Wrong-Site, Wrong-Sided, Wrong-Patient, Wrong Procedure Surgery

Patient Safety Conference
NYS Department of Health
Albany, NY May 2007
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Member of the Board of Directors of the New York State Society of Orthopaedic Surgeons
Wrong-site surgery

Devastating Problem
Affects
Patient
Surgeon
Institution
Wrong-Site Surgery

Results from:

- Poor preoperative planning
- Lack of Institutional controls
- Failure of the surgeon to exercise due care
- Mistake in communication between patient and surgeon
Wrong-site surgery

Not just an orthopaedic problem that occurs because the surgeon operates on the wrong limb

It is a system problem that affects other specialties as well
Wrong-site surgery

While the number of reported orthopaedic surgery cases is not high relative to the total number of orthopaedic professional liability insurance claims, a retrospective study of a sample of insurers across the country provides evidence that 84% of cases involving wrong-site orthopaedic surgery claims resulted in indemnity payments over a ten year period, compared to all other types of orthopaedic surgery claims where indemnity payments were made in 30% of orthopaedic surgery claims during this same period.

AAOS Advisory Statement 2007
Recommendations for Eliminating Wrong-Site Surgery

“Sign Your Site” initiative by AAOS started in 1997
Voluntary effort within the AAOS fellowship since 1998
Wrong-site surgery

By 2000, 77% of orthopaedic surgeons were aware of the program.

Over 50% had instituted a program.

However, this was a voluntary effort, and institutions developed different, sometimes conflicting methods of implementing the program.
Wrong-site surgery

2000 Survey
1 in 5 orthopaedic surgeons will have an occurrence of wrong-site surgery in his or her career
Wrong-site surgery

JCAHO tracking of wrong-site surgery as part of Sentinel Events monitoring. From 1/95 to 9/03, there were 278 incidents reported, of which 35% involved orthopaedic surgery.
Wrong-site surgery

As of end of 1/04
Wrong-site surgery was the 3rd highest sentinel event
Accounting for more than 12% of all sentinel events reviewed by JCAHO since 1995
National Importance of Wrong-site surgery

Overall incidence was sufficient that JCAHO decided to make surgical site identification one of its quality goals beginning in 2003. The Summit convened in May 2003 to develop a “Universal Protocol” to avoid wrong-patient, wrong-procedure and wrong-site surgery. AAOS, as the only U.S. professional medical association with a formal site marking policy, played a significant role in the summit.
Wrong-site surgery

Never before had such a strong national emphasis been placed on the need for surgical site marking and a preoperative verification process as major components of a systems solution to help eliminate the incidence of wrong-site, wrong-patient, wrong-procedure surgery.
Canadian Orthopaedic Association

1994 to 1996 Educational Program

To help eliminate wrong-site surgery

Reported that the number of known wrong-site surgery claims in Canada has subsequently dropped dramatically.
Influence on this thought process on my training

Anyone doing any volume of spine surgery, especially microsurgery, will admit that at one time or another, they have been in at the wrong level. When embarking on a spine surgical career, admit immediately that wrong level exposure will be a constant problem and routinely plan the operative exposure to prevent the occurrence. All of the residents in our program are taught that the three most common errors in limited spine surgical exposures are:

1. Wrong level exploration,
2. Wrong Level Exploration!
3. WRONG LEVEL EXPLORATION!!

Ian Macnab, Backache, 1977
Universal Protocol

JCAHO implementation beginning July 1, 2004

Enhance patient safety
Preoperative surgical site marking became mandatory in U.S. hospitals and surgical centers

JACHO’s adoption of the elimination of wrong-site, wrong-patient, wrong-procedure surgery as a National Patient Safety Goal
Universal Protocol

All accredited organizations are required to use a preoperative verification process and a surgical site marking process.

- Critical access hospitals
- Hospitals
- Health care networks
- Office-based surgical practices

Must implement to maintain JACHO accreditation
American Academy of Orthopaedic Surgeons (AAOS) Advisory Statement

A unified effort among surgeons, hospitals and other health care providers to initiate preoperative and other institutional regulations can effectively eliminate wrong-site surgery in the United States.
Effective methods of eliminating wrong-site surgery

Surgeon, in consultation with the patient, places his or her initials on the operative site using a permanent marking pen and then operating through or adjacent to his or her initials.
Effective methods of eliminating wrong-site surgery

Spinal surgery done at the wrong level can be prevented with an intraoperative X-ray that marks the exact vertebral level (site) of surgery.
Effective methods of eliminating wrong-site surgery

Once patient in operating room, the surgical team should pause to take a “time-out” to communicate about the specific patient and procedure.
Effective methods of eliminating wrong-site surgery

Time-out should include confirmation of the patient’s identity, correct procedure, site, equipment and implants/devices as applicable.
Effective methods of eliminating wrong-site surgery

All members of the team (including the surgeon, assistant surgeon, anesthesiologist, circulating nurse, and scrub nurse) should participate in the time-out to communicate with other members of the team and to raise any questions or concerns.
New York State Surgical and Invasive Procedure Protocol (NYSSI PP)

Developed by the Procedural and Surgical Site Verification Panel (PSSVP)

Reviewed lessons learned from the analysis of occurrence codes 911 and 912 reported to the New York Patient Occurrence Reporting and Tracking System (NYPORTS) from 2003 to 2006
New York State Surgical and Invasive Procedural Protocol (NYSSIP) (NYSSIP)
PSSVP also
Reviewed the Joint commission on Accreditation of Healthcare Organizations’ (J CAHO) database of reviewable sentinel events
Reviewed the clinical literature as well as the collective experiences of the panelists
NYSSI PP

Represents a consensus of the panel on the current best practices in the area of preventing wrong-patient, wrong-site, wrong-side and wrong invasive procedures.

It is the intent of the panel that implementation of NYSSI PP will be adapted to the setting and the procedure.
The document identifies participants in the procedure as members of the “surgical team” but it is intended to include proceduralists, endoscopists and anyone assisting in any way in a procedure.
NEW YORK STATE SURGICAL AND INVASIVE PROCEDURE PROTOCOL

A. SCHEDULING
Scheduling must include:
1. Entire procedure, exact site, level, digit, and side/laterality (including spelling out “Left”, “Right” and “Bilateral” – no abbreviations other than C-Cervical, T-Thoracic, L-Lumbar, S-Sacral when identifying spinal levels – e.g. L4-5).
2. Specific information on implant/implant system and/or equipment.
3. Specific information on removal of device.
4. Information on harvest and donor sites.
5. The Operating Room (OR), or the person responsible for accepting requests to schedule procedures, must verify the information provided by the surgeon/physician. The information should be verified in a manner agreed to by both the institution and physicians (read-back, fax, e-mail, etc).

B. CONSENT DOCUMENT
Consent documentation must include:
1. First and last name, date of birth of patient and medical record number of the patient.
2. Name and description of surgery or procedure in terms that are understandable to the patient (correct site/side, level and digit with the side spelled out as “Left”, “Right” or “Bilateral”).
3. No acronyms or abbreviations (except spinal levels noted in section A above).
4. Specific implant/implant system to be placed or device to be removed.
5. Patient/family/guardian/health care agent signature and date.
6. Witness signature and date.
7. Physician signature and date.
8. If the consent is altered or illegible it must be re-done and re-signed by all parties.

C. PRE-OPERATIVE/PRE-PROCEDURAL VERIFICATION PROCESS
Verification of the correct person, procedure site and side must occur (as applicable):
1. At the time the surgery or invasive procedure is scheduled.
2. At the time of admission or entry into the facility.
3. With the patient involved, awake and aware, if possible.
4. Anytime the responsibility for care of the patient is transferred to another caregiver or location in the pre-operative or pre-procedural process.
5. Before the patient leaves the pre-operative area or enters the procedure/surgical room.
6. In ALL clinical settings where invasive procedures are performed, including but not limited to endoscopy suites, catheterization laboratories, interventional radiology suites, intensive care units, labor and delivery areas, emergency departments, etc. There are recognized benefits to applying this to all bedside procedures.
**Orthopaedic Spine Surgery**

**Patient Name**: ________________  **D.O.B.**: ________________

**Address**: __________________________

**Date of Surgery**: ________________

**Phone**: __________________________  **Hospital**: ________________

**Soc.Sec. #**: __________________________  **Insurance**: ________________

**Diagnosis**: ________________

**Surgical Procedure/Levels**:  
With—**ANESTHESIA SPECIAL REQUESTS**:__Hypotensive Anesthesia__ __Wake-up Test__

**APPROXIMATE LENGTH OF SURGERY**: ________________  **Units of Blood**: ________________

**Instrumentation to be used**: ________________

**Cell Saver**: ________________  **Spinal Cord Monitoring**: ________________

**Surgical Assistance Requested from Dr.(or group)**: ________________

for ________________

**Brace Post-Op**:  **No**  **Yes**  **Type**: ________________  **Approx. time in brace**: ________________

**PRE-OP CHECKLIST**:

**Labs**:  
____ Routine  
____ Other ________________

**X-Rays**:  
____ PA Lat  **F.S.**  ________________  **L/S**  
____ Side Bending -- R or L Thoracic  **R or L Lumbar**  **PFT**  **ABG**

**Med. Photos**:  
____ Pre-Op  **Post-Op**

**Consults**:  
____ None  
____ Medical  **Cardiovascular**

____ Other ________________

**Other Diagnostic Tests/Levels/Reasons**: ________________

(MR & CT) ________________  ________________  ________________

**DR Scheduled**: ________________ by ________________  **Notes**: ________________  **(Initial Please)**

**Insurance OK**: ________________ by ________________

**Office Packet**: ________________ by ________________

**Blood Info Sent**: ________________ by ________________

**Rx**: ________________ by ________________

**Peach Packet**: ________________ by ________________

**Consults**: ________________ by ________________

**Pre-Op F/U**: ________________ by ________________
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6. In ALL clinical settings where invasive procedures are performed, including but not limited to endoscopy suites, catheterization laboratories, interventional radiology suites, intensive care units, labor and delivery areas, emergency departments, etc. There are recognized benefits to applying this to all bedside procedures.
CONSENT FORM
(to be signed by patient wherever applicable)

Date ___________ Time ___________

PERMISSION FOR OPERATIVE AND/OR DIAGNOSTIC PROCEDURE AND/OR TREATMENT

1. I hereby authorize Dr. ___________________________ and associates or assistants of his/her choice at Montefiore Medical Center to perform upon me/the patient named above the following operation(s) and/or procedure(s):

PAPER PRINT OR TYPE. USE CLEAR TERMINOLOGY & INDICATE LEVEL OF SPINAL SURGERY, RIGHT AND LEFT MUST BE WRITTEN IN THEIR ENTIRETY.

2. Dr. ___________________________ has fully explained to me the nature and purposes of the operation(s) and has also informed me of expected benefits and complications (from known and unknown causes), attendant discomforts and risks that may arise, as well as possible alternatives to the proposed treatment, including no treatment. I have been given the opportunity to ask questions, and all my questions have been answered fully and satisfactorily. I acknowledge that no guarantees or assurances have been made to me concerning the results of the above operation(s), treatment(s) or procedure(s).

3. It has been explained to me that during the course of an operation unforeseen conditions may be revealed that necessitate an extension of the original procedure(s) set forth in paragraph 1. I therefore authorize and request that the above named surgeon, his associates and/or assistants perform such related surgical procedures and administer whatever is necessary and desirable in the exercise of their professional judgment.

4. I further consent to the administration of such anesthesia, sedation and/or blood transfusions as may be considered necessary. I recognize that there are always risks to life and health as well as benefits and alternatives associated with anesthesia, sedation and blood transfusions and these have been explained to me.

5. I further consent to disposal by hospital authorities, or possible use for research purposes, in accordance with its accustomed practice, of any tissues or parts which may be removed.

6. I confirm that I have read and fully understand the above and that all the blank spaces have been completed prior to my signing. I have crossed out any paragraphs above which do not pertain to me.

Interpreter if required

SIGNATURE ___________________________

PRINT NAME AND ADDRESS ___________________________

Witness

SIGNATURE ___________________________

PRINT NAME ___________________________

Physician obtaining consent

SIGNATURE ___________________________

PRINT NAME ___________________________

DATE SIGNED ___________________________

INFORMED CONSENT DISCUSSION: I hereby certify that I have explained the nature, purpose, benefits, risks of, and reasonable alternatives to the proposed procedure(s)/operation(s), and sedation and/or blood/blood products, when applicable. I have discussed potential problems related to recuperation, the likelihood of achieving treatment goals and the risks, benefits and side effects of reasonable alternatives, including the possible consequences of receiving no treatment. I have offered to answer any questions and fully answered such questions. I believe that the patient/relative/guardian fully understands what I have explained and answered.

Remarks:

Physician

SIGNATURE ___________________________

PRINT NAME ___________________________

DATE ___________________________

ATTENDING PHYSICIAN OPERATIVE SITE/SIDE VERIFICATION: I hereby confirm that the procedure described above, including laterality, where applicable, is correct.

Attending Physician

SIGNATURE ___________________________

(To be completed on the day of surgery.) DATE ___________ TIME ___________

12ME (02/06)

Side 1 of 2
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# Pre-Operative Checklist

<table>
<thead>
<tr>
<th></th>
<th>Floor Nurse</th>
<th>Circulating Nurse</th>
</tr>
</thead>
</table>
| 1. | Patient Identification in Place  
Full Name, DOB, M.D. (legible) |             |
| 2. | Operative consent completed, witnessed and signed  
If not by patient reason why |             |
| 3. | Level of consciousness:  
alert  
confused  
unresponsive  
silent |             |
| 4. | Advanced Directives:  
Living Will  
Health Care Proxy  
DNR  
suspended  
continued |             |
| 5. | Allergies:  
N/A  
others: |             |
| 6. | Dentures removed:  
YES  
NO  
N/A |             |
| 7. | NPO since: |             |
| 8. | Implants:  
YES  
NO  
where: |             |
| 9. | Skin integrity assessed:  
YES  
NO |             |
| 10. | OR Notified of Specific Isolation Precautions:  
YES  
NO |             |
| 11. | Labs:  
H & P  
Chest X-Ray  
ESR  
Tyg & Bowen  
Blood Available |             |
| 12. | Pre-op:  
TFR & BP  
Height & Weight  
Voided  
Time |             |
| 13. | Jewelry removed:  
YES  
NO  
placed in safe  
given to family  
taped |             |
| 14. | Hair Spray / Gel |             |

AMS / Floor Nurse Signature  
Circulating Nurse
A pre-operative or pre-procedural verification checklist must be utilized to ensure availability and actual review of the following, prior to the start of the procedure:

1. Relevant documentation: History & Physical, signed consent and any other documents required by the organization as part of the pre-operative evaluation process. The consent must be signed by the patient/legal representative, and surgeon.

2. Relevant images, properly labeled and displayed including photographs.
   - In “High Risk” procedures (as determined by the surgeon), the images should be reviewed by the surgeon and radiologist together pre-operatively.
   - Someone other than the primary surgeon confirms the name, date of the study and “Left-Right” orientation.
   - The surgeon is responsible for assessing what films/images are appropriate for viewing before and during the surgery.
   - When intra-operative imaging studies are performed, appropriate consultation should be available for interpretation of intra-operative studies.

3. Relevant diagnostic reports or studies (ultrasound, endoscopy, etc.).

4. Relevant pathology reports.

5. Necessary patient-specific implants and special equipment.

6. Confirm identity using two (2) identifiers, confirm procedure and site marking if appropriate.

D. MARKING THE OPERATIVE/PROCEDURAL SITE

1. The physician/dentist/podiatrist doing the procedure must do the site marking using his/her own initials. Site marking must be legible and unambiguous (see exceptions).
   Note: If the surgeon’s initials are “N.O.”, utilize three initials.

2. All sites involving laterality (e.g. brain) and/or paired organs, multiple structures (fingers/toes, hernias, lesions) or multiple levels (spine). Make the mark at or near the incision site(s) so that it will be visible when the patient is draped. (See following exceptions).

3. For hand and foot surgery, the surgeon must mark the surface(s) of the digit to be operated on, anterior, posterior or both.

4. The appropriate site must be verified before any cast is split. For relevant orthopedic cases, the skin/site should be marked immediately after cast/splint is removed.

5. For surgery of the spine, pre-operative skin marking is required to indicate laterality, when appropriate. A second time out must be performed when the intra-operative imaging is done to confirm the level.

6. When the site or level is not visually identifiable, the surgeon must obtain an intra-operative image, using markers that will not move, to confirm the exact level/site.

7. Do NOT mark any non-operative site(s).

8. The mark must be visible in the operative field after the patient is prepped and draped.

9. The mark must be made using an FDA approved marker that is sufficiently permanent to remain visible after completion of the skin prep. Adhesive site markers should not be used as the sole means of marking the site.
Radiology Centers need to be made to understand that not all Offices nor all OR’s are equally equipped.
Radiology Centers need to realize that not all Offices nor all OR’s are the same.
Helping the surgeons comply with these necessary regulations

NYSSOS requests that Administrators and Radiology Chiefs involve the surgeons and surgical staff in these major decisions.
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Intraoperative marking film in spine surgery - 2nd “time-out”
Problems with intraoperative imaging
Problems with intraoperative imaging

- Obesity
- Osteopenia
- Revision surgery
- Landmarks gone
- Experience of radiology technician
- Quality of radiology equipment
Problems with intraoperative imaging
Problems with intraoperative imaging
10. In the event of multiple surgical procedures by different surgeons, all relevant surgical sites must be marked prior to the first surgery. The surgeon marking the site(s) must be present for and participate in the "time out" performed for each procedure he/she marks.

11. Marking must take place with the patient/family involved, awake and aware, if possible.

12. If a smaller mark is necessary, such as near the eye in Pediatric Ophthalmology cases, a dot near the eye constitutes the site marking. A special purpose wristband is also an option.

13. A special purpose wristband must be used for patients:
   - who refuse marking,
   - a neonate (as marking may cause a permanent tattoo),
   - problematic surgical site(s) to mark (e.g., perineum or anus) or when marking can be done only after shaving a patient’s head prior to a neurosurgical/cranial procedure.
   - The first and last name of the patient, a second identifier, the anatomical site and name of the procedure must be written on the special purpose wristband.

14. Final verification of the site mark must take place during the "time out".

E. EXCEPTIONS TO SITE MARKING

1. Single organ cases, which do not involve laterality (e.g., hystrectomy, appendectomy).

2. Spinal block for pain management or epidural does not require an intra-operative marker if fluoroscopy is used. However, it does require skin marking.

3. Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g., cardiac catheterization).

4. Dental cases, where the operative tooth number or name(s) can be indicated on documentation or the operative tooth (teeth) including laterality can be marked on the dental radiographs or dental diagram.

5. Endoscopic or other procedures done through a midline orifice.

6. Situations in which the primary pathology itself is plainly visible (single laceration).

7. When the operative pathology has been identified by real time imaging in the immediate pre-operative period such as for frameless stereotactic neurosurgical procedures or microcalcifications in a breast biopsy.

8. Life threatening emergency when any delay in initiating the surgery would compromise the safety or outcome of the patient (e.g. ruptured aortic aneurysm).

9. When movement of a patient to create a marking would compromise the safety or outcome of the procedure (e.g., movement of a patient with an unstable spine fracture.)

NOTE: A practitioner is NOT exempt from the site-marking requirement when he or she is in continuous attendance with the patient (from the time of the decision to do the procedure through the conduct of the procedure). The requirement for "time out" applies as well. This is based reports of wrong-sided procedures being done despite the continued presence of the person performing the procedure from time to decision to completion of the procedure.
Anterior access vascular surgeon, spine surgeon also present; two posterior surgical sites for spine surgeon
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F. "Time Out" Immediately Before Starting the Procedure

Purpose: To conduct a final verification of the correct patient, site/side, procedure and, as applicable, implants.

The "time out" must be conducted in the location where the procedure will be done, after the patient is prepped and draped and just before starting the procedure. This applies to all invasive procedures performed in all settings. All work should cease during the "time out" to allow all members of the team to focus on the "time out". For instances when the procedure is being performed without assistance, it is strongly advised to enlist an observer or assistant to participate in the "time out". It must involve the entire operative/procedural team, use "active communication", and be documented. The "time out" is a standardized procedure, and documentation indicates the procedure was followed in its entirety without deviation.

"Time out" includes the following:
1. Identification of the patient using 2 patient identifiers, such as, name (first and last) and a second identifier as determined by the organization.
2. Identification of the correct site and side(s).
3. Procedure to be performed and proper patient position.
4. Availability of correct implants and any special equipment or special requirements.
5. Verification of the wristband and chart takes place as the patient is brought into the room and before the "time out". The "time out" requires that all participants agree on the information and does not require checking the wristband at that time.
6. Radiological review, when germane to the case (see below).

The above information should be confirmed with the medical record and should be documented along with the identification of those who participated in the "time out".

Additional Confirmatory "Time out" should be undertaken if a new surgeon arrives and is assuming primary responsibility for the case, or if the patient/operative site is re-draped. The name of the patient and the procedure should be verified during this second "time out".

Radiological Review: The surgeon performing the operation is responsible for determining that the images to be displayed are relevant to the surgery. A second team member confirms that the image belongs to the patient (first and last names and second identifier) and that the image is displayed in the correct orientation, using markers on the image. The team confirms the site and side of the lesion as part of the "time out".

- For spinal cases in which an intra-operative image is used to determine the spinal level, a second "time out" must be performed to review the image and correlate with intra-spinal markers.

Procedures Performed Outside the OR: The person(s) performing the procedure must conduct and document the "time out" confirming all of the above information with another person when possible.

For Surgical Procedures: Instruments/equipment are not offered until after the "time out" is performed.

For the procedure if there is any discrepancy in information identified by any member of the surgical team. Resolve the discrepancy or disagreement before proceeding.
All work stops for the “time out”
F. "TIME OUT" IMMEDIATELY BEFORE STARTING THE PROCEDURE

Purpose: To conduct a final verification of the correct patient, site/site, procedure and, as applicable, implants.

The "time out" must be conducted in the location where the procedure will be done, after the patient is prepped and draped and just before starting the procedure. This applies to all invasive procedures performed in all settings. All work should cease during the "time out" to allow all members of the team to focus on the "time out". For instances when the procedure is being performed without assistance, it is strongly advised to enlist an observer or assistant to participate in the "time out". It must involve the entire operative/procedural team, use "active communication", and be documented. The "time out" is a standardized procedure, and documentation indicates the procedure was followed in its entirety without deviation.

"Time out" includes the following:

1. Identification of the patient using 2 patient identifiers, such as, name (first and last) and a second identifier as determined by the organization.
2. Identification of the correct side.
3. Procedure to be performed and proper patient position.
4. Availability of correct implants and any special equipment or special requirements.
5. Verification of the wristband and chart takes place as the patient is brought into the room and before the "time out". The "time out" requires that all participants agree on the information and does not require checking the wristband at that time.
6. Radiological review, when germane to the case (see below).

The above information should be confirmed with the medical record and should be documented along with the identification of those who participated in the "time out".

Additional Confirmatory "Time out" should be undertaken if a new surgeon arrives and is assuming primary responsibility for the case, or if the patient/site is re-draped. The name of the patient and the procedure should be verified during this second "time out".

Radiological Review: The surgeon performing the operation is responsible for determining that the images to be displayed are relevant to the surgery. A second team member confirms that the image belongs to the patient (first and last names and second identifier) and that the image is displayed in the correct orientation, using markers on the image. The team confirms the site and side of the lesion as part of the "time out".

- For spinal cases in which an intra-operative image is used to determine the spinal level, a second "time out" must be performed to review the image and correlate with intra-spinal markers.

Procedures Performed Outside the OR: The person(s) performing the procedure must conduct and document the "time out" confirming all of the above information with another person when possible.

For Surgical Procedures: Instruments/equipment are not offered until after the "time out" is performed.

If the procedure if there is any discrepancy in information identified by any member of the surgical team. Resolve the discrepancy or disagreement before proceeding.