Provision of Consistently Safe and High Quality Patient Care: Challenges and Solutions

Paul Lee, MD, LLD

Chair, Department of Ophthalmology

James Bagian, MD, PE

Director, Center for Healthcare Engineering and Patient Safety

Problem/Challenges

- Harm to patients in peri-op period
- Lack of robust systems-based approach
- Standardized approaches lacking
- Denial
- Culture

Background


Correct Site Surgery

Ensuring Correct Surgery

The Problem
(What's the Rate?)

- The (non-VA) Rate in NY State was about 1 in 15,500 surgeries in 2001 (NYPORTS mandatory reporting system)
- The VA Rate in 2001 was about 1 in 25,000 surgeries (using NYPORTS's Definition) - averages to one a month
- These numbers assume 100% were reported and counted

The Problem
(What Happened?)

Based on Review of VA Root Cause Analyses:

- 44% were left-right mix-ups on the correct patient
- 36% were wrong patient
- 14% were wrong implant or procedure on correct patient
- 7% were wrong site (*not* left-right) on correct patient

The Problem
(Where on the body?)

- Eye
- Groin or Genitals
- Chest
- Leg
- Hand, Wrist, or Finger
- Abdomen
- Back
- Head, Neck, Mouth, Anus, Colon, Buttock

Five Steps in Directive

1. Consent Form must state:
   - site of the procedure
   - laterality (if applicable)
   - name of the procedure
   - reason for the procedure

Would have Prevented 45%

Five Steps in Directive

2. Marking the Site
   - Mark with Initials, an “X,” or “YES”
   - **Mark All Sites**
   - Physician or Other Privileged Provider
   - Mark Close to Site
   - Don’t Mark Other Side or Elsewhere

Would have Prevented 65%

Five Steps in Directive

3. Patient Identification

The patient must be asked to *state*:

- full name
- social security number or birth date
- site of the procedure

Staff check answers against the marked site, I.D. band, consent form, other documents

Would have Prevented 75%

Five Steps in Directive

4. Take “Time-out” in the OR

Before Surgery Starts OR Staff Verbally Verify their Agreement on:

- the name of the patient
- the procedure to be performed
- the site of the procedure, including laterality
- the implant to be used (if applicable)

Would Have Prevented 85%

Five Steps in Directive

5. Check Imaging Data

When physicians will refer to pre-existing images, facilities must ensure that two members of the OR team have confirmed that the images are available, correct, properly labeled, and properly presented.

Would Have Prevented 20%

Effectiveness of 5 Steps

- About 80% of incorrect surgeries described in RCAs would have been caught by 3 or 4 steps
- Less than 5% would have been caught by only one step
- System promises effectiveness and a degree of fault tolerance

Ensuring Correct Surgery in the Veterans Health Administration

Days to hours before surgery

☑ Step 1: Consent Form

The consent form must include:

- patient's full name
- procedure site and side
- name of procedure
- reason for procedure

☑ Step 2: Mark Site

The operative site must be marked by a physician or other privileged provider who is a member of the operating team

☞ Do **NOT** mark non-operative sites

Just before entering OR

☑ Step 3: Patient Identification

OR staff shall ask the patient to state (NOT confirm):

- their full name
- full SSN or date of birth
- site for the procedure

☞ Check responses against the marked site, ID band, consent form and other documents

Immediately prior to surgery

☑ Step 4: "Time Out"

Within the OR when the patient is present and prior to beginning the procedure, OR staff must verbally confirm through a "time out":

- presence of the correct patient
- *patient properly positioned*
- marking of the correct site and side
- procedure to be performed
- availability of the correct implant

☑ Step 5: Imaging Data

If imaging data is used to confirm the surgical site, two members of the OR team must confirm the images are correct and properly labeled

For more information see the Veterans Health Administrative Directive 2004-028 and your Patient Safety Manager _____

* *Indicates new item for Directive 2004-028 (http://www.patientsafety.gov/CorrectSurgDir.pdf or http://www.ncps.med.va.gov/CorrectSurgDir.pdf)*

Revised August 2004

Produced by the Department of Veterans Affairs National Center for Patient Safety (www.patientsafety.gov or www.ncps.med.va.gov)

Lessons (1)

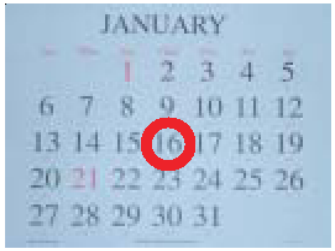
- Clear and accepted problem
- Involve key players in pilot tests of specific changes (volunteers)
  - Surgeons
  - Nurses
  - Anesthesia Providers
  - Patient Safety Managers
- Least Force Necessary – acknowledge existing business processes

Lessons (2)

- Provide Leadership/Direction, specifically:
  - Provide a detailed example of a local policy document for implementation – don't force each hospital/facility to write a new policy from scratch
  - Rationale should be included as a Contextual Reference
  - Provide Cognitive Aids and Tools to facilitate compliance

Ensuring Correct Surgery in the Veterans Health Administration

Days to hours before surgery



☑ Step 1: Consent Form

The consent form must include:

- patient's full name
- procedure site
- name of procedure
- reason for procedure

☑ Step 2: Mark Site

The operative site must be marked by a physician or other privileged provider who is a member of the operating team

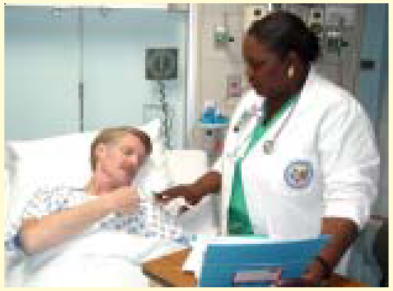
☞ **Do NOT mark non-operative sites**

Just before entering OR

☑ Step 3: Patient Identification

OR staff shall ask the patient to state (NOT confirm):

- their full name
- full SSN or date of birth
- site for the procedure



☞ Check responses against the marked site, ID band, consent form and other documents

Immediately prior to surgery

☑ Step 4: "Time Out"

Within the OR when the patient is present and prior to beginning procedure, OR staff must verbally confirm through a "time out":

- presence of the correct patient
- marking of the correct site
- procedure to be performed
- availability of the correct implant

☑ Step 5: Imaging Data

If imaging data is used to confirm the surgical site, two or more members of the OR team must confirm the images are correct and properly labeled

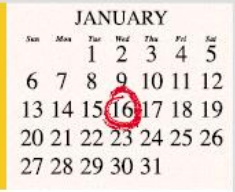
For more information see the Veteran's Health Administration Directive and your Patient Safety Manager _____

Produced by the Department of Veterans Affairs National Center for Patient Safety
(*www.patientsafety.gov* **or** *vaww.ncps.med.va.gov*)

October 25, 2002

Ensuring Correct Patient, Correct Site, Correct Procedure

Days to hours before procedure



Step 1: Consent form or procedure request form

The consent form must include:

- patient's full name
- procedure site
- name of procedure
- reason for procedure

Step 2: Mark site of invasive procedure

The operative site for an invasive procedure must be marked by the person in charge of the procedure or another senior team member who has been fully briefed about the operation or procedure.

! Do NOT mark non-operative sites

Just before entering operating theatre or treatment room

Step 3: Patient identification

Staff must ask the patient to state (NOT confirm):

- their full name
- date of birth
- site for, or type of procedure

! Check responses against the marked site, ID band, consent form and other documents

Immediately prior to procedure

Step 4: "Team time out"

Within the operating theatre or treatment room when the patient is present and prior to beginning the procedure, staff must verbally confirm through a "team time out", when all other activity in the operating room is stopped:

- presence of the correct patient
- the correct site has been marked
- procedure to be performed
- availability of the correct implant where required

Step 5: Imaging data

If imaging data are used to confirm the site or procedure, two or more members of the team must confirm the images are correct and properly labelled.

This Protocol has been adapted with kind permission from the Department of Veterans Affairs National Center for Patient Safety (USA) Directive on Ensuring Correct Surgery.

Safety+Quality

Royal Australasian College of Surgeons

Case Example - IOL

- Paul do you want to summarize the IOL issue on a slide?
- Follow with an additonal slide summarizing what the interventions were
  - Problem recognition of faculty
  - Leadership taking ownership and clearly articulating expectations with sense of urgency
  - Etc…

ORIGINAL ARTICLE

Incorrect Surgical Procedures Within and Outside of the Operating Room

Julia Neily, RN, MS, MPH; Peter D. Mills, PhD, MS; Noel Eldridge, MS; Edward J. Dunn, MD, MPH; Carol Samples, BGS; James R. Turner, BS; Audrey Revere; Ralph G. DePalma, MD; James P. Bagian, MD, PE

Objective: To describe incorrect surgical procedures reported from Veterans Health Administration (VHA) Medical Centers from 2001 to mid-2006 and provide proposed solutions for preventing such events.

Design: Descriptive study.

Setting: Veterans Health Administration Medical Centers.

Participants: Veterans of the US Armed Forces.

Interventions: The VHA instituted an initial directive, "Ensuring Correct Surgery and Invasive Procedures," in January 2003. The directive was updated in 2004 to include non–operating room (OR) invasive procedures and incorporated requirements of The Joint Commission Universal Protocol for preventing wrong-site operations.

Main Outcome Measures: The categories included 5 incorrect event types (wrong patient, side, site, procedure, or implant), major or minor surgical procedures, location in or out of the OR, therapeutic or diagnostic events, adverse event or close call, inpatient or ambulatory events, specialty department, body segment, and severity and probability of harm.

Results: We reviewed 342 reported events (212 adverse events and 130 close calls). Of these, 108 adverse events (50.9%) occurred in an OR, and 104 (49.1%) occurred elsewhere. When examining adverse events only, ophthalmology and invasive radiology were the specialties associated with the most reports (45 [21.2%] each), whereas orthopedics was second to ophthalmology for number of reported adverse events occurring in the OR. Pulmonary medicine cases (such as wrong-side thoracentesis) and wrong-site cases (such as wrong spinal level) were associated with the most harm. The most common root cause of events was communication (21.0%).

Conclusions: Incorrect ophthalmic and orthopedic surgical procedures appear to be overrepresented among adverse events occurring in ORs. Outside the OR, adverse events by invasive radiology were most frequently reported. Incorrect surgical procedures are not only an OR challenge but also a challenge for events occurring outside of the OR. We support earlier communication based on crew resource management to prevent surgical adverse events.

Arch Surg. 2009;144(11):1028-1034

ORIGINAL ARTICLE

ONLINE FIRST

Incorrect Surgical Procedures Within and Outside of the Operating Room

A Follow-up Report

Julia Neily, RN, MS, MPH; Peter D. Mills, PhD, MS; Noel Eldridge, MS; Brian T. Carney, MD; Debora Pfeffer, RN, MBA; James R. Turner, BS; Yinong Young-Xu, ScD, MA, MS; William Gunnar, MD, JD; James P. Bagian, MD, PE

Objective: To describe incorrect surgical procedures reported from mid-2006 to 2009 from Veterans Health Administration medical centers and build on previously reported events from 2001 to mid-2006.

Design: Retrospective database review.

Setting: Veterans Health Administration medical centers.

Interventions: The Veterans Health Administration implemented Medical Team Training and continues to support their directive for ensuring correct surgery to improve surgical patient safety.

Main Outcome Measures: The categories were incorrect procedure types (wrong patient, side, site, procedure, or implant), major or minor surgery, in or out of the operating room (OR), adverse event or close call, specialty, and harm.

Results: Our review produced 237 reports (101 adverse events, 136 close calls) and found decreased harm compared with the previous report. The rate of reported adverse events decreased from 3.21 to 2.4 per month ($P=.02$). Reported close calls increased from 1.97 to 3.24 per month ($P\leq.001$). Adverse events were evenly split between OR (50) and non-OR (51). When in-OR events were examined as a rate, Neurosurgery had 1.56 and Ophthalmology had 1.06 reported adverse events per 10 000 cases. The most common root cause for adverse events was a lack of standardization of clinical processes (18%).

Conclusions: The rate of reported adverse events and harm decreased, while reported close calls increased. Despite improvements, we aim to achieve further gains. Current plans and actions include sharing lessons learned from root cause analyses, policy changes based on root cause analysis review, and additional focused Medical Team Training as needed.

Arch Surg. 2011;146(11):1235-1239. Published online July 18, 2011. doi:10.1001/archsurg.2011.171

Findings & Conclusions

- Introduction of systems-based policies and techniques reduced reported adverse events and increased reporting of close calls
- Situation improved but not ideal
- Need for improved interteam communication and techniques
- Same issues identified in Case Example

Case Example - Clinic (Hakan?)

- Paul do you want to summarize the Hakan issue on a slide(s)?
- Follow with an additonal slide summarizing what the interventions were taken

Findings & Conclusions

- Sub-optimal inter-team communication
- Lack of shared goals and mental model regarding methods, roles, and responsibilites
- Communication requires more than email to build cooperation and trust
- Allotting resources to solve problems
  - Part of everyones job

Overarching Points

- View care processes from perspective of the goal
  - Patient care that is safe and effective from patient's perspective
- Consider all system components
  - Get out of silo – "Master of Universe Approach"
- Need for true quality assurance that assesses competency – MOC etc
- Professional Responsibilities

Professionalism: A Personal Litmus Test

- I am proud to have any clinical decision I make published on the front page of the newspaper for all of my friends, colleagues, and patients to read.
- The clinical care and the manner in which I treat my patients is the same that I would choose for someone I love.
- If I witness any patient receiving care that doesn't comport with the two criteria above it is my **DUTY** and **OBLIGATION** to take action.