

ClaimsRx

clinical & risk management perspectives

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Risk Management and Patient Safety Strategies for Surgeons

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Learning Objectives

In the surgical setting, reduce professional liability risk exposure by:

- Adopting and adhering to patient safety protocols to avoid common but preventable errors (e.g., wrong site surgery, surgical fires, surgical site infections and post-operative complications)
- Implementing risk management-based communication and follow-up strategies (e.g., communication and informed consent with patients, communication and follow up with other providers, disclosure of unanticipated outcomes)

Introduction

NORCAL claims history indicates that most surgery-related litigation involves surgical/technical errors, failure to diagnose, misdiagnosis, or failure to recognize a complication. Research also indicates that surgical malpractice may not be causally related to the filing of a lawsuit. A Harvard Risk Management Foundation study showed that when paired with an unexpected

- Providing adequate documentation in the surgical report.

Target Audience

All healthcare providers involved in providing surgical services.

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outcome, the following problems—problems related to communication and follow up among surgeon, patient and other members of the healthcare team—were frequent litigation triggers:

- Failure to adequately communicate the reason for surgery

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- Failure to answer questions clearly
- Failure to return patient telephone calls
- Failure to see patients prior to discharge
- Failure to actively involve the patient in the treatment decision-making process
- Failure to transfer important patient information to other members of the healthcare team.¹

Consequently, even the most conscientious and skilled surgeon, one who has provided treatment at or above the standard of care, may find herself party to a lawsuit simply because she failed to recognize the importance of building rapport with the patient and/or adequately communicating with her peers.

This *Claims Rx* will address a variety of circumstances that have resulted in NORCAL claims involving surgeons:

- Postoperative complications
- Wrong site surgery
- Surgical fires
- Surgical site infections

Although the case studies chosen primarily focus on orthopedic cases, the associated risk management recommendations should provide risk management and patient safety guidance that is appropriate for all surgeons.

Failure to Recognize Postoperative Complications

Case Study #1

Allegation: The patient developed compartment syndrome, which resulted in neurological deficits following a right knee anterior cruciate ligament (ACL) reconstruction.

The Event: At the time of treatment, the patient was a 40-year-old man who weighed 390 pounds, had high blood pressure, smoked and had alcohol abuse problems. After a fall at work, he developed severe pain in his right knee. An MRI revealed that he had torn his ACL. Shortly after the fall, he told his primary

care physician (PCP) that he wanted gastric bypass surgery. His PCP, however, recommended that he have the torn ligament in his right knee repaired prior to a gastric bypass so that he could more easily exercise following the procedure. The PCP referred the patient to Orthopedic Surgeon #1.

Following an examination and an MRI review, the surgeon diagnosed an ACL tear and a medial meniscus tear. The surgeon discussed the risks, benefits and alternatives of ACL reconstruction surgery, which involved placing screws into the patient's femur and tibia to anchor the ACL graft. The patient consented to the procedure.

On 2/09 at 2:03 p.m., the surgeon inflated a tourniquet on the patient's thigh and started the ACL reconstruction. The site of the femur where the screw was to be placed was identified and a small pilot hole was drilled, and then enlarged. A guidewire was then placed through a screwdriver and the femoral screw, both of which were designed to accommodate the guidewire. The guidewire was then directed into the pilot hole under direct observation through arthroscopic equipment. With the guidewire in place, the surgeon encountered trouble placing the first bone screw. Thinking the problem might be related to the patient having abnormally dense bones, he released the arthroscopic camera with his left hand so he could use both hands to turn the screwdriver. The screwdriver somehow slipped out of his hand, however, and the guidewire and screw dislodged from the pilot hole. Without the guidewire in place, the screw became lost in the tissue of the knee.

The surgeon then spent approximately two and a half hours searching for the screw. Because the screw was biodegradable, he eventually decided to move on and complete the surgical procedure. In his second attempt, he was able to place the femoral screw and then the tibial screw without difficulty. The tourniquet was finally released at 8:41 p.m.

Although not noted in the operative report, the anesthesia record indicates that during the procedure there

were several occasions when the tourniquet was “down” (i.e., the pressure was released). The following illustrates tourniquet time in connection with the procedure:

1:15 - Anesthesia starts
2:03 - Surgery starts - tourniquet inflated
4:13 - Tourniquet down
4:55 - Tourniquet pressure re-applied
6:55 - Tourniquet down
7:48 - Tourniquet pressure re-applied
8:41 - Tourniquet down
9:04 - Patient in postanesthetic recovery
9:05 - Anesthesia end

Based on this timeline, the tourniquet was up and inflated for a total of 303 minutes. Additionally, the tourniquet was around the thigh but not pressurized for 95 minutes.

After the patient was awake, the surgeon told him about the lost screw. He informed the patient that it could be left in since it was biodegradable and that if it caused any problems, it could be removed at a later date. Shortly after this conversation, the patient told Nurse #1 that he was experiencing numbness in the lower portion of his leg. She reported this to the surgeon, who explained that it was to be expected because of the lengthy surgery.

At 1:00 a.m. the following morning, the patient told Nurse #1 that he was in pain, was experiencing numbness in his entire right leg and foot and that the muscles of his thigh were hard and tight. The nurse believed that the patient was merely elaborating on his prior complaint of numbness. Therefore, she did not feel it was necessary to contact a physician. At this point, she charted that the patient’s thigh muscles did not appear tight and that the patient’s circulation appeared to be intact. At 4:00 a.m. the patient was given Toradol® (ketorolac tromethamine) for pain relief.

At 5:30 a.m., Nurse #1 telephoned Orthopedic Surgeon #2, who was on-call, to report that the

patient had dark urine and numbness in his leg; she did not mention the previously reported muscle tightness. Orthopedic Surgeon #2 ordered tests to rule out rhabdomyolysis. The possibility that the patient might have compartment syndrome did not occur to Orthopedic Surgeon #2 until two hours later, at which point he immediately went to the hospital and made arrangements for the patient to get compartment pressures measured. He notified Orthopedic Surgeon #1 of his suspicion of compartment syndrome at 8:00 a.m. Orthopedic Surgeon #1 immediately went to the hospital and diagnosed compartment syndrome. While at the patient’s bedside, Orthopedic Surgeon #2 criticized Orthopedic Surgeon #1’s surgical technique.

At 10:00 a.m., Orthopedic Surgeon #1 performed a fasciotomy of the right thigh. When the patient was being transferred from the operating table to the bed, he sustained a pulmonary embolism. Code blue was called and the patient was successfully resuscitated. The patient was transferred to the ICU. During his hospitalization, the patient was noted to have paraesthesia of the right leg and foot drop. A follow-up MRI prior to discharge showed that the knee was healing and the retained screw was visible. The patient was discharged from the hospital on 3/31.

On 5/11, the patient returned to Orthopedic Surgeon #1’s office for follow-up. Orthopedic Surgeon #1 noted minimal motor and sensory function below the knee. The patient obtained a second opinion regarding his knee from Orthopedic Surgeon #3, who ultimately performed a right knee arthroscopy and found that the tibial screw had pulled out of the bone. Orthopedic Surgeon #3 removed the tibial screw. He did not find the original lost screw.

The patient brought a medical liability lawsuit against the hospital, Orthopedic Surgeon #1 and Orthopedic Surgeon #2, alleging that negligence during the ACL repair and delays in diagnosing the compartment syndrome were the cause of neurological deficits in his right leg.

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Discussion

Tourniquet time: Experts who reviewed this case were almost unanimous in the opinion that the excessive tourniquet time caused the compartment syndrome. Unfortunately, lack of documentation regarding Orthopedic Surgeon #1's reasoning for allowing the tourniquet to be in place for so long diminished the ability to defend his actions.

Time spent searching for the screw: Experts felt that spending two hours looking for a biodegradable screw was excessive, particularly since the reason Orthopedic Surgeon #1 felt he could stop searching was *because the screw was biodegradable*. Orthopedic Surgeon #1 also knew (as he later told the patient) that if the lost screw bothered the patient, it could be retrieved at a later date. As one expert pointed out, if Orthopedic Surgeon #1 had spent just 15 minutes looking for the screw instead of two hours, he would have had the same conversation with the patient about the screw, but he would not be dealing with all of the complications that were ultimately related to the extensive amount of time he spent searching for the screw.

Brevity of the operative report: Most of the experts reviewing this case were critical of Orthopedic Surgeon #1's operative report. It contained no mention of where and how Orthopedic Surgeon #1 looked for the screw; no record of an intraoperative x-ray being obtained; no record of tourniquet times; and no explanation as to why, even when the search time for the screw was taken into account, the procedure lasted at least two hours longer than average. One expert stated that he would expect to see a five- to six-page operative report in a case with these types of complications.

Patient choice: Experts questioned Orthopedic Surgeon #1's decision to perform an elective knee surgery on this patient. Weighing 390 pounds and being a cigarette smoker, he was a high-risk patient for any type of surgery. They felt that the majority of physicians under the same circumstances would recommend that the patient lose weight first before proceeding. One expert

suggested that if the patient was unable to lose weight in preparation for a knee surgery, he would probably not be dedicated to his rehabilitation following a bariatric procedure. This same expert pointed out that an injured ACL does not prevent physical activity like walking or light jogging; but instead impacts a patient's ability to engage in activities that require twisting, turning and lateral movement, activities such as tennis, basketball or skiing. None of these activities were pertinent to the patient.

Lack of an assistant surgeon: Experts questioned why no assistant surgeon was used. They felt that a patient of this size, who presented as a high-risk surgical candidate to begin with, would have benefited from an assistant at the surgery. An assistant surgeon could have provided advice and assistance when Orthopedic Surgeon #1 encountered complications.

Failure to recognize the signs of compartment syndrome: Although compartment syndrome following ACL repair is uncommon, experts felt that Nurse #1 should have recognized the possibility of a compartment syndrome diagnosis when the patient first started complaining about numbness, loss of sensation and muscle tightness at 1:00 a.m. the morning after the procedure. If she had contacted Orthopedic Surgeon #1 at that point, there is a possibility that the fasciotomy would have been done eight and a half hours earlier, which would have significantly improved the patient's outcome.

Handling an unexpected outcome: Orthopedic Surgeon #1 did the right thing in talking to the patient about the lost screw following the surgery. However, whatever rapport Orthopedic Surgeon #1 may have gained with the patient following the surgery was seriously diminished by Orthopedic Surgeon #2's criticism of Orthopedic Surgeon #1's surgical technique at the patient's bedside.

Due to negative reviews, lack of documentation and other factors unrelated to the allegations in the case

that made the claim difficult to defend, this case was settled.

Risk Management Recommendations

- Provide adequate documentation in the surgical report, particularly when surgery has been complicated.
 - In addition to the customary data, the surgery report should contain a description of any procedure or activity that was clearly outside the expected norm for such a case.
- Consider using an assistant surgeon when the patient's condition may make an otherwise complicated procedure more challenging.

- Carefully consider patient selection criteria when a procedure is elective and document justification for proceeding when the patient does not meet criteria.
- Avoid criticizing another provider's work, particularly when in the presence of a patient or family members, whether the provider at issue is present or not.

Wrong Site Surgery

Wrong site, wrong procedure and wrong person surgeries are not as rare as one might think. According to The Joint Commission, which tracks these "sentinel events" (an unexpected occurrence involving death or serious physical or psychological injury), they are reported at a rate of five to eight new cases per month

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Deep Vein Thrombosis (DVT)

The patient in Case Study #1 developed DVT, which might have been avoided had he been prophylactically anticoagulated. DVT is a condition that occurs when a blood clot forms in the deep veins of the circulatory system. When a part of the thrombus detaches/separates from the vein wall and lodges in the pulmonary artery, the blockage of the artery is referred to as a pulmonary embolism. Pulmonary embolism is the leading cause of preventable hospital death. Unfortunately, as many as 80 percent of patients with DVT have no clinical signs of the disease; the routine screening of patients for asymptomatic DVT is logistically difficult and has not been effective in preventing venous thromboembolic disease.¹ Consequently, the most important DVT intervention is prevention. Various practice guidelines provide tools to identify patients at risk for developing DVT and the appropriate mechanical or pharmaceutical interventions to prevent it. For example, the American Academy of Orthopedic Surgeons (AAOS) has developed a "Clinical Guideline on Prevention of Symptomatic Pulmonary Embolism in Patients Undergoing Total Hip or Knee Arthroplasty," which is available on its website at: www.aaos.org/Research/guidelines/PE_guideline.pdf (accessed 5/17/2008).

In order to decrease the likelihood of pulmonary embolism, providers are encouraged to take each patient's DVT propensity into account and weigh the risks and benefits of the various available DVT prophylactic treatments. Evidence of this evaluation and the reasoning behind the choice of prophylaxis or the choice to forego it should be documented in the patient's medical record.

For more information about DVT Prophylaxis, see the March 2008 *Claims Rx* entitled: "Deep Vein Thrombosis Prophylaxis: Evaluation, Treatment and Monitoring," which is available on the NORCAL website at: www.norcalmutual.com/publications/claimsrx/mar_08.pdf (accessed 5/14/2008).

¹ The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Available on the American College of Chest Physicians (ACCP) website at www.chestnet.org/education/guidelines/currentGuidelines.php (accessed 5/17/2008).

in the United States and are now the most frequently reported sentinel event.² As the following case indicates, wrong site surgeries are primarily the result of miscommunication, poor recordkeeping, lack of standardized processes, and/or failures on the part of care providers to appropriately adhere to established processes.

Case Study #2

Allegation: *The patient fell after undergoing operations on both knees due to a wrong site surgery, resulting in permanent disability.*

The Event: A 70-year-old female patient presented to an orthopedic surgeon on 6/28. He noted the following:

- Both knees were without deformity.
- There was bilateral weakness of the quadriceps.
- There was complete range of motion bilaterally, but pain at the extreme range of flexion.
- The left knee showed effusion with tenderness over the lateral retinaculum, tenderness over the lateral joint line with crepitation of the lateral-femoral joint and a positive McMurray sign.
- The right knee showed no effusion, no McMurray sign and no joint line tenderness.

The orthopedic surgeon diagnosed her bilateral knee pain as being most likely caused by early osteoarthritis. He ordered an MRI of the left knee to rule out meniscal pathology. The patient returned on 7/6 to discuss the MRI. The orthopedic surgeon explained that the MRI showed a complex lateral meniscus tear of the left knee. He recommended an arthroscopic partial lateral release and lateral partial meniscectomy of the left knee. He never mentioned the right knee.

On 7/30, the patient presented for surgery at the surgical center. She signed a consent form for left knee arthroscopy and wrote “Yes” on her left knee. After the patient’s left knee was marked, the anesthesiologist performed a femoral nerve block on the left knee.

Nurse #1 prepared and draped the **right knee**. (There had been a right knee arthroscopy in the surgical suite

immediately before the surgery at issue.) The operative time out (surgical pause) was performed by the nurse **after** the orthopedic surgeon performed his first incision. The nurse stated, “Right knee arthroscopy.”

According to surgical center policy, the operative time out was to be performed before any incisions were made, and the person performing the time out was to read from the consent form.

The fact that the nurse stated “Right knee arthroscopy” indicates that she did not look at the consent form during the time out, as the consent form indicated a left knee procedure. Furthermore, even though the nurse called out the incorrect limb, the anesthesiologist, who had previously performed a block on the left knee, did not recognize the error. Additionally, the orthopedic surgeon who worked up the left knee for surgery did not recognize the error.

During the **right knee** procedure, the orthopedic surgeon found a tight lateral patellofemoral band, a large patellofemoral plica and a significant lateral meniscal tear. There was a Grade 2 and 3 chondromalacia and significant synovitis caused by wide crystal particles in the knee. He performed a partial synovectomy and a lateral release, after which the patellar subluxation returned to its normal position. He also debrided the lateral compartment of the lateral meniscal tear. When the surgery was completed, the orthopedic surgeon realized that the surgery was supposed to have been done on the left knee. The drape was removed and the “Yes” was clear on the patient’s left knee. When the error was recognized, the patient was still under anesthesia.

The orthopedic surgeon decided to perform the left knee arthroscopy while the patient was still under anesthesia. The left knee was prepared and draped. During the procedure, examination of the left patellofemoral joint revealed significant synovitis, which he resected. The left knee also exhibited a tight patellofemoral band on the lateral side and a large central posterior horn discoid type meniscus tear. The anterior cruciate ligament and posterior cruciate ligaments were intact and the medial meniscus was pristine. Chondromalacia was shown to be a Grade 2. A lateral meniscectomy was performed using a shaver so as to create a stable rim.

Postoperatively, the orthopedic surgeon explained what occurred to the patient's husband. He also charted the circumstances in the operative note. When the patient was awake, the orthopedic surgeon again explained what had happened. The patient was not charged for the surgery and the surgery center agreed to pay for all of her postoperative care.

Following surgery, the patient fell on her **right knee** while getting out of bed at her home. MRI confirmed a right meniscal tear and a stress fracture. Shortly thereafter, the patient brought negligence claims against the surgery center and the orthopedic surgeon. She claimed that she had never had any trouble with her right knee and that the surgery to her right knee had caused her fall. Her resulting injuries, she alleged, necessitated a future total right knee replacement. Further, she made a claim for battery, as she had never consented to surgery on her right knee.

Discussion

Although this patient would arguably have needed the type of surgery that was performed on her right knee, the case had to be settled. Due to the battery element, regardless of how seemingly minimal a patient's injuries might appear from having surgery performed on the wrong site, a wrong site surgery claim is extremely difficult to defend. (A study showed that 84 percent of the cases involving wrong site orthopedic surgery claims resulted in indemnity payments.³) The foregoing case is a classic example of a battery claim based on lack of consent. By law and pursuant to medical ethics, a patient has a right to determine what is done to her body. This patient never consented to surgery on her right knee and since surgery was performed on the right knee, she was the victim of a battery.

Punitive damages and battery

When a provider fails to obtain consent for a medical procedure, regardless of whether the procedure is performed negligently, he or she can be sued for battery. In California, medical battery claims are not subject to the Medical Injury Compensation Reform Act (MICRA),

which means the \$250,000 non-economic damages cap and protections related to punitive damages do not apply. Additionally, depending on the circumstances, punitive damages are not generally covered in medical liability insurance policies.

Risk Management Recommendations: Protocols for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery

Joint Commission Universal Protocol to Prevent Wrong Site Surgery

In 2003, The Joint Commission approved its Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™, and in 2004 it became a mandatory intervention in hospitals, ambulatory care and office-based surgery facilities in the United States. This protocol is applicable to all operative and other invasive procedures.

The principal components of the Universal Protocol are:

- Confirmation of the details (e.g., correct patient, correct procedure, correct site) of the procedure prior to its commencement.
 - This should be performed with the involvement of the non-sedated patient.
- Marking of the site of the procedure with an indelible marker.
- Scheduling of a “time out” with all of the members of the surgery/ procedure team immediately before starting the procedure.
 - It is prudent to document the “time out” in the hospital's surgical record as well as in the surgeon's operative report.
- Adaptation of the requirements of the Universal Protocol to all procedure settings, including bedside procedures.²

On February 23, 2007, The Joint Commission convened its second Wrong Site Surgery Summit to address the continuing problem of wrong site surgery, a problem that remains despite the fact that the Universal Protocol had been mandatory for over

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three years. The participants agreed that the current Universal Protocol was effective if it was properly implemented and consistently followed. They also reached consensus on the proposition that the Universal Protocol needed further refinement and elaboration. At this time, however, the original Universal Protocol remains unchanged.⁴

The Universal Protocol, its Implementation Expectations, Frequently Asked Questions and other resources for implementing the protocol are available on The Joint Commission website at: www.jointcommission.org/PatientSafety/UniversalProtocol (accessed 5/17/2008).

The American Academy of Orthopedic Surgeons (AAOS) “Sign Your Site” Initiative

In 1997, the AAOS started their “Sign Your Site” campaign. In 2003, the AAOS, in coordination with The Joint Commission, revised its Advisory Statement on Wrong-Site Surgery and added a “Checklist for Safety” and “Recommendations for Management Following Discovery of Wrong-Site Surgery.”⁵ The checklist is reproduced at the end of this article, and the recommendations are summarized in the following content. Providers are encouraged to use this type of checklist to ensure *correct* site surgery.

AAOS Recommendations for What To Do When a Surgery Is Performed on the Wrong Site

In general, if during or following a surgical procedure the surgeon determines that the surgery has been performed on the wrong site, the surgeon should do what is necessary to ensure the patient’s safety and welfare and adequately report circumstances in the medical records. As soon as it is reasonable, the patient (or patient representative) should be told what has happened and the probable consequences of the wrong site surgery.

If the discovery of the wrong site procedure is made while the patient is under general anesthesia, the surgeon should:

- Return the patient, as nearly as possible, to the condition that the patient was in prior to the procedure.
- Perform the originally consented-to procedure unless there are medical reasons not to, e.g., proceeding with the procedure would extend the length of the procedure so as to materially increase the risk of injury to the patient, or the surgery might result in an unacceptable level of disability.

If the procedure is being performed under a local anesthesia and the patient can understand that a wrong site surgery has occurred and is competent to give an informed consent, the surgeon should:

- Advise the patient of what has occurred and recommend the best course under the circumstances
- Answer the patient’s questions and then proceed as directed by the patient
- Return the patient, as nearly as possible, to the condition that the patient was in prior to the procedure.

If the surgical procedure has been completed, and it is later determined that the surgery was performed at the wrong site, the surgeon should discuss the mistake with the patient or patient representative and recommend an immediate plan to remedy the issue unless there is a reason not to proceed.²

Surgical Fires

It is estimated that between 50 and 100 or more surgical fires (fires on or in a surgical patient) occur in the United States every year. Of those fires, approximately 21 percent occur in the patient’s airway and 44 percent occur on the head, neck or upper chest.⁶ Up to 20 percent of the fires that are reported result in serious injury or death.⁷

Fortunately, most surgical fires can be prevented with formal patient safety protocols and procedures, and clinician fire prevention education and training. Unfortunately, as the following recently closed NORCAL claims illustrate, even the best patient safety initiatives will not be effective if clinicians fail to implement them.

Case Study #3

Allegation: *During a craniotomy evacuation of a subdural hematoma, the patient suffered a third degree burn over a large area of his head, resulting in permanent scarring.*

The Event: Following a sustained beating during which he was repeatedly kicked in the head with steel-toed boots, the patient was admitted to the hospital through the emergency department. CT scan showed that the patient had a subdural hematoma.

The surgeon determined that a left side burr hole evacuation of the subdural hematoma and placement of a subdural drain catheter was necessary. The patient was placed in a supine position with his head turned to the right exposing the left side and was supported with a donut headrest. The patient's hair was shaved and he was prepped by the operating room scrub nurse using DuraPrep™. The surgeon blotted the incision site with a towel to make sure it was dry.

The surgeon made a small incision, controlling small vessel bleeding with a Bovie cautery. He had begun further dissection into fatty tissue and fascia in the subgaleal space to explore the skin flap, when he noticed smoke coming from the operating table. The operative procedure was stopped and the surgeon poured two liters of sterile solution over the smoking donut headrest and removed it. He noted the patient had sustained second degree burns on the back of his neck where the donut headrest had been. Once the fire was extinguished, the surgeon continued the craniotomy, which thereafter was unremarkable.

Following the surgical fire, the patient underwent skin graft surgery at the location of the burns. Additional future surgery was required to expand the skin on his scalp so it would cover the burned area.

Discussion

In this case, the patient was prepped in a manner that was inconsistent not only with hospital policies, but also with the directions on the DuraPrep™ packaging.

According to the hospital fire prevention policies and procedures:

- Electric cautery is not to be used in the presence of flammable agents.
- Pre-procedure skin prep agents must not be allowed to pool under the patient.
- Flammable solutions must be allowed to dry before draping the patient.

According to the DuraPrep™ packaging, prep towels should be placed under both sides of the patient's neck to absorb excess solution, and then removed prior to draping.

In this case, the patient was draped and the donut headrest was placed prior to the application of DuraPrep™, which contains alcohol and is flammable. Experts surmised that the DuraPrep™ flowed down the drape and pooled underneath the patient's head directly under the occipito-auricular area, then a spark from the cautery unit followed an alcohol trail into a puddle of DuraPrep™ and caused the fire. Although the surgeon made sure that the incision area was dry, he only assumed that all of the DuraPrep™ that had been applied to the patient had been allowed to dry prior to using the cautery unit. In general, medical liability claims arising from surgical fires are extremely difficult to defend—particularly, as in this case, where members of the surgical team have not taken adequate measures to minimize fire risks. In this case, it was determined that the violations of hospital policy could not be successfully defended, and the case was settled.

“Captain of the Ship” Doctrine

In the foregoing case, the surgeon, who relied on the nurse to follow appropriate protocol in prepping the patient, might possibly have been held liable for the nurse's negligence under what is referred to as the “Captain of the Ship” Doctrine. This legal doctrine imposes respondeat superior liability on the surgeon for the acts of the individuals under the surgeon's supervision and control during an operation. Although this doctrine is losing favor in California and through-

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out the United States, it was successfully used in a recent California incorrect sponge count case (*Fields v. Yusuf*, Cal. App. 4th 1381 (2006)). How expansively the “Captain of the Ship” Doctrine will be applied in California medical liability actions is still in question.

Case Study #4

Allegation: *A surgical fire that occurred during surgery to remove a nasal lesion resulted in permanent scarring to the chest, neck and face of the patient.*

The Event: A 26-year-old female patient presented to a general surgeon to have a nasal lesion removed. Local anesthesia with sedation was used, but the patient appeared to be sensitive to sedation as evidenced by slowed breathing that required bagging. The surgeon therefore decided to provide oxygen through a nasal cannula.

The patient’s face was then prepped and draped in the usual sterile fashion using PhisoHex® (hexachlorophene) solution without alcohol. After the surface of the patient’s skin was dried, the surgeon sharply excised the right nasal lesion flush with the patient’s skin. Direct pressure was applied for hemostasis. However, the base of the wound continued to ooze. The surgeon decided to use electrocautery. When the surgeon touched the tip of the electrocautery device to the wound base, there was an immediate explosion under the drapes and in the region of the patient’s upper chest. The flames then spread across the patient’s face. The surgeon immediately attempted to extinguish the flames on the patient’s face, using hands, elbows and chest. She then pulled the towels and drapes off the patient and patted out the flames. As she removed the towels and drapes, she ordered that all of the oxygen in the operating room be turned off.

The estimated time between the explosion and the extinguishing of the flames totaled between five and fifteen seconds. After visually confirming that the patient had no more flames on her face, the surgeon noticed that the tip of the oxygen tubing was on fire,

so she removed the tubing from the operating table. The surgeon then applied cold compresses to the patient’s burns and applied Baciguent® (bacitracin). The patient was then transferred to a facility specializing in the treatment of burn victims.

Luckily, the patient recovered from her burns with minimal scarring. She filed a medical negligence claim against the surgeon and the hospital, which was settled for a confidential amount.

Discussion

The experts opined that the use of electrocautery on the nasal lesion concurrently with the use of oxygen via nasal cannula was contraindicated. They pointed out that if oxygen is administered through a nasal cannula, it should be turned off and the room adequately ventilated before any electrocautery is used. Because oxygen is heavier than air, it tends to pool in low areas such as the chest, neck, and the back of the nasal passages. The experts felt that the use of the electrocautery in the oxygen-rich environment caused the explosion and fire in this case.

Risk Management Recommendations

Pursuant to Joint Commission National Patient Safety Goal 11, ambulatory care organizations and office-based surgery centers are specifically required “to educate staff, including operating licensed independent practitioners and anesthesia providers, about how to control ignition sources, manage combustibles, and establish guidelines to minimize oxygen concentration during surgical procedures.” But because the risk of surgical fires exists in any setting where there is an ignition source, oxygen and fuel, The Joint Commission encourages all hospitals to implement the recommendations that were published in Sentinel Event Alert Issue 29, which is available on The Joint Commission website at: www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_29.htm (accessed 5/17/2008).

The ECRI Institute has updated its surgical fire risk reduction recommendations, which are available on the National Guideline Clearinghouse website at:

www.guideline.gov/summary/summary.aspx?doc_id=3688 (accessed 5/17/2008). The American Society of Anesthesiologists (ASA) approved a Practice Advisory for the Prevention and Management of Operating Room Fires on October 17, 2007, which is available on its website at: www.asahq.org/publicationsAndServices/orFiresPA.pdf (accessed 5/17/2008).

Providers are encouraged to access and utilize these guidelines where appropriate. For more information about the prevention of surgical fires, see the December 2007 *Claims Rx* entitled “Reducing the Risk of Surgical Fires,” available on the NORCAL website at: www.norcalmutual.com/publications/claimsrx/dec_07.pdf (accessed 5/17/2008).

Surgical Site Infections

Case study #5

Allegation: *Negligent total knee replacement resulted in methicillin-resistant staphylococcus aureus (MRSA) infection and prolonged recovery in a 65-year-old man.*

The Event: The patient had a history of diabetes, smoking and chronic knee pain. Degenerative joint disease in his right knee was diagnosed based on MRIs and x-rays. After an initial work up and informed consent, the patient presented to surgery. The surgeon wrote by hand his usual preoperative orders: Ancef® (cefazolin) was ordered to be given one hour prior to the surgery. The surgery went well, and the patient was discharged. Three days later he complained of knee pain and redness and swelling at the incision site. Examination of the site revealed purulent material. Cultures of the wound were taken, which grew MRSA.

Postoperative review of the events revealed that the Ancef® was not given. Not only were the physician’s handwritten orders difficult to read, but a new nurse unfamiliar with the surgeon’s routine was staffing the preoperative unit. She did not know if the hospital had a protocol on preoperative prophylaxis and simply assumed that if there was a protocol, someone else had taken care of it.

When the infection was diagnosed, the physician, who was rushed and on his way to another surgery, quickly gave information about the infection to the patient and his wife. He did not allow time for questions. The patient’s family members had read recent media reports of the increasing numbers of MRSA infections occurring in the hospital. Among themselves, they discussed how certain members of the staff had not washed their hands before attending to the patient. The patient’s daughter, a cosmetologist, noted that some of the nurses had cracked, chipped fingernails and that many of them had long hair that was not restrained.

The patient filed a claim against the hospital and surgeon, alleging that the postoperative infection was the result of the failure to use prophylactic antibiotics and inadequate infection control protocols and procedures.

Discussion

During the deposition of the surgeon, the plaintiff’s attorney questioned the surgeon’s general infection control techniques. When asked how he prepped a site, the surgeon said he had the nurses shave the patient right before surgery, then use a standard surgical prep and drape. He was then asked if he was aware of studies which show the infection rates in clipping versus shaving. He curtly replied that he had been shaving patients for 30 years.

Experts were supportive of the surgeon’s work-up of the patient. However, they were critical of the missed prophylactic antibiotic administration. The failure to administer antibiotics had multiple causes: the physician’s illegible handwriting, the nurse’s lack of knowledge and the hospital’s lack of standardized protocols for preoperative antibiotic prophylaxis. Although experts felt that it would be difficult to prove that the surgeon’s or hospital’s negligence caused the infection, the plaintiff’s attorney was prepared to cite multiple other infections occurring in the hospital and media information about MRSA. He was also prepared to highlight the surgeon’s and the hospital’s lack of adherence to all Institute for Healthcare Improvement (IHI) and Centers for Disease Control and Prevention

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(CDC) guidelines on prevention of surgical infections. For these reasons, the case settled out of court with payments made by the hospital and the surgeon.

SSI Information and Risk Management Recommendations

Nosocomial (healthcare associated) infections, commonly caused by surgical site infections (SSI), are estimated to occur in 2.6 percent of the approximately 30 million operations performed each year in the United States—the second most frequent adverse event reported in hospital care. It is estimated that 40 to 60 percent of these infections can be prevented. According to the IHI, the following four practices and associated implementation recommendations can significantly reduce the incidence of SSIs:

1. Appropriate use of prophylactic antibiotics for surgical site infections

Hospital teams across the United States have developed and tested antibiotic use process and systems changes that have resulted in lower SSI rates. The IHI recommends the following measures for the prophylactic antibiotic process:

- Ensure that patients receive prophylactic antibiotics within one hour prior to the surgical incision.*
- Ensure that prophylactic antibiotic selection is consistent with national guidelines.
- Discontinue prophylactic antibiotics within 24 hours after the end of surgery (48 hours for cardiac patients).

IHI Implementation Recommendations

- Use preprinted or computerized standing orders that specify which antibiotic is to be used, timing, dose, and when it is to be discontinued.
- Create pharmacy- and nursing-oriented protocols that address preoperative antibiotic selection, timing, and dosing based on patient characteristics and the kind of surgery he or she is going to receive.
- Ensure that operating room drug stocks only include standard doses and standard drugs as recommended in national guidelines.

- Assign dosing responsibilities to a particular member of the healthcare team.
- Seek input from pharmacy, infection control, and infectious disease departments to ensure the appropriateness of the antibiotic selection, timing and duration.
- Include verification that antibiotics have been administered in the “time-out” or pre-procedural briefing so that administration can occur prior to the procedure.⁸

2. Appropriate hair removal

Studies have shown that shaving the patient with a razor prior to surgery creates a greater risk of wound infection than clipping, depilatory use or no hair removal. According to the IHI, hair removal may not be necessary for many procedures. When it does need to be done, IHI recommends using clippers, since depilatory creams can cause skin reactions. They further recommend that the hair removal be done outside of the operating room to limit the presence of loose hairs.⁸

IHI Implementation Recommendations

- Ensure that clippers are available and staff is adequately trained in their proper use.
- Use signs and posters to remind clinicians not to use razors.
- Tell patients not to independently shave the surgical site prior to surgery.
- Remove razors from the hospital.
- Request that the purchasing department no longer purchase razors.⁸

3. Controlled postoperative serum glucose for cardiac surgery patients

Studies have shown that the degree of postoperative hyperglycemia correlates with the rate of SSI in patients who have undergone major cardiac surgery.

IHI Implementation Recommendations

- Use one standard glucose control protocol for cardiac surgery.
- Ensure that responsibility and accountability is

*Because it takes longer to infuse, Vancomycin[®] can be started within two hours prior to incision.

determined and assigned for blood glucose monitoring and control.

- Early enough in the preoperative period, regularly check glucose levels to identify patients with hyperglycemia so that risk can be assessed and treatment can be initiated if appropriate.⁸

4. Immediate postoperative normothermia for colorectal surgery patients.*

Studies indicate that colorectal surgery patients have a lower risk of SSI if they are prevented from becoming hypothermic during the perioperative period.⁸ Anesthesia, anxiety, wet skin preparations and skin exposure in cold operating rooms can cause patients to become clinically hypothermic during surgery.

IHI Implementation Recommendations

Hospital teams throughout the United States have developed and tested process and systems changes that have lowered the risk of SSI in colorectal surgery patients. These changes include:

- Prevention of hypothermia during all phases of the surgical process.
- Use of warmed forced-air blankets preoperatively, during surgery and in PACU.
- Use of warmed fluids for IVs and flushes in surgical sites and openings.
- Placement of warming blankets under the patient.
 - Be aware that some of the older water-circulating units have caused patient burns.
- Placement of hats and booties on patients.
- Prevention of operating rooms and other patient areas becoming excessively cold overnight.
- Measurement of temperature with a standard type of thermometer.⁸

Talking to Patients about Unanticipated Outcomes

An “unanticipated outcome” can be defined as a negative or unexpected result stemming from a diagnostic test, medical judgment or treatment, surgical intervention, or from the failure to perform a test,

treatment or intervention. As some of the closed claims examined in this *Claims Rx* indicate, an unanticipated outcome is not always the result of medical error or professional negligence.

A patient has a need and right to know about her condition and to make educated, meaningful healthcare decisions in the event of an unanticipated outcome. Disclosure is not only required by medical ethics, but it also can restore the patient’s faith and trust, allowing the healthcare team to provide the best possible care going forward. Finally, disclosure can be a powerful liability risk management tool. Many healthcare professionals have found that rather than prompting litigation, communication about errors actually defuses anger and may prevent litigation.

Disclosure and the Informed Consent Process

Disclosure really starts when a patient and provider engage in the informed consent process. Ideally, during initial consent discussions, the patient is exposed to possible adverse outcomes associated with the anticipated treatment or procedure. Frequently, patients have a difficult time understanding that adverse outcomes are the occasional outcome of medical treatment and not necessarily the result of medical error.

A significant number of medical negligence claims involve an unanticipated outcome that is a known risk of the procedure. Sometimes during the consent process these risks are not addressed, or they are discussed but the patient does not understand them or later forgets about discussing them. Ensuring that the patient understands what he or she is consenting to is the responsibility of the provider. Providers must, therefore, be able to determine whether the patient actually understands what she is agreeing to. In a case where the physician doesn’t understand the patient’s language, engaging an interpreter may be legally required. If a patient only understands sign language, a sign language interpreter may be required. Finally, if the patient does not read, or cannot understand medical terminology, the provider must alter the consent

*This recommendation does not pertain to patients already utilizing therapeutic hypothermia.

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process to ensure that the patient comprehends what is being discussed. A patient who cannot understand her provider has not given a valid *informed* consent.

Documentation of the informed consent process, including efforts to ensure patient comprehension, can be used as a guide for providers in post-surgical discussions with the patient when complications lead to an unanticipated outcome. For example, the informed consent notes in the medical record can be used as a reference in a discussion with a patient that might start: "Do you remember when we discussed that one of the risks of the ACL reconstruction is nerve damage? Unfortunately, during the procedure it happened. This is what we need to do..." A truly informed patient who feels she has made meaningful decisions about healthcare and fully realizes the risks is less likely to file a medical liability claim. But if a claim is filed, documented evidence that unanticipated outcomes have been discussed, particularly extra efforts to confirm comprehension of such outcomes, provides significant support to a provider's defense.

NORCAL's Nine Steps For Responding To Unanticipated Outcomes

When an unanticipated outcome occurs, the best response is one that is thoughtful and organized. The order in which NORCAL's Nine Steps are completed may vary depending on the individual situation, whether the outcome is a known complication or the result of medical error, and whether additional institutional policies exist. In every instance, however, caring for the patient's immediate needs should always come first. The nine steps are designed for hospital, group and individual physician office settings. An involved provider should ensure that all steps are addressed, which may involve delegating an action to others .

1. CARE: Take Care of the Patient
2. PRESERVE: Preserve the Evidence

3. DOCUMENT: Document in the Medical Record
4. REPORT: Complete Mandatory Reports If Required
5. NOTIFY: Notify Claims Department of Your Malpractice Carrier
6. DISCLOSE: Conduct the Initial Disclosure Discussion
7. ANALYZE: Analyze Unanticipated Outcome to Prevent Recurrence and/or Improve Future Outcomes
8. FOLLOW THROUGH: Conduct Subsequent Disclosure Discussion(s)
9. HEAL: Heal the Healthcare Team

Responding promptly to unanticipated outcomes helps to preserve the physician-patient relationship, ensures that the patient's medical needs are met, and possibly averts litigation. Moreover, the healthcare team's understanding of why and how the event occurred can lead to corrective action and prevent the occurrence of similar events in the future. These processes can serve to improve overall patient care in a medical group, hospital or clinic.

For more information about responding to unanticipated outcomes, see the May 2007 *Claims Rx* entitled "Managing the Risks of an Unanticipated Outcome: Before, During and After the Event," which can be accessed on the NORCAL website at: http://www.norcalmutual.com/publications/claimsrx/may_07.pdf (accessed 05/18/2008).

Conclusion

As with many medical liability claims, claims against surgeons involve communication problems at various levels. Consequently, in order to improve the quality of patient care and reduce medical liability risk, surgeons should focus on improving communication with patients and other providers, improving documentation and improving adherence to patient safety protocols and procedures. ■

SIGN-YOUR-SITE

A Checklist for Safety

- _____ Surgeon involves the patient in confirming the operative site during the marking of the operative site by the surgeon. Copies of the operative permit/informed consent form should state the site and side of surgery.
- _____ Surgeon signs initials to the operative site in permanent marking pen.
- _____ Other members of the operative team verify the correct site.
- _____ Surgeon verifies that X-rays and medical records are for the correct patient, as well as confirming the identity of the patient.
- _____ Member of the operative team double-checks each of the following items against the marked site:
 - _____ Medical records
 - _____ X-rays and other imaging studies
 - _____ Informed consent
 - _____ Operating room/anesthesia record
 - _____ Correct equipment/implant/device available
- _____ In spine surgery or when the bone or level is not identifiable visually, surgeon takes an intraoperative X-ray using markers that do not move to confirm the site.

Complete all the items on this page. Relying on a single preventive effort only can result in errors!

Patient Name: _____

Physician: _____

Procedure(s): _____ Date: _____

Signature of Person Completing the Checklist: _____

Checklist materials derived from and revised by the American Academy of Orthopedic Surgeons (AAOS) with the permission of the North American Spine Society (NASS). The revised version is reprinted with the permission of the AAOS and the NASS. December 2003

Notes

¹ Dwyer K. Analysis of CRICO surgery-related cases. Forum 2004;23(4):5-9.

² Second Wrong Site Surgery Summit – February 23, 2007. "Performance of the Correct Procedure at the Correct Body Site." Available on The Joint Commission Website at: www.jointcommission.org/NR/rdonlyres/96936A98-D608-4044-B104-8A1D5423ECBE/0/Synopsis_WSS_II.pdf (accessed 5/18/2008).

³ Guide to the Ethical Practice of Orthopaedic Surgery-7th edition[®]. December 2003. Available on the American Academy of Orthopedic Surgeons website at: www.aaos.org/about/papers/ethicalpractguide.pdf (accessed 5/18/2008).

⁴ Facts about the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™. Available on The Joint Commission Website at: www.jointcommission.org/PatientSafety/UniversalProtocol/up_facts.htm (accessed 5/18/2008).

⁵ Wong D. Surgical site marking comes of age. April 2004 AAOS Bulletin. Available on the AAOS website at: www2.aaos.org/aaos/archives/bulletin/apr04/feature1.htm (accessed 5/17/2009).

⁶ Surgical Fires. HRC Risk Analysis. Vol. 2. Safety and Security 13.1. September 2006.

⁷ Practice Advisory for the Prevention and Management of Operating Room Fires. Available on the American Society of Anesthesiologists website at: www.asahq.org/publicationsAndServices/orFiresPA.pdf (accessed 5/17/2008).

⁸ 5 Million Lives Campaign. Getting Started Kit: Prevent Surgical Site Infections. How-to Guide. 2008. Available on the Institute of Healthcare Improvement website at: www.ihl.org/IHI/Topics/PatientSafety/SurgicalSiteInfections/ (accessed 5/18/2008).

ClaimsRx

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Risk Management and Patient Safety Strategies for Surgeons

Original release date: July 2008

Expiration date: July 31, 2009

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Please evaluate this educational activity as a whole by checking the appropriate box:

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As a result of this activity, I will make the following change(s) in my practice:

- Change/improve communication with patients (general)
- Change/improve communication with patients whose health literacy is limited
- Change/improve communication with other providers
- Change/improve follow-up systems
- Change/improve documentation practices
- Other _____

Was this activity free of commercial bias? Yes No

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