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INSIDE

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False Information from Patients With Dementia Threatens Safety

(This is part one of a two-part series on the risk management and patient safety implications of treating patients with dementia. This month's issue explores the risks such as acting on incorrect information from the patient. Next month, we will address how to comply with the Health Insurance Portability and Accountability Act.)

Growing concern about the patient safety risks posed by dementia is prompting some U.S. healthcare systems to address the issue with policies and procedures designed to avoid misinformation and other threats.

The prevalence of dementia increases with age, with estimates ranging from 1% to 2% of adults at age 65 up to a high of 30% by age 85, according to the Alzheimer's Association. Physicians fail to recognize dementia in 19% to 67% of patients in the outpatient setting, the Alzheimer's Association reports.

A primary concern with dementia patients is receiving incorrect or incomplete information from them and basing care decisions on that bad data, says **Marcus Escobedo**, MPA, senior program officer with The John A. Hartford Foundation in New York City, which focuses on improving the care of older adults. But in addition, dementia increases the risk of wandering, complicates communicating with the patient, and may interfere with nutrition if the patient refuses to eat properly, he notes. Falls also are greatly increased with dementia patients.

"THESE ARE PATIENTS THAT REQUIRE AN INCREASED LEVEL OF ATTENTION IN ALL ASPECTS OF HEALTHCARE."
— MARCUS ESCOBEDO, MPA, THE JOHN A. HARTFORD FOUNDATION

"This is a huge risk. Patients with dementia are at greatly increased risk for everything from medication errors to elopement,

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and healthcare providers often do not realize how great that risk is," Escobedo says. "These are patients that require an increased level attention in all aspects of healthcare."

Healthcare professionals and staff members also can be at risk because patients with dementia can be physically abusive in response to their confusion, fear, and agitation, Escobedo says.

The Pennsylvania Patient Safety Authority began investigating patient safety threats from dementia when a patient's family member reported several near misses prompted by the patient providing incorrect information to hospital staff, says **Michelle Feil**, MSN, RN, CPPS, senior patient safety analyst with the Authority, in Harrisburg. Feil recently authored a report on the problem and potential risk reduction strategies. *(The report is available online at http://bit.ly/1YdxyY6.)*

Healthcare facilities reported 3,710 events through the Pennsylvania Patient Safety Reporting System between January 2005 and December 2014 involving patients with dementia or potentially unrecognized dementia, she found, and 63 were traced to hospital staff obtaining inaccurate information or consent from these patients.

Feil and her colleagues identified these five ways in which dementia led to patient safety concerns:

- failure to recognize pre-existing dementia;
- failure to assess competence and decision-making capacity of patients with dementia;
- failure to identify a reliable historian or surrogate decision-maker for patients with dementia;
- failure to contact a reliable historian or surrogate decision-maker when information or consent was required for care;
- failure to communicate the patient's dementia diagnosis, competence, and decision-making capacity with all members of the healthcare team.

Detection is key

Detecting the dementia is the first step to avoiding patient safety risks, Feil says.

"Risk managers have to make sure that clinicians have a process in place to screen patients for cognitive impairment," she says. "Any patient 65 years or older should be screened on admission. It's a problem that goes undetected because the patient or family may be unaware or in denial, or perhaps it is not as obvious when they are home in a familiar environment."

Escobedo agrees, and he notes that hospitals and healthcare systems instituting routine screening for older patients have detected much higher rates of dementia than otherwise would have been documented.

Feil recommends the Mini-Cog

EXECUTIVE SUMMARY

Dementia poses a threat to patient safety in several ways. Detecting dementia is the first step in addressing the risk.

- Risk managers should ensure that all patients older than 65 are screened for dementia.
- A popular screening tool takes only three minutes to administer.
- Wandering and incorrect information are major concerns.

screening tool, which takes about three minutes to administer. *(The tool is available online at http://bit.ly/1UynKpO.)* The family member who reported the problem to the Pennsylvania Patient Safety Authority lobbied for hospitals to use a black wristband to denote dementia risk, but hospitals resisted adding another wristband color after recent efforts to standardize the wristbands, Feil says. Instead, some hospitals are using a special sticker that can be added to any wristband for a patient with cognitive impairment, and similar notifications can be placed at the bedside or on the door to the patient's room.

Healthcare professionals must be careful, however, not to assume cognitive impairment with all elderly patients, Feil notes. Doing so would be disrespectful and deprive patients of their autonomy. Even when a patient does have dementia, Feil says, they still should be allowed to make decisions that do not affect their health or safety.

Dementia can go unnoticed in healthcare settings even when it is documented, Feil points out. The primary physician may have noted the dementia diagnosis in the patient's record, but other members of a multidisciplinary team may not notice and will accept inaccurate information from the patient. That bad information then is entered into the patient's record and can lead to patient harm.

Family members can help

Once dementia is known, the healthcare team should work closely with a family member or friend who is familiar with the patient's condition, Escobedo advises. In addition to helping provide correct information, this caregiver can help avoid situations in which the patient becomes agitated and removes tubing or fights someone trying to provide a bath or other care.

"It is important to have a system in place to identify those family members or friends and bring them into all conversations about the treatment or goals of the patient," he says. "Behavioral problems should be turned around and seen as expressions of unmet needs, and it's the role of the provider to determine what those needs might be by talking to the family caregiver about what is comforting, what is agitating, what helps the person remain calm in certain situations."

If the conditions stipulated by the power of attorney have been met, then that person now has the authority to make decisions for the patient.

> "ANY PATIENT 65 YEARS OR OLDER SHOULD BE SCREENED ON ADMISSION."

Some hospitals place dementia patients in rooms that have a clear line of sight from the nursing station, which helps prevent wandering and other potentially dangerous behavior, Escobedo says. Medications also should be monitored to avoid those that are known to worsen dementia symptoms, he says.

There are best practices for older patients and delirium that can be helpful in improving patient safety. One Escobedo recommends is the Hospital Elder Life Program (HELP) developed at Yale University in New Haven, CT, which uses volunteers, staff training, and protocols that are designed to keep patients engaged and safe. *(For more information on HELP, see the resources at the end of this article.)*

"The first hurdle is getting people to realize that dementia poses this kind of risk that is not found with all patients, or even all elderly patients," Escobedo says. "Once that risk is known, there are effective ways to address it."

SOURCES

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- **Michelle Feil,** MSN, RN, CPPS, Senior Patient Safety Analyst, Pennsylvania Patient Safety Authority, Harrisburg. Phone: (717) 346-0469.

RESOURCES

- The **Nursing Home Toolkit** is provided by the University of Pittsburgh (PA) School of Nursing. The Toolkit contains resources to help staff in senior living communities promote non-pharmacologic behavioral health strategies to address behavioral and psychological symptoms of distress that occur in long-term care, especially among residents with dementia. The toolkit is available online at http://bit.ly/1rFyAxN.
- A **fact sheet** from the Hartford Institute for Geriatric Nursing at New York University in New York City explains how dementia can complicate care. The sheet is available at http://bit.ly/1TqXYBJ.
- The **Hospital Elder Life Program (HELP)** in Boston is a patient care program that promotes optimal care for older adults in the hospital. Information on HELP is available online at http://bit.ly/1NiERx7. ■

Risk Manager Dismisses Complaint after Patient Secretly Records Surgery

A patient's secret recording of her surgery revealed what one risk manager calls "inexcusable and reprehensible" behavior, including disparaging remarks about her body, comments that could be considered racially offensive, and suggestions that the woman be touched inappropriately by members of the OR team. The recording also documents what could be malpractice: a surgeon administering penicillin after he verbally acknowledged her allergy.

The response of the hospital's risk manager also is being criticized as insufficient and likely to encourage a lawsuit.

Ethel Easter was concerned about her surgeon's attitude after an office encounter in which she felt he had been rude and dismissive, so before surgery she hid a small recording device in her hair braids, according to a report in *The Washington Post*. *(The story is available to readers online at http://wapo.st/1oEw4cM.)* Soon after she was sedated, the surgeon recounted their dispute to the other doctors and said, "She's a handful. She had some choice words for us in the clinic when we didn't book her case in two weeks."

The comments soon became personal and disparaging, with the surgeon and the anesthesiologist repeatedly referring to her navel and laughing. At one point, the anesthesiologist said Easter was "always the queen," and the surgeon responded, "I feel sorry for her husband."

The surgeon also called the patient "Precious" several times, which Easter interpreted as a disparaging reference to a 2009 movie character who is African American (like Easter), illiterate, obese, and sexually abused. At one point, the anesthesiologist asked, "Do you want me to touch her?" and the surgeon replied "I can touch her." "That's a Bill Cosby suggestion," someone said. "Everybody's got things on phones these days. Everybody's got a camera."

The surgeon twice asked "Do you have photos?" He "thought about it," he said, "but I didn't do it."

Drug order and allergy

The recording makes clear that the surgeon knew Easter was allergic to penicillin but decided to administer Ancef, an antibiotic that causes side effects in some penicillin-allergic patients, and said a small amount should not produce any significant reaction. After surgery, Easter's arms swelled, she developed a persistent itch, and had trouble breathing. She eventually had to go to the hospital emergency department for treatment of the allergic reaction.

Easter sent a complaint letter and a copy of the recording to the director of risk management and patient safety at the hospital, who replied that she had taken the step to remind surgical staff of the need for proper decorum, but said, "After carefully listening to the recording that you provided, Harris Health does not believe further action is warranted at this time."

The risk manager also pointed out that the hospital is part of the Harris Health System, but the doctors in the recording are employees of the University of Texas Health Science Center at Houston. Easter interpreted that information as the risk manager saying the problem was not the hospital's responsibility. Both organizations issued statements declining to comment.

The case is reminiscent of a 2015 lawsuit in which a jury ordered an anesthesiologist and her practice to pay a patient $500,000 for disparaging remarks made during surgery and a false diagnosis on his chart. The anesthesiologist was recorded saying she wanted to "punch you in the face and man you up a little bit," among other comments. *(Readers can read "Anesthesiologist ordered to pay $500,000 after patient's smartphone records insults,"* Healthcare Risk Management*, August 2015, at http://bit.ly/1TvSZUw. For more discussion of improper OR behavior, readers can read "Crack down on OR antics as public, plaintiffs' bar learn of poor behavior,"* HRM*, November*

EXECUTIVE SUMMARY

A patient secretly recorded her surgical team making disparaging remarks about her, including some that can be considered racially offensive and suggestive of sexual abuse. The hospital's risk manager responded to the patient in a way some critics say was dismissive and insufficient.

- The recording also documents the surgeon acknowledging the patient's penicillin allergy but ordering the drug anyway.
- The patient is considering a lawsuit.
- No action was taken by the hospital apparently, other than reminding surgical staff to behave.

2015, at http://bit.ly/23e2dFY.)

An essay in the *Annals of Internal Medicine* in 2015 stirred controversy in the medical community and the general public when it revealed how anesthetized patients are sometimes treated with disrespect and even subject to what could be considered assault. *(Access to the essay is available online at http://bit.ly/1Taj9qY. The cost is $32.)*

Behavior was out of line

The behavior of the surgical team indicates a hospital culture that does not respect patients and could threaten patient safety, says **R. Stephen Trosty**, JD, MHA, ARM, CPHRM, president of Risk Management Consulting in Haslett, MI, and a past president of the American Society for Healthcare Risk Management (ASHRM). Trosty has dealt with serious OR misbehavior in the past when he was the risk manager at a hospital, and he calls this incident "inexcusable and reprehensible."

The comments and the suggestion of sexual contact cannot be tolerated, Trosty says.

"It must be dealt with in the most stern and severe manner, and this means more than just talking to the physicians and operating room staff. Physicians or staff who commit these type of actions have to be disciplined, up to and including loss of privileges or firing," Trosty says. "If this is allowed to continue, or it appears not to be taken seriously, then it will continue. This is the problem in many, if not most hospitals, and why it remains such a recurring problem."

If the only consequence of such behavior is having an administrator remind you to behave, there is little incentive to discontinue this type of conduct, Trosty says. People who act in this manner either do not see why they are wrong or do not care, he says, and either situation must be changed.

It appears that malpractice was committed by giving the patient the antibiotic after discussing that she was allergic to it, Trosty says.

"This is clearly in violation of the standard of care and in the common sense practice of medicine," Trosty says. "To say that it is only a small amount, and so should not have a negative effect, is nothing short of malpractice and a blatant disregard for the patient."

Response called incorrect

The risk manager's response was disappointing, Trosty says. To merely indicate in a letter that the staff members would be talked to is dismissive of the patient's legitimate complaints and concerns, he says. It demonstrates a lack of concern for the patient or what happened to her.

> "I THINK THAT THIS RISK MANAGER DID EVERYTHING WRONG THAT COULD BE DONE WRONG."

At a minimum, Trosty says the risk manager should have arranged a meeting with the patient and listened to her concerns. She also should have considered having the physicians present to hear what the patient had to say and to respond to her complaints. But the risk manager would have needed to meet with the physicians ahead of time to be sure that they did not become argumentative or overly defensive. If she did not think that response was possible, then the physicians should not be present.

She also should address the issue of the antibiotics, because the recording seems to document a clear example of malpractice, Trosty says. The risk manager's cavalier response only served to further anger the patient and could lead to an even greater determination to sue the physicians and the hospital, he says.

To suggest that the hospital was not responsible because the doctors were employed by another entity demonstrates a clear lack of understanding of the law related to this behavior and what it takes to constitute malpractice on the part of the hospital for actions of physicians operating in that facility, Trosty says. The doctors had to be credentialed and privileged by the hospital, have to abide by hospital policies and procedures, and have to be subject to discipline by the hospital. The hospital cannot evade responsibility merely by claiming they were employees of another entity.

"I think that this risk manager did everything wrong that could be done wrong," Trosty says. "It is a clear statement that what happened to the patient does not seem to warrant the time or attention of the risk manager or the hospital."

Risk not taken seriously?

The risk manager apparently did not take this situation seriously, another risk management expert says. Was there any investigation to determine if these types of disrespectful, mocking comments are typical in this facility or an outlier, asks **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, LHRM, a patient safety and risk management

consultant with The Kicklighter Group in Tamarac, FL, and a past president of ASHRM. If there was an investigation, the findings should have been discussed as part of a disclosure session with the patient, she says.

Kicklighter notes that research has shown that decorum in the operating room can affect patient safety. She wonders how many times this patient abuse happens, but is never known, because there was no recording and surgical staff do not report it. She asks why other members of the team aren't stopping these inappropriate comments.

These situations should be referred for peer review, and some disciplinary action should result, she says. Consideration also should be given to requiring the physicians and staff to attend a medical ethics course, she says. The matter also should have been referred to the hospital's ethics committee, she says.

"The root issue with these types of situations is that if OR staff do not report such remarks during the procedure so the supervisor can step in and intervene, or at least write an incident report that makes its way to risk management, we will never know how prevalent this unacceptable behavior is," Kicklighter says. "It used to be that empathy and compassion were traits required when caring for patients, but now many of my friends and acquaintances remark that their animals receive better care, and better informed consent, from their veterinarians than they do from their personal physicians. Communication is a lost art or skill in the medical field, and I predict it will get worse with the overwhelming use of email, texts, and social media in general."

SOURCES

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Round 2 of Audits for HIPAA Are Focusing on Business Associates

The Health and Human Services Office of Civil Rights (OCR) announced recently that it is launching a second round of audits during 2016 to assess compliance with the Health Insurance Portability and Accountability Act (HIPAA), and this time, it is including business associates. That change means that healthcare organizations should act now to ensure their business associates are fully compliant and not exposing the healthcare organizations to fines and other penalties.

This new round of audits underscores how HIPAA compliance is an ongoing responsibility, not a goal to meet and then move on, says **Jessica Forbes Olson**, JD, an attorney with the law firm of Fox Rothschild in Minneapolis, MN. The focus on business associates will test whether healthcare organizations have fully vetted and educated the vendors they trust with protected health information (PHI), she says.

"Covered entities and business associates often make the mistake of believing that HIPAA compliance is a one-time project, rather than an all-the-time practice. The upcoming OCR audits should be the impetus many entities need to do a self-audit and ensure their HIPAA 'ducks' are in order," Olson says. "Recent OCR enforcement activity has shown that the cost of compliance is a drop in the bucket compared to the cost of non-compliance we've seen come in the form of OCR settlements of hundreds of thousands or millions of dollars."

Round two of the OCR audits will include reviewing compliance with HIPAA Privacy, Security, and Breach Notification rules, as with the first round. The addition of business associates in round two makes the

EXECUTIVE SUMMARY

The Health and Human Services Office of Civil Rights (OCR) is conducting a second round of audits to assess compliance with the Health Insurance Portability and Accountability Act. Unlike the first round, OCR is including business associates.

- OCR is emailing notices to entities that might be audited.
- A questionnaire will help determine audit targets.
- Auditors will be looking for non-compliance issues that were most common in the first round.

risk even higher for healthcare organizations because OCR can hold the healthcare provider accountable for a business associate's shortcomings.

The round two audits will occur in three phases, Olson explains. First there will be desk audits of covered entities, then desk audits of business associates. The last phase will be follow-up on-site reviews. OCR is expected to conduct about 200 audits, including the desk audits, Olson says.

OCR has identified the audit pool and begun contacting the healthcare providers and business associates by email, Olson explains. Covered entities must respond within 14 days, so Olson urges healthcare providers to make sure that these automated emails are not lost in spam or junk email folders.

The initial email will be followed by a pre-audit questionnaire. However, Olson notes that receiving a pre-audit questionnaire does not necessarily mean the covered entity will be audited. Many more entities will receive a questionnaire than eventually will be audited. OCR chooses audit targets based on information in the questionnaires, which ask for details about the healthcare organization's operations, including items such as revenue, patient volume, and the number of employees. The questionnaire also asks the entity to identify all business associates. Healthcare providers should make sure there is a current and accurate list available.

Don't think that you can fail to respond to the initial OCR email. If you fail to respond, perhaps because the email was lost in your system, OCR will draw on public information to gather much of the information sought in the questionnaire, Olson explains. Of course, failing to respond to OCR could play into the agency's decision of whether to audit your organization.

If OCR targets your facility for a round two audit, you will receive another email notifying you of that fact.

Common problems

OCR will conduct the desk audits through the rest of 2016, and on-site audits are not expected until 2017, says **Peter A. Blenkinsop**, JD, an attorney with the law firm of Drinker Biddle in Washington, DC. In choosing the covered entities to audit on site, OCR will focus on specific areas of concern that were identified in round one of the audits, and it primarily will target the most common types of non-compliance.

> "… THE COST OF COMPLIANCE IS A DROP IN THE BUCKET COMPARED TO THE COST OF NON-COMPLIANCE WE'VE SEEN COME IN THE FORM OF OCR SETTLEMENTS OF HUNDREDS OF THOUSANDS OR MILLIONS OF DOLLARS."

"There is a very good chance that they will be focusing on things like making sure that covered entities and business associates have conducted a comprehensive security risk assessment. With addressable safeguards under the security rule, they will be looking for the entities to show that they have either implemented those addressable safeguards or they have documented what alternative safeguards they've chosen to put in place to meet that same objective," Blenkinsop says. "Those are areas where OCR found many deficiencies in phase one."

Additional problems commonly found in the round one audits include a notice of privacy practices that meets the requirements of the privacy rule, employees training on HIPAA policies and procedures, and transmission security. Blenkinsop notes that although OCR does not require encryption, it does expect covered entities to protect data transmitted over an open network, and that expectation usually means encryption. An alternative would be transmitting the data through a closed network.

Device and media control also was a common area of non-compliance in earlier audits. This control becomes especially important if you allow employees to store PHI on laptops, phones, and other devices. The covered entity must have policies and procedures in place to protect PHI on these devices, which have figured in some of the largest and costliest data breaches.

OCR will focus on those areas, but a covered entity can be asked about any aspect of HIPAA compliance. One of the best ways to prepare for a potential round two audit is to study OCR's audit protocols, Blenkinsop suggests. The protocols are available online at http://1.usa.gov/24hFxqF.

"The minimum that covered entities should be doing is to come up with a readily available list of your business associates, and if you're a business associate, you should have a

list of other vendors who are essential sub-business associates of you," he says. "You need to be able to produce those quickly if OCR asks for them, and you also should know where your HIPAA policies and procedures are and that they are up to date. When the desk audit begins, you will have just 10 days to respond with the documents that OCR requests. You don't want to wait until that request comes to start putting things together."

Result: A broader review?

The audit could be only the start of a compliance nightmare. If OCR finds serious deficiencies, it may conduct a more comprehensive compliance review, which could lead to civil and criminal penalties, Blenkinsop notes. However, OCR has stated that the main purpose of the audits is to identify compliance and security challenges so that it can provide better training and resources for HIPAA compliance, he says.

"I think that should alleviate some concern on the part of covered entities and business associates who have been making a good faith effort to comply," Blenkinsop says. "If you've been making a good faith effort and have a program that shows you were trying to comply, I think it's unlikely that these audits are going to result in a penalty for you."

Blenkinsop expects the round two audits to show compliance failures are more common in smaller entities, as was the case in round one. Larger entities are more likely to have a dedicated department and staff for compliance, whereas at smaller entities, the job may fall to someone who has plenty of other responsibilities as well, Blenkinsop notes. However, larger organizations are more likely to be targeted by hackers seeking PHI, which should serve as its own motivation to comply with HIPAA, he says.

However, overall enforcement activity from OCR has been increasing steadily for a few years, notes **Michael A. Moroney**, JD, an attorney with the law firm of Carroll McNulty and Kull in Basking Ridge, NJ. The round two audits should be seen as only one more reason to make sure your organization has a thorough, well-organized HIPAA compliance plan, he says. Just having a HIPAA notebook on a shelf and asking patients to sign a HIPAA notice isn't going to cut it.

"We've always told our clients that it costs far less to address HIPAA compliance head-on and develop a good program than it does to defend yourself and try to mediate penalties from OCR," Moroney says. "It may be disruptive to develop a good plan, but it's better to do it on your own time and with your own budget than to wait until it's too late and OCR tells you what the plan is going to be, how much you're going to spend on it, and what the timeframe is. OCR typically is very onerous when it comes to telling you how to develop a compliance plan."

SOURCES:

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American College of Surgeons Says No to Most Concurrent Surgeries

Responding to concerns about surgeons operating on more than one patient at a time, the American College of Surgeons (ACS) recently updated its *Statements on Principles* with a section that makes clear that surgeons should not conduct two procedures simultaneously.

"A primary attending surgeon's involvement in concurrent or simultaneous surgeries on two different patients in two different rooms is not appropriate," the guidelines say.

The guidance comes in a section on the "Intraoperative Responsibility of the Primary Surgeon," which includes new language on concurrent, overlapping, and multidisciplinary operations. The ACS is unequivocal about a surgeon operating on two patients in two rooms and moving from one to the other as necessary: That situation should never happen. There are some situations, however, in which the ACS says it is acceptable for the surgeon to have two patients undergoing surgery at the same time.

"In general, the patient's primary attending surgeon should be in the operating suite or be immediately available for the entire surgical procedure," the statement says. "There are instances consistent with good patient care that are valid exceptions. However, when the primary attending surgeon is not present or immediately available, another attending surgeon should be assigned as being

immediately available."

Some leeway is given for overlapping operations, such as when the key or critical elements of the first operation have been completed and there is no reasonable expectation that there will be a need for the primary attending surgeon to return to that operation. In that situation, the ACS says that it is acceptable for the surgeon to hand off that patient to a qualified practitioner who performs non-critical components of the first operation, such as wound closure, while the surgeon goes to another room and begins surgery on a second patient.

The surgeon also can have a second patient's surgery begun by another practitioner and step in to perform the critical elements after completing the first patient. In that situation, however, the ACS says that the surgeon must assign immediate availability in the first operating room to another attending surgeon because the surgeon may not be able to leave the second patient if trouble arises with the first.

The patient should be informed of the surgeon's involvement in more than one procedure at a time, ACS says.

Consent questioned

Concurrent surgery became widely known to the general public when *The Boston Globe* published an expose about a malpractice suit filed by a plaintiff who was paralyzed during spinal surgery at Massachusetts General Hospital in Boston. He contends that his injury was due, in part, to the fact that his surgeon was splitting his time between that operating room and another where he was operating on a second patient at the same time. Massachusetts General has since limited surgeons from doubleBooking some complex surgeries.

In addition to patient safety concerns, some critics said the patient should be informed of such practices. A hospital spokesman told the newspaper that surgeons are "encouraged and expected" to tell patients when they'll be absent for part of the surgery, but not required. (The Boston Globe *story is available online at http://tinyurl.com/zowtss6. For more on the controversy, readers can read "Concurrent surgeries: How much is too much?"* Healthcare Risk Management, *January 2016, available at http://bit.ly/1OYZXRm.)*

The updated ACS guidelines are available online at http://bit.ly/1Mwqq8a. ■

Hospital to Pay $2.2 Million for Allowing Reality Show to Breach Privacy

In a scathing indictment of hospital collusion with reality television, the Department of Health and Human Services' (HHS') Office for Civil Rights (OCR) has reached a $2.2 million settlement with New York Presbyterian Hospital (NYP) in New York City for what OCR says was the "egregious" disclosure of two patients' protected health information (PHI) to film crews and staff during the filming of "NY Med," an ABC reality show featuring real-life trauma cases at the hospital.

The two patients did not give permission for the release of PHI or filming. In particular, OCR found that NYP allowed the ABC crew to film someone who was dying and another person in significant distress, even after a medical professional urged the crew to stop. Announcing the settlement, OCR Director **Jocelyn Samuels** said the hospital yielded too much control to the film crew and must be held responsible for the distress caused to patients and family members.

"This case sends an important message that OCR will not permit covered entities to compromise their patients' privacy by allowing news or television crews to film the patients without their authorization," Samuels said. "We take seriously all complaints filed by individuals, and will seek the necessary remedies to ensure that patients' privacy is fully protected. By allowing individuals receiving urgent medical care to be filmed without their authorization by members of the media, NYP's actions blatantly violate the HIPAA Rules, which were specifically designed to prohibit the disclosure of individual's PHI, including images, in circumstances such as these."

OCR also found that NYP failed to safeguard PHI and allowed ABC film crews virtually unfettered access to its healthcare facility, which effectively created an environment in which PHI could not be protected from impermissible disclosure to the ABC film crew and staff. In addition to the $2.2 million, OCR will monitor NYP for two years as part of this settlement agreement, which will help ensure that NYP will remain compliant with its HIPAA obligations while it continues to provide care for patients.

NYP came under serious criticism

after the initial allegations, and in 2015, the Greater New York Hospital Association announced that emergency departments in the city would ban television crews.

The television show aired video of an 83-year-old man's last moments after being hit by a garbage truck on April 29, 2011. The show also aired emotional conversations between his family and the treating physician. Although the patient's face and those of his family members were blurred, his family members saw the show when it was broadcast and said they could identify him. The family contends that the man never gave permission to be recorded for broadcast, and ABC did not claim he did. As other hospitals had done with film crews, NYP had allowed ABC to record patients first and ask permission later. The American Medical Association and other professional groups have criticized that practice.

The family filed complaints with the New York State Department of Health, ABC, The Joint Commission, and OCR. A report from the state health department concluded that the hospital violated the man's rights because he was "unaware and uninformed that he was being filmed and viewed by a camera while receiving medical treatment."

The Resolution Agreement and Corrective Action Plan can be found on the HHS website at: http://1.usa.gov/1WJa3HG. OCR also issued a FAQ on the application of the HIPAA Rules in media access to PHI, available at the same site. *(For more on the case, see "Greater New York Hospital Association says no more reality television access,"* Healthcare Risk Management*, September 2015, at http://bit.ly/1NtZ9DF.)* ■

DOJ Sues Two Hospital Systems For Allocating Marketing Territories

The Department of Justice (DOJ) announced recently that it is suing Charleston (WV) Area Medical Center (CAMC) and St. Mary's Medical Center in Huntington, WV, for unlawfully agreeing to allocate territories for the marketing of healthcare services, a move that DOJ says deprived consumers of the benefits of access to important information about competing healthcare providers.

The department filed the civil antitrust lawsuit in the U.S. District Court for the Southern District of West Virginia, while simultaneously filing a proposed settlement that, if approved by the court, would resolve the lawsuit. According to the department's complaint, the matter centers on how hospitals compete to attract patients by marketing their healthcare services, including through print advertisements, such as newspaper advertisements, and outdoor advertisements, such as billboards. Advertising also spurs hospitals to compete for patients by investing in providing better care and a broader range of services, the complaint notes.

The complaint alleges that CAMC and St. Mary's curtailed competition for years by agreeing to geographic limits on the marketing of competing healthcare services. CAMC agreed not to place print or outdoor advertisements in Cabell County, WV, and St. Mary's agreed not to place print or outdoor advertisements in Kanawha County, WV, according to DOJ. The agreement disrupted competition, deprived patients of information needed to make informed healthcare decisions, and denied physicians working for the defendants the opportunity to advertise their services to potential patients, Assistant Attorney General **Bill Baer**, JD, of the department's Antitrust Division, said in a statement accompanying the announcement.

"These hospitals limited competition by agreeing on how and where each would advertise competing healthcare services," Baer said. "Marketing is an important tool that hospitals use to compete for patients. Today's action will end the hospitals' anticompetitive agreement and promote competition."

CAMC is a nonprofit corporation that operates four general acute-care hospitals with a total of 908 beds and a medical staff of more than 120 employed physicians. St. Mary's is a

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nonprofit corporation that operates a general acute-care hospital in Cabell County with 393 beds and a medical staff of more than 50 employed physicians. St. Mary's also serves as a teaching hospital for medical students and residents from Marshall University School of Medicine in Huntington.

The proposed settlement prohibits CAMC and St. Mary's from agreeing with other healthcare providers, including hospitals and physicians, to limit marketing or to divide any geographic market or territory. The proposed settlement also prohibits communications between the defendants about their marketing activities, subject to limited exceptions. The hospitals also will implement compliance measures designed to prevent the recurrence of these types of anticompetitive activities. ■

$20 Million Agreement Is Largest CA Settlement

A Southern California hospital has agreed to a record $20 million settlement in a case involving a newborn left brain damaged by an error, which is the largest malpractice settlement ever in California.

The child was harmed by a nursing staff member who failed to properly monitor a feeding tube, which resulted in brain damage, says the family's San Diego attorney **Michael Bomberger**, JD. The entire $20 million settlement, including payment disbursements, will be protected and supervised by the courts. The confidential settlement doesn't allow the hospital to be named.

The case took more than three years to resolve, and it was settled only after the hospital was faced with a trial before a jury, Bomberger says. In preparing the case for trial, Bomberger and his trial team conducted nearly 20 focus groups, prepared strategies to depose defense experts, and identified the weak points in the hospital's case, he says.

The litigation team consulted with and retained medical experts to determine the extent of the harm and the level of care that would be required for the child, Bomberger notes. That information was used to develop a future prognosis for the child and come up with a life care plan that would ensure the child received the level of care that was appropriate, he says.

In most cases involving this type of brain damage, both parties agree to the use of a certified nursing assistant at an average of $17 an hour, Bomberger says. However, in this case, the foreseeable problems will require a registered nurse at an average of $47 an hour due to the high probability of seizures, shunt failure, and medication overdose. That added expense contributed significantly to the size of the settlement, he says.

SOURCE

- Michael Bomberger, JD, Estey Bomberger, San Diego. Telephone: (800) 925-0723. ■

Special report on EMTALA next month

The July 2016 issue of *Healthcare Risk Management* will feature a special report on the Emergency Medical Treatment and Labor Act (EMTALA) and how hospitals and healthcare systems are letting down their guard on what remains a significant liability and safety risk.

Hospitals have been under scrutiny recently for violations of EMTALA, with one hospital agreeing to pay $100,000 for an improper transfer. From 20012 to 2015, the Centers for Medicare and Medicaid Services received an average of 431 EMTALA complaints per year, and it determined that about half warranted investigation. A prime problem, some experts say, is that risk managers have become complacent about EMTALA and see it as a requirement that has been effectively integrated into emergency care.

HRM will explore how facilities can run afoul of EMTALA. We'll look at recent examples to show how failure to understand the nuances of EMTALA requirements can lead to investigators in your facility and substantial payouts. ■

CE/CME 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.

HEALTHCARE RISK MANAGEMENT™

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CE/CME QUESTIONS

1. **According to the Alzheimer's Association, physicians fail to recognize dementia in up to what percentage of patients in the outpatient setting?**

   A. 67%
   B. 45%
   C. 31%
   D. 16%

2. **According to Michelle Feil, MSN, RN, CPPS, senior patient safety analyst with the Pennsylvania Patient Safety Authority, when should patients with dementia be allowed to make decisions?**

   A. Never
   B. Only when the decision does not affect the patient's health or safety
   C. Only when the decision has long-lasting consequences
   D. Always, unless a family member says otherwise

3. **Which of the following is true about the second round of audits for the Health Insurance Portability and Accountability Act (HIPAA)?**

   A. The Office of Civil Rights (OCR) will focus on areas previously identified as compliance problems, but a covered entity can be asked about any aspect of HIPAA compliance.
   B. OCR will focus only on areas previously identified as compliance problems.
   C. OCR will focus only on new concerns, and areas previously identified as compliance problems will not be discussed.
   D. OCR will focus only on business associate agreements.

4. **What does the American College of Surgeons say about a primary attending surgeon's involvement in concurrent or simultaneous surgeries on two patients in two rooms?**

   A. It is not appropriate.
   B. It is appropriate.
   C. It is appropriate only when performing identical procedures.
   D. It is appropriate only when performing elective procedures.

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

Treating Physician Did Not Violate Standard of Care for Failure to Treat Brain Swelling, Jury Finds

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News: A 12-year-old girl was taken by ambulance to a hospital. She exhibited symptoms of hyperglycemia, abnormal respiration, and an accelerated heart rate. The physician in the emergency department treated her with insulin. Ten minutes later, the physician noted that the patient had acidemia (significant amounts of acid in the blood). He responded by placing the patient on an insulin drip. About 10 minutes after that, the blood test results indicated that the patient had high blood sugar, abnormally low sodium and chloride, and a high white blood cell count. The patient began to exhibit signs that fluid was collecting in a lung. The physician responded by having the patient prepped for insertion of a breathing tube. A CT scan indicated swelling and herniation of the patient's brain, and her blood pressure abruptly dropped. The patient was taken by helicopter to the pediatric intensive care unit at a different hospital. As a result of her diabetic ketoacidosis (DKA), the patient remained in a coma until her parents decided to have her taken off life support. The girl's parents sued the hospital and the treating physician. They argued that the treating physician had administered too much insulin, which they alleged caused the brain swelling. They also argued that the treating physician had failed to administer mannitol, which they claimed would have reduced the patient's brain swelling. After a trial, the jury members found in favor of the physician and the hospital, and they concluded that the physician had not violated the standard of care.

Background: In 2008, a 12-year-old girl started complaining of nausea and vomiting. The girl's mother contacted the girl's pediatrician. The pediatrician believed that it was merely the stomach flu and told her to come in for an in-person evaluation if the symptoms grew worse. The girl was suffering from DKA. The girl had not exhibited signs of diabetes before, so she had not been undergoing any treatment for diabetes at the time. The next day, the girl exhibited severe symptoms, and the girl's mother called for an ambulance. The girl was noted to have hyperglycemia (elevated blood sugar), abnormal respiration, and an accelerated heart rate.

At the hospital, the treating physician attempted to treat the hyperglycemia with insulin. Ten minutes later, the physician noted the presence of acidemia. He placed her on an insulin drip. About 20 minutes after the patient arrived at the hospital, blood tests indicated that the patient had high blood sugar, abnormally low sodium and chloride, and a high white blood cell count. The patient began to exhibit signs that fluid was collecting in a lung. The treating physician responded by having the patient prepped for insertion of a breathing tube. A CT scan indicated swelling and herniation of the patient's brain, and her blood pressure abruptly dropped.

The decision then was made to have the patient taken by helicopter to the pediatric intensive care unit at a different hospital. At this time, the patient was not showing signs of headache, vomiting, incoherence, incontinence, or lethargy, which are symptoms that would have indicated brain swelling.

Financial Disclosure: Co-author Jamie Terrence, author Greg Freeman, Exec. Editor Joy Daughtery Dickinson, & Nurse Planner Maureen Archambault have no financial relationships with companies having ties to this field. Co-author Damian Capozzola represents Currie Medical Specialties in an action against Tenet Healthcare and is in an administrative action against Westside Regional Center. Arnold Mackles, physician reviewer, writes CME/CE courses, is on The Sullivan Group advisory group, & is a stockholder, speaker, author & consultant for Innovative Healthcare Compliance Group.

After arriving at the pediatric intensive care unit, the patient became comatose. She remained in a coma for two days, after which her parents decided to have her taken off life support.

In 2010, the girl's parents sued the hospital and the treating physician. They argued that the treating physician negligently administered too much insulin, which they alleged caused the patient's brain swelling. They also claimed that the hospital did not have hard copies of the appropriate resources that the physician needed to consult while treating the patient. The parents said that, as a result, the physician needed to consult the internet to look up options for treating the patient. Finally, the girl's parents argued that the treating physician had failed to administer mannitol, which they claimed would have reduced the patient's brain swelling.

The lawyers for the hospital and treating physician argued that the physician did provide the appropriate level of care, but that the patient's DKA already had progressed too far for the physician to be able to save the patient. The lawyers for the hospital and treating physician also argued that the patient did not exhibit symptoms of brain swelling that would have put the treating physician on notice that he should administer mannitol. The lawyers for the defense thus argued that the treating physician fully complied with the standard of care applicable to a treating physician in an emergency department.

After a trial, the jury found in favor of the hospital and the treating physician. The jury concluded that the physician had not violated the standard of care in treating the patient.

What this means for you: This case is an example of how an expert can explain the standard of care that physicians are expected to follow while treating a patient. In a trial for medical malpractice, it is common for both parties to present experts discussing the appropriate level of care that a physician must follow and whether the treating physician met that standard of care. The issue of the standard of care played a particularly important role in this case, in which the experts discussed the standard of care for an emergency department physician. In some states, the plaintiff in a medical malpractice lawsuit will need to prove a higher level of recklessness for emergency department physicians than for other physicians. Healthcare practitioners should consult with legal counsel to be aware of the legal standards guiding their areas of practice and determine whether any special standards of care apply in their state. Healthcare practitioners should take steps to ensure that they are complying with that standard of care.

This case also illustrates the importance of not only being aware of the appropriate standard of care, but also taking steps to make a record that the healthcare practitioner is complying with that standard of care. In this case, for example, the lawyers for the hospital and treating physician used the medical entries for two purposes:

- to demonstrate all of the steps that the treating physician took to administer treatment to the patient;
- to set forth all of the patient's symptoms to explain the treatment that the physician decided to administer.

In particular, the lawyers for the hospital and treating physician introduced evidence of the treating physician's medical entries, which showed an absence of symptoms of brain swelling (headache, vomiting, incoherence, incontinence, and lethargy). This evidence helped to establish that the appropriate standard of care did not require an administration of mannitol, because the patient's symptoms did not include these telltale signs of brain edema. When administering healthcare, therefore, it is important for a practitioner to keep diligent and thorough records of patients' symptoms. These records later may be useful to explain the conclusions reached by the healthcare practitioner, as well as the decisions about what treatment to provide. These diligent and thorough records also can be useful to explain why the healthcare practitioner did not reach other conclusions and decided not to administer other treatments.

It is also critical that emergency medicine physicians gather as much information about their patients as possible. Families, friends, or whoever presents with the patient should be listened to. Without the benefit of knowledge of the patient's medical history, emergency department doctors often must rely on what they see now without understanding what may have been going on 24 hours ago or even five years ago. Asking the right questions is essential. No symptom or complaint should be minimized. No patient's feeling or concern should be ignored. Patients live in their bodies, and they know when something is not right. It's up to the physicians to unravel the mysteries, get to the source of the problem, and try to fix it. Physicians get in trouble when they jump to conclusions without taking the time to obtain information, which happens more often than one would think.

The handoff between shifts is another risk factor. The off-going physician gives information to his or

her relief. The incoming physician often takes that information and continues care based on it. The problem is that if that information is based on a poor history from the patient or family and the treatment plan is incorrect, the liability for any errors falls on both physicians.

Physicians have a responsibility to complete a full assessment when assuming care of a patient. Documenting that assessment based on the physician's interpretation, and not based on what was documented by the previous physician, is essential. This practice is the expectation and will provide protection from liability if thoroughly done and documented.

Finally, this case may reflect how a change in technology can lead to a change in what is required under the applicable standard of care. In this case, the lawyers for the patient argued that the hospital was required to maintain hard copies of medical resources that the physician could consult during his treatment, under the applicable standard of care. The jury members disagreed, however. They were not persuaded that the hospital was negligent by not having hard copies on site; nor did they conclude that the physician violated his duty of care by looking up treatment options on the internet. It is unclear whether this same result would have been reached by another jury in a different jurisdiction (or even another jury in the same jurisdiction).

In any event, this case does indicate that it may be possible to use new and developing technologies to meet the applicable standard of care in ways that were not available previously. Healthcare practitioners should consult with counsel regarding the standard of care in their jurisdiction. They then should ensure that they have the necessary resources available to provide the appropriate treatment for patients. It takes a confident physician to know when additional resources are needed. Patient recovery is the objective, and using all available resources to achieve it safely and without causing harm is the goal.

REFERENCE

Indian River County Circuit Court, Florida, Case No. 2010-CA-073141 (April 5, 2016). ■

No Liability for Spine Stabilization Surgery Without Intraop Neurophysiological Monitoring

News: In 2012, a 52-year-old woman was in an automobile collision and was taken to a hospital. A CT scan indicated that the patient suffered serious injuries, which included three spinal fractures, three fractured ribs, bruises to her brain, air in her cervical spine, and fluid around her lungs. Several hours later, the patient complained of numbness in her left calf. She also was unable to lift her legs due to her pain. After obtaining informed consent, two neurosurgeons at the hospital operated on the patient. When the surgery was completed, the patient was paralyzed from the chest down. She sued the hospital and her treating physicians. The lawyers for the patient alleged that the surgeons should have used intraoperative neurophysiological monitoring during the surgery. Her lawyers argued that if the surgeons had used this monitoring equipment, they would have been able to detect changes to the neurological system during the surgery, which could have prevented or mitigated her injury. After a trial, the jury found in favor of the hospital and the treating physicians.

Background: In 2012, a 52-year-old woman was a passenger in a car that was struck by two other vehicles. She was taken by helicopter to the hospital. At the hospital, the treating physicians performed a CT scan on the patient. The CT scan revealed that the patient had suffered several serious injuries: three spinal fractures, three fractured ribs, bruises to her brain, air in her cervical spine, and fluid around her lungs.

The patient was examined by a neurosurgeon at the hospital. The neurosurgeon came to the conclusion that there was no immediate need for surgery. Hours later, however, the patient started complaining of numbness in her left calf. In addition, the patient stated that she could not lift her legs because the pain was too great.

After consulting with the patient's husband and obtaining informed consent, the neurosurgeon decided to perform spine stabilization surgery on the patient. She and another neurosurgeon spent about five hours operating on the patient. When the patient awoke from the surgery, she was paralyzed from the chest down, with some use of her arms and hands.

The patient sued the hospital and its physicians for medical malpractice. She sought damages in excess of $20 million. Her lawyers argued that the neurosurgeons should have used intraoperative neurophysiological monitoring during the surgery. The lawyers for the patient argued

that if the neurosurgeons had used this form of monitoring, they would have detected changes to the patient's neurological system during the surgery. By using this form of monitoring, the surgeons would have been able to take the necessary steps to prevent, or at least to mitigate, the neurological damage that led to the patient's paralysis, the patient's lawyers argued.

The lawyers for the hospital and surgeons argued that the surgeons did not violate the applicable standard of care by deciding not to use intraoperative neurophysiological monitoring. The lawyers for the defense called expert witnesses who explained that this sort of monitoring would be appropriate for surgery on the spinal cord. But because the neurosurgeons were operating on the vertebrae, and not on the spinal cord itself, the expert witnesses explained that the surgeons properly determined that it was not necessary to employ intraoperative neurophysiological monitoring. They explained that the appropriate standard of care does not require the use of this monitoring during the patient's surgery in this case.

After a trial, the jury found in favor of the hospital and physicians. The jury concluded that the surgeons had not violated the appropriate standard of care by deciding not to use intraoperative neurophysiological monitoring.

What this means for you:
This case illustrates that although healthcare practitioners should employ all procedures that are necessary and appropriate, the law does not require practitioners to employ every single possible procedure that is available. The mere fact that the surgeons *could* have used intraoperative neurophysiological monitoring during the patient's surgery does not necessarily mean that the surgeons *should* have employed this monitoring technique during the surgery. It is important for healthcare practitioners to consult with attorneys to determine the appropriate level of care to which they should be held. They can use this information to make an informed decision about which procedures are necessary and appropriate to use in order to meet this level of care.

This case also provides another example of how an expert witness can explain the appropriate standard of care that physicians are expected to follow during their practice of medicine. During a trial for medical malpractice, it is common for the lawyers of both sides to call expert witnesses to testify about the appropriate standard of care and whether the physicians met the standard of care. Here, the expert witnesses for the hospital and physicians were able to explain to the jury that the appropriate standard of care did not require the neurosurgeons to employ intraoperative neurophysiological monitoring during the patient's surgery. Healthcare practitioners should consult with counsel to ensure that they fully understand the standards of care guiding their practice. With this information, practitioners then can take steps to ensure that they are complying with the appropriate standard of care and also to ensure that they document their decisions so that they can demonstrate that they did, in fact, comply with the appropriate standard of care.

Finally, this case illustrates the importance of obtaining informed consent before going forward with surgery. Healthcare practitioners should be aware of the requirements needed to obtain informed consent from the patient or from another person on behalf of the patient. In this case, for example, the neurosurgeon made sure to discuss the potential benefits of spine stabilization surgery before going forward with the surgery. Moreover, in addition to obtaining informed consent, it is important for practitioners to maintain documentation of informed consent. This documentation can include the date and time of the discussion with the patient and/or the patient's family; the information provided about the surgery, including the potential benefits and possible risks of the surgery; and whether any questions were asked and the answers provided. It is amazing how frequently physicians fail to obtain a meaningful informed consent from their patients and, even more frequently, fail to document it. Every human being has the right to say what they want in terms of medical treatment. Physicians have the responsibility to make sure that patients have enough information to be able to say what treatment they want. To do less than that is not only risky for the physician, but it also does a disservice to the patient. A patient might not sign a surgical consent form receiving sufficient information. The physician performing the procedure should provide this information and then obtain informed consent. The more information that the physician provides, the wiser the patient's decision will be. Also, if the physician properly documents this consent process, a lawsuit will be less likely, regardless of the outcome.

REFERENCE

DeKalb County Superior Court, Georgia, Case 4A50193 (March 25, 2016). ■