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INSIDE

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Smothered Newborn Shows Patient Safety, Liability Risks

A tragic newborn death illustrates the patient safety risks posed by simply leaving an infant to sleep in the arms of its mother, risks that are increasing with the emphasis on more physical contact between the mother and child.

An Oregon woman is suing a nurse and Portland Adventist Medical Center, where her four-day-old son died. Monica Thompson filed an $8.6 million lawsuit against the hospital and the unnamed nurse, claiming they were at fault for her child's death because the newborn was put in bed with her at night to breast-feed while she was unsupervised and medicated with painkillers and sleep aids. *(See the story on page 112 for more about the incident and the lawsuit.)*

She was medicated with Ambien and Vicodin a few hours before a nurse walked into the room, gave her the baby, and left, according to the suit. Thompson said she fell asleep with the baby in her arms and woke up to find her son not breathing.

Her son suffered brain damage and was removed from life support after doctors said his comatose state was irreversible.

> ALTHOUGH NOT A COMMON INCIDENT, THE INJURY OR DEATH OF A NEWBORN IN THE MOTHER'S ARMS IS A KNOWN RISK AND MUST BE ADDRESSED.

Although not a common incident, the injury or death of a newborn in the mother's arms is a known risk and must be addressed, says **Susan C. Wallace**, MPH, CPHRM, patient safety analyst with the Pennsylvania Patient Safety Authority (PPSA) in Harrisburg.

In Pennsylvania alone, Wallace's research found about 30 incidents per year in the several years she studied. Her analysis of

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reports submitted to the PPSA from July 2004 to 2013 revealed almost 300 incidents of family members dropping their newborns after falling asleep, newborns slipping out of family members' arms to the floor, and newborns receiving bumps to their heads while being cared for by their families. More than 9% of the incidents resulted in serious patient harm. *(Wallace's full report on this safety risk is available online at: http://bit.ly/2gPZ7Zp.)*

Most incidents (85.3%) occurred when the newborn was younger than four days old. Of those falls, 42.7% occurred on day one and 32.8% occurred on day two.

Hospitals must create policies and procedures to protect newborns from this risk, but that can be complicated by competing, and legitimate, efforts to provide more skin-to-skin contact between mother and child, more breast-feeding, and less time away from the child's family. Breast-feeding also produces hormones that make both mother and child sleepy.

Newborn injuries and deaths in the mothers' arms often occur during or after breast-feeding when the mother falls asleep, Wallace says. Mothers are excited to be with their new babies and underestimate how exhausted they are, she says. If the mother becomes groggy or falls asleep, the baby can smother against the mother's skin, clothing, bedding, or a pillow. Entrapment also is possible, and the mother could drop the baby onto the floor.

Events of this type documented by the PPSA occurred in the early morning hours, and in one instance the nurse was rounding and found a baby turned blue in the mother's arms 15 minutes after last checking on them.

"It's important for hospitals to take an active role in informing them that, though these events are rare, they do happen. Ideally, it would be done in the doctor's office before they go in labor, so it's in their minds that this can occur," she says. "The push for skin-to-skin contact and breast-feeding means they are holding their babies a lot more and a lot longer than they ever have before as hospitals try to follow these guidelines that encourage bonding."

Hospitals Addressing the Risk

Hospitals should encourage mothers to be alert for the risk and call for a nurse or hand the child to the father or another family member, Wallace says. The baby's bassinet often is in the room, but if the mother is sleepy or tired she may not be able to place the child there safely when that requires getting out of bed. Manufacturers are beginning to

EXECUTIVE SUMMARY

A hospital faces a lawsuit after a newborn child smothered in the mother's arms. The case illustrates the patient safety threats posed by leaving a baby with the mother soon after birth.

- Efforts to promote skin-to-skin bonding pose unintended risks to the child.
- Hospitals must create policies for close monitoring of newborns with the mother.
- Patients and families should be educated on the risks and prevention strategies.

design neonatal beds with the bassinet attached to the side of the bed, and some bassinets can be positioned over the mother's lap like a meal table. Both designs help reduce the risk to newborns, but do not eliminate the problem. *(The PPSA offers several resources on patient education and statistics on newborn injuries, which can be found at: http://bit.ly/2eSJnI3.)*

The five hospitals in the Portland area, including Portland Adventist Medical Center, have addressed the newborn risk through improved policies and procedures in recent years, says **Linda Helsley**, level II nursery clinical specialist at Mount Auburn Hospital in Cambridge, MA. She recently worked on newborn patient safety with five hospitals in the area.

"We eliminated all the PRN hypnotics from the postpartum order sets for exactly that reason. If they were going to give a hypnotic to a new mom, they wanted it to be a thoughtful, careful decision and put preventive measures in place if they were going to give those drugs," Helsley says. "The number one advice to risk managers would be to look at the postpartum order sets and make sure you don't have PRN hypnotics on there. Also, hypnotic use in younger women has become very common, with women coming in to have their babies and assuming they will continue their use of Ambien."

The hospitals in the Portland area, and others addressing this risk, will provide sleeping aids during long labors but avoid them postpartum, Helsley says. Hospitals also should evaluate the mother postpartum to determine the risk of leaving the baby with her. Consider factors like the length and severity of the labor, the delivery, any medications, physical weakness, and emotional factors.

"If the mother is very tired or numb from an epidural, for instance, you want to have someone standing by the bed if she's breast-feeding in the middle of the night," Helsley says. "They may be more tired than they've ever experienced, and they're also in a bed that is unfamiliar. A hospital bed often has them at a 45 degree angle, which changes how the mother and baby move and where the baby ends up if it slips from her arms."

> "IT IS NOT UNCOMMON FOR A PARENT NOT TO TELL ANYONE ABOUT A NEWBORN FALL, SO IT IS POSSIBLE THAT THOSE INCIDENTS ARE UNDERREPORTED."

When the risk is high, the hospital can require that there be an awake, alert adult present to monitor the child. That can be the father or another family member, a friend, or hospital staff, Helsley says.

Hospitals that still have nurseries rather than the baby staying in the mother's room most time of time, usually smaller hospitals, face the additional challenge of adequate communication between the nurses, Helsley says. When a nurse is caring for the mother and child in the same room, that nurse is more aware of the risk factors that may make it dangerous to leave the baby in the mother's arms, she explains.

"If a nurse is in charge of six or eight babies, and another nurse is caring for the mother, the nursery nurse might bring the baby to the mother without any knowledge of the things that the other nurse knows," Helsley says. "They have the added responsibility to communicate fully about the mother's condition and any risk factors that are not apparent."

Risk managers should watch for incidents involving newborns in their falls and unusual occurrences databases, Helsley says. Falls of just a few feet from a hospital bed can be serious or deadly to infants because they are top heavy and tend to land on their heads, leading to skull fractures, she notes.

"It is not uncommon for a parent not to tell anyone about a newborn fall, so it is possible that those incidents are underreported. Research has shown that to be the case, because they've just had this new baby and they're horrified that they dropped it, and they're afraid to tell anyone," Helsley says.

Patients May Resist

Nurses have long battled the risks posed by leaving a newborn in the mother's arms, says **Connie Furrh**, RN, a risk manager who has worked in neonatal care since 1970.

"This is not new. Moms always think they can handle it, and nurses have always tried to educate them that it can be dangerous. We always told them not to sleep with your baby in the bed," Furrh says. "But you sometimes have to recognize that the mothers are the mothers and we're just nurses, and it can be hard to say, 'I'm taking your baby away whether you like it or not.'"

Nurses also are charged with so much education for new mothers — cord care, circumcision care, colic, basic safety issues — that the risk of

smothering in her arms can get lost in all the rest, if they absorb much of anything in their exhaustion and medicated state. Posting illustrations of the risk and what it looks like when the baby slips from a sleeping mother's arms can help.

Co-sleeping has been debated and researched for years, Furrh notes. There are definite benefits but certainly serious risks, as well. Even when the hospital has a policy prohibiting or limiting co-sleeping, the challenge for nurses is enforcing that policy when the parents disagree, she says.

Nurses often find it challenging to educate parents about the risk of co-sleeping and get them to comply with precautions.

"They're only with us for 24 hours now, so they're going to do what they want at home. But our answer is to just say, 'Our rule is don't do it here, and here is why,'" Furrh says. "In all things at the hospital, all we can do is say, 'Here is what we think is best for you,' but people don't always abide by that. Our job is to try to teach them the best thing for their health and the health of their child, but ultimately they get to make the decision because they are the parents."

Furrh notes that the nurse in question must be traumatized by the experience. Nurses caring for newborns are especially dedicated to their jobs and their patients, she says, and the accidental death would be devastating.

She also notes nurses typically are burdened with heavy workloads. It is unrealistic to expect them to sit with mothers as they nurse. Healthcare aides may be employed for that precaution, but hospitals don't tend to hire a lot of staff to just sit and watch a patient, she notes. If there is no family member to help, waiting while the mother finishes nursing could mean neglecting other patients.

Although it is not clear what policies were in place at Portland Adventist Medical Center or exactly what the nurse in question did or didn't do, Furrh says nurses can be placed in difficult situations when trying to do the right thing.

"Did the nurse try to take the baby but the mother groggily said, 'No, you're not taking my baby?' Did she resist the nurse and didn't remember it the next day?" Furrh asks. "What does the nurse do? Is it assault if you forcefully take the baby away from her?" ■

SOURCES

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Family Sues Nurse and Hospital After Newborn Death

An Oregon woman is suing Portland Adventist Medical Center and an individual nurse after her four-day-old son died. Monica Thompson is seeking $3.5 million from the nurse and $5.1 million from the hospital.

She claims they are responsible for her child's death because the nurse put the newborn in bed with her at night to breast-feed while she was unsupervised and medicated with painkillers and sleep aids. The nurse is not named in the lawsuit, referred to as Nurse X.

Thompson seeks damages for the baby's "desperation and anxiety" as he was suffocated and his mother's "severe emotional distress upon unintentionally killing her firstborn child." She also seeks compensation for counseling expenses for depression and post-traumatic stress disorder. *(The lawsuit is available online at: http://bit.ly/2xin3z0.)*

The lawsuit includes the following allegation of the events:

"On the late evening of Aug. 5, 2012, Jacob was taken to the nursery so that Mrs. Thompson could rest before being discharged. During that late evening, close to midnight, Mrs. Thompson was given a combination of the narcotic painkillers and sleep aids.

"At approximately 3 a.m., Nurse X transferred Jacob from the nursery to Mrs. Thompson's room to be breast-fed. Nurse X put Jacob next to his mother in her bed so that she could breast-feed him. Nurse X left the room and left mother and son unattended.

"About an hour later, still drowsy and groggy, Mrs. Thompson noticed her son was unresponsive in her arms. She called for a nurse while she tried to get him to respond.

Mrs. Thompson tried to stimulate her son's suckling reflexes without success. She touched his eyes and got no response. She poked him and talked to him with no reaction. When no nurse came to help, Mrs. Thompson carried her son to the hallway and frantically yelled for help. A nurse noticed the situation, examined Jacob, and called a Code Blue; Jacob was not breathing. Jacob was taken to a room where a Level II team worked on stabilizing his vital signs. Meanwhile, Mrs. Thompson saw her son being rushed away and had to remain in her room awaiting the outcome."

The lawsuit cites several alleged failures by the defendants, including not putting policies in place to avoid leaving newborns with medicated mothers and for monitoring babies while with mothers. However, it also alleges that such policies were not followed if they existed, so it is not clear whether the hospital actually has such policies. The hospital has not released any statement on the pending litigation. ■

Hospital Loses Tax-exempt Status Over 501(r)

The IRS has revoked the tax-exempt status of a hospital for noncompliance with section 501(r) of the Internal Revenue Code, following the lead of state tax courts that have been increasingly harsh when scrutinizing tax-exempt hospitals.

The IRS released a copy of the letter informing the hospital that its tax-exempt status has been revoked. While the identity of the hospital is not included, the letter states that the exemption was revoked because the hospital failed to conduct a community health needs assessment, adopt an implementation strategy, and make it widely available to the public — all aspects of the complex requirements of section 501(r). *(Text of the letter can be found at: http://bit.ly/2voCeBG.)*

To be tax-exempt under section 501(c)(3) of the Internal Revenue Code, an organization must not have any of its earnings inure to any private shareholder or individual. Section 501(r) specifies how organizations demonstrate compliance with that and other components of the 501(c)(3) law, and some hospitals are not giving proper attention to this requirement, says **Laura Kalick**, JD, LLM, tax consulting director for the Healthcare and Nonprofit and Education Practices with BDO, a consulting firm in Washington, DC.

Kalick is familiar with the case in which the hospital's tax-exempt status was revoked and says it is a government-owned hospital, which probably played a role in the revocation.

Compliance Rules for Tax Exemption

A hospital must meet the general requirements of 501(c)(3) but also the community benefit standards, and section 501(r), Kalick explains. The 501(r) rules govern how hospitals can bill patients for medically necessary emergency care, and features the following four main components:

- **501(r)(3):** Establishes the requirement to conduct a Community Health Needs Assessment (CHNA). Every hospital must conduct a community health needs assessment and file a report every three years. Based on that report, the hospital must create an implementation strategy for meeting the needs of the community, and that report must be publicized on the organization's website.
- **501(r)(4):** Governs financial assistance policies (FAP). The hospital must indicate that anyone potentially eligible for its FAP will not take extraordinary collection actions until it is known whether person qualifies for the assistance.
- **501(r)(5):** Sets limits on charges and defines average general billing (AGB) and methodologies for calculating the limitations.
- **501(r)(6):** Sets communication requirements, timetables, and restrictions for billing and collections.

The rules took effect for hospitals on the first day of the 2016 fiscal year. Hospitals must be in compliance with all four components to qualify for tax-exempt status, but there is flexibility in how the requirements can be met. Organizations can use different processes and methodologies at different facilities.

"The 501(r) rule applies to any hospital licensed in the state that has 501(c)(3) status, and you have many hospitals that are owned by governmental entities and have dual status. They are exempt from tax because they are governmental entities, but decided they wanted to apply for 501(c)(3) status back probably in the late '70s or early '80s because they wanted the benefit

of having certain benefit plans that were available only to 501(c)(3) organizations," Kalick says. "Also, it's a little bit easier to go out and get charitable donations when you have 501(c)(3) status, so hospitals that would have been tax exempt anyway got 501(c)(3) as well."

Those hospitals complained when the 501(r) rule came out in 2010, arguing they shouldn't have to comply because they are tax exempt already, but the IRS would not back down and insisted that all 501(c)(3) hospitals must comply.

"The regulations are about 250 pages, very detailed and laying out exactly what you have to do and the consequences of not doing it. There also are rulings and notices that amplify these regulations," Kalick says. "Then, the IRS trained at least 30 agents initially to go out and start examining 501(c)(3) hospitals to see if they were in compliance with the rules. Because most of the requirements are supposed to be made widely available to the public on the website, the agents can start there and easily see if the hospital has not complied."

FAP in Multiple Languages

The rule requires the FAP be published on the website in English and any other language used by a portion of the community numbering at least 1,000 people or 5% of the population, whichever is less.

"So, you can go to some hospitals' websites and the financial assistance plan is translated into 10 or 12 languages. If an IRS agent wants to see if the hospital is in compliance, all they have to do is go to the website and see what's up there and what's not," she says. "It's very easy. We've had a barrage of hospital clients informed that they're being examined by the IRS for noncompliance. They're very serious about this."

> "IF AN IRS AGENT WANTS TO SEE IF THE HOSPITAL IS IN COMPLIANCE, ALL THEY HAVE TO DO IS GO TO THE WEBSITE AND SEE WHAT'S UP THERE AND WHAT'S NOT."

The hospital that received the IRS letter was examined that way and did not have the required CHNA, Kalick says. She is familiar with the case and says an IRS agent first determined that the CHNA was not on the website — a violation in itself — and then asked hospital officials if one existed. The officials said no, and they refused to create one because it was too expensive and unnecessary, Kalick says.

"The revocation came about because the IRS said it was an intentional disregarding of the rules. It was not inadvertent, and it was not minor," Kalick says. "Basically, the hospital said they don't care because they don't really need the 501(c)(3) status. If this were not a government hospital but instead was one that depended on their 501(c)(3) status, they would have jumped through hoops to make sure their exemption was saved."

Losing the tax exemption means all income is subject to taxation, and that could be retroactive to the point of noncompliance, Kalick explains. That could be disastrous to a hospital that is not already tax exempt because it is owned by a government, she says.

"If you have tax-exempt bonds outstanding that are dependent on your status as a 501(c)(3) organization and you lose your tax-exempt status, those bonds will be called. If you have $50 million in bonds outstanding, that becomes a current liability and you have to pay off those bonds," Kalick says. "That would be disastrous. Property tax exemptions also can be dependent on your 501(c)(3) status, so you could lose property tax exemption at the same time."

The hospital that received the IRS letter might be fine in the end because it is a government entity with tax-exempt status aside from 501(c)(3), but Kalick says the revocation is a signal that the IRS is serious about compliance. She suspects there are many hospitals complying with the letter of the law, and that could hurt them.

There are hospital administrators who say they don't have to conduct

EXECUTIVE SUMMARY

The IRS has revoked the tax-exempt status of a hospital that did not comply with the requirements for section 501(c)(3). Many hospitals may be at risk for noncompliance.

- The 501(r) requirements of the rule can be especially challenging.
- The IRS expects strict compliance with the specific requirements.
- Losing tax-exempt status could be financially ruinous to a hospital.

a CHNA because they're creating a community report that is in compliance with the rules of the state, and that's essentially the same thing, Kalick says. They say they've been substantively complying.

"That's not the case. They haven't been complying and when the IRS notices, it's going to be serious trouble," she says. "Others will say they have a policy that doesn't meet all the rules of 501(r), but they do provide charity care and it's obvious they should be tax-exempt. No, you have to be in compliance with the rules."

Watch the Details

Details matter. For instance, the hospital must denote and publish which physicians affiliated with the hospital do not accept the terms of the FAP, charging patients and pursuing debts as they choose rather than following the hospital policy.

If the IRS notifies a hospital that it is being audited, the hospital should immediately assess whether it is in strict compliance with 501(r).

"You have a little bit of lead time sometimes when they give you that notice, so you should take that time to assess what is on your website and make sure every single thing is there," Kalick says. "The reason you got the notice is because the IRS looked and something wasn't there, so you have to find it and fix it."

Kalick also suggests checking other hospital websites and comparing them to one's own. If they are including information or particular language that you don't, find out why.

IRS Has High Expectations

The IRS has said that it will not revoke tax exempt status when the noncompliance is minor and not willful, but the example they give is a hospital where the sign in the ED explaining the FAP fell off the wall.

"That's what they mean by minor and not willful," Kalick says.

Hospital mergers and acquisitions also are no excuse, she says. A hospital administrator may assume there is no need to comply with the 501(r) rule if his or her facility is about to be acquired by another. The administrator may assume the new organization will fold his or her facility into an existing compliance program. In truth, the acquiring organization will expect the other to have a proper 501(r) compliance program before the acquisition.

"If they find out that you don't comply with the rule, that poses a tremendous tax liability because you might be held liable for taxes you would have paid going back to some time in the past," she says. "That would be a nasty surprise to the organization acquiring your hospital, and you don't want to explain to your bosses why your failure to comply is threatening this deal." ■

SOURCE

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Copy-and-Paste Brings Compliance Risks

Overuse of copy-and-paste in medical records poses risks to patient safety and quality of care, but it also is a compliance risk.

It can be appropriate to copy and paste in an electronic medical record (EMR), but physicians can overuse it, says **Janice Jacobs**, CPA, CPC, CCS, CPCO, ROCC, managing director with Berkeley Research Group in Washington, DC. They can legitimately use it to save time and not have to retype information that is not specific to a particular date of service, information such as patient demographics that remain static from one encounter to the next.

"Unfortunately, everyone has gotten on the copy-and-paste bandwagon and they're using it for way too much information," Jacobs says. "The risk is that they are carrying forward old and outdated information. If they're cutting and pasting information, they may be carrying forward information that is outdated or just not relevant to the current encounter being documented, particularly if the patient has a new complaint and this is not a continuation of the treatment from the previous encounter."

That can lead to coding and other compliance risks, Jacobs says.

"Perhaps on the earlier visit, a lot more work was done that required a certain amount of reimbursement, but this visit was minimal in comparison and the reimbursement should be much less," she explains. "Copying and pasting lots of information runs the risk of upcoding, and also the risk of creating a medical record that is so loaded with text and repeated information

that it is almost impossible to tell what happened and when. That could result in upcoding but also downcoding, where you leave money on the table just because no one can tell what really happened with any certainty."

Accidentally Copying Wrong Text

The physician also may inadvertently copy and paste information from another clinician, which then becomes part of the current physician's account of care, muddying the timeline and responsibility for the patient, she says. It also is possible for physicians to copy information from one patient's record to another patient's.

"I have audited records where the physician had the exact same note, word for word, in 25 patient medical records. Obviously, there was nothing customized to that particular patient, so if someone else comes in and tries to assume care for that patient, they are depending on a note that was the same for 25 patients, which means it may not tell them key information about this one particular patient," Jacobs says.

CMS is aware of this risk and looks for evidence of extensive copied text, Jacobs says.

"They will look for records that look identical, and there is the potential for having money taken back if they see no change from one note to the next," Jacobs says. "They are very much aware of this problem."

Study Finds Heavy Copying

The prevalence of copied text was hard to define until recently, when new software allowed **Michael D. Wang**, MD, a physician in the Department of Medicine at the University of California, San Francisco (UCSF), to distinguish manually modified text from automatically updated imported values in electronic note templates.

> "I HAVE AUDITED RECORDS WHERE THE PHYSICIAN HAD THE EXACT SAME NOTE, WORD FOR WORD, IN 25 PATIENT MEDICAL RECORDS."

Wang and his colleagues studied records from an inpatient electronic record at UCSF Medical Center. They analyzed 23,630 inpatient progress notes written by 460 clinicians, including direct care hospitalists, residents, and medical students on a general medicine service over an eight-month period. *(An abstract of the report is available online at: http://bit.ly/2wqepeJ.)*

They found that 18% of the text was manually entered, 46% copied, and 36% imported. Residents manually entered less (11.8% of the text) and copied more (51.4%) than did medical students (16.2% of the text manually entered and 49% copied) or direct care hospitalists (14.1% of the text manually entered and 47.9% copied).

With less than one-fifth of note content manually entered, Wang says the results cast doubt on the validity of many electronic records.

Prohibiting copy-and-paste would be a drastic solution, as it can be a timesaver when used judiciously, Jacobs says.

"Education and training with real examples is the best solution, along with internal auditing and monitoring," Jacobs says. "The compliance should be specifically looking for evidence of this problem, and when found, take it back to the physician and show them real-life examples from their own patients. Show them how the record has the same note for every single date of service, and if you're audited you're going to have to give this money back. That usually gets their attention." ■

SOURCES

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EXECUTIVE SUMMARY

Physicians can create compliance risks by overusing copy-and-paste in electronic medical records. The records can result in upcoding and the loss of reimbursement.

- Some use of copy-and-paste is legitimate.
- Repeating notes for different patients is dangerous.
- Records can become so confusing as to be unusable.

Nurses Suspended for Viewing Patient's Genitals

Denver (CO) Health Medical Center suspended five nurses for three weeks after confirming they intentionally viewed a patient's genitals without cause, including opening his body bag to view the deceased man's body parts.

The hospital released a statement confirming the suspensions after local television station KMGH received a tip that the nurses had admired the man's genitals while he was incapacitated, and after his death even opened the body bag to view parts of his body. A hospital spokesman confirmed those actions when contacted by the station's news department.

A nurse not involved in the incidents overheard one of nurses talking about it and reported the comments to administration, according to Denver Health Medical Center spokesman **Josh Rasmussen**. The nurses worked in a medical unit.

A representative from the hospital's risk management department contacted the Denver Police to report the incidents, according to a police report.

"Multiple staff members viewed the victim while he was incapacitated, including after he was deceased," a Denver Police report says. "The complainant, Risk Management for Denver Health, made a mandatory report."

Police officials consulted a prosecutor, who determined there was insufficient evidence to prove a crime was committed. No charges were filed, and the police referred the matter back to Denver Health to handle internally, the report says.

The hospital originally disciplined two nurses during an internal investigation, but three more nurses were suspended by the end of the investigation. Rasmussen describes the discipline as "serious," and their personnel files will reflect the suspensions.

Four of the nurses ultimately returned to work. One left the hospital voluntarily. ■

American Hospital Association Calls for Reducing Regulatory Burden on Hospitals

The American Hospital Association (AHA) calls on Congress to reduce the regulatory burden on hospitals and health systems, calling the burden "substantial and unsustainable."

AHA Executive Vice President **Thomas P. Nickels**, JD, recently sent a letter to the House Ways and Means Health Subcommittee, suggesting several steps that Congress can take to immediately reduce the regulatory burden on hospitals and health systems. *(The letter is available online at: http://bit.ly/2xbbnyf.)*

As an example, the AHA cites how the Centers for Medicare & Medicaid Services in 2016 released 49 rules related to hospitals and health systems, totaling nearly 2,400 pages. There also has been an increase in subregulatory guidance such as FAQs and blogs to help hospitals and health systems understand how to implement administrative policies, Nickels noted.

"In addition to the sheer volume, the scope of changes required by the new regulations is beginning to outstrip the field's ability to absorb them," he said.

The AHA letter suggests many ways Congress can reduce the regulatory burden on hospitals and health systems. Two of the suggestions relate to HIPAA, which AHA cites as particularly onerous.

HIPAA regulations restrict the sharing of patient data for healthcare operations, including the use of data for quality assessment and improvement activities, and they interfere with outcomes evaluation, as well as activities related to evaluations of provider competence and performance, he said.

"A clinically integrated setting and each of its participating providers must focus on and be accountable for all patients," according to the letter. "Moreover, achieving the meaningful quality and efficiency improvements that a clinically integrated setting promises requires that all participating providers be able to share and conduct population-based data analyses."

HIPAA should allow all patients' medical information to be disclosed to and used by all participant providers in an integrated care setting, Nickels wrote, and it should not be necessary for a patient to have a direct relationship with all of those organizations that technically use and have access to the data. Treating providers also should be allowed access to patients' substance use

disorder treatment records, according to the letter, instead of how HIPAA currently requires patient consent before treating providers can access those records.

Nickels also urged Congress to pass the Overdose Prevention and Patient Safety Act (H.R. 3545), saying it would "fully align requirements for sharing patients' substance use disorder treatment records with HIPAA regulations that allow the use and disclosure of patient information for treatment, payment, and healthcare operations."

The letter also called on Congress to cancel Stage 3 Meaningful Use requirements, saying it creates a significant regulatory burden without producing any clear benefit to patient care. ■

Study: Pathologists Want More Active Role in Error Disclosure

Pathologists want to play a more active role in conversations about errors with patients, instead of turning to the treating physician to handle it, according to a recent study.[1]

"I was pleasantly surprised that some of these pathologists were willing to play a more active role in conversations about errors with patients, rather than taking the easy way out of hiding behind their microscope and letting the treating physician handle the discussion with the patient," says **Thomas H. Gallagher**, MD, one of the study's authors. Gallagher is a professor in the department of bioethics and humanities at the University of Washington in Seattle.

Researchers held five structured focus groups in Washington and Missouri with 45 pathologists in academic and community practice. Participants discussed the nature of pathology errors, how clinicians respond to pathology errors, and what roles pathologists should play in error disclosure to patients. Some findings include the following:

• Most pathologists lack training in error disclosure.

Regardless, the majority believed that, going forward, pathologists should offer to participate more actively in error disclosure to patients.

• Pathologists believe neither treating physicians nor patients understand the subtleties and limitations of pathologic diagnoses.

"It would be especially surprising to patients, and some clinicians, how pathologic diagnoses are not black and white," says Gallagher. Rather, the diagnoses require considerable judgment and interpretation.

> "IT WOULD BE ESPECIALLY SURPRISING TO PATIENTS, AND SOME CLINICIANS, HOW PATHOLOGIC DIAGNOSES ARE NOT BLACK AND WHITE."

This complexity complicates discussions about pathology errors. "What would seem like a straightforward question — 'Is there cancer present on this specimen?' — can be much harder to answer definitively than patients and other providers think," says Gallagher.

This complexity in diagnosis makes it hard to know what constitutes a pathology error. "It's difficult to determine how to best communicate about these events," says Gallagher.

• Pathologists' lack of confidence in communication skills, and fear of being misrepresented or misunderstood, are major barriers to their participation in disclosure discussions.

"I was surprised at the degree to which some pathologists feel isolated," says Gallagher. "On the one hand, they are critical team members. But they're often working alone, and may have not direct contact with the treating team."

Pathologists face not one, but two challenging conversations when disclosing errors — one with the treating physician, another with the patient. Pathologists in the study believed they were poorly prepared for these discussions, a problem that was identified in previous research on disclosure of radiology errors.[2] "Pathologists don't feel like they are prepared to handle either of these complex conversations," says Gallagher.

Gallagher says the study highlighted these two important ethical issues:

• how challenging it can be to implement what seems like a straightforward ethical principle of truth-telling after errors;

• that much more work is needed to fully understand the nature of "collective accountability" of multidisciplinary teams.

"How do we understand roles,

responsibilities, and accountability when something has gone wrong in the patient's care?" asks Gallagher.

In addition to providing much-needed education to pathologists on error disclosure, ethicists can act as coaches or consultants.

"Ethicists can provide real-time support in the process of helping a team understand what happened and prepare to communicate with the patient — and with each other — about what happened," says Gallagher. ■

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2. Brown SD, Lehman CD, Truog RD, et al. Stepping out further from the shadows: Disclosure of harmful radiologic errors to patients. *Radiology* 2012; 262: 381–386.

SOURCE

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Risk Analysis Tool Available for Specialties

A healthcare professional liability insurer released a risk analysis tool for free, with data drawn from closed malpractice claims to identify the greatest malpractice risks by specialty.

Boston-based Coverys offers its Risk Analytics Dashboard online at: https://dashboard.coverys.com/. The tool shows the areas of greatest risk based on medical professional liability claims data to help healthcare providers understand and minimize common risks and reasons behind such events. The dashboard analyzes the insurer's data from more than 14,000 malpractice claims since 2011 in a variety of clinical specialties.

The dashboard analyzes claims in specialties, including emergency medicine, anesthesia, general medicine, obstetrics and gynecology, orthopedic and podiatric surgery, pediatrics, radiology, general, vascular, and thoracic surgery. It offers insights related to risk management issues, allegations, or reasons for claims, and an overview of finances associated with each specialty. ■

One-third Have Experienced Cybersecurity Incidents with Medical Devices

More than one-third of medical device professionals reported that their organizations have experienced a cybersecurity incident in the past year, according to a recent survey.

In addition, the Deloitte poll found that 37% of respondents said that their organizations did not experience such an incident in the last year, while 27% said they didn't know if they did. The poll respondents include professionals from medical device or component manufacturers, healthcare IT organizations, medical device users, and regulators.

The respondents also said that identifying and mitigating the risks of fielded and legacy-connected devices presents the industry's biggest cybersecurity challenge, with 30% saying that was the top risk. They also listed embedding vulnerability management into the design phase of medical devices (20%), monitoring and responding to cybersecurity incidents (20%), and lack of collaboration on cyberthreat management throughout the connected medical device supply chain (18%).

Post-incident risk management also was a concern. Only 19% said their organizations are "very prepared" to address litigation, internal investigations, or regulatory matters related to medical device cybersecurity incidents. Fifty-six percent said they were "somewhat prepared," and 13% said they were not prepared to address these issues in the next year.

The report is available online at: http://bit.ly/2m3mXmp. ■

COMING IN FUTURE MONTHS

- Nurse arrested for refusing blood draw
- OIG auditing telemedicine
- Better background screening
- OB emergency departments: Risks and benefit

HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **In the case in which an Oregon woman is suing Portland Adventist Medical Center and an individual nurse after her four-day-old son died, what is the primary allegation?**

   a. The newborn was placed in bed with the mother at night to breast-feed while she was unsupervised and medicated.
   b. The newborn mistakenly received medication intended for the mother.
   c. The newborn was put in a bassinet that was improperly fitted with bedding that smothered the child.
   d. The newborn did not receive proper breast-feeding because nurses could not stay to monitor the mother and child.

2. **What is one preventive measure put in place by the five hospitals in the Portland area to address the newborn safety risk, according to Linda Helsley?**

   a. They prohibited the use of postpartum hypnotics.
   b. They eliminated all the PRN hypnotics from the postpartum order sets, but they may still be ordered.
   c. They prohibited patients from using over-the-counter sleep aids.
   d. They began monitoring for sleep supplements such as melatonin.

3. **Under Internal Revenue Code 501(r)(3), how often must a hospital file a report on its Community Health Needs Assessment?**

   a. Every year
   b. Every other year
   c. Every three years
   d. Every four years

4. **In the study by Michael D. Wang, MD, how much of the text in the medical records was manually entered?**

   a. 10%
   b. 18%
   c. 38%
   d. 60%

CME/CE OBJECTIVES

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

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

LEGAL REVIEW & COMMENTARY
EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

Physician, Hospital Negligence Found After Hypoxic Brain Damage to Infant

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News: A woman presented to a hospital for the delivery of her baby. After returning to the hospital following a discharge, the patient went into labor. She underwent an artificial rupture of membranes and was in a state of tachysystole. The physician prescribed Pitocin to augment the progression of labor and contractions. The fetus' vitals indicated signs of hypoxia, and the Pitocin continued. The infant was delivered via spontaneous vaginal delivery and was diagnosed with severe hypoxia.

The infant was transferred to a children's hospital, where he was diagnosed with severe hypoxic ischemic encephalopathy, seizures, respiratory distress, and coagulopathy. He later was diagnosed with cerebral palsy, requiring 24-hour care. A jury determined the child's injuries were caused by the negligence of the physician and hospital, and returned a verdict for $14.5 million.

Background: In anticipation of the delivery of her child, a woman was given an estimated due date of July 14, 2012. She received prenatal care at a hospital in Erie, PA, before she transferred to a Clearfield hospital roughly four days before the estimated delivery date. Throughout the pregnancy, tests revealed the fetus was in good health.

On the afternoon of July 19, 2012, the patient presented to the Clearfield hospital with contractions spaced every 2-3 minutes, dilation of three centimeters, and an 80% effaced cervix. Just after 1:00 p.m., the treating physician discharged the patient with instructions to return when her contractions strengthened or her membranes ruptured. The mother returned to the hospital approximately three hours later, reporting pain, similar contraction frequency, and showing 5-6 centimeters of dilation.

DURING THE LABOR, FETAL MONITOR TRACING SHOWED INCREASING DECELERATIONS AND OTHER FINDINGS INDICATING PROGRESSIVE FETAL HYPOXIA, HYPOXEMIA, AND ACIDOSIS.

Her dilation increased after admission to the hospital's labor and delivery ward. She underwent an artificial rupture of membranes, revealing thick meconium-stained fluid. It was reported that the patient was frequently in tachysystole throughout the laboring process, a condition categorized by six contractions in a 10-minute period. Despite this, and without any signs of complication, the physician prescribed the patient Pitocin at 6 mu/min to augment the progression of labor.

During the labor, fetal monitor tracing showed increasing decelerations and other findings indicating progressive fetal hypoxia, hypoxemia, and acidosis that should have required intrauterine resuscitation and emergency delivery. Instead, the physician proceeded with spontaneous vaginal delivery.

The child was delivered at six pounds, 14 ounces. He appeared physically normal but was severely depressed,

requiring immediate advanced neonatal resuscitation and intubation. The child's Apgar scores were 1, 2, 3, 4, 4, 4, and 5 at 1, 5, 10, 15, 20, 25, and 30 minutes, respectively. He had severe metabolic acidosis on cord PH, indicative of acute hypoxia during labor. The child was treated with therapeutic cooling the next day at a children's hospital and diagnosed with severe hypoxic ischemic encephalopathy, seizures, respiratory distress, and coagulopathy. The child also was diagnosed with cerebral palsy, for which he will require 24-hour care.

The infant's parents contended the physician negligently administered a high dosage of Pitocin, failed to properly monitor the pregnancy and observe that the mother's contractions had been progressing, and failed to swiftly deliver the baby when the heart rate began to drop. In her complaint on behalf of her son, the plaintiff listed 27 distinct injuries. The complaint also alleged negligence by the Clearfield hospital for failure to monitor the labor and otherwise alleged similar contentions as those set forth against the physician.

The defendants contended the physician followed proper procedures and that the injuries were the result of other factors not within the hospital's control, such as the mother's obesity, fetal exposure to secondhand smoke, and other health problems. The defense expert opined that the placenta was abnormally small for the size of the fetus and might have been inadequate to sustain the needed oxygenation during the second stage of labor.

The jury found the physician 60% negligent, while the Clearfield hospital was found to be 40% negligent. The plaintiff was awarded $14.5 million for past and future medical expenses, future lost wages, and past and future pain and suffering.

What this means to you: The American College of Obstetricians and Gynecologists reported the number of induced labors has doubled since 1990. Considering this statistic, it is imperative that medical professionals use uterine stimulants, such as Pitocin, properly. These stimulants are used frequently to induce labor when it does not begin naturally. The stimulants also are used, as here, to augment the strength and frequency of contractions when labor is stalled, or otherwise progressing improperly.

When uterine stimulants are used, it is critical to establish baseline vital signs to determine the way in which the mother and child react to the drug. Furthermore, once the stimulant is administered, monitoring and documenting vital signs allows for faster detection of problematic changes in the mother's or the fetus' condition. Such documentation should include the dosage and timing of all medications administered, and any side effects. Changes in pulse and mother's blood pressure also should be monitored closely. Some stimulants, when given intravenously, should be diluted in IV fluid, and should not be administered if there is any question about the condition of the fetus, such as nonreassuring fetal heart rate tracing. Methergine, in particular, is not to be given intravenously, and should not be administered to a woman with hypertension.

Against this background, it is clear that the physician here did not act within the standard of care. He did not act appropriately when the fetal monitoring strips were not reassuring. When a mother is in a state of tachysystole, administration of a uterine stimulant is inadvisable absent other indications necessitating such a medication. In fact, there were several indications that contraindicated the use of Pitocin, such as decreased heart rate and blood pressure. Note also that when the patient presented to the hospital the first time, she was already 80% effaced. Fetal monitoring should have started then, as this was a high-risk patient with three risk factors: hypertension, obesity, and a smoking history. When she returned a few hours later, monitoring showed a slowing of the fetal heart rate during and immediately after each contraction, indicating decelerations during contraction. These did not return to baseline following the contractions, possibly due to tachysystole or other issues. These, combined with the presence of thick meconium following artificial rupture of membranes, were clear indicators that the fetus was in severe distress. An immediate cesarean section should have been considered and offered to the patient.

Meconium is produced in utero when the fetus is stressed and the contents of the bowel empty into the amniotic sac. The meconium can enter the fetal lungs during the laboring process, further compromising the oxygen saturation of blood reaching the brain. Pitocin was contraindicated and well below the standard of care, as contractions needed to slow to allow the fetal heart to recover between contractions.

This case also illustrates the value in documenting and monitoring medication administration. This serves to prevent negative effects of improper medication dosage and helps develop a medical record. Patients can suffer allergic reactions to medications, adverse interactions with other unknown medications or alcohol, or side effects from medication. Not only is monitoring and documentation important, but responding promptly and correctly

is equally imperative for the care of a patient. Medical professionals must be educated and familiar with hospital policies relating to specific medications and circumstances.

Considering physicians may overlook changes in patient vitals, it also is imperative that hospitals empower supporting medical staff to report and react to concerning changes. The creation of a chain of command for medical professionals is valuable in situations where physicians neglect to either monitor medications or respond to problematic changes. Nurses and physician assistants should feel confident in their ability to quickly consult with their head nurse, director of nursing, and chief nursing officer. Further, such personnel should be reminded that they act as patient advocates, and that asking for help does not equate to incompetence. Individuals in the chain of command must be sufficiently competent and confident to manage such requests, and, to avoid misunderstandings, the chain of command must be very clearly articulated to each employee.

A prudent practice in labor and delivery departments is validation of inter-rater reliability for all involved with interpretation of fetal monitoring strips. Confirmation of a standard language and parameters leaves little for debate when abnormalities are noticed. Nurses and physicians can engage in rapid and open decision-making discussions free of power struggles. In most OB emergencies, there is no time to ascend the chain of command.

Finally, physicians should be instructed to encourage medical professionals to communicate changes in patient vitals immediately to ensure they can act quickly and appropriately in all situations. In labor, the vitals of a fetus can change fast and, as in this case, the changes can cause devastating and irreparable harm. Therefore, communication among all staff members must be encouraged and reinforced. ■

REFERENCE

Decided on Jan. 27, 2017, in the United States District Court, W.D. Pennsylvania; case No. 3:14CV00149.

Defendants Prevail on Negligent Postoperative Care Claim

News: In summer of 2012, a woman underwent surgery on her knee, including the insertion of a small, localized artificial component. The patient returned in 2014 for a follow-up appointment, including minimally invasive surgery. She returned shortly thereafter, complaining of knee pain, swelling, and other symptoms. The physician assistant drained an abscess in the patient's knee to reduce the discomfort and swelling. The patient returned several times for additional treatment, complaining of similar but worsening symptoms. The physician drained the abscess and concluded that the fluid did not indicate any signs of infection. The physician did not test the fluid or consult an infectious disease specialist.

The patient sought a second opinion from a hospital, which then tested the fluid from the drained abscess and found indications of infection. Assuming the infection and ensuing treatment was a cause of negligence by the initial physician, the patient filed suit against him and the medical facility in which he operated. The jury returned a verdict in favor of the defendants.

Background: On Aug. 2, 2012, a woman sought care for her right knee. Surgery was performed on the patient's knee, including medical femoral condyle resurfacing and implantation of an arthrosurface component. In 2014, the physician performed further arthroscopic surgery on the patient's right knee.

After the 2014 procedure, the patient presented to the physician at an orthopedic and sports medicine facility for postsurgical care. The patient returned on multiple occasions, complaining of effusion, ecchymosis, swelling, loss of range of motion, and pain. On July 9, 2014, the physician assistant aspirated fluid from the patient's knee and noted that the patient was experiencing symptoms not unusual for an individual who underwent surgery two weeks prior. Specifically, the physician assistant noted mild swelling, reasonable range of motion, and that the patient walked without the use of assistive devices. The patient was prescribed physical therapy and was instructed to return in one month for a follow-up.

The patient returned July 18 and the physician aspirated fluid from the knee, but did not test the fluid in any way, including for infection. Instead, he noted that the patient did not complain of any infection-related symptoms such as fevers, chills,

malaise, or flu-like symptoms. The fluid, while slightly bloody, was noted to appear noninfectious. Thus, the physician concluded that the patient's increased swelling and pain were due to the patient's commencement of physical therapy.

The physician continued to treat the patient through Sept. 19, 2014. Throughout this time, the patient continued to experience effusion, ecchymosis, swelling, and increasing pain and loss of range of motion. On Oct. 30, the patient sought a second opinion at a different hospital. The ensuing aspiration confirmed an infection in the right knee. The patient underwent a two-stage revision of the previously implanted component. She first underwent removal of the component and placement of an antibiotic-impregnated cement spacer. She then underwent surgical revision to a total knee arthroplasty.

The patient filed suit against the physician and orthopedic and sports medicine facility for failure to diagnose, to treat, to remove fluid, and to consult with an infectious disease specialist. The defendants denied liability and contended the fluid had a noninfectious appearance, the plaintiff did not complain of any other symptoms suggestive of an infection, and the swelling was attributable to an increase in use. The jury found in favor of the defendants.

What this means to you: A critical point in the defendants' successful malpractice defense arose from the blood test obtained when the patient sought a second opinion for her knee. After the care administered by the defendant physician, the patient underwent a blood test that revealed she did not suffer from an infection at the time the physician aspirated the fluid from her knee. When asked about the presence of an infection at trial, the defendant's medical expert stated the patient "had a completely normal sedimentation rate and a normal C-reactive protein" and that if she was infected at the time of the arthroscopy on June 26, why were her C-reactive protein and her sed rate normal. "These are markers for infection, they were completely normal." This evidence, when coupled with the fact that the fluid appeared noninfectious, strongly suggested that a test of the fluid for infection was unnecessary. Further, it makes clear the fact that the physician considered several possible causes for the swelling, pain, and other symptoms.

The determination that the defendants met their duty of care was made at least because of the physician's continued and diligent postoperative treatment of the patient. Eleven months after the physician performed the medical femoral condyle resurfacing and implantation of an arthrosurface component, he saw the patient a second time to perform an additional arthroscopic surgery on her knee.

However, the physician also could have followed up with the patient within the relevant three-week period in which a different treatment option may have been available. Postoperative follow-ups are critical for ensuring the patient recovers quickly and without complications leading to lawsuits, especially when introducing foreign materials into the human body. The first follow-up appointment postsurgery was 11 months. This falls well beyond the three-week period on which the defense relied so heavily. That notwithstanding, the physician otherwise was diligent in his postoperative care regarding the additional arthroscopic surgery.

Considering the outcome of this case, it is wise for medical professionals and hospitals to set up systems for ensuring follow-up appointments are generated, especially after surgery. This can help mitigate any arising complications, such as infections.

It also is worth noting that the physician assistant always noted whether the patient used assistive devices to walk. This was one of many entries in the medical record that provided a basis to support the defense verdict. All medical professionals should be alert and pay particular attention to relevant symptoms related to the procedure. In cases involving prosthetics, use of antibiotic materials are advisable where practicable to avoid infections.

Another consideration is informed consent. Infection is a risk factor whenever an invasive procedure takes place. This includes the initial surgery, the arthroscopy, and each aspiration of fluid. In fact, the aspiration of the fluid within the knee joint to check for the presence of infection could have been when the infection occurred. Had the patient been fully aware that the development of a subsequent infection was not an unusual possibility, she may not have felt the need to commence litigation. Surgeons must be especially diligent about providing and documenting informed consent that covers common surgical risks before commencing with surgery. The most conservative and safe approach would have been to inform the patient that a collection of fluid surrounding an artificial implant may suggest the presence of infectious microorganisms, and advise her on what options for continued care are available. However, in this case, because the patient underwent physical therapy, a diagnosis of overuse rather than infection certainly was within the bounds of reason, given the circumstances. ■

REFERENCE

Decided on Feb. 3, 2017, in the United States District Court, E.D. Missouri; case No. 15-CV-1333.