



Healthcare Risk Management®



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Perinatal safety improved with focus on high-risk factors and education

HCA sees dramatic drops in complications, liability after special effort

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— *Legal Review & Commentary*

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A large hospital system has seen a 45% reduction in new obstetrical claims after implementing a series of steps that focus on the high-risk factors most likely to contribute to birth injuries, and similar drops were seen in categories such as mechanical injuries and birth trauma. The dramatic results were produced by providing more education to staff and enacting some safety standards that are stricter than those considered acceptable in most hospitals.

The leaders of the program at Hospital Corp. of America (HCA) say the same steps could be used in any hospital to the same effect, and they suggest that risk managers take advantage of the experience of their health care system. HCA is the largest health care provider in the country, with 190 hospitals and 44,000 beds. Obstetrical services are provided at 123 of those hospitals, and HCA delivers about 225,000 births annually — about 5% of births nationwide.

Those big numbers also meant HCA dealt with a substantial number of obstetrical claims, says **James D. Hinton**, vice president of risk insurance at HCA in Nashville, TN. And more importantly, these obstetrical claims

EXECUTIVE SUMMARY

One hospital system has dramatically reduced its obstetrical claims and liability costs with a detailed analysis of what factors lead to birth injuries and new rules that reduce the risk to patients.

- Fetal monitoring and vaginal birth after cesarean were especially problematic.
- The system provided extensive training for all labor and delivery nurses.
- The parent company provided discounts on insurance premiums to encourage participation.

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cost far more than other types of claims. From 1995 to 1999, obstetric claims represented only 8% of total claims but 30% of total claim payments, he explains.

"We also found that 50% of all dollars paid on claims above \$1 million were obstetric," Hinton says. "Our rate of obstetrical claims was not unusually high, but the cost of those claims made obstetrics one of the most serious risk management issues for HCA, maybe our biggest concern."

Every hospital that delivers babies has the same issues that HCA addressed, he notes. HCA had the advantage of a massive database of information from its many hospitals, which helped it zero in on the factors that could have the most impact on reducing injuries and claims. The HCA success

story offers a way for other hospitals to benefit from that data analysis, Hinton adds.

"We had to do something, and what we did really worked," he says. "We've reduced the frequency of claims by over a third, and our total costs are down by almost 50%. For HCA, that's an annual savings of somewhere around \$40 million. It's been hugely successful."

HCA spent about \$2.5 million on the effort, mostly for additional education for staff, but Hinton says that was a good investment when the system's annual cost for obstetrics claims was averaging \$120 million. He emphasizes that the same results, and the same ratio of expenditure to savings, could be achieved by any smaller health system or an individual hospital.

Fetal monitoring, VBAC were hot issues

HCA first identified some of the hospitals in its systems that had the highest rates of obstetrical claims and started gathering data on exactly how the claims came about: what type of claims result, what issues led to the birth injuries, and how the injuries might have been prevented. Using that data, HCA started developing a master strategy for the whole system.

The HCA initiative involved several strategies, including the development of a hospital and divisional perinatal task force and perinatal guidelines, data collection and analysis, on-site education for high-risk obstetrics, on-site consultation by HCA's experts as needed, and post-claim follow-up to learn from every less-than-optimal birth experience. HCA began the effort in 1996 with 40 hospitals and then expanded the effort until all HCA hospitals were included in 2002. Between 2002 and 2005, the health system added new initiatives as the program expanded and built on its successes, explains **Janey Myers, BSN**, assistant vice president of the perinatal safety initiative.

Hospitals were required to track obstetrics claims and report data on a quarterly basis, Myers notes. The accumulation of data helped Myers and her colleagues drill down to the real risk factors for those claims. HCA provided a discount on its malpractice insurance to member hospitals as an incentive to participate fully. (See p. 28 for more on the premium incentives.) The data gathered by HCA revealed that these four "hot-topic" issues resulted in a high proportion of obstetrics claims:

- fetal heart monitoring;
- vaginal birth after cesarean (VBAC);
- delays in performing emergency cesareans;

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Editorial Questions

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- injuries associated with operative vaginal deliveries.

The data steered HCA to several risk reduction initiatives, including more extensive use of fetal heart monitoring, medication safety protocols, a zero-tolerance policy for kernicterus, and universal screening for jaundice. (See p. 28 for more on some of the initiatives.)

Fetal monitoring a major issue

Much of the effort involved education aimed at labor and delivery nurses, Myers says. For instance, the perinatal safety group identified fetal monitoring — specifically, the failure of nurses and physicians to communicate adequately when they recognize changes in fetal well-being — as a high-risk factor for obstetrical claims.

“We saw that over 50% of the claims were related to monitoring-related events,” she reports. “It was a failure to recognize what they were looking at, failure to intervene, intervening improperly, or failure to document.”

To address that issue, HCA implemented a system in which all 4,800 labor and delivery nurses throughout the HCA system underwent additional training on fetal monitoring with a two-day session from the Association of Women’s Health, Obstetric, and Neonatal Nurses (AWHONN). (For contact information at AWHONN, see box, this page.) HCA also collaborated with the American College of Obstetrics and Gynecology (ACOG) to develop web-based fetal monitoring training for physicians and nurses. (For contact information at ACOG, see box, this page.)

The training was not for the novice nurse but rather was intended to improve the skills of nurses already considered competent in fetal monitoring. Nurses were required to have six months’ experience on the job before they could go through the two-day course.

The emphasis on fetal monitoring began to pay off immediately, Myers says. From 2001 to 2003, there were an average of 58 monitoring-related obstetrics claims per year, but after the additional training was provided in 2003, the number of claims dropped to only 20 in 2004.

“Fetal monitoring was improved by an emphasis on training and competency, but also teamwork and communication,” she reports. And it wasn’t only the nurses, Myers says. “Physicians needed this training as much, if not more, than

the nurses,” Myers says. “They had to learn to communicate, to use the same terminology, to get across a sense of urgency when necessary and to intervene.”

Another dramatic improvement involved the prevention of kernicterus, a form of brain damage caused by excessive jaundice. Kernicterus results when the substance that causes jaundice, bilirubin, is so high that it moves out of the blood into brain tissue.

The condition has tragic effects on the child (and results in very expensive lawsuits) but is completely preventable with proper monitoring of bilirubin levels, so HCA declared kernicterus a “never event.” That meant a zero-tolerance policy for kernicterus; not even one case could be accepted as just an unfortunate outcome.

To eliminate kernicterus, HCA implemented a new policy that requires testing bilirubin levels on all newborns. That policy goes above and beyond what is considered the standard of care in obstetrics, Myers explains, but it is the only way to ensure that no baby will ever suffer kernicterus at an HCA facility.

The results were undeniable. From June 2004 to February 2005, there were 1.2 cases of kernicterus in the HCA system per month, a rate that Myers says was typical over the past several years. But after the mandatory bilirubin testing was implemented, there were zero cases from February 2005 to June 2005.

“We implemented universal screening so that we can predict the risk of jaundice and kernicterus with every single baby we deliver,” she says. “In

SOURCES

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addition to practically eliminating kernicterus, we have been able to reduce the number of babies coming back to our emergency room with hyperbilirubinemia, high levels of jaundice, by 84%." ■

Injuries and claims drop sharply at HCA

These are some of the results from the perinatal safety initiative at Hospital Corp. of America (HCA):

- Incidents of trauma during birth were reduced from 9.8 per 1,000 births in 2002 to 4.6 per 1,000 in 2004. Mechanical injury claims fell from 74 in 2001 to 38 in 2004. This was achieved by focusing on inappropriate use of vacuum extractions and forceps. HCA developed a standard approach to identifying patients appropriate for vacuum and forceps delivery, along with protocols for safe use of those techniques and a web-based vacuum extraction course.

- The number of new obstetrics claims was 253 in 1996 and held steady until 2001 when it dropped to 222, and then it dropped sharply in 2004 to 127. The number of claims in 2005 was 140.

- Actuarial projections for reported claims per 10,000 births were approximately 14 for 1996 through 2000 and then fell to 12 in 2001 and 2002. The number dropped sharply to 8.3 in 2003.

- The actuarial projection for settled claims per 10,000 births was between 4.8 and 5.8 for 1996 to 1999. Then it dropped to 3.7 in 2000, 3 in 2001, 3.2 in 2002, and 3.5 in 2003. ■

Premium credits encourage hospitals to act

When Hospital Corp. of America (HCA) in Nashville, TN, began its focus on obstetrical malpractice claims, the parent company required all of its member hospitals to start collecting extensive data on all births and report on a quarterly basis. While HCA could require that, system leaders knew that compliance and the quality of the data would depend on the motivation of risk managers and executives at individual hospitals.

So HCA offered cold, hard cash as an incentive.

The system has its own captive insurance company that insures all its hospitals and charges each hospital a premium for malpractice insurance. To encourage robust participation in the data collection effort, HCA offered premium credits if the hospital met certain criteria, explains **James D. Hinton**, vice president of risk insurance at HCA.

"If they are very proactive, working on issues that we believe will prevent claims from recurring, they can earn up to 15% of their premium back," he says.

HCA makes the same offer with some other risk reduction initiatives, and Hinton explains that the premium credit takes away one of the main excuses that hospitals offer with these programs. With nurses in short supply and many of the risk reduction programs requiring nurses to be off the floor for training, the premium credit counters the excuse that taking those nurses off duty is just too expensive.

With the perinatal program, HCA said every hospital could earn 4% of its premium back if it got 95% of their nurses trained in the fetal monitoring program within a certain time frame.

"This was a way to acknowledge that the training has a cost, but we are more than paying for that cost with the premium credit," Hinton says. "It was a success because the premium credit allowed people to do the right thing without having to sacrifice a lot of money from their individual hospital's budget." ■

VBAC risk results in strict criteria or total ban

Vaginal birth after cesarean (VBAC) was tied to a number of obstetrics claims in the Hospital Corp. of America (HCA) system, and inexperience in this procedure may have contributed to the problem, notes **Janey Myers**, RN, assistant vice president of the HCA perinatal safety initiative.

The HCA system includes several smaller hospitals, and some were performing VBAC before they were ready, she says. VBAC is somewhat controversial because it can be dangerous for some patients, but even those professionals who advocate its use say it must be done carefully and with staff who are prepared to respond if anything goes wrong, Myers explains.

Unfortunately, the data collected by HCA

suggested that some of its hospitals were performing VBACs without the proper staffing or safety measures, Myers says. That may have been attributable to a push in recent years among some patients who seek a VBAC rather than going through a second cesarean.

"Most hospitals, including many of ours, do not have 24-hour obstetrics coverage with doctors there ready to respond at any time," she says. "The literature on VBAC clearly shows an increased rate of uterine rupture, and the professional groups have gone from saying that a physician should be 'readily available,' to saying they should be 'immediately available,' but still without defining what that really means."

HCA leaders decided that they needed to define the term and hold member hospitals to certain criteria. For HCA hospitals, "immediately available" now means the physician must be at the bedside within five minutes. That is a tough standard for some hospitals to meet because it requires substantial cooperation from on-call physicians. In addition, hospitals had to guarantee compliance with minimal staffing and competency guidelines and provide additional education regarding VBAC.

"So some of our hospitals had to determine whether they were going to continue offering VBAC, whether it was going to be feasible in terms of their staffing," Myers says. "If not, they were going to just have to say that VBAC is too risky for them and they can't do them anymore."

The issue was not debatable for HCA hospitals. They either had to meet the new criteria or stop doing VBAC, and many decided to just stop. The rate of VBAC among all deliveries in the HCA system was 15.3% in 2001 and fell steadily to 7.5% in 2004. ■

Nurses OK'd to begin rolling on C-sections

The length of time it takes to begin an emergency cesarean is a well-known malpractice risk, and one hospital system has cut the percentage of emergency cesareans that take more than 30 minutes to begin by nearly two-thirds.

The guidelines calling for a maximum of 30 minutes have in fact become a bright line determinant of liability in court, notes **Janey Myers**,

BSN, assistant vice president of the HCA perinatal safety initiative. If it took 31 minutes or longer from the time an emergency was declared to the first incision, a jury usually will find the hospital liable — even though the professional guidelines were never meant to be so rigid.

13% miss 30-minute deadline

HCA found that about 13% of all emergency cesareans were not performed within the 30 minute deadline, Myers says. Further study of the issue revealed that the causes were tied to an inability to get the team together quickly and an inconsistent definition of "emergency."

One problem was that in a typical scenario, a nurse would call the obstetrician at home in the middle of the night and say that she thinks an emergency cesarean is needed. The doctor then has 20 or 30 minutes, by most hospital requirements, to get to the hospital and evaluate the patient. During that time, nothing is done to move toward the emergency cesarean because the doctor has not officially declared the emergency. Then when the doctor gets there and agrees that an emergency surgery is needed, it can take another half-hour or more to assemble everyone and begin the procedure.

HCA changed all that by declaring that labor and delivery nurses can declare the emergency on their own and are empowered to deploy the emergency cesarean team and begin the operating room setup.

"When the physician gets there, everyone is ready to rock and roll and get that baby out," she explains. "The doctor still has to confirm that the emergency procedure is necessary, and if he or she does, then you've saved a half-hour of valuable time. If not, we're out some supplies and we've inconvenienced a few members of the team, but it's well worth it to avoid something that can be a life-threatening event for either mom or baby."

As a result of the changes at HCA, the window of time from when the nurse suspects an emergency to surgery has been cut from nearly an hour to 20 minutes in 90% of the cases. The percentage of emergency cesareans that take more than 30 minutes to begin has been cut from 6.9% in 2002 to 2.4% in 2004.

Any emergency cesarean that takes more than 30 minutes is thoroughly investigated to determine why and how those causes can be addressed. ■

Sexual misconduct requires firm stance

Patients may misinterpret touching, comments

Sexual misconduct or harassment of patients in health care can be a major liability risk and probably happens more than you think, say a risk manager and attorney who are experienced in dealing with such issues. Concerns often go unreported until a lawsuit is filed, they say, and many health care workers don't realize how their seemingly innocuous actions can be perceived as misconduct by patients.

Deborah S. Stephens, RN, BSN, JD, CPHRM, risk manager at Spectrum Health in Grand Rapids, MI, and **Bridget Tucker Gonder**, RN, BSN, JD, CPHRM, associate legal counsel for the health system, say health care workers can get into trouble when they forget that patients are not as familiar with medical procedures as they are and are not used to being touched intimately as a routine matter.

"They're accustomed to doing procedures, even intimate procedures, and not even thinking twice about it," Gonder says. "To the clinician, it's nothing at all, but the patient is wondering why he's lifting her gown up."

For instance, Gonder describes a scenario that happened at Spectrum, in which a male electrocardiogram (EKG) technician entered an emergency department treatment room to perform an EKG on a woman. The man pulled down the sheet covering the woman, opened her gown, and started putting leads on her chest. The woman later complained that she felt sexually violated.

"It was probably the 50th time he had done that, that day. He just saw it as another patient and he was going through his routine," she says. "The patient had never been through this and was very much upset that a man just walked in and bared her breasts and started touching her."

Real risk for health care employers

Stephens and Gonder estimate that they have handled about 20 allegations of sexual misconduct or harassment of patients over the past 10 years, and they sense that the frequency is on the increase. While they cannot discuss individual cases at Spectrum, they note that there is significant potential employer liability from sexual misconduct. The employer can be accused of negligence, malpractice, breach of fiduciary duty, infliction of emotional distress, assault, negligent hiring or retention, battery, and negligent supervision. And of course, there is the risk of terrible publicity if sexual misconduct is reported at your facility.

Gonder cautions risk managers not to assume that your current policies and procedures are sufficient to address sexual misconduct and sexual harassment. Most health care organizations have a policy on sexual harassment, but few have policies that specifically address sexual misconduct involving caregivers and patients.

A policy on sexual misconduct should ensure a consistent approach to handling allegations that protects the patient and the accused employee, Stephens says. Much of Spectrum's policy addresses the manner of notification, how people will be interviewed, and it stresses the importance of allowing the employees do adequately defend themselves. **(See p. 31 for factors that contribute to allegations of sexual misconduct.)**

EXECUTIVE SUMMARY

Sexual misconduct toward patients presents major liability risks for health care employers, and risk managers should educate staff about how to avoid false allegations. There also are valid instances of sexual misconduct that the risk manager can help prevent.

- Many allegations stem from boundary violations.
- It is the caregiver's obligation to prevent misunderstandings.
- All claims of misconduct should be investigated quickly and thoroughly.

Some true predators to watch for

While many allegations are grounded in misunderstanding or carelessness by the caregiver, there are instances of true sexual misconduct in health care settings, Stephen and Gonder stress. Risk managers must be on the alert for sexual predators and those professionals who let their own emotional needs and problems lead them into serious misbehavior. **(See p. 31 for warning signs of sexual boundary violations.)**

"There is no doubt that people take advantage of the situation to prey on patients," Stephens says. "There are some who do it because they

SOURCES

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have their own problems, such as addictions, and there are some who are just predators and see an opportunity.”

It also is important to know that sexual misconduct — both true misconduct and cases of misunderstanding — is not strictly male on female, Gonder says. “We’ve had elderly males wake up and say they were sexually assaulted by a female nurse, and the investigation revealed that she was inserting a Foley catheter. We had another where the nurse was checking a groin dressing and she pulled up his gown and said, ‘Things are looking good down there!’” she recalls. “That was misperceived by both him and his wife — maybe more so by his wife.” ■

Patients can misread gestures, think misconduct

While some allegations of sexual misconduct are valid, many are the result of a misunderstanding, says **Deborah S. Stephens**, RN, BSN, JD, CPHRM, risk manager at Spectrum Health in Grand Rapids, MI. But that doesn’t let the caregiver off the hook, she stresses. It’s the health care professional’s obligation to make sure that well-intended behavior is not misconstrued.

Stephens teaches staff at Spectrum to watch out for certain situations that increase the likelihood of a sexual misconduct allegation and to be extra careful then. There also are certain things that the caregiver should or shouldn’t do to reduce the risk.

In teaching about how to reduce the risk, she offers this list of factors contributing to allegations of sexual misconduct:

- lack of communication by the health care provider;
- failure to adhere to personal space boundaries;
- failure to ask permission to apply medical touch;

- failure to have witnesses present during sensitive exams;
- comforting or consoling gestures, such as hugging;
- inappropriate sexual joking;
- inability to perceive nonverbal cues from the patient;
- language barriers;
- a patient with a history of sexual abuse, which can leave him or her extra sensitive to touch and boundary violations. ■

Warning signs of sexual boundary violations

Sexual boundary violations often are not overtly “wrong” until you put all the pieces together and see that the health care professional is no longer maintaining a professional distance from the patient, says **Deborah S. Stephens**, RN, BSN, JD, CPHRM, risk manager at Spectrum Health in Grand Rapids, MI.

Bridget Tucker Gonder, RN, BSN, JD, CPHRM, associate legal counsel for the health system, also cautions that the patient may not view these transgressions as unwelcome initially. But often, the extra attention or flirting from a physician eventually will make the patient uncomfortable and lead to sexual misconduct charges.

Stephens and Gonder offer these warning signs that a health care professional may be committing sexual boundary violations:

- increased or inappropriate self-disclosure by the professional;
- longer appointments or appointments at the end of the day;
- meetings outside the office;
- use of alcohol or misuse of drugs;
- suggestive or seductive statements;
- intrusion into the patient’s personal life, such as calls to his or her home or attending social engagements when the provider knows the patient will be there;
- requests for secrecy;
- inappropriate physical or sexual contact;
- sharing personal information with the patient.

The health care professional who commits sexual misconduct often is experiencing situational stress from difficulties at work or home, and some are addicted sex or drugs, Stephens says. Others have a personality disorder, but many have poor

communication skills and an ignorance of boundaries that makes them think the patient wanted the behavior. That's no excuse when it comes to actual sexual misconduct, Gonder says.

What do patients think?

Stephens and Gonder offer additional examples of how staff are encouraged to consider the way patients may perceive misconduct. Staff are encouraged to discuss these scenarios and the potential ramifications. As these examples show, sometimes the caregiver's intention is clear and sometimes it is not:

- As the physician is performing an assessment that involves touching the patient, he is discussing last night's date. This makes the patient uncomfortable, and she wonders why the doctor is sharing private information. Doing so while touching her heightens her discomfort. Was the doctor flirting with the woman, or was he just clueless that his comments were inappropriate?

- A nurse is attending to a mentally disabled patient and does not take the time to explain what she is doing. As she tries to apply a monitor strap, he pulls away in fright and later reports that she touched him inappropriately. How could the nurse have prevented the problem?

- A physician tells his attractive patient that he enjoys dating long-legged women like her and asks what kind of man she likes. Is there any doubt that the comment is inappropriate? What if she responds favorably? Does that make difference in whether it was wise to make the comment? ■

Know steps to prevent and respond to allegations

Allegations of sexual misconduct must be taken seriously, and risk managers should have steps in place to both prevent them and respond appropriately, say **Deborah S. Stephens**, RN, BSN, JD, CPHRM, risk manager at Spectrum Health in Grand Rapids, MI, and **Bridget Tucker Gonder**, RN, BSN, JD, CPHRM, associate legal counsel for the health system.

They suggest taking these steps to prevent sexual misconduct:

- Educate staff regarding patient rights.
- Set the standard for professional conduct.
- Develop a policy regarding sexual misconduct.

- Take all allegations seriously.
- Avoid conflicts of interest.
- Investigate complaints immediately.
- Teach boundary violation prevention techniques to all staff and physicians.

Spectrum has put most of its 10,000 employees and physicians through education sessions in the past two years, including discussion sessions and viewing of a video made in-house that illustrates some of the scenarios leading to misconduct allegations.

At Spectrum, employees are educated about boundary violations, which Stephens says can be the cause of many patients feeling they were the victims of sexual misconduct. The burden is on the health care provider to make sure the patient does not feel that boundary has been violated, Gonder says. It's not enough to say that your intentions were pure but the patient felt the situation was inappropriate, she says.

"We had one physician whose routine was to go sit on the patient's bed and chat, touch the patient on the arm and get very chummy for a few minutes, and then he would start the examination," Gonder says. "One patient was offended and thought that he was being sexual with her. When we told him, he was just shocked that it offended anyone. People have to be sensitive to how people are responding, and they have to know that not everyone likes to be touched."

That physician was saved when a female social worker who happened to be in the room confirmed the physician's intentions. Stephens says risk managers should encourage the use of chaperones and witnesses much more than is common in most organizations.

Investigate quickly and thoroughly

Once the allegation is made, they recommend following these steps to investigate:

1. Take the allegation seriously. Never dismiss a complaint out of hand.
2. Remain impartial until you have all the facts.
3. Remove the accused staff member from patient care while you investigate.
4. Start the investigation immediately.
5. Provide patient comfort in whatever way the patient feels is appropriate. This may include access to a counselor, social worker, or medical care.
6. Offer to put the patient in touch with local law enforcement.
7. Notify the patient's attending physician.
8. If the patient is a minor, notify the parent or

guardian and child protective services.

9. Interview the staff member and any potential witnesses.

10. Follow your human resources policies.

11. Offer employee assistance services to the accused employee. ■

Hospital shows just culture can work

(Editor's note: This month's Healthcare Risk Management includes the third a three-part series on the "just-culture" approach to improving patient safety. Previous issues included stories on how the just-culture approach works, potential problems with implementing it, and tips for implementing a just culture. This month's final installment is a report on one hospital's experience in adopting a just culture.)

Adopting a "just culture" approach can be an effective way to improve patient safety in a hospital, judging from the experience of one large hospital that made the move in recent years to a just culture instead of the more common "blame-free" approach used by many health care providers.

As part of a nationwide effort by the parent company, Kaiser Foundation Hospital in San Francisco began shifting to a just culture five years ago, says **Helen Archer-Dusté**, RN, MSN, CHC, assistant administrator for quality at the hospital. To make the move, Kaiser established key steps to achieve each year, such as requiring in the first year that executive leaders must be trained in patient safety and just culture, then mandatory training for physician leaders and managers, and training in human factors for

other leaders and staff. Part of the education process for staff was explaining the hospital's new approach to discipline for willful violation of safety procedures.

Leadership must be fully involved in introducing the just culture approach, or the effort will fail, says **Linda Groah**, RN, MSN, FAAN, chief operating officer of Kaiser Foundation Hospital San Francisco and recently the risk manager. She says it is not enough for leaders to merely approve the idea; they must be active participants.

"Just culture can't just be frosting on the cake," she says. "It has to be a fundamental part of who you are as a health care provider, and that can only come when the top leadership makes it so."

The just culture approach is different from the "blame-free" or "nonpunitive" philosophy in that it allows for individuals to be held personally accountable for their unsafe actions and in some cases punished. (Accountability, and even punishment, can be found in the nonpunitive approach as well, but they are more of an option under a just culture.)

Staff are aware, appreciative

Dusté says surveys have shown that staff awareness of patient safety issues have improved significantly over the past five years, and also the staff's appreciation of how important safety measures are. Groah and other senior leaders also do monthly patient safety "walk-arounds" to talk with staff about patient safety issues, and she says the staff have adopted the culture well. Most staff report that they appreciate a system that will hold someone responsible for willful violations of safety rules rather than claiming a totally blame-free culture, she says.

"When you are working hard to keep patients safe, you don't want to think that the other guy who disregards all the rules is going to be treated the same way," she says. "That's only natural."

Groah says the switch to a just culture approach was prompted by a belief that safety could be improved if people were more accountable for their actions. "If you say 'blame-free' to some people, it means no accountability, and we thought that was the wrong message," she says. "We want people to be accountable for their actions, but we're here to support them and help them do the right thing."

Paul Preston, MD, an anesthesiologist and associate chief of quality, says most health care professionals have a hard time respecting a blame-free approach.

EXECUTIVE SUMMARY

Administrators at a San Francisco hospital report that its experience in adopting a just-culture approach has been successful and improves patient safety. The approach is more effective for health care than a blame-free approach, they say.

- Staff appreciate a just-culture approach.
- Some rules are considered inviolate, and violations will bring discipline.
- A just-culture approach still involves systems analysis.

SOURCES

For more information on Kaiser Foundation Hospital's experience with a just-culture approach, contact:

- **Linda Groah**, Chief Operating Officer; **Helen Archer-Dusté**, Assistant Administrator for Quality; **Paul Preston**, Associate Chief of Quality, Kaiser Foundation Hospital, 2425 Geary Blvd., San Francisco, CA 94115-3358. Telephone: (415) 202-2000.

"I don't know that anyone can really have a blame-free environment because if you don't do something you knew you absolutely had to do, there's blame there whether the organization says so or not," he says. "When I say it's our responsibility not to egregiously violate the bright-line things, everyone smiles and nods because that's what they want for themselves when they're patients."

Zero tolerance on some items

Groah gives the example of how the hospital uses a just-culture approach when enforcing the Universal Protocol that is intended to prevent wrong-site surgeries. The protocol requires a timeout to confirm identity and other details, and the anesthesiologist is primarily responsible for calling the timeout.

If the anesthesiologist does not take the lead for some reason, the circulating nurse or the surgeon must call the timeout, Groah says. Ultimately every person in the operating room is expected to speak up if the procedure is about to begin and no one has called a timeout. And once a timeout is called, it is mandatory that each person participate.

If all of the team members do not take part in this timeout or they do not implement the timeout at all, the privileges for the surgeon are suspended and the entire team is suspended. That is a tough stance, but Groah says it is consistent with the just-culture approach. Employees know that discipline is an option when their behavior is willful, she says. So far, compliance with the Universal Protocol has been consistent, and no surgical personnel have been disciplined.

"Other failures to follow safety protocols have resulted in discipline," Groah says. "It's not our desire to discipline employees for systems problems or simple mistakes, but everyone in this organization knows that discipline is an option when you willfully put patients at risk." ■

Many hospitals not close to IOM goals

Nearly 9% of hospitals have no patient safety systems plan, according to recent research suggesting that risk managers need to reevaluate how they are striving to meet the Institute of Medicine safety goals.

Hospitals' development and implementation of patient safety systems is "at best modest," according to the study.¹ (To see an abstract of the study, go to <http://jama.ama-assn.org/cgi/content/abstract/294/22/2858?etoc>.)

Daniel Longo, ObLSB, ScD, a researcher in the department of family and community medicine at the University of Missouri-Columbia School of Medicine, and fellow researchers assessed the status of hospital patient safety systems in Missouri and Utah in 2002 and again in 2004 to see whether the hospitals had worked to improve patient safety by focusing on the "systems' necessary to facilitate and enhance quality and protect patients" rather than focusing on individual errors. Quality and risk managers responded to a 91-question survey on computerized physician order entry (CPOE) systems, specific patient safety policies, drug storage and administration, adverse event/error reporting, and more.

The surveys revealed that 74% of hospitals had fully implemented a written patient safety plan, but nearly 9% reported no plan. Surgery appeared to have the greatest level of patient safety systems, according to the study.

"Data are consistent with recent reports that patient safety system progress is slow and is a cause for great concern," according to the researchers. "Efforts for improvement must be accelerated."

Longo says progress has been modest and risk managers must greatly accelerate efforts to comply with the IOM goals.

"Health care providers have not met the challenge laid out to them by the IOM, I think this makes hospitals very vulnerable from a risk management perspective," he says. "Risk managers should demand a budget for these improvements and the leverage is that these goals have been out there a while, other hospitals are meeting them, and if you're not meeting them, you're opening yourself up to all sorts of criticism that you knew these changes should be made but did nothing."

Longo goes so far as to say risk managers should stand their ground and not accept a

response of “no” from upper management. “If they are resistant to making these changes, I as a risk manager would look for employment elsewhere,” he says. “Risk managers should not put themselves in the position of working for an organization that says it supports safety but will not put their money where their mouth is.”

Longo’s research should be of concern to risk managers, says **David Bates**, MD, a member of the executive committee for the Center of Information Technology Leadership at Partners Healthcare System in Boston, chief of the division of general medicine at the Brigham and Women’s Hospital in Boston, and professor of medicine at Harvard Medical School, also in Boston. He notes that the study was conducted in only two states and therefore might not be representative of the entire country, but he says he suspects nationwide results would be similar.

“The research confirms that there is a lot of room for improvement,” he says. “The practices described in this report represent a to-do list for hospitals. Risk managers would do well to ask themselves how they would have responded to the same questions and what they are doing to meet these goals.”

Reference

1. Longo DR, Hewett JE, Ge B, et al. The long road to patient safety: A status report on patient safety systems. *JAMA* 2005; 294:2,858-2,865. ■

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JCAHO issues alert on meds at hand-off

The Joint Commission on Accreditation of Healthcare Organizations has issued a new *Sentinel Event Alert* that urges special attention to the accuracy of medications given to patients as they transition from one care setting to another, or one practitioner to another. The failure to reconcile medications during these patient hand-offs can cause serious patient injuries and even death, the Joint Commission warns.

According to the *Alert*, medication reconciliation should occur whenever a patient moves from one location to another location in a health care facility (for example, from a critical care unit to a general medical unit); or from one health care facility to another or to home; and/or when there is a change in the caregivers responsible for the patient. (See the full *Alert* at http://www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_35.htm.)

To reduce the risk of errors related to medication reconciliation, the *Alert* recommends that risk managers ensure these steps are taken:

- Put the list of medications in a highly visible place in the patient’s chart and include essential information about dosages, drug schedules, immunizations, and drug allergies. Reconcile

COMING IN FUTURE MONTHS

■ Root-cause vs. shallow-cause analysis

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CE Questions

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity each semester, you must complete the evaluation form provided and return it in the reply envelope provided in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

9. Which of the following is true of the education for labor and delivery nurses to reduce obstetric injuries and malpractice cases provided by Hospital Corp. of America (HCA)?
 - A. The training was for new nurses only and provided at orientation.
 - B. The training was only for nurses involved in particularly serious malpractice cases.
 - C. The training was only for novice nurses with little experience.
 - D. The training was not for the novice nurse but rather was intended to improve the skills of nurses already considered competent in fetal monitoring.
10. How did HCA reduce injuries and malpractice cases from vaginal birth after cesarean (VBAC)?
 - A. It established new criteria and member hospitals had to meet the new criteria or stop doing VBAC.
 - B. It announced voluntary guidelines that can improve VBAC safety.
 - C. It banned VBAC at all HCA facilities.
 - D. It established a physician peer review board that must approve all VBAC requests.
11. According to Deborah S. Stephens, RN, BSN, JD, CPHRM, and Bridget Tucker Gonder, RN, BSN, JD, CPHRM, who is responsible for making sure there is no misunderstanding that leads to sexual misconduct allegations?
 - A. The patient and health care professional share the obligation equally.
 - B. Family members must make sure the patient understand medical touch.
 - C. Chaperones are responsible for explaining what is happening to the patient.
 - D. It is the health care professional's obligation to make sure that well-intended behavior is not misconstrued.
12. At Kaiser Foundation Hospital, if all of the surgical team members do not take part in the timeout or they do not implement the timeout at all before surgery, what happens?
 - A. All of the team members receive a verbal warning.
 - B. The privileges for the surgeon are suspended, and the entire team is suspended.
 - C. The surgeon must file a written explanation.
 - D. No one is blamed, but team members are reminded of the rule.

Answers: 9. D; 10. A; 11. D; 12. B.

medications at each interface of care, specifically including admission, transfer, and discharge. The patient and responsible physicians, nurses, and pharmacists should be involved in this process.

- Provide each patient with a complete list of medications that he or she will take after being discharged from the facility, as well as instructions on how and how long to take any new medications. The patient should be encouraged to carry this list and share it with any caregivers who provide any follow-up care. ■

CE objectives

After reading this issue of *Healthcare Risk Management*, the CE participant should be able to:

- **Describe** legal, clinical, financial, and managerial issues pertinent to risk management in health care.
- **Explain** how these issues affect nurses, doctors, legal counsel, management, and patients.
- **Identify** solutions, including programs used by government agencies and other hospitals, for hospital personnel to use in overcoming risk management challenges they encounter in daily practice. ■



Failure to detect soft-tissue mass obstruction leads to death, confidential pretrial settlement

By Blake Delaney
Buchanan Ingersoll PC
Tampa, FL

News: After a woman began to experience difficulty breathing, she was rushed to the emergency department (ED), where doctors suspected that the woman's airway was obstructed by a large mass in her throat. The doctors sent the woman to a nearby hospital and recommended that the soft-tissue mass be surgically removed. Upon her transfer, however, the ED physician and the ear, nose, and throat (ENT) specialists declined to order a computed tomography (CT) scan of the woman's neck. They failed to surgically intervene and instead said that the woman merely had swollen tonsils. The next morning, the woman, while home alone, began to experience acute respiratory distress, and she subsequently died before paramedics could arrive. The administrator of the woman's estate brought suit against the hospital, and the parties reached a confidential settlement before trial.

Background: A woman involved in a motor vehicle accident required an extended stay at the hospital for treatment of her injuries. During this hospitalization, she underwent a tracheostomy to provide an airway and to remove secretions from her lungs. The tracheostomy tube remained in place for 60 days following the accident.

Following the patient's discharge from the hospital, she participated in a physical therapy program. The woman was slow to progress in the program because she was experiencing difficulty breathing during the exercises. One day, approximately four months after having been discharged from the hospital, the woman told her therapist

that she felt as if her throat was swollen. Upon the physical therapist's suggestion, the woman's grandmother took her to the ED of a second hospital to be examined for breathing difficulties.

At the second hospital, the woman complained that she had been experiencing shortness of breath for three days and that it had been getting worse. The examining nurse noted that the patient had expiratory wheezing with exertion and that audible wheezing was apparent even away from the bedside. Recognizing the patient's previous tracheostomy, the ED physician suspected that the woman had a soft tissue mass in her throat, and he ordered chest films. The physician then consulted with another doctor in the ENT department to discuss having the soft tissue mass surgically removed. The two doctors agreed to transfer the woman back to the original hospital where she had had the tracheostomy procedure performed. The referring physicians noted on the woman's transfer sheet that the woman had been seen for respiratory distress from a large mass in her throat relating to a previous tracheostomy, and that the patient was being referred to see a specialist due to the airway obstruction potential of the mass. The doctors also sent the chest films they had taken with the woman.

Upon arrival at the original hospital, an ED physician observed that the woman had experienced a worsening of respiratory distress above her baseline, and he noted that her noisy respirations became worse with activity. He diagnosed the patient as having a soft-tissue mass that was

causing stridor. Although the doctor initially recorded that a CT scan of the woman's neck would be appropriate, he later crossed out the notation. Instead, he transferred her to the ENT department for future assessment and care.

The ENT team of specialists evaluated the woman and reviewed her history of ventilator dependency and previous tracheostomy. They found that the woman had large tonsils and symptoms of obstructive sleep apnea. However, the team failed to find any airway obstruction. Instead, the woman was told that she had swollen tonsils, an exacerbation of asthma, and probable obstructive sleep apnea. The ENT specialists determined that no intervention was necessary, and they discharged the woman from the hospital.

Upon discharge, the woman's friends noted that she continued to audibly wheeze during the entire 45-minute ride home. The following morning, the woman was alone in her home when she began to experience acute respiratory distress. She called 911, but she was wheezing so hard that the 911 operator had trouble understanding her speech. The woman subsequently became unable to speak, ceased to breathe, and died by the time paramedics reached her.

An autopsy revealed a round mass attached to the anterior surface of the woman's trachea. The medical examiner concluded that the mass occluded the woman's airway in a position between her trachea and vocal cords, which caused her to suffocate. The administrator of the woman's estate filed suit alleging negligence against the hospital which originally had performed the tracheostomy and which ultimately failed to discover and remove the large mass in her throat. Expert witnesses for the plaintiff testified that the defendant's failure to discover the narrowing of the woman's trachea was clear negligence and the proximate cause of the woman's death. The parties reached a confidential settlement agreement one day before trial was scheduled to begin.

What this means to you: This scenario, exemplifying an unfortunate case of missed opportunities, is all too common in the world of risk management.

"A failure-to-diagnose claim is one of the most common — if not *the* most common — causes of action brought by a patient alleging medical malpractice against his or her health care practitioner," says **Patti L. Ellis**, RN, BSN, CPHRM, LHRM, corporate risk manager at Pediatrix-Obstetrix Medical Group in Sunrise, FL. The patient in this case had several ED visits and

multiple encounters with various health care providers, and yet she appears to have not received the proper level of care and treatment.

The factual scenario highlights several concerns to be addressed by the risk management departments at both hospitals involved in this case. The first concern involves whether the patient was medically stable such that she should have been transferred or discharged. If not, the physicians and hospitals may have violated the Emergency Medical Treatment and Labor Act (EMTALA). EMTALA provides that any patient who comes to a hospital's ED requesting examination or treatment for a medical condition must be provided with an appropriate medical screening examination. If the patient is suffering from an "emergency medical condition," the hospital is obligated to provide the patient with treatment until he or she is stabilized, or transfer the patient to another hospital.

"The ER [emergency room] physician at the second hospital was on the right track in suspecting a soft-tissue mass based upon the patient's clinical presentation and history of tracheostomy," notes Ellis. However, his work-up was limited to ordering chest films and seeking consult with an ENT, and his plan of care was to transfer the patient back to the original hospital where the tracheostomy was performed for further care by a specialist. "In hindsight, we have to ask whether the patient was truly medically stable for transfer," says Ellis. She also questions whether the manner of transfer was appropriate, and she notes that the scenario omits mention of whether the patient was transferred from the second hospital to the original hospital by ambulance or by private automobile.

The original hospital also may have violated EMTALA in discharging the woman following the patient's transfer from the second hospital. "There was clearly a discrepancy in diagnosis between the ER physician and the ENT consultants. Again, we have to ask whether this patient was truly medically stable at the time of her discharge," notes Ellis. Indeed, she was still experiencing respiratory distress on the way home, and she died the next morning after suffering acute respiratory distress. Ellis wonders what discharge instructions, if any, the patient received.

Ellis further questions whether the ED physician at the original hospital documented his rationale for not ordering the CT scan. Although the physician's initial plan of treatment was to obtain a CT scan of the patient's neck, Ellis wonders why he crossed out his notation. "The basis for his judgment should have been recorded in the

patient's chart," says Ellis. "Such documentation makes it easier to defend the actions or inactions of a physician years down the road in a courtroom facing a jury."

Finally, Ellis notes that the ED nurse at the second hospital who recognized the patient's wheezing possibly should have taken a greater role in advocating for her patient, especially given the patient's recent history and clinical presentation. "The ER setting should be high on the risk manager's list for evaluating risk and initiating opportunities for critical thinking, process improvement, patient safety, and avoidance of malpractice," suggests Ellis. Ellis emphasizes that good record-keeping is critical. "Documenting a physician's rationale underlying his or her medical judgment for interventions — or lack thereof, recording both negative and positive findings, and making note of differences in medical judgment between health care providers are all effective risk avoidance methods," she concludes. ■

Delays in testing cause woman's death

Cerebral aneurysm case yields \$500,000 settlement

News: A morbidly obese woman went to the emergency department (ED) complaining of a headache. Although medical personnel ordered a computed tomography (CT) scan, the test could not be performed because the patient was too large to fit on the hospital's CT scan table. The woman eventually was transferred to two more hospitals before a successful CT scan revealed bleeding in her brain. Doctors then attempted two cerebral angiograms, the second of which confirmed the results of the CT scan. The woman then was transferred to a fourth hospital for a third angiogram, but she died before the test was performed. The woman's family brought suit and alleged that the negligent delays in completing her diagnosis led directly to her death. During trial, the hospitals settled with the woman for \$500,000. The jury found the woman's neurosurgeon 80% liable and awarded damages in excess of \$5.6 million.

Background: A 37-year-old woman, weighing 417 pounds, presented to the ED complaining of a severe headache. ED staff ordered a diagnostic CT scan, but the hospital's scan table was unable to fit

the patient due to her excessive weight. Medical personnel also could not use ultrasound as a rapid imaging tool because the patient's large amount of body fat would have interfered with the ultrasound waves. Consequently, doctors sent the woman to another hospital the next day, but that hospital also was unable to perform the scan. Finally, the patient went to a third hospital, where a successful CT scan revealed bleeding in her brain.

Doctors suspected that the bleeding was the result of a cerebral aneurysm, which, if left untreated, could result in a catastrophic neurological event. The next day, a neurosurgeon ordered a cerebral angiogram to be performed by a neurologist in order to confirm the existence of a cerebral aneurysm. Again, however, the patient's obesity interfered with the neurologist's ability to perform the test. A second neurologist attempted a cerebral angiogram the following day, and this time the results confirmed bleeding in the patient's brain.

Despite the apparent urgency posed by the woman's condition, doctors transferred the patient to her fourth hospital in nine days. Although doctors were planning to attempt a third diagnostic angiogram the following morning, the woman neurologically decompensated within 12 hours of her arrival, and she ultimately lapsed into a coma. She died 45 days later.

The woman's husband filed a lawsuit alleging negligence on the part of the neurosurgeon, the first neurologist, the first and third hospitals involved in the treatment of his wife, and the medical center system that operated the hospitals. At trial, the plaintiff argued that the delays caused by the defendants in completing his wife's diagnosis directly resulted in her death. Specifically, the plaintiff contended that after the first hospital decided to transfer the patient due to the inadequacy of its CT scan table, medical personnel mistakenly transferred the woman to another hospital similarly ill-equipped to handle the procedure. Additionally, the delays by the neurosurgeon and neurologist during the woman's hospitalization further prevented the timely and essential performance of corrective surgery.

In response, the defendants raised several arguments to show that their actions did not legally cause the woman's death. The defendants first argued that the second hospital to which the decedent was transferred did, in fact, have the proper equipment to perform a CT scan, but that the attempted scan simply failed. Further, they contended that the decedent's health was a contributing factor to the woman's ultimate death. Not only

did her excessive weight contribute to any delays in performing a CT scan and angiogram, but the woman's pre-existing hypertension, diabetes, history of asthma, and morbid obesity prevented her from being a good candidate for surgical correction of aneurysm on an early or emergency basis. Consequently, the woman's health required doctors to delay surgery until her medical condition stabilized. In addition to deflecting blame for causing any delays in completing the patient's diagnosis, the defendants also disputed the effects, if any, that the delays had on the woman's ultimate fate. They pointed out to the jury that because the woman was not a candidate for surgery during her 11 days of hospitalization due to her physical condition, any claimed delays in diagnosis did not cause her to suffer significant damages.

Finally, the defendant hospitals tried to pass liability along to the neurosurgeon and neurologist. They noted that on the second and third days of the woman's hospitalization, the neurosurgeon had scheduled consultations with the patient in favor of attempting any tests or procedures to prevent the woman's condition from worsening. Further, the defendants reminded the jury that even though the neurosurgeon had recommended angiogram testing for the possibility of an aneurysm, he had failed to follow-up to make certain that the neurologist performed the procedure in a timely fashion.

At the close of trial and during jury deliberations, the medical center system that operated the defendant hospitals settled with the plaintiff for \$500,000 on behalf of the two hospitals. When the jury concluded its deliberations, it found the neurosurgeon to be 80% liable for the plaintiff's damages and the first hospital to be 20% liable. The jury did not find any negligence on behalf of the neurologist, the third hospital, or the medical center system. The court awarded the decedent's estate \$5.6 million.

What this means to you: Due to the increase in obesity of the American population, the underlying factual scenario in this case is not uncommon.

"Health care facilities must be prepared to accommodate the special needs of the morbidly overweight patient," says **Patti L. Ellis**, RN, BSN, CPHRM, LHRM, corporate risk manager at Pediatrix-Obstetrix Medical Group in Sunrise, FL. Considering the comorbidities typically experienced by morbidly obese persons and the increased potential to forego routine medical care or follow-up testing, Ellis notes that it is not surprising to see these patients show up in the ED with a true medical emergency.

A hospital's ED, radiology/nuclear medicine

department, operating room, and critical care areas, which are most likely to encounter unusually large patients without warning, are especially vulnerable to a situation similar to the one presented in this case, stresses Ellis. Therefore, as a patient safety and quality improvement initiative, Ellis suggests that these areas of the hospital perform a risk assessment of available equipment, diagnostic capabilities, personnel, and other resources to serve obese patients. Considering that the average CT scan table has a limited weight capacity, the facility may want to consider investing in new equipment.

"While the purchase of oversized patient care equipment can be costly, the price of defending a lawsuit can be higher," says Ellis.

Nevertheless, if your facility cannot accommodate morbidly obese patients and if the facility has elected to not invest in oversized equipment, Ellis emphasizes the importance of developing a patient care protocol for addressing these special needs. The risk manager should make note of the closest facility with an available oversize CT scanner, MRI, and other equipment. In the event that a patient has to be transferred to another facility that has the available service and equipment, the medical record should be well documented. The record should reflect the reason for the transfer, the acceptance by the receiving facility (including the name and title of the person accepting), consent from the patient or the patient's legally authorized representative, and the patient's condition at the time of transfer.

"As with any patient care protocol, be sure it's doable and approved by the hospital's medical staff," says Ellis.

Of course, the inability of the hospitals to accommodate the patient's large size in this case is not the only cause for concern. After all, even health care facilities lacking the resources to purchase the latest and greatest technology are able to adequately treat patients. In this case, Ellis questions why the neurosurgeon failed to follow-up with the neurologist to make sure the angiogram was performed in a timely fashion. Although health care practitioners may face shortcomings in the resources available to them, Ellis notes that there is no substitute for emphasizing the importance of good communication and documentation.

Reference

• Antonio Riley, *Individually, and as Administrator of the Estate of Elaine Riley v. Catholic Medical Center of Brooklyn and Queens Inc., Mary Immaculate Hospital, St. Joseph's Hospital, Richard Johnson, MD, and Richard Zupcak, MD*, Queens County (NY) Supreme Court, Index No. 3439/97. ■