

Preventive Action

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REDUCING LIABILITY IN COMPLEX CASES

By the Risk Management Experts at
First Professionals Insurance Company



Defining Your Role

Most medical errors are attributed to system errors – not faulty medical judgment. System failures increase with medical complexity and the number of physicians involved even when involvement is tangential. Malpractice claims attributed to a failure to timely diagnose and treat patients that are being followed by multiple physicians is an alarming trend. A common root cause of these claims is faulty coordination and management of care – easily prevented with fundamental risk management practices.

The most prevalent type of error in medical malpractice claims is not medical at all.⁽¹⁾ Surprisingly, claims that are absent a medical error are the most frequent type of claim. One example of claims that are absent a medical error is those involving the failure to supervise or monitor the patient’s case. When the root cause of claims is attributed to a lack of coordination and management, even the strongest defense may not prevail. Although every case is unique, juries tend to adopt higher expectations in direct relation to the size of the medical team.

System failures, such as faulty communication of clinical concerns and stat test results contribute to the number of adverse events, resulting in severe patient injury and costly medical malpractice claims. Inadequate documentation of the entire process often undermines the defensibility of otherwise acceptable medical judgment.

Delay in diagnosis continues to remain one of the most prevalent allegations in malpractice claims.⁽²⁾ Among the most frequent causes are lost or misdirected diagnostic test results. A common root cause in these cases is the failure to address abnormal test results in a timely manner. The unfortunate end result is often an absence or delay in treatment to the point of irreversible damage

to the patient – and to a defense. In a survey of 42 academic medical centers across the United States, factors that contribute to medical error were identified and include order entry, decision making, and complex systems.⁽³⁾

Delineation in physician responsibility and care is a fundamental risk management measure that is essential in complex medical cases and those with a sizeable medical team. Consultations, orders and reports should clarify your specific role in the care and treatment of the patient and document its parameters. Recall this caveat as the medical team morphs. Failure to act on abnormal (diagnostic) results is a common source of medical error.⁽⁴⁾

“ The most prevalent type of error in medical malpractice claims is not medical at all. ”

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Case Synopsis: Delay in Diagnosis and Treatment

Wrongful death action of a 52-year-old female due to an alleged failure to diagnose and treat an aortic dissection. Although the case was defensible in terms of medical causation – the patient's chances of surviving the dissection were virtually nonexistent upon her initial presentation – the lack of delineation in the medical management and coordination of care among the healthcare team necessitated settlement. Medical records could not support which physician was responsible for pursuing emergent diagnostic work-up or acting on the results of same. Consequently, aortic dissection was not included as a differential diagnosis, the patient was misdiagnosed with pancreatitis and surgical intervention was delayed.

Risk Management Guidelines:

- Determine who the primary attending physician is: direct communication accordingly.
- Clarify the reason for your participation and the extent of same.
- Define your role and document the date and time of initial and final contact and contributions in the care and treatment delivered.
- Do not assume responsibility for management beyond parameters.
- Document follow-up efforts and communication of test results.
- Verify when outstanding diagnostic studies, labs, and consults are complete.
- Clarify that on-call physicians, covering physicians, and physician extenders under your supervision are fully apprised and have delineated their respective care and treatment.
- Advise the patient and/or family member(s) of your participation in the medical team and the extent of same – document such disclosure.
- Document discussions with other clinical team members, including your understanding of your role and the parameters of your care.
- Provide directions for the daytime office and after-hours communication pathway of stat diagnostic test results and emergent orders.
- Document the chart in a way that clearly supports your medical rationale.
- Seek legal or risk management guidance when uncertain how to proceed from a liability standpoint.

⁽¹⁾ *Physician Insurers Association of America. Research Department. PIAA Risk Management Review Combined Specialties. 2006 Edition. Rockville, MD 20850*

⁽²⁾ *Closed PIAA Cumulative Data Sharing Report. Closed Claim Data 1985 to 2006.*

⁽³⁾ *University HealthSystem Consortium, Performance Improvement Benchmarking Survey Results. Oak Brook, IL: Author; 2000*

⁽⁴⁾ *The Patient Safety Handbook. Youngberg, B.J., Hatlie, M.J., 2004. Jones and Bartlett. Sudbury, MA 01776*

Risk Management News Alert

Darvon (propoxyphene) and Darvocet (propoxyphene & acetaminophen)

The U.S. Food and Drug Administration (FDA) recommends against continued prescribing of the pain reliever propoxyphene due to new data revealing that its use can cause serious toxicity to the heart even when used at therapeutic doses. The drug manufacturer (Xanodyne Pharmaceuticals Inc.) of Darvon and Darvocet has voluntarily withdrawn the drugs effective 11/19/2010. Manufacturers of generic brands of propoxyphene are likely to adhere to the FDA request that it be withdrawn from the market.

The results of the latest study showed that when propoxyphene was taken at therapeutic doses, there are significant changes to the electrical activity of the heart; prolonged PR interval, widened QRS complex and prolonged QT interval. These changes can be seen on ECG and can increase the risk for serious abnormal heart rhythms.

The FDA recommends that healthcare professionals:

- Stop prescribing and dispensing propoxyphene-containing products
- Contact patients currently taking propoxyphene-containing products and ask that they discontinue the drug
- Inform patients of the risks associated with propoxyphene
- Discuss alternative pain management strategies
- Be aware of the possible risk of cardiac conduction abnormalities in patients taking propoxyphene and assess patients for these events if they present with any signs or symptoms of arrhythmia
- Report any side effects with propoxyphene to the FDA's MedWatch program

Although the FDA's predicate for withdrawal of the drug is the risk for abnormal heart rhythm, propoxyphene may also be a factor in accidental and intentional overdose either alone or in combination with other CNS depressants. Product manufacturers warn that propoxyphene should not be prescribed for patients who are suicidal or have a history of suicidal ideation.

In terms of liability concerns, physicians who have prescribed Darvon, Darvocet and propoxyphene-containing products can help lessen their exposure to what is presently viewed as a potential product liability issue by adhering to FDA safety recommendations and fundamental risk management measures.

Risk Management Guidelines:

- Determine if you or those in your practice are affected by the propoxyphene issue
- Adhere to all FDA safety recommendations
- Identify all patients that are or could be affected
- Identify and inform patients that are at increased risk for complications
- Inform all affected patients and document your discussions
- Consider flagging charts (and/or EMR) for patients with a history of propoxyphene use
- Address and document the presence or absence of clinical symptoms
- Implement individual cessation, weaning or alternative pain management regimens
- Educate staff members and all physician extenders. Revise any applicable policy and procedures
- Update patient history forms to include the use of propoxyphene and alternative medications
- Refer patients that are or may be affected to the appropriate medical specialist
- Remain up-to-date regarding both the clinical and liability issues applicable to your medical practice
- Contact the FDA for specific information regarding propoxyphene at 1.800.332.1088
- Seek legal or risk management guidance should uncertainty arise

References:

U.S. Food and Drug Administration. FDA Safety Announcement 11-19-2010

<http://www.fda.gov/Drugs/DrugSafety/ucm234338.htm>.

Darvocet-N (Propoxyphene Napsylate and Acetaminophen) Manufactures Product Insert 2009

Darvon, Darvocet Banned. WebMD Health News. DeNoon, Daniel J. Nov.19, 2010. •

Red Flags Rule Will Not Apply To Most Physicians

Federal Trade Commission regulations issued in 2007, known as the “Red Flags Rule” (“Rule”), required that certain entities develop and implement written identity theft prevention and detection programs to protect consumers from identity theft. However, the Rule did not specifically state whether physician practices were subject to the Rule requirements. It remained uncertain if physicians, lawyers, dentists and other professionals should be classified as “creditors” for the purposes of compliance with the Rule just because they do not receive payment in full at the time that they provide their services.

Clarification came in December 2010 with passage of “Red Flag Program Clarification Act of 2010”, which limits the type of “creditor” that must comply with the Rule.

Not billing or receiving payment in full at the time a physician provides services will not result in the physician being considered a creditor under the Rule.*

In light of the new law, the Rule will not apply to most physician practices.

For physicians who are otherwise not exempted, First Professionals has developed a packet of materials to help clarify the Rule pertaining to patient identity theft protection standards. The packet contains an overview of the new Rule, risk management guidelines, and website references. It also contains several forms and templates to assist with compliance measures.

For additional information regarding the Rule or the Red Flag Program Clarification Act of 2010 go to:

- <http://www.ftc.gov/bcp/edu/microsites/redflagsrule/index.shtml>
- <http://www.ftc.gov/bcp/edu/pubs/articles/art11.shtm>
- <http://www.gpo.gov/fdsys/pkg/BILLS-111s3987enr/pdf/BILLS-111s3987enr.pdf>
- www.ama-assn.org

*The law indicates that creditors that fall under the Rule are only those who regularly and in the ordinary course of business: (1) obtain or use consumer reports, directly or indirectly, in connection with a credit transaction; (2) furnish information to certain consumer reporting agencies in connection with a credit transaction; or (3) advance funds to or on behalf of a person, based on the person’s obligation to repay the funds or on repayment from specific property pledged by them or on their behalf (this does not include creditors who advance funds on behalf of a person for expenses incidental to a service provided by the creditor to that person). Creditors that fall under one of the above-mentioned categories must comply with the Rule.

News Alert

DESPITE PREVENTATIVE EFFORTS, SURGERY MISTAKES CONTINUING

Despite a nationwide effort to prevent surgical errors, a new study published in the *Archives of Surgery* reveals that doctors are still reporting wrong-site and/or wrong-patient surgeries. In 2004, U.S. hospitals adopted universal protocols introduced by The Joint Commission. Those protocols included a pre-procedure verification, a surgical site marking, and a “time-out” performed immediately before the surgical procedure. The study found that although these protocols have largely been adopted, mistakes continue to occur. For the study, researchers examined a database of errors that doctors reported to PIAA Member COPIC between January 1, 2002 and June 1, 2008. Chairman and CEO of COPIC, Ted Clarke, MD, said, “COPIC voluntarily provided the data used in this study and I and four other physicians employed by COPIC co-authored it, along with Dr. Philip F. Stahel and several other physicians. Our involvement is an illustration of COPIC’s continuing commitment to improve patient safety.” Of the 27,370 incidents in the database, the study found 25 surgeries were performed on the wrong patient and 107 operations were on the wrong body part. In considering the reasons for the mistakes, researchers found diagnostic errors accounted for 56% of the operations on the wrong patient and 100% were due to errors in communication. Errors in judgment resulted in 85% of wrong-site procedures, and not performing a time-

out accounted for 72% of the cases. Dr. Clarke added, “As this study demonstrates, often the problem is not a reckless or incompetent provider so much as a systemic communications breakdown. The findings of this study, and the attention it draws to this issue, will help improve patient safety not just in Colorado but also nationally.” (*Associated Press*, 10/18/10) —

PATIENTS CHANGING DOCTORS DUE TO ERRORS—REAL OR IMAGINED

A new survey of primary care patients in North Carolina found that almost one out of six patients believed their physician had made the wrong diagnosis or a treatment error, and nearly one in seven changed practices as a result. The findings were published in the *Archives of Internal Medicine*. Lead author of the study, Dr. Christine E. Kistler, of the University of North Carolina at Chapel Hill, said, “Patients perceive mistakes in all types of outpatient clinics from primary care to specialty care, eye doctors to dentists, and they often change their doctors because of these perceptions.” However, Kistler added, that in some cases it didn’t appear the doctor had done anything wrong. “It’s possible that the doctor has not explained their plans appropriately and that communication might improve what the patient expects to happen,” she said. (*Reuters*, 9/14/10) —

Case Study: Failure to Diagnose Post-op Complications

Editor's Note: This case analysis reflects an actual First Professionals' case.

Case Analysis

A 43-year-old female underwent laparoscopic cholecystectomy. Post-op nursing notes documented that the patient was febrile, complained of moderate discomfort, and had an increased white blood count. The surgeon ordered palliative treatment and the patient was discharged two days later. On post-op day six, the patient's husband phoned the surgeon's office reporting increasing pain and fever. An appointment was scheduled for the following day. However, later that evening, the patient was re-admitted on an emergency basis and found to have extensive damage to the hepatic ducts necessitating a biliary repair procedure. Following surgery, the patient experienced a somewhat stormy but gradual recovery. Suit was filed against the surgeon alleging negligent surgical performance and post-op care.

While the surgical complication itself could be defended, the physician's post-op management necessitated settlement of the case. Medical experts were unable to support the delay in diagnosis of the surgical complication postoperatively in light of the clinical indications of complication and the insured's failure to more closely monitor the patient. Experts held that the patient should have been re-evaluated shortly after the original hospital discharge given ongoing complaints of pain and discomfort in the face of an elevated white count. Consequently, settlement of the case was necessitated.

Risk Management Discussion

Frequently, claims involving post-operative complications involve known risks. Early recognition and appropriate case management are key factors in reducing a physician's exposure in these situations. Consider the following loss prevention measures in order to help reduce errors and deter lawsuits and preserve defenses necessary to defeat the unavoidable claim:

- Utilize informed consent
- Re-evaluate post-op patients prior to discharge
- Obtain all outstanding labs and diagnostic studies prior to discharge
- Document the absence of clinical indications of complications
- Schedule prompt follow-up appointments
- Document no-shows or cancellations
- Provide written post-op instructions, outlining the expected side effects and the unanticipated signs and symptoms that should be reported
- Give high priority to post-op patient complaints

If a complication develops, consider the following steps:

- Inform the patient – express empathy
- Document your medical rationale
- Increase communication
- Seek legal or risk management guidance

This information does not establish a standard of care, nor is it a substitute for legal advice. The information and suggestions contained herein are generalized and may not apply to all practice situations. First Professionals recommends you obtain legal advice from a qualified attorney for a more specific application to your practice. This information should be used as a reference guide only.

Legal FAQs For information specific to your state of practice, contact First Professionals' Risk Management Department



What is the most significant benefit of a well-documented chart?

In addition to patient safety, records that support your medical rationale in a case or explain why a less than perfect outcome may have occurred are generally not pursued as claims.

Can a physician be liable for the actions of a physician extender, even if the supervising physician's actions are appropriate?

Yes. The supervising physician may be vicariously liable for the negligent acts of the physician extender. Under expanding theories of tort liability,

physicians are increasingly being held responsible for the acts of physician extenders in all clinical settings.

Do Florida physicians need to co-sign charting entries made by Physician Assistants?

Effective July 1, 2010, FLORIDA physicians are no longer required to cosign for a physician assistant. According to Section 358.347(3), FS, a physician supervising a physician assistant pursuant to the Florida statute may not be required to review and cosign charts or medical records prepared by such physician assistant.

It is important to note, however, that each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than four currently licensed physician assistants at any one time.

In addition, there are still other conflicting areas where the physician is required to cosign (thus the "may not be required" language in the statute) such as in an obesity clinic, pain management, and if a patient is referred from another physician and the PA performs the initial evaluation – the physician must review and cosign within 15 days.

Are HIPAA compliance mandates anti-electronic?

No. Doctors can communicate via e-mail, the telephone or fax machines. However, they must protect their patients' protected health information while doing so.

In what ways do the HIPAA Security Rule and Privacy Rule differ?

Although the Security Rule is closely linked with the Privacy Rule, the Security Rule entails the privacy of electronic protected health information. ●