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Waterborne pathogens: Give them special attention or the lawsuits will soon follow

Risk managers must work with engineers, infection control to minimize risk

The water sitting in the pipes in the walls throughout your facility could pose a liability risk you've never considered — waterborne pathogens can grow in your water system and provide unique opportunities for infecting your patients.

When those opportunities present themselves, you can be certain a lawsuit will follow.

Most common among the likely pathogens is *Legionella*, the bacteria that can cause Legionnaires' disease. But there are steps you can take to make such an outbreak unlikely. The risk manager's role, some experts say, is to make sure your maintenance and infection control departments are taking the necessary steps to prevent such problems. If you don't, you'll be the one dealing with lawsuits that some consider a slam-dunk for plaintiffs.

The risk of *Legionella* and similar waterborne pathogens is not unique to health care facilities, but they are at more risk than other types of organizations, says **J. Glenn Morris Jr.**, MD, MPH, chairman of the department of epidemiology and preventive medicine at the University of Maryland School of Medicine in Baltimore, and chairman of a task force that studied nosocomial *Legionella* recently in Maryland.

"*Legionella* infection can occur in many health care settings, but the risk is highest in acute-care hospitals that treat patients who are already suffering from a serious chronic disease or a suppressed immune system," Morris says.

Legionella bacteria were first recognized with an outbreak of pneumonia that occurred among attendees of an American Legion convention in 1976. Since then, more than 39 species and 61 serogroups of *Legionella* bacteria have been recognized. More than half of these species/subgroups have been associated with human disease. *Legionella pneumophila*, the first *Legionella* bacteria species identified, accounts for approximately 90% of infections.

Legionella can cause Pontiac fever, an often undiagnosed and generally

mild and self-limited respiratory illness, but it also can cause Legionnaires' disease, a potentially severe bacterial pneumonia that is accompanied by fever, fatigue, and cough. The Centers for Disease Control and Prevention (CDC) estimates between 10,000 and 20,000 cases occur each year in the United States. Nosocomial infections leading to Legionnaires' disease account for 23% of reported cases to the CDC. Nosocomial cases have a higher mortality rate than community-acquired cases.

The *Legionella* bacteria must be inhaled; ingesting it will not cause disease. That is why health care facilities can be such fertile grounds for *Legionella* outbreaks, Morris says. A health care facility presents many opportunities to inhale the bacteria from showers, whirlpools, humidifiers, and inhalation therapies. And, of course, a health care facility has a much higher proportion of weakened, susceptible patients than a typical business.

Extended-care facilities can be at especially high risk, says **Tim Keane**, president of *Legionella* Risk Management, a consulting firm in Chalfont, PA. Long-term care patients can be particularly weakened, and incontinence can expose the patient to more than the typical number of showers.

"It's amazing, the lack of awareness in risk management in hospitals," Keane says. "A lot of people think it's an infection control problem, so they don't get involved."

Baltimore outbreak results in four deaths

Legionella outbreaks can quickly turn into a nightmare for risk managers. Keane says these lawsuits usually are an easy win for the plaintiff.

"It's like asbestos in that if you get the disease, you can sue and you'll win," he says. "But it's better than asbestos. With asbestos, it's tough to prove where you got it. With *Legionella*, they can test different sites like your workplace and the hospital. If they get a match, they have to prove negligence, that the engineering standards were not implemented. That's usually not difficult."

The number of published trial results seems few, but that may be because, Keane says, "the lawyers I talk to always recommend that the defendants settle."

One terrible outbreak of Legionnaires' disease in a health care facility occurred in Havre de Grace, MD, near Baltimore, in July 1999. Officials at the Harford Memorial Hospital reported that four patients diagnosed with Legionnaires' disease died from the illness. The patients were among five originally diagnosed with the disease at the hospital, says **Louis Sperling**, JD, vice president for human resources and legal counsel for the health system Upper Chesapeake Health.

The problem was traced to the hospital's hot-water system, though investigators never found the specific cause of the *Legionella* infiltration, Sperling says. Extensive testing found *Legionella* at several hot-water outlets throughout the facility. The infected patients were different in many ways, and they were not on the same unit or in nearby rooms, though most of them were immunocompromised.

The state health department recommended superheating the water supply, but the hospital continued to find positive test results after that treatment. Then the hospital started superchlorinating the system, and that eliminated the *Legionella.* Sperling says the hospital continues to superchlorinate the water system as a precaution and has had no positive results in a year and a half.

A *Legionella* outbreak is particularly difficult for a hospital because the public reacts with near panic at the mention of Legionnaires' disease, Sperling says. Even the hospital staff were wary, he says.

"Risk managers have to be concerned about this," Sperling says. "Risk management has a responsibility to ensure that the lines of communication necessary to prevent this kind of outbreak are in place. It's one thing for engineering to say they've got it under control, but our risk-management department ensures that, if there is any positive reading at all, that is relayed to risk management and to infection control. Risk management plays a coordinating role, making sure

everyone is talking to each other."

Risk management should establish the level of caution that will be utilized within the facility, Sperling says. Engineering, for instance, may decide that the water should be tested twice a year and low-positive results can be ignored. There may be engineering standards that justify that decision, but risk management may determine that the organization needs to be much more cautious. Sperling and the risk manager at Harford Memorial, for instance, decided that they should do weekly testing for a while after the outbreak; now monthly testing is done.

"That was a risk-management decision that took us far beyond the engineering and clinical standards," he says. "We determined that there was reason for organization to be extraordinarily cautious now."

Death's fallout

Investigations after the deaths never revealed any deficiencies in the hospital that could have caused the outbreak, Sperling says. Even when the *Legionella* outbreak occurs without any obvious cause, there is tremendous liability risk for the hospital, he says.

"There was a case filed after the deaths. There definitely is going to be legal fallout any time you have four people die," he says. "You're going to have someone wanting to point the finger at you."

Sperling declined to say how the lawsuit was resolved. He confirmed, however, that "the liability risk is significant."

Another *Legionella* source was discovered in August 2000 at St. Joseph Medical Center in Towson, MD. Officials there banned showers and distributed bottled water to patients after an inspection of the hospital's hot-water system revealed the presence of *Legionella*. The hospital, just north of Baltimore, began treating the hot-water system after tests revealed elevated levels of *Legionella* bacteria, according to hospital spokeswoman **Linda Harder**. No patients contracted Legionnaires' disease, but one patient was confirmed as having *Legionella* and recovered.

Earlier, in 1998, two patients died and three others were ill with Legionnaires' disease at a hospital in Tarbes, France. In that case, hospital officials reported that the bacteria were transmitted in the hospital by vapors rising from hot water used in physical therapy treatments.

After the outbreaks near Baltimore, a Maryland state health task force released recommendations to hospitals that included routinely testing water systems, giving doctors quick access to diagnostic tests and setting up Legionnaires' response teams to deal with outbreaks. **(See p. 76 for Maryland's recommendations.)** The CDC also issued guidelines for preventing nosocomial Legionnaires' disease. They can be found at www.cdc.gov/ncidod/hip/pneumonia/2_legion.htm.

Problem addressed by Joint Commission

The Joint Commission on Accreditation of Healthcare Organizations makes it clear that hospitals must take the proper steps to protect patients from waterborne pathogens. But it has not specified exactly what they must do. In the utility standard, EC.1.7 (previously EC.1.9), the Joint Commission says accredited facilities must "reduce the potential for organizational acquired illness," but it is a utility equipment standard, not an infection control standard. Two new intent statements were added to the standard in 2001. Intent item "i" addresses water-based systems and requires that equipment for recirculating water be continuously properly designed, accurately installed, and adequately maintained.

Most frequently, *Legionella* grows in a water system that allows water to stand for too long at

the temperature most favorable to the bacteria. The bacteria grow between at 86° and 110° F, so a big part of the solution is to keep hot water at a higher temperature and cold water pipes insulated to a lower temperature. Stagnation is another big threat, Keane says.

"Patient-care areas tend to have a lot more plumbing and outlets than your typical room, even your typical bathroom. If you convert that room to an office, suddenly all those pipes aren't used any more and the water can just sit there," Keane says. "If you're renovating and close down a unit for a week, you have to flush those pipes and make sure the water's good before you use it again. Typically, nothing is done."

Engineering and infection-control professionals have extensive resources for the details of how to prevent waterborne pathogen outbreaks. Keane suggests that the risk manager should be the one overseeing the risk control by ensuring that the other departments are taking the necessary steps.

"Hospitals take for granted that water coming out of the faucet is clean, but that's not necessarily the case," Keane says. "The water supplied by the city is clean enough for a healthy person to drink, but other things can happen in your own building." ■

Maryland issues guidelines for preventing *Legionella*

The Maryland Department of Health and Mental Hygiene in Baltimore recommends that acute-care hospitals routinely test water systems for the *Legionella* bacteria, that doctors have ready access to the proper diagnostic tools, and labs be required by law to report Legionnaires' disease cases to the state.

The recommendations go beyond current Centers for Disease Control and Prevention guidelines, which recommend environmental testing only after a case of *Legionella* infection has been identified. These are some of the specific recommendations:

- Acute-care hospitals should routinely perform "risk-based" environmental cultures for *Legionella*, including cultures of the hospital hot-water system.
- All acute-care hospitals should have in-house capability to perform *Legionella* urinary antigen tests. If not, they should contract with a laboratory that will provide urinary antigen testing and results within 24-48 hours. Hospitals performing solid organ or bone marrow transplants or those caring for transplant patients should have the in-house capability to culture *Legionella* directly from patient specimens. All other hospitals should have a system in place to submit cultures to a microbiology laboratory within 24 hours of specimen collection.

Dept. of testing & eradication

The task force also studied methods for preventing *Legionella* infection and killing the bacteria when it is detected in hospitals. The panel recommended that health care facilities establish teams to handle environmental testing and eradication.

Hot water temperature limits should be raised to 122° F (from 110°, the temperature currently used by most hospitals) so that *Legionella* is less likely to survive. When new hospitals are built, or hospitals are remodeled, water systems should be designed to minimize the risk of *Legionella* infection. ■

PA considers changing joint and several liability

In a move meant to rescue health care providers from the state's malpractice insurance crisis, the Pennsylvania legislature may soon pass the Fair Share Act, a bill abolishing joint and several liability for any defendant found to be less than 60% liable for causing an injury.

The state House of Representatives recently passed the bill and the Senate will consider it. The bill is "a common-sense measure that maintains a plaintiff's right to collect damages while bringing fairness, balance, and stability to Pennsylvania's liability insurance system," says **Carolyn F. Scanlan**, president and CEO of the Hospital & Healthsystem Association of Pennsylvania (HAP). "This critical reform will help to keep doctors practicing, hospital services open, and patients healthy."

'I'll sign if . . .'

Scanlan said that there is broad support for these essential reforms. The governor has said he will sign this bill if the Senate concurs on the bipartisan reform, and both gubernatorial

candidates have both come out in favor of reforming Pennsylvania's tort system, Scanlan says. If the reforms are approved, Pennsylvania will join the 35 other states that have already reformed joint and several liability.

In its current form, the legal concept of joint and several liability holds each defendant in a lawsuit financially liable for the full amount of a damage award, even if the defendant's legal responsibility is deemed to be minimal.

"Joint and several liability is inherently unfair to businesses and individuals," Scanlan says. "It lets the most negligent defendant off the hook while penalizing defendants who were only remotely involved."

Scanlan says that, without this critical change, insurers will continue to avoid doing business in Pennsylvania, leaving health care providers with two options: diverting patient-care resources to paying exorbitant insurance premiums or cutting services. Pennsylvania hospitals are estimated to pay more than $180 million in additional premiums for medical liability insurance compared to one year ago, according to a statewide survey of medical professional liability coverage released by HAP in May.

"Most of these premium increases preceded the collapse of the Pennsylvania liability insurance market," Scanlan says. "Hospitals now going into the market for renewal or replacement coverage as of July through September 2002 — when more than half of all hospital policies expire — are expecting even larger additional premium hikes that will further erode patient access to care. If a hospital cannot afford or get insurance coverage, services will suffer." ■

Language barriers pose risk to health and liability

One patient reported that he "would tell the doctor 'OK,' but I didn't understand anything." That is a quote from a patient surveyed in a new study that suggests language barriers increasingly pose a threat to patient safety and, as a result, are a growing liability risk for health care providers.

The survey report, "What A Difference An Interpreter Can Make: Health Care Experiences of Uninsured with Limited English Proficiency," is being released by The Access Project, a Brandeis University (Waltham, MA)-affiliated national resource center for local groups working to improve access to health care. The survey found that a significant portion of respondents who needed an interpreter, but did not get one, reported leaving the hospital without understanding how to take prescribed medications, says **Mark Rukavina**, Access Project director.

"A Hispanic man in Virginia was prescribed three medicines, but mistakenly assumed he should take all three at once," Rukavina says. "He wound up in the emergency room with a severe reaction. An interpreter was then found who explained in Spanish that he was not supposed to take all three at once."

Provider = burden

Dennis Andrulis, PhD, a research professor at SUNY Downstate Medical Center in Brooklyn, NY, and lead author of the report, says the findings should be of concern to health care risk managers. As it becomes more apparent that many patients need help communicating, the burden on providers grows, he says. Failure to provide that assistance could easily result in a lawsuit.

"The patients in our survey who could not speak English are sending a strong message: failure to communicate effectively may cost patients their health, and it may be bad business for doctors and hospitals," he says.

In addition to reducing medical errors and liability, Andrulis says providing an interpreter could help the organization's bottom line. Survey results strongly suggest that having an interpreter may help non-English-speaking patients get information on financial assistance available to pay for medical care. More than half of the respondents who needed but did not receive interpreters said they were never asked if they needed help in paying for medical care, compared to just more than one-third of those who needed and got an interpreter.

The report found that patients who needed and received interpreter services were more likely to say the hospital was open and accepting than those who did not use interpreters and more inclined to say that they would use the hospital again if they become insured. **(See related article, p. 78.)**

Rukavina says the finding on medications has serious implications for a health system that is struggling to improve the quality of care for an increasingly diverse population. For patients not

fluent in English, lack of an interpreter could lead to misdiagnosis and negative health outcomes. The lack of an interpreter could result in patients not complying with a prescribed treatment regimen. One survey respondent stated, "I didn't buy my medicines because I didn't understand the instructions."

"This is a wake-up call for hospitals that are worried about malpractice suits," he says. "If they care about preventing medical errors, they'll pay close attention to our finding strong association between interpreters and understanding medication instructions."

Data were collected during the summer of 2000. The report is based on interviews with patients who had no health insurance and received care at one of 23 hospitals in 12 states: Arizona, California, Florida, Georgia, Idaho, Louisiana, Nevada, New York, North Carolina, Ohio, Tennessee, and Virginia. More than 44 million people speak a language other than English at home, according to the U.S. Census. In five states — California, New York, Texas, Hawaii, and New Mexico — more than 10% of the population has limited English proficiency. ■

A new consent form is developed for interpreters

Language difficulties in health care usually are solved with the use of an interpreter, but one manager in Oklahoma realized that the interpreter could create new privacy and liability concerns. She solved the problem by developing a special consent form for use with a language interpreter.

The problem became apparent while watching an interpreter help a Spanish-speaking patient, says **Glennda Gore**, RHIA, director of health information services and privacy officer at McAlester (OK) Regional Health Center. Gore had been thinking about compliance issues related to the Health Insurance Portability and Accountability Act (HIPAA), trying to spot risks within her organization. Most of her concern had focused on medical records, but then she overheard the interpreter helping a mother understand her treatment.

"It hit me that we were releasing information by using the interpreter, and we didn't really have permission," Gore says. "The back and forth involves privileged information; and while sometimes the interpreter is a family member or nurse, sometimes it is a secretary or a housekeeper. We have to use whoever we can find that speaks the language."

Gore developed a standard consent form that is now used for any type of language interpretation. **(See form, inserted in this issue.)** The top part of the form explains that the language interpreter will have access to private medical information during the interpretation process, but not to any medical records. The bottom part of the form repeats the same information in Spanish, the most common foreign language encountered at McAlester.

The form is presented to the patient before the language interpreter conveys any medical information, and the interpreter may help explain the form to the patient. Once the form is signed, the interpreter is free to discuss privileged medical issues. In addition to Spanish-speaking patients, the form is used for hearing-impaired patients who need sign language interpretation. If they are English-speaking, they can read the English portion of the form on their own and give consent.

The consent form could easily be adapted to any other language when necessary, Gore says.

The interpreter would have to translate the English portion into the other language, but Gore says the wording is simple enough that any interpreter should be able to do so.

"We drew it up ourselves and got legal to sign off on it. They had no problems with it," she says. "We provided the forms to our nursing staff and also to the admitting office. They pull it out any time they see the patient doesn't speak English."

Gore says *Healthcare Risk Management* readers are free to reproduce the form and adapt it for their own use. ■

Injury prevention model may improve patient safety

A team of Medical College of Wisconsin researchers, led by **Peter Layde**, MD, professor of family and community medicine and co-director of the Injury Research Center, are proposing a new way to look at injuries that, they

say, will be more useful in preventing them.

Their work appeared in the April 17 issue of the *Journal of the American Medical Association*. Most people in the medical field who have been working on this problem have focused on what could be called an error-reduction approach, which Layde refers to as the "name, blame, and shame approach."

That strategy is based on quality improvement principles used in manufacturing industries. It involves identifying errors as a means of preventing them. But Layde tells *Healthcare Risk Management* that the manufacturing approach has these limitations in the health care industry:

- It is often hard to identify when an error has occurred. Physicians reviewing a record may disagree about whether there was an actual error.
- Many injuries don't occur due to an error. It could be a side effect of a medication or procedure which is preventable but not due to error.
- The error approach causes defensiveness because no one wants to be accused of an error.

"Our approach focuses on what could be done to prevent injury by looking at the whole chain of causation to find the weakest link," Layde says. "Then that link can be corrected. It may or may not be a person."

Don't expect better behavior

Layde proposes using an alternative model to patient safety based on the principles of injury prevention that have been useful in public health to prevent other injuries. He says the model provides a theoretical framework and also some practical research tools for studying and improving patient safety.

He points out the dramatic reduction in injuries in manufacturing and transportation over the last 50 years using the same principles. An injury approach doesn't look just at the injury event itself, but at the whole context in which the injury happened. It focuses on the agent of injury and the vehicle by which it was introduced.

He points out that injury-control approaches that try to modify a person's behavior have not been shown to be very effective.

"You can't reliably make everybody behave better," he says. For example, 40 years ago, fatalities in car accidents were much higher per 100,000 miles. The first approach was to try to educate people about driving drunk; that did little to reduce the toll. Later, when cars and highways were engineered to be safer, along with education, the toll dropped dramatically.

Here's how Layde translates that into medical injury: If a patient is given the wrong medication, the consequences can be disastrous. The error model would focus on the person who gave the medication and punish him or her. That doesn't get to the root cause in the system. In the injury-prevention model, the whole system of giving medication would be modified. One step might be computerized patient orders. That would prevent errors from illegible handwriting. The computer could check for drug interactions or patient allergies. A bar code on the patient's wristband could be checked. Injuries would be prevented. All of these approaches are more effective than just trying to modify a nurse's behavior.

"We are now doing some studies which implement this approach in different settings to identify risk factors and to monitor the occurrence of injuries," he says. "We are questioning the conventional dogma about the best approach to address patient safety. We want to encourage debate and discussion on the topic." ■

Reader Question

Consent must be obtained when filming your patients

Question: We require consent before we allow an outsider, such as a news crew, to videotape patients. But what about recordings made for our own purposes? We want to shoot promotional material in patient-care areas, and we've been told we can skip the consent process since the emergency department, for instance, might be considered a public area.

Answer: Attorneys could debate the question of whether an emergency department is a public area in which one can videotape freely, but that's not necessary because the Joint Commission on Accreditation of Healthcare Organizations has made it clear that you must obtain consent in all cases.

In a recent clarification of existing standards, the

Joint Commission states that filming or videotaping in patient-care areas is acceptable only if the patient, or the surrogate decision maker, gives permission. The clarification was included in a set of frequently asked questions and answers released by the accrediting body.

Clarification of the standard

These are some points made in the clarification of the information management standard:

• In a situation where the patient is comatose or otherwise unable to give informed consent and no surrogate decision maker is available, the hospital may film or videotape itself or retain another to film or videotape patient-care activities within a policy stating informed consent is required before that patient's film or videotape can be used for any purpose. Anyone who films or videotapes must sign an appropriate confidentiality commitment.

• The film or videotape must remain in the physical possession of the health care organization and not be released to anyone else or used for educational or other purposes until appropriate informed consent is obtained. This means anyone who is not an employee of the health care organization who does the filming or videotaping cannot have the organization's film or tape or a copy of the film or videotape until consent is obtained.

• If the patient or surrogate does *not* give consent and the patient already has been recorded, the patient must be either removed from the film or videotape or it is destroyed.

• In addition to obtaining consent from individual patients, the health care organization has an obligation to announce that filming or videotaping may be occurring when emergency services are provided. An example is posting signs that say, "Filming or Videotaping is Under Way." ■

HHS urges safeguarding of ventilation systems

More help is available for risk managers trying to revamp their emergency preparedness plans in light of potential terrorist attacks. The Department of Health and Human Services (HHS) has released new guidelines for protecting ventilation systems in commercial and government buildings from chemical, biological, and radiological attacks.

The guidelines provide recommendations that address the physical security of ventilation systems, airflow and filtration, systems maintenance, program administration, and maintenance staff training. In announcing the guidelines, HHS Secretary **Tommy G. Thompson** said the guidelines offer "practical advice to building owners, managers, and maintenance staffs on the steps they can take to protect their ventilation systems."

Reducing and minimizing

The Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) prepared the guidelines with input and review by the Office of Homeland Security's (OHS) Interagency Workgroup on Building Air Protection and more than 30 other federal agencies, state and local organizations, and professional associations. OHS director Tom Ridge announced that the guidance "offers reasonable and practical measures to reduce the likelihood of a contaminant attack and to minimize the impact if one occurs."

The guidelines recommend that security measures be adopted for air intakes and return-air grilles, and that access to building operations systems and building design information should be restricted. The information also recommends that the emergency capabilities of systems' operational controls should be assessed, filter efficiency should be closely evaluated, buildings' emergency plans should be updated, and preventive maintenance procedures should be adopted. The document also cautions against detrimental actions, such as permanently sealing outdoor air intakes.

Get the guidelines

According to the guidelines, protective measures should be tailored to fit the individual building based on several factors, including the perceived risk associated with the building and its tenants, engineering and architectural feasibility, and cost. *Guidance for Protecting Building Environments from Airborne Chemical, Biological, or Radiological Attacks,* DHHS (NIOSH) Publication No. 2002-139, is available on the NIOSH web page at www.cdc.gov/niosh. Copies also can be obtained calling the NIOSH toll-free information number, (800) 35-

NIOSH [(800) 356-4674]. ■

Eight states lead U.S. in senior dollars for court

A new independent study shows that much of the increased government funding for senior care between 1995 and 2001 has actually gone for lawyers and other litigation expenses, not toward improved patient care for seniors.

The actuarial study, conducted by Chicago-based AON Risk Consultants Inc., examines the skyrocketing cost of general liability and professional liability claims against long-term care providers who rely on federal dollars to help cover patient care costs for three-quarters of the country's elderly and disabled residing in nursing homes.

"In a stark and statistically undeniable manner, many in the trial-lawyer community are targeting dollars meant for seniors' long-term care as a reliable and generous source of income."

The study reveals that the problem is worse in Florida, Texas, Arkansas, Alabama, Mississippi, Georgia, California, and West Virginia. Among the independent study's objectives are to identify the national trends in the cost of general liability and professional liability (GL/PL) claims for long-term care and identify state-specific trends and their correlation to future national trends. These are some key national findings:

- The average long-term care GL/PL cost per skilled nursing bed has increased at an annual rate of 24% from $240 in 1990 to $2,360 in 2001. National costs now are 10 times higher than they were in the early 1990s.
- GL/PL costs have absorbed 20% ($3.78) of the $18.47 increase in the countrywide average Medicaid reimbursement rate from 1995 to 2000.
- Almost half of the total amount of claim costs paid for GL/PL claims in the long-term care industry is directly going to attorneys.

Charles H. Roadman II, MD, president and CEO of the Washington, DC-based American Health Care Association (AHCA), says the results suggest that tax money is not going for the health care objectives that most people expect. The AHCA is a nonprofit federation of affiliated state health organizations, together representing nearly 12,000 nonprofit and for-profit assisted living, nursing facility, developmentally disabled, and subacute-care providers that care for more than 1.5 million elderly and disabled individuals nationally.

"In a stark and statistically undeniable manner, many in the trial-lawyer community are targeting dollars meant for seniors' long-term care as a reliable and generous source of income," Roadman says. "Taxpayers and our federal lawmakers need to be aware that critical health care dollars are being diverted out of patient care for the nation's poorest and most vulnerable seniors. This analysis sheds light on a problem that should be troubling to every taxpayer, federal official, and senior citizen who relies on Medicaid."

The cost per bed

In California, for instance, the average loss cost per bed has increased from $970 in 1995 to $2,320 in 2001. As the average Medicaid per-diem reimbursement has increased 18% over the past six years — from $79.71 in 1995 to $94.28 in 2000 — the GL/PL loss cost has increased almost 100%. As a result, although the Medicaid reimbursement rate has increased $14.57 during this period, lawsuit and liability insurance costs have absorbed 17% ($2.41) of that growth.

"At a time when 'improved quality of care' is the rallying cry for the administration, the Congress, and the public at large, taxpayers should expect to see dollars earmarked for senior care actually used for this important purpose — not to pay for skyrocketing lawsuit costs," Roadman says. ■

Respiratory therapy ampuls a tough read

The Huntingdon Valley, PA-based Institute for Safe Medication Practices (ISMP) has issued a stern warning about labels on respiratory therapy medications packaged in plastic containers called ampuls. The labels are "virtually impossible" to read and pose a serious risk to patient safety, the group says.

Part of the problem is that manufacturers package respiratory medicines in plastic ampuls that are too similar in shape and color, the ISMP reports. In addition, the ampuls' translucent packaging can make it extremely difficult to see the drug name, strength, lot number, and expiration date embossed

on each vial.

The Food and Drug Administration has not responded to the problem despite numerous complaints from health care professionals over the past decade, according to the nonprofit ISMP. Better labeling has been stymied by fears that volatile ingredients in inks, adhesives, and paper could enter and taint medications packaged in vials made of low-density polyethylene, the ISMP reports. There is some legitimacy to that concern, but some solution must be found, the group says.

One solution might be to use colored ink or paper labeling on the portion of the ampul that doesn't come in contact with the drug solution. ■

Dose, quantity errors top list of medication problems

The top-three causes of reported medication are omission errors, improper dose / quantity, and unauthorized drugs, according to the MedMARx 2000 Report, released recently by the U.S. Pharmacopeia (USP). The high number of omission errors indicates that when drug therapy is needed, patients may not, in fact, be getting the medications they need, the report says.

Additionally, when a drug is given, it may be at the wrong dose, or worse yet, the wrong drug entirely.

The report findings also note that with medication errors that caused harm, actions taken were more frequently documented in 2000 (60%) as compared to 38% in 1999, perhaps signaling that hospitals are doing a better job of documenting medication error information.

MedMARx is an Internet-accessible and anonymous reporting program used by hospitals to track and trend medication errors. The de-identified data submitted by participating hospitals are stored in a central national database at USP and are analyzed for educational and research programs.

Diane D. Cousins, RPh, USP vice president for practitioner and product experience, says the trends indicate that while progress in reporting errors is being made, the same types of errors are occurring again and again.

"This tells us that there are deeper, more systemic causes for these errors," she says. "The systems need to change in order to reduce errors."

The 1999 MedMARx report analyzed 6,224 medication-error reports from 56 facilities. USP analysis indicated that most reported errors (97%) did not result in patient harm. In the MedMARx 2000 Data Report, the number of reporting facilities increased threefold to 184, with a sevenfold increase in the number of reports, totaling 41,296.

In both the 1999 and the 2000 reports, the most frequently identified causes of error were performance deficit and procedure / protocol not followed. Computer entry and transcription inaccurate / omitted became two of the five most frequent reasons for medication errors. Both the 1999 and 2000 reports indicate that distractions, workload increase, and inexperienced staff are the most common contributing factors to medication errors. In the 2000 report, staffing issues became one of the five most frequently cited reasons for medication errors — accounting for 33% of records (an increase of 6% compared to the 1999 data). ■

Wrong-patient errors are underreported

Two recent studies suggest that risk managers should take a closer look at how they measure errors in their organizations. One study suggests you should beware of using patient charts to track medical errors because doctors are so inconsistent in how they assess the same charts. Another study indicates that there may be many more "wrong-patient" errors than commonly believed.

In the first study, the researchers found that physicians who were asked to make conclusions based on patient charts were wrong about one-third of the time, says **Eric J. Thomas**, MD, of the University of Texas-Houston Medical Center and lead researcher on the project. Using multiple reviewers improved the chance of getting an accurate analysis of the charts, but there still were enough errors to warrant caution. Thomas says the findings are particularly relevant because the 2000 Institute of Medicine Report *To Err is Human* relied on physicians reading patient charts.

The University of Texas study involved charts for patients hospitalized in Utah and Colorado in 1992 *(Ann Intern Med* 2002; 136:812-816). After three independent reviews of 500 medical records, the following were measured: reliability and the effect of varying criteria for reviewer confidence

in and reviewer agreement about the presence of adverse events.

For agreements in judgments of adverse events among the three sets of reviews, the statistics ranged from 0.4 to 0.41 for adverse events and from 0.19 to 0.23 for negligent adverse events. Rates for adverse events and for negligent adverse events varied substantially depending on the degree of agreement and the level of confidence that was required among reviewers.

Thomas and his colleagues conclude that "estimates of adverse-event rates from medical record review, including those reported by the Institute of Medicine in its 2000 report on medical errors, are highly sensitive to the degree of consensus and confidence among reviewers."

"The marked disparity in the number of events chronicled by these two databases — one voluntary, one mandatory — suggests that the voluntary Joint Commission database is incomplete."

In another study, **Mark R. Chassin**, MD, MPP, MPH; and **Elise C. Becher**, MD, MA, of the Mount Sinai School of Medicine in Los Angeles, say hospitals seriously underreport the number of patients undergoing medical procedures intended for someone else *(Ann Intern Med* 2002; 136: 826-833).

"Among all types of medical errors, cases in which the wrong patient undergoes an invasive procedure are sufficiently distressing to warrant special attention. Nevertheless, institutions underreport such procedures, and the medical literature contains no discussions about them," they wrote.

The article by Chassin and Becher examines the case of a patient who was mistakenly taken for another patient's invasive electrophysiology procedure. After reviewing the case and the results of the institution's root-cause analysis, they discovered at least 17 distinct errors, no single one of which could have caused the adverse event by itself. They determined that those specific "active" errors interacted with a few underlying system weaknesses to cause harm. The most remediable of these were absent or misused protocols for patient identification and informed consent, systematically faulty exchange of information among caregivers, and poorly functioning teams.

The researchers point out that the Joint Commission on Accreditation of Healthcare Organizations maintains a national database of sentinel events, which include errors such as this one. But reporting the incidents to the Joint Commission is voluntary and the database contains 17 reports of an invasive procedure done on the wrong patient over the past seven years. Additional information about adverse events is compiled by individual states, at least 15 of which maintain their own error-reporting systems. New York state has received reports of 27 "incorrect patient/invasive procedure" incidents from April 1998 through December 2001.

"The marked disparity in the number of events chronicled by these two databases — one voluntary, one mandatory — suggests that the voluntary Joint Commission database is incomplete,"

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the researchers wrote. "But even mandatory state reporting systems may underestimate the true incidence of 'wrong-patient' procedures. All error-reporting systems depend on hospitals' internal incident reports as sources for their data, and research has shown that clinicians file incident reports for only a small percentage of actual errors."

A recent analysis of the New York system, for example, determined that for one of the adverse events for which reporting is required (deaths within 48 hours of surgery), only 16% of cases were reported in 1999, Chassin and Becher report. ■

Nurse accused of 10 deaths in MO hospital

Authorities say a former Veterans Affairs hospital nurse killed 10 patients with succinylcholine, and 31 more deaths may be related.

Police in St. Louis have arrested Richard A. Williams, who worked at the Truman Memorial Veterans Affairs Hospital in Columbia, MO, 10 years ago. The 36-year-old nurse had been a suspect for some time, but has denied any wrongdoing. Williams left the hospital in 1993.

Police exhumed 13 bodies in 1993 but failed to determine the cause of death. However, toxicology tests in 2001 found succinylcholine in the tissues of 10 patients, leading to murder charges against Williams. The authorities say a total of 41 deaths were considered suspicious at the hospital. For the 10 patients Williams is charged with killing, the police say he was the only staff member on duty at the time and had access to succinylcholine. ■

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OB/GYN patient dies after egg harvest: $30 million verdict and settlements

By **Jan J. Gorrie**, Esq.
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News: After a year of being unable to conceive a child, an obstetrician and her obstetrician husband sought fertility treatment, which led to her undergoing an egg-harvesting procedure. The procedure led to uncontrolled internal bleeding in part because she was taking aspirin and heparin to treat her antiphospholipid antibody syndrome (APD). Once the bleeding became apparent, the husband had her transported to the hospital where he worked and he performed emergency surgery. Despite the successful emergency surgery, the patient fell into a coma two days later and died nine days afterward. The husband brought suit against the treating obstetricians and hospital where he performed surgery, claiming that each in turn had failed to meet the prevailing standard of care. The hospital settled prior to trial for $5 million and the jury returned a verdict against the treating OB/GYNs for a combined $25 million.

Background: After trying to conceive a child for more than a year, an obstetrician and her husband, who also was an obstetrician, presented to an OB/GYN fertility specialist for treatment. Her primary OB/GYN recommended in vitro fertilization. The decedent's ovaries were hyperstimulated, which allowed an increased number of eggs to mature at the same time. Before the oocytes were retrieved, the primary OB/GYN diagnosed the patient with APD, a condition that makes the implantation of embryos in the uterine lining difficult because the uterus is more susceptible to blood clots. The primary OB/GYN prescribed heparin and aspirin therapy. While the effects of heparin disappear within hours of taking it, aspirin's ability to thin blood can stay in the body for weeks.

On Dec. 29, the patient underwent the egg-retrieval procedure at the referral defendant OB/GYN's office and 18 eggs were harvested. The plaintiff claimed that the referral OB/GYN's nurses were told of the primary OB/GYN's administration of heparin and aspirin. A routine ultrasound was performed after the procedure but, according to testimony provided at trial, the referral physician never saw the results of the test after he was verbally told that everything appeared normal. Evidence of the ultrasound presented at trial indicated that the results actually showed a large mass, later determined to be blood, forming in her abdomen.

Following the egg-harvesting procedure, the patient drove from the referral physician's office to the primary OB/GYN office for a previously scheduled treatment for her ADP. The treating physician's nurse initiated the ADP therapy — heparin and aspirin — about 3½ hours after the egg-retrieval procedure had been completed. The patient then complained of unusual lightheadedness and became pale. Her blood pressure

dropped. The nurse immediately terminated the procedure and attempted to contact the primary OB/GYN. According to the testimony of the primary obstetrician's nurse, it took 1½ hours for the physician to respond. By the time the primary OB/GYN examined the patient, she was lethargic and hallucinating. Her husband was contacted, and he immediately went to the primary physician's office to see his wife. The husband determined that her condition was critical and had her transported to the hospital where he worked.

The husband performed emergency surgery and discovered that 75% of her blood had pooled into her abdomen. At trial, the husband testified that he removed several handfuls of blood clots.

The patient was in stable condition following the operation and appeared to be recovering for the next two days. However, on Dec. 31, her heart stopped beating. She lost consciousness and remained in a coma until her death nine days later.

The plaintiff claimed that, just prior to her death, the decedent's nurse made no attempt to summon a physician even though the patient's lungs were failing. As for the treating and referral physicians, the plaintiff averred that their treatment of his wife fell below the prevailing standard of care and that they should have communicated about her underlying complications. Specifically, as to the referral physician, the plaintiff contended that the physician prior to the patient leaving his office should have personally reviewed the ultrasound. The plaintiff also claimed that the primary OB/GYN should have responded more quickly to his office's emergency call.

The defendant argued that the plaintiff's actions were the sole cause of his wife's death. The suit claimed that if the husband had taken his wife promptly to the nearest emergency room instead of the hospital where he practiced, she would have received treatment faster, possibly saving her life. It also claimed that the fact he operated on his wife showed that he reacted with distracting emotion and not skill in performing the emergency surgery. The plaintiff countered that the decedent was in the defendants' care for five hours while she was bleeding, whereas she was only under her husband's direct medical care for 15 minutes before he was able to successfully stop her bleeding. The defendant physicians also contended that the decedent and her husband were both well-trained physicians and should have been aware that aspirin would increase the probability of internal bleeding during the egg-retrieval procedures. They claimed that they were not liable because the decedent was informed of the inherent risks and chose to undergo the procedure anyway.

Prior to trial, the hospital settled with the plaintiff for $5 million. The jury in the trial against the treating and referral physicians returned a verdict awarding the plaintiff $25 million — half for wrongful death and half for pain and survival damages. The jury apportioned risk 50/50 between the defendant physicians.

What this means to you: Doctors certainly can be patients, and just because the patient happens to be one does not mean that medical professional liability will not occur. And, as always, physicians and health care facilities simply have to take patients as they find them regardless of their education and training.

"With that in mind, this case poses an interesting dilemma: Does the standard of care change when the patient is herself a physician of the same specialty as the treating and referring physicians?" says **Ellen Barton**, JD, CPCU, a risk management consultant in Phoenix, MD. "In addition, does the fact that the patient's husband is a physician of the same specialty change the standard of care, especially as it relates to the need to communicate fully regarding the risks and benefits of procedures? I think the best way to answer the question is to say that the standard of care does not change; however, it is incumbent on the primary and referring physicians to understand that while the patient and her family may be more sophisticated consumers of health care, the basic responsibility to communicate fully and ensure the greatest possible understanding remains theirs since in this situation they are the professionals. Thus, while the conversations may be more technical and go into greater detail, it remains clear that the legal responsibility for the physician patient's care remains with the treating and referring physicians."

Not only do physicians need to communicate effectively with their patients, but they also must communicate with each other particularly when one is the primary physician and the other is the referring physician.

"This case also points out the need for communication between the referring and primary physicians as the physician patient went back and forth between them for various treatments and procedures. While this case is in large part about the 'practice of medicine,' there is also

a large component of 'administrative' breakdown. Not only did the defendant physicians not seem to share critical information regarding the patient's condition and subsequent tests, but the referring physician's failure to personally review the ultrasound reliance on a technician's oral opinion that 'everything appeared normal' falls below the standard of care. Thus, the protocols regarding response time by physicians to nursing staff in an outpatient setting should be reviewed so that a patient's condition is not compromised by a lack of or tardy response, as seems to have been the case here," Barton says.

Finally, family members treating family is discouraged because of the chance of losing objectivity.

"The issues surrounding the patient's physician husband performing emergency surgery is clearly an interesting one. And, while in this case, he may have saved her life — at least temporarily — hospitals should address this issue through the Medical Staff Bylaws and Rules and Regulations," concludes Barton.

Reference

• *Tony Matteo, MD, as Adm. of the Estate of Suzanne Wester Matteo, MD v. Jerome Check, MD, and Admed Nazari, MD v. Tony Matteo, MD, Holy Redeemer Hospital and Nurse Newhall,* Philadelphia Court of Common Pleas. Case settled. Thomas Kline, Esq., of Philadelphia, for the plaintiff. ■

Ignored order leads to patient's death

News: Following routine prostate surgery, the patient had recovered and was transported to a floor unit. Once on the unit, the patient was left under the care of a nurse's aide, who failed to appropriately monitor him. Three hours later, a code blue was called and the patient died. Prior to trial, the hospital settled with the decedent's family for $750,000.

Background: The patient was admitted to the hospital for routine prostate surgery. Following successful surgery, the attending physician left instructions with the recovery room staff that the patient be checked every hour; and if his heart rate exceeded 120 beats per minute, the physician should be called. The decedent was started on morphine sulfate via continuous drip IV and the physician departed. Shortly thereafter, the patient was transferred from the recovery room to the unit. The patient was doing well and spoke with his wife, who left the hospital shortly afterward.

The patient's medical records showed that at 8 p.m., a new syringe of morphine sulfate was inserted into the Baxter pump. When the plaintiff's attorney first obtained the patient's medical record, only one nurse had signed the patient's chart indicating that the entire syringe of morphine sulfate had been used; when records were obtained later, another nurse had cosigned the entry. For the next two hours and 40 minutes, no hospital personnel monitored the decedent except a nurse's aide. At 9 p.m., the nurse's aide noted that the patient's heart rate was 128 beats per minute; however, the attending physician was not notified. At around, 10:30 p.m., the nurse's aide again checked on the patient, this time to find him totally nonresponsive. At 10:54 p.m., a code blue was called, but the patient failed to respond and died.

The patient was survived by his wife and three emancipated adult children, who brought suit against the hospital. The plaintiff's claimed that the hospital staff failed to follow the physician's orders and appropriately monitor the patient. The plaintiff maintained that this failure resulted in the patient's death from either an adverse reaction to the morphine sulfate or a morphine overdose.

The defendant hospital countered that the decedent's death was not caused by an overdose or adverse reaction to morphine sulfate and that its staff had not been negligent. However, prior to trial, the hospital settled for $750,000 with the patient's family.

What this means to you: "Even though it doesn't appear that the discharge from the PACU [perianesthesia care unit] was inappropriate in this scenario, the first thing a risk manager might consider is to revisit the criteria for discharging a patient from the PACU postoperatively and who can discharge on what criteria in order to verify that practice and policy match. Further, the use of enough analgesic [morphine] to require a replacement at 8 p.m. is troublesome, even in a postoperative patient. If this were a PCA [patient-controlled analgesia] unit, the patient administers the doses, but they are controlled to prevent an overdose. If the morphine was administered in a continuous pump, that is rather unusual, especially after

routine surgery. Either way, the nurses should have been alert to the fact that the patient was self-administering the drug [with a PCA] with such frequency, or that the continuous drip rate was apparently rather fast, or still yet questioned why morphine was given continuously, or brought the rate of self usage to the doctor's attention," notes **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, CHt, director of risk management services at Miami Jewish Home and Hospital for the Aged, also in Miami.

"Controlled substances require the signatures of two licensed registered nurses; failure to do so at the time of the change out of the morphine is troubling. It could have been a simple failure to sign, or something else. In this case, the two copies of the medical record — one with one signature and one with two — is a red flag, especially when considering the time frame within which the attorney obtained the first copy and the longer time frame when he got the second copy. While medical records can be amended after the fact, in this instance, the appearance of the second signature at a later date is certainly suspect. It is a nursing standard of practice that a nurse not give a drug with which they are not familiar, meaning that they know the indications, usual dosage, usual route, intended effect, untoward effect, contraindications, and complications. The nurse has a responsibility to question or verify the order with the ordering physician if the order or dose is unusual. The pharmacist is the fail-safe step in the process in those instances of an unusual dose, drug or route, or contraindication. Based on the facts in this scenario, one wonders if the nurse or the pharmacist questioned the continuous morphine drip," observes Kicklighter.

"While medical records can be amended after the fact, in this instance, the appearance of the second signature at a later date is certainly suspect."

"The post-op orders were for the patient's heart rate [vital signs] be monitored every hour and the surgeon be called if the rate exceeded 120/minute. Even a nurses' aide can take blood pressures, check a pulse, and count a heartbeat. For this not to be done for more than two hours is of concern as is the further failure to contact the surgeon when the rate was found to be elevated over the designated threshold. Even with an order to check the patient's heart rate every hour, it was 1½ hours between the 9 p.m. and 10:30 p.m. check when the patient was found unresponsive, and yet another 24 minutes before a code was called. Failure to carry out a doctor's order is a deviation from accepted standards," adds Kicklighter.

"The risk manager in this situation might investigate the communication system and practices when transferring a patient from the PACU to a unit if the unit is understaffed or does not have the proper staff to carry out post-op monitoring orders and procedures. In this scenario, if that were the situation on the unit, maybe the patient should have remained longer in the PACU? In addition, since a CNA is capable of taking a patient's vital signs, the risk manager might investigate why that was not done in this situation and if it is a common occurrence on this unit," concludes Kicklighter.

Reference

• *Phyllis Furman as successor in interest to the estate of Arthur Furman, deceased, Carrie Furman, David Furman, and Stephen Furman v. San Pedro Peninsula Hospital,* Los Angeles County (CA), Superior Court, Case No. NC-025 673. ■