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## IN THIS ISSUE



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# Unsafe for every need: Too many details for patient safety goals can be trouble

*Some efforts to comply with goals can backfire*

As hospitals continue their efforts to comply with the National Patient Safety Goals issued by the Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations, some risk management and quality assurance experts are issuing a strong warning: Don't go overboard with your efforts to write new policies and procedures because they can create unnecessary liability risks.

The problem occurs when well-meaning hospital leaders develop overly detailed and prescriptive policies and procedures to ensure compliance with the safety goals, says **Geri Amori**, PhD, ARM, FASHRM, president of Communicating HealthCare, a risk management consulting firm in Shelby, VT, and past president of the American Society for Healthcare Risk Management (ASHRM). Some health care organizations are painting themselves into a corner with these new policies and procedures, she says.

"You create a policy and procedure that nobody can keep up with," she says. "Then you go to court and the attorney says, 'You have a policy and procedure. Why didn't you follow it?' Either you have to make an excuse for not following it or you have to say you didn't know about it. Neither one sounds good in court."

### *Get real and keep it that way*

That's not to say that policies and procedures won't be necessary in your efforts to meet the patient safety goals. It might even be appropriate to develop entirely new policies and procedures. But Amori says you must be careful not to make them so strict that they don't apply to all situations and your staff can't follow them. Policies and procedures should be based on reality, not an ideal, she says.

"I think what's happening is we're getting these new goals but we don't know how to deal with them, so we create more policies and

procedures because that's what we know how to do," she says. "All we're really doing is creating more liability."

## System analysis necessary for safety goals

JCAHO announced the first set of National Patient Safety Goals a year ago and they are in effect through this calendar year. In January 2004 the next set of goals take effect. The goals are intended to help accredited organizations address specific areas of concern regarding patient safety. Each goal includes no more than two evidence- or expert-based recommendations. To ensure a greater focus on priority safe practices, no more than six goals are established for any given year. Each year, the goals and associated recommendations are reevaluated; some may continue while others will be replaced because of emerging new priorities. New goals and recommendations are announced in July and become effective on Jan. 1 of the following year.

*(Editor's note: For the 2003 and 2004 goals, see the JCAHO web site at www.jcaho.org. If six goals aren't enough to keep you busy,* ***see the story on p. 88*** *for 30 new patient safety practices released recently by the National Quality Forum.)*

All JCAHO-accredited health care organizations will be surveyed for implementation of the recommendations, or acceptable alternatives, as appropriate to the services the organization provides. Alternatives must be at least as effective as the published recommendations in achieving the goals. Hospitals have a strong motivation to comply — failure by an organization to implement any of the applicable recommendations (or an acceptable alternative) will result in a special Type I recommendation — and that is spurring some of the policy and procedure overkill Amori says will create new liability.

Developing a proper response to the patient safety goals should involve far more than just writing or revising a policy, Amori says. First, she says you should look at the processes that the goal assesses in your own institution. Then you need to look at the broad reasons why your system works the way it does regarding that goal.

"You're really doing a failure mode analysis and sort of a root-cause analysis to determine why it's working that way in your system," she says. "Is there something in your policies and your system that is creating a system where you are not monitoring high-risk medications or that allows you to misidentify patients, or whatever the goal is? Once you have the data showing what's going on in your organization, only then do you go about developing policies and procedures to improve the situation."

If you put too much focus on writing the policy and procedures, you may not be paying enough to the actual process improvement, she says. When you have created a better process, then you might want to document that through a new policy and procedure.

"We've said that for a million years in risk management," Amori says. "Policies and procedures don't change behavior. They should memorialize the type of behavior we think is important. Change the behavior first and write a policy and procedure that reflects that change."

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### Editorial Questions

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That advice is seconded by **Marie Pears,** RHIA, CPHQ, quality coordinator at Meadville (PA) Medical Center. She says her hospitals has struggled with its efforts to comply with the patient safety goals, at first developing some policies and procedures that went overboard. For the 2003 goal regarding identification of patients, for instance, Meadville at first developed a policy that required proper identification for any kind of encounter with a patient, but then Pears and others realized that wasn't what JCAHO intended. But they still had to figure out how to meet that goal.

"We did have policies and procedures for patient identification in place already but we didn't have two patient identifiers, so we went to work on that," she says. "In this case, we almost went overboard because we said that whatever you do with the patient you have to use those two patient identifiers. But in some cases that's not necessary. We wrote the policy saying that at first, then we went back and rewrote it. That's an example of how you can go overboard with your policies and procedures."

### Meeting JCAHO goals may not be enough

Another example shows how the first reaction to the JCAHO goals may not be the best for your institution. For the goal involving the proper identification of the surgical site, Meadville noted that JCAHO wanted the patient to be identified when the patient enters the surgery room.

The hospital's policy already ensured that the identification was confirmed by then, so the first reaction was to say that the goal had been met. But then the team working on that goal realized that Pennsylvania law requires the patient be identified *before* going into the surgery room. That prompted a close look at whether the entire pre-surgery identification system was sufficient.

"When we took a close look at it, we decided to revise our policy and procedure because there was a potential for misidentifying the patient after the patient leaves the holding area but before entering the surgery room," she says. "So now we have a surgical pod where everyone stops and we identify the patient, the surgical site, and the procedure."

### Goal-oriented groups

That experience with patient identification confirmed the value of the team approach Meadville uses for meeting the patient-safety goals. Pears put together an overall team made up of key department leaders to address the goals, then that group broke up into smaller teams to look at individual goals. After allowing some time for the smaller teams to work, everyone regrouped to discuss their findings and recommendations.

Some teams determined that the hospital was already meeting that goal and no further action was needed. (In that case, Pears still was careful to document the team's analysis and recommendations.) To keep up with all the teams' work and ensure that the goals would be met on time, she used a matrix that listed each goal, who was working on it, the team's recommendations, and when any actions should completed.

Each team investigated what Meadville should do to comply with the goal, mainly by asking these questions: What is the patient safety goal? What problems have we had that pertains to this patient safety goal? Do we have data available on this topic? Do the data show we've had a problem in this area? Do we already have a policy and procedure in place? Are we already in compliance with what the goal says? Is that enough or do we want to do better? How far beyond compliance do we want to go?

The goals give you areas to focus on that might not otherwise capture your attention, Pears says. Even if it seems you are already meeting the

safety goal, Pears says you should still study each one carefully. Use the patient safety goals as a reason to carefully assess your own policies and procedures for loopholes and weaknesses.

You won't have to develop a new policy and procedure for every goal, Pears says, but you will want to take a look at each policy and procedure addressing the goals. Some might be fine as is, some might need improvement, and some goals may need completely new policies and procedures. Whether you're refining or developing them from scratch, Pears echoes the advice of risk managers:

"You certainly can go overboard with policies and procedures," she says. "You need to keep them simple. The more complicated a policy and procedure gets, the harder it is for people to comply and that gives you more chance for error. You could be creating a problem just by the way you're writing the policy and procedure."

### Physicians may be more wary than others

When addressing the patient safety goals, don't be surprised if physicians are more skeptical than others about your efforts. They tend to be resistant to such efforts in general and many are expressing concerns about how new policies and procedures could be a burden to their practices, says **Fred Meyerhoefer**, MD, a retired pediatrician who now consults with physicians regarding JCAHO compliance.

"Physicians can be concerned about putting themselves in a legal bind, maybe more so than the hospital, when you're talking about how to treat the patient and respond to some of the patient safety goals," he says. "But I've found that when I talk to them and show them why this is good patient care even if they have to alter their practices a little bit, the majority of them have backed off."

In many cases, physician compliance comes down to how detailed you have made your policies and procedures, he says. Physicians will be skeptical of any policy and procedure that dictates an overly specific manner of care, and unlike many hospital staff, physicians have the clout to speak up and say no. With hospital staff you might not find out until it's too late that you've written too much into your policy and procedure.

Amori says that, in general, you should avoid writing a highly detailed policy and procedure. When in doubt, err on the side of being too general, she says.

"It can be extremely detailed if there is a complex process that only can happen one way, but my guess is 99.9% of our processes aren't that way," she says. "In most cases, you're probably better off not spelling out the step-by-step details of what a nurse should do in a certain situation, unless it's absolutely a situation where you know that's the best way and the nurse knows where the policy and procedure is, and it happens with enough frequency that people are going to know to look there. Otherwise, you're giving a plaintiff's attorney lots of ammunition and you're going to have lots of frustrated staff." ■

## National Quality Forum has 30 ways to increase safety

Representatives of leading health care and consumer groups have endorsed 30 patient safety practices they say should be universally used in health care settings to reduce the risk of harm resulting from processes, systems, or environments of care.

The list includes informing patients that they are likely to fare better if they have certain high-risk, elective surgeries at facilities that have demonstrated superior outcomes; specifying explicit protocols for hospitals and nursing homes to ensure adequate nurse staffing; hiring critical care medicine specialists to manage all patients in hospital intensive care units; making sure hospital pharmacists are more actively involved in the medication use process; and creating a culture of safety in all health care settings.

The consensus report was released recently by the National Quality Forum (NQF) and funded in part by the Agency for Healthcare Research and Quality (AHRQ). For the entire list of 30 patient safety practices in the new report, *Safe Practices for Better Healthcare: A Consensus Report*, see the NQF web site at www.nqf.org.

### Building a better system

The report reflects consensus among the NQF's 173 member organizations about the need to put better systems and procedures in place to help prevent medical errors like those outlined in the landmark 1999 Institute of Medicine report

*To Err is Human*. The NQF consensus report is based in part on work by a team of researchers at AHRQ's Evidence-Based Practice Center at Stanford University and the University of California at San Francisco that identified 73 patient safety practices for which there were varying levels of scientific evidence in 2001.

Many additional candidate measures were considered, and the 30 voluntary consensus standards in the NQF report were culled from a list of 220 candidate practices based on each practice's specificity, effectiveness, potential benefit, ability to generalize, and readiness for implementation. The report also identified 27 practices that have great promise for reducing adverse events and should have high priority for further research. ■

# Universal consent forms raise questions of ethics

Using a universal consent form for multiple procedures anticipated for a patient can nearly double the consent rate for most of the invasive procedures performed in an intensive care unit (ICU), according to researchers in Chicago.

But observers say the tactic may violate the spirit of the informed consent process.

The suggestion for such a consent form arose in one of the first detailed studies of the informed consent process in an ICU. In that study, the researchers found that the rapid, unpredictable pace of critical illness combined with the inability of very sick patients to make decisions took a serious toll on patient autonomy. When caregivers relied on standard practice, patients or their proxies had the opportunity to consent to or refuse invasive procedures recommended by their doctors only 53% of the time.[1] A large fraction of procedures were performed with implied consent because they were deemed necessary by caregivers.

After the authors devised a universal consent form that explained the risks and benefits for the eight most common ICU procedures and presented the options to patients and families as soon as they were admitted to the ICU, they were able to raise the consent rate to 90%, says **Jesse Hall**, MD, professor of medicine and chief of pulmonary and critical care at the University of Chicago.

"Precise, widely accepted guidelines for obtaining consent in the ICU environment do not exist," Hall says. "Physicians can't even agree on which procedures require consent. Our goal was to begin to standardize the process and to find ways to make it more effective."

The study was performed in a 16-bed ICU at a university hospital. For two months, from Nov. 1 to Dec. 31, 2001, the researchers charted the consent rate for invasive procedures. They found that only 53.1% of the time (155 out of 292 procedures) did patients have the opportunity to consent to or refuse treatment. ICU physicians attributed their inability to get consent to the emergent nature of the procedure and the lack of an available proxy when needed.

### Consent rates higher with universal form

In the intervention period, March 1 to April 30, 2002, a universal consent form that explained the risks and benefits of each procedure was presented to patients and families soon after they came to the unit. For this period, the consent rate increased to 90.5%, with consent secured in advance for 308 out of 340 procedures.

"This is a far more acceptable level of patient participation," Hall says. "It enabled us to be more responsive to family wishes and also allowed patients themselves to make more decisions."

Before the universal consent form was introduced, patients made their own decisions in only 28.4% of cases. Proxies made the rest. Using the comprehensive form allowed the patient to make the call in 34.4% of cases.

Comprehension by both patients and proxy decision makers was high and did not differ between the two periods. "We have shown that education of clinicians, patients, and proxies regarding the process of informed consent can improve this process in critically ill patients," the authors conclude.

### Eight common procedures

The universal consent form described eight commonly performed procedures: placement of an arterial catheter, a central venous catheter, a pulmonary artery catheter, or a peripherally inserted central catheter, lumbar puncture, thoracentesis (surgical puncture through the chest wall with drainage of fluid from the thoracic cavity), paracentesis (surgical puncture through the abdominal wall with drainage or aspiration of

fluid from the abdominal cavity), and intubation/mechanical ventilation.

### Form may be practical, but at what expense?

Another researcher who has studied consent forms extensively says the University of Chicago proposal may be well intended but it seems to violate the spirit of the informed consent process. **Melissa Bottrell**, MPH, project manager at the National Center for Ethics in Healthcare at the Veterans Administration Puget Sound Health Care System in Seattle. Bottrell says the universal consent form may solve a practical problem for clinicians but does not benefit the patient.

"It seems like they're trying to put a solution on the problem without realizing what the real problem is," she says. "They're saying they don't get documentation of consent, so that's in essence a legal problem, a lack of consent. So trying to solve that with this form, but I worry that the real effect is that they get a piece of paper without going through a true process of informed consent."

Bottrell points out that the situation may change significantly after the universal consent form is signed. The patient's condition may worsen or improve, for instance, or relatives may simply change their minds about what should be done for the patient.

Though the University of Chicago researchers say they urge clinicians to consider such a change in circumstances and repeat the informed consent process if necessary, but Bottrell says she doesn't think that would happen much in a real world environment. Once the consent is obtained, she says, clinicians are unlikely to consider whether it is still valid.

"Informed consent is about shared decision making," she says, "but having this form signed before there might be a change in the patient's decision-making status, or a change in the patient's condition that would affect that decision, essentially allows the clinician to opt out of that shared decision-making process because they already have documented consent."

"There is coercive power with the clinician in the ICU saying we might need to do these eight procedures and want you to sign off on them now," Bottrell continues. "It puts the patient in a situation in which it seems shared decision making will be less likely to happen rather than more likely, which is not the goal of a consent form in the first place. It solves some of the practical problems with obtaining consent but it doesn't fulfill the sprit of obtaining informed consent."

Bottrell notes that the proposed universal consent form differs in one important way from consent forms used up front for multiple procedures such as weekly dialysis treatment. In those situations, the patient's condition is unlikely to change significantly during the period covered by the consent form, she says.

### Other consent forms also can be faulty

Even the standard consent forms used more commonly in all health care settings might not be as good as you think. Bottrell's previous research suggested that many of them amount to nothing more than a waste of time and may actually create more of a litigation problem than they could ever prevent.

She and her colleagues were amazed at how poorly most informed consent forms achieve their goals. Bottrell says most of the forms are "a waste of paper. They're worthless."

**In an effort to protect the provider, most consent documents are written so much from the hospital's perspective that they do not even make a good-faith effort at informing the patient.**

Risk managers may have to take some responsibility for that, she says. In an effort to protect the provider, most consent documents are written so much from the hospital's perspective that they do not even make a good-faith effort at informing the patient, Bottrell says. They are written so clearly with the hospital's interest in mind that they often become a complicated legal document no typical patient could possibly understand, she says. When that happens, the document becomes nothing more than a legal formality, and Bottrell says she is surprised that courts do not reject them more often than they do.

When the document reaches that level of legal complexity and one-sidedness, it achieves nothing, she says. At that point, it does not even achieve protection for the hospital and may backfire in that regard.

"When it is so clearly written from the hospital's perspective, the form becomes worthless. It just doesn't function as intended," she says. "All they do is create more paperwork and lead the patient to believe that you're only out to protect

the hospital rather than inform the patient. That can lead to some real animosity if things go wrong later."

Unfortunately, Bottrell is not talking about just some informed consent forms. She's talking about nearly all the forms currently used by hospitals. In her recent study, Bottrell and her colleagues analyzed 540 informed consent forms from 157 hospitals nationwide, and they found that "most forms did not meet accepted standards of informed consent or patient physician interactions."[2]

They examined the forms to see if they included the basic elements of informed consent — nature of the procedure, risks, benefits, and alternatives — as well as features that might enhance physician-patient interactions and encourage shared decision making.

They found that only 26% of the forms included all four basic elements of informed consent, 35% had three, 23% had two, 14% had only one, and 2% had none of the elements. Ninety-six percent of the forms indicated the nature of the procedure.

Seventy-five percent of the forms authorized treatment, and 59% appeared to protect the hospitals and caregivers from liability, but only 40% clarified information about the procedures and only 14% aided patients in the decision making.

## State laws can prompt better consent forms

Bottrell found that forms from the states that actually require all four informed consent elements in the form were no more likely to have them. The researchers noted that many of the forms included phrases such as "I certify that no guarantee or assurance has been made as to the results that may be obtained," making the tone of the form more like a waiver to get the hospital off the hook.

"Such a construction may even reduce the likelihood of a quality informed consent process by increasing the perception of physician or institutional self-protection over patient care, and causing patient anxiety an annoyance from having to sign another piece of paper," the researchers concluded.

The irony, they say, is that trying to use the forms that way does not actually provide much legal protection for the hospital but it most definitely thwarts any effort at informing the patient.

Bottrell acknowledges that the informed consent document often does not represent the entire informed consent process in a health care setting. Ideally, the doctor and the patient have had a careful, meaningful conversation before signing the form, which some risk managers would argue is only an administrative record of the actual informed consent process. That may be the case sometimes, she says, but a faulty informed consent document can unravel much of the work done by the doctor by making it seem that the hospital wants a free ride if anything goes wrong.

## A worksheet for patient and doctor

Bottrell and her colleagues recommend a wholesale revamping of the informed consent process so that it revolves around a worksheet that the patient and doctor can work through together.

Rather than anything resembling a legal document, the worksheet should be a form that they can use to facilitate a personal discussion about the medical treatment, with plenty of questions prompting the patient to respond. Questions could include phrasing such as "This is a reasonable decision for me because . . . ." with the patient filling in the rest as a demonstration that he or she has been adequately informed.

She also suggests that the same list of eight common procedures used in the University of Chicago universal consent form could be used as a checklist to prompt clinicians during the informed consent process in the ICU. That would be a better solution than asking for universal consent up front, she says.

"The problem is they're trying to solve the problem of obtaining consent in emergency situations by just showing proof of documentation," she says. "You could just as easily have the same conversation without necessarily having the form signed. If it's true that the physician does anticipate a number of procedures, you can have that conversation and use the checklist to remember to check them off and talk about them. It can be good to address these issues up front all at once, but not obtain consent."

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# Insurance policy to cover violations of HIPAA rules

A San Francisco insurer is offering health care providers what it says may be a first in underwriting — a professional liability insurance policy specifically geared toward electronic-based and web-enabled transactions for health care operations. The policy might be especially useful in insuring against violations of the Health Insurance Portability and Accountability Act (HIPAA), the company says.

The insurance is offered by Healthcare First, a unit of the brokerage services division of Arthur J. Gallagher & Co.

Healthcare First president **David Wynstra** tells *Healthcare Risk Management* that the insurance product was developed in response to the way many health care systems have become more dependent on electronic-based transactions via the Internet to carry out business basic functions.

"As a result, those organizations are now assessing their information technology risks and liability exposures," he says. "This corporate liability coverage will continue to indemnify electronic-based transactions that health care organizations use to manage, process, and disseminate information. Moreover, the coverage now helps indemnify corporate policyholders from damages resulting from HIPAA events, such as unauthorized disclosures of protected health information arising out of computer security violations."

### *Coverage for inadvertent violations*

Wynstra says the intent of the policy is to cover organizations for inadvertent HIPAA violations and the policy would not cover any fraudulent activities. Health care providers would benefit in situations in which an unauthorized disclosure is made that results in damage to an individual or organization, and that party decides to sue for damages.

Though that may sound appealing to risk managers worried about violating the new HIPAA provisions, Wynstra notes that the coverage will not cover fines levied by the government for HIPAA violations. That is consistent with other forms of insurance that commonly cover civil liabilities but cannot pay fines imposed by government agencies or law enforcement.

The eHealth/Internet Liability Policy will be underwritten by Mt. Hawley Insurance Co., a subsidiary of RLI Corp., and will provide premium discounts to health care providers accredited by URAC, an accrediting body in Washington, DC. The policy covers more than just HIPAA violations, says **Michael Lamprecht**, national practice leader of e-Insurance with Arthur J. Gallagher & Co.

The policy provides worldwide cyber liability coverage for exposures such as privacy infringement arising out of computer security breaches and contingent bodily injury arising from web site content, he says. The policy provides coverage for media perils such as copyright and trademark infringement, libel, slander, defamation, and product disparagement.

Wynstra notes that the underwriter will expect your organization to take all appropriate precautions regarding HIPAA, including the implementation of policies and procedures.

"There's a rather rigorous underwriting program," he says. "Certainly, a security audit is necessary. We expect to see that the insured has taken all necessary steps to comply with HIPAA." ■

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## Reader Questions

# Tired of back injuries? Let technology do heavy lifting

**Question**: We have been trying to reduce back injuries among our nurses and other staff for years, but we're not satisfied with the results. Despite extensive education and training for staff, we're still spending a fortune on workers' comp and lost work time. What are we doing wrong?

**Answer:** You might need to do some shopping. Increasingly, hospitals and other health care facilities are finding that they can't seriously reduce back injuries without using machines to do the lifting, says **Butch de Castro**, PhD, MSN/MPH, RN, senior staff specialist for occupational health and safety with the American Nurses Association in Washington, DC.

"If you're still seeing a high rate of musculoskeletal injuries among your staff, you might need to look at adopting more of the technology that can assist nurses with these high-risk tasks," he says. "Some of the lifting techniques and proper body mechanics are a little bit outdated now and not really proven to be that effective in the long run. There's a change now in the way people are looking at this problem, and technology is really seen as the way to reduce the risk."

The idea of relying more on technology immediately raises the question of costs, but de Castro says there are a number of options ranging from the inexpensive to the very sophisticated and pricey. Simply using nonfriction transfer boards, for instance, can greatly reduce the effort and risk in moving a patient to or from a bed.

On the other end of the spectrum are built-in devices like the sling lifts that can raise a patient out of bed and, with a nurse using a remote control, move the patient across the room. Some facilities may adopt such devices for all patients, while others might reserve their use for high-risk transfers. De Castro says the ideal solution would be to adopt technological solutions to the greatest extent possible and keep manual lifting to an absolute minimum.

Exactly what devices you should adopt will be determined by your own patient population, your desire to reduce injuries, and your budget. No matter how much you can spend, the investment will be worthwhile, de Castro says.

"Technology is successful in reducing not just injuries but also costs. In the long run, the cost savings can be tremendous," he says. "The goal of the technology is to eliminate the risk of the ergonomic hazard to people and let the machines take it instead. You can reduce the staff person's risk to zero from that task and let the technology carry that burden."

That reflects a change in how the experts now look at back injuries among nurses, de Castro says. There is more focus now on the lifetime risk of a nurse and the cumulative effect of lifting and handling patients over the years. Even if there is no acute injury, the daily effects of lifting add up over time and the risk of injury rises with the person's age. Experts now say the advice followed for years, in which nurses were educated about proper lifting, is at best inadequate. It may be nearly useless, he says.

"We need to find a way to take that lifting burden off the nurse, as opposed to making sure the nurse does manual lifting in the correct way," he says. "Even with proper techniques, the burden is still there if the nurse is doing manual lifting."

Nurses also are getting savvy about the risk of musculoskeletal injuries at work and taking a hard look at the techniques employers use to reduce that risk. De Castro says he has heard reports of nursing staff being offered positions at other facilities and refusing to accept the position because they would have to use manual lifting. Similarly, he has heard of staff being lured away to facilities that use lifting devices instead of manual lifting techniques. Such differences can be important when health care providers are facing a shortage of nurses and other skilled staff, he says.

De Castro offers one important tip about how to choose the right lifting technology for your organization: Involve the frontline health care workers in the decision. You can waste a lot of money and not reduce back injuries by just flipping through a catalog and picking some equipment to order.

"Make sure your investment is fruitful by getting frontline workers' input into choosing and purchasing the equipment. If your staff isn't willing to use it or is uncomfortable with it, they're going to use manual lifting or use the new equipment improperly," he says. "Getting them involved gives them a sense of ownership as well. They know their needs, what patients they will need to manage, and what devices might be useful."

For more information on what kind of lifting technology is available and how to decide what is right for you, de Castro recommends the web site www.patientsafetycenter.com. ▼

# Falling Leaf programs tell who is most at risk to fall

**Question:** Our hospital recently acquired a long-term care facility that I'm now responsible for, and the first thing I noticed was the disturbingly high rate of falls among the elderly patients. I've heard of a Falling Leaf program that might help, but no one at the facility is familiar with it. Can you help?

**Answer:** Falling Leaf is a program that identifies the patients at highest risk for falls and then aggressively works to monitor them and find the root cause of their falls. The program can dramatically

reduce the number and severity of falls in any health care setting, says **Carolyn Spradlin**, RN, BSN, CPHQ, CPUR, program manager for nursing homes with MissouriPRO, a quality improvement organization that contracts with the Centers for Medicare & Medicaid Services to assist health care providers with improving care and patient safety.

Spradlin developed the Falling Leaf program four years ago when she was administrator of a long-term care facility, as an adaptation of another strategy known as the Falling Star program. Falling Star involves assessing patients or residents for their risk of falls and then identifying those at high risk with a visible symbol, usually a falling star graphic placed on the patient's door. The idea is that the staff will then know to watch that patient more carefully and intervene more quickly if they observe unsafe behavior.

That strategy has been successful for many health care providers, but Spradlin recommends the Falling Leaf program as an improvement. With Falling Leaf, the key difference is that there is more emphasis on identifying the patients at extreme risk, not just those at risk of falling, and the program encourages staff to find the root cause of the patient's falls. Falling Star and Falling Leaf can both be used in the same facility, she says, with Falling Star as the overall program and Falling Leaf concentrating on the subset of patients at the highest risk.

**With Falling Leaf, the key difference is that there is more emphasis on identifying the patients at extreme risk, not just those at risk of falling, and . . . encourages staff to find the root cause of the patient's falls.**

Using Falling Star alone can reduce falls, she says, but it can have the unexpected drawback of obscuring those most at risk.

"The problem is that when you assess someone for a risk of falls, and no matter what assessment you decided to use, you're going to end with a large number of people at risk," she says. "Then if you make symbols for everyone at risk, the staff can get accustomed to seeing falling stars everywhere. That means no one really gets special attention. There are too many of them."

To select those who should included in the Falling Leaf program, Spradlin says you can use any number of assessment tools to find patients at risk for falling. Whatever you use, those scoring at the top of the scale are the ones to designate as Falling Leaves. But Spradlin also says there are certain red flags that should automatically classify the patient as a Falling Leaf: Previous falls at your own facility, and anyone newly admitted to the facility. All long-term care patients should be placed in the Falling Leaf program for 72 hours on admission because the staff doesn't know the patient and the patient is unfamiliar with the surroundings. (Falling Leaf works in any health care setting, Spradlin says, but it might not be necessary to include all newly admitted patients in all settings. Make that decision based on your patient mix.)

Once placed in the Falling Leaf program, each patient is monitored monthly by the patient safety committee or fall prevention team and removed when appropriate improvements have been made. The fall prevention team also affixes a falling leaf symbol to the patient's door, notifying everyone that the patient is at extreme risk of falling.

Spradlin recommends using small magnetic Falling Leaf signs, similar to refrigerator magnets that can be put on the metal doorframe at the entrance to the patient's room. These signs can be removed easily, which makes it more likely they will be moved when the patient is moved from one room to another.

The strategy involves more than simply identifying the patient as high risk. Falling Leaf also requires that the staff observe the patient more frequently, for instance, and develop a more intricate care plan and change it often if necessary.

"But the biggest issue is determining why there is a fall problem," Spradlin says. "The caregivers need to determine why the person keeps putting themselves in this unsafe condition. Are they trying to go to the bathroom? Are they hungry? Are they lonely and looking for someone to talk to?"

Pain is another common factor, and Spradlin says better pain control usually results in fewer falls. Finding the root cause of the falls can be challenging sometimes, but she says staff must be determined. The Falling Leaf program also involves all staff in the facility who might encounter patients, not just nurses and other caregivers. If a maintenance person or housekeeper passes a room with a Falling Leaf, that person is encouraged to look inside and note whether the patient is doing anything risky. If so, the staff member is supposed to inquire about

the patient's needs and encourage him or her to wait for nursing assistance. Spradlin also recommends that you keep a simple log at the nursing station where all staff can note their observations about Falling Leaf patients.

"The focus is on the true needs of the person and what might be leading to the falls, rather than just saying they're doing an unsafe behavior. There's a tendency to pick up the person, reset the alarm, and hope you catch them the next time," she says. "We need to create a whole culture among staff so that we find out why they're falling instead of just stopping the fall." ■

# NJ malpractice premiums up 71% in just one year

With 2003 insurance quotes now in, New Jersey hospitals report an average annual medical malpractice insurance premium of nearly $1.9 million, a 71% increase over the average 2002 premium of $1.1 million. All told, New Jersey hospitals have seen their medical liability insurance premiums jump 378% in the last five years, according to a survey of the state's hospitals by the New Jersey Hospital Association (NJHA).

The findings are based on initial responses to a survey of the state's 117 hospitals, says NJHA president and CEO **Gary Carter**.

"For the average hospital, a $1.9 million annual bill can be staggering, especially considering all the other financial burdens it must bear," he says. "These growing costs are undermining hospitals' ability to continue offering accessible and quality health care to their patients, not to mention depleting their medical staffs of respected physicians who are fleeing the state because of out-of-control premiums."

The five-year trend shows that the average hospital premium was $389,000 in 1999, with premiums breaking the $1 million mark last year, when the average annual hospital premium was slightly more than $1 million. Carter says the data show that hospitals, which are sometimes overlooked in proposed legislative fixes to this problem, are also feeling the financial pressures of sharply rising premiums.

"This information underscores the importance of a long-term solution to this problem, a remedy that will address these growing pressures on hospitals as well as physicians," Carter says. "Five years ago, we may not have recognized the start of a troubling trend. But with five years of data showing rapid increases, it's clear that we need reforms that will reach to the very core of our tort system. A problem this persistent will not be cured with a one-time Band Aid." ■



## 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

- Preventing fires during surgery
- EMTALA myths
- Why you should help patients complain
- Assessing your insurance coverage for gaps
- Crew resource management

## 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

5. Based on the comments of Geri Amori, PhD, ARM, FASHRM, president of Communicating HealthCare, choose the correct statement:
A. You usually should write extremely detailed policies and procedures for meeting JCAHO's patient safety goals.
B. You usually should avoid writing extremely detailed policies and procedures for meeting JCAHO's patient safety goals.
C. You should write an extremely detailed policy and procedure for meeting a JCAHO patient safety goal only if you did not already have a policy and procedure in place and it will be completely new.
D. You should never write extremely detailed policies and procedures for meeting JCAHO's patient safety goals.

6. According to the study at the University of Chicago, authors reported a ____ consent rate after devising a universal form that explained the risks and benefits for the eight most common ICU procedures and presented the options to patients and families as soon as they were admitted to the ICU.
A. 70%
B. 80%
C. 90%
D. 100%

7. In the research conducted by Melissa Bottrell, MPH, project manager at the National Center for Ethics in Healthcare at the Veterans Administration Puget Sound Health Care System, what percentage of the consent forms she studied contained all four elements of informed consent?
A. 12%
B. 26%
C. 39%
D. 54%

8. In the Falling Leaf program described by Carolyn Spradlin, RN, BSN, CPHQ, CPUR, program manager for nursing homes with MissouriPRO, patients admitted to the facility are placed in the program for a specified time as a cautionary step. Indicate which time period she recommends for a long-term care setting.
A. 12 hours
B. 24 hours
C. 36 hours
D. 72 hours

**Answers: 5-B; 6-C; 7-B; 8-D.**

Healthcare Risk Management's
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# A lack of consent and facial burns lead to a $376,000 verdict in Texas

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**News:** After an initial round of laser surgery on her face, the patient consented to a second procedure, which was limited to an eyelid tuck and minor laser surgery to her chin. Despite the limitation, the ophthalmologist performed a full-face laser procedure, inadvertently resulting in second- and third-degree burns.

A Texas jury returned a verdict of $376,000, finding the doctor liable for negligence, medical battery, and fraud. The jury's award included $250,000 in exemplary damages, although the trial court reduced that amount to $200,000 in order to comply with the jurisdiction's statutory cap on such damages.

**Background:** On May 30, the patient met with an ophthalmologist who suggested that she undergo an eyelid tuck as well as erbium laser procedure to remove facial pigmentation. Although both procedures were scheduled for June 10, only the erbium laser surgery was performed that day.

The patient already was anaesthetized when the ophthalmologist realized the consent form referenced only the erbium laser procedure and not the eyelid tuck. The ophthalmologist believed it was a clerical error, but decided to perform only the consented-to procedure.

The patient followed up with ophthalmologist seven days after the surgery. She had broken capillaries and oozing sores. Even though she was told she could expect a four-month healing period, she agreed to an eyelid tuck and additional erbium laser surgery to touch up a small scar on her chin. The patient signed a consent form to that effect and the surgery was scheduled for one week later, on June 24.

Both the ophthalmologist and his nurse testified that, on the morning of the surgery, the patient verbally requested another full-face erbium laser procedure. The doctor claimed the patient made the request even though she had not recovered from the first procedure or consented to this extra procedure in writing.

Nevertheless, the ophthalmologist performed the full-face laser procedure in addition to the eyelid tuck and chin touch-up. He claimed that the lack of written consent was merely a clerical error.

The patient, however, denied that she requested the second full-face procedure and argued that she expected only the procedures to which she had given her expressed, written consent. She testified that when she spoke with the ophthalmologist on the morning of surgery, he stated he would do the eyelid tuck but would not perform a second full-face erbium laser procedure.

The second surgery caused severe scarring on the patient's face, equivalent to second- and third-degree burns. The patient and her husband brought claims of battery, fraud, negligence, and negligent misrepresentation against

the ophthalmologist and his laser institute.

The jury found that the ophthalmologist's negligence proximately caused the patient's injuries, that he performed the full-face resurfacing without the patient's consent, and that he committed fraud against the patient.

The jury awarded $126,000 for the damages caused by the doctor's negligence and battery on the patient and $500 for damages caused by the physician's fraud. In addition, the jury determined there was clear and convincing evidence of fraud and awarded $250,000 in exemplary damages. Because of a statutory cap, the trial court reduced the exemplary damages to $200,000.

**What this means to you:** This case brings into play a couple of risk management concepts: Obviously, the first is informed consent and the policies and procedures that it entails. The second related concept is the inconsistency in how the physician dealt with the lack of specific informed consent in performing the two procedures.

Physicians who perform procedures such as laser surgery and minor surgery in their offices should adopt and adhere to policies and procedures akin to those more commonly found in outpatient and inpatient settings dedicated to such services.

"The physician obviously used some kind of form to memorialize the patient's informed consent to procedures; however, adherence to what was on the form seems to be lacking — or at least it was with regard to this particular patient," notes **Reba Crutcher Qualls**, RN, LHCRM, CLNC, of Risk & Quality Solutions in Nokomis, FL.

For the first surgery, the informed consent was not complete and only the procedure consented to was performed by the doctor. However, in the second visit, the doctor ignored the consent form and performed a procedure for which he lacked written consent.

"On a positive note, it does seem that the consent form was reviewed prior to initiating the actual procedure in both instances, and so there may have been a policy (or at least habit of) regarding the review of the consent form at that juncture," says Crutcher Qualls. "However, in the second instance, despite the review of the written consent form, the lack of consent did not result in the procedure not being performed.

"The physician clearly demonstrated two different standards of care by first correctly respecting the written consent and performing only the documented procedure and then, second, erroneously ignoring the written consent and performing a more complex procedure when only limited written consent had been provided. In doing so, the patient was permanently injured," adds Qualls.

Informed consent forms are an integral part of the medical record, and as with all documentation, if it was not documented, it is difficult to show that it did not happen.

"As this case illustrates, consent forms should be handled uniformly and in the manner demonstrated in the first surgery — not the second. Bottom line, if there is no evidence of written consent, do not perform the procedure," advises Qualls.

### Reference


• *Baribeau v. Gustafson,* Texas Court of Appeals (Bexar County). Case No. 04-01-000732-CV (2002). ■


## Injury coverup leads to a $1.5 million settlement

**News:** An elderly nursing home resident with a history of dementia fell and hit his head. Evidence of the incident was concealed by the nursing staff. Fortunately, his daughter saw him the next morning, realized that something had happened, and arranged for him to be hospitalized. Following admission, it was determined that in addition to sustaining a head injury, the patient's Coumadin level was excessive. Efforts to regulate the medication failed and the patient died five days later. The deceased patient's estate brought suit against the nursing home, claiming negligence. The total settlement from various providers was $1.5 million.

**Background:** The 87-year-old man's daughters were no longer able to care for him at home, so he was placed in a nursing home. He was admitted to the nursing home with a history of Alzheimer's disease, past aortic value replacement with prosthesis, congestive heart failure, atrial fibrillation, and pleural effusion. One spring evening, a charge nurse forced the patient into his room, causing him to fall over his walker and strike his head. The charge nurse put him to bed and, with

the assistance of other nurses, concealed all evidence of the fall.

The next morning, he was visited by one of his daughters, who recognized that he was not feeling well and was in great pain. She arranged for him to be hospitalized. Once admitted, the hospital staff discovered he had sustained a head injury and, more importantly, the internal injury was coupled with a "panic level" of the blood thinning medication Coumadin. He died five days later of intracerebral bleeding.

The estate brought suit against the attending physician, clinical laboratory, and nursing facility for negligence in caring for the deceased. Through discovery the plaintiffs obtained evidence implicating negligence, particularly on the part of the nursing home. Evidence against the nursing home included a facility investigation report naming the charge nurse as having injured the patient.

The facility's report was then contradicted when another of the nursing home's senior nurses misrepresented the facts of the incident to the state regulatory agency. In addition, nursing home records indicated that the patient had a history of falling and that he had, in fact, fallen earlier that day. However, the care plan prepared by the facility for the deceased failed to address the life-threatening risks such as his propensity for falling, wandering, and bleeding due to the blood-thinning medication. Furthermore, the charge nurse did not even know what a care plan was and was unable to identify one.

The facility records also indicated that the nursing home employed the charge nurse as a supervisor over the patient's entire unit, even though he had no prior nursing home experience. The charge nurse's lack of qualifications violated the facility's own job qualification requirement of a minimum of one year of nursing home experience.

The charge nurse testified that he had no idea what any of the facility's policies or procedures were on any medical or nursing topic, much less topics pertinent to the care of this patient.

The plaintiff further demonstrated the charge nurse's incompetence by producing records that the nurse had been suspended for three days prior to the patient's fall. Also contributing to the charge nurse's liability was the fact that he held a second full-time job as a prison nurse, and that the nursing home was fully aware of this fact.

The estate averred that all of the staff nurses failed to recognize the excessiveness of the blood-thinning medication, ignored the family's repeated requests to stop administering it, and failed to contact the attending physician regarding the medication in a timely manner. The nurses also failed to follow up on critical lab testing that the attending physician had ordered on the date of the incident and failed to respond to the communications from the laboratory regarding the patient's dangerously high levels of Coumadin.

Discovery revealed that two weeks prior to the incident, the nursing home administrator circulated a memorandum stating that all employees were responsible for effective follow-up on lab results. In addition, records obtained from the regulatory agency showed that the facility had been reprimanded for staffing shortages and staffing competency issues.

The patient's roommate testified that he saw the fall and that the charge nurse and other nurses cleaned blood from the floor. The roommate also testified that the patient was moaning and making sounds indicating he was in pain throughout the night and the next morning, providing evidence of his conscious pain and suffering. The patient's daughter corroborated the presence of pain the next morning.

Although the defendants argued that the patient died from a stroke rather than from intracranial bleeding, each settled. The attending physician and his business paid $190,000 on a $200,000 policy limit. The clinical laboratory paid $125,000. Approximately one week prior to trial, the nursing home settled for $1,275,000.

**What this means to you:** Nursing home litigation is on the rise, and the evidence reported in this case seems to support the premise that some increase is merited. In light of the evidence, it's little wonder the defendants were interested in settling their case.

The single most striking aspect of this case was the cover-up, not only at the time of the incident but also before the state's regulatory agency. It seems that no one on staff actually came out and told the patient's daughter what actually had occurred.

"The actions taken by the nurses in this instance were in clear violation of the Code of Ethics for Nurses as adopted by the American Nurses Association at its June 2001 meeting," states **Cheryl A. Whiteman**, RN, MSN, CPHRM, a risk manager for Cigna Healthcare of Florida Inc., whose opinion does not necessarily reflect Cigna's.

"Clearly, the charge nurse that caused the patient to fall, the nurses that helped 'clean up' afterwards, and the supervisory nurse that provided erroneous information to the regulatory agency were not promoting, advocating for or striving to protect the health, safety, and rights of this particular patient. Neither were the nurses preserving integrity and safety, nor were they particularly compassionate or respectful toward the patient. Their actions were quite the opposite," she says.

There is a national shortage of nurses and, rather than hire a perhaps more qualified but albeit temporary and more expensive agency person, staff nurse positions may be filled by nurses that are not as highly skilled or trained as desired. Further, nurses, like other workers, should be allowed to work more than one full-time job.

"However, even in times when it is difficult to fill positions with nurses that are not already overworked, basic qualifications should be covered or at least noted in the employee's personnel file. While we are not told why the nurse had been suspended, it does seem that the facility did know of at least some of the nurse's shortcomings," notes Whiteman.

It is almost impossible to believe that a nurse would not be aware of the need for, or at least recognize, a patient care plan, particularly for patients in long-term care facilities.

"Regardless, at a minimum, the caregiver should have access to the patient's medical history," Whiteman says. "The patient history in this case would have played a pivotal role in addressing the situation. At a minimum, the nurse should have known that the patient was on a blood thinner and known that falls and even bumps suffered by such patients may be more critical.

"The lack of a patient care plan can lead to a lack of coordinated care. When caregivers are not provided with the necessary tools, it makes it difficult to render the care needed. Although, in this case it might not have had any positive effect given the charge nurse's actions toward the patient," she adds.

It is not surprising that all of the defendants settled prior to trial. Even the clinical laboratory recognized the prudence in a nominal settlement. Indeed, the decision to settle may have been triggered by the fact that many states have laws penalizing the abuse, neglect, and abandonment of elders and dependent persons.

"You never want to settle, even for minimal amounts, unless it is necessary. But the stack was really against the providers in this instance. Any time you have an overtly callous act by a person who is expected and charged with care giving, it is difficult to avoid liability," concludes Whiteman.

## Reference


• *Estate of Oscar Gonzalez, deceased, O. Lopez de Gonzalez, et al. v. Unidentified Nursing Home, Unidentified Parent Company of Nursing Home, et al.,* Harris County (TX) Probate Count, Case No. 320195-401. ■