



## The High Costs of Wrong-Site Surgery

by Karol DeVito, RN, Risk Management Consultant

Wrong-site surgery is a preventable error with a high price paid both emotionally and financially. Along with the harm done to the patient, media hype leads to a loss of public trust and respect. In addition, this complication is expensive both to defend and in eventual payout.

A recent Florida case of wrong-site surgery led to a plaintiff's verdict of \$3.8 million after a surgeon performed a discectomy and fusion at level C6-C7 instead of level C5-C6. The patient alleged chronic neck pain, limited range of motion and residual nerve damage.

Defending these types of errors is nearly impossible. A study by Physician Insurers Association of America reports that 84 percent of orthopedic wrong-site claims and 68 percent of other surgical specialty wrong-site surgeries resulted in payment. In contrast, only 19 percent of all other types of claims resulted in payment.<sup>1</sup>

The definition of wrong-site surgery seems obvious; however, the breath of events that can be included under this term is broad. "Wrong-site" surgery includes wrong-side surgery, wrong-level/part surgery and wrong patient or procedure. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) considers all wrong-site surgeries to be sentinel events, regardless of the magnitude of injury.<sup>2</sup> Despite efforts to prevent this error, wrong-site surgery has increased every year from 1995 through 2001.<sup>3</sup>

Wrong-site surgery is a problem that affects all surgical specialties and all surgical settings. Of 150 JCAHO sentinel event reported cases of wrong-site surgery between 1998-2001, 126 have root cause analysis information. Of these 126 cases, 41 percent relate to orthopedic/podiatric surgery; 20 percent to general surgery; 14 percent to neurosurgery; 11 percent to urologic surgery; and the remaining to cardiovascular-thoracic, ear-nose-throat and ophthalmologic surgery. Fifty-eight percent of

the cases occurred in either a hospital-based ambulatory-surgery unit or freestanding ambulatory setting, with 29 percent occurring in the in-patient operating room and 13 percent in other in-patient sites such as the Emergency Department or the ICU.<sup>4</sup>

JCAHO has identified a number of factors contributing to the increased risk for wrong-site surgery, as well as several common root causes.<sup>5</sup>

### JCAHO Addresses Wrong-site Surgeries

One of the six National Patient Safety Goals for 2003 announced recently by the joint Commission on Accreditation of Healthcare Organizations (JCAHO) covers wrong-site surgeries. The goal and its associated recommendations call for elimination of wrong-site surgery by implementing a process to mark the surgical site and involve the patient in the marking process.

For details, visit [www.jcaho.org](http://www.jcaho.org) or call (630) 792-5000.

### Risk Factors

- Emergency Cases
- Unusual Physical Characteristics i.e., Morbid Obesity or Physical Deformity
- Unusual Time Pressures
- Unusual Equipment or Set-Up
- Multiple Surgeons
- Multiple Procedures

### Root Causes

- Communication Failures - failure to involve the patient or family, and between surgical team members
- Incomplete Preoperative Assessment - failure to review the medical record or any imaging studies immediately preceding the procedure
- Inadequate Policies & Procedures for Validating the Correct Operative Site - absence of any formal verification, absence of a final check in the OR, absence of any oral communication, absence of a checklist, lack of availability of information in the OR

Simply put, wrong-site surgery should not occur. While there is no magic panacea to prevent wrong-site surgery, a number of practices have been suggested to help eliminate its occurrence.

### Site Verification and Validation

The American Academy of Orthopedic Surgeons (AAOS) initiated the "sign your site" campaign in 1997.<sup>6</sup>

This program recommends that the surgeon use a permanent-marking pen (clearly visible on any color skin) to place his/her initials on the site of the surgery and then operate through or adjacent to the initials

### Recommendations

- The surgeon should not proceed unless the signature is visible
- For spinal surgery, an intra-operative x-ray can mark the exact vertebral level
- Have a formal policy and procedure in place for preoperative assessments
- Develop a verification checklist that ensures that all available sources of information have been checked before incision
- The checklist should include all documents referencing the intended operative procedure and site: the medical record, x-rays and other imaging studies and their reports, pathology reports, the informed consent document, the OR record, the anesthesia record, and direct observation of the marked operative site on the patient

- Ensure that any checklist or protocol can accommodate atypical scenarios such as emergency surgery and trauma
- Include oral information along with the checklist to ensure that all relevant information sources were checked
- Involve the patient in the physical marking of the operative site to enhance reliability
- When laterality (one side) is at issue, the words left or right should be spelled out in their entirety on all documents especially the operative consent form and operative schedule
- The anticipated level(s) for spinal surgery should be indicated on the operative consent form and operative schedule
- Whenever possible, the surgeon of record should physically see and talk to the patient in the peri-operative area on the day of surgery
- Always repeat the patient's name and surgical site aloud to the receiving person in front of the patient
- Conduct a final check in the operating room

- Each member of the healthcare/surgical team should orally verify agreement of the operative procedures
- Train the team so that each member feels comfortable to raise concerns and other members understand that they should never belittle or dismiss another's inquiry
- Do not allow time pressures to short-cut completion of the verification process
- Monitor compliance with the policies and procedures

*A copy of the "Sign-Your-Site Checklist for Safety" is available at [www.aaos.org](http://www.aaos.org)* ■

### References:

1. Physician Insurers Association of America. Claims Data. Rockville, MD: PIAA 1996.
2. Joint Commission on Accreditation of Healthcare Organizations. Sentinel event policy and procedures [online]. 1999 Jun 15 [cited 2000 Jun 8]. [www.jcaho.org/sentinel/se\\_pp.html](http://www.jcaho.org/sentinel/se_pp.html)
3. Meltzer B. Wrong-site surgery: are your patients at risk? *Outpatient Surgery Magazine*. 2002; III (2): 26-35.
4. Joint Commission on Accreditation of Healthcare Organizations. A follow up review of wrong-site surgery. *Sentinel Event Alert*. 2001 Dec 5. Issue 24. [www.jcaho.org/edu\\_pub/sealert//sea24.html](http://www.jcaho.org/edu_pub/sealert//sea24.html)
5. Ibid.
6. American Academy of Orthopedic Surgeons. Report of the task force on wrong-site surgery. 1997 Sept [revised Feb 1998]. [www.aaos.org/wordhtml/meded/tasksite.html](http://www.aaos.org/wordhtml/meded/tasksite.html)

## Wrong-Site Cases: An Expensive Error

### MAG Mutual Claims: 1985-2002

|   | Year | Total Paid  |
|---|------|-------------|
| • Laminectomy performed on L 2-3 rather than L 3-4 resulting in total disability.   | 1993 | \$1,208,720 |
| • Inadvertent ligation of left pulmonary artery on a three-week-old baby girl.  | 2002 | \$1,052,973 |
| • Wrong-side kidney removed (for cancer).   | 1992 | \$725,309   |
| • Laminectomy performed at L 4-5 instead of L5-S1.  | 1996 | \$316,700   |
| • Patient underwent quadrantectomy & axillary node dissection for infiltrating carcinoma. She actually had fibroadenoma. There was a mix up with report of another patient. | 2000 | \$260,956   |
| • Microdiskectomy performed on wrong level L 3-4. Correct level L 4-5.  | 2001 | \$202,208   |
| • Patient underwent hysterectomy after ultrasound noted pathology in left ovary. During surgery, the right ovary was removed.   | 2002 | \$186,598   |
| • Surgery to remove cyst performed on left thumb instead of the right thumb.  | 1991 | \$153,519   |
| • Pacemaker placed in wrong patient.  | 2002 | \$113,631   |

# Online Communications and Consultations

by Dan Wright RN, JD, Manager Risk Management

Electronic email can be a powerful tool, but if used inappropriately, it exposes the healthcare provider to liability risks. We suggest that you adopt carefully drafted policies and procedures to minimize risk and enhance effectiveness. Not only must staff be well educated on these policies, patients also must clearly understand the parameters put in place. To minimize your liability risks, the following risk management suggestions are offered:

## EMAIL COMMUNICATIONS

- Develop a comprehensive policy. Address benefits, limitations (confidentiality) and responsibilities of ALL parties
- Obtain written, signed, informed consent. Include “hold harmless” language addressing technical system failure, intercepted and/or misaddressed e-mail
- Use password-protected screen savers
- Install current virus protection software
- Insist that an urgent medical event or a request for a same-day appointment necessitate a telephone call to the practice. Advise patients that a reasonable response time is 24-48 hours. Document this discussion
- Instruct patients who do not receive a response from you to call the office
- Refrain from sending mental health or protected sensitive information such as HIV or drug/alcohol use
- Avoid diagnoses or treatment suggestions via email
- Keep copies of all email, replies and confirmations of receipt
- Be aware of licensure requirements in various states

## FEE-BASED ONLINE CONSULTATIONS

A clinical consultation provided by a physician to a patient using the Internet or other similar electronic communications network in which the provider expects payment for service is known as a “fee-based online consultation”. Any online consultation that is given in exchange for payment introduces additional risks. In a fee-based online consultation, the physician has the same obligations for patient care and follow-up as in face-to-face, written and telephone consultations. For example, an online consultation should include an explicit follow-up plan that is clearly communicated to the patient.

AMA policy states that physicians may be compensated a fair fee of their choosing for consultation services rendered to **established patients** regardless of whether the consultation is provided by electronic mail or other form of communication. If you are considering providing online consultations for a fee and want to minimize your liability exposure, you should:

- Have a previously established physician-patient relationship
- Obtain the patient’s informed consent to participate in the online consultation for a fee
- Maintain and integrate online consultation records into the patient’s medical record
- Let patients know what costs are up front and that health insurers may not reimburse them
- Charge a fee under the right circumstances—the online consultation should be substantive and clinical in nature and specific to the patient’s personal health status. You should not charge for appointment scheduling, refills and other administrative routine communications
- Make sure that the clinical information you offer the patient comes from you
- State to the patient that the information that you are providing is based upon the information that the patient made available to you during or prior to the online consultation and therefore may not be an adequate substitute for an office visit

The Internet presents incredible opportunities for enhancing the practice of medicine. Increasingly, physicians are interacting with patients via a variety of online activities such as Web sites and email. However, given the lack of legal guidance in this area, and the evolving technology, physicians are well advised to understand the risks associated with online activities. ■

### Resources:

1. Journal of the American Medical Informatic Association (Volume 5, Number 1, Jan/Feb 1998).
2. eRisk Working Group for Healthcare [www.medem.com](http://www.medem.com).

# EMTALA - Duties of On-Call Physicians

by David Tansill, JD, Senior Staff Attorney

The Emergency Medical Treatment and Active Labor Act (EMTALA) was enacted in 1986 to prevent hospital emergency rooms from dumping indigent patients, although EMTALA's application extends to patients who are not indigent.<sup>i</sup> While EMTALA principally requires hospitals that receive federal funds to perform certain acts, it has significant meaning for physicians who are on call to hospital emergency rooms as well. If an emergency room physician determines a patient requires the services of an on-call physician who fails or refuses to respond within a reasonable time after notification, the on-call physician is subject to having civil money penalties up to \$50,000 per violation assessed against him or her by the federal government. When the emergency room physician believes the benefits of the patient's transfer to another facility outweigh the risks of transfer given the on-call physician's absence, he or she has a duty under EMTALA to report the identity of the on-call physician to the hospital that receives the transferred patient, and that hospital has a duty to report the on-call physician to the federal government.<sup>ii</sup> The obligation of the on-call physician to respond to a request for assistance in an emergency situation exists without regard for whether the patient is "his" or "her"

patient. It makes no difference under EMTALA whether the on-call physician has previously seen the patient.

The Centers for Medicare & Medicaid Services (CMS) recently issued a Notice of Proposed Rulemaking (NPRM) to clarify on-call responsibilities.<sup>iii</sup> CMS proposes to give hospitals discretion to maintain on-call lists in a manner that best meets the needs of the hospital's patients. Physicians, including specialists and sub specialists, are not required to be on call at all times. However, hospitals must have policies and procedures to be followed when a particular specialty is not available or an on-call physician cannot respond because of situations beyond his or her control.<sup>iv</sup> CMS does not interpret EMTALA to prohibit physicians from being on-call at more than one hospital at one time. When an on-call physician is simultaneously on-call at more than one hospital in a geographic area, all hospitals involved must be aware of the on-call schedule. Patients presenting at one hospital may not be transferred to another hospital merely for convenience of the physician.<sup>v</sup>

CMS allows hospitals flexibility in complying with EMTALA's requirements for on-call coverage. CMS acknowledges that private practice demands, conferences, vacations, days off and other similar factors

should be considered in making an on-call list. In its recent NPRM, CMS specifically dispels the rumor that a hospital must provide 24/7 coverage for a specialty with at least three physicians on staff. In determining EMTALA compliance, CMS will generally consider all relevant factors, including the number of physicians on staff, other demands on these physicians, the frequency with which the hospital's patients typically require services of on-call physicians, and the provisions the hospital has made for situations in which a physician in the specialty is not available or the on-call physician is unable to respond.<sup>vi</sup>

It is not uncommon for plaintiffs in medical professional liability claims to allege EMTALA violations concerning an on-call physician's failure to respond. Patients cannot sue physicians for EMTALA violations as they can hospitals, but EMTALA allegations can inflame jurors in professional liability cases against physicians. Physicians should consult with their hospitals if they have any questions about on-call responsibilities at those facilities. ■

i 42 USCS § 1395dd

ii 42 CFR 489.24

iii Federal Register, Vol. 67, No. 90 (67 FR 31403) May 9, 2002

iv CMS State Operations Manual (Appendix V, page V-15, Tag A404)

v CMS Director Memo, "Simultaneously On Call" (June 13, 2002)

vi Federal Register, 67 FR 31403

MAG Mutual does not presume to establish any standard of care or establish rules for the practice of medicine. The particular patient-care strategies or range of patient-care strategies mentioned in this newsletter should be tempered by the physician's judgment.

This publication is produced to inform you of issues relating to medical professional liability insurance and other matters of importance to physicians. Material given in this newsletter does not constitute legal advice or opinion. If you have questions in any of the areas discussed in this publication, you should seek a qualified legal opinion.

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