SIGN, MARK & X-RAY
Prevention of Wrong-Site Spinal Surgery

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Introduction
The Sign, Mark and X-ray (SMaX) campaign is in its second iteration since the first release in 2001 by the North American Spine Society. This updated document and its recommendations are the result of a multisociety effort to continue to proactively address the issue of wrong-site spinal surgery and provide education to assist in its prevention. The developing work group included representatives from the North American Spine Society, American Academy of Orthopaedic Surgeons, American Association of Neurological Surgeons/Congress of Neurological Surgeons, American Society for Spinal Radiology and the Scoliosis Research Society. The document, its protocols and tools are intended for all spine care providers performing procedures on the spine. Recommendations are consistent with:

- The Joint Commission Universal Protocol
- The Joint Commission 2014 National Hospital Patient Safety Goals
- American Academy of Orthopaedic Surgeons’ Sign-Your-Site Program
- World Health Organization Safe Surgery Checklist
- American College of Surgeons Statement on Ensuring Correct Patient, Correct Site, and Correct Procedure Surgery
- Association of periOperative Nurses’ Comprehensive Surgical Checklist

Wrong-Site Surgery
Extensive efforts have been made to address wrong-site surgery by a variety of professional, regulatory and quality organizations; however, wrong-site surgery continues to occur. The number of all types of wrong-site, wrong-patient, wrong-procedure events voluntarily reported and reviewed by the Joint Commission has increased from 26 in 1998, when the first Sentinel Event Alert on wrong-site surgery was issued, to 109 in 2012, with peaks of 149-152 between 2009 and 2011. The Joint Commission issued the Universal Protocol on July 1, 2004 providing procedures for the prevention of wrong-site surgery; between 2004 and 2005, wrong-site events reviewed by the Joint Commission increased from 50 to 90. Wrong-patient, wrong-site, wrong-procedure events were one of the top three most frequently reviewed sentinel event categories in 2011-mid 2013.* Wrong-site surgery is not limited to any single specialty, but is a system problem that affects many surgical specialties.

Wrong-site surgery (operating on the wrong anatomical site) can be prevented in many cases. The use of checklists and standardized processes can help decrease the risk of wrong-site surgery. Ideally, checklists should be posted in the operating room and easily visible.
Risk factors for wrong-site surgery include:

- Emergency cases
- Involvement of multiple surgeons
- Multiple procedures performed during a single trip to the operating room
- Unusual time pressures
- Unusual patient characteristics, including morbid obesity, transitional anatomy, abnormal number of ribs, low bone density or physical deformity
- Unusual equipment or set-up in the operating room
- Anterior or posterior thoracic surgery
- Reoperation
- New or novel procedures or exposures

Root causes often identified issues related to communication, preoperative assessment and procedures used to verify the surgical site.

- Communication issues
- Failure to involve patient (or family, if appropriate) in identifying the site
- Incomplete or inaccurate communication between the surgical team
- Exclusion of certain surgical team members from the process
- Surgical team members who didn’t feel comfortable calling attention to an error and/or an environment where the surgeon could not be questioned
- Surgeon-only verification of site
- Preoperative assessment issues
- Incomplete preoperative assessment (ie, failure to review records or imaging studies immediately prior to surgery)
- Verification procedure issues
- Absence of formal procedures or checklists
- Absence of final site review in the operating room
- Absence of oral communication in verification
- Relevant information not available
- Staffing issues
- Failure to obtain intraoperative radiography or misinterpretation of the image

There are two types of wrong-site spinal surgery: either surgery done at an unintended level or on an unintended side. The most common error in spine surgery occurs when a procedure is done one level above the intended site.

**Reporting**

The consequences of wrong-site surgery negatively affect both patient and surgeon. They can lead to increased health care costs and legal action. Patients may be subjected to health repercussions including a medical condition that may not have been addressed, trauma to non-involved tissue, increased pain, possible prolonged recovery, adverse effects to biomechanics, and potentially additional surgical procedures. They may also experience psychological distress and lose trust in care providers.
Wrong-site surgery is a reportable sentinel event to the Joint Commission which requires performance of a root cause analysis. The Centers for Medicare and Medicaid Services (CMS) announced in August 2007 that Medicare would no longer pay for additional costs associated with many preventable errors, including those considered never events. Since then, many states and private insurers have adopted similar policies. Since February 2009, CMS has not paid for any costs associated with wrong-site surgeries. These never events are also often required to be publicly reported at the state level and can also draw unwanted media attention.

The advent of registry reporting may present opportunities for nonpunitive, confidential reporting on the incidence of wrong-site spinal surgery. Found in other industries with established safety systems (most notably aviation), the goal of nonpunitive, confidential reporting is to identify errors, including near misses, for the purpose of correction and prevention—not punishment or liability.

**Wrong-Site Spinal Surgery Prevention Tools**

Spine care providers are encouraged to share campaign protocols and tools with their colleagues and operating room staff. Providers are encouraged to download and make copies of these documents for use in practice.

- **Sign, Mark & X-ray Checklist for Safety.** Outlines a series of steps and double-checks to help prevent wrong-site spinal surgery.
- **Take-Home Sheet: Patient Diagnosis Diagram.** Provides a diagram for the physician to outline the site(s) of pathology to the patient during office discussions. There is space to indicate the differential diagnosis and plan of treatment (including side and levels of any proposed surgery). The patient can share this summary of the office visit with other health care providers such as physical therapists. When brought to surgery, the handout serves as an additional check of side and level to help avoid wrong-site surgery.

**Sources**

*According to the Joint Commission, sentinel event reporting is voluntary and represents only a small proportion of actual events. No conclusions should be drawn about frequency of events or trends over time.*


Disclaimer

This material is made available for educational purposes only. It is not intended to represent the only, nor necessarily best, method or procedure appropriate for the medical situations discussed; rather it is intended to present an approach, view, statement or opinion of the authors which may be helpful. This document should not be construed as including all proper methods of wrong-site surgery prevention or excluding other acceptable methods reasonably directed to obtaining the same results. The ultimate judgment regarding any specific method is to be made by the physician in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution. The authors disclaim any and all liability for injury or other damages resulting to any individual and for all claims that may arise out of the use of techniques discussed.

For more information, contact:
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Patient Take-Home Sheet: Thoracic/Lumbar Spine
This diagram is provided to give you information about your spine condition. Please share this information with any other health care providers included in your care. If surgery or any other invasive treatment is part of your treatment plan, please bring this document with you at the time of your procedure.

Patient/Diagnosis: __________________________________________

Plan: _______________________________________________________

Site and Side of Surgery/Procedure, if necessary: ______________________

☑ Anatomic Notes. Your spine has one of several common anatomic differences that is important for healthcare providers to be aware of, for example, transitional anatomy, extra ribs, pre-existing implants, ______________________
Patient Take-Home Sheet: Cervical Spine
This diagram is provided to give you information about your spine condition. Please share this information with any other health care providers included in your care. If surgery or any other invasive treatment is part of your treatment plan, please bring this document with you at the time of your procedure.

Patient/Diagnosis: ____________________________________________

Plan: _________________________________________________________

Site and Side of Surgery/Procedure, if necessary: _________________

☐ Anatomic Notes. Your spine has one of several common anatomic differences that is important for healthcare providers to be aware of, for example, transitional anatomy, extra ribs, pre-existing implants, __________
Sign, Mark & X-ray Checklist for Safety

Pre-Procedure Verification
Surgeons are encouraged to personally obtain informed consent or participate in marking. Avoid acronyms whenever possible.

- Patient (or patient representative, if underage or unable to participate) involved in confirming identity, correct procedure site (including side and levels), and correct procedure through:
  - Informed consent; and/or
  - During marking

- X-rays and medical records verified correct patient, as well as confirming patient identity via two means (ie, name and birthdate). The following items should be double-checked against the procedure site by the surgeon/proceduralist and operative/procedure team:
  - Medical record specifying planned procedure
  - Informed consent
  - Correct equipment/implant/device available
  - Operating room/anesthesia record
  - Diagnostic reports, x-rays, other imaging studies and their reports (marked “L” or “R” to prevent being placed backwards on the light box)

Time-Out (Before Skin Incision or Start of Invasive Procedure)

- A time out should occur before procedure start and, if the patient has more than one procedure, before starting each procedure.
  - # of procedures ____     # of time outs ____
  - Documented time out in surgical record

- Immediate members of the operative/procedure team should be present and stop all other activities (unless an emergency) to verify and agree on correct site (including side and level(s), patient, procedure and consents). Team should raise any questions/concerns to be resolved before proceeding.
Site Marking:
Surgical/Interventional Procedures and Spinal Injections

At minimum, mark the site when there is more than one possible location for the procedure and when performing the procedures in a different location could harm the patient. Site marking should be completed by a licensed independent practitioner ultimately accountable for procedure and who will be present when the procedure is performed.

- Marking completed prior to patient receiving any drugs that would affect participation (sedation, anesthesia, etc.) and prior to procedure.

- Correct vertebral level identified using a reliable, consistent counting technique throughout procedure.

- Mark general spinal region at or near the procedure site with the surgeon’s/proceduralist’s initials on the skin using a permanent marking pen. Marks should be legible and unambiguous. (Example: If surgeon’s initials are “N.O,” use three initials). Nonoperative sites should NOT be marked. Marks are visible after skin preparation and draping.

- Intraoperative imaging techniques used to locate and mark exact vertebral level, after exposure using radiopaque markers that do not move. Markers should be close to the level on the lamina. Adhesive or suture markers should not be sole means of marking site. Appropriate consultation to interpret intraoperative x-rays should be used where available and reasonable.
  - Second time out occurred to review the image and compare with markers.
  - Fluoroscopy used to verify site in the case of spinal injections.

- Consider having an assistant/scrub nurse always stand opposite the side where the surgeon/proceduralist should stand.

In the event of a life-threatening emergency or when marking would compromise the patient’s safety or outcome (such as movement of a patient with an unstable spine fracture), not all these steps may be followed.

Patient Name: __________________________________________________________
Physician Name: ________________________________________________________
Procedure(s): __________________________________________________________
Date: __________________________________________________________________
Name& Signature of Person Completing Checklist: ____________________________