Wrong Site Surgery Statistical Summary and Highlights

- Requirement to report Sentinel Events to UDOH was instituted on Oct 15, 2001 through the administrative rule process.
- Wrong site surgeries are one type of Sentinel Event required for reporting by licensed hospitals and ambulatory surgical centers.
- 34 wrong site surgical cases have been reported between 10/15/01 and 12/05/05.

To view full summary and highlights, please see page 2.

UCRH Patient Safety Failure Mode and Effects Analysis Results

The data was taken from a Failure Mode and Effects Analysis of the use of the Operating Room Verification Checklist. The tool used was from the Institute for Healthcare Improvement and the information presented is a summary of that analysis.

To view full analysis see page 2.

C-cubed Consensus Procedure


To view entire article see page 6.

C³ Patient Safety Surgery Procedures Brochure

(Correct Patient, Correct Procedure, Correct Site)

Help us, help YOU have a safe surgical experience.

To find out how see page 7.
WRONG SITE SURGERY STATISTICAL SUMMARY AND HIGHLIGHTS

- Requirement to report Sentinel Events to UDOH was instituted on Oct 15, 2001 through the administrative rule process

- Wrong site surgeries are one type of Sentinel Event required for reporting by licensed hospitals and ambulatory surgical centers.

- 34 cases have been reported between 10/15/01 and 12/05/05

- 52% were female, 48% male

- Ages of the patients ranged from 1 day to 93 years

- Total number of facilities reporting events were 21 of a possible 83 (25%)
  - 15/53 hospitals reported (28%)
  - 6/30 ambulatory surgical centers reported (20%)

- Types of events included: wrong knee surgery, wrong finger digit, wrong back disk, wrong sided hip surgery, wrong patient for circumcision, etc.

- Users group was established in 2002 as a collaborative between Utah Department Of Health (UDOH), Utah Hospital Association, Utah Medical Association, and Health Insight. The Sentinel Event users group developed a survey instrument to inventory how patients were identified and marked. Results indicated wide variability ranging from yes/no, X marks the spot, X means no – do not operate here, X/O, happy faces, stickers with scissors, physician initials, patient initials, etc.

- SE Users group worked to establish the consensus standard – C³ or C-Cubed Standard for Correct Patient, Correct Procedure, Correct Site

- C³ Standard was agreed on by hospitals and newspaper ads were published 11/6/05

- All physicians (approximately 7500) who are renewing their licenses through DOPL in 2005 were sent a letter with a copy of the C³ standard with their renewal letter in November 2005

- A Patient Education brochure was developed and put on the UDOH WEB site and made available for anyone to use. http://health.utah.gov/psi/C3initiative.htm

UCRH PATIENT SAFETY FAILURE MODE AND EFFECTS ANALYSIS RESULTS

AUGUST 29, 2005

The following data are taken from a Failure Mode and Effects Analysis of the use of the Operating Room Verification Checklist. The tool used was from the Institute for Healthcare Improvement and the information presented is a summary of that analysis. The UCRH Surgical Services Quality Coordinator facilitated completion of the FMEA with the UCRH Surgical Services Practice Council and UCR QRD Consultants. It should be noted that the Practice Council provided the majority of the action items.

Continued on Next Page
### STEP 1: Verification of the correct patient using two patient identifiers

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Causes</th>
<th>Effects</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient agrees during verification but information is incorrect</td>
<td>Patient does not actively communicate name and birth date</td>
<td>Wrong patient</td>
<td>Ask patient to <strong>state name and date of birth</strong></td>
</tr>
<tr>
<td>Patient cannot participate in verification</td>
<td>Patient is unconscious No family available</td>
<td>Wrong patient</td>
<td>Use <strong>two patient identifier</strong> process</td>
</tr>
<tr>
<td>Identical patient name-different birth date</td>
<td>Birth date is wrong on the ID band or can't read all of birth date on ID band</td>
<td>Wrong patient</td>
<td>Implement process to ensure ID band is checked on nursing unit <strong>before</strong> pt comes to OR Fix the ID band label maker</td>
</tr>
<tr>
<td>Checking 2 patient identifiers when patient is using an alias name</td>
<td>Patient is using alias name for privacy</td>
<td>Wrong patient, procedure</td>
<td><strong>Develop procedure/protocol for checking 2 patient identifiers when patient is using alias</strong></td>
</tr>
<tr>
<td>Multiple trauma patients to OR at same time</td>
<td>Trauma patient ID process</td>
<td>Wrong patient-Mix-up of patient information</td>
<td>Correct problems in trauma ID process</td>
</tr>
</tbody>
</table>

### STEP 2: Verbal verification of the planned/scheduled procedure with the patient

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Causes</th>
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<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient signs consent for wrong procedure, wrong side</td>
<td>Patient not well enough informed</td>
<td>Wrong procedure/site</td>
<td><strong>Add layman terms</strong> for procedure to the procedural consent along side of the medical terminology</td>
</tr>
<tr>
<td>All planned procedures are not on the consent</td>
<td>Procedure(s) not correctly scheduled --incomplete consent</td>
<td>Pt doesn't get all of the procedures he/she thought were going to be done</td>
<td>Preop nurse <strong>prompts</strong> patients--is there anything else you are expecting the surgeon to do today?</td>
</tr>
</tbody>
</table>

### STEP 3: Verification of the patient verification with OR schedule, consent, H&P

<table>
<thead>
<tr>
<th>Failure Mode</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Procedure added but it is not on schedule so this step can't be completed properly</td>
<td>Patient is using alias name Patient desires something additional or surgeon adds additional procedure at last minute</td>
<td>Wrong procedure(s) or incomplete procedure(s); or procedure done without consent</td>
<td><strong>Consult with surgeon</strong> for discrepancies between any of these 3 documents</td>
</tr>
<tr>
<td>Multiple trauma patients to OR at same time</td>
<td>Trauma patient ID process</td>
<td>Wrong patient-Mix-up of patient information</td>
<td>Correct problems in trauma ID process</td>
</tr>
</tbody>
</table>

Continued on Next Page
### STEP 4: Direct Visualization that correct site is marked, where applicable

<table>
<thead>
<tr>
<th>Failure Mode</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Wrong body part is prepped</td>
<td>“Yes” is written outside of operative field, front and back and digit specific</td>
<td>Wrong body part is prepped and case must be re-prepped and draped; Or wrong-site surgery</td>
<td>Add visualization of “yes” after prepping and draping as well as before to the protocol</td>
</tr>
<tr>
<td>This checklist step is required at wrong point in OR process</td>
<td>Verification takes place before site is prepped and draped but not after prepping and draping.</td>
<td>Wrong site surgery; delay</td>
<td>Move this step to later in the checklist to be completed right before the time out; and as part of step 2 verification of procedure</td>
</tr>
<tr>
<td>Site mark is smeared onto adjacent body part</td>
<td>Marked too close to prepping</td>
<td>Incorrect verification of site and delay; wrong-site surgery</td>
<td>Allow site marking dry time prior to prepping</td>
</tr>
<tr>
<td>Checking 2 patient Wrong site is marked</td>
<td>MD inattention or error</td>
<td>Delay or wrong-site surgery</td>
<td>Visualize “Yes” at correct site and use very active communication during final time out</td>
</tr>
<tr>
<td>Wrong site prepped and draped</td>
<td>Surgeon marks after patient is draped</td>
<td>Wrong site; or delay</td>
<td>Marking occurs prior to prep, the “Yes” is visualized and confirmed as part of the time out.</td>
</tr>
<tr>
<td>Can't visualize “yes” after prepping and draping</td>
<td>“Yes” is covered by drape</td>
<td>Wrong site procedure, or re-draping</td>
<td>Obtain/use clear drapes</td>
</tr>
</tbody>
</table>

### STEP 5: Verification of correct patient ID on all radiography images, where applicable

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Causes</th>
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<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging verification does not occur prior to time out.</td>
<td>Images not available when completing checklist. Image front and back are not identified and the image is backwards on viewing screen</td>
<td>Wrong images, Delay in procedure, wrong surgery</td>
<td>Reinforce completion of active Time Out process which includes checking radiography images Check front vs back display of image</td>
</tr>
<tr>
<td>This step is not consistently completed on the checklist-nurse doesn’t know if it’s done or not</td>
<td>Surgeon checks films on computer prior to entering OR</td>
<td>Incomplete documentation; Wrong site surgery</td>
<td>Reword this step on checklist to take off the word “All” so as to refer to images viewed in the operating room only.</td>
</tr>
<tr>
<td>Verification is not real time at point of care</td>
<td>Access to computer is outside of OR room</td>
<td>Wrong site surgery</td>
<td>Review opportunities for point of service access</td>
</tr>
</tbody>
</table>
### STEP 6: Verification of any required implants, may occur intra-procedure

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Causes</th>
<th>Effects</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Correct implant not available</td>
<td>Inventory not checked prior to procedure bring correct implant, surgeon changes implant request, Implant request not scheduled.</td>
<td>Case delay, Case cancelled, different implant results in less desirable outcome</td>
<td>Check implant availability/preference when the procedure is scheduled.</td>
</tr>
<tr>
<td>Wrong implant used</td>
<td>Implant not verified with surgeon</td>
<td>Less desirable outcome or return to surgery</td>
<td>Visualize requested implants prior to procedure; verbalize with surgeon what implant is wanted.</td>
</tr>
</tbody>
</table>

### STEP 7: Intraoperative x-rays are performed to verify and mark the “specific spinal level”

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Causes</th>
<th>Effects</th>
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</tr>
</thead>
<tbody>
<tr>
<td>2 patient identifiers not verified on x-rays</td>
<td>Wrong x-rays brought into OR</td>
<td>Wrong level of spine, delay</td>
<td>Always check 2 patient identifiers on x-rays</td>
</tr>
</tbody>
</table>

### STEP 8: A “Time Out” final team verification using active communication occurred prior to start of procedure

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Causes</th>
<th>Effects</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time out not done effectively</td>
<td>Surgeon hassles circulator; Unclear who initiates time-out</td>
<td>Incomplete documentation; wrong pt, site, procedure</td>
<td>Require physician to initiate time-out. The time-out is fully utilized to perform thorough final verification of correct patient/site/procedure</td>
</tr>
<tr>
<td>Inattention during time-out</td>
<td>All team members don’t actively participate; Not all team members present</td>
<td>Wrong site, person, procedure</td>
<td>All team members take time out seriously or face serious, immediate consequences from leadership/administration</td>
</tr>
</tbody>
</table>

### Step 9: Circulator completes and signs checklist

<table>
<thead>
<tr>
<th>Failure Mode</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Step inadvertently missed; process step not completed</td>
<td>Step(s) of checklist not completed, form not signed</td>
<td>Incomplete documentation/wrong person, site or procedure done</td>
<td>The time-out is fully utilized to perform thorough final verification of correct patient/site/procedure. This allows for completion of this step.</td>
</tr>
</tbody>
</table>
**C³ CORRECT PATIENT, CORRECT PROCEDURE, CORRECT SITE**

Marking and Time-Out Procedure  
Utah Patient Safety Steering Committee  
Sentinel Event Users Group, September 2005

**Patient Surgery Safety Procedures**

*Site Markings and Explanations*

- **Step 1:** The accountable person (surgeon or procedural person is preferred) performing the procedure should mark the site with the patient prior to pre-operative medication or anesthesia when feasible.

- **Step 2:** Markings should be made with the word “YES”. A line or dots for pediatric, facial or cosmetic surgeries may be utilized when necessary. Procedures involving right/left distinction, multiple structures such as fingers and toes, or multiple levels as in spinal procedures should be differentiated by the markings. A surgical skin marker should be used for marking the site and the mark should be visible after the patient is prepped and draped.

*Patient Verification*

- **Step 3:** Patient and/or person giving consent (if patient is unable due to cognition problems, consciousness, language, readability of the consent form, or understanding) should indicate that correct site has been marked. If patient refuses marking, documentation of the refusal must be secured. If the H&P, surgical consent, patient’s view of the site and nurses view of the site do not all agree, the patient is not brought into the operating room. If x-rays are available, the surgeon shall review prior to beginning the procedure.

**Time Out**

- **Step 4:** The facility will define the accountable person (surgeon or procedural person is preferred) for calling a “time out” prior to actual start of the procedure.
  1. The “time out” includes active (affirmative) participation from the procedure team, including but not limited to support staff, anesthesia, provider and nursing staff.
  2. The “time out” is to occur in the location where the procedure is being performed (operative, procedure or patient room) but prior to actual commencement of procedure.

- **Step 5:** The “time out” must include:
  1. C¹ - Correct patient must be verified with two patient identifiers defined by the facility.
  2. C² - Correct procedure (including implants) must be verified with consent form and medical documentation.
  3. C³ - Correct site (procedures involving right/left distinction, multiple structures such as fingers and toes, or multiple levels) must be verified with consent form and medical documentation.

**Exception:** The exception to the above marking procedure would be in the case of emergency surgery where the provider is present continuously with the patient from the time the decision to perform the procedure and until procedure is complete. A “time out” should still occur unless it would add more risk than benefit to the patient.
C³ C-CUBED

PATIENT SAFETY SURGERY PROCEDURES

HELP US, HELP YOU HAVE A SAFE SURGICAL EXPERIENCE BY FOLLOWING THE ENCLOSED PROCEDURES.

We are a group of healthcare professionals in the state of Utah committed to providing high quality and safe care. We recognize that we can not do this alone. We therefore need your help in preventing wrong site surgeries in our institutions. The way that you can help us is by understanding and following the safety procedures listed below.

Marking and Explanations
Step 1 – The provider who is doing your procedure should have met with you, explained to you what to expect from the surgery experience, and marked your site prior to you getting any medication or anesthesia.

Step 2 – Your site should be marked with a “YES”. If you are a child or are having cosmetic surgery a line or dot is acceptable. The site should be marked with a surgical skin marker and visible after you have been prepped and draped.

Patient Verification
Step 3 – It is you or your legal guardian’s job to make sure that the site that is marked is the correct site. This means that a health professional will verify with you by asking the following C³ questions:

C¹) Who you are?
C²) What surgery you are having?
C³) On which part of the body are you having the surgery?

If you are the wrong patient, OR this is the wrong procedure OR it is on the wrong site
STOP!! STOP!! STOP!! STOP!!

If you have confusion OR you are unsure, STOP the process and ask for clarification and verification!

The health professional will be verifying the information you give them with their records, any pictures, x-rays, or reports.

If you refuse to be marked, the health professional must document your refusal.

TIME-OUT
Step 4 – Much like a captain of a ship or airplane, a review of the safety check list is essential. This is the purpose of a TIME-OUT right prior to surgery.

TIME-OUT may take place in the operating room and you, the patient may not actually be awake.

Step 5: One more round of verification steps to protect your safety! Your provider should call the time out in order to check the following:

C¹) Are you the correct patient? – at least two identifiers must be used.
C²) Have you consented to the right procedure? – your consent form and medical documentation will be reviewed against the currently planned procedure.
C³) Is this the right site? - this is verified with the medical record, your consent form, and any images available.

Questions to ask your provider team
1) What is the name of the surgery you are performing?
2) Where or what body part will you be operating on?
3) What are the risks of this procedure?
4) Who is in charge of the surgery team? What is their name?
5) What have been the steps that you have take to assure that my surgical procedure is correct?
6) What are your plans for a time out?
7) How can I help in assuring that I do not experience wrong site surgery?

References and sponsorships

20 Tips to Help Prevent Medical Errors.
www.ahcpr.gov/consumer/20tips.htm

Ways You Can Help Your Family Prevent Medical Errors!
www.ahcpr.gov/consumer/5tipseng/5tips.htm
Acknowledgements

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The Consortium includes the following members:

- Utah Department of Health
  - HealthInsight
- UHA, Utah Hospitals and Health Systems Association
- University of Utah, Department of Medical Informatics
- LDS Hospital, Intermountain Health Care
- Missouri Department of Health and Senior Services
- Missouri Patient Care Review Foundation
- University of Missouri-Columbia, School of Medicine

This report was prepared by Iona Thraen and Lori Brady. We wish to thank all contributors for their articles in this issue.

For more information about this project, contact Iona Thraen at (801) 538-6471 or ithraen@utah.gov.