Healthcare RISK MANAGEMENT

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Warning! 'Loss of chance' theory becoming a growing threat in malpractice

Courts taking more lenient approach to when this argument can be used

"Loss of chance," which is arguing what might have been if medical treatment or diagnosis had taken place earlier or been properly carried out, has been an available legal tactic for plaintiffs for decades; however, it was a relatively dormant legal theory in past years because courts limited how and when it could be used. Now it is becoming popular with plaintiff's attorneys again, and some defense attorneys say it is even more threatening now.

Loss of chance is appearing more because courts and state legislatures are allowing the argument when the chance of survival was less than 50%, explains **Jacqueline M. Carolan**, JD, partner with the law firm of Fox Rothschild in Philadelphia. Previously, loss of chance usually required there be at least a 50% chance of survival. In recent years, Massachusetts, Michigan, Wyoming, and Delaware have allowed damages below the 50% threshold.

Loss of chance is appearing more because courts and state legislatures are allowing the argument when the chance of survival was less than 50%.

"Some states are showing more leeway, and some that never recognized loss of chance are saying maybe they should start eroding that prohibition and let it in," Carolan says.

The tactic might be known by other names; in Pennsylvania it is known as "increased risk of harm." The argument is used most often in cancer cases, but it also is used also in cases of stroke and similar problems in which prompt treatment can make a significant difference in outcome. In 2008, the Massachusetts Supreme Judicial Court affirmed a jury ruling in Matsuyama v. Birnbaum by saying that even though the patient had only a 37.5% chance of survival if the defendant doctor had properly diagnosed his stomach cancer dur-

INSIDE

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ing a physical, loss of chance could be used to award the plaintiff that percentage of the $875,000 the jury determined was due for wrongful death. The plaintiff received $328,125 for wrongful death and another $160,000 for pain and suffering.

In its ruling, the Massachusetts Supreme Judicial Court said that the state should join "the substantial and growing majority of states" that have found the 50% threshold too limiting.

The use of loss of chance will differ from state to state, explains **Karl J. Protil** Jr., JD, equity shareholder with the law firm of Shulman Rogers Gandal Pordy Ecker in Potomac, MD. Protil recently represented the plaintiff in a Virginia case in which a woman's CT scan was misinterpreted and her cancer diagnosis delayed, which lawyers said caused her to die two years earlier than she might have. Virginia requires a "substantial" loss of chance, which is not defined.

"This is all determined by the law of the state, and some do not recognize loss of chance at all, but the majority of them do," Protil says. "States have said that when the patient loses some opportunity for a better outcome, that has some value and you are able to recover for that."

Risk managers should educate clinicians on the increased threat from loss of chance, Carolan suggests. Counsel them to avoid giving patients false hope with comments such as, "It's going to be OK," which is a phrase Carolan hears patients repeating in depositions all the time.

"They don't have to be Debbie Downers all the time, but they do need to give a balanced approach, and that means the good and the bad," she says. "Sometimes there is an expectation that everything is going to be solved in healthcare, and sometimes unfortunately it can't be."

In states that allow loss of chance, and particularly those with more lenient interpretations, defendant hospitals might see more

Executive Summary

Medical malpractice plaintiffs are increasingly using the "loss-of-chance" argument. The tactic is more of a threat now that courts are showing leniency in when and how it can be used.

- ✦ "Loss of chance" involves a consideration of what might have happened if the defendant had acted properly.
- ✦ Hospitals might need to consider this threat when making settlement decisions.
- ✦ Courts have lowered the threshold for when the tactic can be used.

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Editorial Questions

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cases taken to a jury, says **Buckner Wellford**, JD, shareholder with the law firm of Baker Donelson Bearman Caldwell & Berkowitz in Memphis, TN. Many malpractice claims are successfully defended on the causation claim, he notes. "If that causation requirement is relaxed, then you have significantly increased the number of claims that will not get knocked out by a judge but will instead go to a jury," Wellford says. "That definitely changes your settlement posture because the case can come down to how a jury feels rather than the medical science showing causation or not."

Without loss of chance, Wellford says, the defendant usually can get a good feel for whether the plaintiff would be able to prove that the injury, more likely than not, changed the outcome. *(See the story below for more on defending a loss of chance claim.)*

"When the burden changes from 'more likely than not' to something looser under loss of chance, you are at a disadvantage in determining how to resolve the case," Wellford says. "With loss of chance, the judge may look at evidence that would have been nowhere near enough to get the plaintiff over that hump for causation, but he may send it to the jury and let them figure out how much it is worth."

SOURCES

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Defending loss of chance can be a true challenge

Arguments over loss of chance often come down to a battle of the experts regarding how much difference the alleged malpractice made in the outcome, says **Jacqueline M. Carolan**, JD, partner with the law firm of Fox Rothschild in Philadelphia.

Did the patient lose 5% of the possible life span with this diagnosis? Was it 35%, or 55%?

Defendants can be put in the tough position of saying the patient was going to die anyway, so that percentage loss doesn't really matter. That statement can sound callous, whereas the plaintiff will counter with the emotional argument by asking the jurors if they wouldn't treasure that extra 5% to spend time with their child or spouse."It can be a tough argument for the defense, because for many of those jurors who are so afraid of cancer, a 5% difference in the outcome means a lot. Courts used to say that if the loss wasn't at least 50%, you didn't have a claim, but now some courts are letting that 5% claim in when previously they wouldn't allow it," Carolan says.

"It's difficult in this age of sound bites to get 12 people to really understand the medicine and the statistics, and they can see this as an appealing way to give something to the plaintiff."

A plaintiff's attorney will use loss of chance to argue for appropriate damages, not necessarily the evidence of malpractice, says **Karl J. Protil Jr.**, JD, equity shareholder with the law firm of Shulman Rogers Gandal Pordy Ecker in Potomac, MD. The attorney will tell the jury that even though the patient would have died anyway, no matter what the doctor did or did not do, the patient was robbed of an opportunity.

"You still have to prove the loss of chance, that if the doctor had done something differently then the patient's outcome would be substantially different. It has to be a progressive disease where if you catch it at point A you have a certain chance, but you caught it at point B and you have a diminished chance of survival," Protil explains. "Cancer fits that model perfectly."

The defense against loss of chance is to claim that even if the disease had been caught at the earliest opportunity, it still would have progressed and that there is no way to know that the doctor's action or error caused any harm or hastened death. The plaintiff then must counter with evidence showing otherwise.

Protil takes this stand: "That's not much different from the defense in every cancer case. The difference is that a good loss of chance argument can significantly increase the damages." ✦

Guidelines offer steps for disclosure

New guidelines available from the American Health Lawyers Association (AHLA) codify the many issues to discuss and decisions to make when a healthcare facility is considering disclosure of a serious clinical adverse event (SCAE). The guidance could reduce some of the concerns that can make risk managers and clinicians hesitant to fully disclose errors.

The AHLA guidance describes disclosure of a SCAE as "a multi-faceted process that requires careful planning and coordination by clinical and administrative personnel within the provider organization." The task force was chaired by **Elisabeth Belmont**, JD, corporate counsel at MaineHealth, a health system based in Portland, ME.

"In analyzing disclosures of information in connection with SCAEs, there are regulatory and legal considerations to consider regardless of the type of incident," Belmont says. "Although those considerations may vary according to the particular jurisdiction, this checklist is intended to guide healthcare providers in their analysis and encourage them to be proactive to ensure that their personnel and applicable policies are in alignment on such disclosures prior to the occurrence of a SCAE." *(For excerpts from the guidelines, see below. For additional resources, see p. 90.)*

In an era of increasing transparency, disclosure of SCAEs assumes greater importance, Belmont says. Healthcare providers must balance the interests of a patient's desire for a fully transparent environment with the need to observe the principles of a "just culture" to promote an environment in which clinical personnel are willing to come forward and disclose medical errors in the interests of system safety, she says. *(See the story, p. 89, for more on how to implement the guidelines.)*

"An inadequate or poorly executed disclosure of a SCAE will serve to frustrate frontline practitioners, negatively affect the reputations of the provider organization and individual practitioners involved in the incident, and encourage medical malpractice claims," Belmont says. "For this reason, it is important that healthcare providers review their current processes to ensure that regulatory and legal considerations are analyzed prior to the disclosure."

Investigation and mitigation of the SCAE is a cooperative endeavor involving the affected clinicians, medical staff and nursing leadership, and hospital administration, Belmont says. A risk manager often is the individual tasked with the coordination and investigation of a SCAE, she says. The risk manager needs to work with medical staff and nursing leadership and hospital administration in the investigation of a SCAE and any related disclosures to the patient and his family, state regulatory agencies, accrediting bodies, the media, or other third parties, she says.

"A risk manager should engage these stakeholders in a dialogue to develop a process for the investigation and mitigation of SCAEs," Belmont says. "At the time of the occurrence of the SCAE, all of the contributing factors may not be apparent. A root cause analysis may take several weeks to complete in the case of a complex therapeutic misadventure, and the results of the analysis may indicate that the cause is a system failure as opposed to the actions of an individual practitioner." *[*Healthcare Risk Management *sent a special ebulletin about the AHLA guidelines to readers on June 18. If you didn't receive the bulletin, we don't have your e-mail address. To receive occasional news ebulletins, please contact customer service at (800) 688-2421 or customerservice@ahcmedia.com.]*

SOURCE/RESOURCE

- **Elisabeth Belmont**, JD, corporate counsel at MaineHealth, Portland, ME. Telephone: (207) 661-7010. Email: belmoe@mainehealth.org.
- "Considerations in the Disclosure of Serious Clinical Adverse Events (SCAEs)," published recently by the American Health Lawyers Association, is available at http://tinyurl.com/6wzvbsg. ✦

Executive Summary

New guidelines from the American Health Lawyers Association offer detailed list of issues to consider and questions to ask before disclosing a serious adverse event. The guidelines could alleviate some fears about disclosure.

- ✦ Most of the guidelines suggest topics to investigate before disclosure.
- ✦ There are no requirements or firm standards, only suggested considerations.
- ✦ The guidelines are available at http://tinyurl.com/6wzvbsg.

Guide provides questions, but answers are up to you

These are excerpts from "Considerations in the Disclosure of Serious Clinical Adverse Events (SCAEs)," published recently by the American Health Lawyers Association and available at http://tinyurl.com/6wzvbsg:

- Does the SCAE fall within the definition of "Never Events" promulgated by the Centers for Medicare and Medicaid Services (CMS) and thus is subject to non-reimbursement

by Medicare? Additionally, is the SCAE subject to the applicable state billing law or Medicaid program "Never Events" policies or considered to be an "avoidable" hospital complication under a commercial insurer's payment or billing policies?

• If the SCAE does not fall within the definition of "Never Events," was a request for reimbursement submitted to the patient's insurance carrier?

• Has a Root Cause Analysis been initiated? Has the cause of the SCAE been identified and, if so, with what level of certainty?

• Has the SCAE been reported to the provider's risk manager, legal counsel, and professional liability insurance carrier? If so, has the involved professional liability insurance carrier(s) denied coverage for the SCAE or reserved the right to do so at a later date?

• Is the reporting of the SCAE to one or more regulatory agencies mandated by state law and, if so, under what circumstances? Which regulatory agency(ies) must be notified, and what specific information must be included in the report(s)?

• Does the applicable state law mandate disclosure of the SCAE to the patient and/or the patient's family and other third parties and, if so, what specific information is required to be disclosed?

• Is the information that may be, or is required to be, disclosed to the patient and/or the patient's family and other third parties consistent with any mandated report of the SCAE to state regulatory agency(ies)?

• If a meeting is held with the patient and/or the patient's family, who may the patient and/or patient's family bring to the meeting — other relatives, significant other, friend, attorney, clergy?

• Will the patient and/or the patient's family be provided with anything in writing and, if so, who will have input in the preparation of the written response, and has the final draft been reviewed by the risk manager, legal counsel, and professional liability insurance carrier?

• Will the provider allow the meeting to be recorded by the patient, if requested?

• Who will be designated to attend the meeting on behalf of the provider and the involved clinician(s)?

• If the family requests copies of the patient's medical records, are they authorized to receive them under applicable state and federal confidentiality laws and regulations in the absence of written patient authorization?

• Is the information that may be disclosed to the patient and/or the patient's family consistent with any mandated report of the SCAE to state regulatory agency(ies)? ✦

Lead clinicians should know AHLA disclosure guidelines

The American Health Lawyers Association (AHLA) guidelines on disclosure of serious adverse clinical events (SACEs) are an excellent compendium of all the issues that should be raised, says **Ellen L. Janos**, JD, an attorney with the law firm of Mintz Levin in Boston who often has helped hospitals make decisions regarding disclosure of adverse events.

"It's a set of considerations, not requirements, and that's what makes it so useful," Janos says. "This is a resource you can pull out and go through it step by step to make sure you haven't overlooked anything, that you're covering all the right issues and decide whether to disclose and then how to go about it."

Janos points out that not all of the issues raised in the guidelines should prompt an affirmative action. For example, the AHLA guidance suggests considering what records to turn over to the patient or family. Janos says the answer usually should be "none." Handing over source documents could impede a free and frank discussion by clinicians, she says.

"I also think these guidelines should be required reading by certain clinical staff in hospitals, such as the vice president for medical affairs and president of the medical staff," she says. "I don't think they have a full appreciation for the full range of considerations that come into play with a disclosure like this."

As useful as they are, one expert in disclosure reminds risk managers that the guidelines only come into play once you know about a SCAE. Don't let adherence to the guidelines make you overly confident that you have adequately addressed the issue of adverse events and disclosure, cautions **Dean Sittig**, PhD, faculty member at the University of Texas Health Science Center at Houston, who specializes in clinical information systems and clinical decision support.

"The thing that worries me the most is that there is another kind of error where no one even knows it was made. I'm a big fan of disclosing, but there is still a huge number of errors that are unknown," Sittig says. "These guidelines are useful when we know what happened, but we have to keep looking for the ones we don't know about."

SOURCES

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Resources to report adverse events

Two online services are available for reporting adverse events through the PDR Network in Montvale, NJ:

• **RxEvent** – Implemented in 2011, RxEvent is an online network to collect and distribute adverse drug events in the United States, available to all prescribers via integration into electronic health record (EHR) platforms and other online services, including directly at www.RxEvent.org. The service was designed to improve the convenience of adverse event reporting for physicians (including those in hospitals and healthcare systems), the cost-efficiency for manufacturers and the quality of information reported to the Food and Drug Administration.

• **EHRevent.org** – Launched in late 2010, this national electronic health record (EHR) safety reporting system enables physicians and other healthcare providers to report issues related to the implementation and use of EHRs. Available at www.EHRevent.org, the system collects EHR problems reported by physicians and then creates reports that medical societies, professional liability carriers, and the FDA can use to help educate providers on the potential challenges of EHRs in order to advance patient safety and care. ✦

Hospital cuts med errors 30%, falls 88% with TeamSTEPPS

Butler County Health Care Center (BCHCC) in David City, NE, is small — 25 beds serving a rural community of 2,500 — but the administrators think big. Using a program that enhances teamwork, the hospital has reduced medication errors that reach the patient by 30% and patient falls by 88%.

The improvements came as a result of the free Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) program offered by the Agency for Healthcare Research and Quality, which improves communication teamwork. *(See p. 91 for more on TeamSTEPPS.)*

The effort began as BCHCC was working on a project to reduce medication errors, explains CEO **Don Naiberk**. "We had had a couple of medication errors that, although they didn't result in harm to the patient, were significant and could have caused harm," Naiberk says. "We really felt like we needed to do something different."

> *"TeamSTEPPS doesn't by itself solve your patient safety problem, but it gives you the tools to work together and identify those root causes better."*

By studying error reports and the results of root cause analyses, the organization learned that poor communication was the most frequent cause of mistakes. The organization's staff needed to find a way to work as a team, not as independent healthcare providers. TeamSTEPPS training was identified as a way to help BCHCC staff overcome communication barriers and improve workplace culture. With that goal in mind, Naiberk and two other hospital leaders – a registered nurse from the outpatient department and the new director of patient safety — took the master training course offered by AHRQ in 2008.

BCHCC began implementing TeamSTEPPS incrementally. The Surgery Department was among the first, and two TeamSTEPPS stools were introduced there: CUS ("I'm Concerned, Uncomfortable, this is a Safety issue") and the two-challenge rule, which requires assertively voicing a concern at least twice to make sure it is heard. The Magic Wand exercise — in which participants are asked what they would improve in their department if they had a magic wand — was used in the first meeting to help identify safety problems that were rooted in exchanges with other departments and staff members.

After a few sessions, it was evident that a global approach was needed to improve patient safety, Naiberk says.

Training began with supervisors and

Executive Summary

A small rural hospital in Nebraska has reduced medication errors by 30% and falls by 88%. The improvements were achieved with the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) program offered by the Agency for Healthcare Research and Quality.

✦ The program encourages teamwork and open communication.
✦ Hospitals can send employees to free master training sessions.
✦ TeamSTEPPS provides specific tools and techniques for improving communication and reducing errors.

managers. During a supervisor retreat, TeamSTEPPS fundamentals were taught in a four-hour session. After evaluating this phase of the training, the TeamSTEPPS team realized that more support for TeamSTEPPS was required, so five more master trainers were added, including a member of the medical staff. To increase its effectiveness, training became more interactive, and class size was limited to 14 participants.

A series of two half-day training sessions for all employees was scheduled during a four-week period to intensify the training and results. Training was held off site to minimize distractions and lend a sense of priority to the sessions. Finally, training groups were implemented across departmental lines. *(See the story below for details on how TeamSTEPPS was implemented at the hospital.)*

All 117 employees at BCHCC have received TeamSTEPPS Fundamentals training, and the hospital regularly offers refresher courses and training for new employees, Naiberk says. There have been numerous improvements as a result, he says. The most prominent improvements were reducing medication errors that reach the patient by 30% and patient falls by 88%, both the result of using TeamSTEPPS tools to identify problems and improve communication, he says.

"The program leads you to identify the underlying issues in any target problem. TeamSTEPPS doesn't by itself solve your patient safety problem, but it gives you the tools to work together and identify those root causes better," Naiberk says. "Staff communicate better, and there don't seem to be the conflicts that we used to have. They're given tools to deal with conflict and avoid having things escalate to the point that administration has to intervene."

SOURCE

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TeamSTEPPS encourages teamwork, communication

Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) is a systematic approach developed by the Department of Defense and the Agency for Healthcare Research and Quality (AHRQ) to integrate teamwork into practice. It is designed to improve the quality, safety, and the efficiency of healthcare.

TeamSTEPPS is based on 25 years of research related to teamwork, team training, and culture change, according to information provided by AHRQ. As a direct outcome of the 1999 Institute of Medicine (IOM) report, To Err is Human, TeamSTEPPS introduces tools and strategies to improve team performance in healthcare.

The program includes a comprehensive set of ready-to-use materials and a training curriculum to successfully integrate teamwork principles into any healthcare system. TeamSTEPPS has a three-phased process aimed at creating and sustaining a culture of safety using these resources:

- a pretraining assessment for site readiness;
- training for onsite trainers and healthcare staff;
- an easy-to-use comprehensive multimedia kit that contains fundamentals modules in text and presentation format; a pocket guide that corresponds with the essentials version of the course; video vignettes to illustrate key concepts; and workshop materials, including a supporting CD and DVD, on change management, coaching, and implementation.

Healthcare providers may attend free master training sessions scheduled throughout the year and around the country. For the schedule and other information on TeamSTEPPS, go to http://teamstepps.ahrq.gov. ✦

Creative ideas keep staff on TeamSTEPPS

Butler County Health Care Center (BCHCC) in David City, NE, has an enthusiastic team of master trainers who provide training and coaching in the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) program offered by the Agency for Healthcare Research and Quality, which improves communication teamwork.

Without constant reinforcement and the instilling of the TeamSTEPPS tools as new habits, the old, less desirable habits will return, says CEO **Don Naiberk**. The master trainers brainstorm to come up with ideas to keep TeamSTEPPS in front of the staff. These were some of their ideas:

- BCHCC has a stuffed penguin mascot named YaYa that travels around the hospital, building situational awareness. He moves to a different location each week and carries a sign that holds the name of a TeamSTEPPS tool or strategy. There is a weekly prize drawing for employees who complete a form listing where they found YaYa, what his message is, and what the message means (how or where can it be used). There's a bit of excitement

and mystery associated with YaYa and a bit of healthy competition in finding him, Naiberk says. The explanation of YaYa's tools have been complete and detailed, showing either the staff learned well or are diligently looking in their pocket guides to refresh their memories, he says.

Knowing that poor communication was a major cause of error and confusion in the hospital, another cartoon penguin character, Didga U. Know, was created. His purpose is to alert staff about new policies or other important information. When Didga is posted at building entrances to give staff a heads-up, it is their responsibility to seek out the new information through their supervisors, posted notices, and the hospital's online resources.

Because of remodeling, there is a temporary, unfinished wall in the hospital dining room that was made into a TeamSTEPPS graffiti wall. Its artwork and text reinforce TeamSTEPPS tools and strategies. Staff members are invited to share their team success stories by posting them on the wall.

• A "Play and Learn" TeamSTEPPS session is held the first Friday of every month. Sessions feature a tool or strategy and an opportunity to practice using it. Along with the featured tool, simple team-building exercises are conducted. The Play and Learn is set up in the staff cafeteria during break times, and treats are used to encourage participation.

• BCHCC developed a DVD to introduce TeamSTEPPS to new hires as part of their orientation. It explains the concept of teamwork and the tools and vocabulary of TeamSTEPPS so individuals will understand the team tools when they are used. As new hires are added, they are trained in TeamSTEPPS Fundamentals in group settings. A quarterly Fundamentals training in two four-hour sessions is held to ensure all employees have the same training and understanding of the TeamSTEPPS concepts. ✦

Information exchanges bring new risks to hospitals

States such as Maine, New York, Texas, Florida, California, and Michigan are setting up health information exchanges (HIEs), which are computer networks connecting disparate medical practices to help doctors share patient files online. Other states soon will follow. But have you considered the potential risks associated with these new avenues of data sharing?

There are serious risks to consider before jumping in to this new healthcare arena, says **James M. Kunick**, JD, chair of the Intellectual Property & Technology group at the Chicago-based law firm Much Shelist.

"From a sick patient's perspective, an HIE is the greatest thing since sliced bread because it turns every hospital experience into a scene from Star Trek's Enterprise, with the doctor able to link into a database with every bit of information about the patient," Kunick says. "But making all the data so readily available raises all kinds of questions about consent and how you protect that data."

Promoted as part of healthcare reform and the move toward meaningful use of electronic records, the goal of HIE is to facilitate access to and retrieval of clinical data to provide safer and more timely, efficient, effective, and patient-centered care. HIE is also useful to public health authorities in analyzing the health of the population.

Formal organizations are emerging to provide form and function for health information exchange efforts, many of them supported financially by statewide health information exchange grants from the Office of the National Coordinator for Health Information Technology. These grants were legislated into components of HITECH (Health Information Technology for Economic and Clinical Health Act) of the American Reinvestment and Recovery Act in 2009.

Due to a gap in the federal law, states can set their own rules about whether to inform patients that their information is being shared across the state, Kunick says. A major concern for patients is the threat of identity theft, because medical providers suffer more breaches than any other type of organization every year.

Most of the risks are related to the fact that a hospital is responsible for protecting a patient's data, but it is turning that data over to another party, the HIE, which will then

Executive Summary

Health information exchanges (HIEs) promise to improve the availability of patient data, but they also carry liability risks for hospitals. Data breaches through the HIE could expose the hospital.

✦ Federal law allows states to set their own rules about HIEs.
✦ Allowing patients to opt in to HIE participation can lower the hospital's risk.
✦ Hospital administrators might not be considering the risk sufficiently before deciding to participate in an HIE.

make it available to other parties, Kunick explains. That makes the situation ripe for a violation of HIPAA (Health Insurance Portability and Accountability Act). *(See the story below for more on how a hospital can protect itself.)*

One consideration is whether patients should have the ability to opt out of an HIE or if the HIE should obtain the patient's opt-in before any data is shared, Kunick says. The federal regulation does not require an opt-in, he notes. "Not only should it be clear that patients have to opt in, but there also should be an option to opt in on a more conditional basis," he says. "A patient should be able to say you can include general health information, for instance, but no information about sexual issues or past health concerns. If you don't allow that option, there is the possibility that patients won't be as candid with their doctors as they should be."

Kunick cautions that although HIEs are being promoted by many groups as the way of the future, hospitals are lagging behind in their assessment of the risk.

"It's one of a hundred things on their radar, and it hasn't come to a head yet because there hasn't been a ton of litigation and publicity about this," he says. "That doesn't mean you want to leave yourself exposed and get involved in making this issue better known."

SOURCE

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Opt-in can help protect hospital from HIE risks

When participating in a health information exchange (HIE), the primary exposure for a hospital is the potential breach of a patient's protected information, which would violate HIPAA (the Health Insurance Portability and Accountability Act), says **James M. Kunick**, JD, chair of the Intellectual Property & Technology group at the Chicago-based law firm Much Shelist.

"The hospital has the responsibility to protect the information, and if they provide it to the HIE without the patient understanding that the information might go there, when there is a breach in confidentiality, the hospital is likely to end up one of the defendants in a lawsuit," Kunick says. "Even though they really did nothing wrong, they still have to defend themselves for providing information to an exchange that did not adequately protect the data."

In such a case, the hospital would have to prove that it did due diligence before entering into a relationship with the HIE, Kunick says. The best way for a hospital to protect itself is to establish an opt-in program for HIE participation, even if the state does not require it, he suggests.

"You already will give them the HIPAA consent form in which they acknowledge that you have their personal health information, but you can add an opt-in for them to agree that you may provide that information to a health information exchange," he says. "You don't require it, but you inform them up front and you tell them what the risks are, and you ask them to opt in. Some will say no, and with the others, you have that to rely on if anything happens later." ✦

EHRs may reduce claims by improving safety, quality

Malpractice claims dipped dramatically among Massachusetts physicians after they began using electronic health records (EHRs), according to new research, although it's not clear whether the record-keeping was connected to the decline in claims.

Despite its limitations, however, the research provides more evidence that electronic health records "improve quality and safety and, as a result, prevent adverse events and reduce the risk of malpractice claims," says study co-author **Steven Simon**, MD, an associate professor with Harvard Medical School in Cambridge, MA, and an internist with VA Boston Healthcare System.

In the new study, researchers tracked malpractice cases for 275 physicians who were surveyed in 2005 and 2007. Of those, 33 were targeted by malpractice claims. Forty-nine claims related to alleged medical malpractice that took place before the physicians adopted EHRs, and two occurred after.

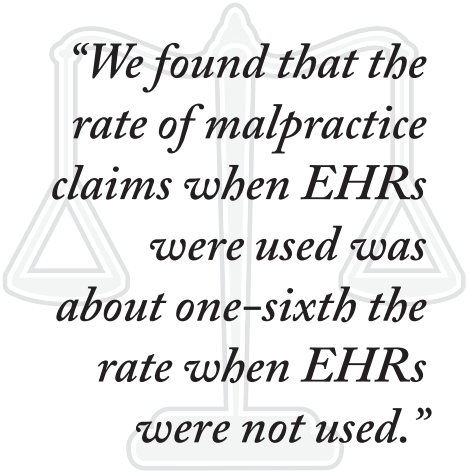
Of the 189 physicians surveyed in both 2005 and 2007, a total of 27 (14.3%) were named in at least one malpractice claim. Overall, 33 of the 275 physicians from multiple surgical and medical specialties who responded in 2005 and/or 2007 incurred a total of 51 unique claims; 49 of these claims were related to events occurring before EHR adoption, and two were related to events

occurring after EHR adoption. The use of EHRs was associated with a lower rate of malpractice claims, with an estimated relative risk of 0.16.

The researchers estimate that medical malpractice claims were about 84% less likely after EHRs were put into place.

The study says factors other than EHRs could account for the difference in claims. Physicians who used the records, for example, could be early adopters whose style of medicine was less likely to spawn malpractice claims. Also, Massachusetts made major changes to the state's healthcare system in 2006.

"We found that the rate of malpractice claims when EHRs were used was about one-sixth the rate when EHRs were not used. This study adds to the literature suggesting that EHRs have the potential to improve patient safety and supports the conclusions of our prior work, which showed a lower risk of paid claims among physicians using EHRs," the authors wrote. "By examining all closed claims, rather than only those for which a payment was made, our findings suggest that a reduction in errors is likely responsible for at least a component of this association, since the absolute rate of claims was lower post-EHR adoption."



Implementation of EHRs "may reduce malpractice claims and, at the least, appears not to increase claims as providers adapt to using EHRs," they wrote.

The full report is available online at http://tinyurl.com/72sgdhb. ✦

Hospital pays $9 million for False Claims Act allegations

Overlook Medical Center in Summit, NJ, and its parent companies have agreed to pay the United States $9 million to settle allegations that they violated the False Claims Act, the Justice Department announced recently.

The settlement resolves allegations that Overlook owned and operated by AHS Hospital Corp. and Atlantic Health Systems, overbilled Medicare for patients who were treated on an inpatient basis when they should have been treated as observation patients or on an outpatient basis.

The settlement partially resolves a False Claims Act suit filed by former employees of Overlook, said **Stuart F. Delery**, JD, acting assistant attorney general for the Department's Civil Division, in announcing the settlement. "We expect hospitals that participate in Medicare will bill for their services accurately and honestly," Delery said. "Hospitals have a responsibility to ensure that the Medicare rules are not abused and patients who should be treated as outpatients are not admitted as inpatients, increasing the hospitals' reimbursements."

The settlement is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced by the Department of Health and Human Services in May 2009. The partnership between the two departments has focused on efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover more than $7.7 billion since January 2009 in cases involving fraud against federal healthcare programs. The Justice Department's total recoveries in False Claims Act cases since January 2009 are over $11.3 billion.

In a similar case, Christus Spohn Health System Corp. has paid the United States more than $5 million to settle allegations regarding violations of the False Claims Act, U.S. Attorney **Kenneth Magidson**, JD, announced recently. The allegations included inappropriately admitting patients to inpatient status for outpatient procedures.

The settlement resolves allegations that six Christus Spohn hospitals in and around Corpus Christi, TX, submitted false claims to the Medicare program by using

inpatient codes for procedures that should have been billed under an outpatient code. The investigation leading to the settlement began in March 2008 after a former director of case management filed a lawsuit under the qui tam provisions of the False Claims Act alleging the six hospitals were submitting false claims to the Medicare program by billing for services that should have been performed on an outpatient basis as if they were more expensive inpatient services.

The allegations stated that these hospitals routinely were billing outpatient surgical procedures as if they required an inpatient level of care, which greatly increased the amounts paid to these hospitals by the Medicare program. These patients often were discharged from the hospital in less than 24 hours.

In this case, the whistleblower will receive 20% of the $5.1 million recovery. ✦

TJC releases tool to address miscommunication in healthcare

An estimated 80% of serious medical errors involve miscommunication between caregivers when patients are transferred or handed-off, according to the Joint Commission Center for Transforming Healthcare, which recently released a new tool to address the problem.

The Hand-off Communications Targeted Solutions Tool (TST) is intended to assist healthcare organizations with the process of passing necessary and critical information about a patient from one caregiver to the next, or from one team of caregivers to another, to prevent miscommunication-related errors. In addition to patient harm, defective hand-offs can lead to delays in treatment, inappropriate treatment, and increased length of stay in the hospital, the group reports.

The Hand-off Communication TST was created to measure the effectiveness of handoffs within an organization or to another facility, and provide proven solutions to improve performance. Using the tool and the solutions from the Center's Hand-off Communications Project, healthcare organizations have reduced readmissions by 50% and have reduced the time it takes to move a patient from the emergency department to an inpatient unit by 33% percent, the center reports.

Accredited organizations can access the TST and hand-off communications solutions on their secure Joint Commission Connect extranet. All of the hand-off communications solutions that were developed by the center and the leading hospitals can be found on the center website at http://tinyurl.com/7923wnz. ✦

COMING IN future MONths

- ✦ Managing BYOD in your hospital
- ✦ Hospital nearly eliminates med errors
- ✦ Most lab errors don't occur in the lab
- ✦ Reducing early deliveries reduces risk

CNE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- describe the legal, clinical, financial and managerial issues pertinent to risk management;
- explain the impact of risk management issues on patients, physicians, nurses, legal counsel and management;
- identify solutions to risk management problems in healthcare for hospital personnel to use in overcoming the challenges they encounter in daily practice.

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CNE QUESTIONS

1. Why does Jacqueline M. Carolan, JD, partner with the law firm of Fox Rothschild, say loss of chance is appearing more in medical malpractice cases?
   A. Because courts and state legislatures are allowing the argument when the chance of survival was less than 50%
   B. Because the U.S. Supreme Court recently affirmed it as a legitimate legal theory
   C. Because the poor economy is making it a more promising legal avenue for recovery
   D. Because the U.S. Congress recently passed legislation allowing its use.

2. In what type of medical malpractice cases is loss of chance most commonly used?
   A. Psychiatric care
   B. Orthopedic injuries requiring long periods of recovery
   C. Plastic surgery
   D. Cancer, stroke, and other cases in which timely diagnosis and treatment are critical.

3. In addition to risk managers and other administrators, who does Ellen L. Janos, JD, an attorney with the law firm of Mintz Levin say should be familiar with the recently released guidelines on disclosure of adverse events?
   A. Senior clinical leaders
   B. Case managers
   C. Board members
   D. Physician practice managers

4. In the report co-authored by Steven Simon, MD, an associate professor with Harvard Medical School, what was the conclusion regarding electronic health records (EHRs) and malpractice claims?
   A. There was no effect on malpractice claims.
   B. The rate of malpractice claims when EHRs were used was about one-sixth the rate when EHRs were not used.
   C. The rate of malpractice claims increased slightly when EHRs were used.
   D. The rate of malpractice claims increased by 40% when EHRs were used.

Legal Review & Commentary

A Monthly Supplement to HEALTHCARE RISK MANAGEMENT

Medication error case settles for $8.25 million prior to trial

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News: A baby boy, born prematurely at 24 weeks, and weighing less than 2 pounds, was in the hospital's neonatal intensive care unit. After successful heart surgery, the hospital's pharmacy technician incorrectly transcribed a physician's order for a sodium chloride intravenous bag into the compounding machine. A sodium chloride solution containing 60 times the amount ordered was formulated and administered. The baby went into cardiac arrest and died. The hospital settled with the boy's parents for $8.25 million.

Background: A baby boy was born prematurely at 24 weeks on Sept. 6, 2010. He weighed less than 2 pounds at birth and was being treated in the hospital's neonatal intensive care unit. His condition improved after 40 days of treatment. On Oct. 15, 2010, the baby successfully underwent heart surgery. Following the surgery, a physician ordered a sodium chloride IV. According to the complaint, a pharmacy technician incorrectly transcribed the order into the hospital's IV compounding machine. The machine created a customized IV bag containing 60 times the sodium chloride than originally was ordered. This faulty bag was administered to the baby. After administering the IV, a blood test on the baby was performed. The test reported abnormally high sodium levels. However, the resident reading the blood test results assumed the numbers were a mistake. Another blood test was ordered, but it was not ordered to be done immediately. Eight hours elapsed, and the second blood test was not completed. The baby went into cardiac arrest from the overdose of sodium chloride and died.

~e fact that human error caused the incident and the systems in place failed to detect the error would have made this case di°cult to defend.

Immediately following the baby's death, the hospital launched an investigation. Several factors were found to have contributed to the administering of a lethal dose of sodium chloride. Physicians primarily transmitted their medication orders electronically to the pharmacy's drug dispensing system. However, the automated compounding system used to prepare the custom IV bag in this case was not connected to this electronic system.

The physician's order was manually input into the compounding machine by a pharmacy technician. This input resulted in the transcribing error. Additionally, when the technician initially input the incor-

FINANCIAL DISCLOSURE: Executive Editor **Joy Daughtery Dickinson** and Nurse Planner **Maureen Archambault** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Philip Nash**, **Barbara K. Reding**, **Alvin Safran**, **Christine A. Turiano**, and **Jonathan D. Rubin**, co-authors, have no relevant relationships to disclose.

rect order into the compounding machine, the machine's automated alerts were not activated to warn about the lethal dosage. Furthermore, the original label affixed to the bag of custom-made solution correctly identified the solution's composition, but a second label was placed over that original label. This second label only indicated the physician's original order.

Several hospital policies were changed as a result of this incident. Pharmacists must now double check IV bags before they leave the pharmacy to guarantee the solution correctly matches the label affixed to the bag. Alerts on IV compounding machines also have been activated. In addition, blood tests ordered after a physician suspects a mistake or faulty test reading must be completed immediately.

Hospital officials informed the baby's parents about the errors and apologized. A medical malpractice suit against the hospital alleging wrongful death was filed in April 2011. The case settled for $8.25 million before going to trial.

What this means to you: This case represents a true system failure in which all checks and balances on several levels failed. The transcribing error was the first in a series of errors.

Sometimes the way in which one reacts to an error is more important than the actual error. It was reported that a second label was placed over the original label on the IV solution. The placement of the second label over the original label would have made it that more difficult for the nurse administering the drug to detect the error because the second label was consistent with the order, not what was actually in the IV bag. The dispensing of drugs with two labels needs to be a major part of any analysis concerning this incident. The receipt of any drug with two labels on a care unit, whether side by side or one over another, should prompt the highest degree of scrutiny. The care unit should not try to figure it out. It would not be unreasonable for the care unit to return such an IV bag to the pharmacy. At that point, all stages of the medication process for that order should be rechecked. This case represents an instance in which an opportunity to rectify the error was missed.

In this instance, the fatal overdose was administered in an intensive care unit (ICU). Lab results came back indicating the abnormal sodium level. The physician ordered retesting but did not order it stat, and some eight hours transpired in the interim. Another opportunity to possibly rectify the error was missed. This situation raises some concerns over the level of supervision in the ICU.

There appears to be a large degree of human error here, but it is still most important that the analysis of the incident focus on what happened and why the system(s) failed. Those who are responsible for putting the correction plan together must tread the fine line between blame and accountability. Conducting a root cause analysis (RCA) when human error played a significant role in the incident can be awkward. The person conducting the RCA needs to give much thought as to who should be invited to the RCA. More specifically, should the person(s) who made the error(s) be invited to participate? Some believe that the only way to analyze exactly what happened is to have all of the players directly involved in the incident participate in the RCA. While the obvious benefit is that those who were directly involved can best explain what happened, the disadvantage is that having the persons who committed the error participate in the RCA can have a chilling effect on the process. It can make the participants feel uncomfortable about asking probing questions. It also can be traumatic for the person who committed the error to relive it. Another factor to take into consideration is your state's discoverability laws. In some states, all statements (written or verbal) by defendants are discoverable, even if made during the peer review process. Under these circumstances, careful consideration must be given with respect to having potential defendants participate directly in the RCA.

Another difficult issue that needs to be considered is what corrective action, if any, should be taken against the individual(s) who made the error. The current risk management philosophy says a non-punitive culture is the best way to establish a culture of safety. A just culture strives for a system approach to analyzing an error rather than a punitive approach. The analysis should focus on what happened rather than who made the error. Nevertheless, a just culture does not preclude accountability for one's actions. *(Editor's note: For more information on a just culture, see "Hospital shows just culture can work,"* Healthcare Risk Management, *March 2006.)*

In its correction plan, the hospital stated it would institute a double-check system in the pharmacy. While this system sounds good on paper, a great deal of thought needs to go into any double-check system. Each healthcare facility should describe how a double check or a double review is to take place. The danger in a double review is that the

second review becomes a "rubber stamp" of the initial review. The double check needs to be devised in a manner that ensures a second review is as independent as possible.

Electronic medical records and electronic order entry can prevent many errors. On the other hand, we are learning that electronic records create their own unique problems. In this case, the pharmacy's system did not send out any alert over the discrepancy between the physician's order and the pharmacist's incorrect transcription. Hospitals are struggling with the major challenges of standardizing electronic systems, or at least having electronic systems that communicate critical information to each other.

The decision to settle this case rather than to take it to verdict appears to be a reasonable one. The fact that human error caused the incident and the systems in place failed to detect the error would have made this case difficult to defend. Of course, the decision to settle rather than defend takes into account sustainable jury verdicts in each state. There can be a large disparity in sustainable verdicts from state to state.

Another interesting risk management issue in this case involves the disclosure and apology. The hospital seems to have followed the textbook manner in apologizing and disclosing quickly and transparently. Once again, state laws regarding discovery of disclosures and apologies can play a significant role in determining how the disclosure is conducted. While it was unquestionably the right thing to do ethically and morally, one cannot help but notice that it did not result in any appreciable savings to the hospital.

It is hoped that other healthcare providers can learn lessons from this tragic event.

Reference

Circuit Court of Illinois, Law Division, Cook Co. Case No. 2011-L-003535. ✦

Settlement for failure to timely perform C-section following drop in fetal heart rate

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News: A 32-year-old pregnant woman presented to the hospital on Aug. 14, 2005, due to onset of labor. At 9:30 a.m., the fetal heart rate monitor showed a dangerous drop in the baby's heart rate from 140 beats per minute to 60 beats per minute. The hospital did not contact the attending obstetrician until 30 minutes later. The obstetrician arrived within 22 minutes but did not perform an emergency cesarean section (C-section) until a half hour after his arrival. The baby, whose umbilical cord was compressed, suffered permanent brain damage. After a five-day trial, the parties reached an $8.5 million settlement.

Background: The 32-year-old patient had an uneventful pregnancy, with all prenatal testing yielding normal results. She arrived at the hospital at 1:30 a.m., after experiencing initial labor pains. A fetal heart monitor was placed on the patient's abdomen. At 9:30 a.m., the monitor showed a drop in the baby's heart rate from 140 beats per minute to a dangerously low rate of 60 beats per minute. Telephone records showed that the labor and delivery room nurse and nurse manager did not call the attending obstetrician until almost 10 a.m. The obstetrician arrived at approximately 10:22 a.m. and performed an emergency C-section at 10:55 a.m. The procedure was completed in four minutes. It was alleged that umbilical cord compression was the cause of the drop in the fetal heart rate. The baby suffered a hypoxic brain injury, resulting in permanent brain damage and the need for full-time care. He is unable to see, walk, or hold his head up. He is also prone to seizures and feeds through a straw.

The patient, individually and on behalf of her baby, brought a lawsuit against the hospital, obstetrician, nurse, and nurse supervisor. She claimed the delay in delivering the baby after signs of fetal distress caused the baby to suffer a hypoxic event, which resulted in permanent injury to the baby. The defense argued that the nurses and physician acted in accordance with accepted medical practices. They argued that the child's brain damage was the result of prior

placental infection. Additionally, the physician argued that he could not immediately perform a C-section on arrival to the hospital, as there was no anesthesiologist available at that time.

Following five days of trial, the parties agreed to a settlement of $8.5 million. Six million dollars of that amount will be allocated to the baby, and $2.5 million will be allocated to the child's parents for pain and suffering. The hospital's insurer paid the bulk of the settlement, with the physician's insurer paying $1 million toward settlement.

What this means to you: When a claim is asserted, one of the initial steps in managing organizational risk is to determine whether the claim meets the criteria for medical negligence. This step would be accomplished through investigation and evaluation of the adverse event as soon as the facts and circumstances of the occurrence were reported to risk management. Conducting a root cause analysis and thorough event investigation as guided by the risk manager provides valuable information to aid in determining the value of and plan for directing the case upon receiving a notice of intent to pursue litigation.

Another step in the risk management process is to consider the strengths and weaknesses of the case to determine whether the organization will choose the path to settle, the path that leads to trial, or to deny the claim altogether. Risk managers in consultation with legal counsel and claims management specialists make such decisions. Claim dollars spent prior to settlement or trial preparation also factor into the equation.

There are advantages to either decision. If the case has little strength on behalf of the healthcare organization, adopting a settlement strategy saves trial costs, the potential for a sympathetic jury, and an unfavorable and costly plaintiff verdict. If the case has merit for the defense, strong supportive documentation, and an impressive group of expert witnesses, it might prove beneficial for the organization to take the case to trial with the expectation of achieving a verdict for the defense. Settlements, by nature, are frequently more predictable when compared with trial and verdict risks. It is not unusual that the strengths and weaknesses of cases, combined with the uncertainty of trial outcomes, prompt the drive toward settlement more often than toward trial.

At the heart of it all ... remains a child who is prone to seizures, unable to see or walk, and who requires constant care and monitoring.

This case is curious in that both a five-day trial and a settlement occurred. It makes a risk manager wonder what happened during the five days of trial testimony to persuade the defense counsel, the plaintiff's attorneys, or both to seek and achieve settlement rather than a verdict. It is also possible that the tedious and highly emotional effects of a trial, especially one involving a child, moved the parents to request an end to the proceedings and receive an expedient resolution in this matter. The structure of the settlement is of interest as well, as it includes what could be considered compensatory as well as punitive damages.

The defense and plaintiff counsels presented assertions that could have been probable compelling factors in the move from trial to settlement. The plaintiff claimed a variety of delays in performing an emergency C-section resulted in hypoxia, permanent brain damage, and the need for full-time, lifelong care; the defense argued the child's outcomes were due to a previous placental infection. Such statements again beg the question as to what was disclosed at trial to change the plans for the direction of this case.

At the heart of it all, however, remains a child who is prone to seizures, unable to see or walk, and who requires constant care and monitoring. Did 82 minutes of delays and failure to intervene in a timely manner permanently alter the life of what otherwise would have been a happy, healthy child? Or was an insidious infection to blame for the adverse outcome? The case is settled, and one might never know the answers to those questions. What is known is that care providers must be diligent in doing no harm by assessing, monitoring and intervening as needed, as quickly and appropriately as possible, to ensure the safety and wellbeing of all patients.

Reference

Superior Court of New Jersey, Law Division, Hudson County. Case No. HUD-L-3895-07. ✦