

Advanced Heart and Vascular Center			
Policies and Procedures			
Policy Code: NPSG.001		Universal Protocol	
Approved By: Sandra Germany, Administrator	Effective Date: 06/18	Review Date: 5/26	Revision Date: 2/21

PURPOSE

To standardize safe practices to ensure correct patient, correct procedure, and the correct procedural site/side.

POLICY

AHVC will implement the use of a Universal Protocol that includes pre-operative/pre-procedure verification, marking of the operative/procedure site, and a “Time-Out”, or pause, immediately before starting the procedure when performing any invasive or surgical procedure.

DEFINITIONS

- Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery: A set of principles and processes developed through expert consensus to assure that the correct person receives the correct operative procedure involving the correct location.
- Pre-Procedure Verification: A gathering and verification process to ensure that all relevant documents and studies are available prior to the start of a procedure and that they have been reviewed and are correctly identified, labeled, and matched to the patient’s identifiers. All relevant documents should be congruent with each other, the patient’s expectations, and patient care team’s understanding of the intended patient, procedure, site, and, as applicable, specific equipment and/or implant(s). This is an ongoing process that is initiated at the decision to perform a procedure and continues through all treatments and interventions up to and including the “Time Out” before the start of the procedure.
- Time Out: A step which the entire cath lab team pauses after the patient is prepped and draped and audibly verbalizes consensus on the correct patient, surgery/procedure, physician, side/site, patient, and presence of implants and other required equipment, documents, allergies, fire risk, and other relevant information.

PROCEDURE

- Pre-Operative/Pre-Procedure Verification process:
 - 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:
 - 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 occurs at each of the following times for persons scheduled for a procedure/surgery:
 - At the time a 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.
 - Any time the responsibility for care of the patient is transferred to another member of the procedural care team, at the time of, and during, the procedure.
 - With the patient involved, awake and aware, if possible.
 - Prior to transport to the procedure room, the medical record is reviewed for the following items to ensure all relevant documents, studies, and special equipment are available prior to the start of the intervention and that the identified patient's expectations are the same as the cath lab team's understanding of the intended procedure:
 - Physician's order
 - History and physical
 - Signed operative/procedure consent form identifying the specific surgery/procedure

- Physician progress notes
- Nursing assessment
- Diagnostic test results
- Any required Implant(s), devices, and/or special equipment for the procedure
- Verbalization of the scheduled surgery/procedure by the patient/family (or legally designated representative)
- In the event of any discrepancy between documented information and/or the patient's identification of the intended surgical/procedure at any point in the protocol, the provider who is to perform the procedure is contacted for clarification and the discrepancy is resolved prior to proceeding with the procedure.
- The medical record should indicate documentation of the pre-procedure verification and details of resolution of any discrepancy.
- Marking the procedure site
 - The site/side for all new implants, generator changes, and loop recorders will be marked prior to the procedure and "Time Out," and, if possible, with the patient involved.
 - The physician will mark his/her initials with a standard surgical marking pen on the patient's correct side for new implants and generator changes, or the appropriate intercostal space for loop recorders.
 - In the event the patient refuses to have the site marked, a 2nd "time-out" will be performed verifying the correct side and site immediately prior to making the incision.
- "Time-Out" immediately before starting the procedure:
 - The "time-out" is conducted prior to starting the procedure. It is the final "stop and verify" step in which the entire cath lab team pauses and verbalizes consensus on the correct patient, consent, procedure, physician, fire risk, and special equipment/implants.
 - The "time-out" has the following characteristics:

- It is conducted in the room where the procedure/surgery will be performed and occurs just before starting the procedure.
- The same standard is followed for every “time-out”.
- It is initiated by the circulating nurse of the team.
- It involves interactive verbal communication between the immediate members of the procedure team, including the cardiologist/provider performing the procedure, the circulating nurse, the radiologic technologist, and other active participants as appropriate for the procedure, who will be participating in the procedure at its inception.
- Each team member is able to express concerns about the procedure verification. It is conducted in a standardized fail-safe mode in which the procedure is not started until all questions or concerns are resolved.
- During the “time-out”, other activities are suspended, to the extent possible without compromising patient safety, so that all relevant members of the team are focused on the active confirmation of the correct patient, procedure, and other critical elements.
- When two (2) or more procedures are being performed on the same patient, a “time-out” is performed to confirm each subsequent procedure before it is initiated.
- The “time-out” addresses the following:
 - Correct patient identity.
 - Confirmation that the correct access site is identified.
 - An accurate procedure consent form.
 - Agreement on the procedure to be done.
 - Correct site marked, if applicable
 - Correct patient position.
 - Implants and special equipment are available and ready for use.
 - The need to administer antibiotics or fluids for irrigation purposes.
 - Safety precautions based on patient history or medication use.

- Known fire risk posed by the procedure related to CHG prep, oxygen source, ignition source, and is site above xyphoid.
- Should staff members note differences during the “time-out” process, a complete review of all documentation, as well as a physical assessment of the patient, will be conducted to resolve any stated differences.
- The correct access site, patient, procedure, patient position, and presence of any implant(s) and/or special equipment will be verified, with all staff members in agreement before proceeding with the procedure.
- In the event differences are noted during the “time out” verification process and reconciliation processes are untaken, the primary physician performing the surgery/procedure will be the final authority approving commencement of the procedure once all pertinent information has been verified and all staff members are in agreement.
- The “Universal Protocol Operating/Procedural Site Verification and Time Out Form” or “Universal Protocol Invasive Procedure Site Verification and Time Out Form Non-Perioperative Area” or the electronic documentation system is used to document the patient identification, site verification process.
- Responsibilities
 - Cath Lab team: Every member of the surgical/patient care team is responsible for participating actively in the implementation of the Universal Protocol. Each member is responsible for assuring that the patient is identified prior to performing any test, procedure, studies, or documentation that is part of the pre-operative identification and assuring that the results and documentation are appropriately labeled. Each member has a responsibility to speak up regarding discrepancies.
 - Patient: The patient (or legally responsible representative) is responsible for actively participating in the implementation of the Universal Protocol. The patient is to actively participate in each identification effort. The patient has a responsibility to “speak up” if their expectations of the procedure, specific equipment, implant(s), etc. do not meet their expectations.

REFERENCES

The Joint Commission, National Patient Safety Goals – Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery