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Industry and Company News
Rescuers at the University of Washington in Seattle reviewed 464 consecutive orthopedic malpractice claims from The Doctors Company that closed between January 2008 and April 2010. Their analysis, titled “Lessons Regarding the Safety of Orthopaedic Patient Care,” was published in February 2013 in the Journal of Bone and Joint Surgery. A few highlights from this study follow; I encourage you to read the entire paper.

Degenerative conditions accounted for 56 percent, and traumatic injuries accounted for 44 percent of total orthopedic claims. Emergency treatment was related to 29 percent of total claims. It is significant that 81 percent of these claims were related to surgical treatment. This prevalence of claims relating to intraoperative events contrasts with general surgery, where most claims result from pre- and postoperative events. The anatomic sites of the adverse events giving rise to these claims were lower extremity, 45 percent; upper extremity, 30 percent; spine, 15 percent; and hip, 10 percent.

Major allegations in the claims included:

- Failure to protect structures in the surgical field, 15 percent.
- Fracture management errors, 14 percent.
- Failure to prevent, diagnose, and treat infections, 11 percent.
- Implant malposition, 8 percent.
- Failure to prevent, diagnose, and treat complications, 7 percent. The complications included:
  - Compartment syndrome, 28 percent (60 percent involved fracture fixation).
  - Skin ulcers, 19 percent.
  - Pulmonary embolism, 15.5 percent.
  - Reflex sympathetic dystrophy, 12.5 percent.
  - Hematoma, 12.5 percent.
  - Medication errors, 4 percent.

Nineteen percent of knee arthroplasty claims alleged implant malposition, and 16 percent were related to infection. Thirty-three percent of knee arthroscopy claims alleged failure to diagnose or treat the presenting problem, and 13 percent were related to infection.

Twenty-one percent of shoulder arthroscopy claims alleged inadequate postoperative care, 16 percent were related to medication errors, and 16 percent were related to equipment issues.

Thirty-two percent of spine procedure claims involved injury to structures in the surgical field (77 percent involved spinal cord and nerves), 15 percent alleged failure to diagnose or treat the orthopedic problem, 9 percent involved implant malposition, 9 percent involved patient dissatisfaction with the final outcome, and 6 percent involved wrong-level surgery.

Forty-nine percent of hip arthroplasty claims alleged implant malposition, 17 percent alleged failure to protect surrounding structures (50 percent involved nerves, and 50 percent involved new fractures), and 9 percent involved patient dissatisfaction with the final outcome.

The following vignettes are representative of orthopedic claims:

### Clinical Presentation

**Intractable back pain:** An L4/5 microdiscectomy was performed using a rongeur.

**Unexpected Outcome**
BP at closure was 64/40; EBL 3L. Abdominal US showed iliac artery bleeding. A nicked artery was repaired with a graft. Post-op the patient developed DIC; no platelets were available. Transferred to larger hospital, where bleeding from graft was diagnosed; clotting factors depleted; cardiac arrest. Autopsy showed complete transection of iliac artery.

### Clinical Presentation

**Shoulder hemiarthroplasty for degenerative arthropathy.**

**Unexpected Outcome**
Plastic reamer became lodged in humeral shaft, and implant wouldn’t fully seat. While “reaming out” the reamer and cement, the humeral shaft cortex was perforated. When implant

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Defective Devices

by Jerrald R. Goldman, MD, Governor Emeritus, and Victoria H. Rollins, MHA, RN, Director, Patient Safety Programs, The Doctors Company

Device manufacturers often contact physicians with issues regarding implantable devices. Contact can range from an alert of issues with the device to a U.S. Food and Drug Administration (FDA) Class I recall.

Implantable devices may be recalled for a variety of reasons: product efficacy, defects, sterility issues, risk to public health, or a violation of FDA regulations. Most recalls are carried out voluntarily by the manufacturer; however, the FDA can request a recall if the manufacturer does not take action on its own.

The FDA classifies recalls into three categories:

- **Class I recalls** are the most serious. They involve a health hazard with a reasonable probability that the use of the product will cause serious adverse health consequences or death.
- **Class II recalls** present a remote possibility of adverse health consequences from the use of the product.
- **Class III recalls** involve a situation where the use of the product is not likely to cause adverse health issues.

Consider the following case study:

The claim involved a 58-year-old female with a history of valgus knee arthritis. She had a total knee replacement. Five years after the replacement, the patient returned to the orthopedist complaining that her knee felt “loose” and was making a popping sound. After examination, the orthopedist recommended an arthroscopy to inspect and correct the instability. During the arthroscopy, the orthopedist replaced the plastic post with a slightly thicker post but noted that, although there was some medial wear in the device, the replaced post had not failed.

A year later, the patient called the orthopedist after a fall. She was directed to the emergency department, where she was evaluated by another orthopedist. The patient claimed that the first orthopedist had used a defective knee component and had concealed the information.

The first orthopedist refuted the allegation, stating that she had never received notice the knee component was defective and that she had used the device with a number of patients without problems or complaints. After the patient filed a lawsuit, the orthopedist learned from the manufacturer’s representative that one of the posts in the hardware had been found to be defective. Although the manufacturer had identified the post defect, it was not enough to warrant an FDA recall during this time period. In this case, the FDA did not consider that the device met the requirements for a class recall. However, had the physician known of the defect, disclosure to the patient should have occurred—an action that might have prevented the malpractice allegation.

If you receive a patient complaint about a device or are concerned that an incident might lead to a claim, it is essential that you notify your Regional Claims Office. Your claims specialist will take action immediately to protect you and advise you of the next steps. Find details on reporting an incident or a claim at www.thedoctors.com/claims. If you receive a class recall notification, it is imperative that you disclose it to your patient.

The FDA has mandated that manufacturers must include a unique device identifier (UDI) on all devices, starting with implantable devices. Implementation of the UDI system is expected to begin in 2014. UDIs can be captured in the EHR and used for device-tracking over time. The use of UDIs may allow for more accurate adverse event reporting, reviewing, and analyzing so that problem devices can be...
Anti-MICRA Ballot Measure Filed; Oklahoma Special Session
by Hal Dasinger, Vice President, Government Relations

In the last issue of The Doctor’s Advocate, I discussed efforts by The Doctors Company and others to prevent the Consumer Attorneys of California (CAOC) from getting legislation passed that would raise or eliminate the cap on noneconomic damages that is central to California’s Medical Injury Compensation Reform Act of 1975 (MICRA). In an attempt to increase pressure on the legislature, CAOC and its front group, Consumer Watchdog, filed a proposed ballot measure with the attorney general seeking to raise the MICRA cap to over $1 million. The drastic increase to the MICRA cap is buried in a lengthy proposal that would also require use of the state database monitoring prescription drugs and mandate physician drug testing.

The stated goal of the personal injury lawyers was to push the legislature and MICRA supporters to compromise on an increase to the cap in order to avoid an expensive campaign to defeat the ballot measure. The tactic was unsuccessful and, in fact, appears to have backfired completely. Shortly after the measure was filed, Assembly Speaker John Perez (D-Los Angeles) appeared on a local television network affiliate in Los Angeles and pointed out that, with a ballot measure in the works, no legislator needed to take a potentially controversial stand on legislation that might alienate supporters.

Despite constant efforts by CAOC to pressure the governor and legislative leaders to support an end-of-session attack on the cap, the California legislature adjourned at midnight on September 12, 2013, without a MICRA amendment coming to the floor of either house. The Doctors Company and other members of the MICRA coalition spent the last weeks of the session lobbying legislators and explaining why the coalition has grown to more than 900 organizations opposed to any increase in the cap.

With the session over for this year, the focus has shifted to the ballot measure. Members of the MICRA coalition have formed a committee to oppose the measure and have begun organizing the opposition campaign and raising funds to defeat the measure—with over $30 million contributed so far. The trial lawyers are likely to begin gathering signatures in late October or early November. If the measure qualifies, it will be on the November 2014 general election ballot. Supporters of MICRA are well organized and committed to defeating the measure should it qualify for the ballot.

Oklahoma Reinstates Tort Reforms in Special Session
In response to a pair of 2013 decisions by the Oklahoma Supreme Court invalidating the Comprehensive Lawsuit Reform Act of 2009, the Oklahoma legislature met in a special session and enacted new laws reinstating many of the key provisions of 2009 reforms.

The 2013 legislation reenacted the 2009 language, providing for a variety of mostly procedural reforms that will be on the November 2014 general election ballot. Supporters of MICRA are well organized and committed to defeating the measure should it qualify for the ballot.

Learn more about DOCPAC or download a contribution form at www.thedoctors.com/DOCPAC. To learn more about the coalition’s efforts to protect MICRA, connect with Californians Allied for Patient Protection at www.micra.org, on Twitter at @MICRAworks, and on Facebook at bit.ly/FB-CAPP.

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and cement were replaced, cement leaked out and caused thermal necrosis of radial nerve.

Clinical Presentation
Total knee arthroplasty for degenerative arthropathy.

Unexpected Outcome
Post-op patient couldn’t dorsiflex foot, c/o pain, and developed foot drop. Returned to surgery and found partial laceration/crush of peroneal nerve proximal to fibular neck (possibly a saw injury). Post-op developed a MRSA wound and joint infection with prolonged recovery.

Clinical Presentation
External fixation of severe tibial plateau fracture.

Unexpected Outcome
Post-op, developed intermittent loss of pulses and sensation in toes. Four days later, ORIF performed, and, in the PACU, patient had no dorsalis pedis pulse, couldn’t move foot, and c/o pain. Foot became edematous, mottled, and tight; calf became hard. Compartment pressure not measured, and vascular consult not obtained. CT scan two days later c/w compartment syndrome. Incisions opened and found extensive muscle loss—may need BKA.

Clinical Presentation
Thirteen y/o to ER with arm pain due to wrestling injury. X-ray showed transverse fracture of proximal third of radius and ulna with a 2 mm lateral displacement of distal radial segment. Cast was applied in ER.

Unexpected Outcome
Saw orthopedist five weeks later; fracture healed and cast removed. Mother thought arm looked deformed, but orthopedist said it was fine. Obtained a second opinion because arm couldn’t be fully extended. X-ray showed alignment of radius and ulna on A-P view, but, on lateral view, there was a malunion of the radial fracture with angulation and possible rotation. Radial shaft osteotomy with internal fixation performed.

Clinical Presentation
Patient with ankle pain due to severe osteoarthropathy of talonavicular joint had arthrodesis with bone graft. Patient was diabetic with history of peripheral neuropathy, but surgeon felt sensation was intact. Blood glucose was 300 on day of surgery, but patient wanted to proceed.

Unexpected Outcome
Cryotherapy was used post-op to control pain and swelling. Instructions for its use were given by a PA two weeks before surgery; no documentation of discussion or risks; no written instructions; no informed consent. Five days post-op, frostbite injury occurred with skin necrosis requiring multiple débridements and skin grafts.

Clinical Presentation
Patient with chronic back pain had uneventful arthrodesis of posterolateral L3/4 with placement of screws and an autogenous graft from the iliac crest.

Unexpected Outcome
X-rays taken two weeks later showed displaced L4 screws. Right lower screw was lateral to L4 vertebral body, and the screw on the left was in the spinal canal. Surgeon did not recognize these misplacements. Patient developed L4 radicular pain and saw another surgeon, who ordered a CT scan and saw the problem. The screws and plating system were removed.

Clinical Presentation
Thirty y/o morbidly obese male fell on knee and saw surgeon four days later for pain. Leg was immobilized and elevated. MRI six days later showed dislocated patella. H&P noted family history of DVT and lupus; no lab tests were ordered. Surgery was uneventful.

Unexpected Outcome
Eight days later, the patient died suddenly. Autopsy revealed pulmonary saddle embolus and DVT in the leg with a 3” larger calf circumference. PCP’s medical records documented that he had a genetic increased risk for DVT and a diagnosis of lupus. Family claimed they told surgeon that the patient’s mother had died from a clotting disorder and that the patient had the same condition, but the surgeon replied he had “everything under control.”

Degenerative conditions accounted for 56 percent of total orthopedic claims.

Clinical Presentation
Morbidly obese diabetic with hypertension, CAD, and osteomalacia had total knee arthroplasty. During surgery, femur was fractured and repaired with bone graft. Post-op x-ray was OK. He was discharged to a SNF for rehabilitation.

Unexpected Outcome
At the SNF, patient had sudden severe pain upon standing; x-ray showed displaced fracture of femoral shaft and lateral femoral condyle. Patient had ORIF with cables and a plate. In PACU, he developed foot numbness with foot drop, but perfusion appeared to be OK, so he was again discharged to the SNF, where he developed cool foot and no leg pulses. Angiogram showed abrupt cutoff of popliteal artery at level of cable fixation. When repaired with a vascular graft, cable found looped over artery and nerve. Post-op developed muscle necrosis in posterior compartment and had AKA.

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identified and corrected more quickly. UDIs may also reduce medical errors by enabling healthcare professionals and others to identify a device and obtain important information concerning its characteristics more rapidly and precisely. It will also provide a standardized identifier to allow manufacturers, distributors, and healthcare facilities to more effectively manage medical device recalls.1

Patient Safety Recommendations

- Involve the patient in an informed consent discussion that encompasses the possible complications and side effects of device implantation so he or she can understand the benefits, risks, and alternatives.
- Dictate in the postoperative report the type of implanted device and its serial number or UDI, and copy the post-op report to the office record. Note the UDI number on the patient’s card in the office record on the first post-op visit.
- Assign a specific individual in the practice the responsibility of receiving, assessing, and acting on device recall information.
- Review and understand the recall information provided by the manufacturer before determining the next steps for the practice and affected patients.
- Have a process in place for notifying patients of medical device recalls. Follow FDA and manufacturer recommendations regarding actions to take, even if the action is monitoring only.
- Obtain manufacturer guidance; complete a clinical assessment; and discuss treatment options, risks, benefits, and alternatives with the patient.
- Document the date the notice was received, the source of the notice, the device or product name and model number, the names of patients in the practice who were notified, and actions taken. Monitor patient compliance with and response to the notification.
- Subscribe to the FDA recall web service, and assign a staff member to review the website at specific intervals: www.fda.gov/safety/recalls.
- Follow the established process for properly handling explanted devices.
- If the device is removed in a hospital setting, the hospital retains responsibility and will ordinarily store it and maintain custody or control. Direct patient requests for the device to the hospital risk manager.
- For Class I recalls, work with the surgical facility where the device was implanted to verify which patients have the device. Notify the patients immediately, and determine the appropriate course of action.
- For Class II or III recalls, it is appropriate to inform patients of their options. Contact your patient safety risk manager at (800) 421-2368, extension 1243, or patientsafety@thedoctors.com for a sample letter.

Not all devices recalled are defective, and patients may not incur health problems. Not all recalls require revision or explantation. Monitoring the device may be the recommended option. The patient’s safety must be the highest priority, and care should be taken to confirm device failure if revision surgery or explantation is being contemplated.

After reading the recall information, determine whether the patient must be seen and assessed and how quickly action must be taken. Depending on the category of the recall, the physician practice can be responsible for taking appropriate corrective action. The time frame for acting should be determined by the manufacturer’s recommendations and the classification of the recall.

Reference


New On-Demand CME Activity

Excessive or inappropriate use of opiates in the treatment of pain is a major national problem in the delivery of healthcare. Risks and Complications of Opiates, will help you prevent adverse outcomes while you earn CME credit. For complete details on all of our education and CME programs, go to www.thedoctors.com/cme.
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Clinical Presentation
An outpatient right knee arthroscopy for medial meniscus tear was scheduled. Patient missed pre-op appointment, and orthopedist told OR the patient was probably a no-show, but patient showed up and surgeon was called.

Unexpected Outcome
Surgeon stopped the admission process because he hadn’t done an H&P. He arrived and did a rushed H&P and informed consent for the right knee. Patient transported to OR while the assigned RN was at lunch. Admission process was incomplete before transfer, and right knee was not marked. OR nurse prepped both knees. Patient’s name and surgical procedure were not put on the grease board. Right knee x-rays were in OR but were not reviewed. Surgeon operated on left knee—a never event.

Clinical Presentation
Seventy-five y/o with hip pain due to degenerative osteoarthropathy underwent anterior total hip arthroplasty. A prosthesis with a smaller-than-usual stem was used due to surgeon’s concern about fracture.

Unexpected Outcome
Two weeks post-op, patient c/o pain on lateral aspect of hip and a limp; x-rays were unremarkable. Seen again at four weeks for persistent pain and limp; no x-rays ordered. Second opinion obtained at four months due to leg length discrepancy with external rotation deformity. X-ray showed subsidence of femoral component of hip prosthesis with fracture on posterior medial proximal femur and 2.5 cm leg shortening. Opinion: too-small stem caused subsidence and both the fracture and leg shortening.

Reference

Investigation performed at the University of Washington, Seattle, under the auspices of the Washington State Orthopaedic Association.

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include standards for expert testimony, immunity from liability for volunteers, court discretion over venue, and a definition of frivolous litigation.

Other reforms revived by the new laws include provisions affecting the use of credentialing information as evidence of negligence by a healthcare facility, a law requiring an affidavit that the plaintiff has acquired an expert opinion alleging negligence, and language limiting the ability of the plaintiff to dismiss an action without prejudice after a pretrial hearing.

Oklahoma enacted legislation in 2011 that lowered its cap on noneconomic damages to $350,000. That code section was not invalidated by the recent court opinions and so was not addressed in the special session.
New Risk Tip Series

We’ve launched a series of three-minute video risk tips designed for busy healthcare professionals.

“The Doctors Company has become the leader in efforts to reduce risk and keep physician practices safe,” said Robin Diamond, JD, RN, chief patient safety officer. “We encourage healthcare providers to watch these innovative video risk tips, share them with their colleagues, and, most importantly, put the suggestions shared in this series to work in their practices.”

Recent videos include “Reduce Medical Errors by Standardizing Patient Handoffs” (www.thedoctors.com/handoffs), “Four Tips for Providing Expert Testimony” (www.thedoctors.com/testimony), and “Top Tips for Avoiding HIPAA Violations” (www.thedoctors.com/violations).

Top Attorneys Sharpen Defense Strategies at Summit

When it comes to defending your livelihood and reputation, we seize every opportunity to gain the advantage. Our Annual Legal Summits are central to providing the industry’s most aggressive defense. We bring together our nationwide network of defense attorneys to share insights about developing litigation trends, the latest plaintiffs’ strategies, and successful defense practices.

We recently convened the 2013 Midwest Legal Summit—a meeting that gave more than 100 attorneys from Illinois, Indiana, Kansas, Kentucky, Michigan, and Ohio the opportunity to hone their defense strategies.

Animated Video on the Future of Health Care

Using findings from our groundbreaking Future of Health Care Survey, we’ve created an animated video that reveals how doctors view coming changes. View this video and subscribe to our YouTube channel at www.youtube.com/doctorscompany.

You can also follow us on Twitter at @doctorscompany and find us on LinkedIn and Facebook.

Reader Survey Results

Our commitment to protecting the practice of good medicine extends to delivering information on issues that matter to doctors.

Earlier this year, we asked members across the nation to participate in The Doctor’s Advocate reader survey. More than 2,100 physicians took the time to reply and to write in almost 500 comments outlining information they would like to see in future issues.

We received high marks for the relevance of our articles, and we learned that articles on claims case histories and analysis continue to be the most popular.

As a result of your comments, we’re adding a brief overview—“Article at a Glance”—to each main article to help you decide quickly if the content is relevant.

Thank you to everyone who participated in the reader survey. You’re helping us ensure that The Doctor’s Advocate continues to be a valuable member resource.

Significant Tribute Plan Milestone

We recently distributed a $138,599 award to one qualifying member. It’s our highest Tribute® Plan award to date—and another milestone for our unrivaled member benefit. To see your estimated balance and project your award, sign in at www.thedoctors.com.