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EMTALA: How can you know what is enough and when you've gone too far?

EMTALA response teams might be necessary to ensure compliance

When you drive to work tomorrow, take a close look at what is near your health care facility. If there is a liquor store or an apartment building, you may have a lot to do if you want to avoid violating the Emergency Treatment and Active Labor Act (EMTALA).

The Centers for Medicaid and Medicare Services (CMS, formerly the Health Care Financing Administration) recently issued a set of clarifications intended to answer some nagging questions about how to comply with EMTALA, but sources tell *Healthcare Risk Management* that the clarification makes EMTALA as clear as mud. Of particular concern is the 250-yard rule, which requires hospitals to provide emergency care to anyone within 250 yards of the hospital's campus.

Or does it?

The CMS clarification seems to weaken the rule, or at least suggest that risk managers have been overly cautious in their interpretation of it. The clarification asks whether a hospital must provide care whenever someone presents for emergency medical care anywhere within 250 yards of the hospital's main building, even if the individual is in an area that is not hospital-owned and operated. The answer is "no," as EMTALA applies only when a person comes to the hospital campus itself. **(See p. 112 for the complete clarification from CMS.)**

At first glance, that seems like a concrete answer. But experts in EMTALA aren't buying it. They say the CMS clarification does not apply to the situations most troublesome to hospitals and leaves many unanswered questions. The example used in the CMS clarification concerns a customer at a fast-food restaurant who collapses. The restaurant is within 250 yards of the hospital, but CMS says the hospital has no EMTALA obligation because the restaurant is not affiliated with the hospital or on its property.

But that example does not include anyone running to the hospital and asking for help, says **John C. West**, JD, MHA, DFASHRM, senior health care consultant with AIG Consulting in Atlanta.

"That's really the key point," West says. "Nobody thinks we have to just magically know that the person collapsed and run down the street to help. But what if someone runs into the emergency department and says the person at the restaurant needs help? That's the question everyone's wondering about."

Indeed, that is the scenario that led to the 250-yard rule in the first place. On May 16, 1998, a 15-year-old boy was shot less than a block from Ravenswood Hospital Medical Center in Chicago. Following hospital policy, emergency department staff refused to go outside and help him. The boy's friends and police officers pleaded with them for help, but they refused. Police eventually dragged him inside the hospital, but the boy soon died. CMS determined that the hospital violated EMTALA and fined it $40,000.

Soon after, CMS explained that EMTALA applied to people seeking help within 250 yards of the hospital. West says the recent clarifications are difficult to interpret, but he thinks CMS was trying to point out that the hospital must be *notified* before EMTALA kicks in.

"The clarifications really don't help people interpret the rule, and I'd still say people have to play it safe and think of the 250 yards as a good guide," West says. "If someone is in need of care, and someone comes in asking for help like at Ravenswood, you need to provide care. That doesn't mean you have to go a mile away, but do you have to go 250 yards? I still say yes."

Lots of 'crazy implications'

Mark Kadzielski, JD, head of the West Coast health practice for the law firm of Fulbright & Jaworski in Los Angeles, agrees that the CMS clarification does not end concerns over the 250-yard rule. Like West, he says CMS clarified some of the more obvious situations — like the fast-food restaurant — without addressing the gray areas.

The clarification implies that EMTALA applies only to 250 yards from the main hospital building *if that point still is on the hospital campus.* But Kadzielski says that CMS originally implied that the 250 yards could well extend beyond hospital property and that the clarification does not actually address that discrepancy.

"Given this 250-yard rule and all its crazy implications, you absolutely have to play it safe," he says. "My advice would be that if a request is made for emergency service, the better part of valor is to go get that person. It's better than trying to argue about these interpretations."

Know your limits

West and Kadzielski agree that there is no need to actually measure off 250 yards from your hospital property, but it is a good idea to have a general sense of what is within 250 yards of your hospital property. You might think in terms of streets or other landmarks instead of the precise distance, West says. But no matter where you draw the line, there will be some point at which you have to say, "That's too far."

"What do you do when your staff walk out there and they see the person just beyond whatever boundary you've decided on?" West says. "I don't think it was meant to be a hard-and-fast rule, so that if someone is 251 yards away, they don't qualify for your attention. I think CMS will want to see that you made a reasonable, good-faith effort, and that's going to require some judgment calls."

The area around your facility will make a big difference as to how much trouble this rule will be. If you are in a rural area with little or nothing within 250 yards of your campus, there may be little to worry about. But if you are in an urban area, you could have businesses and even residential buildings within that area.

What if there's a bus stop or liquor store down the street near your hospital parking lot? Kadzielski asks. Are you responsible for the aftermath of a knife fight that breaks out in the parking lot of the liquor store? If someone comes and tells you there's a victim lying there, the answer is yes, say both West and Kadzielski. But if no one notifies

Tips on those gray areas within the 250-yard rule

The key to complying with the Emergency Treatment and Active Labor Act (EMTALA) 250-yard rule is to have a specific policy and to inservice staff on responding properly to these situations. Here are some suggestions from the experts:

• **Prepare a written policy.** The policy should indicate that the hospital intends to comply with EMTALA and will make reasonable efforts to assist people in need near the campus.

• **Indicate the physical parameters to your staff.** But emphasize that judgment calls may be necessary. It might be permissible to go a little farther in some cases, or not as far in other cases, says **Mark Kadzielski**, JD, head of the West Coast health practice for the law firm of Fulbright & Jaworski in Los Angeles.

"Do you have to run a gurney down the street in six feet of snow? Maybe not," Kadzielski says. "Let people know you don't expect them to run 250 yards no matter what's going on."

• **Include hospital security in your inservices.** Because security officers may be the ones to receive notice that help is needed, they need to understand when EMTALA applies and how to initiate the hospital's response.

• **Designate certain staff members to respond.** You might need to say that certain nurses would respond from the emergency department, for instance. It's probably not a good idea to let a physician leave the emergency department because that could leave the area uncovered, says **John C. West**, JD, MHA, DFASHRM, senior health care consultant with AIG Consulting in Atlanta.

• **Provide necessary supplies.** It's a good idea to set aside a gurney and a basic emergency kit that responders can grab and go.

• **Always call 911.** The protocol should require that the hospital call 911 whenever staff go out for a patient, unless the patient is immediately outside the door. This ensures that there is no delay in case the hospital staff cannot help the person for some reason.

• **Always enlist the aid of hospital security.** When staff must leave the hospital to get the patient, make sure hospital security responds as a safety measure.

• **Caution your staff not to take unnecessary risks.** EMTALA does not require that your staff forge into danger. Make sure your staff knows that they should not put themselves at unnecessary risk.

"If there's a brawl in the bar across the street, call 911 and let them handle it. Someone's going to be hurt, and it might be your people," West says. "Make sure your people are trained to avoid violence. They shouldn't try to be medics on a battlefield." ■

you that a person needs emergency care, there is no EMTALA obligation.

Here's another twist: What if your security guards are on routine patrol of a hospital parking lot and see the knife fight at the liquor store? Nobody came to ask for help, but a representative of the hospital now knows that there is a person lying in a pool of blood just beyond the campus. Does that count as notification and start the EMTALA obligation?

"Yes," Kadzielski says. "Without the 250-yard rule, the guard is just a witness and can call 911. But with the rule, he should activate your plan for complying with the 250-yard rule."

EMTALA response teams

Experts agree that hospitals must have a system in place for responding to those EMTALA obligations. West and Kadzielski both suggest creating EMTALA response teams that can be notified and go out to get the patient. Though they suggest enacting a formal policy, the actual implementation doesn't necessarily have to require increased staff or supplies, they say.

The hospital that prompted the whole debate has such a plan in place. Ravenswood's policy requires hospital employees to call a special internal telephone number to report cases where they believe someone on or near the hospital campus needs immediate medical assistance. An emergency department nurse or physician will then determine how best to treat the person, and there is no prohibition against the staff going outside.

A Ravenswood spokeswoman declined to comment further on their plan because the hospital still is in litigation from the 1998 incident. ■

A (gray) clarification of the 250-yard rule

The government draws lines

Question: Is a hospital obligated to comply with the Emergency Treatment and Active Labor Act (EMTALA) whenever an individual presents for emergency medical care anywhere within 250 yards of the hospital's main building, even if the individual is in an area that is not hospital-owned and operated?

Answer: No. Generally, a hospital campus is defined in regulations as the physical area immediately adjacent to the hospital's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis by the Centers for Medicaid and Medicare Services regional office to be part of the hospital campus [42 CFR § 413.65(a)(2)].

We consider the parking lot, sidewalk, and driveway that are on hospital property to be part of the hospital for EMTALA purposes [42 CFR § 489.24(b)]. For purposes of EMTALA, the parameters of a hospital's campus are not determined by drawing a circle 250 yards around a hospital's main building and concluding that every building, area, and structure that happens to be located within those boundaries is part of the hospital campus.

For EMTALA purposes, an individual seeking emergency care who presents to a location on the hospital campus as interpreted above will be considered to have "come to the hospital" if a request is made on the individual's behalf for emergency care. A hospital has no EMTALA obligation with respect to individuals who present to other areas or structures that may be located within 250 yards of the hospital's main building that are not part of the hospital (except those areas like parking lots that serve the hospital). Examples of separate entities that are not part of the hospital for EMTALA purposes, even when located within 250 yards of the hospital's main building, including fast-food restaurants or independent medical practices.

(Note: The entire clarification can be found on-line at http://hcfa.gov/medlearn/emqsas.htm.) ■

Patient safety profiles delayed by complaints

Like it or not, the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) plan for using patient safety management profiles to rate hospitals is moving forward. Some health care providers say the plan will create unfair comparisons and increase liability exposure.

Healthcare Risk Management has learned that you will be subject to some sort of safety rating before long. In recent months, health care providers swamped the Joint Commission's board of directors with objections and concerns, leading the committee to slow down implementation of the plan, says **Ken Shull**, FACHE, president of the South Carolina Hospital Association in West Columbia. Shull also chairs the Joint Commission's Accreditation Process Improvement Implementation Task Force. The board sent the plan to his committee for further review.

The board had been considering whether to proceed with a plan that would score hospitals and other providers according to how well they complied with certain standards and best practices considered key to providing a safe environment for patients.

The board decided that the health care community had some legitimate concerns and decided to send the plan back for another look. The committee has met once to consider the plan and likely is to meet once more on the same topic.

"They wanted field input to make the plan worthwhile, meaningful, doable, and not have it lead into more liability than necessary," Shull says. "It's considered a very important issue and it's on a fast time frame."

Without delay

Shull says that his committee hopes to present its recommendations to the Joint Commission board in November and that the plan might be implemented soon after. Even though the proposal has generated so much criticism, Shull says the Joint Commission is determined to enact some version of it without delay. He acknowledges that much of the concern is legitimate and says he hopes his committee's work with overcome some of the problems.

"Disclosure of anything is a touchy issue for health care," he says. "Concern about liability is a

top priority. I think the general feeling is that the we need some release of data, but we have to be careful about it and make sure it's accurate, fair, and presented in a way that people can understand, a way that is relevant to how people obtain health care."

Hospital association voices concerns

Some of the complaints came from the Illinois Hospital and HealthSystems Association (IHHA), which recently asked the board of the Joint Commission to hold off on the plan for patient safety management profiles until it could be significantly revised. The plan to use *Sentinel Event Alerts* as a compliance measure was a particular concern to the association.

In a strongly worded letter based on comments from IHHA's Quality Measurement Advisory Group and accredited member hospitals, IHHA vice president **Pat Merryweather** said that both the proposed profiles and the *Sentinel Event Alert* assessment structure were "flawed technically, scientifically, and conceptually."

Though the patient safety management profile is supposed to reflect the hospital's progress in implementing patient safety processes, IHHA contends that the standards have not been empirically demonstrated to bear any relationship to safety outcomes. Nor does the profile directly measure the safety of the hospital or the care it delivers, according to IHHA. The American Hospital Association also has asked the Joint Commission to withdraw the profiles.

"These standards have not been empirically demonstrated to bear any relationship to safety outcome as the new index of standards has not been empirically demonstrated to bear any relationship to safety outcomes," Merryweather stated in the letter to the Joint Commission. "Providers do not have feedback on their individual scores when surveyed. Hospitals will not be able to determine if their scores are accurate or not. There are no checks and balances built into this approach. Since surveyor scores are subjective and the variance among two provider scores can be due to the surveyor subjectivity, JCAHO needs to have reliable measurements for the basis of any composite profile.

"Since variations in score can be due to surveyor subjectivity, JCAHO needs to apply statistical measures to reach acceptable confidence levels and control for these variations. A single score based upon an average does not control for variance and allows for no confidence in the measurement. JCAHO needs to make clear as to how scores will be updated based upon corrective actions taken by providers that have received Type I recommendations. A change in a score should be reflected in the profile so that it accurately reflects hospital performance. JCAHO needs to define the overall average score that a provider is being compared to including the comparative organizations and for what time period." **(See p. 114 for more of the IHHA concerns.)**

Merryweather says in order to allow for continuous innovations in care and treatment, providers will always develop new and improved ways to address diseases and patient safety care issues. She says the Joint Commission needs to fully train surveyors about alternative approaches and needs to be prepared to update the recommendations in prior alerts based upon information gathered from the field. The Joint Commission might need to build in expiration dates because new literature is emerging constantly, and it might need to be prepared to change the recommendations of any historical sentinel events based upon information gathered from the providers at survey time.

"Finally, this approach is completely unnecessary because the new Patient Safety standards already require that providers develop mechanisms to incorporate new recommendations from *Sentinel Event Alerts* and other reliable sources," Merryweather wrote. "Thus, compliance with the alerts, in aggregate, is already in included in the current JCAHO standards. Even with this approach, assessment and surveyor training needs to be examined."

What data to gather and how to report them

Shull says Merryweather's comments were typical of those the board received and forwarded to his committee. He says the committee is considering two main issues: What information should be included in the profile, and how to publicly report those data. As proposed, the patient safety management profile would be part of the Joint Commission survey process, with each organization getting a report card on how it manages hospital safety. Each hospital would receive a score with quantitative numbers that could theoretically be used to compare providers. That is one of the biggest concerns.

"The information would be live and in color on the web, accessible to anyone. There's no easy way to display data like that and make sure

people understand them in the way you intended," Shull says. "I don't care how many disclaimers you have on something; if there is a graph, chart, or picture, people are going to look at that and forget all the words. They will make assumptions that you may not have intended, and that may not be an accurate assumption."

The committee is reassessing one of the provisions that troubled Merryweather and the others who expressed concern: The plan to use the Joint Commission's *Sentinel Event Alerts* as a way to calculate the hospital's patient safety management score. The *Sentinel Event Alerts* are periodically published by the Joint Commission as a way of highlighting sentinel events and bringing attention to the type of dangers involved, plus the lessons learned by the health care providers. Shull explains that the original idea was for the alerts to be used as criteria for determining how well a hospital has addressed patient safety, in effect considering each one a lesson and then seeing how accredited hospitals have put those lessons to use. But there has been criticism that the plan to use the *Sentinel Event Alerts* is too complex.

Karen Reeves, vice president of professional services with the South Carolina Hospital Association in Columbia, has been monitoring the situation since the Joint Commission first proposed the plan. Though Shull is her boss, Reeves is not shy about voicing her opinion of the project he is trying to improve.

"Thank God that didn't fly," she says. "The Joint Commission wants to develop a methodology for a grid that would show a numerical score like 90%, with that number used as an indicator of patient safety. But it's a black box methodology. It's not been disclosed how you would calculate that numerical score, so there's no reason to think it's valid or reliable."

Limit alerts?

The plan to use the *Sentinel Event Alerts* as a measure of patient safety causes particular concern for Reeves. She is concerned that the Joint Commission would cavalierly throw too many of the *Sentinel Event Alerts* at hospitals and not realize how much work is required to comply with them.

"They wanted to tell hospitals in October of each year that you have to show compliance with these 10 alerts for next year. But if you tell me in October that you're focusing on these 10 things, there is no way that in January I can have a good process in place for doing that," she says. "It would be much better for them to say here are 20 alerts, and you need to pick a couple that involved concerns at your hospital, implement them, and then explain to the surveyor why you chose those."

Shull has heard similar concerns from many other health care providers and observers. He says that, despite some serious misgivings by different parties, the patient safety management profile will be a reality within a matter of months. The actual implementation date may come after the grace period built into most new Joint Commission standards and procedures.

"We're going to have to click this together pretty quickly," Shull says. "It's on a fast track because it's important. The public, employers, and insurers are all looking for information like this. It's all part of the increased awareness and emphasis on medical errors and patient safety." ■

Is patient safety profile plan dangerously flawed?

Here are some of the concerns expressed in the Illinois Hospital and HealthSystems Association's (IHHA's) letter criticizing the Joint Commission on Accreditation of Healthcare Organization's (JCAHO) plan for the patient safety management profile:

- Providers need to know what standards comprise the different categories as well as the methodology being proposed for weighting of categories. Providers will need to have their individual scores on each standard and the aggregation into new categories as a subject of discussion during survey and as part of the final preliminary report at the conclusion of each survey.
- In order for the graphs to be of any value to the consumer and accurately reflect a hospital's performance, in addition to the above criteria, the graphs need to be properly scaled and displayed with data that reflect a level of confidence (which may involve usage of ranges and standard deviation techniques). It needs to be made clear to the public that these are process and structure standard and do not directly measure the safety of the hospital or the care it delivers.
- The IHHA is concerned that there will be significant inconsistency in surveyors' assessment of hospital compliance. As *Sentinel Event*

Alerts now are routinely issued monthly, JCAHO needs to develop a plan to train the surveyors with each new *Sentinel Event Alert* as well as assess the reliability of the surveyor training and surveyor assessment skills.

• If compliance with alerts is scored in this fashion, the result will look and feel like a Type I Recommendation. Thus, similar to Type I Recommendations, JCAHO needs to establish a process for correction and reassessment on areas that are deemed incomplete or noncompliant. JCAHO also needs to update its reports to the public upon assessment.

• JCAHO needs to establish an expert panel to select targeted areas so that the energies of hospitals are devoted to sentinel event issues that are truly of highest priority for patient safety if these alerts are going to be driven by general themes rather than JCAHO experience with the sentinel event reporting policy and database.

• JCAHO needs to establish an expert panel (or a series of panels unique to each issue) to identify recommendations of best practices for each *Sentinel Event Alert.* Recommendations need to be thoroughly discussed in the *Sentinel Event Alerts,* with appropriate literature citations, and examples need to be provided of different approaches. If these recommendations are to be scored and publicly disclosed, then a review process must occur as it does with new standards. ■

Cause of MRI accident leads to improvements

The terrible accident in which a metal oxygen bottle introduced to an MRI room killed a child primarily was "a failure of hospital systems," according to the hospital's investigation. The hospital's report and public statements indicate that it is following the latest risk management advice to get to the process failures at the root of the accident rather than blaming individuals.

The fatal accident occurred recently at the Westchester Medical Center in Valhalla, NY. A 6-year-old boy was undergoing an MRI exam when the machine's powerful magnet pulled a metal oxygen tank through the air and into the machine, fracturing his skull. Officials at the Westchester Medical Center said the tank had been brought into the exam room accidentally after the boy was already in the magnetic imaging machine and the 10-ton electromagnet was switched on. The county medical examiner's office said the boy died of blunt force trauma, a fractured skull, and bruised brain.

Where is the failure?

The boy, who had undergone surgery before the MRI exam, was sedated when he was struck, says **Edward A. Stolzenberg**, president and CEO of Westchester Medical Center.

"As I have said before, this is more a failure of hospital systems than a failure of people," he says. "Part of accepting responsibility for this by the Medical Center is the promise to all our patients, visitors, and staff that patient safety is the No. 1 priority. We have made 32 safety changes in the last few weeks and have asked the leading national expert in MRI safety to come here . . . and review our work."

Emanuel Kanal, MD, of the University of Pittsburgh Medical Center, was scheduled to spend a day at Westchester offering his opinions and meeting with staff. The hospital also initiated a national review of MRI patient safety by persuading the American College of Radiology (ACR) to create a Blue Ribbon Panel on MRI Safety to establish the first-ever set of accepted guidelines, policies, and recommendations for safe MRI practice. The ACR has responded by scheduling a conference on the issue this month in Reston, VA.

"An accident of this kind could have happened at any hospital or radiology facility in the U.S. and could still happen even today," Stolzenberg says. "We are working tirelessly to prevent this tragedy from happening anywhere, ever again."

Nonmagnetic respirators

Stolzenberg says MRI manufacturers have reported that oxygen tanks and other metal objects are removed from MRI magnets around the nation at least every other week. He noted that during the week of July 30, immediately after the MRI accident, Westchester bought the last two MRI-compatible (nonmagnetic) mechanical respirators and fire extinguishers from the nation's largest distributor. Magmedix, of Gardner, MA, reports that every hospital and MRI facility in the country is buying up such nonmagnetic supplies at an unprecedented rate.

The company has been inundated with calls and purchase orders for these products.

Agency issues hazard report, recommendations

In another sign that the health care industry is taking notice of MRI hazards, the nonprofit research agency ECRI has issued a hazard report and recommendations for MRI safety. ECRI reports that a wide range of objects have been drawn into MRIs, including IV poles, parts of a forklift, a helium cylinder, a mop bucket, a laundry cart, a chair, a ladder, a patient lift, a light fixture, a floor buffer, a pulse oximeter transformer, tools, scissors, and traction weights.

However, ECRI says the incident at Westchester Medical Center appears to be the first death directly caused by an object being drawn into an MRI. ECRI experts say the most important recommendation is to make sure that someone is responsible for safety. That person needs to establish safety policies and procedures, as well as personally ensuring that nothing improper is brought into the MRI room.

Time for training

Among its 14 recommendations, ECRI advises that all personnel who enter the MRI room receive formal safety training and that they always assume that a magnetic field is present. In addition, areas where the magnetic field exceeds 5 G should have restricted access for personnel and equipment. There should also be a list of MRI-safe equipment, and patients, staff, and equipment should be screened for magnetic objects before entering the MRI room.

Stolzenberg says there was a similar incident at the hospital in 1997 when an oxygen tank was introduced into the magnetic field. There was no patient in the MRI at the time. The Westchester CEO says the hospital has taken immediate steps to improve MRI practices. These are some of the changes:

- purchasing and using only nonferrous oxygen cylinders, fire extinguishers, and other supplies;
- increasing the safety zone around the MRI machine;
- adding new warning signs and physical markers to identify and secure the area;
- removing the door to the control room to minimize obstacles in responding to patient care or staff needs;
- enhancing the intercom system between the control room and the MRI scanning room;
- new comprehensive programs for ongoing inservice training for MRI and non-MRI staff;
- overhauling the safety orientation for MRI patients and contract service workers, such as ambulance drivers.

Incident review reveals lapses in procedure

The Westchester's incident review report obtained by *Healthcare Risk Management* reveals that the tragedy began with an attempt to provide adequate oxygen to the patient during the MRI exam. These excerpts from the report outline the sequence of events:

- "Immediately prior to beginning the actual filming, the anesthesiologist attempted to turn up the oxygen flow . . . without any success. As there was no direct microphone communication between the MRI technologist and the anesthesiologist, the anesthesiologist knocked on the window between the MRI room and the console room to get the technologist's attention. The technologist responded by leaving the console room and going to the door of the MRI room. The anesthesiologist informed the technologist he had no oxygen. The technologist left the MRI room, walked through the console room into the computer room (which is the location of the oxygen flow into the MRI room). A second technologist who was in the console room at the time accompanied the first technologist into the computer room to assist in addressing the oxygen supply."
- "A nurse preparing to leave the MRI suite was passing the MRI door, which she observed to be wide open, saw and heard the anesthesiologist. In response to the apparent urgency of his concern the nurse noticed two [oxygen] cylinders in a handcart on the floor in the patient care alcove across the hall from the door of the MRI. She recalls one was empty and one was full. The nurse recalls lifting the cylinder by the regulator and transferring it to the anesthesiologist."
- "The oxygen cylinder was introduced into the magnetic field surrounding the MRI and was immediately drawn to the core of the magnet causing head trauma to the patient."
- "The nurse recalls that the anesthesiologist took the oxygen cylinder from her while she was in the hallway. She states she is not certain as to how many inches or feet he may have been from the inside of the MRI or out of the doorway."
- "The anesthesiologist recalls that a nurse

brought the cylinder into the MRI room. As it was being drawn into the bore of the magnet he tried to catch it, but could not."

Report addresses core causes of accident

The incident review could form the basis for a root cause analysis if the incident is reported as a sentinel event. The document is divided into five basic issues: Systems, Human Resources, Environment of Care, Information Management, and Other Factors. The review of the incident concluded that these were the critical factors associated with the delivery of oxygen to a patient undergoing MRI:

- A poorly designed oxygen delivery and monitoring system that failed to ensure the continuous delivery of oxygen and deprived the attending anesthesiologist of the means to both determine the availability of oxygen and switch sources without assistance.
- Ineffective communication systems impeded the anesthesiologist's attempts to communicate his concern for the patient's safety to the others in the MRI suite and to monitor their efforts to assist him.
- The storage of MRI-incompatible material in the MRI Suite.
- The failure to safely identify and safely secure the restricted magnetic field area.
- Ineffective education of both hospital and nonhospital staff regarding the dangers associated with MRI magnetic fields.
- Absence of and incomplete written policies and procedures related to the provision of oxygen in MRI. **(See article below for more on systemic deficiencies identified in the report.)**

Stolzenberg emphasizes that "the hospital accepts full responsibility for this terrible tragedy" and says media accounts focusing on the nurse who actually introduced the oxygen tank to the room are not productive. The individual would not have been able to make such a mistake without deficiencies in the hospital's policies and procedures, he says. ■

Systemic problems led to MRI accident

Here are some of the systemic problems identified by Westchester Medical Center in Valhalla, NY, and the corrective actions the hospital took:

- **Inadequate oxygen supply in the MRI room.**

The system in place related to the delivery of oxygen safely to the patients during performance of MRI was not effective. 2-H cylinders secured to the wall in the computer room were the source for oxygen for patients during MRI scanning.

Action: Remove the H cylinders as the oxygen source for patients during MRI. Only nonferrous oxygen cylinders will be used for those patients requiring oxygen during scan. Currently, the patients requiring oxygen will be met at the entrance of the MRI unit by MRI personnel who will transfer the patient from the regular hospital cylinder to a nonferrous aluminum cylinder and escort patient into MRI suite. For outpatients who bring their own tanks, this unit will be stored in the patient's automobile during the procedure. When the patient's study has been completed, the patient will be switched from MRI-compatible tank to either a hospital cylinder or to the patient's own tank outside the MRI area.

- **Oxygen supplies could be insufficient during an MRI, requiring a resupply.**

There was a flowmeter in the MRI room and the practice was to change the H cylinder when it was at or below 500 pounds per square inch (psi). When the patient in question first entered the MRI room, the flowmeter was turned on and indicated oxygen flow. Immediately before the scanning was begun, the anesthesiologist attempted to increase the flow without success.

Action: The source for patients requiring oxygen during an MRI scan will be exclusively nonferrous cylinders. A full nonferrous E cylinder will be provided for each patient. It will be the responsibility of the MRI technologist / RNs to ensure a full cylinder is provided per patient. MRI personnel will monitor pressure readings of the tank in use every 15 minutes; if the reading reaches 500 psi, the tank will be replaced with a full cylinder.

- **There was no written policy regarding oxygen in the MRI suite.**

The department of radiology had written policies / procedures related to MRI scanning and safety, but there was no written policy related specifically to the provision of oxygen during the MRI scan.

Action: Written policy / procedure to include training of responsible personnel

will be developed. The respiratory therapy department will communicate the written policy and associate training to involved staff. Documentation of training and ongoing competency will be maintained. This will include current staff and new staff members as part of general orientation to the MRI milieu.

• With no written policy or education on oxygen use in the MRI suite, the procedure followed was not consistent.

Staff were not trained specifically in how to provide oxygen during an MRI, and staff members had different habits.

Action: Development of written policies/procedures related to training and education of appropriate staff and ongoing competencies will be maintained.

Human resources problems also

• No written procedure existed for management of oxygen delivery sources for patient undergoing MRI studies. Competencies have not been developed.

Action: Upon completion of policy/procedure and appropriate training, competencies will be developed and assessed according to organizational policy.

• MRI orientation and inservice training did not include adequate or effective methods to maintain a safe level of awareness on an ongoing basis.

Action: Development of an orientation and inservice program for all staff who enter this area including but not limited to staff, visitors, contracted services. Develop methods to address maintenance of an ongoing safe level of awareness related to the MRI.

• The physical environment was not appropriate for the processes/treatment being carried out.

When the oxygen source for a patient in the MRI room was not adequate, an attempt was made to provide supplemental oxygen. A ferrous oxygen E canister was introduced into the magnetic field. The patient care area adjacent to the MRI Scanner was not treated as a restricted magnetic field area.

Action: The restricted magnetic field area around the magnet should be expanded to include the alcove or patient care area. Noncompatible MRI equipment (such as oxygen tanks, pulse oximeters, ventilators, stretchers, and fire extinguishers) where available will be utilized. Utilize additional signage and physical markings to identify and secure area. Reinforce policy and procedures for screening all who enter the secure area and include use of screening tool. Develop screening tools that give consideration to methods and limitation in vision, fluency, language, and literacy.

• Policies exist to address specific risks but a comprehensive risk assessment process was not in place.

Action: An outside expert will conduct an environmental MRI risk assessment.

• Other items were found to be dangerous.

The fire extinguishers adjacent to the MRI scanner were ferro-magnetic. A code cart with ferro-magnetic materials was in the patient care area adjacent to the MRI scanner.

Action: Replace with MRI-compatible fire extinguishers. Revise and review policies/procedures, emergency for cardiac and respiratory events including delineation of responsibilities. Assure appropriate staffs are trained accordingly. Door to console room has been removed to minimize obstacles in technologist response to patient care needs (or staff). A plastic, breakaway chain has been placed across the scan room as a visual reminder that this is a restricted area. Code cart has been relocated to safe area.

• Controllable equipment factors did contribute to the event.

H cylinders were used as oxygen source for patients. Ferrous materials were in an area adjacent to the magnet and were easily accessible to restricted magnetic field.

Action: Only MRI-compatible oxygen cylinders will be permitted anywhere in the MRI suite. The restricted field area surrounding the magnet was revised to include the alcove or patient area.

• Necessary information was not available when investigating the incident.

No clock in the MRI room to provide accurate documentation of timing.

Action: An MRI-compatible clock was installed.

• Communication among participants was not effective.

Communication between a person other that the patient in the MRI room during the scan is achieved by that individual knocking on the window between the MRI and console room to attract the attention of the MRI technologist performing the scan.

Action: Evaluate MRI-compatible communication enhancements. ■

Lab error kills two patients

Two patients at St. Agnes Medical Center in Philadelphia died from a laboratory error in the calculation of the Prothrombin test (PT), according to a statement issued by the Philadelphia Department of Public Health. The error led to the administration of excessive doses of warfarin (Coumadin).

The report says the error occurred when the laboratory used an incorrect formula number in calculating the PT, which was compounded when technicians ordered the wrong reagent after switching to a more sensitive test. Before the error was discovered, 932 hospital patients received incorrect test results and almost 100 received incorrect doses of Coumadin.

Flawed PT testing at St. Agnes was conducted from June 4 to July 25 and was discovered after a patient questioned his Coumadin dose, according a statement from the hospital. An investigation by the hospital uncovered the mistake, at which point it informed local and state health departments.

The Philadelphia Department of Public Health subsequently investigated five deaths that occurred at St. Agnes during this period. Two of the deaths occurred after incorrect PT test results caused patients to receive excessive doses of Coumadin. Death resulted from intracranial hemorrhages. The other three deaths were determined to be from natural causes, according to a public health department statement.

In its report, the state health department cited the hospital for not properly implementing the new PT testing program, ordering the wrong reagent, not performing adequate verification testing and failing to identify miscalculations of the International Normalization Ratios through laboratory quality assurance review. ■

Cops: Pharmacist diluted cancer drugs for money

A Kansas City, KS pharmacist has been charged with routinely diluting chemotherapy drugs prescribed for cancer patients in an effort to increase his own profits. Patients received as little as anywhere from 1% of the intended dose, police say.

The U.S. Attorney's Office in Kansas City charged pharmacist Robert Courtney with one felony count of misbranding and adulteration of a drug. The charges were filed after investigators served a search warrant on the Research Medical Tower Pharmacy, which Courtney owns and operates. Courtney pleaded not guilty.

Authorities said the scheme was uncovered when a sales representative for Eli Lilly & Co., a chemotherapy drug manufacturer, noticed that the amount of cancer drug prescriptions seemingly being filled and billed for by Courtney's pharmacy far exceeded the amount of the drugs the pharmacy purchased. The drugs involved, Taxol and Gemzar, are used to treat cancers of the lung, ovary, breast, pancreas, and for Kaposi's sarcoma.

After authorities were notified, several prescriptions filled by Courtney's pharmacy were sent for laboratory testing at the request of investigators.

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Editor: **Greg Freeman**, (770) 998-8455.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Coles McKagen**, (404) 262-5420, (coles.mckagen@ahcpub.com).
Managing Editor: **Lee Landenberger**, (404) 262-5483, (lee.landenberger@ahcpub.com).
Production Editor: **Nancy McCreary**.

Editorial Questions

For questions or comments, call **Greg Freeman**, (770) 998-8455.

One prescription obtained by authorities contained none of the cancer drug whatsoever, and evidence indicates that many patients received only a third of the intended dose.

The pharmacy billed doctors and patients for the full strength of diluted drugs, and the potential profits for Courtney were substantial. One doctor prescribed 1,900 mg of Gemzar, which would have cost the pharmacy $1,021.25 to fill, but the amount actually found in the intravenous bag the pharmacy provided was only 450 mg, which cost the pharmacy about $241.88. ■

Citing deception, NY physicians sue HMOs

A New York physicians' group is suing six health maintenance organizations (HMOs) and alleging a regular pattern of deception and breach of contract by the health plans serving half of the state's insured population. The suit asks for relief from what it calls illegal business practices.

Six class-action lawsuits were filed on behalf of the 27,000 members of the Medical Society of the State of New York (MSSNY) seeking monetary damages for the abusive practices alleged by MSSNY against the same six carriers. The suits name Aetna Inc., Cigna Corp., Empire Blue Cross & Blue Shield, Oxford Health Plans Inc., and United HealthGroup Inc.— all in New York City. A suit also was filed against Excellus Inc., a nonprofit group, in Rochester, NY. All of the managed care firms issued statements stating the claims were without merit and denied charges made in the lawsuits.

MSSNY general counsel **Donald Moy** says the group filed the suit because the health plans systematically engaged in practices to deny medically necessary care, to bundle and reduce claims based on CPT codes, and to revise payments of claims retrospectively. The health plans "apply their own edits to CPT codes, and don't inform physicians of the edits, changes to the edits, or a decision to downcode a claim," he says.

For instance, Moy says a physician might order two separate treatments for a patient on the same day, and even though the two claims were filed under two separate codes on the same day, health plans would routinely bundle the claim under one code. That would allow them to approve a lower payment to the physician, Moy says.

Another questionable practice involves denying payment to specialists because the insurer asserted it never received an approved referral from the primary care physician. Moy says that excuse is often cited enough to suggest that it is a systemic strategy.

MSSNY also charges that the insurers use software that automatically downcodes health care services provided by plaintiff physicians. Moy says they also practice routine downcoding of reimbursement to physicians identified as high utilizers of specific codes without performing chart reviews to determine if the downcoding is appropriate.

The suit also contends that health plans use guidelines from actuarial firms to determine the medical necessity of care and the length of time a patient needs to be hospitalized, but those guidelines are based on the most optimistic scenarios.

Other physicians' groups have filed similar litigation against insurers in other states in the past few years; many of those suits now are before the U.S. District Court in Miami. ■

Healthcare Risk Management's
Legal Review & Commentary™
A Monthly Supplement

Complications with twins lead to $4.9 million Ohio settlement

By **Mark K. Delegal**, Esq., and **Jan Gorrie**, Esq.
Pennington, Moore, Wilkinson, Bell & Dunbar, PA
Tallahassee, FL

News: A woman pregnant with identical twins was admitted to a hospital for her scheduled inducement. The admission and inducement had been arranged by her family practitioner, her principal caregiver throughout the pregnancy. He only was to have initiated the inducement process and was counseled to call an obstetrician and other specialists for the actual delivery.

He failed to do so. One twin was delivered without complications and is perfectly healthy. But the second twin's umbilical cord prolapsed and now is severely mentally retarded and physically impaired. The complication resulted in a delay of about 30 minutes in the second child's delivery due to the time needed to assemble the team of physicians needed to perform an emergency cesarean section.

The hospital, family practitioner, and anesthesiologist settled prior to trial for a combined $4.9 million.

Background: The woman, pregnant for the first time, was being cared for by her family practitioner in her hometown, a small, rural community. Until the time of delivery, he provided nearly all her routine prenatal care; an obstetrician had performed an ultrasound and amniocentesis. Pregnant with identical twin girls, her pregnancy progressed without any undue complications and she wanted the twins to be delivered at the local hospital.

The 60-bed hospital had a limited medical staff and few specialized allied health professional personnel. Since the family practitioner was not privileged at the hospital to perform the actual delivery, he was required by the hospital to obtain an obstetrical consultation.

During the morning, the woman, who was at term, was admitted to the hospital. As dictated by the hospital's credentialing of the family practitioner, he consulted with a board-certified obstetrician prior to initiating the inducement. The obstetrician advised the family practitioner to proceed. The family practitioner was only to oversee the patient' s labor, not the delivery. As soon as the mother was ready to start pushing,

EMTALA conference scheduled

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the family practitioner was to call in an obstetrician, anesthesiologist, pediatrician, and respiratory technician.

Labor was induced and progressed fairly normally until about 10:30 p.m. when the mother suffered an arrest of labor. Her labor failed to progress until about 5:30 a.m. the next morning. When her labor reinitiated the family practitioner, without calling in the team of experts or consulting with the obstetrician, instructed the mother to push. Without the obstetrician, anesthesiologist, pediatrician, or respiratory technician present, the family practitioner improperly but successfully used a vacuum extractor and delivered the first twin without complications.

While delivering the second twin, the umbilical cord prolapsed, compressing between the twin in the birth canal and the mother's pelvis. The family practitioner was alone and had not assembled the required consulting physicians.

It took 30 minutes to assemble the surgical team and for it to perform the emergency Cesarean section. The second twin was delivered without a heartbeat and without respiration. The extended time in which the umbilical cord was prolapsed was too long. The infant was resuscitated but suffered profound brain injury.

The plaintiffs' theory of liability against the family practitioner was that he failed to manage the mother's arrest of labor, that he should have called an obstetrician to evaluate the arrest of descent and dilation. The plaintiffs maintained that, most likely had an obstetrician been called at that stage of labor a cesarean section could have been performed and both twins would have been born without complications.

Additionally, the plaintiffs claimed that having failed to recognize and evaluate the arrest of labor, the family practitioner failed to call in the team of experts obstetrician, anesthesiologist, pediatrician, and respiratory technician to the hospital prior to instructing the mother to resume pushing for the delivery of the twins as had been required by the hospital.

The plaintiffs also insisted that had a surgical team been present in the hospital at the time of the umbilical cord prolapse of the second twin, an emergency cesarean section would have been carried out more promptly and the second twin would have been born prior to any brain damage.

The plaintiffs also brought suit against the anesthesiologist because she had been called within five minutes of the second twin's umbilical cord prolapse and it took her 15-20 minutes to arrive at the hospital even though she only lived 2.3 miles from the hospital. The plaintiffs maintained that the anesthesiologist' s delay in responding to the emergency call resulted in the emergency cesarean section being further delayed.

The case was settled prior to trial for a combined $4.9 million among the parties, including the hospital, family, practitioner, and anesthesiologist.

What this means to you: Rural hospitals face many challenges. They struggle to maintain adequate nursing and allied health professional staff; they compete with larger, metropolitan hospitals for patients and funding; and they try to keep an active, viable medical staff.

This case certainly deals with the dilemma of a small, rural hospital stretching its medical staff by allowing family practitioners to have even limited obstetrical privileges. Unfortunately, until health manpower shortage area facilities are willing to draft, implement, and enforce strict credentialing / privileging criteria, this type of unfortunate scenario is likely to continue, says **Ellen L. Barton**, JD, a risk management consultant in Phoenix, MD.

From the time the family practitioner provided prenatal care and up to the inducement of labor, he had an obligation to inform the patient of the possible constraints he would be under, Barton says. Apparently this caveat was acceptable to the mother and the family practitioner agreed to initiate labor, she adds. Once the family practitioner initially carried out this duty to the patient, the physician was obligated to follow the hospital's credentialing protocols, she adds. Following her admission, the family practitioner took step one in notifying and consulting with the obstetrician as required by hospital policy. However, that was the last appropriate step the family practitioner took, observes Barton.

"When the mother's labor arrested, the family practitioner should have contacted the obstetrician for an additional consultation," Barton continues. "Although she did not go into the delivery phase, her condition had changed significantly and it should have been reported to the obstetrician. Despite failing to make the second consult, the family practitioner certainly should not have proceeded with the delivery specifically against the strict instructions given in the initial consult with the obstetrician. In addition, when the physician was noncompliant with the credentialing protocols, the hospital staff clearly had an obligation to intervene through a prescribed

chain of command.

"For example, staff could have asked the family practitioner to call the team of experts as required, and if the family practitioner failed to comply, then the staff should have been empowered to contact either the administrator on call, chief of the medical staff, or other appropriate staff to request an immediate intervention. Accordingly, this case requires not only a review of the standards for credentialing and granting privileges, but also a review of hospital sanctions for physicians who fail to comply with hospital protocols, and a review of what hospital staff are required to do when a breach of protocol occurs," states Barton.

"Unfortunately, as long as there are medically underserved areas with critical health care manpower shortages, small, rural health facilities will continue to be challenged to work with what is available to them. Protocols and restrictions on privileges can be a viable mechanism for stretching the available medical staff; however, if not effectively enforced as seen in this case, they simply cannot serve their purpose," concludes Barton.

Reference

Doe v. ABC Hospital, et al., Union County (OH) Court of Common Pleas. Attorneys for the plaintiffs were John G. Lancione and John A. Lancione of Cleveland. ■

Hot tea leaves big settlement

News: While recovering from back surgery, an elderly patient became chilled and requested hot tea. The tea was very hot and burned the patient's lips and breasts.

Prior to trial, the hospital settled with the woman for $150,000.

Background: A 75-year-old woman was admitted to a hospital for elective, lower-back surgery. The surgery was performed in the morning. She had been anesthetized for the surgery. When she awoke, she was taken to the recovery room. After a few hours, she was returned to her noncritical care room. During the next 12 hours, she was given substantial amounts of pain medication and several sleeping pills.

At about 2 a.m. the morning after surgery, she asked a nurse for hot tea. When the nurse returned with the cup of tea, the patient said it was not hot enough and asked that it be heated further. The nurse advised her that the tea was hot enough. The nurse said the patient acknowledged the comment.

Before the patient took her first sip, the nurse left the patient's room. Moments later, the patient took a sip. The tea burned her lip and she spilled some on her chest, burning her left breast and chest, resulting in second- and third-degree burns to approximately 5% of her body.

The woman claimed the defendant hospital and its nursing staff's care fell below the standard of care in serving a cup of very hot tea to an elderly and heavily medicated patient recovering from major surgery performed only 16 hours earlier. She maintained that the tea had been served at an unsafe temperature. The plaintiff also claimed that she should not have been left alone and unassisted under the circumstances.

In addition, the patient claimed that four to six needle procedures would be required to attempt to alleviate the pain from the burned skin to reduce the scarring. She also alleged that the permanent scarring and disfigurement over a large portion of her left breast could have been avoided or at least mitigated had the hospital immediately treated her with aloe vera.

The defendant hospital disputed the nature and extent of the plaintiff's injuries. The hospital maintained that the injuries, if any, were not severe and certainly did not merit the outpatient needle procedures sought by the patient.

Prior to trial, the hospital settled with the patient for $150,000.

What this means to you: Hospitals are not only responsible for providing quality medical care services, but must also provide a broad range of general health care services, including large- and small-scale food and beverage preparation for their patients and staff.

While food services are increasingly being handled or managed by outside vendors, when patients need something to eat or drink between regular meals and during periods when the large-scale food operations are not open, preparing and providing supplemental foods and beverages often becomes part of the nursing staffs' duties.

In this scenario, the first questions facing the

risk manager is where did the nurse get the tea and how was it heated.

"At a minimum, hospitals and health care facilities should have procedures for the use of appliances used to heat food or liquids for patients. Specifically, while microwaves in patient care areas have been the subject of controversy over the years, if microwaves are in fact allowed and used, the only temperature setting that should be allowed is low. Alternatively and perhaps in addition to temperature regulations, food thermometers should be available to test the foods and liquids prior to giving them to patients," states **Isabelle Smith**, risk manager, Tampa (FL) General Hospital.

"Only patients who are allowed to have additional food and liquid should be given such. In the absence of any dietary restrictions, it would generally be up to the unit nurse to assess the patient' s level of consciousness and ability to feed or drink by themselves. Under the circumstances of the present case, I am not so sure that even if the nurse had stayed with the patient that the outcome would have been any different. The tea would still have been too hot, the patient would have still spilled it, and the injury would have ensued," says Smith.

"However, when incidents of burns or trauma to the skin occur at the hospital and they are not related to the patient's underlying condition, it does behoove the facility to consult with an expert to immediately address the situation. Obviously, if additional harm has been done, all measures to appropriately address and treat the harm must be explored. And documentation in these incidents is the best silver bullet for mitigating damages in the long run. In this instance, it does not seem that the extent of the plaintiff's injuries were adequately documented or accessed by the hospital given the dispute regarding the extent and nature of the injuries and the follow-up care required," adds Smith.

"Any time an institution settles after disputing the nature and extent of a patient's claimed injuries, those on the outside looking in may wonder what they were thinking. However, in this particular case, burns do leave scars and it seems that the picture must have been worth $150,000, not just a thousand words," concludes Smith.

Reference

Settled prior to filing suit in Los Angeles County (CA). ■

Documentation
FAX-BACK SURVEY

Supplement to: *Case Management Advisor, Complementary Therapies in Chronic Care, Contraceptive Technology Update, ED Management, ED Nursing, Hospital Access Management, Healthcare Benchmarks, Hospital Case Management, Hospital Employee Health, Hospital Home Health, Hospital Infection Control, Hospital Payment & Information Management, Hospital Peer Review, Healthcare Risk Management, Medical Ethics Advisor, Occupational Health Management, Patient Education Management, QI/TQM, Rehab Continuum Report, Same-Day Surgery*

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Nearly every profession involves paperwork, but in health care, the need for thorough and accurate documentation is especially great. After all, poorly documented care can result in claims denials, lawsuits, and even criminal investigations. We'd like to hear your thoughts on why appropriate documentation is important in your work.

Do you think of documentation primarily as an issue of **(please circle only one item)**:

A. Coding
B. Outcomes measurement
C. JCAHO or other accreditation
D. Federal or state regulatory requirements
E. Other (please list) _____

On a scale of 1 to 5, please rate the following considerations by their relevance to you professionally:
(1 = extremely relevant to me; 5 = not relevant to me at all.)

__ Poor documentation could lead to legal or regulatory consequences.
__ Poor documentation could be an obstacle to accreditation for my department/facility.
__ Poor documentation could cost my facility money because of claims denials.
__ Accurate documentation is necessary to ensure proper care for patients along the continuum of care.
__ Accurate documentation is necessary to prove my/my department's effectiveness to administrators.
__ Accurate documentation helps me to identify critical needs in my department.
__ Accurate documentation is required to fulfill managed care contracts.

In your own words, why is documentation important in your work?

_____

_____

What sort of information or advice would help you better deal with your documentation responsibilities?

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