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Warning: Reprocessing disposables is accepted, but there are still some risks

Best choice: Outsource the work and choose a provider carefully

Reprocessing medical devices labeled for single use offers substantial savings, but the practice has been controversial since it first started gaining popularity more than 10 years ago. Now, with years of experience to look back on, risk managers and clinical experts say reprocessing can be a sensible cost-cutting strategy as long as you pay attention to certain potential risks.

Risk managers must be fully aware of any reprocessing that takes place in the organization and ensure that it is done appropriately, says **John Metcalfe**, JD, vice president of risk management services at Memorial Health Services in Long Beach, CA, which has been reprocessing for 10 years. While there appears to be little risk to the patient, if any, from using reprocessed devices, he notes that is true only when appropriate quality standards are met. The decision to reprocess often is made by clinicians who look at the research and decide whether the cost savings is justified, but Metcalfe says risk managers must be in the loop.

Metcalfe's system contracts with an outside company to reprocess some single-use medical devices and says he is comfortable with the arrangement.

EXECUTIVE SUMMARY

Reprocessing of single-use medical devices has grown in popularity and appear to pose little or no clinical risk. However, risk managers must be aware of what reprocessing is taking place and ensure that quality standards are met.

- Outsourcing probably is better than doing the reprocessing in-house, many legal experts agree.
- Don't assume that all liability risks are transferred to the reprocessor.
- Consider whether it is appropriate to notify patients.

In 10 years, there has been no patient injury or other problem related to the reprocessed devices and no lawsuits alleging such harm, he says. The Food and Drug Administration (FDA) database also shows no adverse events traced to the use of reprocessed single-use devices.

"It was a real debate years ago, but as time goes on, it looks like it was making a mountain out of a mole hill. There was good reason to be cautious, but time has shown the risk just hasn't materialized," Metcalfe says.

However, not all risk managers and hospitals agree that reprocessing is safe. Children's National Medical Center in Washington, DC, for example, does not reprocess single-use medical devices. A spokesman told *Healthcare Risk Management* that hospital leaders decided against reprocessing so patients could be certain that care was provided with the most sterile and highest quality instruments possible.

A surprising number of risk managers don't even know whether their institutions reprocess single-use devices, much less what procedures are followed, says **Elizabeth Litten**, JD, an attorney with the law firm Fox Rothschild in Princeton, NJ.

"There is very little case law on this, but the potential risk if something goes wrong can be substantial," she says. "This is something that should be a priority for risk managers. Top on the list should be finding out whether you reuse these devices and exactly how."

Risk managers also should ensure that policies and procedures are formal and adequate to ensure patient safety, she says.

Can save 50% on devices

Dan Vukelich, executive director of the Association of Medical Device Reprocessors (AMDR) in Washington, DC, says third-party reprocessing offers significant cost savings.

On average, reprocessed medical devices offer a 50% cost savings, he says, as compared to purchasing a new device. Third-party reprocessing provides at least as high, and perhaps even a higher degree, of sterility assurance than in-hospital reprocessing, he says. Because of economies of scale, third-party reprocessors often have more capital available than hospitals to invest in high-tech cleaning, sterilization, and testing equipment.

In addition, Vukelich says third-party reprocessing offers hospitals significant risk management benefits. Hospitals that outsource their reprocessing needs effectively free themselves from malpractice costs that could arise in connection with improper reprocessing. Metcalfe also cites that transfer of liability as a major benefit of outsourced reprocessing. "We transferred all the potential liability for almost anything and everything that can happen with that device to the reprocessing agency," Metcalfe says. "So that can be the best of all worlds."

However, some legal experts caution that the theory is not rock-solid. The hospital still may be held liable in the unlikely event that a patient is injured by a reprocessed device, they say. **(See p. 135 for more on the legal analysis.)**

Vukelich notes that government-regulated, third-party reprocessors in the United States have

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reprocessed more than 40 million devices with no evidence of an increased risk to patient safety. "Reprocessors' safety record is every bit as good as, if not better than, the safety record of the original equipment manufacturers," he says.

However, Vukelich cautions that not everything can be reprocessed. "AMDR members have collectively reprocessed tens of millions of devices with few problems. Though numerous devices labeled for single use can be safely reprocessed, it is AMDR's view that not every device should be," Vukelich says. Devices with certain design features, such as narrow tubing, lumens, and interlocking parts, can harbor debris, which makes them inappropriate for reprocessing. Some examples are noncompression heart stabilizers, used in cardiovascular surgery for the purpose of moving, lifting, and positioning the heart while sustaining hemodynamic stability, and many endoscopic and laparoscopic tools. "AMDR member companies reprocess only a small percentage of the numerous devices used by hospitals," Vukelich reports.

Though in past years more hospitals did their own reprocessing, he says today the vast majority of reprocessing of single use devices in the is done by third-party companies, which are stringently regulated by the FDA.

Vukelich notes that the "single-use" label is used at the manufacturer's discretion, often as a way to sell more devices, and that the designation of a device as "single use" is not an FDA requirement. Indeed, "single use" does not always mean that a device is not suitable for reprocessing, as evidenced by the fact that some original equipment manufacturers now reprocess

Risk is not always on processor, lawyer warns

Don't be so sure that you're off the hook for any potential liability just because you are using a third party to reprocess single-use devices, cautions **Elizabeth Litten**, JD, an attorney with the law firm Fox Rothschild in Princeton, NJ.

There are still too many unknowns regarding reprocessed devices to be sure that you can transfer the risk, Litten says. After an adverse event, the disclosure that a reprocessed device was used could just make things worse, she says. Even if the device — or the fact that it was reprocessed — had nothing to do with causing the adverse outcome, the patient can respond negatively to the "ick" factor of a reused device. And of course, the plaintiff's attorney can play on that same sentiment in court even if there is no actual evidence of increased risk.

"If you didn't notify the patient that you were using reprocessed devices, and most people don't, then you've got the added issue of whether you deceived your patient," she says. "Plus, there is the possible allegation that you billed for a new device when it wasn't really new, which could be billing fraud."

Strictly from a risk management perspective, it might be a good idea to notify patients in the informed consent process that reprocessed devices will be used, Litten says. From a practical standpoint, many organizations resist that disclosure because it may scare patients or invite lawsuits.

Litten cautions that it could be foolhardy to assume that you are transferring all liability risk to a third-party reprocessor.

"There aren't sharp, bright lines yet in terms of who is responsible when something goes wrong. I would not advise my clients that they're off the hook and all the liability will fall on the reprocessing company," she says. "One determinant will be who knew about the reprocessing and approved of it. If the cardiac surgeon says he had no idea you were reprocessing this item and doesn't think that was safe, you could end up with a bigger problem than you expected." ■

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their own "single-use" devices, and some have changed the labels on certain "reusable" devices to "single use" without significantly changing the devices.

Also, the government-regulated standards for reprocessing are stringent and sometimes even higher than those required of new products, says **Arthur Goodrich**, vice president of business development with Ascent Healthcare Solutions, an independent third-party reprocessor in Phoenix. Ascent has reprocessed more than 50 million devices for more than 1,700 health care facilities nationwide.

"If we have received clearance from the FDA to reprocess an item, we have had to submit a dossier on the procedures for processing that device that is, in most cases, more complex and detailed than the original manufacturer had to submit when that device was put on the market," he says.

One risk manager with experience in this area recommends using only outside reprocessors rather than taking on the task yourself. **Ches Alper**, MD, is manager of risk management education with Health Care Indemnity, the captive insurance company for Hospital Corporation of America (HCA), based in Nashville, TN. When HCA investigated reprocessing six years ago, the risk management department told affiliate hospitals that there was no undue risk or potential liability as long as they

Beware of risks from counterfeit medical devices

While you're checking your organization's policy on reprocessing single-use medical devices, it's a good idea to review how your supply infrastructure wards off counterfeit items.

Counterfeit items can creep into the health care supply if you do not use safeguards to keep them out, warns **Vincent Volpi**, CEO of PICA Corp., a company that conducts corporate investigations and security consulting for health care providers and other companies. Because the fake items — which include stolen and illegally packaged or imported products — are not of the same quality and not properly regulated, they pose a substantial risk to patient safety, he says.

The most common counterfeit products are simple items like sutures, Volpi says. But there also are diverted products that are sold through secondary sources, not the original manufacturers or their authorized distributors. A third group is reprocessed and repackaged products that are sold as new and unused.

"Many hospitals and health care organizations buy products in the secondary markets because they are cheaper. Most often, the reasons they are cheaper are that they are destined for sale overseas where the price points are lower, or they're stolen, usually from hospitals or health care organizations," Volpi explains. "The products also may be expired and designated for donation to poor countries or destruction, or they may be repackaged."

Volpi urges risk managers to investigate how purchasing departments cut costs when buying medical supplies. The pressure to cut costs can sometimes lead staff to make bad decisions, he says, and risk managers might be shocked at what they find when they go digging.

"Betraying the trust of your patients to save a few bucks is not only immoral, it is a bad business decision," he says. "It exposes the organization and its members to liability, ridicule and a diminished reputation in an industry where faith and confidence is the prevailing currency."

Tips for avoiding counterfeit devices

To avoid counterfeit, diverted, or repackaged product that potentially increases risk and liability, Volpi says risk managers should follow these steps:

- Always buy from reputable sources, ideally approved by the manufacturer in accordance with Food and Drug Administration (FDA) guidelines.
- Educate the purchasing departments about the dangers of buying from unapproved and questionable sources. These sources range from eBay and other Internet sources to consolidators who maintain product in self-storage units, to overseas distributors with no real physical address or known person associated.
- Secure inventories of medical products the same way retailers do with high-value merchandise. Controlling these inventories will radically diminish theft and keep hospitals and health care providers from buying back their own inventories, with the risk associated with acquiring them from less-than-reputable sources. ■

SOURCE

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outsourced the work.

"We visited the top reprocessors and were very comfortable with what we saw. But we decided that no hospital is capable of meeting the reprocessing requirements set up by the government and that it would not be wise to take on that responsibility," he says. "In six years, we have not had any reported problems or claims arising from reprocessed items." **(Editor's note: Another equipment issue that risk managers should be aware of is the risk of encountering counterfeit medical devices. See story, p. 136.)** ■

ED falls not same as others, require different strategy

Falls occur in the emergency department (ED) with distressing frequency, but the typical fall prevention strategies that work in other areas of health care may not be so effective in this special setting. Emergency medicine professionals and risk managers are learning that one size does not fit all when it comes to reducing falls in the ED.

Methodist Hospital in Indianapolis is leading the way in addressing this particular challenge of fall reduction, and ED nurse **Mary J. Ross**, RN, BSN, CEN, says it has been difficult to even quantify and compare fall rates. Though there are plenty of data on falls in health care facilities, most of that information is not broken down by department, and there is little available that specifically applies to EDs, she says.

Ross and other nurses at Methodist decided to do their own literature search to break down some of the statistics in a way that would be useful in the ED, and they also drilled down in to Methodist's own fall numbers. They compared ED falls to falls in an inpatient setting, using the Hendrich II Fall Risk Scale, and the results were surprising. The patients who fell in the ED often did not fit the risk profile commonly used by inpatient units. **(See article, above, for more on the Methodist Hospital research.)**

For starters, the patients were much younger, reflecting the more varied age groups that appear in the ED and not the elderly patients that are most often at risk of falling on inpatient units. The falls in the ED also were likely to have alcohol or drugs in their system — not a typical risk found elsewhere in the hospital.

Like many hospitals, Methodist relies on the

EXECUTIVE SUMMARY

Falls in the emergency department (ED) are not the same as falls in other areas of health care. The fall risk profiles and fall reduction strategies that work elsewhere may not be applicable in the ED.

- Intoxication is a major risk factor for falls in the ED.
- Most ED falls happen in the hallway, not from the bed.
- ED-specific strategies can help reduce falls.

Study revealed unique aspects of ED falls

Research into fall reduction in the emergency department (ED) started in January 2006 at Methodist Hospital in Indianapolis. ED nurse **Mary J. Ross**, RN, BSN, CEN, provides this synopsis of the work:

The ED team implemented the quality improvement project using the Plan-Do-Study-Act model. Ross and her colleagues studied all patient falls in the Methodist ED for a two-year period from Oct. 1, 2003, to Sept. 30, 2005. One goal was to apply the Hendrich II Fall Risk Scale retroactively to determine if it would have accurately predicted the falls. In addition, the team collected data on type and severity of injuries sustained in the fall, the use of side rails, the location within the ED of the fall, intoxication, prior history of falls, ED diagnosis, and whether the patient was admitted or released.

There were 57 falls by 56 patients during the study period. The total ED volume was 190,000 visits, meaning there were 0.3 falls per 1,000 visits. The average age of the ED fall patient was 50.3 years, and 66% were male. Intoxication was a factor in 55% of the falls. Sixty-six percent of those who fell were admitted to the hospital (not because of the fall). Thirty-four percent had minor fall-related injuries, and there were no serious injuries.

The analysis revealed that only 37.5% of those who fell in the ED would have met the Hendrich II parameters for a fall risk (scoring 5 or greater on the Hendrich II risk factors). Confusion and male gender, two of the risk factors used on the Hendrich II, were confirmed as risk factors in the ED.

Ross and her colleagues concluded that relying on the Hendrich II for identifying patients at risk of falling in the ED can be misleading. ■

risk factors in the Hendrich II Fall Risk Scale to identify patients at risk for fall so preventive measures can be taken. The eight risk factors are confusion and disorientation, depression, altered elimination, dizziness and vertigo, male gender, prescribed use of anti-epileptics, prescribed use of benzodiazepines, and altered mobility. Looking back on the patients who fell in the Methodist ED, Ross and her colleagues found that the Hendrich II Fall Risk Scale did not accurately predict they would fall.

"It was interesting to see the numbers. We're all trained to watch for falls with the elderly patients and those who are confused," Ross says. "But that's not who was falling in our ED. It was patients who were intoxicated or medicated. The conclusion was that the typical fall reduction plan that works elsewhere in the hospital might not work here."

Ross and her colleagues used those findings to develop a fall reduction plan that is specific to the ED. **(See article, below, for details of the fall reduction plan.)** In addition to warning ED staff that the risk profile is different than elsewhere in the hospital, Ross explains to them that location and type of falls are not the same. In most inpatient units, for instance, falls often occur from the bed, and guardrails are a key prevention strategy. Not so much in the ED. "Most patients were falling in the hallway, and guardrails didn't help us," she says. "It was when they were moving about, most often slipping in their own urine."

Ross says the ED staff are embracing the new approach to reducing falls, though as with all new approaches, there was delay as people got used to the new way of doing things. One positive aspect of the work was that the research confirmed what a lot of experienced ED staff already knew. "A lot of staff knew that the intoxicated patient was most likely to fall, so in that sense this work vindicated their experience, which didn't always match with the risk profile they were told to use," she says. "I think the results mostly surprised people outside the ED, the administrators who think in terms of the general patient population and not this different group of patients that we deal with in the ED."

Research highlights unique part of ED

Clarian uses the Safe Passage approach to patient safety, which includes having champions in each unit to promote safety initiatives and other risk management activities, and Ross is the

Action plan calls for red footies, special signage

The emergency department (ED) at Methodist Hospital in Indianapolis recently implemented several fall reduction strategies that are specific to the risks found in their patient population. ED nurse **Mary J. Ross**, RN, BSN, CEN, provides this overview of the effort:

• ED-specific staff training on fall reduction.

The ED staff undergo special training to recognize patients at risk of falling, with an emphasis on watching confused and intoxicated patients. All of the ED staff were inserviced on fall reduction at five staff meetings in June, and Ross also looks for ongoing opportunities to remind people, such as when orienting new staff. Triage staff receive extra education because they have the opportunity to identify a patient as a fall risk from the first moment they enter the ED, Ross says.

• Updated risk profiles.

In addition to the standard profile of a patient at risk for falling, staff are instructed to watch for patients who are intoxicated or medicated, confused or disoriented, and acutely ill or likely to be admitted. Those risk factors were identified from the analysis of falls at the Methodist ED.

• Fall risk signs.

Special signs are used to designate a patient as a fall risk. The sign says "Identify patients at risk for falls!" and lists the most common risk factors. It also instructs staff to activate a warning icon in the computer system. A copy of this sign is placed on the patient's stretcher or hung on the door to the exam room.

• A special fall risk icon in the computer tracking system.

Once a patient is identified as a fall risk, a special icon on the electronic tracking board notifies all staff. The icon uses the same graphics as the fall risk sign to encourage instant recognition.

• Red footies.

Any at-risk patient who undresses or is without footwear is given special red disposable footies that identify him or her as a fall risk.

• Warnings to patient and family.

When a patient is at risk of falling, staff warn the patient and family members. The patient is instructed not to get up without assistance, and a call button is always within reach. Staff members accompany these patients to and from the bathroom. ■

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representative in the ED. She collaborated on the fall reduction project with **Kathryn Davies**, RN, BC, MSN, patient safety clinical nurse specialist with Clarian Health Partners in Indianapolis.

Davies is responsible for many risk management activities for Clarian, including fall reduction, and she says the ED initiative was an eye-opener.

"There's a tendency to want to think that once we've addressed a problem, we've addressed it for everybody in the hospital," she says. "That's not always the case, and the ED research showed just how different some of the patients can be in that area."

Davies notes that in addition to the difference in patients, an ED can be a hard place to implement some of the typical fall reduction strategies used elsewhere. The Methodist ED is a Level 1 trauma center, for instance, so it can be a challenge for staff to monitor patients as much as you might find on other units. "We were really pleased to see that the ED staff delved deeper into the numbers to find meaningful data, rather than just looking on the surface," Davies says. "Falls are such a big problem in health care, so this kind of innovation can have a major impact." ■

Research shows big risk with residency programs

Young doctors, long work hours, and inexperience are a bad combination when you're trying to improve patient safety, according to new research that provides a clear reminder of the risks inherent in a medical residency program.

Risk managers should not be lulled into a false sense of security by relying the work hour limits enacted in recent years, cautions **Carolyn M. Clancy**, MD, director of the Health and Human Services Agency for Healthcare Research and Quality (AHRQ). A recent report from her group says nearly 84% of medical interns reported that they are continuing to work hours that exceeded the limits of a 2003 national standard implemented by the medical profession.[1]

A related study concludes that interns are much more likely to injure themselves mistakenly with a needle or another sharp instrument when working in a hospital more than 20 consecutive hours, or at night.[2] The findings build on previous research and the growing awareness that sleep-deprived, first-year doctors in training working traditional 24-hour shifts make many more serious medical errors and crash their cars more often than those whose work is limited to 16 consecutive hours.

Clancy suggests that risk managers should investigate the work hours of any residency program in their organizations and insist that the limits be respected. "These studies raise troubling questions about compliance with standards that were developed to reduce medical errors due to work hour-related fatigue," she says. "Residency programs that don't comply with these standards could be jeopardizing the safety of both their patients and their interns."

In 2003, the Accreditation Council for Graduate Medical Education (ACGME) introduced work-hour limits for all first-year residents training in U.S. hospitals. Under these standards, interns are limited to a maximum of 30 consecutive work hours (known as the 30-hour rule), which includes time used for sign-out, teaching, and continuity of

EXECUTIVE SUMMARY

Medical residents continue to work longer hours than they are supposed to, according to new research. Longer hours are strongly associated with an increased risk to patients.

- Overworked residents also are at great risk of injuring themselves.
- Risk managers should investigate work hour violations in residency programs.
- Reducing work hours can bring unexpected threats to patient safety.

care. Interns also are prohibited from working more than 80 hours per week (the 80-hour rule), averaged over four weeks, and must be free of all duties for one day in seven (the seven-day rule). In the recent research, an independent, nationwide study conducted by researchers at Brigham and Women's Hospital, Boston, found that 83.6% of interns reported work hours that did not comply with the ACGME standards.

One of the authors of that study, **Christopher P. Landrigan**, MD, MPH, director of the Sleep and Patient Safety Program at Brigham and Women's Hospital, says the long hours threaten patient safety. He suggests the work hour rules may need to be strengthened even more. "Current professional regulations allow doctors-in-training to work 24-30 hours in a row, a limit far beyond established safe limits for pilots and truckers and far beyond the legally enforced 13-hour limit for physicians in Europe," he says. "Yet even this permissive limit is routinely exceeded. To address the epidemic of medical errors in this country, we must start by establishing evidence-based, safe work-hour limits for young physicians, and we must then enforce them."

Hours alone don't dictate quality

In the study involving needlestick injuries, researchers found that interns working during the day following an overnight shift suffered 61% more needlesticks and other sharp object injuries than they experienced during a day that was preceded by a night at home (1.3 per 1,000 opportunities vs. 0.76 per 1,000 opportunities). Furthermore, interns suffered more than twice the rate of injuries during the night (1.48 per 1,000) than during the daytime (0.7 per 1,000). Lapses in concentration and fatigue were the two most commonly reported contributing factors (64% and 31%, respectively).

Unfortunately, simply enforcing the work hour limits may not be enough. Research conducted at several medical schools has found that reducing the amount of work hours alone for surgical residents does not appear to improve quality of patient care. A sample of 156 residents from three surgical specialties completed questionnaires designed to measure subjective impressions about the quality of patient care. More than 88% of residents reported that the quality of patient care remained unchanged (63%) or was worse (26%) after work-hour restrictions had been implemented. Overall, residents reported fewer fatigue-related errors following implementation of work-hour restrictions. However, more errors were perceived to be related to continuity of care, miscommunication, and cross-coverage availability.

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SOURCES

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Has the patient given informed consent?

Surgery staff is last line of defense

The patient is ready for surgery, or so the surgeon says. However, the circulating nurse says the patient is asking about the risks of the surgery and appears to be confused about what procedure is being done. Now the nurse is questioning whether this patient gave informed consent.

"That's been a dilemma for nurses for a very long time," says **Ramona Conner**, RN, MSN, CNOR, perioperative nursing specialist at the Center for Nursing Practice at the Association of periOperative Registered Nurses (AORN). The perioperative nurse is responsible for ensuring informed consent has been obtained and that it's appropriately signed and on the patient's record prior to surgery, Conner says. "The circulating RN is the last guardian, the last one to check it," she says.

So how should this situation be handled to maximize patient safety and minimize the risk to the facility and the surgeon? If necessary, the nurse should delay administering of preoperative meds (if ordered) until the physician is located to answer any issues or unresolved questions the patient still has, says **Waldene K. Drake**, RN, MBA, vice president of risk management and patient safety at Cooperative of American Physicians — Mutual Protection Trust (CAP-MPT) in Los Angeles. Your policy on informed consent should discuss the right of the nurse/supervisor to delay surgery and preoperative medications when a patient has verbalized concerns, Drake says.

The repercussions of not doing so can be severe. The Physician Insurers Association of America says that 15% of all surgical claims involve allegations of failure to obtain informed consent or failure to clarify elements of informed consent.

In 41% of all closed claims that include those allegations, the patients receive payments, the association says.

However, it's a significant liability for surgery center or hospital staff members who aren't surgeons to try to provide the informed consent discussion, says **Anne M. Menke**, RN, PhD, risk manager at the Ophthalmic Mutual Insurance Co. in San Francisco. "In some states, it's illegal, because they're practicing medicine," Menke says. "They're increasing their liability if they try to explain what's going to be happening and why." Instead, the staff should be making certain that the patient understands what's being done and has had a discussion with the surgeon, she says.

Informed consent cannot be delegated to anyone else by the surgeon, she says. "Everyone has role in helping educate the patient about his condition and the proposed treatment of medication or surgery, but only the surgeon has the knowledge requirement to obtain an informed consent," she says. Menke points to a recent malpractice lawsuit in which a $3 million verdict was obtained by a patient who, among other claims, said there was no personal discussion of the eye procedure with the surgeons, although the patient did sign an informed consent.[1] Some facilities put language into their medical staff bylaws that require surgeons to obtain informed consent in their offices prior to surgery. While the surgeon should discuss the benefits and risks of the procedure, the facility should have a separate consent form that the patient signs giving consent to be treated at the facility, sources say. The facility consent should state that the patient has met with the surgeon and discussed the need for and the potential risks of the surgery, sources say.

Often patients have been informed about the risks and benefits of the procedure in the surgeon's office, but they might not have absorbed all of the information given to them and they might not have understood what they were told, Conner says. "Sometimes they feel more comfortable asking an RN until they really clearly understand," she says.

Surgery programs face special difficulties

Some surgery programs face the additional challenge of serving patients who live a long distance away and can't be seen until the day of surgery.

Those patients can be sent the informed consent document ahead to time to read and ask questions, Menke says. The morning of surgery, before patients are sedated, the surgeon personally should obtain the patient's informed consent, she says. However, some patients who had an informed consent discussion on the day of surgery have later sued and argued that they were forced to have the procedure and didn't have time to consider the benefits and risks, Menke warns.

It's important for physicians to convey that they are genuinely concerned about their patients, says **Lewis A. Lefko,** partner with Haynes and Boone, a Dallas-based law firm.. "That's why I prefer informed consent between physician and patient take place in physician's office, rather than when a patient is being rolled into OR," he says. "Surgery centers and hospitals are pretty intimidating."

Keep in mind that informed consent can't be obtained from a patient who is sedated, Menke says. However, if the patient simply has dilated eyes, a family member or staff member may read the consent form to the patient, and then the patient can sign it. That person's name and relationship to the patient should be documented on the form, Menke says.

Additionally, when a patient's surgery unexpectedly changes after the case has started, a modified informed consent may need to be obtained from a relative who has been informed of the situation, sources say. In such a situation, the informed consent should be separately documented.

Before grabbing any type of informed consent form to copy, know who developed it and who commented on it, Lefko suggests. Several states, such as Texas, have medical disclosure panels that develop such forms, he says. **[English and Spanish copies of the Texas informed consent form are available with the on-line edition of the December issue of *Healthcare Risk Management*. If you're accessing your on-line account for the first time, go to www.ahcmedia.com. Click on the "Activate Your Subscription" tab in the left-hand column. Then follow the easy steps under "Account Activation." If you already have an on-line subscription, go to www.ahcmedia.com. Select the tab labeled "Subscriber Direct Connect to Online Newsletters. Please select an archive." Choose "Healthcare Risk Management," and then click "Sign on" from the left-hand column to log in. Once you're signed in, select "2006" and then select the December 2006 issue. For assistance, contact customer service at customerservice@ahcmedia.com or (800) 688-2421.]**

"You can fill those in, but the form doesn't keep you from having discussion," Lefko emphasizes. Also, keep in mind that different physicians may use different techniques, such as laparoscopic vs. an open approach, so the risks may be different, Drake says.

The form can help prepare patients for potential complications, Menke says. "That's also an important piece of informed consent: Patients are important members of the health care team," she says. "If they are better informed, they are better able to make their surgery go as good as possible."

Reference

1. New York jury issues $3 million verdict in medical malpractice case. *LexisNexis Mealey's Personal Injury Report* Aug. 10, 2006; 3. Accessed at www.mealeys.com/free%20views/per.htm#_New_York_Jury> citing *Gropack v. Eric D. Donnenfeld, MD.* ■

Mother injured at hospital where 3 babies died

In a tragic demonstration that increased vigilance is sometimes not enough to prevent medication errors, the same hospital that promised sweeping changes after the accidental deaths of three premature newborns reports that another error has led to the paralysis of a teenage mother.

The incident occurred just weeks after three premature newborns died at Methodist Hospital in Indianapolis when given an overdose of the drug heparin. **(For more information, see *Healthcare Risk Management*, November 2006, p. 130.)** At that time, hospital leaders admitted that the infant deaths were the result of human error and procedural lapses, and they vowed to implement safeguards to prevent a recurrence.

The hospital recently announced that another medication error by a doctor led to the overdose of a new mother, who was left unable to walk and with little feeling and movement in her legs. Her doctors say there is hope for a full recovery, and the baby was not injured.

According to a statement released by Methodist, an anesthesiologist improperly administered an epidural that left 18-year-old Amber Baise unable to walk. The anesthesiologist gave the correct dose of the medication, but gave her too much of it in a short period time, instead of spreading it out over several hours. A software program called "Guardrails," part of the machine that is used to administer epidurals, was supposed to sound an alarm if a drug was being given too quickly, but the hospital says the program wasn't activated to detect that type of error. ■

Claims stabilizing for first time in years, study finds

Insurance claims against doctors, nurses and other medical professionals have stabilized for the first time in years, according to the seventh annual Aon Hospital Professional Liability and Physician Liability Benchmark Analysis, recently released by the insurance giant based in Chicago.

That encouraging news, however, comes with a downside: The average size of malpractice claims continues to rise.

The study, which measured 47,735 claims representing more than $4.4 billion of incurred losses in the United States, found that the overall frequency of medical malpractice claims has not increased for the second straight year. While claim frequency is stabilizing, according to the study, the average size (severity) of malpractice claims continues to increase at a rate of 6%. However, the average amount paid to indemnify claimants is increasing at a rate of only 3%, while amounts

paid to defend against liability claims are growing at 17% as hospitals invest in claims management, explains **Greg Larcher**, director and actuary of Aon Risk Consultants and author of the analysis.

The improved frequency rate that first emerged in the 2005 study appears to be sustained through 2006," Larcher says. "Based on study findings, we believe that the impact of past state level legislative reforms has largely been realized, and we do not expect significant decreases in claim frequency or severity resulting from tort reform in the future unless other states pass legislation that withstands challenges. Patient safety initiatives being implemented today, however, may be critical for sustaining a favorable frequency trend into the future."

Link: Mortality and claims frequency

This year's study found that a statistically significant relationship exists between mortality and claim frequency in certain segments of the database. For example, after adjusting for patient volume and acuity, Texas hospitals with 200 mortalities in 2004 experienced six indemnity claims while hospitals with 150 mortalities experienced four indemnity claims. This finding gives an interesting perspective on how changes in quality might affect claim counts, Larcher says. "While it is logical to believe that organizations that reduce preventable harm to their patients will also reduce professional liability claim counts and costs, our study takes a first step at proving this true with data," he says. "In the long term, the industry would benefit from a more comprehensive measure of quality, beyond mortality, that measures the success of patient safety improvements and their impact on liability costs."

More than 700 health care facilities provided loss and exposure data for the benchmark study. The analysis is co-sponsored by the American Society for Healthcare Risk Management (ASHRM) in Chicago. *[Editor's note: The complete report is available for purchase from Aon. The cost is $250 for ASHRM members and $350 for nonmembers. To purchase a copy, call (800) 242-2626 and request item No. 178701, or go to www.aon.com/hpl_study for more information.]* ■

JCAHO warns about risk of generator failure

The Joint Commission on Accreditation of Healthcare Organizations recently issued a *Sentinel Event Alert* that urges health care organizations to pay special attention to how emergency power systems can fail and recommends specific steps to keep patients safe when the electrical power supply is out.

"Reports from the 2001 floods in Houston, the 2003 blackout in the Northeast, and hurricanes that have hammered the Southeast over the past two years show how severely clinical operations can be affected in health care organizations that lose their electrical power," the Joint Commission says. In a statement accompanying the *Alert,* Joint Commission president **Dennis O'Leary**, MD, notes that "health care facilities are highly dependent upon reliable electrical power; but recent experiences show that emergency power systems are not always sufficient during a major catastrophe."

In addition to the warning, the Joint Commission is adding a new requirement in 2007 that organizations test emergency generators at least once every 36 months for a minimum of four continuous hours. Facilities already must test their generators 12 times a year for 30 minutes. If a test fails, the organization must immediately implement stopgap measures until a permanent fix can be put into place. **(For the *Alert,* go to www.jointcommission.org. Under "Sentinel Events," select "Sentinel Event Alert." Then click on "Issue 37 — September 6, 2006: Preventing adverse events caused by emergency electrical power system failures.")**

The Joint Commission cautions that compliance with minimum National Fire Protection Association (NFPA) codes is not enough to ensure the safety of patients and their care during an emergency situation.

To reduce risks to patients created by power failures, the Joint Commission recommends that health care organizations take these steps:

• Match the critical equipment and systems needed in an extended emergency against the

COMING IN FUTURE MONTHS

- Rapid response teams improve safety
- Suicide assessment: Are you doing enough?
- New strategies for avoiding errors
- Credit checks for new employees

CE objectives

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

- **Describe** legal, clinical, financial, and managerial issues pertinent to risk management in health care.
- **Explain** how these issues affect nurses, doctors, legal counsel, management, and patients.
- **Identify** solutions, including programs used by government agencies and other hospitals, for hospital personnel to use in overcoming risk management challenges they encounter in daily practice. ■

equipment and systems actually on the emergency power system.

• Inventory emergency power systems and the loads they serve.

• Provide training for and test the staff who operate and maintain the emergency power supply system.

• Ensure that generator fuel is available and usable.

• Ensure that the organization management and clinical leaders know how long emergency power will be available and what locations within the facility will not have emergency power in the event of an electrical outage.

• Establish contingency plans for doctors and other caregivers to follow during losses of electrical power. ■

CE Questions

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

21. According to John Metcalfe, JD,which of the following is true regarding past fears that reprocessing single use devices could threaten patient safety?
A. The fears have been borne out, as evidenced by multiple adverse events.
B. It is not clear if there is any risk.
C. There was never any reason to worry about patient safety.
D. There was good reason to be cautious, but time has shown the risk just hasn't materialized.

22. According to Dan Vukelich, what is the typical cost savings from having a company reprocess single-use devices?
A. 10%
B. 30%
C. 50%
D. 80%

23. At Methodist Hospital in Indianapolis, what did research by emergency department (ED) nurse Mary J. Ross, RN, BSN, CEN, reveal as a leading risk factor for falls in the ED?
A. Female gender
B. Age younger than 15 years
C. Weight of more than 200 pounds
D. Intoxication

24. According to Ross, where were ED patients most likely to fall?
A. The bedside
B. The hallway
C. Exam rooms
D. The triage desk

Answers: 21. D; 22. C; 23. D; 24. B.

DISCLOSURE AND CONSENT

Medical and Surgical Procedures

TO THE PATIENT*: *You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

I (we) voluntarily request Dr. _____ as my physician, and such associates, technical assistants and other health care providers as they may deem necessary, to treat my condition which has been explained to me (us) as:

_____

_____.

I (we) understand that the following surgical, medical, and/or diagnostic procedures are planned for me and I (we) voluntarily consent and authorize these procedures:

_____

_____.

I (we) understand that my physician may discover other or different conditions which require additional or different procedures than those planned. I (we) authorize my physician, and such associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment.

I (we) (do) (do not) consent to the use of blood and blood products as deemed necessary.

I (we) understand that no warranty or guarantee has been made to me as to result or cure.

Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical and/or diagnostic procedures planned for me. I (we) realize that common to surgical, medical, and/or diagnostic procedures is the potential for infection, blood clots in veins and lungs, hemorrhage, allergic reactions, and even death. I (we) also realize that the following risks and hazards may occur in connection with this particular procedure:

_____

_____

_____.

I (we) understand that anesthesia involves additional risks and hazards but I (we) request the use of anesthetics for the relief and protection from pain during the planned and additional procedures. I (we) realize the anesthesia may have to be changed possibly without explanation to me (us).

I (we) understand that certain complications may result from the use of any anesthetic including respiratory problems, drug reaction, paralysis, brain damage or even death. Other risks and hazards which may result from the use of general anesthetics range from minor discomfort to injury to vocal cords, teeth or eyes. I (we) understand that other risks and hazards resulting from spinal or epidural anesthetics include headache and chronic pain.

I (we) have been given an opportunity to ask questions about my condition, alternative forms of anesthesia and treatment, risks of nontreatment, the procedures to be used, and the risks and hazards involved, and I (we) believe that I (we) have sufficient information to give this informed consent.

I (we) certify this form has been fully explained to me (us), that I (we) have read it or have had it read to me (us), that the blank spaces have been filled in, and that I (we) understand its contents.

PATIENT/OTHER LEGALLY RESPONSIBLE PERSON (signature required)

_____

DATE: _____ TIME: _____ A.M./P.M.

WITNESS:

_____

Signature

_____

Name (Print)

_____

Address (Street or P.O. Box)

_____

City, State, Zip Code

DIVULGACIÓN DE INFORMACIÓN Y CONSENTIMIENTO

Procedimientos médicos y quirúrgicos

AL PACIENTE: Usted tiene el derecho como paciente a que se le informe sobre su condición y a que se le recomiende el procedimiento quirúrgico, médico o diagnóstico que se utilizará para que, después de conocer los riesgos y peligros involucrados, usted pueda tomar la decisión de seguir con el procedimiento o no. Esta divulgación de información no tiene como propósito el asustarle ni alarmarle; es sencillamente una medida para mejor informarle para que así usted pueda dar o negar su consentimiento al procedimiento.

Yo solicito (nosotros solicitamos) voluntariamente al (a la) Dr(a). _____ como mi médico, y tales socios, ayudantes técnicos, y otros proveedores de atención de salud como ellos estimen necesario, que traten mi condición, la cual se me (se nos) ha explicado como:

_____

_____.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que los siguientes procedimientos quirúrgicos, médicos y / o diagnósticos son planificados para mí, y doy (damos) el consentimiento voluntariamente para estos procedimientos y autorizo (autorizamos) estos procedimientos:

_____

_____.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que quizá mi médico descubra otras o diferentes condiciones que requerirán procedimientos adicionales o distintos a los ya planificados. Yo autorizo (nosotros autorizamos) que mi médico, y tales socios, ayudantes técnicos y otros proveedores de atención de salud realicen tales procedimientos adicionales que son prudentes en su opinión profesional.

Yo doy (nosotros damos) / Yo no doy (nosotros no damos) consentimiento para el uso de sangre y productos de sangre, como se estime necesario.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que ninguna seguridad ni garantía se me (se nos) ha dado con relación al resultado o a la cura.

Asimismo que podrían haber riesgos y peligros al seguir en mi condición actual sin tratamiento, también hay riesgos y peligros relacionados a la realización de los procedimientos quirúrgicos, médicos y / o diagnósticos planificados para mí. Yo comprendo (nosotros comprendemos) que el potencial para infección, coágulos de sangre en las venas y los pulmones, hemorragia, reacciones alérgicas, y aún muerte, son comunes en los procedimientos quirúrgicos, médicos y / o diagnósticos. Asimismo, yo comprendo (nosotros comprendemos) que podrían ocurrir los siguientes riesgos y peligros con respecto a

este procedimiento en particular:

_____

_____.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que la anestesia involucra riesgos y peligros adicionales, sin embargo solicito (solicitamos) el uso de agentes anestésicos para el alivio de y la protección contra el dolor durante los procedimientos ya planificados y los procedimientos adicionales. Yo comprendo (nosotros comprendemos) que posiblemente se tendría que cambiar la anestesia sin darme (darnos) explicación.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que ciertas complicaciones podrían resultar de la utilización de todos los agentes anestésicos las cuales pueden incluir problemas respiratorios, reacción a medicamentos, parálisis, daño cerebral, o aún muerte. Otros riesgos y peligros que podrían resultar de la utilización de agentes anestésicos generales varían de molestia leve hasta daño a las cuerdas vocales, los dientes, o los ojos. Entiendo y acepto (entendemos y aceptamos) que otros riesgos y peligros que resultan del uso de agentes anestésicos espinales o epidurales incluyen dolores de cabeza y dolor crónico.

Se me (se nos) ha dado una oportunidad de hacer preguntas sobre mi condición, las clases de alternativas de anestesia y de métodos alternativos de tratamiento, los riesgos si no se recibe tratamiento, los procedimientos que se utilizarán y los riesgos y peligros involucrados en ellos, y que según mi (nuestro) leal saber y entender yo tengo (nosotros tenemos) la información suficiente para dar este consentimiento consciente.

Yo afirmo (nosotros afirmamos) que se me (se nos) explicó este formulario en su totalidad y que lo he (hemos) leído o que se me (se nos) ha leído, que se han llenado los espacios en blanco, y que entiendo y acepto (entendemos y aceptamos) su contenido.

FIRMA DEL PACIENTE / OTRA PERSONA LEGALMENTE RESPONSABLE (firma requerida)

_____

FECHA: _____ HORA: _____ A.M./P.M

TESTIGO:

_____

Firma

_____

Nombre (letra de molde)

_____

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

Failure to provide treatment by 7 doctors and 1 hospital leads to death and $1.35 million settlement

By **Blake J. Delaney**, Esq.
Buchanan Ingersoll & Rooney PC
Tampa, FL

News: A woman suffering from severe discomfort in her mouth and throat area presented to the emergency department (ED) for treatment. Over the next two days, doctors passed the patient around as they refused to respond to their on-call duties and simply failed to handle the woman as their own patient. Despite test results and symptoms suggesting airway obstruction, the woman was discharged, only to return again the next day. Doctors failed to realize that more substantial treatment was required and continued to treat her with antibiotics and other medication. When an oral surgeon finally realized that some of the woman's teeth needed to be extracted, he performed the surgery and left for vacation. The woman continued to struggle to breathe, however, and after she was passed on to several more physicians, she eventually stopped breathing and died. The woman's estate sued all of the providers involved in the decedent's care, and the parties settled the case for $1.35 million.

Background: A 38-year-old woman presented to the ED complaining of a sore throat and swollen lymph nodes. Noting swelling in the patient's neck, dental decay, tenderness in the mouth, and lockjaw, a doctor called for the on-call oral surgeon and then ordered blood work, an X-ray of the woman's mandible, and a CT scan of her neck. The results of the tests showed a large amount of gas under the woman's tongue and beneath her lower jaw, as well as two abscesses. The ED doctor prescribed ibuprofen for pain, but when that did not seem to work, he prescribed morphine. Then, realizing that the on-call surgeon had failed to respond, he called for the backup oral surgeon. Now five hours after the woman initially had presented, the backup surgeon arrived and ordered that the patient be admitted to the hospital.

Once admitted, the woman was given nalbuphine for her pain and antibiotics to treat her possible infection. Several hours later, hospital staff noted that the patient was having difficulty swallowing liquids, and the original on-call surgeon was again called. He ordered over the telephone that additional antibiotics be administered immediately. But when the woman continued to complain of increased swelling and fears of not being able to breathe, the oral surgeon was called for a third time. The surgeon still failed to report to the hospital to visit the patient, however, and instead told the nurse to call an ear, nose, and throat (ENT) specialist. The ENT doctor ordered over the telephone that a steroid and a different antibiotic be administered to the woman.

The woman awoke the next morning unable to swallow her own saliva. Nurses gave the patient a suction catheter, and the ENT specialist was summoned again. Finding the patient to be suffering from acute distress with muffled speech, a swollen floor of the mouth, and difficulty

handling secretions, the ENT physician ordered that a sore throat spray be administered. He also told the nurses to summon the on-call oral surgeon again, but the surgeon failed to come to the hospital for another two hours. When he finally did arrive, he discharged the patient and gave her a prescription for an antibiotic and pain medication, even though she still was having difficulty swallowing.

The next day, the woman returned to the hospital, still in pain. The oral surgeon was at the hospital, and he concluded that four abscessed and decayed teeth needed to be removed. Because the surgeon had plans to leave town that afternoon, he wanted to perform the surgery that day in his office. He obtained clearance from the woman's family doctor to perform the extraction using intravenous sedation, and following the procedure, he sent the woman home with prescriptions for lithium, antibiotics, and an anti-inflammatory.

The woman again returned to the ED, suffering from shortness of breath, chest pain, a sore throat, a toothache, fluid collection in the alveoli, swelling under the tongue, difficulty swallowing, and swelling of the jaw and face. An ED doctor noticed that she could open her mouth only 2 cm and that her voice was muffled. The physician diagnosed the woman as suffering from Ludwig's angina, a bilateral spreading inflammation of the tissue beneath the skin and area under the tongue. The doctor then called another oral surgeon, who came to the hospital within a half-hour and admitted the woman for observation. The surgeon prescribed two antibiotics and gave orders that the patient's head be raised while she lay in bed and that an oral suction device be provided for her use.

As the woman was waiting for a bed assignment, a nurse documented increased anxiety and complaints of being unable to breathe. A second ED doctor ordered a breathing treatment and called the oral surgeon who had just been consulted, who suggested that the problem was anxiety that could be treated with a benzodiazepine. The second ED doctor did not follow that recommendation, however, and left the woman as found.

A short time later, a nurse summoned the second ED doctor again due to the woman's complaints of shortness of breath. This time, the doctor ordered a neck X-ray, which revealed a collection of air and pus within the patient's pharynx. A respiratory therapist began providing humidified oxygen and advised the oral surgeon of the woman's condition, but the surgeon gave no orders.

Ten minutes later, the ED physician called the oral surgeon again and told him that the woman was continuing to suffer from severe respiratory distress. The surgeon ordered that morphine be administered intravenously every four hours, and he told the ED physician that the woman was not his patient and that the first oral surgeon (who was originally on-call, but who was now out of town) should be called instead. The woman then was moved to a critical care room, where nurses administered racemic epinephrine.

The woman stopped breathing 10 minutes later, but the swelling prevented subsequent attempts to intubate her. Doctors then attempted to make an emergency incision through her skin and membrane to secure her airway for relief of the upper airway obstruction, but that also was unsuccessful because the landmarks had been obliterated by the swelling and the air column could not be located. Doctors finally established a tracheostomy 16 minutes later, but the lack of oxygen already had caused profound and irreversible brain damage. The woman remained alive on life support for 12 days before the artificial measures were ceased.

The woman's estate sued the three ED physicians, the three oral surgeons, the ENT specialist, and the hospital and its nursing staff for negligence. Before the case proceeded to trial, the case settled for $1.35 million.

What this means to you: "This entire case is prime material for a Grade B horror movie," says **Lynn Rosenblatt**, CRRN, LHRM, director of quality and risk management and HealthSouth Sea Pines Rehabilitation Hospital in Melbourne, FL. Although the woman in this case presented with obvious poor oral hygiene indicative of self-neglect, her acute respiratory difficulties did not appear to have caused any alarm. As her condition continued to deteriorate and as her symptoms became increasingly more severe with complex consequences, the patient was unable to rally any effective treatment. "Yet her condition was life-threatening and extremely serious," she notes. "Such neglect screams of total disassociation between the patient and her health care providers."

The patient presented with a classic case of Ludwig's angina, a condition that has been well-documented in medical literature since the 1800s.

The condition causes an infection of the oral-pharynx, producing a massive swelling leading to respiratory compromise. According to Rosenblatt, 75%-95% of cases are caused by serious periodontal disease, with the remaining cases attributed to other highly suspicious causes, such as diabetes, intravenous drug abuse, and HIV-positive serology. Many Ludwig's angina patients are young adults with rather dubious lifestyles. Ludwig's angina carries a mortality rate of 8%-10%, with death most often caused by airway obstruction. While Ludwig's angina is not as common since the advent of modern dentistry and the development of wide-ranging antibiotics, it still is prevalent in certain classes of patients. Rosenblatt questions, therefore, how an ED physician, ENT specialist, and two oral surgeons could have examined the patient on several occasions without diagnosing the ailment.

In any presentation of this type, the provider must consider that the patient will eventually suffer airway obstruction, leading to respiratory insufficiency or even total arrest. If and when that occurs, intubation or tracheostomy is the treatment of choice. Rosenblatt notes that the literature on Ludwig's Angina indicates that in 90% of cases, anticipatory or emergent airway management is essential to survival. In this case, however, such management did not happen until the woman was in severe respiratory distress.

When the woman first arrived at the hospital, the doctor acted appropriately by ordering blood tests, an X-ray, and a CT scan. But he then apparently did not initiate any antibiotics, even though the woman's presentation suggested infection. There also is no indication of exactly what the staff nurses were doing to assess and promote further attention to the seriousness of the patient's condition. Rosenblatt suspects that the nurses were not monitoring the woman's condition as strictly as the situation warranted. But if they were monitoring appropriately, then it does not appear that the results of that monitoring were being communicated in such a manner as to get the attention of the doctors. After all, the physicians who were apparently managing the case — namely the oral surgeons — totally disregarded the Ludwig's Angina diagnosis and its implication, even though airway management in this disease is paramount. "Even with the classic presentation and the diagnosis of a condition with a predictable and very serious prognosis, none of the interventions were serious attempts to stabilize the patient and treat her symptoms appropriately," says Rosenblatt.

The problems continued when the on-call oral surgeon did not respond, causing the patient to go without a surgical consult for more than five hours. Rosenblatt questions the time frame for an on-call physician to respond to a patient who has presented to the ED with an obviously serious situation. "The hospital's medical staff rules and regulations should outline specific parameters for responding to call. Time frames should be spelled out based on the type of consult ordered and the nature of the patient's situation, with ED patients receiving top priority," notes Rosenblatt. In fact, standards promulgated by the Joint Commission on Accreditation of Healthcare Organizations require that a hospital's medical staff policy address the timeliness of consults and interventions. "This was rapidly becoming a medical emergency, but no one seemed to be accountable for that determination. It appears that the patient was treated no differently than if she had presented with a bad skin rash," says Rosenblatt.

"Many busy [emergency departments] establish protocols for repetitive reassessment of a patient, thereby creating documentation that will serve as the basis for interdisciplinary interventions. If this was occurring, apparently no one was paying attention."

She also suggests that the lack of response by the on-call oral surgeon should have attracted more attention from the hospital's ED and nursing staffs. "Many busy [emergency departments] establish protocols for repetitive reassessment of a patient, thereby creating documentation that will serve as the basis for interdisciplinary interventions," Rosenblatt says. "If this was occurring, apparently no one was paying attention."

When the patient finally did receive treatment, she was in so much pain that she required morphine. The administration of intravenous morphine to a patient in respiratory distress concerns Rosenblatt, however, considering that it slows the respiratory process, and this patient already was suffering from inadequate oxygen intake. "The nurses should have noticed any evidence of dyspnea, such as rapid breathing, use of accessory muscles, and cyanosis. These symptoms are indicative of a full-blown emergency," advises Rosenblatt.

It was only at this point that intravenous antibiotics were initiated for the patient. Rosenblatt notes that there is no indication that the medication selected had the right spectrum for what was most likely an anaerobic organism. "In a fumigating infection of this type, such a long delay in initiating treatment can have dire consequences," says Rosenblatt. Indeed, much of what was ordered was based on telephone conversations, thereby raising questions as to the accuracy and currency of information being passed between the physicians and the nursing staff.

The case took a rather unorthodox turn when the surgeon decided to perform oral surgery in his office on a patient who was at considerable risk for respiratory arrest and who was experiencing serious life-threatening complications. "Is it any wonder that many states are passing laws regarding surgical procedures in physician's offices?" asks Rosenblatt. "Clearly the oral surgeon in this case was motivated by his own personal convenience as opposed to what was safe and appropriate for the patient." Based on the oral surgeon's conduct throughout this case, Rosenblatt is suspicious of exactly what information regarding the patient's situation was conveyed by the surgeon to the woman's family physician. Rosenblatt also notes that attempting such a procedure with intravenous sedation in an office setting without emergency backup was incredibly risky and it shows very poor professional judgment.

When the women returned to the ED after her oral surgery, even though she was finally diagnosed with Ludwig's Angina, the professionals involved seemed to be ignoring the reality of the diagnosis and her clinical presentation, Rosenblatt says. The visible swelling of the woman's mouth and tongue, her inability to substantially open her mouth, and her difficulty in speaking warranted a higher standard of assessment and treatment than was provided. "This patient was clearly on the verge of total respiratory failure. Her symptoms of chest pain, shortness of breath, and anxiety are classic to respiratory compromise. Given the history, the diagnosis, and the declining respiratory function, a decision to protect the airway — most likely by tracheostomy — should have been made," advises Rosenblatt.

As this case demonstrates, a failure to properly diagnose can be the basis of expensive litigation, Rosenblatt cautions. But even in light of the $1.35 million settlement, Rosenblatt is confident that a verdict would have been even higher. "Considering that each defendant violated reasonable standards of care so egregiously, punitive damages certainly would have been awarded if this case had gone to trial. This patient clearly commanded more value in death than she did when alive," she says. And in addition to the civil litigation arising from this case, Rosenblatt only can imagine the actions taken by the state regulatory agency, the various medical boards, and internal peer review and quality assurance committees within the facility itself.

Rosenblatt questions whether the reason the woman in this case received such appalling care was because of her financial status. It may be that the reason none of her providers wanted anything to do with ensuring that she received the proper treatment was because they lacked any financial incentive. "If so, that would be a sad commentary on our health care delivery system to the economically disadvantaged, and an even greater stain on society as a whole. In the end, it was a needless and tragic waste of life," concludes Rosenblatt.

Reference

• Anonymous Case in Superior Court, North Carolina (Wade Byrd, Fayetteville, NC; Donnie Hoover, Charlotte, NC; and Sally Lawing, Greensboro, NC, for the plaintiff). ■

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