

**Out of the Frying Pan and
Into the Fire: Combating
Surgical Never Events**

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Out of the Frying Pan

Objectives

- Identify the most common areas where surgical systems break down
- Identify two solutions to practice improvement
- State two changes to the 2009 Universal Protocol

This is Your Captain Speaking

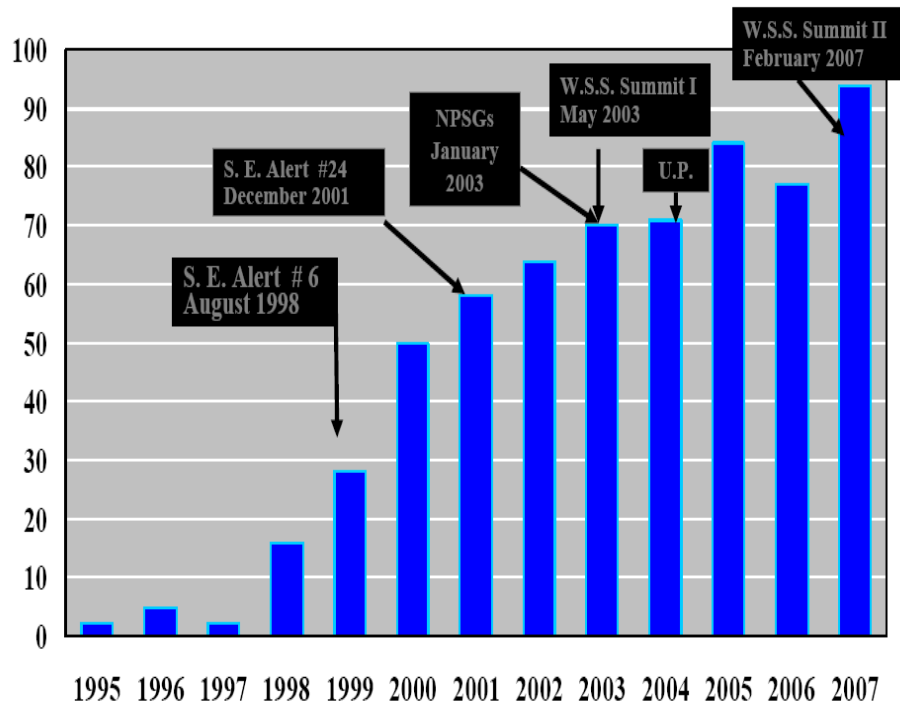
Out of the Frying Pan

Case in Point

- Surgery to have right lower leg amputated below the knee on February 20, 1995
- From: complication of diabetes
- University Hospital in Tampa, Florida
- 12 years later

Why Should We Look at This?

Wrong-site Surgeries Reviewed by Year



- **Number one** sentinel event from the Joint Commission
- 741 wrong site surgeries or 13.2% of all sentinel events
- December 31, 2008 TJC data from 5632 sentinel events

The Joint Commission (TJC)

Sentinel Event Alerts

- Issue 24, December 5, 2001
- Called “A Follow Up Review of Wrong Site Surgery”
- First one issued in August 1998

Wrong Site Surgery (WSS) by Site

2006 TJC data shows following:

- Peripheral nerve 14%
- Spine 10%
- Chest 10%
- Mouth, pharynx, larynx 7%
- Eye, foot, ankle, hand/wrist, eye, kidney, and peripheral vascular were each 5%

The Joint Commission (TJC)

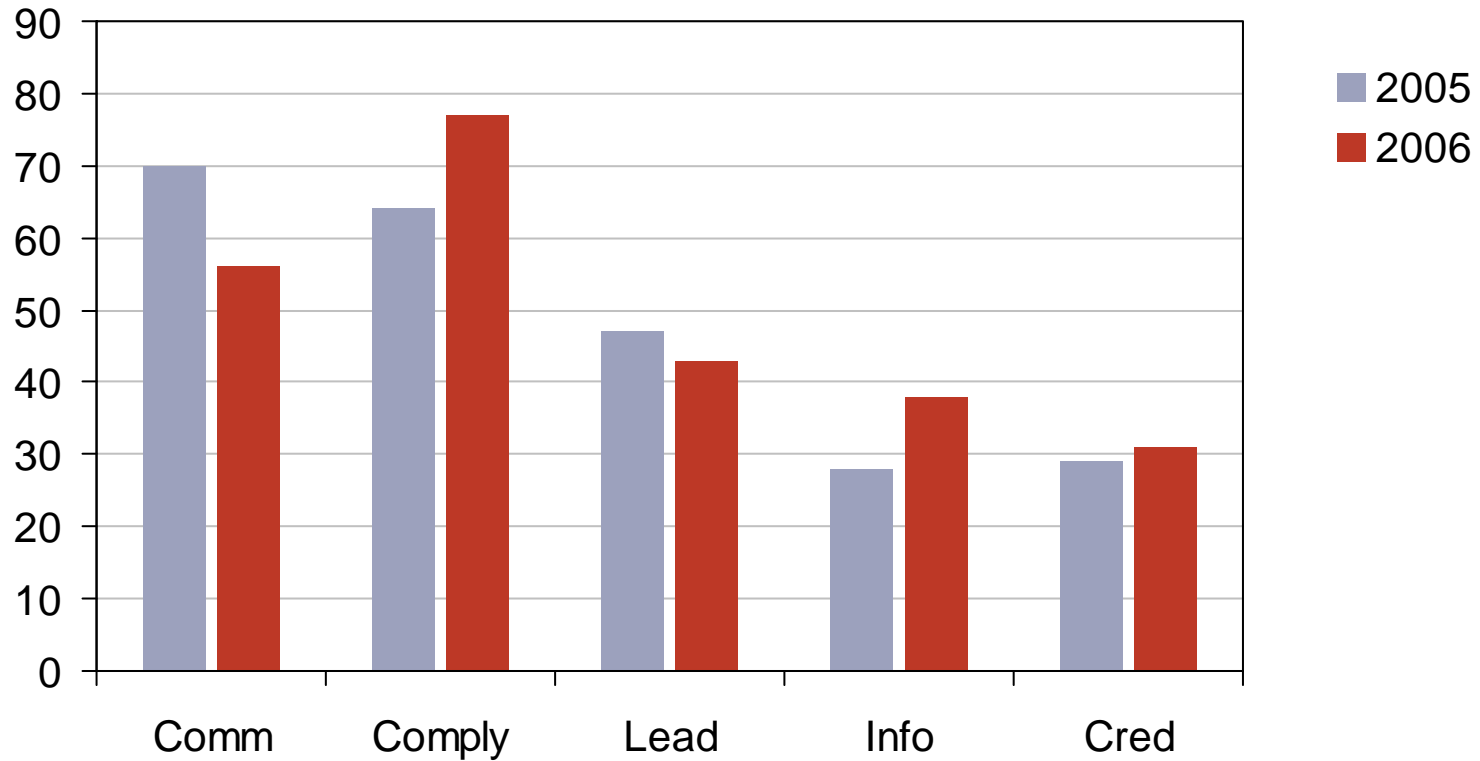
Sentinel Event Alert 2007

- Where did these occur?
 - 58% in ambulatory surgery unit; hospital and freestanding
 - 29% in inpatient hospital OR
 - And 13% other settings such as ED or ICU
- What type were these?
 - 76% were on the wrong body part or site
 - 13% on wrong patient
 - 11% were wrong surgical procedure

TJC Root Causes of Wrong Site Surgery

Root Causes

2005-2006



TJC Root Causes

Analysis 2007

- Multiple factors
- Contributing factors
- Top root causes

California Adverse Event Report (July 1, 2007–June 30, 2008)

Adverse Event Category	No.
Abduction of patient of any age	0
Care by impersonating licensed provider	1
Death after induction of anesthesia	40
Death due to a fall	40
Death/disability due to labor/delivery/post delivery	17
Death/disability due to spinal manipulative therapy	0
Death/disability directly related to hypoglycemia	0
Death/disability due to a burn	5
Death/disability due to disappearance	3
Death/disability due to electric shock	0
Death/disability due to intravascular air embolism	5
Death/disability due to use of restraints/bedrails	46
Death/injury from a physical assault	6
Failure to identify/treat hyperbilirubinemia	0
Hemolytic reaction	2

Adverse Event Category	No.
Infant discharged to wrong person	0
Medication error	34
Oxygen line used for wrong gas/toxic substance	2
Retention of a foreign object in a patient	172
Sexual assault on a patient	53
Stage 3 or 4 ulcer acquired after admission	607
Suicide/attempted suicide	18
Surgery performed on a wrong body part	28
Surgery performed on the wrong patient	3
Use of contaminated drug, device, or biologic	5
Use of device other than as intended	5
Wrong surgical procedure performed on a patient	13
Adverse event or series of adverse events	120
Grand Total	1225

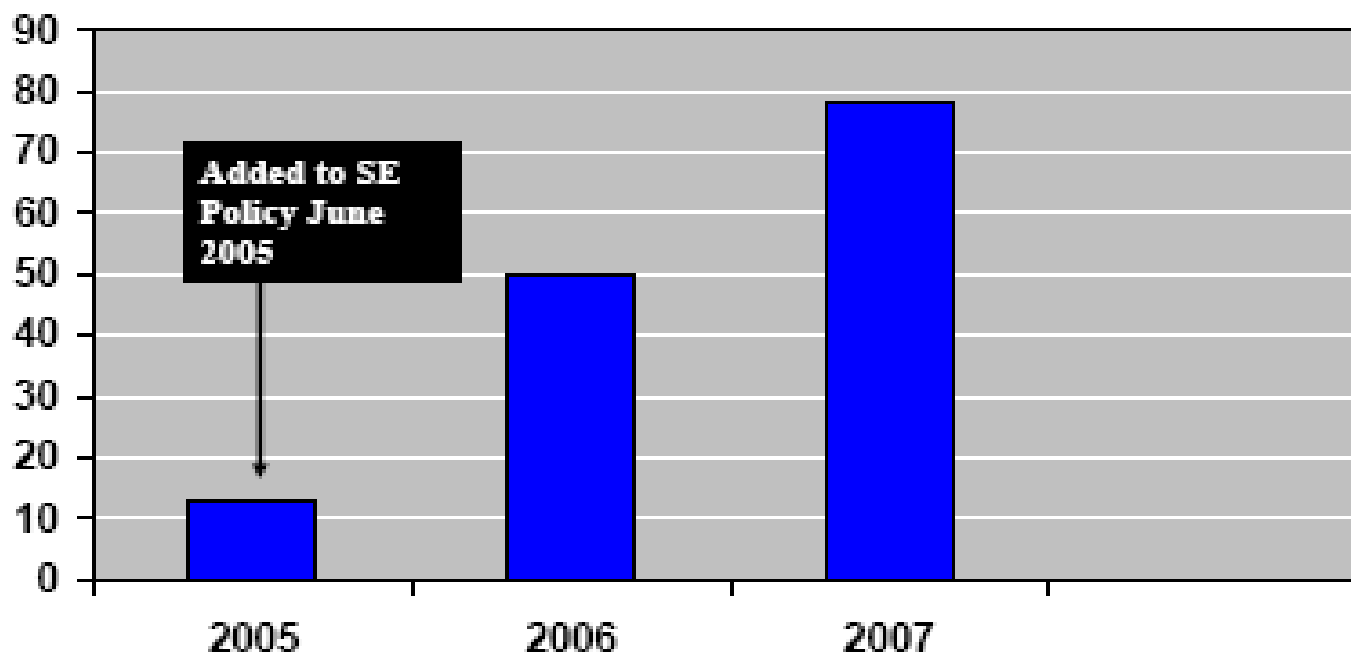
Retained Foreign Objects

-THREE THINGS-
LEFT IN PATIENTS THAT CAN
COST YOUR HOSPITAL MILLIONS



The Joint Commission Findings

Unintended Retention of a Foreign Object Reviewed by Year



A Word About WS Anesthesia

- No comparable registry for wrong-side anesthesia
- ECT
- Additional recommendations
- ASA recommendations

Factors Contributing to Surgical Never Events

- Human factors
- Procedure factors
- Systems
- At-risk behavior and drift

Stories From the Field

- The Minnesota experience
- Rhode Island neurosurgery
- Pennsylvania reports

What the Universal Protocol Won't Prevent

There is recognition that some types of WSS will not be prevented by UP, including:

- Surgery due to mislabeled bx or specimen
- Wrong procedure due to technical error such as lung bx intended but liver bx done
- Incorrect consent form when add on procedure requested by patient and consent not changed

PA-PSRS Analysis

- Wrong site surgery results from one of two problems
 - Misinformation
 - Misperception
- Misinformation usually occurred before the patient reached the OR
- Misperception occurred in the OR after the initial verification

Is This Really a Problem?

- Wrong site surgery is rare (1:100,000)
- RFO is also rare (1:5500-1:7000)
- Most wrong site surgery (WSS) cases do not result in permanent injury (64%)
- Wrong site surgery is a symptom
- Has been called the poster child of sentinel events (Dr. Croteau, TJC)
- The work we do to eliminate wrong site surgery will help us to improve patient safety in other areas

Learning from Others

- Pennsylvania
- Minnesota
- Oregon
- American College of Surgeons
- UCSF

Minnesota Time-Out

Minnesota Department of Health

September 2008

Time-Out Process in Minnesota

	Minnesota Recommendation	Rationale
1.	Prior to the procedure, cover the Mayo stand with a towel with “Time Out” in black lettering.	The time-out towel will serve as a memory trigger to remind the surgeon to initiate the time-out, and provides support to team members who may need to reinforce the need to complete the time-out for every procedure.
2.	The surgeon will initiate the time-out <u>after scrubbing and immediately prior to incision</u> . The surgeon should initiate the time-out by saying, for example, “Let’s do the time-out.”	The surgeon needs to be engaged in the process, and having him/her call for the time-out reinforces its importance. Doing the time-out immediately prior to incision makes it less likely that other conversations or activities will happen between the time-out and the surgery that could distract the surgeon.
3.	All team members will cease their activity. (The anesthesia care provider will continue to manage ventilation.)	No distractions should be present during the time-out, so that all team members can listen for the information and play their part in the process.
4.	The circulating nurse will then conduct the time-out by audibly reading the following information from the patient’s affirmation of informed consent: a.) Patient Name and medical record number b.) Procedure c.) Site procedure (and level, if appropriate) d.) Position of patient	The circulating nurse has access to previously verified source documents, which he/she uses for the time-out. Having the circulator begin the process decreases the odds that other team members will simply agree with the most senior person in the room, which can happen if the surgeon is the first person to speak.

Minnesota Time-Out (continued)

Minnesota Recommendation	Rationale
<p>5. The team verification will be conducted audibly in the following standard role sequence (not concurrently):</p> <ul style="list-style-type: none">a.) The ACP will read the patient's name, medical number, and procedure.b.) The scrub tech will state the procedure he/she has set up for, look for and find the site mark and announce that he/she sees the site marking.c.) The surgeon will state the patient's name, complete procedure, and site.	<p>Visualizing the site marketing during the time-out is crucial, as drapes, other materials or repositioning can obscure the mark. Having the scrub tech announce that they have seen the mark gives them an active role to play in the process, and dramatically lessens the odds of making an error due to an obscured mark. Having the surgeon go last minimizes the confirmation bias that sometimes happens in the OR, when team members defer to the surgeon and are reluctant to correct misinformation.</p>

Additional Time-Out

Additional Time-out Recommendations	Rationale
<p>If the patient will be undergoing multiple procedures, a time-out should be conducted prior to each individual procedure. If the patient is repositioned, an additional time-out should be done, including visualization of the site mark.</p>	<p>During multiple procedures, changes in the OR team may mean that new team members weren't part of the original time-out, and lack key information about the procedure. Repositioning can obscure the site mark, so it needs to be re-visualized.</p>
<p>Information related to allergies, antibiotics, images, and implants should be moved from the time-out to a pre-procedure briefing in the OR just prior to final case set-up. The time-out should be dedicated to the purpose of ensuring the correct patient, correct site, and correct procedure, only.</p>	<p>Moving the other pieces to a pre-procedure briefing will help to facilitate more effective and efficient case flow.</p>

A Little Bit About the UP

- Be familiar with the TJC document on Universal Protocol
- Your policy and procedure should be consistent with the UP
- Start with the informed consent
- Ask the patient what procedure he/she is having done and make sure it is correct on the consent form
- The patient should be involved with the process, to the extent possible

Universal Protocol

- Standardization is important
- Have a consistent standardized approach protocol
- The policy or protocol does need to be flexible enough to meet the patient's specific needs
- The P&P needs to include a requirement for site marking - should focus on cases involving right/left distinction, multiple structures (fingers, toes, ribs), or levels (spine)

2009 Changes

UP.01.01.01 Conduct a pre-procedure verification process

- Verification of the correct person, correct site, and correct procedure occurs at the following times:
 - At the time the procedure is scheduled
 - At the time of pre-admission testing and assessment
 - At the time of admission or entry into the facility for a procedure –whether selective or emergent
 - Before the patient leaves the pre-operative area or enters the procedure room
 - Anytime the responsibility for care of the patient is transferred to another caregiver, including the anesthesia providers at the time of, and during, the procedure
 - With the patient involved, awake and aware, if possible

2009 Changes

- (D) When the patient is in the pre-procedure area, immediately prior to moving the patient to the procedure room, a checklist (for example, paper, electronic, or other medium such as a wall-mounted whiteboard) is used to review and verify that the following items are available and accurately matched to the patient:
 - Relevant documentation (e.g., H&P, consent, nursing and pre-anesthesia assessments)
 - Accurately completed, and signed, procedure consent form
 - Correct diagnostic and radiology test results (e.g. radiology images and scans or pathology and biopsy reports) that are properly labeled
 - Any required blood products, implants, devices and/or special equipment for the procedure

2009 Changes

UP.01.02.01 Mark the procedure site

- For all procedures involving incision or percutaneous puncture or insertion, the intended procedure site is marked. The marking takes into consideration laterality, the surface (flexor, extensor), the level (spine), or specific digit or lesion to be treated
 - Note: For procedures that involve laterality of organs, but the incision(s) or approaches may be from the midline or from a natural orifice, the site is still marked and the laterality noted

2009 Changes

- The procedure site is initially marked before the patient is moved to the location where the procedure will be performed and takes place with the patient involved, awake and aware, if possible
- The procedure site is marked by a licensed independent practitioner or other provider who is privileged or permitted by the hospital to perform the intended surgical procedure or nonsurgical invasive procedure. This individual will be involved directly in the procedure and will be present at the time the procedure is performed
 - Note: final confirmation and verification of the site mark takes place during the time-out

2009 Changes

- The method of marking the site and the type of mark is unambiguous and is used consistently throughout the hospital
- The site marking has the following characteristics:
 - It is made at or near the procedure site or the incision site. Other nonprocedural site(s) are not marked unless necessary for some other aspects of care.
 - It includes, preferably, the surgeon's or proceduralist's initials, with or without a line representing the proposed incision.
 - It is made using a marker that is sufficiently permanent to remain visible after completion of a skin prep and sterile draping. Adhesive site markers are not to be used as the sole means of marking the site.
 - It is positioned to be visible after the patient has his or her skin prepped, is in his or her final position, and sterile draping is completed.

2009 Changes

- For spinal procedures, in addition to pre-operative skin marking of the general spine region, special intraoperative radiographic techniques are used for marking the exact vertebral level.
- A defined, alternative process is in place for patients who refuse site marking or who cannot easily be marked under the following conditions:
 - For cases in which it is technically or anatomically impossible or impractical to mark the site (mucosal surfaces, perineum, premature infants), an alternative method for visually identifying the correct side and site is used. For example, the hospital may place a temporary, unique wrist band on the side of the procedure containing the patient's name, and use a second identifier for the intended procedure and site.

2009 Changes

- For minimal access procedures that intend to treat a lateralized internal organ, whether percutaneous or through a natural orifice, the intended side is indicated by a mark at or near the insertion site, and remains visible after completion of the skin prep and sterile draping
- For interventional procedure cases for which the catheter/instrument insertion site is not predetermined (for example, cardiac catheterization, pacemaker insertion)

2009 Changes

- For teeth, the operative tooth name(s) and number are indicated on documentation or the operative tooth (teeth) is marked on the dental radiographs or dental diagram. The documentation, images, and/or diagrams are available in the procedure room before the start of the procedure.
- For premature infants, for whom the mark may cause a permanent tattoo.

2009 Changes

UP.01.03.01 A time-out is performed immediately prior to starting procedures

- The time-out is conducted prior to starting the procedure and, ideally, prior to the introduction of the anesthesia process (including general/regional anesthesia, local anesthesia, and spinal anesthesia), unless contraindicated.
- The time-out has the following characteristics:
 - It is standardized (as defined by the hospital)
 - It is initiated by a designated member of the team
 - It involves the immediate members of the procedure team including the proceduralist(s), the anesthesia providers, the circulating nurse, the operating room technician, and other active participants as appropriate for the procedure, who will be participating in the procedure at its inception

2009 Changes

- It involves interactive verbal communication between all team members, and any team member is able to express concerns about the procedure.
- It includes a defined process for reconciling differences in responses.
- 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, site, and other critical elements.
- When two or more procedures are being performed on the same patient, a time-out is performed to confirm each subsequent procedure before it is initiated.

2009 Changes

- The “time-out” must, at the least, include:
 - Correct patient identity
 - Correct side and site
 - Agreement on the procedure
 - Correct patient position
 - Relevant images and results are properly labeled and appropriately displayed
 - The need to administer antibiotics or fluids for irrigation purposed
 - Safety precautions based on patient history or medication use
- The completed components of the Universal Protocol and time-out are clearly documented

Questions?

Mission

Our Mission is to protect, defend,
and reward the practice
of good medicine

For additional information, go to www.thedoctors.com and click on Patient Safety