

Risk Matters: Wrong-Site, Wrong-Procedure, and Wrong-Patient Surgery



By Jeffrey A. Woods, JD

Few medical errors are as indefensible as those involving patients who have undergone surgery on the wrong body part, undergone the incorrect procedure, or had a procedure performed that was intended for another patient. These “wrong-site, wrong-procedure, wrong-patient errors” (WSPEs) are termed “never events” by the National Quality Forum and “sentinel events” by the Joint Commission— errors that should never occur and indicate serious underlying safety problems. In addition, the Centers for Medicare and Medicaid Services (CMS) will not reimburse hospitals for any costs associated with WSPEs. Yet, these “never events” continue to occur.

The official website of the Department of Health & Human Services, in an article updated September 2019, noted that although one seminal study indicated that such errors occur in approximately 1 of 112,000 surgical procedures, that estimate only included procedures performed in the operating room; if procedures performed in other settings (ambulatory surgery centers and interventional radiology suites, for example) are included, the rate would be significantly higher. A [study conducted using Veteran Affairs data](#) found that fully

half of the WSPEs occurred during procedures outside the operating room.

Root cause analyses of WSPEs consistently reveal communication issues as a prominent underlying factor. The Joint Commission's Universal Protocol attempts to address these communication issues through redundant mechanisms for verification of the correct site, procedure, and patient as well as site marking, checklists, and "timeouts." However, even when Universal Protocols are implemented, errors can still happen well before the patient reaches the operating room, a timeout is rushed, or production pressures contribute to errors during the procedure itself. As the above-cited article points out, ultimately, preventing WSPEs depends on a combination of system solutions, strong teamwork, a safety culture, and individual vigilance.

SpeakUP[™]



**The
Universal
Protocol**
for Preventing Wrong Site,
Wrong Procedure, and
Wrong Person Surgery[™]
Guidance for health care professionals

Conduct a pre-procedure verification process

Address missing information or discrepancies before starting the procedure.

- Verify the correct procedure, for the correct patient, at the correct site.
- When possible, involve the patient in the verification process.
- Identify the items that must be available for the procedure.
- Use a standardized list to verify the availability of items for the procedure. (It is not necessary to document that the list was used for each patient.) At a minimum, these items include:
 - relevant documentation
Examples: history and physical, signed consent form, preanesthesia assessment
 - labeled diagnostic and radiology test results that are properly displayed
Examples: radiology images and scans, pathology reports, biopsy reports
 - any required blood products, implants, devices, special equipment
- Match the items that are to be available in the procedure area to the patient.

Mark the procedure site

At a minimum, mark the site when there is more than one possible location for the procedure and when performing the procedure in a different location could harm the patient.

- For spinal procedures: Mark the general spinal region on the skin. Special intraoperative imaging techniques may be used to locate and mark the exact vertebral level.
- Mark the site before the procedure is performed.
- If possible, involve the patient in the site marking process.
- The 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, site marking may be delegated to some medical residents, physician assistants (P.A.), or advanced practice registered nurses (A.P.R.N.).
- Ultimately, the licensed independent practitioner is accountable for the procedure – even when delegating site marking.
- The mark is unambiguous and is used consistently throughout the organization.
- The mark is made at or near the procedure site.
- The mark is sufficiently permanent to be visible after skin preparation and draping.
- Adhesive markers are not the sole means of marking the site.
- For patients who refuse site marking or when it is technically or anatomically impossible or impractical to mark the site (see examples below): Use your organization's written, alternative process to ensure that the correct site is operated on. Examples of situations that involve alternative processes:
 - mucosal surfaces or perineum
 - 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

Perform a time-out

The procedure is not started until all questions or concerns are resolved.

- Conduct a time-out immediately before starting the invasive procedure or making the incision.
- A designated member of the team starts the time-out.
- The time-out is standardized.
- The time-out involves the immediate members of the procedure team: the individual performing the procedure, anesthesia providers, circulating nurse, operating room technician, and other active participants who will be participating in the procedure from the beginning.
- All relevant members of the procedure team actively communicate during the time-out.
- During the time-out, the team members agree, at a minimum, on the following:
 - correct patient identity
 - correct site
 - procedure to be done
- When the same patient has two or more procedures: If the person performing the procedure changes, another time-out needs to be performed before starting each procedure.
- Document the completion of the time-out. The organization determines the amount and type of documentation.

This document has been adapted from the full Universal Protocol. For specific requirements of the Universal Protocol, see The Joint Commission standards.

The contents of The Sentinel are intended for educational/informational purposes only and do not constitute legal advice. Policyholders are urged to consult with their personal attorney for legal advice, as specific legal requirements may vary from state to state and/or change over time.