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'Defensive' ordering of procedures, tests can increase your legal risks

Patients might be harmed and sue

If physicians order diagnostic tests or procedures believing that "defensive" medicine will protect them legally, they might find themselves named in a malpractice suit as a result, warns **Kathryn Wire**, JD, MBA, president and principal consultant at Kathryn Wire Risk Strategies, a St. Louis, MO, firm specializing in healthcare risk management and former director of risk and claims for two St. Louis health systems.

"There is no such thing as a benign medical procedure," says Wire. "I had a patient death from post-biopsy sepsis at a hospital where I was working last year. It happens." Any invasive process carries the risk of infection, radiology procedures radiate the patient, contrast material poses the risk of a reaction, and all medications have some risk, she adds.

"If a side effect or complication occurs as the result of an unnecessary procedure or test, the 'unavoidable' defense is lost," Wire says. "The negligence is the ordering of unnecessary care knowing that it involved risk, and the damages are the side effect or other injury."

"There is no such thing as a benign medical procedure. I had a patient death from post-biopsy sepsis at a hospital where I was working last year. It happens."

Long-term epidemiological studies are beginning to suggest increased risks of cancer due to use of CT scans, many of which are unnecessary, she notes. "Unless there is a complication, the plain professional liability risk is minimal," Wire says. "But if a complication occurs, the physician will have exposure for ordering an unnecessary test or procedure."

Larry Burnett, RN, MS, managing director of Chicago-based Huron Healthcare, says, "We are likely to see physicians pay more attention to identifying and addressing over-utilization, as part of a comprehensive risk management strategy."

There is emerging recognition that unnecessary tests are not only wasteful, but also can lead to unnecessary risk of harm to patients, he explains. "Examples could include bleeding, infection, embolic stroke and death from unnecessary cardiac catheterization, and allergic reactions or kidney failure from intravenous contrast given for imaging procedures," he says.

Scott Martin, JD, a partner with Husch

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Blackwell in Kansas City, MO, has represented many providers against allegations that they did not order sufficient testing. "The rationale for not performing additional tests ranges from medical necessity, to test availability, to the inherent risks associated with the test," he explains.

Wire says that she is unfamiliar with any cases in which the ordering of an arguably unnecessary test formed the basis of a claim, "but that factor has been a significant consideration in my decision to settle cases in which the plaintiffs had other allegations."

Duty to evaluate results

Once the test results are received, the physician generally has a separate duty to evaluate and respond to the information, notes Martin. One of his partners recently defended a case involving a biopsy of the pancreas that was interpreted as strongly suggestive but not positive for cancer, which alleged that the subsequent surgery was not necessary because the patient did not have cancer.

Executive Summary

Ordering discretionary diagnostic tests or procedures poses risks for malpractice claims involving side effects, complications and incidental findings, and over-ordering of tests can subject physicians to liability through anti-fraud statutes. To reduce risks:

- ✦ Ensure follow-up on suspicious or abnormal findings.
- ✦ Carefully explain that the patient has a right to refuse the test.
- ✦ Thoroughly document your rationale for each test at the time it is ordered.

"This led to a very extensive Whipple surgery where no cancer was found. The patient sued for postop complications," says Martin. "The plaintiff argued that additional biopsy specimens should have been obtained."

The defense showed that a false positive biopsy interpretation occurs about 10% of the time, without negligence, and doing additional biopsies was not the standard of care, reports Martin. A defense jury verdict was affirmed by Missouri Court of Appeals.[1]

Radiology studies might reveal patient conditions that might not have been considered by the ordering physician. "In the event that any suspicious or abnormal finding is not reported, that could result in a claim," says Martin. "Unfortunately, plaintiff's experts have the ability to retrospectively review these studies while usually knowing the outcome."

Increased sucritiny

Physicians should carefully explain all aspects of a diagnostic test before obtaining the patient's written consent and should highlight the fact that the patient has a right to refuse the test, advises **Elizabeth E. Trende**, JD, an attorney at Squire Sanders in Columbus, OH.

The federal government has heightened its scrutiny of billing patterns in recent months to address fraud in the healthcare system, and physicians who

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Editorial Questions
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order diagnostic tests in excess of statistical norms can expect to be scrutinized, no matter how well-intentioned their efforts, adds Trende. "Become a good keeper of evidence," she recommends. "The reasoning behind your test order may be perfectly rational in your mind, and with the patient's best interests at heart. But you can't enter your good heart before a court of law."

Make every effort to thoroughly document your rationale for each test at the time it is ordered, says Trende. "If you think your position might be reinforced through the opinion of another physician in your group practice, get it in writing," she advises. *(See related story, below, on what puts physicians at risk for anti-fraud violations.)*

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Are you over-ordering? Anti-fraud violations possible

Over-ordering scans or tests, or even "over-treating" generally, can subject physicians and other providers to major liability through the False Claims Act and other anti-fraud statutes, warns **Zack Buck**, JD, a visiting assistant professor at Seton Hall University School of Law in Newark, NJ.

"The 'kyphoplasty initiative,' in which the government has settled with 40 hospitals over the last three years, is one example of the government going after hospitals who have allegedly administered medically unnecessary procedures," he adds. *(For more information on the settlements, go to http://1.usa.gov/wPZBSx.)*

With the ever-growing costs of federal healthcare programs, the government has recently increased its anti-fraud efforts quite substantially under the Obama administration, and it will continue to do so, he says.

"If physicians are administering unnecessary tests, they can trigger False Claims Act liability, which is a severe, blunt statute with mandatory statutory penalties, if they are billing the federal government through Medicaid or Medicare for those unnecessary tests," says Buck.

If diagnostic tests are reimbursable under Medicare and Medicaid, and if the government believes that the tests were not medically necessary, the government can pursue civil and criminal legal actions against the physicians that ordered the tests, says **Brian Bewley**, JD, a partner at Husch Blackwell in Kansas City, MO.

On the civil side, the government's main enforcement mechanisms are the False Claims Act and the Office of Inspector General's Civil Monetary Penalties Law, he notes.[1,2] Under both, the government can pursue a civil lawsuit against a physician who submitted claims for services that were not medically necessary.

"This could include claims for diagnostic tests," says Bewley. "If the government is successful, the consequences from a monetary perspective are pretty serious, including up to treble damages and even exclusion from participating in Medicare or Medicaid."

On the criminal side, the government can prosecute an individual for the same conduct by alleging healthcare fraud, which could mean jail time, says Bewley.

The government is increasingly relying on data mining to ferret out cases of over-treatment and/or fraud, adds Buck. "Some cases of over-treatment directly and clearly harm individuals," he says. "But any time a provider subjects a patient to an unnecessary procedure, the patient isn't getting care that meets the standard."

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1. 31 USC 3729-3733.
2. 42 USC § 1320a-7a. ✦

Your state medical board contacts you? Don't go it alone

Obtain legal representation immediately

According to the most recent data from the National Practitioner Data Bank, the number of medical malpractice suit payments has steadily declined from 2001 to 2011 while the number of adverse actions taken against physicians by state medical boards has steadily increased.

Once a patient files a complaint

with the state medical board, the physician involved might welcome the chance to explain why his or her care was indeed medically appropriate. However, just as with medical malpractice cases, physicians must be careful when responding to state medical board inquiries.

Don't do so without retaining, or at least consulting with, an attorney who concentrates their practice in representing physicians before the medical board, warns **Alan M. Schneider**, JD, an attorney with Cheshire Parker Schneider & Bryan, PLLC in Raleigh, NC. "The damage that can be done to a physician's reputation and livelihood by a disciplinary action is significant," he says. "Not only might the physician's competence or integrity be called into question, but sometimes, depending on the seriousness of the allegations, the physician's license to practice medicine may be jeopardized."

Schneider says he has seen physicians make matters much worse for themselves by panicking and making false statements or submitting fabricated records in response to a board investigation. "This is a big mistake for many reasons," he says. "Most of the time, the cover-up or the false statement is much more serious than the issue being investigated."

While the number of medical malpractice suit payments decreased from 15,898 to 8,419 in 2001-2011, the number of adverse actions taken by state medical boards increased from 5,009 to 5,622 over the same time period, according to data from the National Practitioner Data Bank (NPDB).

"We've seen cases where a patient makes a complaint to the medical board and also files a lawsuit at the same time," says **Lizabeth Brott**, JD, regional vice president of risk management in the Okemos, MI, office of ProAssurance, a writer of medical professional liability insurance. "Coordinating the defense of the licensing action and the professional liability claim can be helpful."

Executive Summary

Doctors are often unaware of the serious implications of a state medical board investigation and are reluctant to obtain legal representation. If contacted by an investigator, physicians should:

✦ Contact the state bar association to find an attorney who specializes in licensure laws and regulation.
✦ Agree to talk to investigators once the physician has consulted with an attorney.
✦ Keep in mind that possible outcomes include restriction, suspension, or revocation of the physician's license.

Physicians facing a disciplinary complaint should immediately notify their carrier, says Schneider. Notification of the carrier might be contractually required under the policy, regardless of whether the policy offers coverage for medical board complaints, and many malpractice insurance policies contain a supplemental payment provision for disciplinary defense costs, he adds. "The dollar amounts available for these disciplinary defense provisions vary significantly. I have seen policies that provide for as little as $5,000 and as much as $25,000," says Schneider. "Certain other policy details tend to vary, such as who gets to choose counsel to represent the physician." *(See story on when to seek legal representation, p. 41.)*

Take these actions

Here is how a state medical board investigation typically progresses:

• Prior to the initial contact with a physician, the investigator usually has conducted a preliminary investigation into the facts and circumstances of the allegations.

"Many board investigators have state bureau of investigation or other investigative experience," says **Lori Meyerhoffer**, MD, JD, a partner with Yates, McLamb & Weyher in Raleigh, NC. "The investigator's role is that of a fact finder."

• The state medical board contacts the physician directly.

"During that interview, the investigator will ask specific questions, based on information already obtained through their investigation," Meyerhoffer says.

The investigator might produce documents for the physician's review and might have specific questions regarding those documents, she adds.

• Medical records might be requested for a specific patient.

"Sometimes the investigator shows up at the door unannounced with a subpoena," says Brott. "You certainly have the right to say, 'I will check with my attorney, and we'll get back to you.'"

Records generally should be provided to the board upon request, advises Meyerhoffer. "However, if there is any doubt concerning production of medical records and other requested documents, notify the board you need to obtain legal counsel, and counsel will produce the medical records, if appropriate," she advises.

• After interviewing the physician, reviewing any documents and, if necessary, interviewing other individuals with knowledge of the events, the investigator will assimilate all information obtained though the entire investigation.

"The investigator will compile a summary report that is submitted to the board and/or the board's attorneys," says Meyerhoffer.

• A settlement conference might be held.

"Basically, they are looking to see if they can settle this, short of taking it to a hearing," says Brott. "The

physician may consider settling just to make it go away. Sometimes, it is in the physician's best interest to negotiate a settlement."

However, physicians might not realize the repercussions of settlement. "If the settlement involves some type of disciplinary action against their license, and oftentimes they do, the settlement may have negative ramifications for a physician's practice," says Brott.

Any settlement agreement involving licensure disciplinary action must be reported to the National Practitioner Data Bank (NPDB), which is queried frequently by licensing boards, credentialing committees, hospitals, and other third-party payers. A settlement could impact the ability to obtain professional liability insurance, participation with third-party payers, and result in termination or nonrenewal of hospital privileges.

• An administrative hearing might be held.

This hearing is similar to a medical malpractice trial. Each side can call and examine witnesses, introduce evidence, and the hearing is conducted by an administrative law judge, says Brott. However, the hearing is held without a jury, and in many states the administrative law judge's findings must be reviewed by the board of medicine before they're enforced. Possible outcomes include the physician being reprimanded or put on probation; or his or her license being restricted, suspended, or revoked, all of which are reportable to the NPDB, she adds.

"The damage that can be done to a physician's reputation and livelihood by a disciplinary action is significant."

"It's a mark against them that will follow them for the rest of their lives," says Brott. "That's why it's so important to have an attorney."

SOURCES

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Don't wait too long to obtain legal counsel

If a state board medical investigator is asking to interview a physician in person or over the phone, "that's a pretty good indication that the physician needs representation," says **Lizabeth Brott**, JD, regional vice president of risk management in the Okemos, MI, office of ProAssurance, a writer of medical professional liability insurance.

Brott advises physicians to ask the investigators' names and the reason they are calling. The physicians should indicate courteously that they will be happy to talk to them once they have consulted with attorneys.

Attorneys have experience interacting with the medical board, says **Lori Meyerhoffer**, MD, JD, a partner with Yates, McLamb & Weyher in Raleigh, NC. They are familiar with the process of an investigation and possible subsequent actions, and they can provide insight as to potential outcomes based on prior board actions, Meyerhoffer says.

"It is often difficult to impossible to reverse statements or admissions made by the physician prior to retaining representation," she says. "The attorney's experience will assist the physician in navigating unchartered territory, provide anticipatory guidance, and assist in negotiating with the board itself."

Coverage varies

While some carriers cover representation for state medical board investigations, the coverage is usually limited, says Brott. Still, physicians often don't realize that the coverage is available to them or might think it makes them appear guilty to be represented by an attorney.

"Oftentimes, physicians don't feel they did anything wrong, and they're very comfortable in trying to handle it themselves," Brott says. "But, for example, if it's a standard-of-care issue, things aren't always black and white. It starts getting grayer." Also, the physician might not anticipate that the patient might make completely inaccurate statements.

Coverage for medical board matters varies by insurer, says Meyerhoffer, and the expenses associated with defending a board investigation can be significant, depending on the allegations and whether formal charges are filed.

"If insurance for representation of medical board matters is optional, physicians should add this coverage to their existing malpractice coverage," she advises. ✦

Patient callbacks can decrease legal risks

The number one reason? A patient's life could be saved

During a telephone call to a congestive heart failure (CHF) patient who was discharged after an emergency department (ED) visit, it wasn't so much what the patient said that was alarming as how she sounded, reports **Stephanie J. Baker**, RN, MBA/HCM, CEN.

"She was very short of breath," she says. "I asked her to get on the scale and discovered she had gained four pounds in the last day."

Discharged CHF patients might not realize the importance of weighing themselves, being diligent about their salt intake, or taking their medications, says Baker, leader for Gulf Breeze, FL-based Studer Group's Emergency Services division.

During another call, Baker spoke to the roommate of a college student who had been discharged two days earlier with viral meningitis. She learned he was unresponsive.

"His labs were OK [upon discharge], but within the next 48 hours he developed meningococcal meningitis," she says. "The physician told me it was a good thing I had called, because he would have been dead by 5 p.m."

Baker has called thousands of patients post-discharge and discovered several times that a patient required immediate intervention.

"The number one reason we make calls is for quality and safety. If you do them long enough, you will save a life," she says.

ID at-risk patients

Of 400 hospitalized patients studied in 2003 by researchers at the University of Ottawa in Canada, 76 patients had adverse events after discharge, and of these, 23 had preventable adverse events.[1] Studer Group recommends that 100% of patients discharged to home receive a post-visit phone call within 48 hours.

"In our experience, organizations that commit to post-visit phone calls typically experience a reduction in risk and liability rates," says Baker.

> *"The number one reason we make calls is for quality and safety. If you do them long enough, you will save a life."*

However, physicians can "start small" by calling patients at risk for rapid deterioration after they are discharged, says Baker, such as children under 2, patients over 75, or patients who had an invasive radiology procedure.

"Whether a sole provider, a physician office, or a multispecialty group, each practice should determine which patients are going to be called," she says. "Then track the results and link them to outcomes."

There are many recent peer-reviewed references that support patient re-contact after hospitalization or an ED visit, says **Tom Scaletta**, MD, FAAEM, chair of the emergency department at Edward Hospital in Naperville, IL.[2,3,4]

Cost is primary consideration

Scaletta says the main barrier to patient callback programs is their cost, which is up to $2.50 per case for outsourced callbacks and double that amount for nurse calls after a hospitalization. He is working to cut that cost in half by using email and texts messages.

"The costs are small relative to the return on investment, which includes reduced risk, improved satisfaction, and increased staff accountability," he says.

Scaletta implemented a patient callback program in 2004 in the ED at Edward Hospital & Health Services in Naperville, IL, to reduce the risk of negative outcomes following discharge.

"Promptly assessing patient well-being and uncovering concerns prevents claims," says Scaletta. "About six years ago, a major insurer offered my hospital a reduced rate, in part because of our callback program. We are now self-insured and always looking for ways to further improve patient safety."

Executive Summary

Patient callback programs might reduce the risk of negative outcomes following discharge by identifying the need for immediate intervention, and they have saved lives.

- ✦ Patients might not realize the importance of complying with discharge instructions.
- ✦ Ideally, 100% of patients discharged to home receive a callback within 48 hours.
- ✦ Physicians can begin by calling patients at risk for rapid deterioration post-discharge.

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- **Tom Scaletta,** MD, FAAEM, Chair, Emergency Department, Edward Hospital, Naperville, IL. Phone: (630) 527-5025. E-mail: tscaletta@edward.org.
- A white paper from Medical Insurance Exchange of CA recommends that a patient callback program be implemented. To read the entire white paper, go to http://www.miec.com. Click on "Resources," "Publications," and under "Specialty-Specific Handbooks," select "Reduce your Risks in the Emergency Department."
- Studer Group's Alliance for Health Care Research published a review of studies on the benefits of hospital callbacks. To access the report, go to http://bit.ly/NMDlk1. ✦

Sued doctors usually in jury verdicts

But even dismissed claims take long to resolve

Physicians come out on the winning end of 80% of malpractice claims that end in jury verdicts, and slightly over half of cases reaching trial are dismissed by the court, according to a new study of more than 10,000 closed malpractice claims that occurred between 2002 and 2005.[1] Only about five out of every 100 claims that are litigated involve a jury verdict.

"Of that group, in almost all of the specialties that we studied, upwards of 60 to 70% verdicts were in favor of the physician," says **Anupam B. Jena**, MD, PhD, the study's lead author. Jena is an assistant professor of healthcare policy and medicine at Harvard Medical School and an assistant physician in the Department of Medicine at Massachusetts General Hospital, both in Boston.

"That is not to say that if you are a physician who is sued, you should fight for the chance to reach the jury stage because if you do, you have a 70% chance of winning," cautions Jena. In fact, the claims that tend to be vigorously defended are the claims that defense attorneys think are very likely to go in favor of the physician, he explains.

It takes an average of 19 months to close malpractice claims and 39 months to resolve cases that go to trial and result in verdicts, according to the study. "The time that was required to close each one of these types of claims was quite variable and quite long," says Jena. "That has implications for both physicians and patients."

Even claims that ultimately were dismissed by the judge took an average of 12 to 18 months to resolve. "In the current system, even claims that are ultimately dismissed still require substantial time and investment on the part of physicians, patients, insurers, and attorneys," Jena explains.

In many of these claims, the allegation of malpractice might be misguided. For example, the EKG and blood tests of a patient with chest pain might suggest ongoing ischemia and a high risk of further heart attack, but the patient might leave the hospital against medical advice. "As someone reviewing the case, one might think that the patient was clearly advised of the risks of leaving," says Jena. However, a plaintiff attorney might argue that the patient did not fully understand what those risks were, resulting in a lawsuit that probably ultimately would be dismissed, he says.

The length of time it takes to resolve claims is likely a major reason why physicians consistently report strong pressure to practice defensive medicine, says Jena, noting that at least 50% of claims are dismissed in court before they get to the jury stage.

"That's a comment on the merit of those claims, which incidentally require upward of $20,000 to defend. That cost doesn't account for lost practice time," Jena says. "Perhaps the most substantial cost to physicians, however, is the anxiety of having a malpractice suit that is ongoing for a year or more."

Executive Summary

Physicians come out on the winning end of 80% of malpractice claims that end in jury verdicts, and slightly over half of cases reaching trial are dismissed by the court, according to a recent study of more than 10,000 closed malpractice claims that occurred between 2002 and 2005.

- ✦ Claims that tend to be vigorously defended are the claims that defense attorneys think are very likely to go in favor of the physician.
- ✦ Even claims that ultimately were dismissed by the judge took an average of 12 to 18 months to resolve.
- ✦ The length of time it takes to resolve claims is a likely reason why physicians report pressure to practice defensive medicine.

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Abuse suspected? Take these actions, or risk lawsuits

Good faith reporting is protected from lawsuits

• A physician fails to recognize signs of probable abuse, and the child is subsequently harmed.

• A child is injured through abuse, and the injuries are not properly diagnosed or treated.

• Abuse is diagnosed, but it is not reported quickly enough, and the child is harmed in the interim.

These are all situations in which a physician could be successfully sued for failing to report suspected child maltreatment to the appropriate child-protection authority or police, which is mandated by every state, says **Jonathan M. Fanaroff**, MD, JD, FAAP, FLCM, associate professor of pediatrics at Case Western Reserve University School of Medicine and co-director of the Neonatal Intensive Care Unit at Rainbow Babies & Children's Hospital, both in Cleveland, OH.

"In addition to liability to the child for malpractice, the physician may be subject to fines or imprisonment," he says. "A few states regard repeated failures to report abuse as a felony offense."

Most states require a physician to report when they suspect or have reason to believe that a child has been abused or neglected, says Fanaroff. Thus, the physicians do not need to be certain, but they should have at least a reasonable suspicion, he says. Physicians who report suspected abuse or neglect to the proper authorities in good faith, meaning that there is a genuine suspicion of abuse or neglect, are immune from liability, adds Fanaroff.

Michael G. Anderson, MD, JD/ESQ, FAAP, FCLM, general counsel and pediatrician at Children's Pediatric Centers in Canton, GA and assistant professor of pediatrics at the Medical College of Georgia in Augusta, says, "This means the good-faith reporter may have an absolute privilege or defense against a lawsuit from an unhappy person who was reported, even if authorities never prosecute for any abuse." Anderson says these practices are used at his organization:

• Pediatricians tell parents they are required to refer all questions of child abuse and neglect to authorities for investigation without having to form an opinion one way or another.

"We treat our patients medically and leave the rest up to law enforcement," Anderson says. "When we explain this is a mere reflexive response, our patients accept our call to the police well without much difficulty."

• Physicians are told not to investigate before reporting when one angry parent accuses the other of abuse.

"Here at the Children's Pediatrics Center, we caution all about moving outside our primary training and practice," Anderson says. "Physicians, however well-intended, are not law-enforcement investigators."

• Pediatricians ensure that the required report is efficiently given.

Anderson finds that the local police departments have the most efficient process for helping physicians fulfill their reporting duties concerning children. Although state governments typically have an alternate method for mandated case referrals, typically the mandated reporter may leave a name and number and waits for a call back, he says.

"The risk of a delayed report remains with a mandated reporter until they actually give an authority the required report," Anderson explains.

• Physicians don't attempt to restrain anyone allegedly involved.

"Simply do your doctor's duty and then stop," he advises. "Leave plenty of room for law enforcement to do their duties, and you may avoid not only legal risks, but even possible physical injury."

Executive Summary

Physicians can be successfully sued for failing to report suspected child maltreatment to the appropriate child-protection authority or police. In addition to liability to the child for malpractice, the physician might be subject to fines or imprisonment.

✦ Physicians who genuinely suspect abuse or neglect are immune from liability resulting from reporting.
✦ Physicians should not investigate first before reporting.
✦ Physicians risk claims for wrongful imprisonment or false arrest if they try to restrain the alleged involved parties.

SOURCES

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Nursing notes overlooked? Legal price could be costly

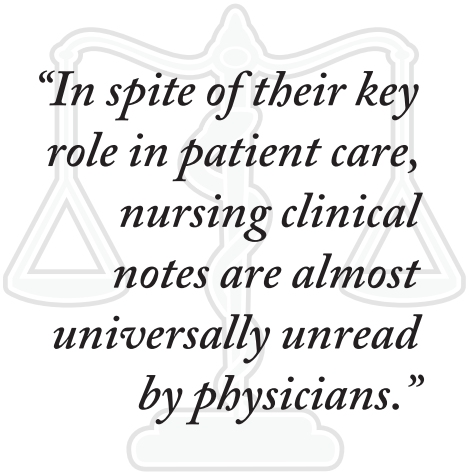
Less than 20% of nursing notes are read by physicians

Nursing notes often are ignored or, at best, casually reviewed by physicians, says **Sam Bierstock**, MD, founder of Champions in Healthcare, a consulting company in Delray Beach, FL, specializing in healthcare information technology. Fewer than 20% of nursing notes are read by physicians, according to a 2011 study.[1]

"In spite of their key role in patient care, nursing clinical notes are almost universally unread by physicians," says Bierstock.

In 2009, the Superior Court of Pennsylvania affirmed an $8.6 million judgment entered against a physician and a medical group in a wrongful death action that involved a physician's failure to read nursing notes.[2] The case involved a 60-year-old patient recovering from surgery in a hospital's rehabilitation unit, who subsequently died from massive gastrointestinal bleeding. **Stephanie M. Godfrey**, JD, an attorney with Pepper Hamilton LLP in Philadelphia, PA, says, "The nursing notes, which indicated that the patient was growing paler each day, had not been reviewed by the attending physician."

In 1994, a Louisiana surgeon was held to have breached his duty of care, in part, because he did not read the nursing notes for his coronary artery bypass patient who developed postoperative wound infections and died of a heart attack about a month after surgery.[3] "Signs of infection were contained in the nursing notes, but the physician did not record similar findings in his own notes, did not review the nursing notes, and did not pursue aggressive treatment of the patient's infections," says Godfrey.



"In spite of their key role in patient care, nursing clinical notes are almost universally unread by physicians."

According to the court, which granted an award of $174,508 to the patient's wife and $50,000 to each of the patient's seven children, the surgeon's actions had exacerbated the patient's critical condition and deprived him of a chance of survival.

Increased exposure

There often are discrepancies in descriptions of clinical findings between nursing notes and physician progress notes, warns Bierstock.

"Any disparity displays a clear lack of consistency in clinical observations and awareness of patient status," he warns. "This can lead to vulnerability to medical legal action for all parties involved."

If physicians don't read nursing notes, they might miss important information that wasn't discovered during their own encounters with the patient, such as subtle changes in a patient's condition, says Godfrey. "A physician who has analyzed all the facts at his disposal will be in a better position to guard against allegations that he misdiagnosed a patient or failed to fulfill his duty of care, than one who has acted without proper consideration of all the facts available to him," says Godfrey.

Lack of information due to failure to read nursing notes might result in misdiagnoses, unnecessary diagnostic tests, inappropriate prescriptions, and medical complications, all of which increase the physician's exposure to malpractice liability, she says. Godfrey gives these risk-reducing strategies:

• Physicians should be educated about the potential liability that can result from the failure to review nursing notes.

Executive Summary

Nursing notes often are ignored or casually reviewed by physicians, but failing to carefully review nursing notes has resulted in successful malpractice lawsuits and increases risk of misdiagnoses, unnecessary diagnostic tests, inappropriate prescriptions, and medical complications.

✦ Physicians might miss important information that wasn't discovered during their own encounters with the patient.
✦ Physicians should view nursing notes at each patient encounter and upon discharge to ensure accuracy.
✦ Physicians should address inconsistencies by visiting the patient with the nurse if necessary.

• Physicians should be encouraged to view nursing notes at each patient encounter and upon discharge to ensure accuracy.

"Physicians should look for any noted changes in the patient's condition which may prevent discharge or which should be addressed in the post-discharge instructions," Godfrey says.

• Training programs should be implemented to ensure that nurses are entering notes properly and physicians are able to view them.

• If there are inconsistencies between nursing and physician notes, the disagreeing parties should discuss their conflicting notes and, if necessary, visit the patient together to confirm findings.

"The discrepancy and any such discussions or follow-up with the patient should be documented," Godfrey says. "In addition, the agreed resolution of the discrepancy should be documented in the record by each of the parties."

References

1. Hripcsak G, Vawdrey DK, Fred MR, et al. Use of electronic clinical documentation: time spent and team interactions. *J Am Med Inform Assoc* 2011; 18:112-117.
2. Hyrcza v. W. Penn Allegheny Health Sys. 2009 PA Super 119 (Pa. Super. Ct. July 1, 2009).
3. Todd v. Sauls, 94-10 (La. App. 3 Cir. 12/21/94).

SOURCES

For more information on reviewing nursing documentation, contact:

• Sam Bierstock, MD, Champions in Healthcare. Phone: (561) 243-3673. Email: samb@championsinhealthcare.com. Web: www.championsinhealthcare.com.

• Stephanie M. Godfrey, JD, Pepper Hamilton LLP, Philadelphia, PA. Phone: (215) 981-4473. Fax: (215) 981-4750. Email: godfreys@pepperlaw.com. ✦

Fewer new claims expected with disclosure

Practice being implemented in Massachusetts after legislation passes

Due to newly passed legislation, physicians throughout Massachusetts soon will be able to utilize a Disclosure, Apology, and Offer process, with the goal of shifting away from "the 'blame and deny' culture of secrecy, in which nobody learns from the adverse incident," reports **Alan Woodward**, MD, chair of the Massachusetts Medical Society's Committee on Professional Liability.

A partnership between the state's physicians and attorneys resulted in significant reforms to the medical liability system including facilitation of the Disclosure, Apology, and Offer approach, Woodward says. That approach is expected to reduce unnecessary and protracted lawsuits while improving patient safety, he says.

"We are taking a model that has been successful in multiple hospital systems, and working to implement it across the state," says Woodward, pointing to a significant reduction in litigation costs reported by the University of Michigan Health System.[1] "The most impressive thing is that by learning from mistakes and instituting policies and procedures to eliminate a recurrence, they have seen a dramatic reduction of the number of new cases, by about 50%," he says.

With Disclosure, Apology, and Offer, doctors will take responsibility for errors and patients won't have to go to a lawyer to get full information and compensation, says Woodward. "This is a fundamental transformation. Right now, we have an adversarial system that is very reactive and punitive and we know drives defensive medicine costs," he says.

In Massachusetts, an injured patient waits an average of five years to receive an award, whereas in the new system awards are expected to be disbursed within months, says Woodward. "Patients [under similar systems] are typically offered fair and appropriate compensation in a timely fashion. That's not how you save money," he says. "What you are saving is the cost of overhead and unnecessary litigation, and the cost of recurrent errors."

Using the Disclosure, Apology and Offer system, the patient's rights aren't compromised in any way, adds Woodward. "If they get through this process and they don't think it's appropriate or just, they still can go forward with litigation," he says. "But they are litigating in an environment where a root cause analysis was done and showed the physician did nothing wrong." *(See story p. 47 on possible legal risks for not disclosing errors.)*

Reference

1. Kachalia A, Kaufman SR, Boothman R. Liability claims and costs before and after implementation of a medical error disclosure program. *Ann Intern Med* 2010; 153(4):213-221. ✦

Executive Summary

Physicians throughout Massachusetts soon will use a Disclosure, Apology, and Offer process as a result of newly passed legislation.

✦ Other similar programs have reported a reduction of new cases by about 50%.

✦ Patients won't be forced to go to a lawyer to obtain full information and compensation.

✦ Physicians who aren't honest about errors likely will face increased scrutiny at trial due to public expectations for transparency.

Physicians who don't disclose will stand out in the courtroom

Juries will want to know why errors were not disclosed

After a patient received a transfusion of six units of the wrong blood due to a mixup of blood samples at University of Michigan Health System (UMHS) in Ann Arbor, the patient experienced flu-like symptoms for a few days and underwent testing, but the patient had no other consequences. The error was disclosed and an offer made for financial restitution, according to the organization's disclosure practices.

"We could not agree on a number, and that case went to trial. We told the jury upfront about the mistake and how we handed it with the patient: straightforwardly, honestly, and apologetically," says **Richard C. Boothman**, chief risk officer. The jury returned a verdict of zero, finding that the patient suffered no harm as a result of the error, which Boothman attributes to providers being open and honest about the mistake.

"When we talked to the jury later, to a person they told us that they were so impressed with the honest way we handled it," says Boothman. "They were equally chagrined at what they perceived as over-reaching by the patient and his lawyer."

With error disclosure becoming more commonplace, Boothman says that the way in which physicians choose to handle unanticipated outcomes will increasingly be the subject of cross examination and argument in court. "I think the penetration, finally, of the importance of honesty could make those who aren't forthcoming stand out for sure," says Boothman. "In the few cases we've had to try since becoming more and more transparent, we have showcased our approach."

Evidence that the physicians were honest with patients about unplanned complications goes a long way to enhance their credibility with juries, says Boothman. "Courtrooms are all about credibility. And there's nothing more credible than folks who have acted consistently with the positions they take later in the courtroom," he says.

The public has much higher expectations for transparency, adds Boothman, and the way doctors conduct themselves in the aftermath of a medical mistake will become increasingly important. Because of this emphasis, the organization's disclosure practices now include follow-up communication with patients in writing to reinforce what has been discussed verbally. "We do that because human beings filter verbal communication and remember it differently after the fact," says Boothman. "To ease the risk of ambiguity, we are pretty careful to put key points in writing now after the disclosures."

SOURCE

For more information on disclosure and liability risks, contact:

• **Richard C. Boothman**, Chief Risk Officer, University of Michigan Health System, Ann Arbor. Phone: (734) 764-4188. Email: boothman@med.umich.edu. ✦

COMING IN future MONths

✦ Must-have clauses in professional liability contracts

✦ Use charting to convince plaintiff attorney not to pursue a claim

✦ Prevent false allegations of inappropriate sexual contact

✦ What recent large verdicts mean for malpractice premiums

CME OBJECTIVES

After reading *Physican Risk Management*, the participant will be able to:

- describe the legal, clinical, financial, and managerial issues pertinent to physician risk management;
- explain the impact of risk management issues on patients, physicians, legal counsel, and management;
- identify solutions to risk management problems for physicians, administrators, risk managers, and insurers to use in overcoming the challenges they face in daily practice.

CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.

2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.

3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.

4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.

5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ✦

CME Questions

1. **Which is true regarding ordering unnecessary diagnostic tests or procedures, according to Elizabeth E. Trende, JD, an attorney at Squire Sanders?**
   A. Physicians don't face malpractice risks for ordering benign medical procedures, even if these aren't clinically indicated.
   B. Once test results are received, the physician does not have a separate duty to evaluate and respond to the information.
   C. Physicians should make every effort to thoroughly document their rationale for each test at the time it is ordered.

2. **Which is recommended regarding state medical board investigations, according to Lizabeth Brott, JD, a regional vice president of risk management with ProAssurance?**
   A. Physicians should contact their professional liability carrier instead of an attorney who specializes in licensure laws and regulations.
   B. It is generally in the physician's best interest to agree to be interviewed without an attorney present in the initial stages of an investigation.
   C. It is never advisable for a physician to inform the board that he or she will check with an attorney before producing requested medical records.
   D. If insurance for representation of medical board matters is optional, physicians should add this coverage to their existing malpractice coverage.

3. **Which is recommended regarding physicians' reporting of suspected child abuse, according to Jonathan M. Fanaroff, MD, JD, associate professor of pediatrics at Case Western Reserve University School of Medicine?**
   A. Physicians can be successfully sued and might be subject to liability if abuse is diagnosed, but it is not reported quickly enough and the child is harmed in the interim.
   B. Most states require a physician to report only when they are certain abuse or neglect is occurring.
   C. Physicians face significant liability risks for reporting good faith suspicions of abuse or neglect.

4. **Which is true regarding making the decision to settle or defend a claim, according to David W. Spicer, JD, an attorney with Spicer & Miller?**
   A. It is nearly always in the physician's best interest to demand that a case not be settled.
   B. Insurance companies routinely settle frivolous suits filed against doctors for nuisance value.
   C. Jurors overwhelmingly rule against doctors on cases in which liability is not clear.
   D. If a physician's insurance policy has low limits and the case has the potential for catastrophic damages, the doctor must evaluate whether to risk his or her entire financial future on the whims of a jury.

Physician Legal Review & Commentary

A Monthly Supplement to PHYSICAN RISK MANAGEMENT

Knee disfigurement following surgery results in a jury verdict of $12.7 million

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News: In 2003, the plaintiff, then 15 years old, underwent knee surgery with the defendant physician. Following the surgery, the physician prescribed a cold-therapy device, which was made by the defendant product manufacturer. After using the device, the plaintiff suffered frostbite and required multiple reconstructive surgeries. The case involved a malpractice claim against the defendant physician and a negligent design claim against the defendant product manufacturer. There were also fraud claims against the physician. The jury awarded the plaintiff $5.2 million in compensatory damages, as well as $7.5 million in punitive damages.

Background: In 2003, the plaintiff, then a 15-year-old woman who was a competitive track and field athlete, underwent knee surgery with the defendant physician, an orthopedic surgeon who is also the head physician for an NFL team. Following the surgery, the defendant physician prescribed a cold therapy device, which was made by the defendant product manufacturer. The plaintiff was to apply the device to her knee to speed her recovery.

After using the device, the plaintiff suffered frostbite and required multiple reconstructive surgeries.

Cold therapy devices, such as the one at issue in this litigation, are used to reduce swelling and promote healing following surgery. They are designed to maintain a constant temperature or temperature range, and they are advertised as being safer than applying ice. As the body temperature is lowered, blood flow might be reduced and nerve impulses might slow down, which can purportedly prevent the patient from detecting pain. During this trial, the jury heard testimony that a patient using the cold therapy device might not feel frostbite setting in because of numbness caused by the device.

Shortly after she began using the device, the plaintiff suffered frostbite at the site where the device was used. She allegedly asked the defendant physician about the cause of her injury, but he claimed he had never seen anything like it. However, the physician had previously settled a claim with a former patient who also suffered frostbite from using the same device. He also allegedly failed to inform the plaintiff that he owned the company that rented the devices to his patients and that he stood to gain financially from

Financial Disclosure: Physician Editor **William Sullivan**, DO, JD, FACEP, Author **Stacy Kusterbeck**, and Executive Editor **Joy Dickinson**, report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

prescribing the device.

The plaintiff alleged that she spent several months with an open wound before she was told that she had frostbite. She eventually required several reconstructive surgeries, and she might require more in the future. The jury awarded the plaintiff $5.2 million in compensatory damages, including past and future economic damages and pain and suffering. The jury found the defendant physician 50% at fault, his company 10% responsible, and the product manufacturer 40% responsible.

The jury also awarded punitive damages of $7 million against the defendant product manufacturer, and $500,000 against the defendant physician.

What this means to you: This case has a large component to it that involves a medical device. Medical malpractice cases involving malfunction, breakage, or other type of device defect can be interesting, complex cases. Such cases also prevent a significant opportunity for healthcare providers to reduce or at least defer liability.

Incidents that involve device malfunction in which it is suspected that the device malfunction caused or contributed to patient injury or illness must be handled carefully. In addition to reducing liability to the physician using the device, such incidents involve potential regulatory compliance for user facilities in accordance with reporting requirements under the Safe Medical Devices Act.

Although much of the following applies to hospital policies and procedures, it is most important that physicians understand them and comply with them. It is the physician's liability that stands to be mitigated by enforcing diligent compliance.

A medical device incident might be as simple as opening a box containing a device and noting that the device is broken. In that scenario, an occurrence report documenting as much information about the device as possible (e.g. lot number, serial number model number, etc.) should be completed. The manufacturer should be voluntarily notified. An inspection of stock for similar devices should be conducted to make sure there are no additional broken units. Devices that are discovered to be defective should be tracked to proactively look for any trends with particular devices.

If a device is used on a patient and breaks or in some other way malfunctions, and it is certain that this device did not cause or contribute to patient harm, the same steps should be taken as in the prior scenario.

If the device malfunctions and is suspected of having caused or contributed to patient harm, the same steps as the first two scenarios should be taken. In addition the device should be sequestered. It should be put through a careful chain of custody documenting all persons who have had possession of the device from the time at which it malfunctioned until the time it reaches its final location (usually the bio-med department). The hospital policy should explain that when the malfunctioning or defective device is part of a surgical specimen, the pathology department must be aware that the device was involved in an incident and needs to save it. The device must be left exactly as found. The settings should not be changed, and there should be no attempt to manipulate the device. If the device is a life-sustaining device, it is important for the chairperson of the department and other users of the device to know that the device has been taken out of service.

We hope that this situation very infrequently. Unfortunately, that lack of frequency usually makes compliance with hospital policy more difficult. All too often, without thinking, a broken or malfunctioning or otherwise defective device is tossed into the nearest trash can. Another common error is try to fix the malfunction immediately or try to determine what caused the malfunction. It should be clearly understood that any manipulation of the device or its settings will result in spoliation of evidence. It is also important to remember that when the Food and Drug Administration (FDA) uses the term "medical device," it does not distinguish between large electronic units and disposable devices. Therefore all of the above recommendations apply to both. The device should remain sequestered until such time as risk management states that it may be returned to service. It might be necessary to keep the device sequestered for potential evidence purposes until the appropriate state's statute of limitations expires. Because this occurrence generally is rare, it is a good idea to notify risk management with any questions immediately. Once the evidence is tampered with, it is too late.

Contracts and agreements with manufacturers often require that devices that malfunction be returned to the manufacturer. Facilities that use these devices have mandatory reporting requirements, and any contract should always make exceptions for legal evidence and regulatory reporting requirements. If the manufacturer is insistent on examining the device, the user facility may invite the manufacturer to visually inspect the device. The manufacturer may be permitted to take pictures of the device. Again, any touching or manipulation of the device or its settings will compromise the evidence.

The potential liability reduction for physicians, as well as all medical providers, for complying with these recommendations is so great that strong consideration should be given to having recurring education sessions or reminders to enforce policy.

Reference:

Superior Court, San Diego, California, Case No. GIC870982. ✦

Failure to diagnose necrotizing fasciitis yields $1.53 million jury verdict

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News: On May 8, 2008, a 38-year old man presented to a health clinic complaining of a cyst near his rectal area that had expanded to the testicles. Despite being referred to the emergency department, admitted to the medical center, and examined by two doctors, the plaintiff did not receive the correct diagnosis and treatment until 58 hours after he first sought medical attention. On May 11, 2008, approximately 58 hours after the plaintiff first sought medical attention, he underwent surgery to debride the necrotic tissue and remove the right testicle and the scrotal sac. Plaintiff alleges that defendants' failure to timely diagnose necrotizing fasciitis caused greater tissue loss and destruction. The jury awarded the plaintiff $1.5 million in medical expenses, lost wages, and non-economic damages. This award was later reduced to about $763,000 because of a state cap on non-economic damages in medical malpractice cases.

Background: On the evening of May 8, 2008, a 38-year old man presented to a health clinic complaining of a cyst near his rectal area that had expanded to the testicles. The plaintiff was referred to an emergency department, where a CT of his pelvis was done. The CT showed subcutaneous air, potential gas, and gangrene in the right scrotal sac and perineum. A white blood cell count was obtained that revealed an elevated count of 29,000 per cubic millimeter. The emergency personnel made a diagnosis of cellulitis/abscess and admitted him to the medical center on the morning of May 9, 2008. The medical center admitting doctor made a diagnosis of scrotal cellulitis and continued treatment with intravenous antibiotics. On the morning of May 10, 2008, the plaintiff was seen by a urology consultant, who, according to the plaintiff's complaint, also made a diagnosis of cellulitis and had "no concerns for necrotizing fasciitis." The urologist requested an infectious disease consult.

"... the plaintiff did not receive the correct diagnosis and treatment until 58 hours after he first sought medical attention."

The infectious disease consult examined the plaintiff on May 10, 2008, and noted that the CT showed air in the soft tissue of the right scrotum and associated soft tissue swelling in the perineum plus right scrotal wall. He also found air along the lateral aspect of the right testis. The infectious disease consult determined that the plaintiff was at risk for necrotizing fasciitis and Fournier's gangrene, and he placed the plaintiff on NPO status that night for "likely surgery."

On the morning of May 11, 2008, the urologist consult performed surgery on the plaintiff. The urologist extensively debrided necrotic tissue and removed the right testicle and the scrotal sac. The plaintiff required an additional five surgeries between May and June 2008, which included a split-thickness graft to his penis and multiple hyperbaric oxygen treatments.

On March 8, 2010, the plaintiff sued the urologist, admitting physician and medical center (later dismissed without prejudice) with negligence. He alleged that defendants failed to appreciate in a timely manner the probable pres-

ence of necrotizing fasciitis, failed to treat the plaintiff's condition in a timely manner, failed to obtain appropriate consultations, and failed to surgically explore and debride the affected tissue. Plaintiff's experts opined that the plaintiff presented to the medical center with signs and symptoms consistent with necrotizing fasciitis, including an elevated white blood cell count. Despite these signs, the defendants failed to diagnose and treat the plaintiff's ailment for 58 hours, which in the experts' opinions exacerbated the tissue loss and destruction.

Plaintiff sought medical expenses, lost wages, and damages. Defendants argued that they provided the appropriate standard of care. On June 22, 2012, the jury awarded about $122,000 for medical expenses, about $7,700 for lost wages, and $1.4 million for non-economic damages. The total award of $1.5 million later was reduced to about $763,000, because of a state cap on non-economic damages in medical malpractice cases.

What this means for you: Any part of the body necrotic/necrotizing (dead) can be a medical challenge and a possible medical emergency. Necrotizing fasciitis is a particularly challenging medical situation and can lead to disfigurement, amputation, and death if not treated promptly and appropriately. This disease often is referred to as the result of "flesh eating bacteria." Proper diagnosis and treatment on a timely basis is essential.

Necrotizing fasciitis damages has resulted in front-page news stories. This situation is an unfortunate example of a missed or mis-diagnosis that led to a significant untoward outcome and disfigurement of a young man.

This type of diagnosis points to a medical emergency if not addressed in a timely manner. The peer review and root cause analysis would ask about the delay in obtaining the infectious disease and urology consults until the second day after admission.

While necrotizing fasciitis is a devastating disease in any area of the body, the location of this focal point, the genital area of a relatively young man, should have made this condition one of more urgency. One wonders why; the timeline and facts we are given should have pointed to a differential diagnosis to include necrotizing fasciitis, at least to the potential development if not addressed on a timely basis. There appears to be a lack of urgency to make a definitive diagnosis and initiate treatment. Again, this is a question to be addressed in the peer review and root cause analysis.

This situation is an unfortunate example of a missed or mis-diagnosis that led to a significant untoward outcome and disfigurement of a young man.

In addition to a thorough peer review including physicians from emergency medicine, infectious disease, radiology and urology, a root cause analysis should be convened that would include these same medical specialties and nursing. Depending on advice from legal counsel, a combined peer review and root cause analysis might be held. The goals from such deliberations are prevention of recurrence and education to change practices to enhance patient safety.

Based on the findings of these deliberations, educational grand rounds sessions for each specialty should be developed and implemented to re-emphasize recognition of the signs, symptoms, and need for timely diagnosis and treatment in cellulitis with a differential diagnosis of necrotizing fasciitis. With the support of the medical staff, an electronic critical pathways algorithm could be developed to assist medical staff in the timely diagnosis of this disease.

The risk management issues, in addition to the facilitation of the peer review and root cause analysis deliberations, include the disclosure meeting with medical center representatives and the patient as required by The Joint Commission and various state statutes, as well as medical ethics.

Any time there is a significant untoward outcome such as this one, the risk manager should be notified immediately. An official investigation should be initiated as soon as the risk manager is advised of this untoward event. A timeline of this patient's continuum of care would show whether there is any area of potential issues regarding the acceptable standard of care. Sometimes it is important to investigate facts early on and implement control systems to prevent the severity of a situation. Establishing a genuine relationship with the patient and their family is an important component of risk management control. With the significant disfigurement in this case, one would expect the patient would assert a claim for damages. That being said, the risk manager should notify the facility's insurance carrier and defense counsel, depending on the facility's risk financing plan (self-insured or commercial coverage). The carrier assigns defense counsel.

Reference:

United States District Court for the District of Maryland, Civil Action No. 1:10-CV-00573-PWG. ✦