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The science of safety: Duke moves in a new direction to improve patient safety

Changes occur after organ transplant sentinel event

In the aftermath of a tragic sentinel event traced back to poor processes, the appointment of **Karen Frush**, MD, as the new patient safety officer at Duke University Hospital System (DUHS) in Durham, NC, raises several immediate questions.

What does she plan to do differently?

And how can her work help prevent another error of that magnitude?

Frush, already chief medical director for children's services at Duke, will continue in that role as she takes on the patient safety position that Duke spent a year filling. Duke launched the search after a 2003 incident at Duke University Hospital in which a heart and lungs with the wrong blood type were mistakenly transplanted into a 17-year-old girl. The girl subsequently died, and Duke admitted that its processes for preventing such a grievous error were inadequate. **(For more on that incident, see p. 3.)**

"I think that event helped clarify the need to work together and have a more formal structure," Frush says. "Although a lot of people at Duke were doing a lot of things in patient safety, you ended up reinventing the wheel and not learning from each other. There's too much to do to all be doing it individually."

The transplant error helped Duke understand the complexity of the health system and the high risk of much of what happens in health care, she says.

"It clarified a need to allow someone the time to focus on patient safety at a physician level, at an administrative level. We knew that patient safety was important, but that incident underscored that we needed to move in a more focused, determined effort," Frush says.

She will spend 75% of her time on patient safety and 25% as a clinician in the pediatric emergency department, which she says will keep her grounded in the day-to-day clinical realities of patient safety.

As the first chief patient safety officer for DUHS, Frush will be responsible for developing a comprehensive patient safety program across all

components of the health system and will provide leadership in strategic planning, analysis, development, implementation, and measurement of patient care quality and safety initiatives. The chief patient safety officer will work closely with leaders at Duke University Hospital, Durham Regional Hospital, Duke Health Raleigh Hospital, the Private Diagnostic Clinic, Duke University Affiliated Physicians and Duke Health Community Care. Frush begins her new responsibilities immediately and will report directly to Victor Dzau, MD, chancellor for health affairs at Duke University and president and CEO of DUHS.

She will work closely with the CEOs, chief nursing officers, patient safety officers, and risk managers at each individual Duke facility. Duke has a system-level risk manager and also one at each facility; Frush says she intends to work closely with them to carry out patient safety goals. Most of her contact with risk managers will be through a health system-level committee for patient safety that she will chair. The system risk manager also is on the committee and the hospital's individual risk managers will be involved in specific projects.

"I see this as a great opportunity to work closely with health system and hospital leadership, as well as physicians and staff on the front lines of patient care. After all, this is where the outcomes of patient safety efforts are ultimately determined," Frush says. "The hospital leadership and all the staff at the hospital need to own patient safety, so it's not my place to dictate exactly what their structure looks like. I provide enough guidance so they understand that it's multidisciplinary and they need the input of many different areas."

Role is to provide the big picture

Frush's job is to provide the big picture for patient safety, she says, and then the risk managers and other leaders will implement that vision in the ways most appropriate to their own facilities. She plans to spend most of her time as patient safety officer at the hospitals, talking to not only leadership but also the frontline staff. "Patient safety happens at the bedside, not in the boardroom," she says.

Frush says her background in pediatric emergency medicine guided her interest in patient safety because so much of that work involves protecting children from accidents and treating them after trauma.

"I believe strongly that we are human and accidents happen, but that's why we have to do all we can to look at the system within which we work to build safety nets and mechanisms into the system so that when we make mistakes that won't lead to an adverse outcome for the patient," she says.

Frush's plans as chief patient safety officer include the development of a Patient Safety

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Center at Duke to further the clinical understanding of the science of safety. The center will support educational initiatives, clinical research and outreach opportunities related to safety.

"This is not just an administrative position. The patient safety officer needs to promote learning and research into patient safety, because everyone, including myself, needs to learn a lot more," she says. "At an academic medical center such as this, we have incredible resources around us, people who are really smart in our medical school, nursing school, and training as residents. We need to use those resources to learn whether our structure for patient safety really works, what mechanisms we can put in place."

The Patient Safety Center will provide support for that work with a statistician, a research assistant, and other aid. Residents and fellows with great ideas can turn to the center for the assistance they need to carry out the research and implement changes, Frush says.

She also plans to make more use of simulation labs to help teach clinicians about teamwork and the concept of "crew resource management," which encourages all team members to take responsibility for protecting the patient and to speak up when they see potential problems.

"We have some learning to do and some retraining to do in terms of how we respect each other's input," Frush says. "We can still have a team leader, but it's a team leader who takes into account the views of the rest of the team, because the patient's safety is most important."

Analytical yet humanistic

Frush intends to emphasize an "analytical-yet-humanistic" response to adverse events at Duke. That means the health system will encourage a blame-free environment but still hold people responsible for their willful disregard of patient safety, she explains.

"If one of our providers chooses to intentionally go against policy, whatever we have in place to protect patient safety, that's an accountability issue," she says. "You still have to go through a process to analyze the problem and identify the systems issues, but there's human error and there's system error. Ignoring safety policies that were put in place to protect patients needs to be addressed."

Frush says it can be tough to balance a blame-free environment with holding individuals accountable when they intentionally, knowingly violate a rule, but that it must be done to protect patient safety.

Duke also has formed safety teams on each unit that conduct rounds to talk with all the staff and families. The teams are made up of nurses, physicians, and others who focus on the particular risks inherent in that unit.

Frush says she sees the patient safety improvements at Duke as a potential source of improvement for other health care providers.

"Part of our goal is to have a center for educational research and training that is helpful not just to folks at Duke but well beyond," she says. "We certainly want to, and will, share the lesson we learn with others. We learned some tough lessons with the organ transplant event, and as we learn other lessons we want to share them so that others don't go through the same thing." ■

Assumptions and a lack of redundancy led to trouble

The 2003 transplant error at Duke University Hospital in Durham, NC, that led to the appointment of **Karen Frush**, MD, as the new patient safety officer at Duke University Hospital System (DUHS) in Durham,, was traced to a lack of redundancy in the system that ensured donor organs matched the patient.

The problem began when a surgeon misinterpreted a message from the organ donor bank, mistakenly assuming that he was being told the organ was a blood-type match when in fact the donor bank was only informing him that the heart and lungs were available for his patient. That error went uncorrected until the surgery was under way, apparently because the Duke system did not have adequate steps in place to require checking the blood type.

In several statements describing the incident and the results of its root-cause analysis, the hospital cited a lack of redundancy as the critical failure. Duke added "multiple confirmations of donor match by members of the care team before the transplantation process begins and improved communications between Duke and the organ procurement organization," according to a statement by **William Fulkerson**, MD, CEO of Duke Hospital.

Duke's root-cause analysis determined that Jesica Santillan, 17, died because the hospital's

organ transplant process lacked redundant steps for confirming blood type and other compatibility factors.

Duke and the organ donor bank describe the series of events this way: When the heart and lungs became available, Carolina Donor Services found two potential recipients and both were at Duke. Both had blood type A, the same as the organs. They called a Duke surgeon on call for adult heart transplantations. When he realized the first organ-matched Duke patient was a child, he referred the call to James Jaggers, MD, the surgeon in charge of pediatric heart transplants.

Jaggers gave Jesica's name to Carolina Donor Services and thought it would look up pertinent information on the national list of patients awaiting transplants. The donor bank proceeded on the assumption that Jaggers knew the organ blood type was A since he had been told in the phone call and had suggested Jesica. Jaggers thought the bank would confirm compatibility through its database before getting back to him with an answer.

Blood type match not confirmed

Carolina Donor Services says the organs arrived with paperwork and labels that clearly indicated the blood type. Duke says the blood type match was not confirmed at that point because the team thought all compatibility had already been checked.

In a letter from Fulkerson to Deanna Sampson, director of policy compliance at the United Network for Organ Sharing in Richmond, VA, which oversees the organ transplant system, he says, "We have concluded that human error occurred at several points in the organ placement process that had no structured redundancy. The critical failure was absence of positive confirmation of ABO compatibility of the donor organs and the identified recipient patient."

The letter goes on to say, "the lack of redundancy was recognized as a weakness. Validation of the ABO compatibility and other key data elements regarding the donor and recipient will now be performed by: the transplant surgeon, the transplant coordinator, and the procuring surgeon. The transplant surgeon will actively confirm the donor and recipient key data elements verbally. During the notification call to the transplant surgeon, the donor key data elements will be communicated. These data elements will be compared to the information in the transplant program's database to confirm blood type compatibility, size compatibility and if there are issues regarding anti-HLA antibodies. An additional verification will be accomplished via telephone contact with the organ procurement organization placement coordinator by the transplant coordinator." ■

Check the slip resistance of floors to prevent falls

Liquids on floors represent the biggest risk for falls in health care facilities, but risk managers often overlook the need to assess the fall risk of a particular area with wet surfaces, not dry ones, says an expert.

Henry Shable, senior risk control specialist with ESIS Risk Control Services in Philadelphia, says risk managers aren't likely to be surprised by the idea that wet floors are slippery, yet people still forget that important fact when they assess the risk of falls with a flooring surface or area.

In many cases, the steps necessary for preventing falls are not complex or unknown, yet they still are not carried out thoroughly and consistently, Shable says. Slip resistance of floors, for example, often does not receive the attention they deserve, he says. Floor-cleaning products may seem safe and slip-resistant after the floor has dried, but that can change as soon as they become wet for any reason.

"You often see that facilities like to keep their floors nice and clean, putting that pretty shine on it. And that's all well and good in a dry condition," he says. "But it's when the floor gets wet that you have a problem. A dry floor can be very safe and then you put a little bit of water on it and it becomes very unsafe."

Shable's company has tested floors in health care facilities and found that they are safe and very slip-resistant when dry, but change to very dangerous as soon as they get wet.

"The lesson is that you can't just assume that a flooring surface is fine because you tested the slip resistance and it scored well when it was dry," he says. "A good flooring surface will always score worse when it gets wet, but it shouldn't go from great to terrible. A good surface will still be a good surface when it gets wet, probably just not as good."

To properly test the slip resistance of your

flooring, you probably will need to call on facilities management or an outside engineer, who will use a device called a tribometer. Shable advises measuring your floor's resistance before applying any new or proposed cleaning product, so that you have a baseline for measuring the product's effect on your own floor.

Product labels not always reliable

If you test a dry surface, it almost always seems safe, Shable warns. He urges caution in interpreting the labels on floor cleaning products that assure you the chemical has been tested for slip resistance on floors and scored well in the safe range.

"What they don't tell you is that they never tested the product wet," he says. "They tested dry in a laboratory condition, but never out in the field after some water got on the floor. The purchasing folks at these facilities need to be careful about what they're buying."

Liquids on floors can come from a wide range of sources, including snow and rainwater tracked in from outside, incontinent patients, spilled drinks, and medical care activities.

"All you need is a little bit on the floor to present a slip, trip, and fall hazard," Shable says.

Other common risks include clutter in pathways, such as resident items in a room or supplies in the hallway. Shable says he shudders when he walks down a hallway and sees equipment lining the walls — a very common scene in health care.

"You can walk down a hallway, and both sides are littered with everything from dirty laundry carts to medication carts and lifts," he says. "Folks have to amble around them and avoid them, which is tantamount to an obstacle course for elderly or infirm patients who find it difficult to walk at all."

Operational controls frequently violated

Operational controls, such as identifying circumstances in which a patient must be lifted by two staff instead of one, can reduce the incidence and severity of falls, but those controls are violated too commonly, Shable says. The facility might be short staffed, for instance, making it difficult for an employee to find someone else to help.

"Or it might be as simple as saying you're too busy to go find some assistance," he says. "They try to move the resident outside of the protocols and a fall happens. That's very common."

When Shable assesses the risk of falls in a health care facility, he investigates whether management has instituted all three types of controls — physical, operational, and management. Physical controls involve keeping the facility clean and free of hazards, and a spill-control program. Operational controls involve defining the manner in which floors are to be cleaned, for instance, and management controls are broader, including such things as establishing an overall program for preventing falls.

Footwear policy important

Shable also recommends implementing a strict work shoe policy in health care facilities. Many employers have only the most vague policies prohibiting open-toed shoes or sandals, while some go a step further and require slip-resistant soles. But even that is not really enough to be effective, he says.

"The fact that employees come in wearing tennis shoes does not mean that is a slip-resistant shoe," he says. "You have to go further and define whether you require a tread pattern that's not worn out, or you can specify a certain type of shoe that is certified as slip-resistant for certain work settings."

Shable notes that some shoe manufacturers even offer guarantees that they will pay the first $5,000 of a claim resulting from a fall. But some employers are reluctant to require such shoe programs because they don't want to obligate low-income employees to paying for a $25 pair of shoes, and they don't want to provide the shoes because of high employee turnover.

"If you can get a shoe requirement through, it's a good idea that can have a big impact on reducing employee falls," he says.

But of course, employees are not the only ones at risk of falling. Shable says it is important to include in your fall prevention program a policy that warns patients and family members about the proper type of footwear for the facility. Family members in particular should be cautioned about the hazard of bringing unsafe footwear for the patient, such as soft slippers with a fabric sole.

"You have to be willing to say, 'These shoes you brought in are inappropriate,'" he notes. "It's easier to say that than to call the family and tell them their loved one has taken a serious fall."

More hazards often overlooked

Shable offers this list of other hazards often overlooked in health care facilities:

- **Changes in floor surface**. The transition from tile to carpet or marble in the entrance lobby to tile in the hallway, for instance, can be critical spots for falls. Even a change from one carpeting to another can be risky.
- **Bold carpet patterns**. Elderly patients already have a difficult time with visual acuity; so bold patterns in the carpet can make it difficult for them to discern objects in their path that could pose a tripping hazard.
- **Lighting conditions**. Many facilities dim the lights in the evening, but that just makes it more difficult to see hazards. Another risk is posed by lighting that abruptly goes from bright to dim, or vice versa. The person's vision is affected, sometimes significantly, by the sudden change.

"That's why so many people fall in theaters," he says. "You're temporarily blinded, you take a few steps and down you go."

- **Floor cleaning operations.** Your efforts to clean the floors properly may actually introduce an unnecessary hazard if done when people are likely to traffic through the area while it is wet. Schedule routine cleaning for off times as much as possible. Even if that means relying more on overnight crews, the additional expense might be worth it.

Investment usually pays off

Paying more attention to these overlooked issues can help you reduce the incidence of falls, if not the severity, Shable says. The average cost of a workplace fall is about $26,000 — including hidden costs such as a manager's time devoted to investigating the incident — but that figure can rise to the hundreds of thousands of dollars in health care, he notes.

"Any reduction in the frequency can result in a very significant reduction in the cost of falls," Shable says. "How much you can expect to reduce the frequency depends on a number of factors, but when I go in to help an employer get a handle on falls, I often tell them that we'll set a goal of reducing falls by 10% over the next year."

The payback on a fall-reduction program almost always justifies your expenditure, Shable says. If you prevent one $100,000 fall, you've probably justified every penny you spent and all the time devoted to the effort, he says.

"It's not uncommon to have management balk when you want to spend $5,000 on a patient lifting device, so don't be surprised if they don't want to spend money on an engineer to come in and test your slip resistance," Shable says. "But in both cases, it shouldn't be hard to show how that money can save you a great deal more in the long run." ■

New research shows brain injuries stem from infection

New research continues to dispel the once widely accepted belief that premature infants suffer brain injury from a lack of oxygen usually attributed to obstetrician error. In fact, infection plays a larger role, according to high-risk obstetrician **Ernest Graham**, MD, an assistant professor at The Johns Hopkins University School of Medicine in Baltimore.

Graham is lead author of a study presented at the 24th annual meeting of the Society for Maternal-Fetal Medicine last February in New Orleans.

"Infection plays a much larger role than lack of oxygen in brain injury among premature infants," Graham says. "To reduce the risk of brain injury in the premature neonate, physicians may have to

pay more attention to infections that occur around the time of birth."

The injury to the premature brain white matter, known as periventricular leukomalacia (PVL), is a condition in which small, cystlike regions of brain tissue die. PVL is the most common form of brain injury in premature infants and results in cerebral palsy in 60% to 100% of those who live to adulthood. Ultrasound, MRI scan, or CT scan of the infant's brain can only identify it.

As part of their analysis, the researchers reviewed the records of 150 cases of white matter injury in premature infants born at Hopkins from 1994 to 2001. Ultrasound recordings taken at three different times after birth assessed rates of PVL. Using control cases without brain injury and matched by length of pregnancy, the researchers studied several factors believed to play a role in causing brain injury, including multiple births, lack of oxygen, and the presence of infections.

Overall, the researchers confirmed previous research that showed in women who had had twins or triplets, subsequent infants were at higher risk for the subsequent development of brain injury.

However, to their surprise, the researchers found a very small portion of cases with brain injury also had metabolic acidosis, a sign that oxygen was lacking. Indeed, the rates of severe metabolic acidosis were statistically the same among the cases with PVL and the in the control cases without brain injury, ranging from 3% to 6%, respectively.

The most striking results came from bacterial cultures of samples from the premature infants' cerebrospinal fluid, blood and trachea. Researchers found a two- to fourfold increase in the rates of PVL among those premature infants with an infection, tested positive by culture samples. The rates of injury were independent of the type of infection, and more than a dozen different kinds of bacteria were found. ■

Stolen ambulance tragedy: $12.5 million payout

Health care providers in Texas have agreed to pay $12.5 million to settle a lawsuit stemming from the theft of an unattended ambulance, which was then involved in an accident that killed a father and seriously injured the rest of his family. The plaintiff's attorney says the settlement underscores the need for hospitals to secure ambulances and other vehicles.

The lawsuit alleged the hospital and paramedics were negligent for not providing proper care to the psychiatric patient who stole the vehicle, and for leaving the ambulance unattended, unlocked, and running.

Northwest Texas Healthcare System of Amarillo, has agreed to settle the case arising from the accident five years ago, according to Dallas attorney **Frank L. Branson**, JD, who represented the surviving mother and two of the children in their lawsuit against Northwest Texas Healthcare System, Northwest Texas Hospital, Amarillo Medical Services, Universal Health Services and two paramedics. The civil suit was settled after a court hearing in Judge John Board's 181st District Court in Potter County, TX.

Ricky Dewayne Chavez, 33, died August 1999, from injuries suffered when a stolen ambulance, driven by Jamie Sue Whiteagle, crashed into the Chavez's family van. Also injured in the accident were his wife, Tina Grady Chavez, and three children, Shelby Delaine Grady, Ricky Daniel Chavez, and Selena Raynea Chavez.

The mother suffered irreparable brain damage, leaving her unable to speak or feed herself. Shelby required several surgeries as a result of severe head trauma. The two other children also suffered physical injuries.

"No amount of money will ever fix what happened to this family," Branson says. "This settlement will help them cover the overwhelming medical costs they continue to incur as a result of this horrific accident. It also will hopefully shed light on the inadequate security measures around the hospital so that nothing like this will happen again and destroy another family."

Patient was mentally ill

Branson says records indicate the woman who stole the van was admitted to Northwest Texas Hospital on Aug. 1, 1999, for a psychological evaluation. Despite diagnoses of psychosis, situational depression, and outward symptoms of mental illness, she was discharged with only instructions to seek assistance from a state-run facility, Branson says. As she left the hospital, she entered an unlocked ambulance, with its engine running, left unattended by the two paramedics.

The theft of the ambulance was captured on a hospital security camera, but neither of the two security guards on duty attempted to stop Whiteagle, Branson says.

Shortly after speeding away in the ambulance, Whiteagle drove through a stop sign, crashing into the Chavez family's minivan. Witnesses told Amarillo police investigators that the ambulance was traveling at a very high rate of speed and the people in the minivan had no chance to react.

In November 2000, Whiteagle pled guilty to manslaughter in connection to the accident and was sentenced to eight years in prison. ■

Flu shortage caused by liability fears? Maybe not

When risk managers first heard that there wouldn't be enough flu vaccine from the two manufacturers still providing it, many probably reacted with the same thought: That's what you get when money hungry trial lawyers run health care companies out of business.

But is that really the cause of the flu vaccine shortage? The two opposing sides in the tort reform debate disagree about the answer, but it seems clear that more than that one cause caused the vaccine shortage.

The American Tort Reform Association (ATRA) in Washington, DC, says fear of liability most certainly was a contributing factor. The group is urging Congress to act on what it calls "the excessive liability exposure that has led to the recent flu vaccine crisis in the United States."

ATRA general counsel **Victor Schwartz**, JD, says the shortage was inevitable when the United States depended on only two vaccine manufacturers. And why were there only two? Because American companies were afraid to take on the trial lawyers who would sue the manufacturer for any problems, real or perceived, after someone receives the vaccine, he says.

"We've been cautioning policy-makers and the American public for more than 10 years not to be too dependent of foreign vaccine manufacturers, and now we have a real crisis," Schwartz says. "Now that one foreign manufacturer has withdrawn its flu vaccine from the market, we must make every effort to assure that there is a liability climate so that vaccines can again be manufactured here in the United States."

Schwartz notes that at one time, there were more than 12 U.S.-based vaccine manufacturers.

American manufacturers are very reluctant to produce vaccines because they generally are given to healthy people, Schwartz explains. ATRA president **Sherman Joyce** says that if a person who has received a vaccine suffers any type of disability, there is a plaintiffs' lawyer waiting in the wings to sue a manufacturer.

"Courts that admit junk science evidence have helped create this crisis," Joyce says. "A vaccine manufacturer can be held liable for millions of dollars, even though its product had nothing to do with the plaintiff's actual injury."

Schwartz says the problem could be solved with federal legislation that would assure persons who are actually injured by vaccines receive prompt and fair payment, similar to the 1986 National Childhood Vaccine Injury Act, which does not apply to flu vaccine. The childhood vaccine program limits the liability of manufacturers enough that companies are willing to stay in the business, he says.

Lawyers say it's not their fault

But, not surprisingly, the trial lawyers have a different view. The Association of Trial Lawyers in America, based in Washington, DC, argues that its members are not the root cause of the shortage and that protecting manufacturers from liability is not the answer.

ATLA president **Todd A. Joyce**, JD, a trial attorney in Chicago, notes that even with liability protections, there are still shortages of childhood vaccines. Since 2000, there have been shortages of eight of the 11 vaccine-preventable childhood infectious diseases plus adult vaccine shortages, the ATLA reports.

Joyce argues that flu vaccine shortages are unrelated to liability. Instead, he says, there are so few flu manufacturers because it is a risky business. Flu vaccine manufacturing is very risky for a number of reasons, most notably because demand for it varies from year to year. Plus, any product that is not sold cannot be saved or stockpiled because a new vaccine must be developed each year to deal with changing strains of the virus.

Few lawsuits filed

Quality control and safety regulations also are a big deterrent, he says. In the late 1990s, the

FDA tightened its inspections of factories making biologic products after contamination of blood products by the AIDS virus and other incidents led to criticism of the agency's inspections. While manufacturing costs have increased, the prices for the vaccines have remained the same.

Joyce reports that there have been very few lawsuits against flu vaccine manufacturers. An ATLA search of lawsuits from 1980 to the present found only 46 reported cases based on flu vaccine injuries, he says. Of the 46 cases, 39 involved the swine flu vaccine, and only seven involved the standard flu vaccine. In five of the seven standard flu cases, the defendant prevailed, while the other two cases are unreported.

"Given the millions of vaccine doses dispensed every year, this is hardly a liability crisis," he says. ■

Respond to the shortage by encouraging sick days

So, if the flu season hits your community hard, will your health care staff suffer because they didn't get enough flu shots?

Quite possibly. But there is something risk managers can do: Urge employees to stay home when they're sick. Flu will spread much more rapidly and cause far more disruption to a health care organization if employees report for duty when sick, says **Lori Rosen**, JD, a workplace analyst for CCH Inc., a consulting firm in Riverwoods, IL, that specializes in employment law. Rosen calls the problem "presenteeism" and advises you to combat it just as much as absenteeism.

Employers say presenteeism is a problem

According to the findings of the 2004 CCH Unscheduled Absence Survey, 39% of employers surveyed report presenteeism is a problem in their organization. Presenteeism is a problem for employers not only because of employees' lowered productivity, but issues of contagion to an otherwise healthy work force.

Organizations that have low employee morale are at even greater risk of sick workers on the job, with 52% of companies with poor or fair morale reporting presenteeism is a problem.

"With a serious flu season looming, the idea of the hero worker that manages to punch in for a full day's work, despite illness, needs to be discouraged," Rosen says. "Being in contact with contagious individuals jeopardizes the health and productivity of all employees. Employers need to emphasize to employees that while they need them at work, they first want a healthy workplace."

Don't encourage martyrs

Some traditional absence control and sick-day policies may inadvertently encourage employee presenteeism, Rosen notes. Organizations that adhere to traditional sick day policies and take disciplinary action to enforce them may make it difficult for employees to do the right thing.

"For example, in an organization that allots each employee five sick days a year, and takes disciplinary action on the sixth absence, an employee who has been wiped out with the flu for several days may choose to come to work ill rather than risk the discipline," she says. "This is especially true at the beginning of the year, when employees are concerned about depleting all of their allowed leave in just a month or two. Unfortunately, that time also is the height of flu season."

Set a good example

Rosen offers these suggestions for how risk managers can minimize the impact of flu season:

- **Foster a healthy environment.** Speak with managers to ensure they're fostering an environment that makes ill employees comfortable to ask to leave the workplace or, better yet, not report to work in the first place.
- **Set a good example.** Managers should be urged not to show up at the workplace with the flu as employees may otherwise simply view the message to stay home as lip service.
- **Set guidelines and make them visible to employees.** Help them understand under what conditions they should stay home and when it's safe to return to work.
- **Review absence control policies to ensure they are not counterproductive**. Programs such as disciplinary action need to be assessed to ensure they are not making ill employees feel required to report to work.
- **Post helpful tips on how to avoid spreading germs**. Guidance is available at www.cdc.gov/flu/keyfacts.htm#goodhabits.
- **Work with your employees and facilities**

department to keep common areas clean. Make sure that common areas of the facilities are cleaned regularly. This may even include cleaning conference rooms between meetings. ■

AHRQ offers a tool for measuring patient safety

Patient safety is on everyone's minds these days, but how do you know how well your organization already is doing on this topic? One way is a tool offered by the Agency for Healthcare Research and Quality (AHRQ), an arm of the Department of Health and Human Services in Washington, DC.

The AHRQ is offering a new tool to help hospitals and health systems evaluate employee attitudes about patient safety in their facilities or within specific units. The Hospital Survey on Patient Safety Culture, being released in partnership with Premier Inc., the Department of Defense, and the American Hospital Association, addresses a critical aspect of patient safety improvement: measuring organizational conditions that can lead to adverse events and patient harm, says AHRQ director **Carolyn M. Clancy**, MD.

"Improving patient safety is not just a function of having the best research findings available," Clancy says. "There has to be an environment or culture that encourages health professionals to share information about patient safety problems and actions that can be taken to make care safer, and that also supports making any changes needed in how care is delivered."

Patient safety culture assessments

Gina Pugliese, RN, MS, vice president of Premier's Safety Institute, says assessments of patient safety culture typically include an evaluation of a variety of organizational factors that have an impact on patient safety, including: awareness about safety issues, evaluating specific patient safety interventions, tracking changes in patient safety over time, setting internal and external benchmarks, and fulfilling regulatory requirements or other directives.

"Premier considers health care organizations' ongoing evaluation of the safety culture in their facilities as a basic yet crucial step in improving safety and overall quality," Pugliese says. "This tool will be valuable in targeting interventions and then measuring their success over time."

The Hospital Survey on Patient Safety Culture includes the survey guide, the survey, as well as a feedback report template in which hospitals can enter their data to produce customized feedback reports for hospital management and staff. These items provide hospitals with the basic knowledge and tools needed to conduct a safety culture assessment and suggestions about how to use the data.

The survey was pilot tested with more than 1,400 hospital employees from 21 hospitals in the United States to ensure that the items were easily understood and relevant to patient safety in a hospital.

The survey can be found on-line at www.ahrq.gov/qual/hospculture/. Printed copies may be ordered by calling (800) 358-9295 or by sending an e-mail to ahrqpubs@ahrq.gov. ■

ISMP: Med errors demand a more focused response

Five years after the landmark Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System*, not enough is being done to address medication errors, warns the Institute for Safe Medication Practices (ISMP) in Huntingdon Valley, PA.

The IOM committee asked the FDA to develop and enforce standards for the design of drug packaging and labeling to maximize safety; require pharmaceutical testing of proposed drug names;

COMING IN FUTURE MONTHS

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- Patient safety kits focus on specific risks
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- Contract workers on site: What's your role?

and establish an appropriate response to problems identified through post-marketing surveillance, especially those that require immediate response to protect the safety of patients.

But so far, there are no new labeling or packaging guidance documents, pharmaceutical companies are not required to test proposed drug names and packaging, a standard process for testing has not been established, and the response to problems is still slow or nonexistent, according to a recent report from the ISMP.

Nevertheless, ISMP lauds the FDA's announcement of plans to review its medication error detection and response procedures, and urges that drug labeling, packaging, and nomenclature be targeted as a special area of focus. Labeling, packaging, and nomenclature issues play a role in about half of all medication errors reported to the FDA MedWatch program, according to the FDA.

Med errors lead to serious injuries, deaths

The ISMP notes that some of the medication errors that continue to be reported to the USP-ISMP Medication Errors Reporting Program, and have in many cases led to serious patient injuries and deaths, including:

- **Medications packaged in look-alike, low-density polyethylene containers.** This includes respiratory medications, flush solutions, eye medications and even injectables.
- **Concentrated liquid morphine.** Containers are still packaged without a prominent warning that the liquid is highly concentrated.
- **Brethine (terbutaline) and methergine (methylergonovine).** ISMP has been writing alerts for the past four years about look-alike packaging for these drugs, which are used in labor and delivery settings but have opposite effects.
- **Acetylcysteine containers.** These containers are still available with labels that list percent concentration, not mg/mL, which is problematic because the product is most frequently dosed in mg amounts.
- **Vaccines (multiple brands).** Various vaccines continue to be confused with each other due to look-alike packaging from the same manufacturer, including tuberculin skin tests and the influenza vaccine.
- **Oral methotrexate.** ISMP recently published a study about medication errors with this drug over a four-year period, which involves more than 100 cases. Most were with patients who accidentally took their doses daily instead of weekly as indicated, mistakes that could have been avoided with specific labeling and packaging changes. ■

CE instructions/objectives

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

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

- **Describe** legal, clinical, financial, and managerial issues pertinent to risk managers in health care.
- **Explain** how these issues affect nurses, doctors, legal counsel, management, and patients.
- **Identify** solutions for hospital personnel to use in overcoming challenges they encounter in daily practice. Challenges include HIPAA and EMTALA compliance, medical errors, malpractice suits, sentinel events, and bioterrorism.
- **Employ** programs used by government agencies and other hospitals (such as EMTALA, HIPAA, and medical errors reporting systems) for use in solving day-to-day problems. ■

CE Questions

1. How does Karen Frush, MD, describe her role?
A. She provides the "big picture," and then the risk managers and other leaders implement the idea.
B. She takes direction from the risk managers at the hospitals and helps them as needed.
C. The corporate leadership provides the "big picture," and she carries out their wishes.
D. Her role is to provide a stopgap solution when problems arise.

2. In the transplant sentinel event at Duke, what did the hospital's root-cause analysis find?
A. Duke's systems were adequate and did not lead to the adverse event.
B. The hospital's organ transplant process lacked redundant steps for confirming blood type and other compatibility factors.
C. The error was initiated by personnel outside the Duke system and Duke staff had no responsibility for the adverse event.
D. While Duke staff made minor errors, they ultimately did not bear any responsibility for the patient's death.

3. What does Henry Shable advise about floor cleaning products used in health care facilities?
A. The manufacturer always tests slip resistance in wet conditions, so reading the label is sufficient to determine appropriate use in your facility.
B. The manufacturer rarely tests slip resistance in wet conditions, so the slip-resistance claims on the label may not be reliable.
C. Any cleaning product labeled for use in health care facilities is sufficiently slip-resistant.
D. Cleaning products are equally slip-resistant on both wet and dry floors.

4. In the case settled recently by Northwest Texas Healthcare System, what did the plaintiff allege the system did wrong?
A. Left an ambulance unattended and running, which was stolen and then involved in a serious accident.
B. Left a minor patient unattended in the emergency room, where she was assaulted.
C. Failed to secure a weapon brought to the emergency room by a patient, and a patient used the weapon on himself.
D. Failed to prevent a psychiatric patient from accessing the roof, where she jumped to her death.

Answers: 1. A; 2. B; 3. B; 4. A.

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

Negligent treatment of epileptic seizures results in death: $1.5 million settlement in New York

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News: A man presented to a hospital after experiencing two epileptic seizures and a constant twitching in his leg. Hospital staff diagnosed him with epilepsia partialis continua and hospitalized him. During the next week and a half, the patient was administered various antiepileptic drugs, but none seemed to work. On his eleventh day of hospitalization, the man suffered a series of general seizures, resulting in cardiopulmonary arrest and death.

The patient's estate sued the hospital for negligence, claiming that the defendant's failure to train and monitor its staff and residents led directly to the patient's death. The hospital settled with the plaintiff for $1.5 million before trial.

Background: A 35-year-old landscaper, having recently suffered two epileptic seizures and exhibiting constant twitching of his right leg, presented to his local hospital's emergency department. Hospital staff observed the man and diagnosed him with epilepsia partialis continua, a disorder involving spontaneous regular or irregular clonic muscular twitching repeated at fairly short intervals (often no more than 10 seconds at a time) in one part of the body for a period of days or weeks. A patient suffering from epilepsia partialis continua often suffers the localized muscular spasms and generalized convulsion throughout sleep, although possibly at a reduced rate.

The patient was hospitalized so that medical personnel could monitor his condition. Hospital staff administered several different antiepileptic drugs, but none of them controlled his seizures successfully. Consequently, the patient was held in four-point restraints and a restraint vest to protect him during his continual seizures. The man also experienced a brief period of suffocation, which caused staff to insert an endotracheal tube to increase ventilation. The patient was in a constant state of agitation during his time at the hospital. On the man's eleventh day in the hospital, he suddenly suffered a series of general seizures, which culminated in a loss of consciousness and cardiopulmonary arrest. The man died shortly thereafter.

The administratrix of the man's estate filed suit against the hospital, claiming its negligence led to the patient's death. The plaintiff first claimed the hospital staff misdiagnosed the patient as suffering from epilepsia partialis continua, rather than from status epilepticus. If staff had correctly identified the man's disorder, the plaintiff alleged, they would have known to administer high doses of a single anti-seizure drug until the seizures were controlled, which would have taken only a few days. The plaintiff further alleged that the hospital was negligent in failing to properly train its residents in the diagnosis and treatment of epilepsy and in failing to properly supervise its residents. The plaintiff based this claim on the

premise that a hospital should be held vicariously liable for the negligence of its residents because residents are often considered both employees of the hospital and students.

In response, the hospital did not dispute that it may have breached the relevant standard of care, but rather focused on the causation problems in the plaintiff's claim. The defendant first argued that when the patient presented to the hospital, his brain was infected due to the constant exposure to insecticides the man had experienced from working in the landscaping business. As a result, the patient's seizures were caused by a brain infection, not by epilepsy. The hospital further maintained that the infection was resistant to traditional drug therapy and would have killed the man eventually. In any event, the hospital claimed, its conduct was not the legal cause of the plaintiff's damages.

The case never proceeded to trial, however. Perhaps fearing a sympathetic plaintiff who was claiming future loss of parental guidance for the decedent's surviving 7-year-old daughter, the hospital settled with the plaintiff for $1.5 million just days before jury selection.

What this means to you: This case involves several issues related to standard of care and possibly to causation, which are subject to review by the facility's risk manager. The major issues/points for consideration relate to the fact that residents are typically considered employees of the hospital and as such are the hospital's responsibility; restraints may have been improperly used; and there seem to have been deficiencies in the providers' awareness of the care, treatment, and types of epilepsy.

"Hospitals are definitely held responsible and liable for the acts of omission or commission committed by its residents. The theory of vicarious liability imposes liability on hospitals for acts of negligence of its residents," says **Stephen Trosty**, JD, MHA, CPHRM, director of CME and risk management for American Physicians in East Lansing, MI.

Residents not only are considered employees of the hospital, but they also are under the direct supervision of attending faculty physicians.

"Hospitals are expected to have adequate supervision of residents and to ensure that residents know when to call for assistance from the attending physicians, which patients/conditions they can treat, and which patients/conditions they should not treat without the direct involvement of the supervising physician. Residents also have to know that if patients are not responding to treatment, then it becomes necessary to call in the supervising physician and, if necessary, to obtain a consult from an appropriate specialist. Residents should know their limitations and be expected to seek and receive assistance when necessary," adds Trosty.

"Before a resident ever touches a patient, they should be well versed in the hospital's protocols or policies and procedures setting forth tasks that residents can perform with and without direct supervision. The protocols should indicate types of conditions and patients for which residents are expected/required to seek input and assistance from their supervising physician, as well as when to call in a specialty consult," he notes. "There should be little room for doubt as to when and how the resident should engage the attending.

"Specifically as to this patient's condition, physicians, both attending and residents, should be trained to recognize the various types of epileptic seizures. They should know the appropriate form of treatment for each type, including medication, and should know when to consider other options to the initial diagnosis if no improvement occurs. It is important that physicians are able to recognize the signs and symptoms of the various types of epilepsy, and to know the appropriate treatment regimen for each," states Trosty.

"With regard to restraints, patients should only be placed in restraints, either physical or medical, if it is necessary for their own self-protection or the protection of others. There should be medical orders for the restraints and the orders should have the basis for use of the restraints. The orders should only exist for a limited period of time and should have to be reviewed and/or rewritten by a physician on a regular, frequent basis [not to exceed 24 hours]," he says.

"Further, patients who are placed in restraints should be closely monitored. The monitoring should be more frequent and continuous than that for other patients. In this case, the need for more frequent monitoring was acute, for the patient had suffered a brief period of suffocation, and had an endotracheal tube, which prevented the patient from even calling out if in need of assistance or in trouble," says Trosty.

Combining the use of restraints with the patient's inability to communicate (due to the endotracheal tube), and then adding the possibility for seizures, produced a formula for potential disaster.

"Knowing that this epileptic patient could have seizures and loss of oxygen during sleep, the hospital had an obligation to provide adequate, frequent monitoring. This is especially true after he was placed into restraints," emphasizes Trosty.

"In addition, the caregivers should have considered that epilepsy can sometimes be exasperated by stress and agitation, and so serious thought should have been given as to the appropriateness of the use of restraints. By increasing the patient's agitation through use of the restraints, the physicians/hospital might have inadvertently been making the epilepsy condition worse and increasing the frequency of seizures. There is no indication that this was ever considered by the physicians and hospital personnel," he notes.

Accordingly to the Epilepsy Foundation, approximately 2.5 million Americans have epilepsy, and 60% of those persons are 15-64 years of age. Seizures disorders strike all demographic groups, and although the socioeconomic or ethic background of the decedent is unknown, the prevalence of epilepsy is higher among minority populations living in poverty than the general population. Research has not been able to determine if this discrepancy is due to racial variations or socioeconomic factors. Death rates also are elevated in people with epilepsy especially when seizures are not controlled. About 25% of those with epilepsy are considered "intractable," which means that seizures persist despite treatment. Epilepsy affects individuals to varying degrees, which are generally placed into three categories of severity based on the spectrum of disability it creates — uncomplicated, compromised, and devastated. Those with very limited, minor seizures, whose condition is more easily controlled with minimal amounts of medication are considered "uncomplicated." Those persons who suffer compromised social, emotional, and educational/employment problems due to the side effects from larger doses of medication are deemed "compromised." The "devastated" group are most likely to have epilepsy as a result of brain disease or injury that also impairs learning, memory, attention, and motor and emotional function; devastatingly impacting all aspects of life. However, in all instances, the risk of seizure-related deaths is increased among patients with poor or little seizure control, and sudden unexplained death occurs across all three groups.

"The physicians should have been considering other possible forms of epilepsy that the patient could be suffering from when there was no positive response to the medication."

Trosty says, "The physicians should have been considering other possible forms of epilepsy that the patient could be suffering from when there was no positive response to the medication. Even though the type of epilepsy they diagnosed can require use of medication for a prolonged period of time before seeing improvement, the lack of progress should have at least resulted in a review of the initial diagnosis. No evidence exists that this occurred. There is also no evidence that a consult was requested with a physician whose specialty was epilepsy. Both of these should have occurred. Many residents have little experience, and minimum familiarity, with epilepsy."

As to how the incident was handled by the hospital, "the hospital appears to have made a serious error in judgment when it tried to claim, as a defense, that the seizures may not have been caused by epilepsy but by an infection due to exposure to insecticides. There is nothing noted in the medical record to indicate that this was given consideration by the physicians, residents

or other medical professionals. All of the treatment was based on a diagnosis of epilepsy, and the medication given was what is given for epilepsy. There is no mention of any testing being done to determine if the brain had been infected, no mention of any effort made to determine how long the man had been exposed to insecticides, what insecticides he had been exposed to, or what the results of such exposure would be. To suddenly raise this causation issue after his death, with no known documentation that this was ever considered or assessed, appears to be a desperate action likely to anger any jury," adds Trosty.

The medical record should support the proposition being made in defense of claim. He adds "that if such an alternative diagnosis was actually considered while the deceased was in the hospital, there should have been documentation of efforts that were made to determine if there was a brain infection, and if a brain infection can be caused by exposure to insecticides similar to those with which the deceased had regular contact. There should have been an indication of some form of attempted treatment for this condition, some medication that was given, some tests that were ordered. There is no indication that any of this occurred. Therefore, if this was actually considered, the hospital and physicians are clearly guilty of malpractice by doing nothing either to confirm, rule-out, or treat this suspected condition. Some acts of commission would have had to occur relative to this hypothesis to negate negligence. Failure to have taken any action, if this was suspected, could be said to amount to medical negligence.

"For the hospital to argue as part of causation that the alleged brain infection was resistant to traditional drug therapy and would have killed the man, they have to show tests that were done to confirm this diagnosis, efforts that were made to identify appropriate drugs for this alleged type of infection, use of these drugs, and continuous monitoring of the patient. None of this is indicated in the facts that are provided. In fact, based upon the fact pattern, it appears that only epilepsy was considered and treated, in which case, the hospital appropriately considered cutting its losses and settled," concludes Trosty.

Reference

- Kings County (NY) Supreme Court, Index No. 42410/00. ■