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Lower the risk of ED malpractice claims by addressing five underlying conditions

ED produces high percentage of claims, but strategies can help

Risk managers often look at the emergency department (ED) as "a little like a container of potato salad left out in the sun. It's a Petri dish for all the terrible things that can happen in your hospital," says one expert.

That attitude has some basis in fact, she says, but there are specific actions you can take to reduce the risk.

The ED is the source for a disproportionate number of malpractice claims at most hospitals, so it should be a primary focus of attention for risk managers, says **Diane M. Sixsmith**, MD, MPH, FACEP, chairwoman of emergency medicine at New York Hospital Medical Center of Queens in Flushing. Twenty percent of all claims originate in the ED, she says.

You cannot make your ED litigation-proof, but you can control ED liability by concentrating on the five conditions that are the basis for most ED claims, Sixsmith says. EDs are fertile ground for litigation for several reasons, she notes.

"People arrive with real conditions, with the potential for significant disability or death, and those conditions often present in subtle ways," Sixsmith says. "The ED is a safety net for society, so the patients are more likely to be unemployed, not well educated, and English might not be their first language. They often have no previous relationship with a provider, making it more difficult to judge their condition.

"That's a recipe for disaster," she adds.

Bedside manner makes a difference

In addition to her extensive ED experience, Sixsmith has been an expert witness and malpractice consultant for 25 years. She spoke on the topic at the recent meeting of the American Society for Healthcare Risk Management (ASHRM) in Nashville, TN, along with **Andrew S. Kaufman**, JD, a partner with New York City's Kaufman, Borgeest & Ryan, a prominent law firm that

defends health care malpractice claims. Both speakers emphasized many of the truisms that risk managers know about malpractice liability are exaggerated in the ED.

For instance, risk managers know that most plaintiffs sue not necessarily because of their medical care but how the staff treated them, especially after an adverse event. That is very true in the ED, Sixsmith says.

A bad personal interaction only will increase the chance of a patient suing when something goes wrong, she says, whereas a patient may be more likely to forgive even a true oversight when the staff seemed to actually care. And unfortunately, the typical overcrowding, short staffing, and fast pace of the ED make it especially difficult for the staff and physicians to be charming with each patient.

Getting off on the wrong foot with a patient in the ED may have a direct effect on your clinical decisions down the line.

"My theory is that the physician/patient and nurse/patient relationship is very much a part of health care," she says. "A bad relationship actually interferes with care. Not getting a good history or not talking to the patient enough to get good information affects the actual care, not just the perception of care. If you're unpleasant with the patient, the patient won't be forthcoming with the information you need to provide optimal care."

Claims come from what you don't do

Risk managers are paying more attention to the ED lately, Kaufman says. ED risk management used to be "if a patient dies leaving your ED, you turned him around so it looked like he was entering your ED," he says with tongue in cheek. "We've come a long way."

ED physicians and staff are at a distinct disadvantage when it comes to avoiding liability, Kaufman says. They have limited time and limited familiarity with patients, he notes, unlike some other physicians who can take their time in making the right decision about a patient they've treated for months.

He points out that 90% of ED malpractice claims involve discharged patients, not those who were admitted for further treatment. That fits with Sixsmith's warning that most ED malpractice claims stem from what physicians and staff *didn't* do, rather than errors they committed.

"It's what you don't do that gets you sued. That's unique in the ED," she says. "So action is better than no action."

Sixsmith and Kaufman urge risk managers to focus on five conditions in the ED that are the root of most malpractice claims.

Kaufman also suggests five specific strategies for reducing your ED's overall malpractice risk. **(See p. 4 for details.)**

Headache can be liability risk

Risk managers should work with medical directors to ensure that clinicians are following best practices for the conditions most likely to result in malpractice claims, Sixsmith says. Some of the risk reduction strategies for the conditions are clinical, but risk managers can

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procedural policies. In some cases, physicians will need the backing of the institution in order to make the right clinical decisions.

These are the five conditions that risk managers and ED staff should focus on:

1. Headache: The patient presenting with a terrible headache is a clinical challenge and a huge liability risk. She might have nothing more than a routine headache, or she might have a subarachnoid hemorrhage from which she will drop dead with little notice. Guess what happens if you assume the former and it's really the latter.

Properly diagnosing a serious and life-threatening cause of headache often requires a CT scan and lumbar puncture, but Sixsmith says ED physicians often stop at a negative CT scan because the lumbar puncture is painful and can be difficult to perform. Those excuses won't matter later if the cold, hard clinical facts indicated a lumbar puncture.

"If the patient needs a particular procedure, you can't say he doesn't need it because it's difficult. Either he needs it or he doesn't," she says. "A standard policy in the ED should be, 'If you think of it, do it.'"

2. Chest pain: Chest pain is inherently tricky for clinicians to diagnose and treat properly, Sixsmith says. But modern treatment strategies also mean that even the sickest patients can fare well if ED staff makes the right decisions.

"Plaintiffs' attorneys can easily claim that the patient would have fared better 'if only . . . '" she says. "Risk factors are very important. If a smoker comes to my ED with chest pain, he gets admitted. No question."

Certain practices can help the ED staff provide the best care for chest pain while also reducing the liability risk, Sixsmith says. Risk managers should ensure that it takes no longer than 30 minutes after the patient first enters the ED for drugs to be administered, and no more than 90 minutes before catheterization. ED staff should obtain a cardiology consult immediately if the patient is unstable.

3. Abdominal pain: Many abdominal conditions present atypically, especially in elderly patients, Sixsmith says. Risk managers should make sure the ED team knows that this common complaint must prompt a thorough examination, not just a simple check. All patients complaining of abdominal pain should undergo a rectal exam, she says, and a normal blood test does not rule out an abnormal process. CT scans and surgical consults should be routine for any abdominal pain that cannot be explained definitively, Sixsmith says. That might not be happening in your ED now, she says, so it is up to the risk manager to deliver that message.

"A CT is now the standard of care for abdominal pain, and I will stake my professional reputation on it," she says. "It's no longer just observation. Make sure your institution makes it easy for ED docs to get a CT scan."

4. Head injury: Head injury is the most time-sensitive symptom that presents in the ED, Sixsmith says, so reducing your liability is all about making sure the patient gets treatment fast. A CT scan should be done within 30 minutes, and there must prompt neurosurgical response.

If the patient must be transferred, make sure the ambulance provider will guarantee a prompt response. Also, encourage ED staff to assume a serious head injury in an inebriated patient until you can determine otherwise. Inebriated patients can be difficult to evaluate for head injury, she says, and besides, they're just more likely to have one.

Another important consideration is nursing observation and how it is documented. In the event of a lawsuit, you want to be able to show that a nurse performed a neurological check frequently. Too often, the record documents just the opposite — especially at shift change.

"I can't tell you how many times I've seen records with the nurse documenting that the

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records with the nurse documenting that the patient's neurological status was all normal and then the next nurse documents two hours later that the patient was unresponsive," she says.

5. Stroke: The primary liability risk with stroke patients involves consultations over the phone, Sixsmith says. Delays in treatment are closely related.

Speed is important, but consultations with a neurologist should not be done over the phone, she says. Get the neurologist there in person to see the patient, but it also is important that ED physicians have the authority to provide treatments considered the standard of care for stroke patients without further authorization.

The ED should be structured so that patients with stroke symptoms can be triaged rapidly and get a CT scan of the head within 45 minutes of arrival.

Keep customers happy

Overall, Sixsmith says risk managers should encourage a focus on customer service in the ED. "Minimize the likelihood that a patient in the ED walks away as an unhappy consumer," she says.

She also urges risk managers to make sure that ED physicians have authority to admit patients to the hospital when they see fit, rather than requiring admission by a physician in the department receiving that patient.

The ability to admit patients will overcome some difficult situations in which the ED physician knows the patient needs to be admitted but can't convince other physician. In such disputes, the ED physician must be able to do what he or she thinks is best for the patient, Sixsmith says, so be sure hospital policy makes that possible.

She also issues a special warning to any risk managers in teaching institutions: Residents are a risk manager's nightmare in the ED. In addition to their relative inexperience, they have a vested interest in deciding that a patient is OK and the symptoms are benign, because they and their fellow residents carry the burden of covering admitted patients. Ensure that residents are closely supervised in the ED, even more so than in other departments, she says.

Sixsmith recounts a case in which a patient's chest pain was misdiagnosed in the ED by a resident, and the man died from an aortic dissection.

"The patient was a lawyer, and no one sent out a lawyer alert in the ED," she says jokingly. "If you have a lawyer in the ED, by all means, get him a real doctor and a cardiology consult." ■

Here are five strategies to reduce your ED's risk

In addition to concentrating on the five conditions that lead to most ED malpractice claims, there are specific strategies you can employ to reduce the overall liability risk in that department, says **Andrew S. Kaufman**, JD, a partner with Kaufman, Borgeest & Ryan in New York City. He advises taking these steps:

1. Improve change-of-shift continuity: Many problems arise when patients are handed off from one physician or nurse to another at the change of shift, he says. If you don't already use a form endorsing the transfer of a patient from one shift to the next, get one. Create a policy stating that the incoming shift must evaluate the patient as a new patient, not just rely on a general statement of the patient's condition from the outgoing shift. Patients are at great risk if the incoming shift assumes the patient is stable because the outgoing shift didn't say otherwise.

2. Caution ED staff that the second visit by a patient should raise a red flag: When a patient shows up in the ED after being discharged earlier, the staff should go out of its way to check that patient very carefully. Never dismiss the patient as a whiner. Instead, the ED staff must consider the chance that it missed something on the first visit. Risk managers should enforce a policy that ED staff must *always* pull the patient's chart from the previous visit to review it for oversights and in light of the patient's current condition.

Diane M. Sixsmith, MD, MPH, FACEP, chairman of emergency medicine at New York Hospital Medical Center of Queens in Flushing, adds that when a patient returns to the ED, "he's giving you a chance to right your wrongs. And juries have no sympathy when you turn them out on the street again."

3. Require a thorough evaluation of the patient even if the ED staff consults the patient's primary care doctor: The malpractice liability rests with the ED and hospital while the person is your patient. Don't allow the ED team to let its guard down because it consulted the patient's primary care physician.

"Either the primary care physician comes in

and takes responsibility for the patient, or you evaluate that patient as if he had no doctor at all," Kaufman says. "You can't forego anything just because you talked to the patient's doctor."

4. Involve the patient's family when the patient wants to leave against medical advice (AMA): When the patient wants to leave before you can provide a full examination or treatment, the ED staff should counsel against that decision and try to get the patient to sign an AMA document indicating that leaving the ED could be dangerous. But Kaufman says one important point often is overlooked: Get the patient's family involved in the discussion.

"The family will be the one suing you if he dies," he says. "They need to know that you tried your best to get him to stay for treatment."

5. Provide specific discharge instructions about when to return: Discharge instructions often include information on what change in symptoms should prompt a return to the ED, but Kaufman says they often don't say anything about the patient returning because symptoms remain the same. For some serious conditions requiring emergency care, the symptoms may remain exactly the same until the patient suddenly dies, Kaufman says.

He suggests that discharge forms can include two boxes for the physician to check, depending on the circumstances: One can say, "Return to ED if you feel worse," and the other can say, "Return to ED if you don't feel better."

"I've had cases where the patient was discharged and had a bad outcome, and then said he didn't return to the ED because they didn't tell him to," he says. "The doctor told him to return if he felt worse, but the patient says, 'I didn't feel worse. I just didn't feel better.'" ■

Make sure hospital security doesn't stray from its role

Hospital security often suffers from complacency and poorly defined roles for the security staff, says a specialist who helps health care providers improve their programs. One of the best ways to improve your security is to make sure your officers aren't misused as impromptu assistants for all manner of scut work, he says.

Security officers in health care often take on way too much work that has nothing to do with protection, says **Fredrick G. Roll**, MA, CHPA-F, CPP, a health care security consultant in Morrison, CO. Roll offered advice on improving health care security at the recent meeting of the American Society for Healthcare Risk Management (ASHRM) in Nashville, TN. When security officers take on additional duties, they are inevitably drawn away from the more vital functions that involve protecting life and property.

"I have seen hospitals have security officers do cleaning, unclog toilets, and run various errands. One worked in the morgue and was responsible for putting toe tags on the bodies," he says. "Some of that is clearly inappropriate; but on the other hand, it is reasonable to have security do some services like escorts and jump starts and opening locked cars."

Where to draw the line

The question is where to draw the line, Roll says. Health care security staff aren't police officers, so they don't have to be on patrol every minute of their shifts, but you also don't want them away from security duties when trouble arises. It won't look good later if you have to explain why it took so long for the security officer to show up.

"If your security officer was upstairs unclogging a toilet when someone got hurt, take out your checkbook and start writing," he says.

Health care providers often contract for security services, so you may not have complete control over the attitude of officers. Most contract security services lean in one of two directions, Roll says. Either they say, "We're cops, and we don't do those other things," or they say, "We'll do anything you want us to do so we can keep the contract."

Neither is really ideal, he says.

"Be cautious with those contractors who are willing to do anything you want just to keep the contract," he says. "That can be very tempting when the hospital is looking for ways to cut back and spread duties to other people, but remember, the liability will be yours in the end. The contractor is going to say they were doing what you asked them to do."

Assess security response times

So how do you know what other duties your security staff can take on? Roll says you first should assess how well they're performing their

primary security duties. The more comfortable you are with their response times for emergencies, the more you can consider adding other duties that might delay that response. The trick is in knowing where the tipping point is, he says.

"My rule of thumb is that I want to see them responding to an emergency with five minutes 95% of the time. For nonemergencies like escort requests, I want to see response within 10 minutes 95% of the time," he says. "If they're doing that, you might be able to expand their duties. But if you do, you go back and measure it again to see how those duties are affecting response time." ■

In a crisis, be prepared: It's OK to say that you're sorry

If your institution is the lead story on the evening news, chances are good that it won't be for all the right reasons. Rather, you'll find that the risk management department is suddenly faced with the challenge of saving the institution's reputation by saying the right thing in the right way.

Even if you have a public relations department, the risk manager often has to get involved with high-profile crises, says **Doug Levy**, JD, senior vice president of Fleishman-Hillard Public Relations in San Francisco. That means you have to know what to say and how to say it.

Those situations can be immensely challenging, but Levy says there actually is the opportunity to make gains in the situation. When public statements are handled well, you can actually improve your institution's public image during the crisis, he notes. But that can happen only if you plan ahead.

"The best way to minimize damage is to prepare, plan, and practice," Levy says.

Plan ahead for crisis response

Levy spoke at the recent meeting of the American Society for Healthcare Risk Management (ASHRM) in Nashville, TN, and stresses that much of the work in responding to a crisis has to be done ahead of time. The health care provider must establish good relationships with the local and national media, and also the community at large, before any crisis happens.

"That fills the goodwill bank, and every step in creating your reputation provides information and decisions essential in being prepared for a crisis," he adds. "If you wait until a crisis happens, you'll just have to do a lot of the foundation steps in a hurry, at high cost and at risk of mistakes."

Your institution's internal reputation also is important, Levy says, so don't overlook the message you send to employees and affiliates. When communicating with different audiences, it can be wise to tailor the message to their different concerns, but be careful not to make them contradictory.

"Eavesdroppers are everywhere," he says. "Consistency is especially critical with internal audiences. They watch for inconsistency."

Never lie when responding to trouble

The message delivered to the public must be honest at all times, Levy says. No matter how much you want to protect the institution, do not be tempted to deny too much.

"Your reputation can be irrevocably damaged, not by the medical or institutional mistake, but by how the institution reacts and responds," he says. "The public will forgive mistakes, but not dishonesty, disingenuousness, or arrogance."

When a crisis erupts, you should be able to respond with a plan that you have already mapped out and tested, Levy says. Who actually speaks for the hospital is particularly important, he says. Spokespeople should be trained and tested, and Levy says it is absolutely imperative that one be a physician, and preferably not the CEO.

The ideal spokesperson should be credible, comfortable, appealing on camera, coachable by the risk manager, constantly available, calm, and possess great stamina.

Express sympathy for the victim

When you first hear of a crisis that will get media attention, Levy says you should assume that it will become public sooner rather than later. But don't overreact. If you respond as if the situation is a huge event, the media will follow suit even if they didn't intend to originally.

He offers these additional suggestions:

- **Focus on the harmed party, not the institution.** Avoid talking too much about how "we" are affected or feeling.
- **Be completely candid.** It's OK to respond to a question with, "I don't know that now." But

avoid saying, "No comment," which always sounds bad.

• **Begin every statement with a note of compassion for the harmed party.**

• **Accept blame if an error was made.** You can assume there will be a lawsuit filed some day, so you should worry about the court of public opinion now. Expressing regret for someone's situation does not increase legal liability.

• **Use your institution's web site.** The media and the public will go there seeking information, so you should use that resource as a way to get your message out. ■

CMS shines light into the gray areas of EMTALA rule

Everyone in health care still is sorting through exactly what the final Emergency Medical Treatment and Labor Act (EMTALA) rule means, and apparently the surveyors working for the federal Centers for Medicare & Medicaid Services (CMS) are no different.

CMS recently issued a guidance memo to state survey agency directors that may provide some insight into how surveyors will interpret your own operations when it comes to those gray areas. The guidance memo instructs surveyors on how to interpret some points that have been confusing or represent a departure from previous versions of EMTALA. Revised interpretative guidelines for EMTALA are being developed and will be the more official instructions to surveyors, but "in the meantime, the attached interim guidance is being provided to surveyors to use when conducting an investigation and assessing a hospital's compliance with EMTALA," according to the cover letter from **Thomas E. Hamilton**, director of the CMS survey and certification group.

Guidance memo highlights

These are some of the points addressed in the guidance memo:

• **Locations on-campus other than the "dedicated emergency department":** "Persons [including visitors] presenting themselves at an area of a hospital on the hospital's main campus other than a dedicated ED must receive a medical screening exam only if they request, or have a request made on their behalf, for examination or treatment for what may be an emergency medical condition. Where there is no verbal request, a request will nevertheless be considered to exist if a prudent layperson observer would conclude, based on the person's appearance or behavior, that the person needs emergency examination or treatment."

• **Other locations off campus:** "If a request were made for emergency care in a hospital department off the hospital's main campus other than a dedicated ED, EMTALA would not apply. The off-campus facility should call the local emergency medical service [EMS] to take the individual to an emergency department (not necessarily the emergency department of the hospital that operates the off-campus department, but rather the closest emergency department) and should provide whatever assistance is within its capability. Therefore, an off-campus location that does not meet the definition of a dedicated ED is not required to be staffed to handle potential EMC [emergency medical conditions]. However, under the conditions of participation [COPs] at 42 C.F.R. 482.12 (f)(3), such departments are required to have written policies and procedures for appraisal of emergencies and referrals when appropriate."

• **When a patient is admitted:** The rule states that a hospital's EMTALA obligation ends toward an individual when the individual has been admitted for inpatient hospital services, whether the individual has been stabilized.

The guidance memo said, "A patient is considered to be 'admitted' when the decision is made to admit the individual to receive inpatient hospital services with the expectation that the patient will remain in the hospital at least overnight. Typically, we would expect that this would be documented in the patient's chart and medical record as the time that the admitting physician signed and dated the admission order."

• **When a patient is considered stable:** "To be considered stable, a patient's emergency medical condition must be resolved, even though the underlying medical condition may persist. For example, an individual presents to a hospital complaining, of chest tightness, wheezing, shortness of breath, and has a medical history of asthma. A physician completes a medical screening examination and diagnoses the individual as having an asthma attack which is an emergency medical condition. Stabilizing treatment is provided [medication and oxygen] to

scenario the EMC was resolved, but the underlying medical condition of asthma still exists. After stabilizing the patient, the hospital no longer has an EMTALA obligation. The physician may discharge the patient home, admit him/her to the hospital, or transfer [the "appropriate transfer" requirement under EMTALA does not apply to this situation since the patient has been stabilized] the patient to another hospital depending on his/her needs or request."

• **Three ways to end EMTALA obligation:** The guidance memo noted that a hospital's EMTALA obligation ends when a physician or qualified medical person makes any one of these three decisions:

1. No emergency exists.
2. An emergency exists which requires transfer to another facility, or the patient requests transfer to another facility. (The EMTALA obligation rests with the transferring hospital until arrival at the receiving hospital.)
3. An emergency exists and the patient is admitted to the hospital for further stabilizing treatment.

For the full guidance memo, go to www.cms.hhs.gov/medicaid/survey-cert/letters.asp and choose item 10, "Emergency Medical Treatment and Labor Act (EMTALA) Interim Guidance (S&C 04-10). ■

Communication failure blamed for sentinel events

Sentinel events at Children's Hospital Boston have been traced to poor communication between residents and attending physicians, prompting a federal investigation and a plan by the hospital to overhaul how the two groups interact.

The hospital is responding to the tragedies with a plan designed to make sure that attending physicians don't leave the younger physicians with too much responsibility by poorly communicating, says hospital spokeswoman **Michelle Davis**. The plan makes clear some issues that previously were uncertain at the hospital, she says, such as when a resident is expected to contact the attending physician about a change in the patient's status.

A review by the Massachusetts Department of Public Health criticized the hospital's management of four cases in the last 13 months. The state inquiry followed concerns expressed by an official at the Boston branch of the Centers for Medicare & Medicaid Services (CMS). Two years earlier, state officials found systemic problems at the hospital contributed to the death of a toddler who suffered fatal brain damage while she waited for surgery. The most recent state review identified cases in which four patients received inadequate care, and three of the patients died as a result.

In one case, the state report concluded that a 5-year-old boy died because all of the doctors treating him believed someone else was taking responsibility for his care. All of the physicians caring for the child thought someone else was taking responsibility for him, the state concluded, and no one noticed the boy had stopped breathing until it was too late.

Attendings ordered to be receptive to residents

CMS delegated the review to the state department. The hospital announced that the state has accepted its plan for addressing the problems and CMS is likely to follow suit.

Among the changes implemented, Davis says the hospital created a uniform, institutionwide set of expectations regarding the role and responsibility of attending physicians and supervision of residents. These standards mandate that attendings respond "fully and respectfully to any questions or concerns expressed by the care team, including residents and fellows."

The attending physician also is required to communicate clearly to each trainee involved in the care of the patient when the attending expects to be contacted by the trainee. At a minimum, the trainees must be told to notify the attending of significant changes in the patient's condition, regardless of the time of day or day of week. The hospital outlined eight situations that automatically qualify as "significant changes" in the patient's condition and require that the resident notify the attending.

In addition, Davis says the hospital created the role of "ombudsperson" to provide trainees and other clinical staff easy access to a senior physician in the institution who will investigate any concerns by trainees or clinical staff that members of the faculty are either slow to respond to requests for help or create the impression that requests for help or advice are unwelcome. The hospital appointed a physician in the hospital's psychiatry department as the new ombudsperson. ■

$50,000 awarded to woman stuck by a used needle

The U.S. District Court in Cheyenne,WY, has awarded $50,000 to a woman stuck by a used needle while visiting a patient at one of Banner Health System's hospitals in that state. A hospital employee had left the needle lodged in a heat register.

The woman did not expect or know that the contaminated needle was in the patient's room, and when she backed into it, the needle stuck in her thigh, says Cheyenne attorney **Diana Rhodes**, JD, who represented the woman along with her colleague **Jim Fitzgerald**, JD.

Rhodes says the plaintiff was motivated partly by a desire to force the hospital to improve its needlestick safety efforts.

"Tort law is not solely for compensation. Its other important purpose is to encourage safe practices," she says. "The hospital has since changed its needlestick safety and prevention standards to comply with existing standards of care, and it is training hospital employees on the new policies."

Finding the source

Although a nurse took the visitor to the emergency department, Fitzgerald says the hospital never informed her of her medical options. In court papers, the attorneys claim that the hospital never told the woman she had a window of opportunity for an injection of gamma globulin to prevent the possibility of hepatitis B infection. Such injections are standard for nurses who sustain needle sticks.

The hospital never could determine the source patient of the bloody needle, Rhodes says. The visitor alleged that Banner was careless in failing to provide a safe hospital environment, and failing to comply with universal precautions for needlestick safety and prevention. The woman has not developed HIV or other bloodborne diseases yet, but according to court filings, she suffered and continues to suffer distress over those possibilities.

The hospital did not provide her with any counseling commonly given to individuals who sustain a contaminated needle stick, according to Rhodes. **Gene Haffner**, spokesman for Banner Health, declined to comment. ■

Hospital pays $2.3M in lawsuit alleging favoritism

The University of Illinois Hospital has paid $2.3 million to settle a lawsuit that charged it and two other school-affiliated hospitals with manipulating patients' diagnoses to get them new livers.

The whistle-blower suit, originally brought by transplant specialist Raymond Pollak, MD, in 1999, alleged that the hospitals diagnosed patients as sicker than they were to boost the number of transplants performed at the institutions and qualify them for government reimbursement programs. Federal and state prosecutors recently announced that the University of Chicago Hospitals and Northwestern Memorial Hospital had paid fines of $115,000 and $23,587, respectively, to settle the suit without admitting or denying guilt.

After saying it would fight the lawsuit, which involved four transplant patients between 1996 and 1998, the University of Illinois Hospital approved the settlement, which does not require it to admit or deny guilt. Pollak received a quarter of the settlement proceeds, and his lawyers were paid nearly $300,000 by the university. The $2.3 million settlement by the hospital was seen as a victory by prosecutors.

Patrick Fitzgerald, JD, U.S. attorney for the Northern District of Illinois, released a statement saying, "This settlement for twice the amount of actual damages sends a clear message to health care providers that they will be held accountable for defrauding government payment programs. By falsely diagnosing patients and placing them in intensive care to make them appear more sick than they were, patients eligible for liver transplants were placed ahead of others who were waiting for organs in the transplant region."

The University of Illinois Hospital confirms the settlement amount, underscoring that the agreement does not include any admission of guilt. The hospital also confirms that the physician is continuing a separate legal action alleging he was improperly forced out of his position.

"The medical center disputes all the allegations and claims made in the government's complaint in the civil action," the hospital's statement says. "With respect to the legal actions filed by one of our faculty members related to his employment, these are allegations only, and the university intends to contest them vigorously in court. As a

matter of policy, the university does not discuss underlying personnel issues in public, nor respond to litigation except through the legal process." ■

Error reporting increases, as does the risk to seniors

More than one-third of hospital medication errors that reach the patient involve seniors, making them an especially vulnerable population in U.S. health care facilities, according to the most recent data on adverse events collected by the United States Pharmacopeia (USP), a nonprofit organization in Rockville, MD.

The group's fourth annual national report summarizes the data collected by MEDMARX, the anonymous national medication error-reporting database operated by USP. The data show a significant increase in the number of errors reported — up 82% over the previous year — but that is a positive trend that indicates more diligent reporting and not necessarily any increase in the number of errors, says **Diane Cousins**, RPh, vice president of the Center for the Advancement of Patient Safety at USP. "We are seeing a strong upsurge in the number of medication errors in the database," she says. "This increase is a positive step toward identifying and eliminating medication errors and ensuring the safety and well-being of all hospital patients."

Cousins says the latest report is based on 192,477 medication errors voluntarily reported by 482 hospitals and health care facilities nationwide. MEDMARX is the nation's largest database of medication errors, containing more than 530,000 released records and by the end of the third quarter of 2004, she notes that the number of records in the MEDMARX database will approach 1 million.

"The report data revealed that more than one-third of the medication errors reaching the patient involved a patient aged 65 or older," she says. "As the senior population continues to increase, USP is calling for hospitals to focus on reducing medication errors among seniors. Seniors and their families need to become more involved in their care."

Specifically with reference to the senior population, the MEDMARX data report revealed these significant findings:

- A majority, 55%, of fatal hospital medication errors reported involved seniors.
- When medication errors caused harm to seniors, 9.6% were prescribing errors.
- The next most common errors when harm occurred were wrong route (7%), such as a tube feeding given intravenously, and wrong administration technique (6.5%), such as not diluting concentrated medications.
- When considering overall errors including those that did not necessarily cause harm, the most common types were omission errors (43%), improper dose/quantity errors (18%), and unauthorized drug errors (11%).

Cousins notes that the vast majority of reported errors were corrected before causing harm to the patient. However, 3,213 errors, or 1.7% of the total, resulted in patient injury. Of this number, 514 errors required initial or prolonged hospitalization, 47 required interventions to sustain life, and 20 resulted in a patient's death. Compared with the previous year's data, a smaller percentage of reported errors resulted in harm to the patient (1.7% vs. 2.4%).

The latest MEDMARX data report also found that incorrect administration technique continues to be responsible for the largest number of harmful medication errors (6.2%). This occurs when medications are either incorrectly prepared or administered, or both. Examples include not

diluting concentrated medications, crushing sustained-released medications, wrong eye application of eye drops, and using incorrect IV tubes for medicine administration.

Health care facilities attributed medication errors to many reasons and often cited workplace distractions (43%), staffing issues such as shift changes and floating staff (36%), and workload increases (22%), as contributing factors.

A limited number of high-alert medications continue to cause the most severe injury to patients when an error is committed. For example, three of the top medications frequently involved in harmful errors were insulin, heparin, and morphine. ■

Doctors' alma maters may help predict malpractice

Graduates of certain U.S. medical schools are more likely to be sued than others, according to a recent report in a safety journal (*Quality and Safety in Health Care* 2003; 12:330-336).

Researchers merged data on malpractice claims from three U.S. states with physician data to calculate the proportion of graduates sued for malpractice between 1990 and 1997. Schools were identified as high or low outliers according to the number of their graduates who had been sued in the past.

They found that graduating from a medical school whose graduates were often sued significantly increased an individual physician's likelihood of being sued. The researchers did not name the individual medical schools they studied, but they highlight commonalities that risk managers may find useful in looking for the higher-risk physician. When comparing malpractice rates among graduates, high-outlier schools were more likely to be public institutions and tended to be more recently established than low-outlier schools. Schools that were classified as high outliers were likely to remain high outliers over time.

The researchers suggest that there are a number of possible explanations for these findings. They speculate that some schools may provide a lower quality of medical education than others, while certain schools might attract students who are more likely to be sued. The institutional culture of schools may also be a factor, they say. ■

Smallpox immunity may persist from childhood

Health care workers who were vaccinated as children may be protected against fatal smallpox infection even if they declined to participate in recent immunization efforts, according to a recent study.

Researchers report that more than 90% of volunteers vaccinated 25-75 years ago still maintain substantial humoral and/or cellular immunity against vaccinia, the virus used to vaccinate against smallpox. Antiviral antibody responses remained stable between one to 75 years after vaccination, whereas antiviral T-cell responses declined slowly, with a half-life of eight to 15 years.

"If these levels of immunity are considered to be at least partially protective, then the morbidity and mortality associated with an intentional smallpox outbreak would be substantially reduced because of pre-existing immunity in a large number of previously vaccinated individuals," the researchers concluded.

However, even if those previously immunized only were infected mildly during a smallpox attack, they still could spread the disease, so health care workers would need to be immunized to protect patients. ■

COMING IN FUTURE MONTHS

- Physician education programs that work
- Enterprise liability: What you need to know
- The plaintiff who wants 'change' at your facility
- Underwriting obstetrical liability

CE objectives

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

1. Describe legal, clinical, financial, and managerial issues pertinent to risk managers in health care.
2. Explain how these issues affect nurses, doctors, legal counsel, management, and patients.
3. 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.
4. 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

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

1. According to Diane M. Sixsmith, MD, MPH, FACEP, chairman of emergency medicine at New York Hospital Medical Center of Queens, what percentage of all malpractice claims originate in the ED?
A. 5%
B. 20%
C. 40%
D. 60%

2. According to Andrew S. Kaufman, JD, a partner with Kaufman, Borgeest & Ryan, 90% of all ED malpractice claims involve:
A. discharged patients.
B. admitted patients.
C. chest pain.
D. obstetrics.

3. In the guidance for surveyors working for the Centers for Medicare & Medicaid Services, what happens in regard to the Emergency Medical Treatment and Labor Act (EMTALA) when a physician determines that no emergency exists?
A. The EMTALA obligation ends.
B. The screening requirement is met, but EMTALA still applies.
C. The decision has no effect in regard to EMTALA.
D. The decision creates a technical obligation to treat the patient.

4. According to the most recent data on adverse events collected by the U.S. Pharmacopeia, what was the most common type of overall error, including those that did not necessarily cause harm?
A. Omission errors
B. Improper dose/quantity errors
C. Unauthorized drug errors
D. Drug diversion

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

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

Patient suffers from debilitating decubitus ulcers: A $694,000 verdict in Missouri

By **Jan J. Gorrie**, Esq., and **Blake J. Delaney**, Summer Associate
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Tampa, FL

News: While recovering from emergency surgery, a 71-year old patient developed decubitus ulcers acute enough to cause nerve damage and necessitate plastic surgery. The hospital staff and two attending physicians failed to closely monitor the elderly patient during recovery despite his known underlying complications, which included alcohol dependency and heavy smoking. The patient brought suit against the providers for the permanent damage he sustained to the sciatic nerve in his left leg. A jury awarded him $694,000. Most of the damages were attributed to the hospital.

Background: The 71-year-old man was taken to the hospital following an automobile accident. As a result of the accident, he sustained a ruptured spleen, which was diagnosed by the emergency department physician. A general surgeon was called, and the patient underwent emergency surgery to remove his spleen. After successful surgery, the patient developed respiratory and hepatic complications that left him bedridden and mostly unconscious. The complications were in part due the fact that the patient was a heavy drinker and smoker.

The patient was placed in the intensive care unit (ICU), where he was under the care of the general surgeon and an intensivist. While in the ICU, the patient's alcohol dependency caused liver compromise, which resulted in elevated ammonia levels. He was given lactulose to balance the ammonia levels, but it had the side effect of causing severe diarrhea. The diarrhea led to the development of decubitus ulcers, including one stage IV ulcer in the sacral/coccyx area. The ulcer was so acute that it caused permanent damage to the sciatic nerve of his left leg, resulting in the loss of voluntary movement. The stage IV ulcer eventually was treated with plastic surgery, but the nerve damage could not be repaired or reversed.

The patient brought suit against the hospital and his two treating physicians. The plaintiff claimed that the hospital failed to assess him as at high risk for the development of decubitus ulcers despite his underlying conditions and failed to implement a skin care plan upon admission. He also claimed that the hospital should have made certain that he was turned every two hours. The patient further averred that the hospital failed to adequately notify the attending doctors about the progression and severity of the ulcers. As to the physicians, the plaintiff contended that they failed to examine, diagnose, and treat the decubitus ulcers and that they neglected to thoroughly examine the patient's medical records, which included a decubitus ulcer chart.

The defendants argued that the patient's ulcers were not preventable because his alcohol dependency caused poor liver function, which required the administration of lactulose even though it caused diarrhea. They also claimed that the

patient had poor tissue perfusion due to compromised respiration from 40 years of heavy smoking. The hospital further averred that the nursing staff had turned the patient at least every two hours, provided adequate treatment of his condition, and properly notified the doctors of the development of the ulcers. Both physicians claimed that they were unaware of the ulcers while the patient was under their care. The jury awarded the plaintiff $694,000 and assigned 85% of the fault to the hospital, 5% to the general surgeon, and 10% to the internist.

What this means to you: "There are instances where, even with the best nursing care, certain elderly patients will develop decubitus ulcers. However, liability issues involving decubitus ulcers are extremely difficult if not impossible to defend and rarely won in or outside of the courtroom," says **Patti Ellis**, RN, BSN, LHRM, a risk management consultant in Miami.

The patient presented with the classic elements for developing decubitus ulcers — he was elderly, suffered from trauma that required emergency surgery for treatment of a ruptured spleen, had a history of heavy smoking and of alcohol dependency, while he hospitalized developed post-op respiratory and hepatic complications, he was bedridden, had diarrhea, and for the most part was unconsciousness.

"These are most definitely high-risk factors for the development of decubitus ulcers and they seem to have been overlooked in this case. Patients must be taken as they present and realize that some will be more prone to becoming more complex and act accordingly," Ellis says.

The Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations requires a complete and well-documented risk assessment of all systems upon the patient's admission to the hospital.

"Given the patient's history and condition, he should have been identified as high risk for the development of decubitus ulcers," notes Ellis.

The hospital claimed that it documented the patient's condition on a decubitus ulcer chart, although the physicians claimed not to have seen any documentation to that effect.

"Poor documentation is usually a major contributing factor to losing cases like this. Complete and thorough assessment and documentation is a critical component of quality patient care," says Ellis. "Such documentation may offer the evidence needed to show that the health care providers assessed the entire patient and not simply the emergency condition."

Early risk identification and risk prevention are key to appropriate care. Unfortunately, it is not uncommon to see situations where there may be fragmented care, documentation and/or communication regarding skin care assessments, repositioning, and wound care among the health care team.

Hospitals and nursing homes more often than not have the appropriate systems and processes in place for addressing decubitus ulcers. These include the use of nursing assessment tools, flow sheets, written wound-care protocols, posted turning schedules, application of skin protection to pressure points, specialized air beds, and multidisciplinary team rounds.

"However, when these systems and processes are not properly utilized, you're going to have a serious problem. Continuity of care and timely communication between the health care team, principally the nursing staff and physicians, can't be stressed enough. In this particular case, better communication and improved continuity of care would have likely resulted in earlier intervention and perhaps prevented the development of a progressive stage IV decubitus ulcer as well as the subsequent sciatic nerve injury," notes Ellis.

In closing, she says that "in certain settings the reporting of stage IV decubitus ulcers to adult protective services may be required so be sure to check your individual state's requirements."

Reference

• *Zane Murphy v. Lake Ozark General Hospital, William Dryden, MD, and David East, MD,* Camden County (MO) Circuit Court, Case No. CV197-231CC. ■

Teen's undetected spinal fracture leads to paralysis

News: A 16-year-old high school football star was in the back seat of a car when the driver lost control and ran off the road. He underwent emergency surgery at a hospital for a ruptured stomach. However, the treating physicians and staff failed to diagnose and treat his fractured spine. The delay in treatment and failure to immobilize the patient resulted in the teen-ager being permanently paralyzed. The teen brought

suit against the hospital and four treating physicians. Two of the practitioners settled prior to trial for undisclosed amounts. The jury found damages to be $4 million; $400,000 of which was apportioned to the remaining health provider defendants.

Background: The 16-year-old high school football player spent that winter Saturday afternoon hanging out with friends. That evening, several went to a teen dance club. Around midnight, he and his friends left the club. A girlfriend of his was driving, and he was a rear-seat passenger in the car. The car was traveling about 70 miles per hour when the driver lost control of the vehicle and drove off the road. It was a serious crash and a very shaken football player climbed out of the Pontiac sedan. Fearing that the car might be on fire, the young man crawled eight feet from the car. The paramedics found him in the grass at about 12:31 a.m.

He was taken to the nearest community hospital and arrived at 1:15 a.m. The emergency department (ED) staff, attending physician, and radiologist evaluated the patient. While seriously injured, the teen was alert, oriented, and even making jokes. At this time, he had movement in his legs.

The examination revealed that he suffered from a serious abdominal injury. A surgeon, roused from his bed, arrived at the hospital, and surgery was initiated around 3:25 a.m. The procedure concluded at 4:55 a.m., and his ruptured stomach was successfully repaired. After recovery, he was taken to the intensive care unit (ICU).

Several hours later, his second and more serious injury was noted. The teen had sustained an L2 dislocation fracture, described in testimony as "nearly tearing his spine in half." The decision was made to transfer him to a teaching hospital because of the severity of the injury.

When he arrived at the tertiary care facility, the teen could still feel his toes although he could no longer move his extremities. That soon changed, and he has since suffered from permanent paralysis from his waist down. He has returned to school but is in a wheelchair and always will be.

The plaintiff brought suit against the ED physician, radiologist, surgeon, and community hospital. While there were subtleties to each claim, the essence of his complaint was that all the health care providers failed to detect the L2 fracture, and did not protect and immobilize it from causing further injury. The plaintiff cited numerous communication breakdowns between the ED and the radiology department, noting that while the radiologist saw an abnormality in the spine, she did not report it to the other caregivers. The plaintiff maintained that the failure to immobilize his spine caused him to suffer motion injury to it, all of which lead to the permanent paralysis. His best evidence of the timing of the injury was that at the accident scene, and even after arriving at the hospital, he had motion in his legs.

Nine days into trial, the surgeon and ED physician settled for undisclosed amounts. The heart of the remaining defendants' defense went to one simple event — the high-speed crash, which subjected the teen's spine to incredible forces. The radiologist and hospital countered that regardless of their care, it was the wreck that caused the injury. A common theme to all defendants, which was incorporated in the instruction to the jury, was the role of the initial accident. The court's first instruction asked if "the wreck was a substantial factor in causing the injury." In this way, the accident could also share the blame for the teen's paralysis.

The jury found a deviation from the standard of care by all four defendants, including the two settling defendants. The wreck was also found to be a causal factor. As to comparative fault, 81% was assessed to the wreck, 4% to the ED physician, and 5% to the surgeon. To the still-standing defendants, 3% was assessed to the hospital and 7% assessed to the radiologist. Damages were valued at $1.7 million for a life care plan and medical expenses, $1.5 million for pain and suffering, and $800,000 for the impairment. The radiologist was assessed $280,000, and the hospital $120,000.

What this means to you: The ED offers lots of potential for negligence claims. In serious trauma cases, the ED staff frequently knows nothing about the patient, except what the emergency transport provides. Trauma patients often arrive unconscious, incoherent, and near death. Frequently the patient presents with multiple injuries requiring complex care rendered by a variety of personnel who must interact in what is often a time restrained response.

Modern communications and emergency response teams have allowed for the ED to have some advance notice of what's on the way. But until the patient arrives, the preparations are theoretical.

"A detailed assessment upon arrival to the hospital is essential to the establishment of all possible injuries and the implication of those injuries — regardless of the level of the sophistication. Without

an accurate evaluation of the trauma to its fullest extent, the patient may be subjected to additional injury that may in fact be more serious than what has already been sustained," says **Lynn Rosenblatt**, CRRN, LHRM, risk manager, HealthSouth Sea Pines Rehabilitation Hospital in Melbourne, FL.

In this case, the teen was awake on arrival at the ED and able to provide some details of the accident and its aftermath.

"Given the nature of the crash, one of the most common responses is to immobilize the back and neck until any spinal injury has been conclusively ruled out. The narrative does not indicate how the emergency medical squad handled the patient, but back immobilization in serious motor vehicle accident is standard protocol. The transport team was not included as a defendant, so it appears that the lack of stabilization began at the sometime after the patient arrived at the ER," notes Rosenblatt.

The physical assessment indicated that the teen had movement and sensation in his legs upon his arrival at the ED. This may indeed have spoken to the possibility that the paralysis could have been prevented with proper attention to back immobilization. The narrative indicates that the radiologist had reason to believe that there may have been injury to the spine, but did not notify the rest of the response team of that fact, which leads to some question as to the communication lines between the teen's caregivers," says Rosenblatt.

Since they were not notified of this significant diagnostic finding, the other staff was unaware that the potential for permanent injury to the cord existed.

"Any notification of an 'abnormality to the spine' — particularly given the circumstance of the accident — would have triggered very aggressive care protocols including surgical stabilization and administration of steroids in order to minimize injury to the cord," notes Rosenblatt. "Given these facts, it would be impossible to attribute the full extent of spinal cord damage to the to the motor vehicle accident. The manner in which the patient was handled over the course of his surgery and immediate post-surgical recovery now becomes a mitigating factor."

In some jurisdictions, an adverse occurrence that may have caused serious irreparable harm to a patient that could have been avoided, such as the radiologist advising the ED staff of the spinal abnormality, is reportable to the state. There also is a requirement that such incidents are reported to the Joint Commission on Accreditation of Healthcare Organizations as sentinel events. Sentinel events under the Joint Commission standards require root-cause analysis, which is used to scrutinize the mishap to the minutest detail.

A root-cause analysis would be a means to determine what procedures could have been established that would have counteracted the failure of the radiologist to communicate her findings.

"In this case, the triage assessment apparently included the need for radiological studies, but the outcome of that was not reported. The development of assessment tools, which integrate potential injury with identification of signs and symptoms and with diagnostics, can be highly beneficial to an interdisciplinary care of the patient. Policies and procedures that outline time lines and reporting responsibilities between disciplines promote effective communication in an often-chaotic situation," says Rosenblatt.

Keeping in mind that the defendant has no true means to accurately determine what a jury will award, many are willing to negotiate. The root-cause analysis is helpful in determining how defensible the situation is and if mediation would be more prudent. In this case the breech of the radiologist appeared to be the initial weak link. Given the fact that the trauma sustained in the auto accident was an acknowledged causation, the overall award and the contributions of the defendants could have possibly been mediated to a lesser amount. This approach also saves the enormous expense of court preparation and trial, adds Rosenblatt.

Also, peer review of the physicians involved would be appropriate. The radiologist's breech may have been sufficient to warrant disciplinary action and a report to the Board of Medicine. Another aspect is that the settlement of the surgeon and the ED physician may not have been sufficient to cover the jury awards attributed to them. In some jurisdictions under the theory of joint and several liability the remaining two defendants can be held responsible for covering the difference between the settlement amount of the first two defendants and the actual jury award for the entire case.

"This is the type of occurrence that no one would anticipate as it was based on human error, but the consequences were so severe that any failure to protect against a similar happening in the future is a worst type of negligence," concludes Rosenblatt.

Reference

• *Robert Blevins v. Muhlenberg County Hospital, et al.*, Muhlenberg County (KY) Circuit Court, Case No. 99 CI 0492. ■

PATIENT SAFETY ALERT™

A quarterly supplement on best practices in safe patient care

Pediatrics program just the beginning of safety overhaul

Adverse events at Duke University triggered response from CMS

Duke University Health System, in Durham, NC, is taking the opportunity to learn from the errors that may have led to several recent adverse events in its pediatrics department and to use those lessons learned to improve patient safety across the system. Following a well-publicized error on a transplant case in February 2003 and two recent burn incidents involving children, Duke University Hospital is instituting widespread patient safety changes, beginning with its pediatrics department.

The Centers for Medicare & Medicaid Services (CMS) initiated a review involving Duke University Hospital on Sept. 4, after the hospital self-reported an incident in which a premature infant received a burn from heated air in an incubator in its intensive care nursery.

The infant is no longer at Duke and has a favorable prognosis, Duke officials report. CMS directed Duke to make patient safety changes following the Aug. 31 incident. By accepting the plan, CMS continues the hospital's participation in the Medicare and Medicaid programs, pending a regulatory follow-up visit.

This arrangement is in itself unique, noted CMS administrator **Tom Scully** in an announcement released by Duke. "Traditionally, CMS would be issuing notices proposing to revoke Duke's hospital certification, Duke would appeal, and a long, cumbersome process would begin," he said. "Instead, we have avoided that normal bureaucratic dance and engaged in a real workout plan with Duke. This will more quickly improve patient safety — and result in real change at Duke Hospital, which is what this is all about."

This latest incident followed two other reported cases at the hospital involving children this year, including a heart/lung transplant case in February and an accidental flash fire in the pediatric intensive care unit in June that resulted in burns to a child. Duke University Health System president and CEO **Ralph Snyderman**, MD, notes that while the incidents were in different units of the hospital, they all involved children, and together, "they inevitably raise concerns about whether we have a systemic problem."

Accordingly, Duke's response ultimately will include several initiatives, including the first comprehensive review of all pediatric care services at Duke University Medical Center and the development of a new model for monitoring patient safety programs.

"Any performance improvement effort — whether directly related to patient safety or otherwise — needs to be monitored for effectiveness to make sure you fix what you think you're fixing," explains **Gail Shulbey**, MA, RN, patient safety officer for Duke University Hospital. "We also intend to make sure that the lessons learned [in pediatrics] are shared broadly throughout our organization. We will start with pediatrics and then expand to other areas."

Shulbey is the first patient safety officer for Duke Hospital; although appointed in January of 2002, she has been at Duke for 23 years. The health system also has created another new position and is aggressively recruiting for a physician to oversee patient safety across the entire system.

In the summer of 2003, an interdisciplinary team began work on the pilot pediatrics program. Duke Hospital is divided into business lines, or clinical service units, she explains. "One of those is dedicated to children. Within that line, we have a patient safety team that developed the

approach — it consisted of nursing, administration, physicians, pharmacists, and others."

A good deal of initial thoughtful discussion was involved, says Shulbey. "We tried to do a literature search and go down the avenues of proven winners, but I've got to say there's not a whole lot out there. Everybody is still in a learning mode, and we are no different."

Given the lack of formal evidence-based research, the staff began reflecting on its own experiences, she adds. "We did a lot of talking about past lessons learned. We asked, 'What did we miss here?' Then, we sought to structure processes in a way that we would not to miss those things again in the future."

Shulbey says the team is looking at actually doing risk assessments for all bedside procedures, identifying potential failure modes through failure mode analysis, and determining what can be done to avoid those failure modes in the future. These lessons learned will then be used to examine other clinical areas.

"The next step is to look at a given procedure that contained a failure mode and ask where else it is done," she explains. "For example, is it done on adults, too? We'll look for areas where there might be similar 'wins,' as well as areas that might need similar fixes. In other words, we will try as much as possible to capitalize on what appears to be a small area, and share with our sister organizations — and hopefully share with others through professional publications."

The undertaking, at first glance, appears overwhelming, Shulbey admits. "There are an infinite number of procedures. Some things are done once every blue moon, and some we do daily. This is a tough nut to crack, especially in an academic setting." So how does she propose to crack that nut? she asks. "We have to go about it step by step. We have to be patient, to recognize the enormity of our staff, and try to bite off those pieces we can chew, while at the same time not being afraid to look at anything."

The pilot program began in September with the team looking at invasive procedures and pediatric intensive care areas. "I can't say there have been any 'Aha!' moments," Shulbey says. "The biggest thing we need to think about is where, outside of these dedicated areas, are children receiving care? For example, how do we watch what's going on in radiology with children? What are the quality indicators we need to monitor there?"

The pilot program could go on indefinitely, given the large number of procedures involved, she notes. Of course, the system won't benefit until findings are shared. "I would guess it will be a good two to three more months before we do that," she predicts. "We don't want to share before we've got it right in terms of methodology and the actual opportunities for failure that we identify." ■

Duke identifies corrective plan of action for patient safety

In a letter to CMS dated Sept. 21, 2003, **William J. Fulkerson**, MD, chief executive officer of the Duke University Health System, outlined Duke's corrective plan of action for improving patient safety. The following enumerates actions Duke's leaders "are taking or have taken:

- ✔ "Duke Hospital's chief operating officer is being assigned to intensively review all aspects of nursing services, clinical engineering, and other operations that have been identified in recent incidents at Duke Hospital. He will be free — indeed is being encouraged — to investigate any area(s) that he believes might pose a safety problem and implement necessary changes in these operations.
- ✔ "We have established a Pediatric Safety Center. Dr. Karen Frush, MD, medical director for children's services, will lead the center which will carry out a comprehensive review of all pediatric care services delivered across Duke University Hospital. She has full authority to take any steps she and her team deem necessary to protect the safety of our pediatric patients. Dr. Marlene Miller, MD, who has earned a national reputation in the field of quality and safety initiatives at the Johns Hopkins Children's Center, will serve as consultant to Dr. Frush and her team.
- ✔ "Looking beyond the care of children and Duke University Hospital specifically, we have established and are currently recruiting a patient safety officer to oversee care across the entire Duke University Health System. This is a new position which will report directly to the Patient Safety and Quality Assurance Committee of the Health System Board of Directors and to the President and CEO of the Health System.
- ✔ "The Health System Board of Directors will invite outside experts to serve on its Patient Safety and Quality Assurance Committee. Joe and Terry Graedon, the syndicated columnists who host "The People's Pharmacy" on National Public Radio and are well known for their advocacy of patient safety, already have agreed to serve on this important committee." ■