FIRST
Do No Harm

In this Issue:
New England Baptist Hospital Beth Israel Deaconess Medical Center describe their processes to Prevent Wrong Level Spine Surgery.

Quality and Patient Safety Division, Massachusetts Board of Registration in Medicine

September 2012

SPECIAL ARTICLES

Prevention of wrong level spine surgery is a challenge for all hospitals that perform these procedures.

In the following articles, New England Baptist Hospital and Beth Israel Deaconess Medical Center share their experiences in developing enhancements to their spine site and level verification protocols.

Preventative Measures to Minimize the Risk of Wrong Level Spine Surgery

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At New England Baptist Hospital our goal is to achieve the best possible outcomes for our patients and to deliver exceptional care. Our surgeons' subspecialty expertise and the clinical capability of our staff are tremendous assets that we leverage to support our goal. Despite our best efforts in both practice and process, complications can occur. When they do, our approach to improvement includes robust analysis in the spirit of inquiry and continuous learning. This article describes our approach to the discovery and resolution of wrong level spinal surgeries in 2008.

Over a period of two years, commencing in 2006, New England Baptist Hospital had five patients that underwent spine surgery with intervention at the wrong level; despite our use of the hospital industry's published best practices at that time. Wrong level spine surgery is not uncommon given the presence of anatomical issues, spine pathology and variation in image quality of radiological studies. When this occurs, there are significant negative impacts on the patient, the surgical team and the institution. It also often results in another surgery to correct the original surgical intervention, creating further anxiety and harm to patients.

In all five cases at the Baptist, the Joint Commission universal protocol to prevent wrong site surgery was followed. However, as we discovered in our root cause analysis, wrong level surgery ***cannot*** be avoided by the preventative measures outlined in the universal protocol. For example, signing the site, as required by the universal protocol, will only identify the spine as the location but does not clearly identify the intended level. While intraoperative films are required in spine surgery, they do not present a fool-proof method of identifying the correct vertebral level with 100% accuracy. In addition, the factors of abnormal anatomy, pathology above the intended level, surgeon fatigue, and administrative issues have been shown to influence the occurrence. (DeVine, et al, 2010)

Event analysis and results:

An interdisciplinary team consisting of membership from the departments of orthopedics, neurosurgery, radiology and perioperative staff was assembled to review all five cases, led by the department chairmen, section chiefs and the division of Quality. The task of this team was to focus on the development of additional preventative measures to minimize the risk of wrong level spine surgery. The team studied root cause for each the five cases, best practice literature review and sought formal advice and counsel from national experts.

After careful review, the team concluded that the wrong level surgeries were not the result of deviation from good practice. A national expert who was engaged to provide consultation on the development of the best possible practice at New England Baptist assisted the team in the identification of other numerous factors, such as the quality of the film image taken, bone mass, spine deformities, previous surgery creating vertebral level identification issues and pathology. The task force made modifications in key areas of the patient care process that would most significantly influence the prevention of wrong level spine surgery.

The following is a synopsis of the change in practice and protocols in Spine Surgery:

Pre-Operative:

The attending physician is required to mark the surgical site with his/her initials using permanent marking pen at or immediately adjacent to the proposed surgical site. This was an existing practice. If in the clinical judgment of the surgeon there are abnormalities or questions about preoperative images, surgeons are required to conduct a review of preoperative images with a New England Baptist musculoskeletal radiologist. Abnormalities are defined as unusual circumstances that may contribute

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to difficulty in identifying the correct level of the spine. These include anatomical irregularities such as transitional vertebrae.

Intra operative Site Marking:

Localization Images:

A preliminary localization film is encouraged in all cases. The benefits of preincisonal localization are twofold. First, this allows the surgeon to place the incision in the most precise level rather than simply estimate this based on external landmarks. Secondly, it allows the surgeon time to evaluate the initial quality of the film and make appropriate adjustments before the surgery has commenced. The identification of imaging uncertainty or problems, either technical or related to patient factors, is better identified and corrected before the patient is prepped and draped and an incision is made. There may be some exceptions to this such as anterior lumbar spine or the clinical judgment of surgeon.

Intraoperative Marking Image:

The marking image is arguably one of the most important preventative measures. It was common practice to use moveable markers to identify the correct level of the spine. Moveable markers, defined as markers that are removed immediately after the marking image is completed and the site is confirmed, were found to contribute to wrong level surgeries since the marker was removed after the marking film was taken. As a result, it was possible to unintentionally migrate up or down a level. The committee made the following recommendations to enhance this process:

- The image marking the correct level of the spine must be done with immovable markers to ensure the correct location and level are identified.
- The image must include prominent landmarks for orientation (thoracic spine is an exception). Examples of prominent landmarks are the bottom of skull for cervical spine procedures and the sacrum for lumbar procedures.
- Anatomical structures that can be marked include lamina, spinous process, transverse process, or facet joint.
- The immovable marker will be replaced with a clearly visible fixed mark in the patient e.g. stitch e.g. bone bite exception if prior hardware is used as marker
- For minimally invasive spine surgery, the marking image must be obtained after the final placement of the retractor for each specific minimally invasive procedure and site, since immovable markers are not always an option in these cases.
- When prominent landmarks are not easily identified (such as the thoracic spine) the surgeon must image the cervical or lumbar spine and count down or up
- If ten minutes has elapsed between the initial localization/marking film and the performance of the irreversible part of the surgery, ***a second localization film*** shall be required and performed immediately prior to the irreversible part of the surgery.
- The attending surgeon is required to be present for all marking images and personally interpret the image.
- The surgeon must ensure all marking images are saved as a permanent part of the patient's medical record.
- In some cases, such as extensive spine deformity procedure, the marking film may not be necessary and the surgeon must document the rationale for the exception on the spine verification checklist.
- The spine level verification form is signed by the attending surgeon and becomes a permanent part of the patient's medical record in addition to the universal protocol checklist.

Radiology Partnership:

Access to musculoskeletal radiologists and the radiology technologists was identified as a key factor in ensuring the successful and timely resolution of imaging uncertainty or problems. The surgeons and the radiologists on the committee worked together to ensure the surgeons and the OR team had the appropriate level of support in conducting and interpreting all images associated with spine surgery. This included ease of access to the radiology team. NEBH radiologists partnered with the surgeons to create a preoperative process that allowed for consultation with surgeons on outside images or to discuss image problems arising from technical or patient factors. A technologist was deployed to the OR to ensure ease of access to a technologist when required. The surgeons and technologists developed a process to ensure an image of satisfactory quality was obtained and the important components of the site verification process were included in the patient's medical record.

Rollout/Education:

The modifications recommended by the task force were unanimously approved by the Medical Executive Committee and the Board of Trustees. An educational initiative was rolled out led by the respective department chairmen. This approached encouraged dialogue from the surgeons to ensure all concerns were addressed.

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Lessons Learned:

The Baptist's approach to all incidents of preventable harm is to conduct a robust root cause analysis and involve a multidisciplinary team in the development and implementation of an effective problem resolution and improvement plan. Our approach is one that focuses on transparency and system improvements for the benefit of our all of our patients, physicians and staff. Through the review of the wrong level surgery cases, we were able to significantly improve the spine site and level verification process for our organization. We are hopeful that this approach has eliminated the risk of wrong site spine surgery and we remain vigilant in the review of all opportunities to eliminate preventable harm.

References:

- ◊ DeVine J, Chutkan N, Norvell DC, Dettori JR. Avoiding wrong site surgery: A systematic review. *Spine*. 2010;35:95:528-536.
- ◊ Hsiang, J. Wrong level surgery: A unique problem in spine surgery. Surgical Neurology International. 2011; 2:47.
- ◊ NASS. *Prevention of Wrong Site Surgery: Sign, Mark and X-Ray (SMaX).*IL: LaGrange;2001.
- ◊ TJC. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery. 2003. Available at: http://www.jointcommission.org/standards_information/up.aspx.

Spinal Surgery Protocol—An Aid in the Identification of the Correct Spine Level

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The Joint Commission Universal Protocol was first developed in July, 2003 in an effort to decrease wrong patient, wrong procedure, and wrong site surgical errors. The standard built on the 2002 recommendations of the American College of Surgeons and the 2001 North American Spine Society's (NASS) "Sign, Mark and Radiography" program that also recommended a checklist for ensuring safety in spine surgery.

In 2008, following a wrong site surgery at BIDMC we realized a need to enhance our existing approach using the Universal Protocol to make it more consistent. At that time we developed a standardized practice for the sign-in, time-out and sign-out for all patients undergoing intraoperative surgical procedures. These processes described by World Health Organization, The Joint Commission and the Association of Operating Room Nurses included recommendations for standardized communication aimed at reducing wrong site, side, and patient procedures and reducing peri-operative complications.

At BIDMC, a checklist for these three phases (sign-in, time-out, sign-out) was embedded into the perioperative information management system to guide consistent practice and documentation of these actions in the on – line medical record. Physicians, nurses and surgical technologists all documented in the on line checklist which then lives on as a part of the permanent medical record. The elements of this process and the associated responsibilities by role can be seen in Figure1 (Page 5).

In 2010, during our evaluation of wrong level spine surgery we determined that the root causes for these level identification errors are different than those found in evaluating other wrong - side or the more broadly categorized wrong – site surgery. We found that despite consistently following our standardized checklists and protocols these protective strategies proved insufficient to prevent errors that resulted in misidentification of spine level leading to surgery at the level adjacent to the intended vertebral level. Eliminating wrong level spine surgery required additional specifications and checks by the surgical team as well as standardized communication among the physicians, the nursing, the surgical technologists and the radiology staff. The literature supported that there are unique challenges for spine surgeons. DeVine et. al conducted a review of wrong site surgery literature and suggested that in addition to the existing check lists recommended by The Joint Commission and NASS that there should be intraoperative imaging after exposure and marking of the fixed anatomic structure which should ideally be compared to the preoperative studies done in advance of spine surgery.

In 2010 we supplemented our existing process with a spine surgery checklist to aid the surgical team in the reliable identification of the correct spine level. Following our event we consulted with our colleagues at the New England Baptist Hospital and reached out to several other medical centers across the country for examples of best practice in this

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area and then developed a **Spine Surgery Protocol** that included the following requirements.

Marking Image:

A marking film must be done with an immovable marker to determine exact location and level.

Attending Surgeon:

Attending surgeon must be scrubbed, place the marker and personally interpret the images. During this process the surgeon reads out each of the landmarks. These steps cannot be delegated. At the close of the procedure the attending surgeon documents attestation signature in the on – line medical record spine checklist.

Additionally:

1. Images must include prominent landmarks for orientation with the exception of the thoracic spine:
   - Bottom of the skull for cervical spine procedures
   - Odontoid process
   - Sacrum for lumbar procedures

2. Anatomical structures that can be marked include lamina, spinous process, transverse process, pedicle or facet joint. The immovable marker will be replaced with a clearly visible fixed mark in the patient (exception if existing hardware is used as maker):
   - Stitch
   - Bone bite

Circulating Nurse:

The circulating nurse leads the closed loop communication with the surgeon using a verbal read back to include all elements of the check list. Documentation of the elements of the spine marking and verification process in the perioperative management system check list in the on line medical record occurs in "real-time." (Figure 2 and Figure 3)

As a part of these processes we required that the entire intraoperative team and the radiology technician are made aware of the intended level and the location that the surgeon believes has been marked. If there is any uncertainty about the marker image, the image must be redone. If there is any uncertainty in reading the x-ray, radiology is consulted for a wet read of the film.

Based on The Joint Commission Sentinel Event statistics as of June 30, 2011, we still have work to do to eliminate wrong site, wrong patient, and wrong procedure events. In 2010 there were 93 of these events voluntarily reported to them. Here in Massachusetts the Department of Public Health Bureau of Health Care Safety and Quality reported that there were 24 reported cases of wrong site surgery and 9 reported cases of wrong surgical procedure in 2009.

While we have not experienced an intraoperative wrong-site, wrong-side or wrong spine level surgery in the operating room since we implemented these strategies, we continue to relentlessly audit our compliance by both review of the documentation and by direct observation audits. We have standardized the role responsibilities and the communication expectations, and in doing so we are optimistic that our operating rooms are safer for our patients.

References:

◊ WHO Surgical Safety Checklist and Implementation Manual. World Health Organization. http://www.who.int/patientsafety/safesurgery/ss_checklist/en.index.html.

◊ The Universal Protocol. The Joint Commission. http://www.jointcommission.org/PatientSafety/UniveralProtocol.

◊ AORN position statement on creating a patient safety culture. In: *Perioperative Standards and Recommended Practices.* Denver, CO:AORN, Inc; 2010.

◊ NASS. Prevention of Wrong-Site Surgery: Sign, Mark & X-Ray (SMaX). IL: LaGrange;2001.

◊ Bulletin of the American College of Surgeons. Statement on ensuring correct patient, correct site, and correct procedure surgery. Vol. 87, No .12, December 2002.

◊ DeVine J, Chutkan N, Norvell DC, Dettori JR. Avoiding wrong site surgery: A systematic review. *Spine*. 2010;35:95:528-536.

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Figure 1

Beth Israel Deaconess Medical Center

Surgical Safety Checklist

A teaching hospital of Harvard Medical School

SIGN IN

Prior to induction of anesthesia

BRIEFING MAY BE ROLLING OR IN STEPS

WHO	WHAT TO DO
1) Prior to Patient's entry into OR: Discuss & create plan for:	
CIRCULATOR:	Are there special airway needs, a risk of hypothermia or need for blood products?
ANESTHESIA PROVIDER:	Responds with needs if any
2) Upon entry into OR – confirm patient's identity:	
CIRCULATOR:	Reads patient's name, DOB & MRN
ANESTHESIA PROVIDER:	Reviews ID band
3) Prior to induction:	
STOP THE LINE: DO NOT INDUCE PATIENT UNTIL TEAM PARTICIPATES	
ALL:	Confirm allergies
CIRCULATOR:	Confirms procedure with: • PIMS scheduled procedure • Consent
SURGEON*:	State the name of procedure including site and side
PATIENT, IF POSSIBLE:	Acknowledges procedure to be done
ALL:	View site marking if applicable
SURGEON*:	Verifies patient's position/need for positioning equipment
ALL:	Any other concerns are addressed

TIME OUT

Before Skin Incision

ALL MEMBERS OF THE TEAM STOP, INTRODUCE SELVES AND PARTICIPATE

WHO	WHAT TO SAY	WHAT TO DO
CIRCULATOR:	Ready to do Time-out	RN at computer with consent in hand.
ALL:	Yes	Stop activities. Turn radios other devices off.
CIRCULATOR:	Patient's name, MRN & DOB	Review name and MRN on computer screen & the consent.
ANESTHESIA PROVIDER:	Jane Doe; MRN# 123456, DOB 5/12/42 - Identity was confirmed upon entry into OR	Re-confirm patient's identity
SURGEON:	Confirms patient's name	
CIRCULATOR:	Allergies	View allergies on PIMS screen.
ANESTHESIA PROVIDER:	Lists allergies or declares none	
SURGEON:	Verbally affirms	
CIRCULATOR:	Antibiotics	
ANESTHESIA PROVIDER:	Name of antibiotic and time completed	Verify documentation in AIMS and time of next dose.
SURGEON:	Verbally affirms	
CIRCULATOR:	DVT prophylaxis Declare name of med given or state not applicable. Declare the pneumatic boots have been applied and are activated or state not applicable.	
CIRCULATOR:	Verification of Procedure	Review consent for accuracy.
SURGEON:	Name of procedure including site and side.	
CIRCULATOR:	Site marking	
SURGEON:	Affirms location of mark or state not applicable.	ALL visualize the mark. Remark site if marking removed during prep process.
CIRCULATOR:	Position	
SURGEON:	Affirms that the patient is in the correct position.	
CIRCULATOR:	Implants and instruments or personnel that have been requested are present or declares the plan to secure them.	Calls out to clinical advisor for assistance in solving the named discrepancy.
SURGEON:	Are all of the requested implants and additional personnel requested in the room or in progress?	
SCRUB:	Names implants, instruments or personnel that have been requested are present or declares the plan to secure them.	
CIRCULATOR:	Please confirm the radiological images.	
SURGEON:	Images present and displayed correctly and patient's name and MRN have been verified.	
CIRCULATOR:	Verify medications on the field	
SCRUB:	States medications on the field, if any	
CIRCULATOR:	Is there anything else we need to disclose.	Records comments if any.
ALL:	Respond as needed (may include special precautions).	

SIGN OUT

Before Patient leaves OR

VALIDATE AND PREPARE FOR HANDOFF

WHO	WHAT TO DO
SURGEON**:	Confirms accuracy of procedure
SURGEON**:	Validates specimen labeling and handling
SURGEON**: CIRCULATOR: SCRUB: ALL:	Completes elements of Incorrect Count checklist, if applicable Identify patient-specific needs to be reported on handoff

KEY:

SURGEON*
Surgeon or designee participating in case

SURGEON
Surgeon or designee authorized to begin procedure

SURGEON**
Attending surgeon. Task may not be delegated.

Figure 2

Spine Level Safety Checklist

Circulating Nurse | Surgeon

Marking image performed? ☐ Yes ☐ N/A

☐ Surgeon informs Circulating Nurse and Radiology Technologist that marking image is satisfactory in terms of quality and localization

Time: _____

1. Reference Point used:

☐ Bottom of skull for cervical procedures
☐ Odontoid Process
☐ Sacrum for lumbar procedures
☐ Other _____ (as dictated to the circulating nurse)
☐ N/A for Thoracic cases

2. Landmark used:

☐ Transverse process ☐ Pedicle
☐ Spinous process ☐ Lamina
☐ Previous instrumentation ☐ Facet Joint
☐ Disc space ☐ Other _____ (as listed by the circulating nurse)

3. Level: _____

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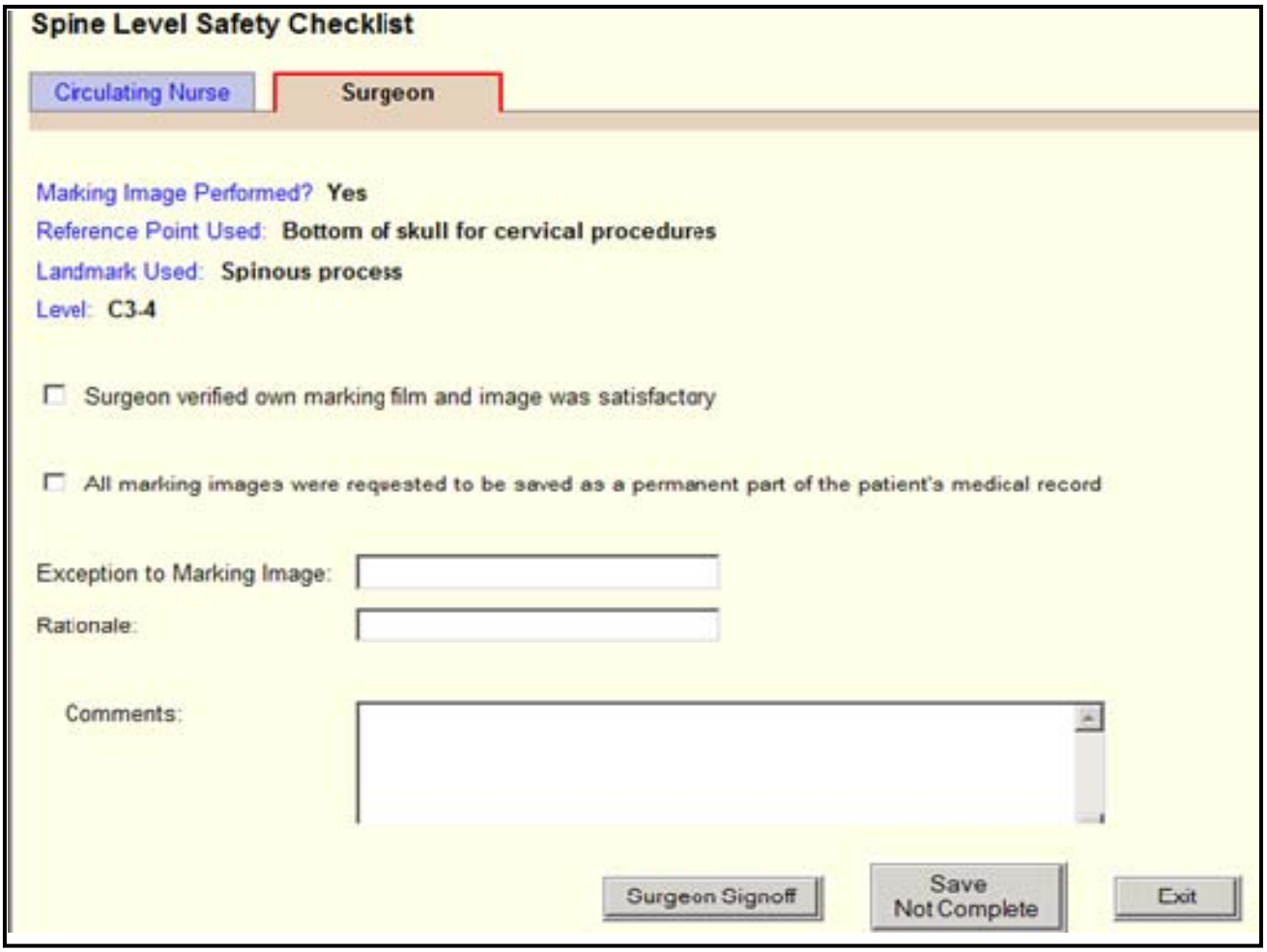
Figure 3



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