# SURGICAL MEDICAL ERRORS: PREVENTING WRONG SITE SURGERY & INVASIVE PROCEDURES

## 2 CONTACT HOURS

## COURSE DESCRIPTION

This course provides the learner with the knowledge and skills that are necessary to individually and collectively insure patient safety with the prevention of wrong person, wrong site and wrong procedure surgeries and invasive procedures. Surgical interventions and other invasive procedures, such as intubation, are at high risk for medical errors and they occur with alarmingly high frequency.

The content of the course includes medical error and wrong site surgery statistics; National Patient Safety Goals relating to some of the root causes associated with medical errors, including wrong site surgeries; ways to recognize and correct error and problem-prone situations; and some processes, such as JCAHO's *Universal Protocol,* to prevent wrong site surgeries in the operating room and other areas where invasive procedures are done.

## OBJECTIVES:

At the conclusion of this course, the learner will be able to:

1. Describe the impact of medical errors and the frequency of wrong site surgeries.
2. Detail ways to prevent medical errors relating to surgery and other invasive procedures.
3. Identify populations at risk for wrong site surgeries and other medical errors.

## INTRODUCTION

*To Err Is Human: Building a Safer Health System,* published in 1999 by the Institute of Medicine Committee on Quality of Healthcare in America, is viewed as the powerful vehicle that jolted, awakened and enlightened the entire healthcare community and the public regarding the seriousness and frequency of medical errors.

This report  was the impetus for serious and wide sweeping introspection and change that involved all those in healthcare and the entire nation, including lawmaking bodies at all levels. Necessary healthcare culture changes, laws, and regulatory body mandates in reference to medical errors shortly followed our nationwide awakening and enlightenment as a result of this ground breaking report.

To read *To Err Is Human: Building a Safer Health System* in its entirety online at no cost, go to www.nap.edu/books/0309068371/html

A couple of years later, in 2001, the Institute of Medicine's Committee on Quality of Health Care in America moved beyond its initial report with their new publication entitled *Crossing the Quality Chasm: A New Health System for the 21st Century*. This publication made many suggestions and recommendations for change with the aim of decreasing and eliminating any proneness to medical errors. Technology and the use of technological advances, among other recommendations, were emphasized in this work

To read *Crossing the Quality Chasm* in its entirety, go to <www.nap.edu/books/0309072808/html>.

**WHAT ARE MEDICAL ERRORS?**

Many equate "medical errors" with "medication errors", which is not accurate. Although medication errors are an example of a medical error, they are only one of many types of medical errors. Some other medical errors include:

- Wrong site surgeries
- Suicides
- Faulty laboratory testing
- Lack of a timely and complete psychiatric evaluation
- Blood and blood product errors
- Diagnostic errors
- Equipment failures and malfunctions
- Falls
- Infections and

- Others

All healthcare professionals are at risk for medical errors and making other mistakes. A nurse could transport the wrong patient to the operating room; a respiratory therapist could give the wrong medication to a patient or intubate the incorrect patient; and a licensed midwife could administer an incorrect dosage of oxytocin to the mother after delivery.

Since 1985, Florida State has mandated the reporting of certain serious adverse incidents within the control of the healthcare industry as well as other conditions, such as epidemic outbreaks, that are primarily outside of the control of the healthcare industry.

Florida Statute 395.0197 requires that certain sentinel events be reported to the State. These sentinel events include ones that result in the death of a patient; brain or spinal damage to a patient; the performance of a surgical procedure on the wrong patient; the performance of a wrong-site surgical procedure; and the performance of a wrong surgical procedure.

Additionally, the Florida Statute requires extensive investigation and follow-up reporting to the State within 15 days of the above sentinel events and also that the patient and/or family member be told about the error. JCAHO also requires this patient and family disclosure. For more information about Florida Statutes go to this link:

http://www.leg.state.fl.us/Statutes/index.cfm?Mode=View%20Statutes&Submenu=1&Tab=statutes

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has also instituted new standards after the publication of "*To Err is Human*" in 1999.

JCAHO mandates that every healthcare facility has formal mechanisms to identify, analyze, and prevent medical errors. They mandate that all sentinel events, affecting patients, staff, and/or visitors, are analyzed and addressed with a corrective action plan. Although JCAHO strongly e*ncourages* healthcare facilities to send the results of all of their timely, thorough, and credible root cause analyses as well as the correlate corrective action plans, it is *mandatory* that all those analyses and corrective plans associated with a death or serious injury, such as one of the following, be submitted to them:

- unanticipated major loss of function;

- the suicide of a patient in a setting where the patient receives around-the-clock care;
- infant abduction or the discharge of an infant or child to the wrong family;
- rape;
- a hemolytic transfusion reaction involving the administration of blood or blood products with major blood group incompatibilities; or
- surgery on the wrong patient or the wrong body part.

Between January of 1995 and December 31, 2004, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has reviewed a total of 2,966 sentinel events. These sentinel events and their reporting permits us to be forewarned about the types of situations and circumstances that are at high risk for error. Each year, JCAHO updates and publishes a compilation of all sentinel events, and other information, in order to communicate this valuable data to all healthcare providers and the public.

Below is a table that shows each type of sentinel event, in descending order of frequency for the year 2004, the number of cases and the percent of all cases for that year.

## Sentinel Event Statistics: As of December 31, 2004

| Type of Sentinel Event | # | % |
|---|---|---|
| Patient suicide | **415** | 14.0% |
| Op/post-op complication | **365** | 12.3% |
| Wrong-site surgery | **370** | 12.5% |
| Medication error | **326** | 11.0% |
| Delay in treatment | **221** | 7.5% |
| Patient death/injury in restraints | **124** | 4.2% |
| Patient fall | **144** | 4.9% |
| Assault/rape/homicide | **107** | 3.6% |
| Transfusion error | **85** | 2.9% |
| Perinatal death/loss of function | **84** | 2.8% |
| Patient elopement | **57** | 1.9% |
| Fire | **51** | 1.7% |
| Ventilator death/injury | **39** | 1.3% |
| Anesthesia-related event | **49** | 1.7% |
| Infection-related event | **57** | 1.9% |
| Medical equipment-related | **37** | 1.2% |
| Maternal death | **38** | 1.3% |
| Infant abduction/wrong family | **21** | 0.7% |
| Utility systems-related event | **18** | 0.6% |
| Other less frequent types | **358** | 12.1% |

| Sentinel Event Outcomes | # | % |
|---|---|---|
| Patient death | **2279** | 74% |
| Loss of Function | **312** | 10% |
| Other | **492** | 16% |
| Total patients impacted | **3083** | 100% |

| Settings of Sentinel Events | # | % |
|---|---|---|
| General hospital | **1935** | 65.2% |
| Psychiatric hospital | **361** | 12.2% |
| Behavioral health facility | **157** | 5.3% |
| Psych unit in general hospi | **150** | 5.1% |
| Emergency department | **124** | 4.2% |
| Long term care facility | **99** | 3.3% |
| Home care | **57** | 1.9% |
| Ambulatory care | **74** | 2.5% |
| Clinical laboratory | **6** | 0.2% |
| Health care network | **2** | 0.1% |
| Office-based surgery | **1** | 0.0% |

| Sources for SE Identification | # | % |
|---|---|---|
| Self-report | 1885 | 63.6% |
| Media | 263 | 8.9% |
| Complaints | 308 | 10.4% |
| Identified during survey | 224 | 7.6% |
| CMS or State reports | 160 | 5.4% |

*Source:* JCAHO Sentinel Event Statistics, December 31, 2004
http://www.jcaho.org/accredited+organizations/sentinel+event/se_stats_1204.pdf

**PREVENTING MEDICAL ERRORS**

On an annual basis, for the last several years, JCAHO has published National Patient Safety Goals for hospitals, long term care and assisted living facilities, ambulatory care, behavioral health care, critical access hospitals, office based surgery, home care, laboratory, healthcare networks and disease specific care. All of these Patient Safety Goals

include not only goals but also, more importantly, ways that these commonly occurring root causes can be prevented. All of the National Patient Safety Goals can be accessed at the Joint Commission on Accreditation of Healthcare Organization's website at www.jcaho.org

The JCAHO (2005) Patient Safety Goals for *Hospitals* are as follows:

"Goal: Improve the accuracy of patient identification.

- Use at least two patient identifiers (neither to be the patient's room number) whenever administering medications or blood products; taking blood samples and other specimens for clinical testing, or providing any other treatments or procedures.

Goal: Improve the effectiveness of communication among caregivers.

- For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the order or test result "read-back" the complete order or test result.
- Standardize a list of abbreviations, acronyms and symbols that are not to be used throughout the organization.
- Measure, assess and, if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values.

Goal: Improve the safety of using medications.

- Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride >0.9%) from patient care units.
- Standardize and limit the number of drug concentrations available in the organization.
- Identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used in the organization, and take action to prevent errors involving the interchange of these drugs.

Goal: Improve the safety of using infusion pumps.

- Ensure free-flow protection on all general-use and PCA (patient controlled analgesia) intravenous infusion pumps used in the organization.

Goal: Reduce the risk of health care-associated infections.

- Comply with current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines.
- Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a health care-associated infection.

Goal: Accurately and completely reconcile medications across the continuum of care.

- During 2005, for full implementation by January 2006, develop a process for obtaining and documenting a complete list of the patient's current medications upon the patient's admission to the organization and with the involvement of the patient. This process includes a comparison of the medications the organization provides to those on the list.
- A complete list of the patient's medications is communicated to the next provider of service when it refers or transfers a patient to another setting, service, practitioner or level of care within or outside the organization.

Goal: Reduce the risk of patient harm resulting from falls.

- Assess and periodically reassess each patient's risk for falling, including the potential risk associated with the patient's medication regimen, and take action to address any identified risks." (JCAHO, 2005)

**ROOT CAUSES ASSOCIATED WITH WRONG SITE SURGERY**

The root causes most generally associated with wrong site surgery include:

- Physical assessment
- Patient identification
- Staffing levels
- Orientation and training of staff
- Communication with the patient and family
- Communication among staff members
- Availability of information

## WAYS TO PREVENT WRONG SITE, WRONG PROCEDURE, WRONG PERSON SURGERIES AND OTHER INVASIVE PROCEDURES

"A long day was ending, and Dr. Charles E. Cox, head of the breast clinic at Moffitt Cancer Center, had two patients left. One was to have her left breast removed. The other, a less radical lumpectomy to take out a tumor.

According to the complaint, the 66-year-old woman had been diagnosed with cancer of her left breast. She came to Moffitt Nov. 20, 1998, to have the tumor removed, a procedure called a lumpectomy. Instead, she was mistaken for a patient scheduled for a mastectomy, or breast removal, the agency says. The patient's name was not disclosed.

The patient didn't sue, but the University of South Florida, which is affiliated with Moffitt, paid an undisclosed sum to settle the matter, a spokeswoman said. [Moffitt] also offered to reconstruct her breast, but the patient has declined so far, Cox said." (Allison, 2001)

*Accurate Patient/Resident/Client Identification*

One area that must consistently be addressed, whether or not the person is in a high risk for medical errors population of not, is patient/resident/client identification. Accurate identification is necessary for all aspects of diagnosis and treatment. JCAHO requires that at least two (2) unique identifiers, other than room number, are used prior to the administration of medications, blood and blood products, blood and other laboratory specimens and other treatments and procedures. Some examples of unique identifiers include the person's:

- first, middle and last name;
- unique code number assigned to that person upon admission;
- social security number;
- birthday in terms of month, day and year;
- photograph; and
- encoded bar code containing two (2) or more unique identifiers.

Another area that must be consistently addressed is JCAHO's *Universal Protocol For Preventing Wrong Site, Wrong Procedure and Wrong Person Surgeries*.

### The Universal Protocol For Preventing Wrong Site, Wrong Procedure and Wrong Person Surgeries

Wrong site, wrong procedure and wrong person surgeries can be prevented. The Joint Commission on the Accreditation of Healthcare Organizations (2003) has established the *Universal Protocol For Preventing Wrong Site, Wrong Procedure and Wrong Person Surgeries* as the standard for the prevention of these surgical errors. The protocol requires that a comprehensive and complete process with three (3) major components be done before all surgical and invasive procedures within and outside of the operatiing room. The setting of the intervention is irrelevant. The procedure must be carried out in all areas where surgical or invasive procdures are done. These settings can include, but are not limited to, radiology areas, endoscopy areas, and special procedure rooms.

Commonly occurring, routine, invasive procedures, such as venipucture and nasogastric tube placment, are <u>not</u> procedures that are included in this *Universal Protocol,* however, most other procedures including biopsies, endoscopies and others that include an incision, puncture, and/or insertion of an foreign body, including a medical instrument, are included in the *Universal Protocol.*

This protocol underscores the need for communication among the members of the healthare team and communicaition with the patient, or legal surrogate, throughout the process which consists of:

1. Pre-operative verification
2. Marking the operative site and
3. Time out

*Pre-operative verification*

The verification of data and documentation is done throughout the pre-procedure course up to, and including during the time out period. This step is done in order to identify any inconsistencies of data, any inconsistencies between healthcare providers, any inconsistencies among the data, the patient and the documentation. If any inconsistencies are noted, they are investigated and corrected immediately. (JCAHO, 2004)

*Marking the operative site*

A visible marking of the operative site is done with special attention to right-left discrimination, multiple surgical sites and to multiple levels, as is the case with spinal surgeries. Adhesive backed dots and marks are NOT acceptable as the only method of marking an operative site.

As we know, they can fall off and move about. The person who will perform the procedure marks the surgical or interventional site. When this is not possible, another person from the surgical team, such as a registered nurse who has full knowledge of the patient and the intended procedure or intervention, can do the marking of the operative site if consistent with applicable state law. Surgical pens that leave visible markings that remain after prepping are used.

The intended site is marked before the person is moved into the procedure oroperating room and, whenever possible, with patient involvement. When the patient is not able to participate, the surrogate decision maker takes on this role. All markings must be unambiguous and consistent throughout the organization. An "X" is strongly discouraged because an "X" can signify no and it can also mark the surgical site. It is, therefore, ambiguous. "No" is also not acceptable. The marking must mark the *intended site*, not an unintended one. Initials, and "yes" are unambiguous and acceptable for surgical site marking.

Previous markings must be completely removed and replaced with new markings when a patient undergoes more than one surgical or invasive procedure during the course of hospitalization, unless the same site is used repeatedly.

Marking the surgical site is not necessary when:

- there is a single, very obvious wound or lesion requiring the intervention, however, multiple wounds and/or lesions must be marked for intervention when these are and others are not considered for intervention;
- a physician, or another healthcare professional, makes a decision to perform a surgical or invasive procedure and remains constantly in the direct presence of the client until the procedure is completed. Placement of a chest tube in the patient's room is an example of this kind of intervention;
- an extreme medical emergency occurs and the benefits of rapidity and timeliness are of greater benefit than marking the surgical, or intervention, site. In unusal emergency the benefits of timeliness outweigh the benefits of verification and site marking. Additionally, during these high priority emergency situations, the physician performing the interventions is in constant attendace; and/or

- the patient refuses the site marking after a thorough discussion of the benefits of this marking and the risks associated with refusing surgical site marking. (JCAHO, 2004)

When, for any reason, the surgical marking is not done, the preoperative verification process and a "time out" must still be done. (JCAHO, 2004)

*Time out*

This final verification stage is done immediately post-op in the operative area so that the right person, the right procedure, the right site and the right implant, if applicable, is again confirmed. Additionally, patient position and special equipment must also be noted at this time.

This formal part of the procedure should involve the entire surgical team. The anesthetist, the surgeon, anesthesia provider, and the circulating nurse must minimally be included as active participants in the “time out” (JCAHO, 2004).
.

*Documentation Of The Universal Protocol*

The *Universal Protocol* does not mandate a specific form or tool for documentation, however, many organizations have found checklists useful for documenting compliance with the *Universal Protocol.*

Minimally, the following must be documented:
- review of all pertinent documents for consistency,
- consistency of the documents with the understanding of the staff and the patient, or designee;
- correct patient identity;
- correct side and site;
- surgical or invasive procedure is agreed to by all;
- correct patient position; and
- availability of special equipment and implants, as appropriate. (JCAHO, 2004)

.

## Special Measures to Prevent Medical Errors Among Populations at Risk

Other measures that can be used to prevent medical errors among populations at high risk for medical errors are described below.

### *Decreased level of consciousness.*

Patients that are not alert, awake and oriented to time, place and person are at high risk for medical errors. Levels of consciousness can be altered by a number of factors including anesthesia, medications, delirium, head injuries and other forces. Patient identification is absolutely necessary when providing care to a person with a diminished, or compromised, level of consciousness. At times, a family member or friend who is visiting this patient/resident/client can assist with this identification process and also serve as a person to question you about questionable treatments and to ask questions of you. All of these things will help to avoid medical errors among the members of this high-risk group.

### *Cognitive impairments.*

Lower levels of cognition place a person at risk for medical errors. Clients that are confused, disoriented, demented or with delirium are at risk for all sentinel events because of the challenges associated with accurate patient identification and the hazards of impaired cognition. Some of these hazards include the risk for falls, elopement, death or injury as a result of restraint use, transfusion errors, fire and infection. Again, patient identification is highly important. It is also helpful, depending on the person's level of cognition, to communicate with the affected person in a way that is understandable to them and to listen to them carefully, especially if they cue you to an impending error, either verbally or nonverbally. The use of pictures and drawings may help you to communicate with a person that is affected with a cognitive disorder, or impairment. The elderly population is most often affected by cognitive impairment.

### *Language barriers.*

One of our best defenses against medical errors is an alert, oriented, mentally competent person who is well educated and informed about their disease process, all of their diagnostic tests and all of treatments that they are, or will be, getting. These "ideal" patients are not frequently encountered. More often, our patients pose challenges, including a language barrier. A person with a language barrier can be as challenging as a person with a cognitive impairment. People with language barriers and cognitive impairments may not understand what

you are saying or asking, and, you do not understand them. You may not know what they are saying or asking. The use of interpreters, family or friends, pictures and drawings should be maximized to overcome a language barrier. Additionally, it is very wise to learn some basic medical terminology and useful foreign language phrases for the populations you frequently care for.

### *Sensory disorders.*

Auditory and visual impairments can also lead to medical errors. A patient that is visually impaired, or even blind, may not be able to detect that an erroneous medication is about to be given or an incorrect treatment is about to be done. Additionally, patients with a visual impairment are at greater risk for falls than those without such an impairment.

Patients with auditory impairments may not hear the healthcare provider’s explanation about what they are about to do and why they doing it. They may not even be able to hear the nurse, pharmacist or laboratory technician call them be the incorrect name. All of these issues lead to medical errors.

Assertive devices, such as eyeglasses, hearing aids, must be consistently provided to the impaired person in order to protect their safety. Additionally, the use of large print or Braille reading materials and magnifying glasses may be helpful for the visually impaired; and speaking loudly while facing the patient with an auditory impairment may offer some protection against medical errors.

### *Infants and children.*

For natural and obvious reasons, infants and children are not cognitively or developmentally able to participate in care and decision making. They are usually unaware of what medications, treatments and procedures they should and should not be getting. They are unable to verbalize questions and concerns regarding erroneous medications, treatments or surgeries. Until they reach a certain age, they are not even able to state their name. Infants and children are at risk for virtually all types of sentinel events, especially abduction, placing the infant with the wrong parents, poisoning, falls and other physical injuries. Eliciting the support and presence of the family is one way to prevent medical errors among this high risk population.

### *Developmental disorders.*

The same concerns and interventions described above for infants and children apply to those with developmental disorders, as specific to the degree of their developmental delay.

### *Psychiatric disorders.*

Lastly, patients/residents/clients with a psychiatric disorder are at risk for sentinel events for a variety of reasons including medications and the nature of their illness. Some psychotrophic medications have sedating effects, thus posing some of the same challenges that those with decreased levels of consciousness have. Also, depressed patients may be at risk for suicide, the most frequently occurring sentinel event according to JCAHO. Additionally, patients with a psychiatric disorder may also be aggressive and violent, thus causing harm to self or others.

This population is also at risk because they may be delusional and out of touch with reality. They may not be able to reliably even state their correct name; they may not be legally, mentally competent enough to accept or reject care or to ask questions.

## REFERENCES

REFERENCES

*WES ALLISON*. St. Petersburg Times. St. Petersburg, Fla.: Jun 1, 2001. pg. 1.A

http://pqasb.pqarchiver.com/sptimes/73511789.html?MAC=d94b31c882ebfa047d493b7b9effffcf&did=73511789&FMT=FT&FMTS=FT&date=Jun+1%2C+2001&author=WES+ALLISON&printformat=&desc=Surgeon+faces+discipline+for+removing+wrong+breast

Joint Commission on the Accreditation of Healthcare Organizations. (2003). Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Sugery.
http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/universal+protocol.pdf

Read the Universal Protocol and the Univervsal protocol guidelenies at

http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/universal+protocol.pdf

http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/up+guidelines.pdf

http://www.jcaho.org/accredited+organizations/sentinel+event/se_root_cause_analysis_matrix.pdf

Table 1: Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events - June 2002

1. .

*Source:* Joint Commission on Accreditation of Healthcare Organizations. Root Cause Analysis Matrix.

<http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/forms+and+tools/root+cause+analysis+matrix.htm

http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/forms+and+tools/root+cause+analysis+matrix.htm