

Preventive Action

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PREVENTING MEDICAL ERROR: Wrong Surgery

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Patient safety and the prevention of medical errors have become the focus of most healthcare providers. Wrong site, wrong procedure, and wrong patient surgery are catastrophic, alarming and preventable medical errors that continue to occur despite increased efforts to eliminate these errors (Figure 1). Malpractice claims entailing wrong surgery are not limited to the surgical specialties. The reduction in surgical errors is a major patient safety goal for virtually all practitioners that can be met with fundamental risk management practices.



In September 2003, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) estimated receiving five to eight new reports of wrong surgery every month. Studies have shown that the majority of wrong-site surgeries occur in orthopedic or podiatric cases (Figure 2). The "American Academy of Orthopaedic Surgeons (AAOS) estimates that an orthopedic surgeon's chance of performing a wrong site surgery during a 35-year career is one in four."⁽¹⁾ The AAOS has taken the lead in efforts to eliminate wrong site surgery. At a national summit involving the AAOS, JCAHO, the American Medical Association, the American College of Physicians, the American College

of Surgery, and the American Dental Association, a Universal Protocol (Figure 3) was developed. The four components of the protocol include: a preoperative verification process; "Sign Your Site" – marking the operative site; "Time Out" – taking time for surgical team members to ensure all processes are completed and accurate prior to starting the procedure; and expected compliance with universal protocols regardless of the surgical setting. For example, the universal protocol would be applicable for an endoscopic procedure performed in a GI Lab, a cataract extraction in an ambulatory surgery facility, an arthroscopy in a private practice or

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For comments, questions, or to obtain additional copies contact the FPIC Risk Management Department at 800-741-3742, ext. 3016. rm@fpic.com

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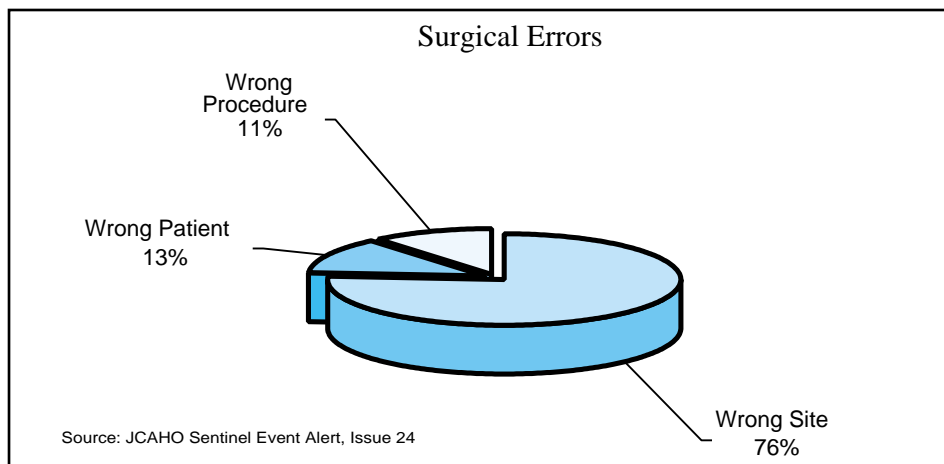


Figure 1 – Types of Surgical Errors

a cardiac catheterization in a cardiac catheterization lab.

A review of surgical errors has identified that patients with unusual physical characteristics, those undergoing multiple procedures, those with multiple surgeons, or those with time pressures to initiate the surgical procedure are at greater risk for surgical error (Figure 3). Other factors that contribute to surgical errors include:

- Unusual equipment or set-up in the surgical suite;
- Staffing problems;
- Distractions;
- Lack of access to pertinent information;
- Failure to require adherence to verification processes;
- Failure to verify and mark the operative site;
- Failure to require a patient assessment; and
- Human factors, such as communication breakdowns, novice providers, and lack of teamwork.

Approaches to Surgical Error Reduction

In addition to implementing the Universal Protocol (Figure 4), other risk management approaches to

reduce the incidence of surgical errors include:

- Involving the surgeon in obtaining informed consent;
- Reducing reliance on memory;
- Improving information access;
- Standardizing surgical processes;
- Improving employee training;
- Improving staffing and work environments;
- Improving communication;
- Improving teamwork;
- Incorporating error proofing in processes;
- Involving the patient and family members in the verification processes; and
- Maintaining or improving diligence in preparing for high-risk patients and procedures.

The reduction of surgical errors is a national patient safety goal for 2004. To eliminate the incidence of surgical errors, surgeons and surgical providers must examine their surgical processes and systems, identify flaws in those systems and processes, address the potential for wrong surgeries, and become actively involved in improving patient safety.

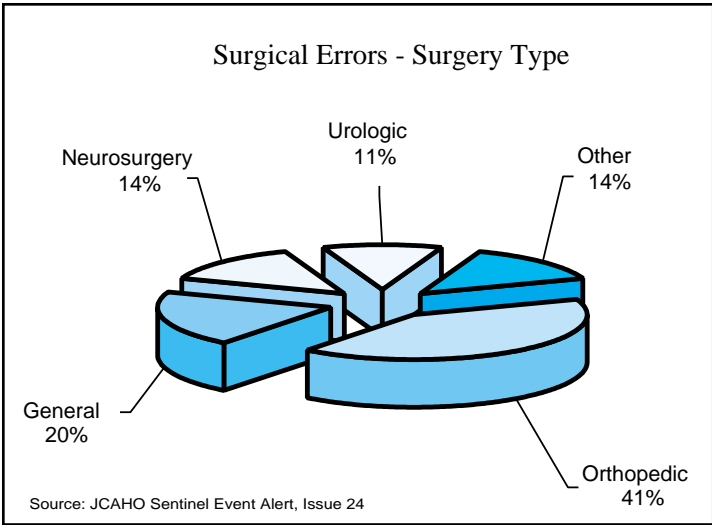


Figure 2 – Surgical Errors by Specialty

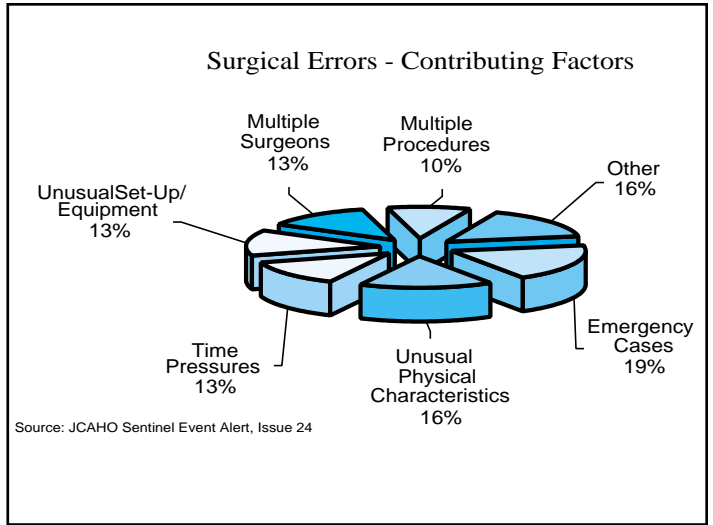


Figure 3 - Surgical Errors – Contributing Factors

¹“Wrong Site Protocol: A standard of care that can and will be used against you,” *Healthcare Risk Management*, (25:9, 100).

US TORT COSTS CONTINUE TO SWELL

A recent study by Tillinghast-Towers Perrin has found that tort costs in the United States have grown to \$233 billion in 2002, the *Dow Jones News Service* reports. The consulting firm also predicts that the costs will grow at a 6-11 percent rate for several years. Tillinghast says that the 13.3 percent increase in 2002 marked the second straight year of double-digit increases in torts costs, after 2001 saw costs rise 14.4 percent. The 2002 figure amounts to 2.23 percent of the gross domestic product – the highest level since 1990. According to the study, the cost of medical malpractice lawsuits in 2002 was \$25 billion.

CHECK YOUR FAX!

Central to your defense in a malpractice claim, disciplinary investigation or governmental audit may be the timing of certain events such as your knowledge of important test results communicated to or from your office via fax. An inaccurate or miss-stamped date, year or time by your fax machine can not only undermine your defense of the care provided but your credibility as well. Two recent claims hinged on the time of knowledge of diagnostic studies. In one case, an x-ray report was transcribed at 13:45 but the fax machine incorrectly recorded the time it was sent at 11:10. The claim alleged that our insured was negligent for failing to provide timely treatment - because he was aware of the x-ray results for over two hours before taking action. In the second case the wrong year stamped on the fax transmittal. It was later determined that a power interruption had caused the fax machine date stamp to change back one year at the time power was restored.

An easy solution is to instruct your staff to routinely monitor the accuracy of the time and date of faxes that are received and sent by your office.

Universal Precautions For Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery

Wrong site, wrong procedure, wrong person surgery can be prevented. This universal protocol is intended to achieve that goal. It is endorsed based on the consensus of experts from the relevant clinical specialties and professional disciplines.

In developing this protocol, consensus was reached on the following principles:

- Wrong site, wrong procedure, wrong person surgery can and must be prevented.
- A robust approach – using multiple, complementary strategies – is necessary to achieve the goal of eliminating wrong site, wrong procedure, wrong person surgery.
- Active involvement and effective communication among all members of the surgical team is important for success.
- To the extent possible, the patient (or legally designated representative) should be involved in the process.
- Consistent implementation of a standardized approach using a universal, consensus-based protocol will be most effective.
- The protocol should be flexible enough to allow for implementation with appropriate adaptation when required to meet specific patient needs.
- A requirement for site marking should focus on cases involving left/right distinction, multiple structures (fingers, toes), or levels (spine).
- The universal protocol should be applicable or adaptable to all operative and other invasive procedures that expose patients to harm, including procedures done in settings other than the operating room.

In concert with these principles, the following steps, taken together, comprise the Universal Protocol for eliminating wrong site, wrong procedure, wrong person surgery:

- Pre-operative verification process
 - Purpose: To ensure that all of the relevant documents and studies are available prior to the start of the procedure and that they have been reviewed and are consistent with each other and with the patient's expectations and with the team's understanding of the intended patient, procedure, site, and, as applicable, any implants. Missing information or discrepancies must be addressed before starting the procedure.
 - Process: An on-going process of information gathering and verification, beginning with the determination to do the procedure, continuing through all settings and interventions involved in the preoperative preparation of the patient, up to and including the "time out" just before the start of the procedure.
- Marking the operative site
 - Purpose: To identify unambiguously the intended site of incision or insertion.
 - Process: For procedures involving right/left distinction, multiple structures (such as fingers and toes), or multiple levels (as in spinal procedures), the intended site should be marked such that the mark will be visible after the patient has been prepped and draped.
- "Time out" immediately before starting the procedure
 - Purpose: To conduct a final verification of the correct patient, procedure, site, and as applicable, implants.
 - Process: Active communication among all members of the surgical/procedure team, consistently initiated by a designated member of the team, conducted in a "fail-safe" mode, i.e., the procedure is not started until any questions or concerns are resolved.

Figure 4 – Universal Precautions

Florida Mandatory Reporting Requirements

Senate Bill 2-D that became effective September 15, 2003, brought about significant changes for healthcare providers in Florida. Section 627.912 of the Florida Statutes has been amended to include specific requirements for reporting closed claim activity. A report must be made for any claim or action for damages for personal injuries that are claimed to have been caused by error, omission, or negligence in the performance of professional services, if the claim resulted in:

- A final judgment in any amount

- A settlement in any amount
- A final disposition of a medical malpractice claim resulting in no indemnity payment on behalf of the insured

Reports must be filed within 30 days to the Department of Financial Services, Office of Insurance Regulation. If you have a situation which you are uncertain as to whether or not reporting is required, please do not hesitate to contact the FPIC Risk Management Department at 800-741-3742, ext. 3016, for guidance.

HIPAA Transactions Rule Problems

Healthcare providers were extended a grace period for compliance with HIPAA transactions and code set rules. The Centers for Medicare and Medicaid Services report that 51.8 percent of claims submitted from December 8 – 12 were received in the proper format - up from 48.4 percent the month prior.

The Centers for Medicare and Medicaid Services reports that the top problems identified during claims testing with Medicare contractors are:

- Errors in data element NM109 (the provider's social security number or employer tax ID number).
- Invalid taxonomy codes (approved codes may be found at www.wpc-edi.com/codes).

- Invalid characters in the data stream.
- Missing SBR (subscriber) data elements, such as date of birth and gender.
- Missing or out-of-order N3 (street address) and N4 (city, state, and zip) segments.
- Missing submitter contact phone number.
- Sending both the billing provider loop and the rendering provider loop when they are the same entity.
- Invalid date formats.

If these are problems that you have encountered, you may find guidance on the CMS website: <http://cms.hhs.gov/providers/edi/>



LOSS PREVENTION

Wrong-site Surgery

Consider the recent case involving a 53 year-old single male who presented with history of chronic temporal headaches and transient blurred vision. Following evaluation, a biopsy of the left superficial temporal artery was performed by the insured. In recovery, it was obvious that the patient had sustained a nerve injury, demonstrating a left facial droop. Within 24 hours the patient was referred to a specialist who performed a re-anastomosis of the left facial nerve. Unfortunately, the patient was left with a permanent facial droop, including pronounced ptosis of the left eye and eyelid. Medical experts who reviewed the case could not support the insured on standard of care or causation, noting that the incision which was made during the biopsy procedure was several inches away from the correct position and directly causative of the nerve injury sustained. Investigation revealed that movement of the drapes after the patient had been prepped went unnoticed by the insured, resulting in the wrong-site incision. Consequently, settlement of the case was necessitated in the amount of \$700,000.

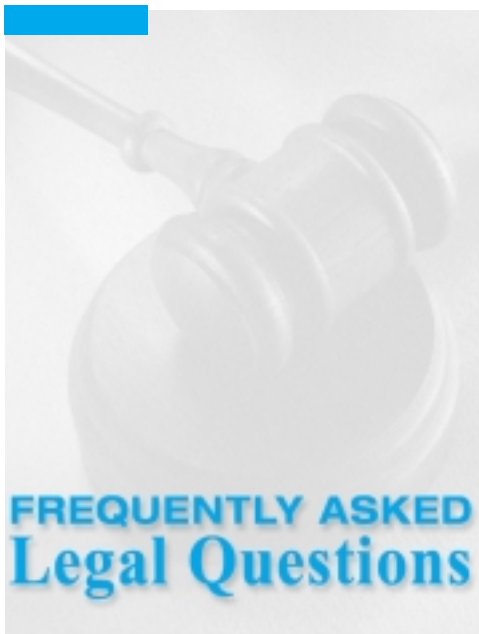
Verify the surgical site a final time after patients have been prepped and draped and before making an incision.



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Q. What action should be taken when a "Notice of Intent" letter is received?

Immediately notify FPIC by calling the Claims Department at 800-741-3742, ext. 3293. FPIC only has a limited number of days to prepare a response on your behalf to the notice of intent and assign a defense attorney, if necessary. It is important to not discuss the case with the patient, the patient's attorney or other parties involved in the care and treatment of the patient. You should gather and secure the patient's records immediately.

Q. What is arbitration and what benefit does it provide?

Arbitration is the submission of a dispute to one or more impartial persons for a final and binding decision. Through arbitration, patients and physicians both benefit because they are able to more promptly resolve malpractice claims and for less cost to each party. It is also believed that arbitration panels will help to avoid unreasonable jury awards, thereby further lowering costs. These cost savings would positively impact professional liability rates and the cost and availability of healthcare services.

Q. How long must a physician retain medical records?

Per Florida Administrative Code 61F6-26, for five years. However, FPIC recommends that records be kept for a seven-year period from the point of last patient contact given the maximum statute of limitations for medical malpractice. However, for patients under the age of one, records should be retained until the child's eighth birthday. If the patient is age one year or older, then keep records for the seven year period.

Q. What is the statute of limitations for medical malpractice?

IN FLORIDA: Two years from the date of the incident giving rise to the action or two years from the time that the incident caused by medical negligence is discovered or should have been discovered, but in no event later than four years from the date of the negligent incident or occurrence. However, the four-year period of repose will not bar an action brought on behalf of a minor on or

before the child's 8th birthday. If it can be shown that fraud, concealment, or intentional misrepresentation of fact prevented the discovery of injury, the period of limitations is extended to seven years from the date the incident giving rise to the injury occurred. This seven-year period does not bar an action on behalf of a minor if made on or before the child's 8th birthday.

Q. Do HIPAA Privacy Rules prevent a physician from discussing a patient's health status, treatment, or payment arrangements with the patient's family and friends?

No. Not, if the information discussed is relevant to the care and treatment of the patient and the patient does not object to the discussion. For example, a physician may discuss the patient's physical limitations to a relative caregiver; to a family member for instructions on medication dosage; or to a friend who may be providing transportation to the patient.