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THOMSON AMERICAN HEALTH CONSULTANTS

IN THIS ISSUE

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Think in terms of access: Radioactive material on site could tempt terrorists

More caution needed than ever before, experts say

Risk managers may have thought about their facilities as potential targets of terrorists, but have you ever considered that you might be the *source* of nuclear material used in an attack?

If you don't act now to ensure you have strict security for nuclear material in use in your facility, there is a real chance that it could be stolen for use in a dirty bomb, the experts warn.

The security of nuclear material always has been a concern in health care, but that risk has grown much bigger since Sept. 11, 2001, says **Dave McIntyre**, a spokesman for the Nuclear Regulatory Commission in Washington, DC, which oversees security at health care facilities and any other setting in which radioactive materials are found.

"Before 9/11, the industry — and to a large extent, the agency — regarded the security of materials in a hospital or industrial setting as a matter of public health and safety primarily. In other words, you keep them locked up so

Prepare your hospital for a very unusual flu season

Vaccine shortages may wreak havoc with hospital EDs, absenteeism

With the unprecedented shortage of influenza vaccine this flu season, hospitals are scrambling to prepare for what may be a record number of flu patients presenting to their already overcrowded emergency departments (EDs) and for staff shortages due to record absenteeism. After almost half of the United States' planned vaccine supply was contaminated, high-risk candidates — including the very young, the elderly, those with chronic illnesses, pregnant women, the immunocompromised, and health care workers with direct patient care — have been identified as those to receive the vaccine.

In response to the national shortage of vaccine, Thomson American Health Consultants has developed an influenza sourcebook to ensure you

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that people aren't exposed to them," he explains. "Since then, everyone has begun to think in terms of access as well to protect the materials from malevolent use."

The nuclear materials found in a health care setting have limited use for a terrorist. They cannot be used to make a nuclear bomb, but they can be used in a dirty bomb, which uses conventional explosives to disperse radioactive material across a wide area, explains **Dan Hodges**, a retired FBI agent and now consultant with OpSec Consultants in Nashville, TN. Even in that use, nuclear materials such as the iodine seeds used in prostate cancer treatment probably would produce limited harmful effects.

But the actual injuries from the material would not be the main focus of such a weapon anyway, he explains. Terrorists would be more interested in creating panic and fear among the population when word spreads that radioactive materials were spread by the bomb, he says. The actual injuries, limited as they may be, would be a secondary objective of the terrorists.

"So the fact that we're not talking about a huge amount of material that could cause a lot of damage is really beside the point. Terrorists would want this material for the shock value, because they realize the value in that," he says. "That's why it is so important to protect it, even if your scientists are telling you it wouldn't be that useful to a terrorist. It would, just in a different way than they might mean."

Hodges says hospitals would be an attractive target for terrorists seeking to access such materials because, by their nature, they have lower security and easier access than many industrial sites with similar material.

A 2003 report from the CIA notes that al Qaeda and other terrorist groups are intent on using

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chemical, biological, and nuclear weapons, but it says that most attacks will be "small-scale, incorporating relatively crude delivery means and easily produced or obtained chemicals, toxins, or radiological substances." The report mentions that the material of interest to terrorists includes the cesium-137, strontium-90, and cobalt-60 used by health care providers.

In addition, the report notes that terrorists may be interested in obtaining biological materials from health care facilities for the same purpose — spreading them with the intent of creating panic, regardless of the actual health implications of such dispersal.

In 2002, the International Atomic Energy Agency addressed the problem of terrorists using stolen nuclear material, issuing a report that makes this statement: "Clearly, theft of radioactive sources is easiest from locations where security is weaker, such as at hospitals and universities. . . . There would appear to be a need for some increase in the level of physical security for desirable sources. It is also logical to promote the collection and removal of disused sources, especially those that are in vulnerable locations."

Terrorists could target site with bomb

The presence of radiological materials in your facility also could increase your risk as the target of a terrorist attack, cautions **Fred Roll**, president of the International Association for Healthcare Security and Safety in Glendale Heights, IL. Keeping in mind that terrorists strive for panic as much as a death toll, they may see your oncology lab or other area with radioactive materials as a good place to plant a conventional bomb.

While the blast may not actually release radioactive material from your equipment or storage, the fact that the bomb site contains radioactive material will add another level of panic to the incident, Roll explains.

"A small explosive device in a radiological storage area will cause contamination or at least an extreme level of concern about contamination," he says. "The first responders are going to go nuts, and the people who have to work there afterward are going to wonder about it."

That means extra precautions are necessary in any area containing radiological materials, Roll says. Most hospitals already have the material behind locked doors, but that might not be enough. The area should be considered security-sensitive, just like the emergency department and the newborn nursery, with similar surveillance and presence by security personnel, he says.

Roll says risk managers who have not reviewed their security for radioactive materials since Sept. 11, 2001, should conduct a thorough review in light of the new threats from terrorists. One thing to consider is how the material comes to your hospital and leaves again, which may require added security and procedures in other areas such as shipping.

"The truth is that we have terrorists out there and we don't always know what they're planning," Roll says. "It might seem like a stretch to think they would go after a hospital's radioactive material, but a few years ago it was hard to imagine what they would do with our airlines." ■

In-house theft may be a bigger risk than burglary

If terrorists want to acquire radioactive materials in your facility, they may not do it by breaking in to the oncology department in the middle of the night. They might just pay a technician to steal the material for them, says **Ray Eganey**, a retired FBI agent and now a consultant with OpSec Consultants in Nashville, TN.

That's why your increased security for areas with those materials must include a higher level of screening for employees, he says.

"The risk of in-house theft is probably greater than burglary," he says. "You have to get sufficient background on everyone working there, from the pharmacist to the clerk who's doing inventory. Most of the stuff that walks out, I'm guessing, it's an employee you can trace it to."

Screening for employees in those sensitive areas should include a thorough background check for criminal charges and convictions, plus a credit check, Eganey says. This screening should be more in depth than any typical background checks before hiring, he says.

Eganey and his partner **Dan Hodges**, another retired FBI agent, offer these other suggestions:

- **Concentrate your radioactive materials in one area.** Do not allow them to be spread throughout the facility in different departments or patient care areas. Having it all in one area will make it much more practical for you to have effective security.
- **Emphasize access control.** Strictly monitor

who can enter areas with radioactive material and keep access logs. This might be an area in which can you justify a big budget for high-tech access control.

• **Include camera surveillance of controlled areas.**

• **Encourage employees to report any suspicious activity**, such as people hanging around the entrance, someone watching as a code is entered into a keypad, or a visitor who is asking unusual questions about what material is kept on site and how to access the area. Also, keep the entrance area clear and have employees report unattended packages.

• **Contact law enforcement immediately if there is any suspicion that radioactive material is missing, along with the appropriate regulatory officials.** ■

Report missing radioactive material promptly

One of the best ways to thwart any attempt at stealing nuclear materials from your facility is to take seriously any report of missing material, says **Fred Roll**, president of the International Association for Healthcare Security and Safety in Glendale Heights, IL. You should have a policy of responding quickly and vigorously to any discrepancy in inventory or chain-of-custody records.

"Never assume it's just a paperwork problem and will get sorted out in due time," he says. "When the consequences are this big, you can not afford to hope nothing is wrong and take your time investigating it. Investigate it to the hilt."

Missing radioactive materials must be reported to the Nuclear Regulatory Commission (NRC), which oversees security and safe handling in health care and other settings. Publicly available reports to the NRC indicate that health care providers often react to the loss of radioactive material by assuming a clerical error, which is sometimes the case. But Roll says the current threat of terrorism requires a lower threshold for alarm.

The NRC incident reports also give a glimpse into how easily radioactive materials can be lost. Roll says losing material is a more serious issue these days because, if your policies and procedures are not tight enough to prevent the accidental loss of the materials, you may never know whether any fell into the wrong hands.

Consider this report to the NRC of an incident at Fox Chase Cancer Center in Philadelphia on March 15, 2002:

"This is to inform you of an incident that occurred at our facility involving a recent shipment of 250 microcuries of phosphorous-32 [P-32] deoxyguanosine 5' triphosphate. . . . The package was delivered to the recipient lab, and the blue plastic container was placed in a freezer that was locked for storage of the material. On March 11, 2002, when the freezer was unlocked and the blue container was removed for use, there was no vial of P-32 inside. The lab worker immediately reported the situation to her Principal Investigator. Initially, the assumption was simply that the facility was shortchanged a vial, and indeed, that is our conclusion after investigation of the incident. . . . It was determined that the initial recipient did not follow the facility's procedure for opening packages of radioactive material and failed to monitor the surface of the package or look inside and verify the contents."

High-tech keypad didn't work

NRC reports also demonstrate that high-tech security is no good if it doesn't actually work as intended. The NRC regularly inspects facilities for nuclear security and issues fines for violations. Wilcox Memorial Hospital in Lihue, HI, was fined $3,000 for a violation identified during an inspection on March 1, 2002.

The NRC described the violation this way: "The licensee failed to control and maintain constant surveillance of licensed material in a controlled or unrestricted area and not in storage. Specifically, on March 1, 2002, the licensee's hot lab facility controlled area, containing curie quantities of molybdenum-99 contained in molybdenum-99/technetium-99m generators and other radiopharmaceuticals, was left unsecured and unattended. The door to the hot lab was shut and had an electronic keypad-type locking mechanism installed; however, it was determined that the lock did not function as designed, resulting in the door being unlocked."

In another incident March 14, 2001, the NRC fined I. Gonzalez Martinez Oncology in Hato Rey, Puerto Rico, $7,500 for an incident with a brachytherapy implant containing 97 millicuries of cesium-137. The implant was removed from a patient and then misplaced, exposing an employee to radioactivity for some time, and then found in a

trash can in the alley behind the office 19 hours after it was lost.

An incident at Howard University Hospital in Washington, DC, on April 4, 2002, caused the NRC to levy a $3,000 fine. During a patient's treatment for a tumor, one of 11 ribbons containing iridium-192 seeds was lost. The hospital never determined how the ribbon was lost but surmised that it must have been flushed down the sewer system because no traces were found in the laundry. ■

JCAHO: Awareness during anesthesia is a problem

A terrifying failure during general anesthesia, once thought to be so rare that it did not warrant much attention, actually is common enough that risk managers should launch a specific, focused effort at reducing the problem, known as anesthesia awareness.

The problem occurs when the patient is sedated and paralyzed properly during the procedure, yet he or she is awake enough to realize what is happening and to feel the surgery. Awareness during anesthesia can be extremely traumatic to the patient who, in effect, undergoes surgery while awake, with the paralytic agent making it impossible to scream.

While the problem has been known for a long time, the health care community largely dismissed concerns by saying this type of anesthesia failure happened very rarely. Many patients who reported their experience after surgery were dismissed with a reassuring pat and told it was only a nightmare.

That no longer is acceptable, says JCAHO and other professional organizations that studied the problem recently. The Joint Commission recently issued a *Sentinel Event Alert* on awareness during anesthesia, one of the strongest messages the accrediting body can send to providers.

And don't think that the trial lawyers won't notice. Now that the Joint Commission has recognized anesthesia awareness as a serious, too-common occurrence and urged you to take preventative steps, attorneys will be eager to get you in front of a jury to explain why you didn't follow through. And you don't want them hearing about the horror of being operated on while awake.

Joint Commission President **Dennis S. O'Leary**, MD, says tens of thousands of patients undergoing surgery each year experience the helplessness of being partially awake while under general anesthesia during surgery, but being unable to communicate their distress to caregivers. Better understanding among health care professionals of this frightening phenomenon could reduce the risk of these events and assure appropriate support for patients when they do occur, he says.

O'Leary says the Joint Commission issued the alert largely in response to concerns within the anesthesia community, not as the result of any increase in reported events. The first reported case of awareness came in 1842, O'Leary notes, but the problem has been seriously studied only in recent years.

"Our informed knowledge about this is quite recent even though the phenomenon has been known for over a century," he says.

The Joint Commission estimates that anesthesia awareness affects an estimated 20,000 to 40,000 patients each year. While that figure represents only one to two cases in every 1,000 general anesthetics administered, the experience is traumatic for those patients who do become aware, O'Leary notes. Patients undergoing cardiac, obstetric and major trauma surgeries are at proportionately higher risk for anesthesia awareness, according to the Joint Commission's *Sentinel Event Alert.*

The frequency of anesthesia awareness has been found in multiple studies to range between 0.1% and 0.2% of all patients undergoing general anesthesia, the Joint Commission reports. With general anesthesia administered to 21 million patients annually in the United States, that produces the estimate of 20,000 to 40,000 cases of anesthesia awareness each year.

Patients experiencing awareness report auditory recollections (48%), sensations of not being able to breathe (48%), and pain (28%). More than half of the patients reported mental distress following surgery, including an indeterminate number with post-traumatic stress syndrome. Some patients describe these occurrences as their "worst hospital experience," and some determine to never again undergo surgery, the Joint Commission reports.

"Anesthesia awareness is underrecognized and undertreated in health care organizations," O'Leary says. "The Joint Commission understands that anesthesia professionals must balance the psychological risks of anesthesia awareness against the physiological risks of excessive anesthesia. This alert is intended to help health care organizations address this problem in an open and constructive

fashion." **(See p. 139 for advice on how to address the problem.)**

The anesthesia community acknowledges that awareness is a serious problem, says **Tom McKibban**, CRNA, MS, the immediate past president of the American Association of Nurse Anesthetists (AANA) and a practicing certified registered nurse anesthetist. The experience is traumatic for patients, and can even have a serious affect on staff who realize afterward that the patient was suffering the procedure without their knowledge.

"We are working with the Joint Commission to reduce the incidence of these events to an acceptable number," he says. "Even though one is too many, we all realize that with the type of anesthesia given today and the critical illness we administer anesthesia to, that we will probably never be able to obliterate it entirely."

To overcome the limitations of current methods to detect anesthesia awareness, new methods are being developed that are less affected by the drugs typically used during general anesthesia. These devices measure brain activity rather than physiological responses. These electroencephalography devices (also called level-of-consciousness, sedation-level and anesthesia-depth monitors) include the Bispectral Index (BIS), spectral edge frequency, and median frequency monitors. These devices may have a role in preventing and detecting anesthesia awareness in patients with the highest risk, thereby ameliorating the impact of anesthesia awareness.

Though a body of evidence has not yet accumulated to definitely define the role of these devices in detecting and preventing anesthesia awareness, O'Leary says the Joint Commission expects additional studies on these subjects to emerge. In its review of the BIS monitor, the Food and Drug Administration determined that "use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation."

O'Leary explains that the Joint Commission is not requiring any specific monitoring technology but rather is encouraging a more comprehensive effort to prevent awareness. The professional anesthesiology associations have guidance for their members about specific technologies, including some that are now in development.

O'Leary notes that the anesthesia professional must often balance the psychological risks of anesthesia awareness against the physiological risks of excessive anesthesia for many critical medical conditions. The Joint Commission has asked the American Society of Anesthesiologists (ASA) and the AANA to address the adequacy of current monitoring practices regarding anesthesia levels, including those that involve little or no technological support.

Roger W. Litwiller, MD, ASA president, cautions that risk managers should not assume clinical wrongdoing when a patient reports awareness after surgery. Administering anesthesia is a tricky business under the best of circumstances, and the balancing act becomes far more delicate in some cases.

"An anesthetic is a continuum, and we begin by giving enough to cause a loss of consciousness, and we continue that throughout the procedure utilizing sometimes the same drugs and sometimes other drugs," he says. "They may occur during a surgical procedure a situation where the patients vital signs deteriorate, maybe because of the severity of the operation of whatever, and that would necessitate lightening the anesthetic. As we being to turn down the amount of drugs given, there is the possibility that you will have the opportunity for awareness."

Must follow up a week later

The Joint Commission's O'Leary says patients at risk for awareness should be warned before surgery that it can occur, and that there are clinical reasons for why. He also urges careful interviewing of patients who report awareness.

"One interesting factor is that if you interview the patient within, say, 24 hours of the procedure, the recall is less than if you interview them a week later," he says. "The frequency of recall goes up by a third to a half. These patients need attention. That is one of most critical issues we are trying to raise with this alert."

But patients aren't usually in the hospital a week later for interviews. So O'Leary says providers should institute a system for follow-up, something akin to the procedure used to check for postoperative infections.

"We are extending the boundaries of potential hospital responsibility beyond the time of admission," O'Leary says. "That's controversial, to be sure, but if you are not doing that kind of follow up at the right time you are potentially missing important information and you are not fully serving the patient."

(For the Joint Commission's *Sentinel Event Alert*

on anesthesia awareness, go to www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_32.htm. Or just go to www.jcaho.org and look for the link under "Accredited Organizations.") ■

JCAHO says risk managers play a role with awareness

Dennis S. O'Leary, MD, president of JCAHO, tells *Healthcare Risk Management* that risk managers should take a lead role in ensuring that all staff members are aware of the problem of anesthesia awareness.

"The patient who has had such an experience can end up anywhere in the hospital," he says, such as the intensive care unit, an obstetrical floor, or an inpatient unit. "As you get away from surgical units, the possibility that nurses and house staff are not aware of this problem goes up. There is a risk of discounting the patient's description or expression of concern."

If the staff is educated throughout the organization, there is a better chance that patient concerns will be address properly and not dismissed, he says.

Roger W. Litwiller, MD, president of the American Society of Anesthesiologists, also notes that you can not rely entirely on anesthesia professionals to deal with the problem because they often have contact with the patient only immediately before and after a procedure. By the time the patient is recovering and possibly remembering awareness, follow-up contact is more likely made by other health care professionals.

"If we can make the whole medical community aware, then we might have the opportunity to catch those cases that otherwise might slip through our fingers," he says. ■

Anesthesia awareness is concern of many players

Anesthesia awareness is not just a problem for the anesthesia department. That was a key message of JCAHO when it issued its recent *Sentinel Event Alert* on the issue.

Preventing this terrible outcome requires the interaction of many players within the health care organization, and the risk manager can be pivotal in making sure the problem is addressed vigorously. The Joint Commission, along with the American Society of Anesthesiologists (ASA) and the American Association of Nurse Anesthetists (AANA), stresses that preventing anesthesia awareness, and dealing properly with patients do experience it, requires an organizationwide effort by top administrators.

That's where the risk manager comes in. For starters, the Joint Commission urges you to develop and implement an anesthesia awareness policy that addresses these points:

- Education of clinical staff about anesthesia awareness and how to manage patients who have experienced awareness.
- Identification of patients at proportionately higher risk for an awareness experience, and discussion with such patients, before surgery, of the potential for anesthesia awareness.
- The effective application of available anesthesia monitoring techniques, including the timely maintenance of anesthesia equipment.
- Appropriate postoperative follow-up of all patients who have undergone general anesthesia, including children.
- The identification, management and, if appropriate, referral of patients who have experienced awareness.

For patients who have experienced anesthesia awareness, risk managers must assure access to necessary counseling or other support for patients who are experiencing post-traumatic stress syndrome or other mental distress.

Clinical advice available

Of course, much of the work in preventing anesthesia awareness will involve clinical decisions. The Joint Commission urges risk managers to refer anesthesia providers to their professional organizations for specific guidance, but the ASA and AANA offer these tips:

- **Consider** premedication with amnesic drugs, such as benzodiazepines or scopolamine, particularly when light anesthesia is anticipated.
- **Administer** more than a "sleep dose" of induction agents if they will be followed immediately by tracheal intubation.
- **Avoid** muscle paralysis unless absolutely necessary and, even then, avoid total paralysis by using only the amount clinically required.
- **Conduct** periodic maintenance of the anesthesia machine and its vaporizers, and meticulously

check the machine and its ventilator before administering anesthesia.

• Anesthesia practitioners should be alert to patients on beta-blockers, calcium channel blockers, and other drugs that can mask physiologic responses to inadequate anesthesia.

Unfortunately, anesthesia awareness may occur despite your best efforts to prevent it. When it does, the Joint Commission expects health care providers to respond in a compassionate way. (In addition to just being good practice, taking the report seriously might help decrease the chance of being sued, since your response to complaints always has a major impact on the patient's decision to seek a lawyer.) It offers these suggestions for responding to a patient who reports awareness:

• **Interview** the patient after the procedure, taking a detailed account of his or her experience and include it in the patient's chart.

• **Apologize** to the patient if anesthesia awareness has occurred.

• **Assure** the patient of the credibility of his or her account and sympathize with the patient's suffering.

• **Explain** what happened and the reasons, such as the necessity to administer light anesthesia in the presence of significant cardiovascular instability.

• **Offer** the patient psychological or psychiatric support, including referral of the patient to a psychiatrist or psychologist.

• **Notify** the patient's surgeon, nurse and other key personnel about the incident and the subsequent interview with the patient. ■

Organ donation shows risk from local coroners

The story spread across the national media like wildfire, and it sounded like a real nightmare for health care risk managers: Two hospitals in Colorado were accused of harvesting a man's organs before he was declared dead. The coroner actually ruled the death a homicide, saying the cause of death was "removal of his internal organs by an organ recovery team."

The only trouble with the story? The coroner's conclusions were dead wrong, according to everyone involved except the coroner himself. The two hospitals were dragged through the mud as people wondered how they could make such a mistake, but the truth is that the hospitals appear to have done nothing wrong.

They're paying for the inexperience and callous comments of the coroner, say hospital officials and an expert panel convened to review the case. Unfortunately, the problem befalling the hospitals may not be unique and could hit any rural health care provider, says **Jan Ronzio**, director of risk management and safety at St. Mary's Hospital in Grand Junction.

"What we have here is a coroner who is a layperson and not following through on what he is supposed to do," Ronzio says. "This is not a unique situation in areas where you have a coroner who is an elected official, not a physician, with no oversight from anybody."

The risk manager's nightmare began in early October when **Mark Young**, coroner for Montrose County in western Colorado, issued this statement: "The death of William Thaddeus Rardin, 31, has been ruled a homicide. The cause of death was removal of his internal organs by an organ recovery team."

Young went on to say that Montrose Memorial Hospital in Montrose and St. Mary's did not follow accepted medical standards or meet state guidelines in determining that Rardin was brain dead after shooting himself in the head.

Rardin had been taken to Montrose Memorial on Sept. 26 and was declared brain dead. After consulting with the Donor Alliance of Denver, which coordinates organ donations in the area, Montrose Memorial transferred the patient to St. Mary's Hospital, where his heart, liver, pancreas, and kidneys were transplanted into other patients.

When Young issued a statement to the media declaring the death a homicide, alleging that the hospitals did not perform proper tests to confirm brain death before proceeding with the organ harvest, he did not specify what tests he thought should have been performed. He issued contradictory statements about the hospitals' intent, at one point, saying that he thought the harvest was done in good faith but also alleging that the hospitals may have avoided the proper tests to get around Donor Alliance rules that would have prevented that organization from paying for the helicopter transfer.

The coroner said criminal charges were possible.

Officials from both hospitals tell *Healthcare Risk Management* that there was nothing unusual about Rardin's case and that the organ donation was handled routinely, adhering to all appropriate standards. **Deborah Ashby**, spokeswoman for St.

Mary's, says, "We don't think there was anything out of the ordinary." She goes on to say that the hospital sees no need to change any procedures and that the only mistake was made by the coroner.

But that doesn't mean that there is no lesson for risk managers. Ronzio, the St. Mary's risk manager, says the case does highlight two potential problems for rural hospitals. The first is the potentially huge ramifications of an inexperienced coroner assessing your work, and the second involves the transport of patients to facilities with more qualified specialists to confirm brain death. Young's suspicions apparently were fueled by the fact that Montrose Memorial performed some tests to determine brain death, but the physicians involved understood that St. Mary's physicians would do more sophisticated tests to confirm brain death before proceeding.

Ronzio says that was accepted procedure, and a necessity when rural hospitals don't have the ability to perform all the tests themselves before transfer. Ronzio says the hospital has solid policies and procedures for assessing brain death, and her review after Young's charges showed they were followed.

"I did a crosswalk between those and the documentation, and we were stellar," she says. "The Joint Commission has already called and said they don't consider this a sentinel event. They are not looking into this because they know it is ridiculous. I am doing a root-cause analysis later on, between the three entities, just to see where we might have done something different as far as transporting a patient."

Young did not return *Healthcare Risk Management's* phone calls seeking comment. According to county officials, Young is a part-time coroner who makes his living as a paramedic. In his initial statement to the media, Young said he had consulted with Montrose County District Attorney **Thomas Raynes**, before declaring the death a homicide, but the district attorney issued a statement saying he had had only a brief, general conversation and did not concur with the coroner's decision.

Young's actions prompted the formation of a committee of 10 coroners, physicians, district attorneys, and organ donor specialists who studied medical records and the coroner's conclusions. The committee's report was scathing in its criticism of Young.

"There was no deviation from acceptable medical standards," Raynes announced. "There was no homicide by removal of organs."

The cause of death should be amended from homicide to suicide, the members urged. The committee determined that Young had reviewed only 10 of 220 pages in Rardin's medical chart and noted Young's admission that he had no prior training or experience in the declaration of brain death other than the research he did on the Internet while investigating this case.

The committee made these findings:

- "The actions of Mr. Young were based on a lack of information and an inappropriate understanding of the medical and legal issues involved. His actions were reckless when, despite ample and competent evidence to the contrary, he rendered the ruling and completed the death certificate indicating that this death was a homicide due to the removal of Mr. Rardin's internal organs by an organ recovery team. It was also irresponsible for him to then release these findings to the media, without appropriate factual confirmation and determination."
- "These actions have served to undermine the public trust in the organ donation system, as well as the public trust in the health care, coroner, and criminal justice systems."

The committee's report was firm in stating that all proper tests were performed to confirm brain death before proceeding with the organ harvest, with no deviation from accepted standards, but Young did not back down. He issued a statement soon after the committee's, saying that he does not consider the matter put to rest and may have a neurosurgeon independently review the case.

Young has threatened to proceed with a coroner's inquest, despite the committee's findings.

"This has created havoc, and the one who's really losing is the family," Ronzio says. "There also are worries that this will hurt the organ donation system, because we've heard of people threatening to take their names off the organ donation list because of this. That would be totally unnecessary, because incidents like this only happen in the movies." ■

Insurer refuses to pay for wrong-site/person surgery

The movement to prevent wrong-site or wrong-person surgery got another boost recently when a major health plan announced that on Jan. 1, 2005, it will stop paying for medical procedures involving those egregious errors.

And don't expect to get paid for a procedure if you leave that 12-inch retractor in the patient's belly, or the next procedure to remove it.

HealthPartners, one of Minnesota's biggest health plans, announced recently that it would not pay for procedures involving "never events," those mistakes so serious and preventable that they should be eliminated entirely, not just reduced. **George Isham**, MD, medical director for HealthPartners, says, "We all agree that patients should not pay for medical care made necessary by one of these errors. This is especially important as consumers are asked to bear more of the costs of their care premiums, deductibles, and copayments."

Noting that some hospitals already waive the costs associated with these errors, Isham says HealthPartners wants to "work with hospitals, physicians, nurses, and others to make sure this is the case for every patient, every time."

Isham notes that the new HealthPartners philosophy extends to all serious, preventable adverse events. Wrong-site surgery is just the most obvious example, he says.

HealthPartners provides health coverage to 630,000 members and has a network of physicians and hospitals, including HealthPartners Clinics. It is the state's third biggest health insurer, after Blue Cross and Blue Shield of Minnesota and Medica.

Providers in Minnesota have been required to report adverse events since July 2003. Isham says there have been 40 adverse events in the first 10 months of reporting from 15 hospitals that contract with HealthPartners.

Of those 40, 14 involved care management and 18 to surgical procedures. The surgical events involved 10 incidences of surgery on the wrong site or wrong patient, or the wrong surgical procedure.

The new policy will require any hospital contracting with HealthPartners to report serious adverse events within 10 days, giving the insurer time to identify the procedures it will not pay for before the end of the billing cycle. ■

LA County: Patient dies as nurse turns off audio alarm

Los Angeles County officials reported recently that a patient at Martin Luther King Jr./Drew Medical Center died after a nurse turned down an audio alarm on his vital signs monitor and then failed to notice that he was having a heart attack.

Incident latest in a string of problems

The incident was the latest in a string of difficulties for the county hospital. Federal officials have reported that three patients died in 2003 after similar instances in which nurses failed to watch their cardiac monitors. The hospital also has experienced a string of accreditation difficulties in recent months, with the Accrediting Council for Graduate Medical Education shutting down several residency programs. The hospital's trauma unit also is under fire for deficiencies and county officials have expressed interest in closing it.

In the latest incident, county investigators concluded that a nurse turned down the AIDS patient's audio alarm and did not see the vital signs monitor's flashing visual alarm. A resident who happened to pass by the room noticed the visual alarm but was not able to revive the man.

Los Angeles County officials also allege that the nurse falsified the 28-year-old patient's medical chart, which listed him in stable condition more than an hour after he died. The nurse was suspended. ■

Reader Question

Nurses must judge quality of consent to be a witness

Question: We've recently become aware that some of our nurses are uncomfortable with witnessing a patient's informed consent when they don't think the patient truly understands what he has been told, or that the physician has not adequately conveyed the risks. Is this the nurse's call to make or should he or she merely attest to witnessing the exchange? We even found a couple instances in which a nurse signed as the witness but added a note (presumably to cover herself) that she was unsure the patient understood. How should we address this problem?

Answer: You've got a problem. If your nurses are so uncomfortable with the quality of the informed consent process that they don't want to

sign as a witness, you should consider that a red flag that you have some serious work to do, suggests **Lew Lefko**, JD, MPH, a health care attorney with the firm of Haynes & Boone in Dallas. Their concerns must be significant if they have come to your attention, so you might find even more reason for concern once you investigate.

And the nurse who added her own note to indicate that the informed consent process was inadequate is handling the situation incorrectly, he says. You must put a stop to that practice immediately, he urges.

But first, Lefko answers a key question: When the nurse signs as a witness to the informed consent process, is he or she expressing approval of the content or merely confirming that an exchange took place? Lefko says the answer is that the witness signature indicates that the informed consent was valid and sufficient in that person's eyes. Merely signing off, with no concern to what actually transpired, is not acceptable.

"When you sign, you're attesting to the consent process — that the patient understood the information, was provided the full picture and all the other factors that go into the process," he says. "If the nurse does not have confidence in that process, it is appropriate to step in and halt the procedure."

But you should hope it never comes to that because the clinicians can address the nurse's concerns. Whatever the problem between the physician and the nurse, adding a note to the witness signature is *never* the right solution, Lefko says.

He explains that in many states, adding such a note to the medical record creates a "rebuttable presumption" that the doctor was negligent in performing the duty to disclose. That's the exact opposite of what normally occurs when the witness affirms that a valid informed consent process took place. In that situation, the record creates a presumption that the process was done correctly and the plaintiff must prove otherwise.

"A note in the record saying she had concerns creates the presumption that something was wrong and now you're going to have to prove otherwise. It puts the burden on you, which is the opposite of where you should be on this question," he says.

So what should a nurse do if he or she is uneasy about signing as the witness? Lefko says the first step should be discussing the concerns with the physician, and ideally that should happen as the informed consent process is ongoing, not at the last minute when it's time to sign the forms. If necessary, the nurse should seek the aid of an intermediary, such as a nursing supervisor or another physician.

While he says nurses should stand up for the patient when appropriate, Lefko suggests that risk managers also educate them about how their perception of the informed consent might be skewed sometimes. For instance, the nurse might not be aware of all the discussions between the patient and the doctor, or there may be cultural factors at work that can affect how the informed consent process is carried out. Some Asian cultures, he notes, depend on a family decision for such matters and not a traditional one-on-one discussion.

"It's good for the nurse to speak up when she has concerns, but they also need to understand that her first impression might not be entirely valid," Lefko says. "Sometimes, the concerns can be dispelled by just pulling the doctor aside to ask, and the doctor might provide an acceptable explanation for why the informed consent process was handled the way it was." ■

COMING IN FUTURE MONTHS

- Strategies for defending fall cases
- New ideas for reducing restraints
- Patient safety goals — how to use them
- The top causes why your insurance rates are increasing

CE objectives

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

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

CE Questions

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. **The semester ends with this issue.** 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.

21. According to Dan Hodges, which of the following is true about nuclear material found in health care settings?
A. It is of no interest to terrorists because it cannot be used to make a nuclear bomb.
B. Terrorists would be interested in it only if they could obtain very large quantities from your facility.
C. Terrorists would be interested in obtaining it because it can be used to create panic and fear when used in a "dirty bomb."
D. It can be used to create a nuclear bomb.

22. According to the Joint Commission, how many cases of anesthesia awareness occur each year in the United States?
A. Fewer than 20,000
B. 20,000 to 40,000
C. 40,000 to 60,000
D. 60,000 to 80,000

23. Why does the Joint Commission recommend interviewing patients about one week after surgery to determine if they experienced anesthesia awareness?
A. They need time to relax after surgery.
B. They have too much going on to be bothered with questions about anesthesia.
C. Most clinicians are too busy to ask soon after surgery.
D. The patient's recollection is likely to be more complete and accurate after one week.

24. According to Lew Lefko, JD, MPH, which of the following is true about a nurse signing as the witness for informed consent?
A. The signature indicates that the nurse considers the informed consent process to be valid and complete.
B. The signature indicates only that the nurse was present during the informed consent discussion, but not necessarily that it was valid.
C. The signature indicates that the nurse was responsible for conveying the majority of the information to the patient.
D. The signature indicates that a nursing supervisor has approved the nurse's participation in the informed consent process.

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

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

Failure to diagnose vitamin deficiency leads to nerve damage: A $1.73 million verdict

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

News: A woman complaining of tingling in her extremities visited a neurologist. Suspecting a vitamin deficiency, the physician admitted the woman to the hospital and ordered blood work to test her vitamin B_{12} levels. The doctor also discussed the patient's condition with a fellow neurologist, who concluded she suffered from radiation damage, depression, and emotional distress. When the first neurologist received the blood work results showing low vitamin B_{12} levels, he failed to follow up with the patient or notify her of the findings. The woman's condition went undiagnosed for an additional month. After suffering a degeneration of sensory nerves in her spinal cord, damage to her brain and peripheral nerves, and a loss of proprioception, the woman filed suit for medical malpractice.

A jury awarded the plaintiff a $1.73 million verdict against the first neurologist, but it rendered a defense verdict in favor of the second neurologist. The plaintiff settled with the hospital for $50,000 prior to trial.

Background: A 58-year-old woman visited a series of internists and physiatrists after experiencing a worsening of tingling in her hands and feet. After none of those physicians could diagnose her condition, the woman visited a neurologist. He discovered that the sensations stemmed from nerve damage in the woman's feet and legs that had been caused by cervical cancer treatments six years before. The neurologist, suspecting a vitamin B_{12} deficiency, admitted the woman to a local hospital and remained as her attending physician.

At the hospital, the neurologist ordered blood work to test his patient's vitamin B_{12} levels. Because the hospital could not perform the test on site, the blood sample was forwarded to a laboratory in California. While awaiting the test results, the neurologist consulted a colleague at the hospital for a second opinion.

The second neurologist noted that the patient's prior chemotherapy may have caused radiation damage to the nerves running from her brain and spinal cord to the rest of her body. He ordered a somatosensory evoked potentials (SSEP) test to evaluate the woman's nerve pathway from the peripheral nerve in her arms and legs through her spine to her brain. The SSEP test results were consistent with radiation damage, but the second neurologist never documented a possible vitamin B_{12} deficiency in his consultation or SSEP report.

The second neurologist further observed that the woman was experiencing hysterical emotional/physiological symptoms due to underlying and untreated depression, and that she suffered from mild physical changes magnified by emotional stress. He recommended the patient be transferred to a rehabilitation center for a psychiatric consult and rehabilitation physical therapy. At the rehabilitation center, the patient was

diagnosed as having acute anxiety.

Thereafter, the first neurologist received the results from the blood work showing low vitamin B_{12} levels. However, the neurologist never followed up with the results or notified the patient. Her vitamin B_{12} deficiency went undiagnosed for an additional month, and she became largely confined to a wheelchair, able to walk slowly only with the aid of a walker.

The woman filed a lawsuit against both neurologists and the hospital alleging professional negligence. Relying on the testimony of four expert witnesses specializing in neurology, internal medicine, medical oncology, and physical medicine, she claimed that the delay in diagnosing her vitamin deficiency directly caused subacute combined degeneration of the spinal cord, a rare progressive disorder producing weakness, abnormal reflexes, clumsiness, and tingling due to the degeneration of sensory nerves in her spinal cord and damage to her brain and peripheral nerves.

The plaintiff also maintained that the defendants' negligence resulted in her loss of proprioception, the ability to sense the position, location, orientation, and movement of the body and its parts.

The first neurologist admitted negligence, but argued that the woman's neurological condition and difficulty in walking would not have been reversible even had he timely diagnosed her condition.

The jury awarded damages for loss of normal life, pain and suffering, necessary help and capital expenses, and medical expenses totaling $1.73 million. However, the jury rendered a defense verdict for the second neurologist. The hospital settled with the plaintiff for $50,000 prior to jury selection for trial.

What this means to you: This case primarily deals with the issues of delay in diagnosis and delay in informing the patient of test results and the appropriate diagnosis. Communication with patients is critical and, if not handled properly, can be disastrous.

"It appears from the fact pattern that the patient had not been involved in the discussion or decision making regarding the blood sample and test for vitamin B_{12} deficiency," says **Stephen Trosty**, JD, MHA, CPHRM, director of CME and risk management for American Physicians in East Lansing, MI, "and if that is the case, then the first neurologist made a serious mistake and might have breached the standard of care relative to informed consent.

"While the blood work was not a procedure or surgery, it was something that dealt directly with the potential diagnosis and had a significant effect on the patient . . . and she, therefore, should have been informed of the test and the reason for it. The patient also should have been told when the test results were expected and that she would be told the results, regardless of what they are. Had the physician done this, the patient would have been a participant in the decision regarding the test, would have known how long it would take to get the results back, and would have had an idea of when to check with the physician if she did not hear from him with the results. This might have reduced her anger and frustration and might have resulted in her contacting the physician to get the results when she did not hear from him.

"By making the patient a partner in decision making, including tests, and letting them know when to expect the results, there is an excellent chance that the patient will contact the physician for the results if the physician forgets to call the patient, overlooks making the call, or does not receive the test results," Trosty adds. "This can serve as a form of second chance for the physician relative to getting test results to patients in a timely manner. This is especially true if the patient is told

that the test results might enable the physician to make a diagnosis of what is wrong with the patient and can affect the course of treatment. This will provide even greater incentive for the patient to contact the physician if she does not hear from him within the expected timeframe."

Physicians have to recognize that it is their legal responsibility not only to diagnose a patient's injury/illness but also to share that information with the patient and to take appropriate medical action, all within a reasonable period of time.

"Physicians and hospitals must have an adequate system for tracking all tests that are ordered, ensuring that test results are returned and seen by the physician, that the test results are shared with the patient, and any necessary or recommended follow-up is discussed with the patient. Many claims of failure to diagnose occur because this type of tracking system does not exist, is not comprehensive (does not contain all of the necessary elements), or is not adhered to. Nothing indicates that the hospital took measures to reach out to the patient, which probably contributed to their decision to settle prior to the selection of the jury," notes Trosty.

"The hospital's culpability was likely strengthened by the fact that the test blood sample had to be forwarded to a lab in California, due to the fact that the hospital could not perform the test on site. While the first physician should have made sure that adequate documentation existed in the medical record regarding notification of the test results to the patient's existing and subsequent providers, the hospital, as the initial recipient of those results, also bore some responsibility for communicating the outcome.

"Furthermore, the medical record documentation should have been adequate to alert the rehabilitation center physician that he (the first neurologist) suspected a possible diagnosis of vitamin B_{12} deficiency and a blood sample had been drawn and sent to the California lab for testing and a determination. This should have resulted in the rehabilitation center physician being notified of the results and/or alerted him to the necessity of checking back with the physician or the hospital to obtain a copy of the test results. In effect, it could have served as a form of quality control to ensure that the test results and diagnosis were shared with the patient and the subsequent treating provider," observes Trosty.

The first neurologist's failure to communicate with the patient after he received the results of the blood test and was able to make a definitive diagnosis resulted in a failure to initiate appropriate and timely medical intervention.

"The physician waited at least one month following receipt of the test results before notifying the patient, thereby unnecessarily delaying the correct diagnosis, as well as delaying the required treatment with vitamin B_{12}" observes Trosty.

As the admitting and attending physician during the patient's hospital stay, the first neurologist had primary responsibility for the treatment of the patient and the diagnosis of her condition.

"By calling in a second neurologist on a consult, he does not give up his primary responsibility for the care and treatment for the patient, and any transfer of the patient to the rehabilitation center should only have occurred with his consent. He remained responsible for notifying the patient, and any subsequent treating physicians, of the test results and recommended treatment. A requested consultation or referral by a physician requires that the referring physician provide all necessary information to the consulting physician. The first physician is expected to obtain a report back from the consulting physician and to ensure that appropriate follow-up has occurred with the patient.

"The two physicians should decide who would take responsibility both for notifying the patient of the results of the consultation and blood test, and for any necessary follow-up. However, a physician who orders tests for a patient is responsible for obtaining the test results, as well as for notifying and following up with the patient," adds Trosty.

While the first neurologist had an obligation to notify the patient as soon as the results came back, and to have her begin receiving vitamin B_{12} he also had an obligation to notify the second neurologist (the one he called in on a consult) of the results of the test so that he too would know the correct diagnosis and could help ensure that the patient began receiving vitamin B_{12}.

"However, the second neurologist appears to have been responsible for the patient's transfer to the rehabilitation center for a psychiatric consult and rehab physical therapy," notes Trosty, "and so he had an obligation to share the results with the providers at the rehabilitation center. He also is the physician who failed to even mention a possible vitamin B_{12} deficiency either in his consultation or SSEP report. It appears that the second neurologist completely missed the correct

diagnosis and did not even consider it as an option or as something to be ruled out. He should have been informed of the correct diagnosis by the first neurologist, and should have assisted in obtaining timely required treatment for the patient.

"It is interesting that the jury rendered a defense verdict for the second neurologist. I think he was fortunate since I believe he might have deviated from the standard of care by not recognizing or documenting a possible vitamin B_{12} deficiency in his consultation or SSEP report. It would appear that he never considered this as a possibility even though he had been called in on a consult by the first neurologist who had ordered a test of the patient for a possible vitamin B_{12} deficiency. The second neurologist provided no information to the rehabilitation center of this possibility, and did not let them know that the first neurologist had ordered the test.

"I think it could be argued that his lack of attention to this possibility, as well as his lack of any related documentation, represented a deviation from the standard of care. Obviously the jury did not agree. However, I think that reinforces the fact that you can never be sure of how a jury will decide and the potentially mercurial nature of jury trials," notes Trosty.

"Diagnostic delays [composed of both diagnostic errors and failure to diagnose] represented approximately 39% of all medical malpractice claims against physicians in 2003 according to data from the Physician Insurers Association of America [PIAA]. The PIAA data has been fairly consistent for the years 1996-2003 for percentage of closed claims related to diagnostic delays. In fact, the top cause of malpractice claims against physicians during this period was 'Failure to Diagnose' with approximately 31% of claims. The No. 3 cause of claims during this period of time was 'Error in Diagnosis' with approximately 8% of claims. Both of these allegations are related to delays in diagnosis and resulting injury to patients," states Trosty.

"It is interesting to note that approximately 27% of failure-to-diagnose claims result in indemnity payment to the plaintiff according to PIAA data. The PIAA database consists of over 250,000 closed claims and represents physician claims from 1986-present. In addition, failure-to-diagnose claims represent a significant allegation/cause of claims for almost every medical and surgical specialty. The frequency of these claims appears to be increasing annually and so do the indemnity payments. Between 1985 and 2003, there was an approximately 268% increase in indemnity payments for failure-to-diagnose claims. It is important to note that these claims often result from a system or process failure, especially related to either inadequate or non-existent tracking and follow-up systems for test results, referrals and consultations, and patient notification.

"Unfortunately, failure-to-diagnose claims often result in high severity of patient injury. Recent PIAA data indicated that approximately 30% of these claims resulted in the death of the patient, 7% resulted in grave injury to the patient, and 32% resulted in some form of permanent injury," Trosty says.

Reference

DuPage County (IL) Circuit Court, Case No. 00L-546. ■

Healthcare Risk Management™

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