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Duke transplant error spurs hospitals, risk managers to reassess programs

Transplant trouble reveals shared weaknesses

Hospitals across the country are taking a hard look at their processes to spot weaknesses similar to those at Duke University Hospital, where a patient died because of a lack of redundancy in the system for matching donated organs.

The lessons from Duke, in Durham, NC, stretch far beyond organ transplants, says **Doug Campbell**, assistant vice president of operations and risk management at Robert Wood Johnson (RWJ) University Hospital in New Brunswick, NJ. Campbell's hospital responded quickly to the Duke incident by revising its own transplant system, adding another redundant step in which clinicians will verify the blood-type match between the donor organ and the recipient. He suggests that risk managers consider this a good reason to take a second look at many similar processes beyond just transplant surgery.

The fundamental error appears to be one that could happen in a wide range of clinical scenarios, he says, so don't assume your systems are adequate.

"You need to take a hard look at this procedure and any other procedure with the potential for a catastrophic mix-up like this, like site verification," Campbell says. "Assume that your steps aren't good enough, and challenge yourself to make them better."

Fifth protocol added as safety measure

Duke's nightmare began when a surgeon misinterpreted a message from the organ-donor bank. The surgeon mistakenly thought 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 of donated organs. **(See p. 39**

for a thorough description of how the mix-up occurred.)

The risk manager at Duke did not respond to repeated requests for an interview, but the hospital has released several statements describing the incident and the results of its root-cause analysis. Lack of redundancy was the critical failure, the hospital reports, so Duke has 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 from **William Fulkerson**, MD, CEO of Duke University Hospital.

Transplant programs across the country responded to news of the event in much the same way, says **Ronald Freudenberger**, MD, FACC, director of heart failure and transplant cardiology at RWJ University Hospital. As soon as word of the Duke incident was made public, and before much information was available about how it happened, Freudenberger called a multidisciplinary meeting to assess the risk of a similar incident occurring at RWJ.

"We had the same response that anyone would have when you witness a terrible car accident," he says. "We were stunned and deeply saddened for those involved at Duke. It's a reminder that these medical mistakes can occur to anyone. It scares us all when a mistake like this happens."

The meeting at RWJ included the risk manager and anyone who had anything to do with transplant surgeries, from surgeons and nurses to social workers and rehab therapists. Twenty people brainstormed about what they knew of Duke's incident and how it could be prevented at RWJ.

"Nobody wanted to be the next Duke, of course," says Campbell. "We thought we had a fine system in place already, but I'm sure Duke thought the same thing."

Freudenberger says the group went through the transplant process step by step and identified four points at which the blood-type match is confirmed. The first is when the donor's local organ-procurement organization checks the blood type; the second is when the national organ-procurement system checks the organ's type against its database of recipients; the third occurs when the RWJ transplant coordinator is called about the transplant and checks for compatibility; and the fourth is when the transplant surgeon confirms the match before proceeding with surgery.

The system used to stop there, but the RWJ team decided to add a fifth protocol: Two nurses are now required to check blood-type compatibility in the operating room as the surgery begins. This is similar to the standard requirement that nurses confirm the blood type before infusing blood products. The group was enthusiastic about implementing the additional step because the Duke incident scared everyone, Freudenberger. Without that wake-up call, the team probably would have resisted adding another step to the process, he says.

To implement the system, RWJ called a meeting of operating room staff, nurses, and administrators to work out the details of exactly how the fifth protocol would work. They developed a new form for the nurses to use, and the new process

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was implemented at RWJ only two days after they first heard of the Duke incident.

Campbell says the additional protocol for transplant surgery makes everyone at RWJ more confident that they will prevent such tragic accidents from occurring, but he says risk managers should take away a bigger lesson about the dangers of complacency. You can never assess your systems and processes too much, he says, and you should remember that sometimes a seemingly obvious and basic step — like confirming a blood-type match — can make a difference between life and death for a patient.

Freudenberger agrees, saying the incident drove home for him the importance of having multiple levels of checks and balances, as well as a written protocol that everyone must follow.

"There's no way to know when you have enough checks and balances, but it's hard to have too many," he says. "Hopefully, we will never find out we have too few." ■

Error occurred when confirming blood type

Sentinel events like the transplant error at Duke University Hospital in Durham, NC, often can be traced to a simple human failing by one individual, but risk managers look beyond that to ask how the system allowed the error to go undiscovered. At Duke, the problem was a lack of redundancy.

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 a heart became available for transplantation, Carolina Donor Services (CDS) found two potential recipients at Duke, both of whom had blood type A, the same as the organ. CDS contacted a Duke surgeon on call for adult heart transplantations. When the surgeon 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 at Duke. CDS maintains that it gave Jaggers all the necessary information about the organ, including blood type. Jaggers then told Carolina Donor Services that the first potential recipient was not medically ready for the transplant, but that another pediatric patient — Jesica — was a candidate. Because the original offer was for only a heart but Jesica also needed lungs, the donor bank had to check on the lungs' availability before giving Jaggers an answer about whether Jesica could have the heart.

Jesica, however, was not the second potential organ recipient with type A blood that CDS had identified at Duke. Jaggers did not discuss the second potential recipient with CDS because the second potential recipient was an adult, but Jaggers handles pediatric transplants. Jaggers says he inquired about the possibility of Jesica receiving the organs because she needed the transplant badly and he hoped the organs would be a match.

Jaggers gave Jesica's name to CDS, thinking the company would look up pertinent information on the national list of patients awaiting transplants, according to a Duke statement that details how the mistake occurred. The donor bank proceeded on the assumption that Jaggers knew the heart was blood type A, because he had been given that information during the phone call. Jaggers thought the bank would confirm compatibility through its database before getting back to him with an answer.

The donor bank contacted the doctor of the second patient it had identified at Duke, but the organs were not a size match for that patient. CDS then called Jaggers back regarding Jesica, and at this point the crucial misunderstanding was about to occur. The donor bank confirmed that the lungs were also available, which Jaggers took as a confirmation that organs were a match in every way because he thought CDS had checked their database for a blood-type match for the organs. However, this didn't happen, and as it turned out, the organs CDS procured did not match Jesica's blood type. The transplant was set into motion despite the blood-type mismatch.

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

A statement from Duke says, "Jaggers does not recall blood-type matching being discussed with CDS, but does recall the discussion including the donor's height, weight, organ function, and cause of death. Dr. Jaggers assumed that they wouldn't have called back and released the organs if they weren't a match. This was a wrong assumption on his part."

Healthcare Risk Management has obtained a copy of a letter written by **William J. Fulkerson**, MD, vice president and chief executive officer at Duke University Hospital, to Deanna Sampson, director of policy compliance at the United Network for Organ Sharing in Richmond, VA, which oversees the organ transplant system. In the letter, Fulkerson writes, "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 continues: "Duke University Hospital has conducted a thorough root cause analysis of the event and the organ procurement process followed in the pediatric thoracic transplant program. During that review 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." ■

Asking permission when permission isn't required

Physicians acted appropriately when they removed Jesica Santillan from life support without the consent of her parents, according to advice offered by an attorney who says such situations can be difficult for risk managers to handle.

Following a series of tests, doctors at Duke University Hospital in Durham, NC, determined that Jesica Santillan, 17, met the criteria for the declaration of brain death. She was pronounced dead at 1:25 p.m. on Feb. 22, 15 days after an error led to her receiving a heart and lung transplant of the wrong blood type. Hospital spokesman **Richard Puff** tells *Healthcare Risk Management* that she was kept on life support until about 5 p.m. so family and friends could say goodbye.

Here is an excerpt from Duke's statement explaining its decision to discontinue treatment: "Some have asked why other doctors were not brought in to provide a 'second opinion' before Jesica was declared dead. In fact, a second pediatric neurologist from Duke was brought in to confirm death. And medical standards for 'brain death' are clear. If a patient is in a deep coma, a decision about whether to maintain life support might require difficult medical judgments. But Jesica was not in a coma; multiple tests had determined that her brain would never again sustain life. We understand that it is extremely difficult for family and friends to accept the loss of a loved one, but the medical outcome was not a matter of interpretation."

Renee McCormick, a spokeswoman for a charity created to pay Jesica's medical bills, released a statement saying the Santillan family didn't know doctors were going to take the patient off life support and wanted to wait until a doctor outside the Duke system could verify she was brain dead. Though the conflict may have been exacerbated by the mistake that led to Jesica's death, such disagreements are not uncommon.

Duke apparently handled the situation correctly, says **Edmund Gronkiewicz**, JD, a health care attorney with Hinshaw & Culbertson in Chicago. Gronkiewicz could not comment specifically about the Duke incident, but his advice for handling such termination-of-care disputes meshes with what Duke officials say they did. Once the patient meets all criteria for declaring death, the hospital should notify the family that support will be discontinued, rather than asking for permission, he says.

"This can become a problem when you attempt to get permission for something that you didn't need permission for," he says. "If the patient is dead, and you've done everything you're supposed to do to be certain of that, then you stop treating the patient and inform the family. When you go and ask them if you can stop treating the patient, the implication is that the patient isn't really dead."

You're on solid legal footing if you take that approach, he says. That situation is different from others in which the patient does not meet criteria

for death but the family needs to decide whether to continue with extraordinary measures. In those cases, the family must be asked. Confusing that situation with one like Duke faced only burdens the family with unnecessary emotional trauma and increases the likelihood that the family will accuse the hospital of malfeasance.

Even when the facts back up your decision, doctors can be reluctant to fight the family's wishes because the situation is so emotional and sensitive. But Gronkiewicz says risk managers should encourage physicians to approach these situations in the right way so as to avoid creating unnecessary problems with the family.

The manner in which you present the situation to the family can make all the difference. Once the patient is declared dead, the best strategy is to inform the family as firmly and clearly as you would in any other death situation, Gronkiewicz says. In other words, tell them the patient is dead, not that you've decided to stop trying to save her. Don't try to couch the news in overly clinical terms that can confuse the family. State clearly that the patient has died, not that there is little hope for recovery.

However, you still should be as sensitive to the family's emotional needs as you can be without backing down. Keeping the patient on life support for some time so family members can gather and say goodbye, as Duke did, is a good idea, Gronkiewicz says.

"There's no harm in giving the family time to accept the situation," he says. "But don't imply that you're waiting for them to make a decision. You can make clear that the measures will be discontinued but you don't mind accommodating the family's needs." ■

When it comes to choosing counsel, give it some push

Choosing legal counsel for your organization is a big responsibility, whether you're entirely responsible for the decision or just one of several people with input. A great deal of money rides on the decision, along with the outcome of future malpractice suits and other legal matters.

Risk managers too often are reluctant to ask the hard questions when choosing legal counsel, and then they sometimes don't establish a good working relationship after the decision is made, say two attorneys who have seen such mistakes made over and over again. The selection process and the ongoing relationship depend on a constructive give and take, a bit of push and pull that ensures both parties get the information they need, says **E. Michael Kelly**, JD, a partner in the law firm of Hinshaw & Culbertson in Chicago. Kelly, who specializes in health care defense, says he encourages risk managers to ask the hard questions when choosing legal counsel.

You just might get what you pay for

It is crucial to get the right fit with your institution, he says. Avoid the shortsighted mistake of focusing entirely on money.

"There has been a movement in past years away from going for the cheapest lawyer you can find," he says. "In the '90s, that was kind of the standard, and hospitals would go to small start-up firms simply because of the rate. You tended to get exactly what you paid for in litigation."

Kelly may be biased in favor of larger firms, because Hinshaw & Culbertson is a major player, with 400 lawyers in 21 offices nationwide. But he makes the point that with so much riding on your work with legal counsel, it's rarely a good idea to skimp on quality for immediate savings. Besides, he says, even the most expensive health care defense is a bargain when compared to other legal arenas.

"Getting good counsel is not as expensive as you might expect," he says. "The upper rate in Chicago is $275 per hour, $300 tops, so even the best health care counsel is a bargain compared to what corporate attorneys get. The defense bar as a whole never charges rates comparable to what you see in a lot of corporate work."

Costs will always be a concern when establishing a relationship with an attorney, so you should thoroughly discuss fees up front, says **Patsy Powers**, JD, chair of the health care working group with Waller Lansden Dortch & Davis in Nashville, TN, another heavy hitter in health care defense. Powers says you shouldn't be shy about discussing fees in detail when interviewing lawyers or firms. You should clearly understand the hourly rate, what expenses will be charged, and how you will be billed.

"Service expectations also should be laid out clearly up front," she says. "Discuss whether you prefer written correspondence, e-mail, or phone calls when the attorney needs to contact you.

Within reason, you should expect the attorney to provide the service in the way that works best for you. Don't hesitate to express your needs and see if the firm can meet them."

Powers advises interviewing attorneys just as you would conduct a job interview — by doing your own research first, preparing questions, and expecting the interviewee to present a good case for why he or she is better than the others. Ask the hard questions, like why an attorney can do a good job for you if he or she has never handled this type of case before.

"If it's a big thing like government compliance or a big-ticket malpractice case, you don't want it to be their first time," she says. "You don't want people learning on your nickel."

The interview is off the clock, so don't rush through it. Take your time and enjoy one of the few non-billable conversations you'll have with an attorney.

Good relationship will include some conflict

Kelly and Powers offer this further advice on how to select legal counsel and maintain a good relationship:

• The risk manager must be involved in the selection process.

Even if a vice president or someone else is responsible for making the final decision, the risk manager must be intimately involved in choosing the legal counsel. The attorney will work closely with the risk manager, so personal rapport between those two people is important. Aside from all the objective measures of an attorney's credentials, the personal interaction can make or break a relationship. You don't want to end up with a situation in which you know the attorney's credentials are superb but you hate picking up the phone to talk to him or her.

"We can sometimes tell up front that we will or won't work well together," Kelly says. "Personalities are different, and you want to know right away whether you're going to mesh well."

Don't be offended if the attorney says he won't like working with you, and don't be shy about saying the same thing. Kelly says the interview process is like dating: "If it's not a match, just move on. Don't try to ignore the differences or think you can change the other person."

• Ask for referrals from friends, but be cautious about relying too much on them.

As with many cases in which you're hiring someone, a referral from a friend can cut through a lot of the preliminary research. Ask colleagues who they have used for similar work and how satisfied they were. "But be wary of hiring someone just because they're friends," Powers says. "Just like specialists in medicine, lawyers tend to develop areas of expertise, and that area has to match with your needs."

• Seek an attorney with whom you can feel confident and open.

Powers says you must feel comfortable enough with your attorney to be forthcoming with information. "Attorneys see a lot of clients who only give us part of the information we need. That restricts what we can do for them, and they don't get the best service they could get."

• Look for fellows in the American College of Trial Lawyers (ACTL), but don't be surprised if they're in short supply.

The gold standard when seeking defense counsel is the senior attorney who is a fellow in the ACTL, arguably the most prestigious legal organization in the country, Kelly says. Only about 4,000 lawyers are awarded the fellowship, after a secret nomination process and a thorough investigation.

"In virtually every jurisdiction, the top lawyers are fellows. But you can't insist that your counsel be a fellow, because no more than 1% of every state's bar can be admitted to the college," Kelly says. "If you find that credential, it's important. Risk managers often don't recognize its significance."

• Ask about the attorney's relationship with others in the business.

"All politics is local and all trials are local," Kelly says. "How many people can this lawyer call and get involved in the case that the risk manager can't? Does he know the right people and will they return his calls?"

In particular, a defense attorney's relationship with expert witnesses can be crucial. Getting the right experts can take a case from being out of control to being manageable, Kelly says.

• Determine what level of dedication you will receive from the attorney.

When working with a law firm that has dozens or even hundreds of attorneys, you need to know up front who will actually be handling your legal matters. It may not be reasonable or cost-effective to demand to that the attorney you originally speak to will handle every single thing for you, but you should understand who will. And the work shouldn't stray too far.

"You don't want your work assigned almost at random to any of the attorneys in the firm," Kelly

says. "Even with 400 attorneys, we normally will have only a handful of lawyers who work with any one hospital. The familiarity is very important. The five attorneys assigned to the hospital will get to know the hospital and won't have to reinvent the wheel every time."

• Strive for a long-term relationship.

The working relationship will improve over time if you've chosen good counsel and you work constructively with them. Switching counsel too often will cost you considerable time and money because of the work required in selecting a firm, and the quality of the legal advice probably will be lower than if you maintain a good relationship with one qualified firm. The best attorneys or firms will expect a commitment of both longevity and work volume from you, at least verbally, before agreeing to represent you.

Commitment has to work both ways

"If the hospital is not willing to commit substantially for five years, I'm not interested," Kelly says. "There's too much effort involved with establishing the relationship. If you're going to move on in a year, it's not worth starting."

A commitment to a certain volume of work also is important to the attorney because he or she may have to bump other long-term clients to make room for you. Avoid entering a relationship just to see if you like the attorney. Remember that if you're not willing to commit to the attorney, there's no reason for the attorney to commit to you. Do the research and then make a decision.

"Besides, do you want to hand over 10 or 15 cases that you just think might be good?" Kelly asks. "Do the courting before the marriage. Divorces are painful."

• Expect conflict, and worry if there is none.

Your legal counsel should be providing the best advice possible, even if that means disagreeing with you and pushing you to do things differently. The disagreement might be unpleasant sometimes, but it might also be necessary.

"If you always get along with your defense attorney, if you never have any difference of opinion, if you always have a smooth relationship, fire him or her," Kelly says. "Your attorney's not doing his job. There has to be some creative tension in the relationship."

Some people are comfortable keeping things strictly businesslike and disagreeing constructively, but for others, a cordial disagreement is not possible without a strong personal relationship. Powers says you need to know which kind of relationship you have. "Otherwise, you get into situations in which the client says OK to whatever you advise, then they hang up the phone and do something completely different."

• Don't require your attorney to rubber-stamp your decisions.

The attorney is technically your hired help, but you won't get much from the relationship if you just want a lawyer's seal of approval for decisions you've already made. "If they want someone to nod their head and do the paperwork, they don't need a good attorney. They need a good assistant," Kelly says. "It always amazes me when people look shocked that I'm offering a point of view different from what they just said."

• Expect your attorney to try new things.

Maintaining the status quo should not be your attorney's goal. After all, you could probably do that on your own or with less expensive counsel. Your attorney should be looking for ways to improve your situation, and you should be willing to hear the new ideas.

"Initially, what I say might hit your ear funny, but that doesn't mean I'm right or wrong," Kelly says. "It does mean I'm doing my job, and you should take it that way even if we end up not going that route in the end."

• Look for a proactive attorney.

Your legal counsel should be contacting you once in a while with new developments or suggestions, rather than just waiting for you to call with a problem, Kelly says. If there is new research that affects how an ongoing case should be handled or if it can be useful your efforts to reduce liability risks, the attorney should be savvy enough to know about the development and then mention it to you.

"The harshest thing I can say about an attorney is that they're phoning it in," Kelly says. "This is not passive work. Expect them to do their job."

• Don't choose an attorney who's willing to fight if you're not.

"If you want to settle all your cases, you don't need me. You might not even need a lawyer and should just get a good bank," Kelly says. "If you want to settle all your cases and act like an ATM that dispenses money when plaintiffs ask for it, that's your decision, but you don't need me around. We won't get along."

• Remember that the attorney must ask a lot of questions to do a good job.

Risk managers sometimes suspect that an attorney is just trying to boost revenue by asking

a lot of questions, but Powers says that is very rarely the case. The attorney must gather substantial background, particularly with a new relationship, in order to proceed in a helpful way.

• **Expect a lot from your lawyer.**

If you need something by 5 p.m. tomorrow and the lawyer has all the necessary information, the answer to your request should be an almost automatic yes, Powers says. If he or she doesn't have the necessary information, the attorney should say your deadline can be met as long as you provide the information by a certain time.

But at the same, Powers cautions that clients and attorneys often have different expectations about how long a task will take. The client may think it will take a couple of hours when the attorney thinks it will take a couple of days. It's a good idea to ask about the expected time for completion up front so there are no surprises.

"You might decide to tell your attorney to do it in a couple of hours so your fees are capped at $1,000," she says. "The lawyer might respond that it's possible, or I might offer a compromise where you get something similar that can be done in that time frame."

• **Speak up when you're unhappy with an attorney's service.**

"My favorite client is the one who tells me when he's unhappy," Powers says. "I'd rather have you tell me there's a problem than to go on and let our relationship deteriorate." ■

Reader Questions

Falls are an RM's business, not the custodial staff's

Question: How much should our risk management department take responsibility for preventing slips and falls in the facility, as opposed to letting environmental services handle that issue? I know we're responsible for any resulting litigation, but shouldn't prevention really be their job, not mine?

Answer: You may not be responsible for cleaning up the wet floors and repairing the broken door frames, but the ultimate responsibility for preventing slips and falls should rest with your department, says **Marva West Tan**, RN, ARM, FASHRM, a risk management consultant in Marietta, GA.

Don't make the mistake of thinking that all, or even most, slips and falls can be attributed to poor housekeeping. Slips and falls can be related to clinical as well as environmental factors. Tan says slips and falls are typically one of the most frequent causes of general and professional liability claims within an institution, as well as a factor in significant morbidity and mortality in older patients, so that means they fall squarely within the risk manager's purview.

"Even though these claims are generally not of a high severity, slip/fall prevention should have high priority in your institutional patient safety program," she says. "For a comprehensive fall prevention program, risk management should partner with nursing, rehab, pharmacy, and environmental services, as each service has expertise and a role to play in reducing unexpected incidents and injuries." ■

HHS: Litigation crisis worse, many lawsuits unfounded

Problems associated with medical litigation have significantly worsened in the past year, according to the Department of Health and Human Services (HHS), which says the spiraling cost of insurance for health care providers is impairing patients' access to health care, as well as the cost and quality of care.

In a report on the problem, HHS says "the crisis has only worsened, in both scope and intensity" since its similar report about a year earlier. "More doctors, hospitals and nursing homes in more states are facing increasing difficulty in obtaining insurance against lawsuits, and as a result more patients in more states are facing greater difficulty in obtaining access to doctors," the report concludes.

The report finds dramatically better situations in states that have enacted reforms in their legal systems. However, it says, the crisis is having repercussions throughout the nation's health care system. One-third of hospitals saw an increase of 100% or more in liability insurance

premiums in 2002, according to the report. And over one-fourth of hospitals reported either curtailment or complete discontinuation of a service as a result of increasing liability premium expenses. The report also contains numerous documented accounts of physicians who have had to close their practices and services that have been shut down because of the crisis.

In 2001, the highest premiums charged to specialists in states without meaningful noneconomic caps had increased by 39%. Since that time, using the same measure, premiums in these states have gone up an additional 51%. Thus, on this basis, specialty premiums have almost doubled in two years.

The main factor causing the crisis is the rise in mega-awards and settlements, particularly for non-economic damages. New data in the report show that the number of payments of $1 million or more reported to the National Practitioners Data Bank (NPDB) has grown rapidly in the past seven years, not only in crisis states such as New Jersey, Pennsylvania, and Ohio, but nationwide. Between 1991 and 2002, the number of payments each year of $1 million or more that were reported to the NPDB increased from 298 to 806. (The new HHS report can be found on the Internet at http://aspe.hhs.gov/daltcp/reports/medliab.pdf and http://aspe.hhs.gov/daltcp/reports/medliab.htm.)

The Coalition for Affordable and Reliable Health Care (CARH), a national organization fighting medical lawsuit abuse, praised the report, particularly its point that frivolous litigation continues to drive up liability costs and has resulted in the loss of access to some health care services. CARH chairman **John Thomas** says the study is proof "that most spectacular jury awards of non-economic damages in medical cases are simply a huge payday for personal injury lawyers." He says the report "confirms what those of us on the front lines know, that the personal injury lawyers and their abuse of the legal system are preventing access to care and taking billions of dollars out of our health care system, both tax dollars and those paid by employers and consumers for health benefits and services."

CARH supports recent efforts by President Bush to cap non-economic damages at $250,000 and to limit attorneys' fees, as does the American Medical Association (AMA). Six more states are now in a crisis regarding liability concerns, according to a new AMA analysis. The AMA says Arkansas, Connecticut, Illinois, Kentucky, Missouri, and North Carolina are the latest states where the current liability system is adversely affecting patient care. The group's recent announcement brings the total number of states in crisis to 18, the AMA said. A June 2002 AMA analysis had previously cited Florida, Georgia, Mississippi, New Jersey, Nevada, New York, Ohio, Oregon, Pennsylvania, Texas, Washington, and West Virginia as states in crisis.

Obstetricians quit delivering babies

More than 5% of Arkansas physicians reported in a recent survey that they have been forced to reduce or discontinue one or more medical services in the last two years due to rapidly increasing medical liability premiums, the AMA reports. Because of a legal climate making $1 million-plus jury verdicts and settlements more common, an increasing number of Connecticut obstetricians are no longer delivering babies, and premiums for neurosurgeons and other high-risk specialists are more than $100,000. In Illinois, where the state Supreme Court has overturned medical liability reforms on three separate occasions, health clinics, hospitals, and small towns are in jeopardy because of physicians no longer performing certain procedures such as brain surgery and delivering babies. High-risk specialists in Kentucky, including emergency room physicians and general surgeons, saw increases in their liability premiums last year of between 87% and 200%. Nearly one-quarter of the state's physicians say medical liability concerns are making them consider leaving the state.

Jury awards are increasing at an alarming rate, with top awards ranging from $4.5 million to $15 million in 2001. AMA president **Yank D. Coble Jr.**, MD, says legislative action is necessary to protect the nation's health care system against runaway lawsuits.

"While lawmakers debate the merits of medical liability reform, their delays are putting patient care at serious risk," Coble says. "The AMA always has held that patients who have been injured through negligence should be compensated fairly. Unfortunately, the current liability system has failed patients. Our system has evolved into a lawsuit lottery where select patients and their lawyers get astronomical awards, and many patients suffer access-to-care problems because of it." ■

Twenty percent of hand surgeons admit to error

One-fifth of hand surgeons admit they have operated on the wrong site at least once in their careers, according to a new survey. But at the same time, they report that a campaign begun in 1998 by the American Academy of Orthopaedic Surgeons (AAOS) to prevent such errors may be showing good results.

Eric G. Meinberg, MD, and **Peter J. Stern**, MD, both surgeons at the University of Cincinnati College of Medicine in Ohio, conducted the survey (*J Bone Joint Surg* 2003; 85-A:193-197). Twenty-one percent of the 1,050 hand surgeons surveyed said they had operated on the wrong site at least once in their careers, and one surgeon confessed to doing it three times. About two-thirds of the errors involved surgery on the wrong finger. Others involved the wrong hand or wrist.

Though wrong-site surgery accounts for only a small percentage of all orthopedic malpractice claims, the researchers say legal claims against orthopedic surgeons account for around 10% of all medical malpractice claims. Plaintiffs win almost all of the wrong-site surgery cases. The researchers call such cases "legally indefensible."

To reduce the incidence of wrong-site surgery, the AAOS in 1998 launched a campaign called "Sign Your Site," suggesting that surgeons write their own initials on the correct surgical site before the procedure begins. About 70% of orthopedic surgeons have heard of that recommendation, and 45% have adopted the practice, the survey found. General surgeons and plastic surgeons who performed hand surgery were less likely to have heard of the "Sign Your Site" campaign. ■

Smallpox vaccination: Is your plan in place?

With the escalating threat of biological warfare against the United States, hospitals must be prepared to treat victims of such attacks while protecting employees and patients. To respond to this need, American Health Consultants offers **Smallpox Vaccination of Health Care Workers: The Real-World Experience**, an hour-long audio conference on Wednesday, March 26, from 2-3 p.m., EST.

Whether you are just beginning your smallpox vaccination program or expanding it, this audio conference will provide the latest strategies and information you need to ensure the smooth management of your program. Learn about adverse side effects of the vaccine, how hospitals are dealing with compensation and liability issues, and screening issues for health care workers who have immunocompromised family members.

The program will be moderated by **William Schaffner**, MD, chairman of the department of preventive medicine at Vanderbilt University Medical Center in Nashville, TN. An award-winning epidemiologist who is overseeing a volunteer smallpox vaccine study at Vanderbilt and who has seen actual cases of smallpox, Schaffner began his career as a medical detective in the CDC's Epidemic Intelligence Service.

Other program speakers include:

• **Kathy Emanuelsen**, MEd, RN, director of occupational health services for Hartford (CT) Hospital, an 800-bed acute-care facility. Emanuelsen and her staff were among the first in the nation to create a smallpox vaccination clinic. She will share how they started the program, briefed staff, counseled volunteers, and successfully managed difficult clinical and administrative issues.

• **Allen Craig**, MD, is state epidemiologist and director of communicable and environmental disease for the state of Tennessee in Nashville. He will discuss vaccination efforts in his state, education for health care workers and facilities, and steps to take for vaccinees before, during, and after inoculation.

Educate your entire staff for one low fee including 1 hour of CE, CME, or Critical Care credits for all attendees. You may invite as many participants to listen as you wish for the low fee of $299. Information on obtaining audio conference instructions and continuing education forms will be included with the confirmation notice, which will be mailed upon receipt of registration. Your fee also includes access to a 48-hour replay following the conference and a CD recording of the program. For more information or to register, call customer service at (800) 688-2421 or contact us via e-mail at customerservice @ahcpub.com. When ordering, please refer to effort code **78981**. ■

Physicians are practicing more defensive medicine

A new survey of physicians, nurses, and hospital administrators suggests that malpractice concerns are leading to the practice of more and more defensive medicine. Large numbers of medical doctors report that they order more tests, refer more patients, prescribe more medication, and suggest biopsies more often than is necessary because of concerns about malpractice.

Large majorities of physicians, nurses, and hospital administrators say they believe that defensive medicine leads to provision of unnecessary or excessive care. Most doctors say fear of liability discourages open discussions of ways to reduce medical errors and is a primary reason why hospitals do not share the results of inquiries into patient injury cases. Large majorities of doctors and hospital administrators do not trust the current justice system to achieve reasonable results, and large majorities of doctors, nurses, and hospital administrators favor replacing the current lay court system with special medical courts staffed by medical experts.

Those are some of the results of a nationwide Harris Interactive survey of 300 practicing physicians, 100 hospital administrators, and 100 nurses in March 2002. The survey was conducted for Common Good, an organization that advocates reform of the civil justice system, including malpractice reform.

41% of docs prescribe drugs unnecessarily

The survey found that, because of the fear of liability, 79% of physicians say they order more tests than are medically needed, 74% of physicians say they refer patients more often than they would if based only on their professional judgment, 51% of physicians suggest invasive procedures such as biopsies more often than they would if based only on their professional judgment, and 41% of physicians prescribe medications more often than they believe is medically necessary.

Overall, 94% of physicians, 66% of nurses, and 84% of hospital administrators say they believe unnecessary or excessive care is provided because of the fear of malpractice. The survey also found that 43% of medical doctors now practicing say they have considered leaving medicine because of the malpractice liability system. Furthermore, most physicians (59%), but only minorities of nurses (22%) and hospital administrators (25%), say they believe fear of liability discourages medical professionals from thinking of and discussing ways to reduce medical errors.

Only small minorities of physicians (17%) and hospital administrators (28%) — but almost half (48%) of nurses — say they feel they can trust the justice system to achieve reasonable results. As a result, very large majorities of doctors (94%), nurses (75%), and hospital administrators (81%) favor medical courts "presided over by independent medical professionals and other experts." ■

CE instructions

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. ■

COMING IN FUTURE MONTHS

- Hospital spends $50 million to improve patient safety
- Risk to your hospital when doctors go bare
- Med students doing pelvic exams: Risky business?
- Slips and falls should be major focus
- Designing an EMTALA plan that works

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

Please review the text, answer the following questions, check your answers against the key below, and then review the materials again regarding any questions answered incorrectly. To receive credit for this activity, you must return the enclosed CE evaluation in the enclosed envelope at the end of each semester. For further information, refer to the "CE Instructions."
This testing procedure has proven to be an effective learning tool for adults. If you have any questions about the new testing method, please contact customer service at (800) 688-2421.

13. Robert Wood Johnson University Hospital added another step to its organ transplant process to ensure that the organ's blood type matches the patient. State where this "fifth protocol" occurs.
A. At the organ donor bank
B. During the initial phone call to the surgeon
C. At the hospital where the organ is harvested
D. In the operating room, as the transplant surgery is about to begin

14. Identify which of the following statements is true in regard to the transplant error at Duke University.
A. The surgeon admits to making the crucial error, but the hospital also says its confirmation process was inadequate.
B. The surgeon admits to the error, and the hospital accepts no responsibility.
C. The hospital takes all responsibility for the error, and the surgeon denies making a mistake.
D. The root cause analysis did not determine that there was any failing by the hospital or the surgeon.

15. Identify which statement is correct in regard to discontinuing life support when a patient meets all reasonable criteria for declaring death, according to **Edmund Gronkiewicz**, JD, a health care attorney with Hinshaw & Culbertson in Chicago.
A. The family must give permission to remove life support.
B. The provider does not need the family's permission to remove life support.
C. State laws will differ on whether the provider needs the family's permission to remove life support.
D. Federal law specifies that the family's permission to remove life support is necessary only when the patient is a juvenile.

16. Select the statement made by **E. Michael Kelly**, JD, a partner in the law firm of Hinshaw & Culbertson in Chicago.
A. Health care defense is usually more expensive than corporate counsel.
B. Health care defense is always more expensive than corporate counsel.
C. Health care defense is less expensive than corporate counsel only in a few areas of the country.
D. Health care defense is usually less expensive than corporate counsel.

Answers: 13-D; 14-A; 15-B; 16-D.

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

Resident performs negligent biopsy and $2.5 million is awarded

By **Jan Gorrie**, Esq.
Buchanan Ingersoll Professional Group
Tampa, FL

News: A woman died following a liver biopsy performed at an outpatient facility by a resident physician. The resident was inexperienced and punctured her lung. Unaware of the injury, the resident and supervising physician left the patient's bedside, and shortly thereafter she aspirated on her own blood and died. Her family members brought suit, and a jury awarded them $2.5 million in compensatory damages.

Background: The 62-year-old Palestinian mother of 10 and grandmother of 25 had previously undergone a successful liver transplant. Several years later, she had abnormal elevations of her liver function. She had undergone liver biopsies in the radiology department under ultrasound guidance without any complications. However, this last time, the biopsy was performed in the gastrointestinal laboratory, where an inexperienced resident fellow performed her biopsy.

Although the facility had a written policy expressly forbidding the performance of liver biopsies on liver transplant patients by inexperienced fellows, the procedure went ahead as scheduled. The resident determined the location of the biopsy using a percussion technique, and he claimed to have confirmed the site by ultrasound measurements. The fellow then inserted the biopsy needle into the patient's side multiple times. The first time, the resident placed the needle though the patient's diaphragm muscle rather than directly into the liver capsule. When he fired the biopsy needle, no tissue was obtained. The applicable standard of care when no tissue is obtained required him to redo the liver percussion to ensure he was inserting the needle into the correct location. But he did not reassess the position of the biopsy needle and removed a piece of the patient's lung.

Following the second attempt, the patient became short of breath. Rather than closely monitoring the patient, the resident and the supervising attending physician left the patient's bedside. Shortly afterward, she suffocated from aspirating her own blood.

Her family, including her spouse, 10 children, and 25 grandchildren, brought suit against the facility for breaching the standard of care. They claimed that had the liver biopsy been performed as prescribed by an experienced fellow or by the attending physician, the procedure would have been performed correctly and would not have resulted in the patient's death. The jury agreed and awarded $2.5 million in compensatory damages.

What this means to you: "No doubt this was a preventable medical misadventure from the start. The fact that this was an elderly woman with a known liver transplant and prior biopsies, with an inexperienced resident fellow performing the procedure with multiple attempts in an outpatient

setting, is like knowing how the story ends without having to read the book," says **Patti Ellis**, RN, BSN, LHRM, a risk management consultant in Miami.

"My first thought is whether or not this patient truly gave informed consent. If it was not disclosed that the resident fellow would be performing the actual procedure, then this was not true informed consent, and both the resident and surgeon, or their employer in this instance, are liable," Ellis says.

"Second, this patient was extremely high risk. Although liver biopsies may be routinely performed in an outpatient setting, in a high-risk patient such as this she might have benefited from an inpatient surgical setting under fluoroscopy. In an inpatient setting, she could have been more closely monitored and would have benefited from the availability of staff to promptly identify and assess her signs and symptoms of a bleed and initiate immediate life-saving intervention, which might have resulted in a much different outcome. I have to ask, where was the patient advocate here?" Ellis asks.

"Third, there's no question that there were breaches in the standard of care. The facility breached [its] own protocol by allowing an inexperienced resident to perform this procedure. The resident breached the standard of care, first by performing the procedure, performing it inappropriately, causing injury to the patient, then failing to identify it and leaving the patient at the bedside. Let us not forget the 'Captain of the Ship' doctrine — ultimate responsibility resides with the attending surgeon. In this instance, the surgeon allowed an inexperienced resident to perform the procedure, failed to properly assess the patient postoperatively, and left the bedside as well," adds Ellis.

"Clearly, this case requires peer review as well as a thorough and well-documented root cause analysis and action plan. And, in some jurisdictions, it may well meet the criteria for reporting as a sentinel event to regulatory bodies. The facility needs to go back and review the protocol and make whatever changes are necessary, including immediate stopgap measures, to prevent a recurrence. Although this case had a tragic outcome for the patient and her family, much can be learned from this. It provides an excellent learning opportunity for attending medical staff, residents, and ambulatory surgical facilities, as well as established risk managers and those new to the profession," concludes Ellis.

Reference

- *Mahmoud Zedan, Executor of the Estate of Fahima Seleman v. The Cleveland Clinic Foundation*, Cuyahoga County (OH) Common Pleas Court, Case No. 374294. ■

Negligent hire, supervision: $850,000 verdict reached

News: After a hospital hired a patient care technician who had a rape conviction, suit was brought against the hospital by a patient alleging sexual assault by the hospital employee. The patient was recovering from surgery when the patient care technician massaged her back and buttocks with lotion. She alleged that in the course of the massage, there had been digital penetration by the technician. After an eight-day trial, the jury awarded the plaintiff $350,000, attributing 25% of the fault to the hospital's negligence and 75% to the perpetrator's wrongdoing.

Background: The plaintiff had a history of eating disorders and laxative abuse, which resulted in damage to her colon. She had undergone an ileostomy and was hospitalized three times afterward to correct problems. She contended that, in the early hours of the morning prior to undergoing additional surgical repair, a hospital staff member sexually assaulted her. She first told her boyfriend, who later that day told a nursing supervisor that the patient care technician had massaged her back and buttocks with lotion. The next day, the hospital was informed that there had been digital penetration during the incident. In the meantime, the hospital employee was not prevented from working.

The patient brought suit against the hospital, alleging that had it not been for its negligent hiring, negligent supervision, and negligent retention of the employee, she would not have been sexually assaulted. The plaintiff found that the employee was on a 10-year probated sentence for molestation of his 16-year-old daughter. The plaintiff contended that the hospital knew this and should have watched him more closely.

At trial, the patient care technician's probation officer testified that he had told the radiology supervisor — the employee's supervisor when first hired — of the conviction. The hospital

contended it did not know of a criminal background when he was hired, even after doing a background check and hearing "glowing" recommendations from former employers. It was not until after he was employed that the hospital learned of the previous conviction. The plaintiff also maintained that there were prior complaints regarding the employee and conscious indifference on the part of the nurses.

The hospital brought the now-former employee into the lawsuit as the responsible third-party defendant. The patient care technician, who was convicted of rape and served time at a local correctional facility, was issued a bench warrant and brought to trial despite having defaulted on answering the hospital's third-party petition. At trial, he made a brief appearance for identification purposes, but never testified.

Plaintiff sought to recover damages for mental anguish and psychotherapy. After eight days of trial, jurors returned a verdict for the plaintiff, placing 25% negligence on the hospital and 75% on the convicted rapist. The total was $850,000.

Post-trial motions will determine whether the hospital is accountable for the full amount.

What this means to you: "The first thing that jumps out in this case is how did an employee who has presumably been hired to work in the radiology department as a patient care attendant [PCA] end up on a patient floor rubbing any patient's back, much less their buttocks," says **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, CHt, director, risk management services, Miami Jewish Home and Hospital for the Aged. "When this was initially reported, it should have raised a big red flag, and risk management should have been notified and conducted an investigation immediately. Additionally, this employee should have been put on temporary leave until the investigation was completed. Depending on the laws in your state, this may come under come under patient- or elder-abuse laws, although you may have the grace period for reporting until your investigation is complete. Also, depending on your state laws, when or if the police are contacted is also an issue for consideration.

"The second red flag in this case is the alleged fact that came out at trial through the testimony of the parole officer. The parole officer made it clear that the radiology department supervisor had been advised of this employee's criminal history — and we have no facts or testimony from the supervisor claiming otherwise. Further, the criminal history revealed that this employee had sexually molested his daughter when she was 16 years old. This means he is a convicted pedophile and, in all states as a result of federal legislation, there is a convicted pedophile registry which is published and readily available to the public. Such a conviction does not necessarily mean a person can't be employed in a health care setting, depending on state statutes, but good risk management and common sense dictate that the person should be hired in a position that had no patient contact," adds Kicklighter. If such a candidate is hired, or where placed if hired, it is an HR/risk and business decision.

This type of risk exposure is not limited to the acute care setting. It could happen in the long-term care setting or any other number of health care settings. The risk management principles are the same as those in which the patient or resident is in the organization's care, control, and custody.

"It is the organization's duty to do a thorough background check on all employees. Even if the state does not require it, it is good business practice to do so. Health care organizations are required to do all kinds of due diligence with businesses and persons with whom they do business; it only stands to reason this would logically extend to personnel. For instance, compliance programs require that we conduct a check to determine whether anyone with whom we contract or otherwise do business with has certain federal sanctions against them. In addition, we are required to conduct Department of Motor Vehicles checks on employees who are on our auto insurance policies. Therefore, if the organization were doing all these checks anyway, to conduct a more thorough background check on employees seems to be an extension of the processes already in place. Thorough background checks would also likely turn up individuals who have had problems dealing with other people's money. This is certainly another significant potential risk exposure to any business if the person is or will be working in a position handling money. A plaintiff could make the case that if an organization is conducting all these other background checks, to not have done the additional background check on this particular employee is negligent," Kicklighter says.

"This is an area where the risk manager should work closely with compliance and human resources/personnel to verify that all prospective employees are appropriately screened

pre-placement and that there is a clause in the pre-hire paperwork in which the prospective employee agrees that if the background check reflects additional or different information from that on the application, the applicant will not be hired, or if already hired will be immediately terminated. This is an area where counsel with an employment background should be consulted for good measure," adds Kicklighter.

"However, one must recognize that unless an organization specifically requests a history check for a longer period of time, the usual background check goes back only seven years. Some convictions are prior to that and will not be reflected on the report unless requested. The other potential problem is if the crime/conviction occurred in another state, it would not appear on a check that is limited to the facility's location. Therefore, the criminal/civil conviction check should be a national check, not just your jurisdiction. However, this may become an expensive proposition if there is not some indication that the more thorough check is necessary," notes Kicklighter.

"Another aspect to consider is the application for consideration of employment. All applications should have a query regarding convictions, both civil and criminal. If the question is answered affirmatively, it warrants the organization's deeper investigation of the circumstances. If the question had been answered affirmatively in this instance and the health care organization didn't conduct an investigation into the particulars, the risk manager should address that lack of procedure, and they should probably engage an attorney at that juncture," states Kicklighter.

"In view of the plaintiff's allegations of prior complaints regarding this employee that were allegedly not dealt with, the risk manager should work with the human resources or personnel department to develop an inservice program for all staff that re-emphasizes how to handle complaints and other infractions of policy, procedures, and standards of care," Kicklighter says.

"In this scenario as presented, the patient did not tell the staff there had been digital penetration until the next day. However, the back rub by a PCA who worked in the radiology department not only should have invoked an immediate call to the risk manager, but in turn, the risk manager should have initiated an immediate investigation that should include interviewing the patient. Had this been done on the day of the report of the back rub, perhaps the additional information would have been shared in a more timely fashion. Although risk management should not make personnel or disciplinary decisions, in this case, had risk management been immediately involved, consideration should have been given to temporary leave or temporarily reassigning the PCA until the investigation was complete," adds Kicklighter.

Reference

- Dallas County (TX) District Court, Case No. 00-09955-F. ■

PATIENT SAFETY ALERT™
A quarterly supplement on best practices in safe patient care

Retained instruments: Rare error or safety concern?

Establish a strategy to make such errors less likely

A paper in the Jan. 16, 2003, *New England Journal of Medicine* has the safety community abuzz; are too many instruments and sponges being left inside patients after surgery?

The paper, widely regarded as the largest and most reliable to date on the subject, reported that such errors occur in approximately 1,500 out of 28 million patients each year. The research was conducted by staff at the Brigham and Women's Hospital in Boston.

The figure of 1,500 was projected from data in insurance records from about 800,000 operations in Massachusetts for 16 years ending in 2001. The researchers counted 61 forgotten pieces of surgical equipment in 54 patients, and calculated that this would translate into a national estimate of 1,500 cases yearly.

"First of all, I think the study was very well done," says **F. Dean Griffin,** MD, FACS, a practicing physician in Shreveport, LA, and chair of the patient safety / professional liability committee of the Chicago-based American College of Surgeons.

"The shortcoming is that all of the patients came from insurance company records, and only dealt with cases that became litigated. You and I know there are more patients [with similar experiences] that didn't sue."

Other observers also have suggested the real number may be higher because hospitals are not required to report such errors to public agencies.

This one shortcoming does not decrease the significance of the study, Griffin says. "It is one of many that come voluntarily from people in medicine that point out problems in quality, to educate our peers so we can do a better job."

Besides, he says, the exact number is not nearly as important as the fact that such errors are being made. "The thing is, one such error is one too many; having an exact number is not that important. We have to do a better job of controlling these errors."

Emergency department key

Perhaps one of the least surprising findings in the study was the fact that emergency department operations were nine times as likely to lead to such errors, given the press of time and the stressful nature of such procedures.

"Your goals may actually be in conflict with safety," notes **James A. Espinosa,** MD, FACEP, FAAFP, chairman of the emergency department at Overlook Hospital in Summit, NJ. "For example, you want to finish on time, so you might do a little less thorough exploration of the abdomen. At the same time, the nurse responsible for checking and counting instruments might be distracted."

Espinosa notes that a number of principles of human performance come into play with such errors. In addition to the aforementioned goal conflict with safety pressures, they include, among others, deviation from nominal work flow and poor coordination across silos. "The more complex the action, the more likely you are to have human performance problems," he notes. "The solution is to build in simplicity."

Complexity clearly is a key problem, adds **Tina Maund**, MS, RN, director of performance improvement at Overlook. "You have multiple technologies at work, very advanced kinds of physical technical procedures being applied, high levels of knowledge, and often high levels of experience being brought to the table," she notes.

"Carrying out a technical procedure at hand using instruments and applying learning and critical thinking [at the same time] is tough."

Griffin agrees. "Technology is growing so rapidly that what we're doing in medicine is increasingly dangerous," he says.

It's important when seeking to understand the causes of these errors that you look beyond the provider, asserts **Marilyn Sue Bogner**, PhD, head of the Institute for the Study of Human Error, LLC, in Bethesda, MD. "The paper examined what other factors there were [in addition to the providers]. That made me feel good," she says.

"We must take a systems approach to error," she continues. "In the context of care, a number of characteristics of defined systems provoke error on behalf of the care provider."

For example, the Boston researchers noted a higher degree of errors for patients with a higher body mass index (BMI). "People never consider the characteristics of the patient — we're always so busy looking at the provider," notes Bogner. "But with obese patients, you have to peel back several vertical inches of fat to get to the area you need to work on, and maybe your vision is obscured."

Even political, regulatory, and legal factors can work their effects down to the provider level, she adds.

Searching for solutions

Given these diverse pressures, how should one approach a strategy to reduce these errors? "First, you have to figure out why the errors happen," Bogner says. "Examine the characteristics of the situation, the patient, and other conditions. Then, what is it about the emergency department that contributes to these errors — time constraints or workloads?" Of course, you also need to talk to the care providers and ask them what the problems are. "Since people understandably don't want to admit to error, ask them about accidents that *almost* happened," she suggests.

"What was the circumstance: the type of surgery, time constraints, and so on? Had the surgeon had any rest, or were there back-to-back surgeries? What time of day was it performed?" Bogner asks.

From there, you can move to potential solutions, such as adjusting staffing or scheduling. Solutions become a bit more problematic if the error stems from the nature of the patient, but even there possible solutions exist. "The researchers talked about using X-rays," she notes. "Maybe that's not necessary for every patient, but you can target obese patients or make an extra special count on people who are larger than the run-of-the-mill patient."

This makes sense conceptually, Griffin says. "Consider the universal precautions we take, for example, in terms of AIDS or hepatitis. Originally, we thought we should treat those patients differently, but the facts are we treat everyone the same; we take the same maximal precaution with every case so as to not have to rely on patient confidentiality issues, and so on; we can just assume everyone has AIDS or hepatitis. In many ways, the universal precaution should apply to this issue; treat everybody maximally, even if the risk is lower. However, that may not be practical."

Since it may be impractical to X-ray the abdomen of every single emergency case after surgery, "you could maybe take a subset," Griffin suggests. However, he recalls a strategy employed by the Mayo Clinic that might be practical.

"In the operating room they built many years ago, there was an X-ray unit incorporated in the doorway, so as the patients were rolled out of the room, it automatically took a picture of them," he notes. "But it's not the standard of care [today]."

Despite the admitted challenges of technology, "this may be an event where technology is an utterly necessary adjunct," Espinosa suggests. "The fact that in the paper the counts were right indicates we may be exploring the limits of human performance." He notes human reliability research that shows people can have difficulty even with a series of simple math questions. "Your mind 'sees' the right answer," he explains. "You can be asked to subtract six from eight, you write down three but you see two."

In some situations, he continues, there is just no substitute for technology. "It would be helpful if there were some way to have a detection system, where all the instruments were tagged in such a way that you could have one sweep of that patient," he suggests. "That would not be the end of the problem, but another way of measuring."

Griffin agrees. "I would hope there would be technology that would provide some type of implantable device in these instruments that would be detected with a probe, but nothing is being done to my knowledge," he says.

Without such a development, Espinosa suggests, the progress that can be made in reducing these errors will be limited.

"Human performance without computer or machine guidance tends to be in errors of parts per hundreds of thousands," he notes. "It's hard

to get past that unless you use very strong technology. So, 50 errors per million is five per 100,000 — it's actually astonishing they can get that low with human performance. To get to parts of tens of millions, you would need much more robust technology."

"Nonetheless," concludes Griffin. "You have to remember to always work toward perfection."

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Pfizer to bar code drugs to reduce dispensing errors

Codes can be read by bar code readers

New York City-based Pharma company Pfizer, Inc. will use a new bar code technology on its hospital unit-dose products in an effort to help reduce dispensing errors at hospitals and pharmacies nationwide. The bar code system — developed in accordance with the new Reduced Space Symbology standards established by the Uniform Code Council (UCC) in Lawrenceville, NJ — allows for each unit of product to be identified by its national drug code, its expiration date, and its lot number in machine and human readable format.

"It is going to improve patient safety, especially dispensing errors, and if we can do it, we should be doing it," says **Rich Hollander,** Pfizer's senior director of packaging services. While the UCC only recently introduced its standards, Pfizer has been working on the problem for two years. "The initial push came through our CEO's office," he recalls. "He asked, 'Why are we not doing something about bar coding — especially on unit doses?' We thought that was a pretty good question, so we began to research what hospitals were looking for, whether there were industry standards, and what we could do about it."

For years, some companies, Merck among them, had been using scanning technology for a single element — the national drug code. So Pfizer began investigating that area, but in talking to hospitals, they found "they couldn't tell us what they wanted," Hollander reports. "The fact was, with very few exceptions, most people were not scanning, but said it would help, and they would love to do it."

Pfizer's due diligence revealed there were no standards governing bar coding. "At the same time, looking at standard linear bar code symbologies, we realized they required a lot of 'real estate,'" he notes. "We would have had to retool our products, which would in turn have decreased production rates. We were willing to do this, but it would have taken a long time."

A couple of key events helped speed the process along. Organizations such as the Food and Drug Administration (FDA) and the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) joined forces to look at preventing dispensing errors, and in August 2002, came out with a white paper calling for bar codes, not only for the drug code, but for the expiration date and lot number (the latter would help with traceability and, if needed, recalls).

"Both [of the new elements] were highly controversial," Hollander says. "After all, opponents asked, how often would you need them?"

However, the paper received a lot of attention. Then, Tommy Thompson, secretary of the Department of Health and Human Services, made a trip to a Veterans Affairs (VA) hospital and saw how they were using bar codes to prevent dispensing errors.

Although that was being done through repackaging rather than on the original product containers, Thompson said it should be considered a benchmark. At his urging, the FDA published a requirement in the Dec. 12, 2002, *Federal Register*.

"Most of the industry was pushing back against this, and saying you did not need the other two elements," Hollander notes. "You didn't have the technologies available to do it, and the size of the packages was also an issue."

At about the same time, the UCC developed its new Reduced Space Symbology standards, calling for the NDC (National Drug Code) to be put on very small packages. "However, you still could not go small enough for 3 cc or 5 cc vaccine vials, or ampules," he says. "With packages that small, nobody knew of a linear symbology that worked."

Pfizer challenged itself to develop one package

configuration that would work without the need to retool product lines, and without compromising the already crowded real estate on the package. "We realized it may be some years before hospital systems can adapt to read them, but we developed a standard we feel will work in any hospital," says Hollander. "We also wanted make sure the human readable quality was just as good." Pfizer introduced its first lot just before the end of 2002. The codes can be read by conventionally available bar code readers. "We've had a lot of favorable comments from hospitals, congratulating us for leading in this effort," he says. "There have been no complaints to date about the human readable aspect."

No data are in yet on error reduction, but Hollander says the NCC-MERP web site (www.ncc-merp.org) contains studies on the VA experience. Pfizer plans to be imprinting on all its hospital unit dose packages by the end of 2003, and on other types of packaging as technology permits. "Ultimately, this system will help reduce dispensing errors, and make sure you are using the right product, at the right strength, for the right patient," he predicts.

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AHRQ unveils web-based medical journal

Focus on medical errors in blame-free environment

The Agency for Healthcare Research and Quality (AHRQ) has launched a monthly peer-reviewed, web-based medical journal that showcases patient safety lessons drawn from actual cases of medical errors. Called *AHRQ WebM&M* (Morbidity and Mortality Rounds on the web), the web-based journal (webmm.ahrq.gov) was developed to educate health care providers about medical errors in a blame-free environment.

In hospitals across the country, clinicians routinely hold morbidity and mortality (M&M) conferences to discuss specific cases that raise issues regarding medical errors and quality improvement. Until now, there has been no comparable national or international forum to discuss and learn from medical errors. AHRQ saw the opportunity to use the web to host an ongoing national M&M conference aimed at improving patient safety by sharing information from anonymous cases.

"The AHRQ WebM&M web site offers the medical community a unique opportunity to learn about patient safety from the experiences of their colleagues across the country and around the world," says AHRQ director **Carolyn M. Clancy**, MD. "The anonymity safeguards will enable physicians to share their experiences without fear of reprisal. Their involvement will contribute to the education of other providers about how to prevent medical errors and improve patient safety."

Every month, five selected cases of medical errors and patient safety problems — one each in medicine, surgery / anesthesiology, obstetrics-gynecology, pediatrics, and other fields, including psychiatry, emergency medicine, and radiology — will be posted along with commentaries from distinguished experts and a forum for readers' comments. Each month, one case will be expanded into an interactive learning module ("Spotlight Case") featuring readers' polls, quizzes, and other multimedia elements and offering continuing medical education credits. Cases are limited to near misses or those that involve no permanent harm.

The web site was developed for AHRQ under a contract to an editorial team at the University of California, San Francisco. The editorial team is led by Robert M. Wachter, MD, associate chairman of UCSF's Department of Medicine and chief of the medical service at UCSF Medical Center. The editorial board and advisory panels include many of the nation's experts in patient safety.

Lucian Leape, MD, a leading patient safety researcher and a member of the AHRQ WebM&M advisory panel, praises the new journal. "To make real progress in patient safety, we have to engage physicians and break down the shame and silence surrounding errors. By presenting real-life cases of medical errors along with dynamic, systems-oriented expert commentaries, AHRQ WebM&M is an ideal way for physicians to learn more about and ultimately improve patient safety."

In its inaugural issue, the web-based journal features cases on a mix-up involving two patients with the same last name in the same hospital room; a mistaken drug administration causing a patient to stop breathing unexpectedly; a procedural mishap requiring emergency vascular surgery; an infusion pump flying into a magnetic resonance imaging machine, narrowly missing a child; and a misdiagnosis of delusions in a man later found to have metastatic brain and spine cancer. ■