescribed and what medications the patient is actually taking. It can be difficult to obtain a complete list from every patient in an encounter, and accuracy is dependent on the patient's ability and willingness to provide this information. A good faith effort to collect this information is recognized as meeting the intent of the requirement. As health care evolves with the adoption of more sophisticated systems (such as centralized databases for prescribing and collecting medication information), the effectiveness of these processes will grow.

This National Patient Safety Goal (NPSG) focuses on the risk points of medication reconciliation. The elements of performance in this NPSG are designed to help organizations reduce negative patient outcomes associated with medication discrepancies. Some aspects of the care process that involve the management of medications are addressed in the standards rather than in this goal. These include coordinating information during transitions in care both within and outside of the organization (PC.02.02.01), patient education on safe medication use (PC.02.03.01), and communications with other providers (PC.04.02.01).

In settings where medications are not routinely prescribed or administered, this NPSG provides organizations with the flexibility to decide what medication information they need to collect based on the services they provide to patients. It is often important for clinicians to know what medications the patient is taking when planning care, treatment, or services, even in situations where medications are not used. A new requirement in this NPSG addresses the patient's role in medication safety: it requires organizations to inform the patient about the importance of maintaining updated medication information.


NPSG.03.06.01

Maintain and communicate accurate patient medication information.

--Rationale for NPSG.03.06.01--

There is evidence that medication discrepancies can affect patient outcomes. Medication reconciliation is intended to identify and resolve discrepancies—it is a process of comparing the medications a patient is taking (and should be taking) with newly ordered medications. The comparison addresses duplications, omissions, and interactions, and the need to continue current medications. The types of information that clinicians use to reconcile medications include (among others) medication name, dose, frequency, route, and purpose. Organizations should identify the information that needs to be collected to reconcile current and newly ordered medications and to safely prescribe medications in the future.


Elements of Performance for NPSG.03.06.01

1. Obtain and/or update information on the medications the patient is currently taking. This information is documented in a list or other format that is useful to those who manage medications. 

Note 1: The organization obtains the patient's medication information at the beginning of an episode of care. The information is updated when the patient's medications change.

Note 2: Current medications include those taken at scheduled times and those taken on an as-needed basis. See the Glossary for a definition of medications.

Note 3: It is often difficult to obtain complete information on current medications from the patient. A good faith effort to obtain this information from the patient and/or other sources will be considered as meeting the intent of the EP.

2. Define the types of medication information to be collected in different settings and patient circumstances. 

Note 1: Examples of such settings include primary care, urgent and emergent care, ambulatory surgery, convenient care, outpatient radiology, and diagnostic settings.

Note 2: Examples of medication information that may be collected include name, dose, route, frequency, and purpose.

- 3. For organizations that prescribe medications: Compare the medication information the patient brought to the organization with the medications ordered for the patient by the organization in order to identify and resolve discrepancies. **R**
 Note: Discrepancies include omissions, duplications, contraindications, unclear information, and changes. A qualified individual, identified by the organization, does the comparison. (See also HR.01.06.01, EP 1)

- 4. For organizations that prescribe medications: Provide the patient (or family as needed) with written information on the medications the patient should be taking at the end of the episode of care (for example, name, dose, route, frequency, purpose). **R**
 Note: When the only additional medications prescribed are for a short duration, the medication information the organization provides may include only those medications. For more information about communications to other providers of care at the end of an episode of care, or when the patient is discharged or transferred, refer to Standard PC.04.02.01.

- 5. For organizations that prescribe medications: Explain the importance of managing medication information to the patient at the end of the episode of care. **R**
 Note: Examples include instructing the patient to give a list to his or her primary care physician; to update the information when medications are discontinued, doses are changed, or new medications (including over-the-counter products) are added; and to carry medication information at all times in the event of emergency situations. (For information on patient education on medications, refer to Standards PC.02.03.01 and PC.04.01.05.)

Goal 7

Reduce the risk of health care–associated infections.

NPSG.07.01.01

Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

--Rationale for NPSG.07.01.01--

According to the Centers for Disease Control and Prevention, each year, millions of people acquire an infection while receiving care, treatment, or services in a health care organization. Consequently, health care–associated infections (HAIs) are a patient safety issue affecting all types of health care organizations. One of the most important ways to address HAIs is by improving the hand hygiene of health care staff. Compliance with the World Health Organization (WHO) or Centers for Disease Control and Prevention (CDC) hand hygiene guidelines will reduce the transmission of infectious agents by staff to patients, thereby decreasing the incidence of HAIs. To ensure compliance with this National Patient Safety Goal, an organization should assess its compliance with the CDC and/or WHO guidelines through a comprehensive program that provides a hand hygiene policy, fosters a culture of hand hygiene, and monitors compliance and provides feedback.

Elements of Performance for NPSG.07.01.01

- 1. Implement a program that follows categories IA, IB, and IC of either the current Centers for Disease Control and Prevention (CDC) or the current World Health Organization (WHO) hand hygiene guidelines. (See also IC.01.04.01, EP 1) **R**

- 2. Set goals for improving compliance with hand hygiene guidelines. (See also IC.03.01.01, EP 1) **R**

- 3. Improve compliance with hand hygiene guidelines based on established goals. **R**

NPSG.07.05.01

Implement evidence-based practices for preventing surgical site infections.

Elements of Performance for NPSG.07.05.01

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| <p>1. Educate staff and licensed independent practitioners involved in surgical procedures about surgical site infections and the importance of prevention. Education occurs upon hire, annually thereafter, and when involvement in surgical procedures is added to an individual's job responsibilities.</p> | <p>R <input type="checkbox"/></p> |
| <p>2. Educate patients, and their families as needed, who are undergoing a surgical procedure about surgical site infection prevention.</p> | <p>R <input type="checkbox"/></p> |
| <p>3. Implement policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Centers for Disease Control and Prevention (CDC) and/or professional organization guidelines).</p> | <p>R <input type="checkbox"/></p> |
| <p>4. As part of the effort to reduce surgical site infections:</p> <ul style="list-style-type: none"> - Conduct periodic risk assessments for surgical site infections in a time frame determined by the organization. - Select surgical site infection measures using best practices or evidence-based guidelines. - Monitor compliance with best practices or evidence-based guidelines. - Evaluate the effectiveness of prevention efforts. <p>Note: Surveillance may be targeted to certain procedures based on the organization's risk assessment.</p> | <p>R <input type="checkbox"/></p> |
| <p>5. Measure surgical site infection rates for the first 30 or 90 days following surgical procedures based on National Healthcare Safety Network (NHSN) procedural codes. The organization's measurement strategies follow evidence-based guidelines.</p> <p>Note 1: Surveillance may be targeted to certain procedures based on the organization's risk assessment.</p> <p>Note 2: The NHSN is the Centers for Disease Control and Prevention's health care-associated infection tracking system. NHSN provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate health care-associated infections. For more information on NHSN procedural codes, see http://www.cdc.gov/nhsn/CPTcodes/ssi-cpt.html.</p> | <p>R <input type="checkbox"/></p> |
| <p>6. Provide process and outcome (for example, surgical site infection rate) measure results to key stakeholders.</p> | <p>R <input type="checkbox"/></p> |
| <p>7. Administer antimicrobial agents for prophylaxis for a particular procedure or disease according to methods cited in scientific literature or endorsed by professional organizations. *</p> <p>Footnote *: A limited number of National Patient Safety Goals contain requirements for practices that reflect current science and medical knowledge. In these cases, the element of performance refers to a practice that is cited in scientific literature or endorsed by professional organizations. This means that the practice used by the organization must be validated by an authoritative source. The authoritative source may be a study published in a peer-reviewed journal that clearly demonstrates the efficacy of that practice or endorsement of the practice by a professional organization(s) and/or a government agency(ies). It is not acceptable to follow a practice that is not supported by evidence or widespread consensus. During the on-site survey, surveyors will explore the source of the practices the organization follows.</p> | <p>R <input type="checkbox"/></p> |

8. When hair removal is necessary, use a method that is cited in scientific literature or endorsed by professional organizations. *



Footnote *: A limited number of National Patient Safety Goals contain requirements for practices that reflect current science and medical knowledge. In these cases, the element of performance refers to a practice that is cited in scientific literature or endorsed by professional organizations. This means that the practice used by the organization must be validated by an authoritative source. The authoritative source may be a study published in a peer-reviewed journal that clearly demonstrates the efficacy of that practice or endorsement of the practice by a professional organization(s) and/or a government agency(ies). It is not acceptable to follow a practice that is not supported by evidence or widespread consensus. During the on-site survey, surveyors will explore the source of the practices the organization follows.

Introduction to the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™

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 preprocedure verification and site marking based on what works best for their own unique circumstances. The frequency and scope of the preprocedure 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 preprocedure verification and site marking precede the final verification in the time-out). Preprocedure 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 preprocedure 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 preprocedure verification is an ongoing process of information gathering and confirmation. The purpose of the preprocedure verification process is to make sure that all relevant documents and related information or equipment are:

- 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

Preprocedure 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 preprocedure area or enters the procedure room

Missing information or discrepancies are addressed before starting the procedure.

Elements of Performance for UP.01.01.01

1. Implement a preprocedure process to verify the correct procedure, for the correct patient, at the correct site. **R**
 Note: The patient is involved in the verification process when possible.

2. 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: **R** **D**
 - Relevant documentation (for example, history and physical, signed procedure consent form, nursing assessment, and preanesthesia 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 preprocedure verification. It is not necessary to document that the standardized list was used for each patient.

3. Match the items that are to be available in the procedure area to the patient. **R**

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.

Responsibility for marking the procedure site is a hotly debated topic. One position is that since the licensed independent practitioner is accountable for the procedure, he or she should mark the site. Another position is that other individuals should be able to mark the site in the interests of work flow and efficiency.

There is no evidence that patient safety is affected by the job function of the individual who marks the site. The incidence of wrong-site surgery is low enough that it is unlikely that valid data on this subject will ever be available. Furthermore, there is no clear consensus in the field on who should mark the site. Rather than remaining silent on the subject of site marking, The Joint Commission sought a solution that supports the purpose of the site mark. The mark is a communication tool about the patient for members of the team. Therefore, the individual who knows the most about the patient should mark the site. In most cases, that will be the person performing the procedure.

Recognizing the complexities of the work processes supporting invasive procedures, The Joint Commission believes that delegation of site marking to another individual is acceptable in limited situations as long as the individual is familiar with the patient and involved in the procedure. These include:

- Individuals who are permitted through a postgraduate education program to participate in the procedure
- A licensed individual who performs duties requiring collaborative or supervisory agreements with a licensed independent practitioner. These individuals include advanced practice registered nurses (APRNs) and physician assistants (PAs).

The licensed independent practitioner remains fully accountable for all aspects of the procedure even when site marking is delegated.

UP.01.02.01

Mark the procedure site.

Elements 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. **R**
 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. **R**

3. The procedure site is marked by a licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed. In limited circumstances, the licensed independent practitioner may delegate site marking to an individual who is permitted by the organization to participate in the procedure and has the following qualifications: **R**
 - An individual in a medical postgraduate education program who is being supervised by the licensed independent 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 independent 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. **R**
 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). **R**
 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

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.

Elements of Performance for UP.01.03.01

- 1. Conduct a time-out immediately before starting the invasive procedure or making the incision. **R**

- 2. The time-out has the following characteristics: **R**
 - 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 timeout.

- 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. **R**

- 4. During the time-out, the team members agree, at a minimum, on the following: **R**
 - 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 timeout.

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