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FEBRUARY 2003

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Liability protection given for smallpox vaccinations, but many worries remain

Lawsuits seem unlikely, but some still left uneasy about plan

Questions still remain about the plan to vaccinate some health care workers against smallpox as health care leaders debate the safety of the vaccine, how it will worsen the shortage of personnel, and its potential liability concerns. Some of these questions may remain unanswered for weeks or months after the vaccinations.

For risk managers, a prime concern is the potential for lawsuits from health care workers adversely affected by the vaccine. Risk management leaders are monitoring the liability issues and many say there is little to worry about. Smallpox vaccinations can be handled pretty much like any other vaccinations for health care workers, says **Michael Seitz**, vice president for risk management with Fairview Healthcare Services in Minneapolis and a board member of the American Society for Healthcare Risk Management. Vaccinations are common in health care settings, and Seitz says the same policies and precautions should apply.

Gina Pugliese, RN, MS, vice president of the Premier Safety Institute in Chicago and a risk manager, agrees that there is no reason to fear the smallpox vaccination plan as an unusual liability risk. Nevertheless, the vaccination plan will be a major endeavor for any hospital, and she says the risk manager should participate in any multidisciplinary committee that makes

Smallpox vaccination handbook available now

Call today for your copy of *Hospital Handbook on Smallpox Vaccination*, a facilitywide resource containing all the information you need about smallpox vaccination in most health care facilities and environments. Learn about possible side effects and adverse reactions and how to protect your staff, patients, and family members against this most controversial vaccine. Read about the challenges of implementing a smallpox care team plus critical

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key decisions about the vaccinations.

Though both risk managers are confident that smallpox vaccinations should not pose an unusual liability risk to health care providers, they also allow that some questions can't be fully answered until the vaccinations have taken place and complications appear.

"We'll have to see if the plaintiff's bar finds a way to pursue some of these issues," Seitz says. "We've been surprised before by the creativity of some attorneys."

Federal protections cover most scenarios

The protection offered by recent federal legislation seems to rule out most lawsuits aimed at health care providers who administer the smallpox vaccine. Without stringent federal protection, the American Medical Association (AMA) considers lawsuits a real possibility and wanted federally backed liability protections in place before initiation of any smallpox vaccine program. The AMA's House of Delegates voted to request initiation of the liability program before starting vaccinations, pushing for an earlier implementation of a provision of the Homeland Security Act. That act was approved by Congress and signed by President Bush in November. It included liability protections but the coverage wasn't slated to take effect until Jan. 24.

In the Homeland Security Act, Congress shielded health care providers and vaccine manufacturers from liability for injuries suffered as a result of the smallpox vaccination by stating that anyone giving or producing the vaccine will be "deemed to be an employee of the Public Health Service." That makes the government the only defendant who can be sued for injuries. The plaintiff would have to sue for compensation under the Federal Tort Claims Act. Under that act, federal employees — a definition that includes anyone administering the vaccine — must observe federal laws and regulations but they generally have no liability for policy decisions, or actions performed in "an exercise of official discretion."

Experts say those limitations would make any vaccine lawsuit a tough case to win. And even a successful case would have plaintiffs digging into the pockets of Uncle Sam, not the hospital or other health care provider who administered the vaccine. The likelihood of a successful smallpox lawsuit is slim, even worse than a plaintiff suing for injuries from a childhood vaccine, experts say. Congress created a no-fault system in 1986 to compensate people for injuries from childhood vaccines, but the hurdles are much smaller than one would face with the current smallpox vaccinations. For injuries from the childhood vaccines, the government reviews and pays claims using a special tax imposed on the vaccines. Plaintiffs only need to show that the vaccine injured them; it is not necessary to prove negligence.

The protection in the Homeland Security Act applies to vaccine manufacturers as well as to physicians and other providers who administer the vaccinations, but the AMA also is calling for protection for those injured from the vaccine. The AMA statement says, "A simple and fair compensation system — like the federal Vaccine Injury Compensation Fund — should be made available

Healthcare Risk Management® (ISSN 1081-6534), including **HRM Legal Review & Commentary**™, is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Healthcare Risk Management**®, P.O. Box 740059, Atlanta, GA 30374.

Healthcare Risk Management is approved for approximately 18 nursing contact hours. This offering is sponsored by American Health Consultants, which is accredited as a provider of continuing education in nursing by the American Nurses' Credentialing Center's Commission on Accreditation. Provider approved by the California Board of Registered Nursing, Provider Number CEP 10864, for approximately 18 contact hours.

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Subscription rates: U.S.A., one year (12 issues), $499. Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $399 per year; 10 to 20 additional copies, $299 per year; for more than 20, call (800) 688-2421. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. **Back issues**, when available, are $83 each. (GST registration number R128870672.)

Editor: **Greg Freeman**, (770) 998-8455.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Lee Landenberger**, (404) 262-5483, (lee.landenberger@ahcpub.com).
Production Editor: **Nancy McCreary**.

Editorial Questions

For questions or comments, call **Greg Freeman**, (770) 998-8455.

to assist anyone who is injured from receiving the vaccine or coming into contact with someone who received it."

Jerome Hauer, assistant secretary at the Health and Human Services Department and an expert on emergency preparedness, addressed the issue at a recent news conference and said the government is considering providing such protection.

"We looked at the liability issue," he said. "It is clearly a key component of this program. I hope to get that resolved in the very near future."

Furloughs not necessary, CDC suggests

Concerns over the risk to health care workers has created resistance among some groups to the vaccination plan, including a harsh response from the 1.5 million-member Service Employees International Union (SEIU), the nation's largest health care workers' union.

"President Bush's smallpox plan puts hospital workers and their patients at unnecessary risk," says **Andrew L. Stern**, SEIU president. Stern says the vaccine is risky for one in six Americans who are pregnant, suffer from eczema or other skin disorders, or whose immune systems are suppressed because of conditions such as HIV, cancer, or transplant treatments. "However, Bush's plan fails to provide free, confidential screening for those conditions before workers or the public are given the vaccine. It also does not do enough to safeguard vulnerable patients who could come into contact with the 500,000 hospital workers being asked to volunteer for the vaccine."

Diane Sosne, RN, national co-chair of the SEIU nurse alliance, says, "Health care workers want to be able to care for patients if a smallpox outbreak occurs, but it is wrong to put caregivers, their patients, and their families at risk when there is a safer way."

After health workers receive the vaccine, the Bush plan calls for millions of firefighters, police, and other "first responders" to be vaccinated. In about a year, the vaccine will be offered to the public. SEIU has asked the president to monitor the initial volunteers who receive the vaccine, track their response, and make that information available so the public can make an informed decision about whether it wants to receive the vaccine.

Concerns over the risk to health care workers have prompted some hospitals to opt out of the smallpox vaccination plan. Grady Memorial in Atlanta and Virginia Commonwealth University in Richmond both say the vaccine risks outweigh the need to protect health care workers. **Carlos del Rio**, MD, chief of medical services at Grady Memorial and a professor of infectious disease, says hospital leaders decided not to participate in the smallpox vaccination plan because the vaccine carries too much risk for individual health care workers. At Virginia Commonwealth, **Hermes A. Kontos**, MD, chief executive of the University's health system, cites similar reasoning. The threat of a terrorist attack using smallpox is not great enough to justify the complications of the vaccine, he says.

Participation is not mandatory and the scale of the vaccinations will vary for each health care provider. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommended smallpox immunization for 510,000 health care workers, saying each hospital should designate a smallpox care team that will be immunized first. That team should include about 40 health care workers per hospital, including the epidemiologist, infection control staff, 15 emergency department (ED) physicians and nurses, eight intensive care unit (ICU) nurses for adult patients, eight pediatric ICU nurses, one infectious disease consultant, one dermatology consultant, four respiratory therapists, four radiology technicians, two engineers, and selected staff from the security and housekeeping departments.

That core team should be able to respond to the

first cases of a smallpox outbreak without exposing health care workers unnecessarily, says **Jane Siegel**, MD, who advised ACIP on the issue as a member of the CDC's Healthcare Infection Control Practices Advisory Committee. Individual hospitals are free to decide the exact makeup of the team.

At the same time the liability question was being debated, hospitals still were waiting for a CDC decision on medical furlough for vaccinated workers. Some smallpox experts have suggested that workers be furloughed to prevent them from spreading vaccinia, the virus used in smallpox shots. The CDC estimates that 30% of those who are vaccinated will feel too sick to work and provide proper patient care for one or more days. Ten percent might have a more serious reaction.

The CDC downplays the risk of transmission, suggesting that furloughs are not necessary. In a press briefing at the CDC, **John Modlin**, MD, chair of the ACIP, said workers could continue to care for patients after receiving the vaccine. It is sufficient to cover the vaccination site with absorbent material such as gauze and at least a single layer of impermeable acoustic dressing until the scab separates, he says. His committee recommends against placing health care workers on leave after receiving smallpox vaccination unless they develop symptoms from the vaccination or do not adhere to infection control precautions.

Modlin explained that "the very close contact required for transmission of vaccinia to household contacts is unlikely to occur in the health care setting." ■

New rules: You have mail, and trouble is enclosed

Recently released guidelines on how to safely use e-mail to communicate with patients will become the standard of care in short order, says one expert. That means health providers must comply with the recommendations quickly or risk increased liability.

The guidelines were released by the eRisk Working Group on Healthcare, a consortium of professional liability carriers, medical societies, and state board representatives that represents more than 70% of insured physicians. The new guidelines set groundbreaking standards, including a mandate that substantive patient-physician e-mail occur solely within the context of a pre-existing relationship. State boards have taken action recently against so-called "on-line doc-in-a-box" services in which physicians provide on-line care and prescribe medication for patients whom they have never seen, says **Mark Gorney**, MD, medical director of The Doctors Company in Napa, CA, the largest doctor-owned medical malpractice carrier in the country, and an eRisk participant.

Patient-physician e-mail is growing rapidly, according to a 2002 Harris Poll analysis, which noted that more than 70% of patients want e-mail access to their physician's office. Many say they are willing to change physicians to get the service and nearly 40% are willing to pay for the convenience. Physicians have indicated that liability, security, and payment concerns are the biggest roadblocks to offering e-mail service.

Gorney says e-mail risks have been discussed for years as the popularity of on-line communications grew, but the guidelines should create a sense of urgency for risk managers.

"Any guidelines, like it or not and though we usually deny it hotly, are interpreted legally as the standard of care," he says. "They're not intended nor designed to be the standard of care, but invariably they seem to become so."

If you ignore the guidelines, the risk for health care providers comes on two fronts, Gorney says. The guidelines will be cited as the standard of care in court and insurers will use them as a yardstick for measuring how well you met their expectations.

"Certainly at the next trial involving on-line communication they become the standard of care when the plaintiff's attorney waves them around in front of a jury," he says. "And if something happens because they did not follow the guidelines, or simply ignored them, their reinsurability is going to be in question after that claim is settled. We'll look at the situation very carefully and if someone has done something in violation of the guidelines, that is someone we will look at very carefully at renewal time."

Many risks looming as use of e-mail increases

Health care has lagged behind most other industries in using e-mail, mostly because of confidentiality issues and other risks, but Gorney says e-mail is becoming increasingly common. Patients, in fact, are demanding that they be able to communicate with their physicians because they know how easy and convenient it is. There's no need to resist those demands, he says, but some limitations

and precautions are necessary.

Misdiagnosis via e-mail is a significant risk, Gorney says. The convenience of e-mail makes it tempting to respond quickly without enough information to make an accurate diagnosis, he says. As has always been the case, it is usually not a good idea to diagnose a patient without seeing him or her and conducting at least a cursory examination. The ease of responding by e-mail doesn't change that, he says.

"If mom sends you an e-mail saying her child is sick and has fever, it might be tempting to send an e-mail saying, 'Give him two aspirin and call me in the morning,'" he says. "Well, if it turns out that kid had meningitis, that doctor has a major problem."

There are more questions involving doctor-to-doctor on-line communication and interstate licensing issues, but Gorney says he expects most liability issues to arise from e-mail communication with patients. So far, while plaintiff's attorneys have not considered e-mail communications a source of big money, that could change very quickly, he says.

"For the near future, this may be only a theoretical problem," Gorney says. "We'll have to wait until some sharp, aggressive attorney discovers this new minefield and takes advantage of it. No really major cases have happened yet, but it will occur, I guarantee you."

12 issues to consider with e-mail

The eRisk group's Guidelines for On-line Communications state that "the legal rules, ethical guidelines, and professional etiquette that govern and guide traditional communications between the health care provider and patient are equally applicable to e-mail, web sites, listservs, and other electronic communications." On-line communications introduce special concerns and risks, however, necessitating the new guidelines.

These are the 12 points of concern, along with the resulting advice, outlined by the eRisk group:

- **Security.** On-line communications between health care provider and patient should be conducted over a secure network, with provisions for authentication and encryption in accordance with eRisk, Health Insurance Portability and Accountability Act, and other appropriate guidelines. Standard e-mail services do not meet these guidelines. Health care providers need to be aware of potential security risks, including unauthorized physical access and security of computer hardware, and guard against them with technologies such as automatic logout and password protection.
- **Authentication.** The health care provider has a responsibility to take reasonable steps to authenticate the identity of correspondent(s) in an electronic communication and to ensure that recipients of information are authorized to receive it.
- **Confidentiality.** The health care provider is responsible for taking reasonable steps to protect patient privacy and to guard against unauthorized use of patient information.
- **Unauthorized Access.** The use of on-line communications may increase the risk of unauthorized distribution of patient information and create a clear record of this distribution. Health care providers should establish and follow procedures that help to mitigate this risk.
- **Informed Consent.** Prior to the initiation of on-line communication between health care provider and patient, informed consent should be obtained from the patient regarding the appropriate use and limitations of this form of communication. Providers should consider developing and publishing specific guidelines for on-line communications with patients, such as avoiding emergency use, heightened consideration of use for highly sensitive medical topics, appropriate expectations for response times, etc. These guidelines should become part of the legal documentation and medical record when appropriate. Providers should consider developing patient selection criteria to identify those patients suitable for e-mail correspondence, thus eliminating persons who would not be compliant.
- **Highly Sensitive Subject Matter.** The health care provider should advise patients of potential privacy risks associated with on-line communication related to highly sensitive medical subjects. This warning should be repeated if a provider solicits information of a highly sensitive nature, such as issues of mental health, substance abuse, etc. Providers should avoid active initial solicitation of highly sensitive topic matters.
- **Emergency Subject Matter.** The health care provider should advise patients of the risks associated with on-line communication related to emergency medical subjects such as chest pain, shortness of breath, bleeding during pregnancy, etc. Providers should avoid active promotion of the use of on-line communication to address topics of medical emergencies.
- **Doctor-Patient Relationship.** The health care provider may increase liability exposure by initiating a doctor-patient relationship solely through on-line interaction. Payment for on-line

services may further increase that exposure.

• **Medical Records.** Whenever possible and appropriate, a record of on-line communications, pertinent to the ongoing medical care of the patient, must be maintained as part of, and integrated into, the patient's medical record, whether that record is paper or electronic.

• **Licensing Jurisdiction.** On-line interactions between a health care provider and a patient are subject to requirements of state licensure. Communications on-line with a patient outside of the state in which the provider holds a license may subject the provider to increased risk.

• **Authoritative Information.** Health care providers are responsible for the information that they provide or make available to their patients on-line. Information that is provided on a medical practice web site should come either directly from the health care provider or from a recognized and credible source. Information provided to specific patients via secure e-mail from a health care provider, should come either directly from the health care provider or from a recognized and credible source after review by the provider.

• **Commercial Information.** Web sites and on-line communications of an advertising, promotional, or marketing nature may subject providers to increased liability, including implicit guarantees or implied warranty. Misleading or deceptive claims increase this liability.

The eRisk guidelines and other advice can be found on-line at www.medem.com. ■

Fee-based consultations carry special concerns

Fee-based on-line consultations come with additional risks, according to the eRisk Working Group on Healthcare, a consortium of professional liability carriers, medical societies and state board representatives. These are defined as clinical consultations provided by a medical provider to a patient using the Internet or other similar electronic communications network in which the provider expects payment for the service. An on-line consultation that is given in exchange for payment introduces additional risks. The eRisk guidelines emphasize that in a fee-based on-line consultation, the health care provider has the same obligations for patient care and follow-up as in face-to-face, written and telephone consultations. For example, an on-line consultation should include an explicit follow-up plan that is clearly communicated to the patient.

In addition to the 12 guidelines for e-mail, eRisk outlines the following additional considerations for fee-based on-line consultations:

• **Pre-Existing Relationship.** On-line consultations should occur only within the context of a previously established doctor-patient relationship that includes a face-to-face encounter when clinically appropriate. State medical boards have begun enforcement actions.

• **Informed Consent.** Prior to the on-line consultation, the health care provider must obtain the patient's informed consent to participate in the consultation for a fee. The consent should include explicitly stated disclaimers and service terms pertaining to on-line consultations. The consent should establish appropriate expectations between provider and patient.

• **Medical Records.** Records pertinent to the on-line consultation must be maintained as part of, and integrated into, the patient's medical record.

• **Fee Disclosure.** From the outset of the on-line consultation, the patient must be clearly informed about charges that will be incurred and that the charges may not be reimbursed by the patient's health insurance. If the patient chooses not to participate in the fee-based consultation, the patient should be encouraged to contact the provider's office by phone or other means.

• **Appropriate Charges.** An on-line consultation should be substantive and clinical in nature and be specific to the patient's personal health status. There should be no charge for on-line administrative or routine communications such as appointment scheduling and prescription refill requests. Health care providers should consider not charging for follow-up questions on the same subject as the original on-line consultation.

• **Identity Disclosure.** Clinical information that is provided to the patient during the course of an on-line consultation should come from, or be reviewed in detail by, the consulting provider whose identity should be made clear to the patient.

• **Available Information.** Health care providers should state, within the context of the consultation, that it is based only upon information made available by the patient to the provider during, or prior to, the on-line consultation, including referral to the patient's chart when appropriate, and therefore may not be an adequate substitute for an office visit.

• **On-line Consultation vs. On-line Diagnosis**

and Treatment. Health care providers should attempt to distinguish between on-line consultation related to pre-existing conditions, ongoing treatment, follow-up question related to previously discussed conditions, etc., and new diagnosis and treatment addressed solely on-line. New diagnosis and treatment of conditions, solely on-line, may increase liability exposure. ■

Try to avoid sensitive material in your e-mail

The SCPIE Companies, an insurer in Los Angeles, recently offered its own advice on reducing the risk of e-mail communication in health care. In addition to endorsing the eRisk guidelines, SCPIE says health care providers must be careful about when they choose to use e-mail. The insurer says appropriate uses for e-mail include scheduling appointments, releasing records such as test results, providing follow-up instructions, explaining general medical information, answering billing questions, sending account reminders, and refilling prescriptions.

However, SCPIE cautions that requests for new prescriptions should not be handled through e-mail. Despite the convenience of e-mail, the patient should be examined in person to assess the medical necessity of any new prescription. Physicians also may consider prohibiting e-mail discussion of HIV test results, mental illness, alcohol or drug addiction, and workers' compensation claims as well. SCPIE recommends that, at the very least, patients should be required to type "SENSITIVE" in the subject line of all e-mail pertaining to these issues. The insurer also advises physicians not to use e-mail for answering clinical questions regarding a condition for which the patient has not been seen in the past six months.

When a physician and patient want to use e-mail, the physician should "discuss the process with the patient and ask him or her to read and sign an on-line communications informed consent form. This form may cover a variety of issues, including instructions for using on-line communications, good communication etiquette, charges for using on-line communications, conditions of using on-line communications, access to on-line communications, risks of using on-line communications and, finally, the patient's signature of acknowledgment and agreement. This information should become part of the legal documentation and medical record," it adds.

SCPIE also suggests that health care providers provide patients with a wallet-sized summary of the contract's highlights. It could be a special laminated card, a sticker affixed to the doctor's business card, or the information could be incorporated into the design of the business card. This is what the insurer recommends you put on the card:

- E-mail is not for emergencies! E-mail is not appropriate for urgent or emergency situations.
- Be concise. Come in for an appointment if the issue is too complex or sensitive to discuss via e-mail.
- Key in the topic (e.g., medical question, prescription renewal, appointment request) in the subject line.
- All e-mail will be filed in your record.
- Office staff may receive and read your messages.

SCPIE's e-mail advice can be found on-line at www.scpie.com. The American Medical Association (AMA) also has published guidelines for using e-mail. They can be found at www.ama-assn.org/ama/pub/category/2386.html. These are some points found in the AMA guidelines:

- As part of the informed consent process for establishing e-mail usage, tell patients who besides you processes messages during usual business hours, and who processes them when you are out sick or on vacation.
- Maintain a patient e-mail mailing list, but do not send group e-mails in which recipients' names and/or e-mail addresses are visible.
- As with phone consultations, if the issue is too complex to discuss via e-mail, ask the patient to schedule an office visit.
- Set up an automatic reply to acknowledge receipt of patients' e-mail messages.
- When you answer patients' e-mail, ask them to acknowledge receiving and reading it.
- At the end of all e-mail messages, insert your "electronic signature"— a preformatted standard block of text that contains your full name and contact information, as well as reminders about security and the importance of alternative forms of communication for emergencies. SCPIE offers this example of an appropriate electronic signature:

John Smith, MD
Dermatology
10 Main St.
Los Angeles, CA 90067
Phone: (310) 555-1212
Fax: (310) 555-4321

E-mail: jsmithmd@doctor.com
- Call the office if the matter is urgent.
- Call 911 in an emergency or go to the ER!
- Please follow security guidelines. ■

Spot the risky surgeon and predict who might get sued

Certain characteristics may help you spot which surgeons are most likely to have malpractice suits filed against them, allowing you to focus your risk management education on those most in need of help, according to a physician who has studied the phenomenon.

Research has shown that surgeons sued for malpractice often share many traits that have little to do with their clinical skills, says **DeWitt C. Baldwin Jr.**, MD, former scholar in residence at the American Medical Association and now scholar in residence at the Accreditation Council for Graduate Medical Education. Baldwin and colleagues researched the common traits of those sued and presented some resulting advice recently at the annual meeting of the American Society of Healthcare Risk Managers. Not all of the common traits relate to easily measured factors such as years of training or where a doctor when to school, he says.

"If I were an insurer or a risk manager, I'd be interested in looking at my surgeons with these characteristics and see which ones are going to be a better risk," he says. "That's just good business."

Baldwin's research has involved malpractice claims for years. In a 1997 study that Baldwin says still offers valid advice, he found that the likelihood of malpractice claims was affected by whether the physician was a solo practitioner, had a registered nurse working in his or her office, was a member of a clinical faculty, or was a member of professional societies. (*WJM* 1997; 166:276-283.)

The study looked at 427 surgeons, all members of a physician-owned malpractice trust. The 427 surgeons represented all those in the trust who had fewer than 0.13 malpractice claims per year and those with more than 0.54 claims per year, the best and worst in terms of malpractice claim frequency. They studied the relationship between the number of malpractice claims and the surgeons' personal, educational, and practice characteristics, and found that the differences between the best and worst in malpractice claims frequency yielded useful lessons.

Terminated surgeons were less likely to have completed a fellowship, belong to a clinical faculty, be members of professional societies, be graduates of an American or Canadian medical school, have specialty board certification, or be in a group practice. The data also suggest that orthopedists with high numbers of claims may be less likely to have a religious affiliation or to have a registered nurse working in their office practice. The findings suggest that "surgeons with lower claim rates may be more likely to manifest exemplary modes of professional peer relationships and responsible clinical behavior," the researchers say.

Although not statistically significant, there was a trend suggesting that orthopedic surgeons with no or low claim rates more often reported church membership than those with multiple claims. Marital status had no relationship to claims status. More of the surgeons who had been terminated for malpractice claims had attended a medical school outside the United States or Canada, compared to those with fewer claims. There also was a trend suggesting that terminated surgeons were less likely to have completed a fellowship. All surgeons, and especially those in OB/GYN, were less likely to be board-certified than their colleagues with fewer or no claims.

Some factors related to academics had no relationship to malpractice claims. There were no significant relationships with undergraduate college major, medical school prestige, membership in the Alpha Omega Alpha society, or years of specialty training.

While much of his research has involved surgeons, Baldwin says he thinks the findings could be applied to any type of physician. The information can be put to practical use, Baldwin says.

"If I use these characteristics, the person I'm trying to identify is the loner, the guy who hires less professional help because they won't question him," he says. "The physicians who are on faculty and members of professional societies are constantly learning from others, constantly getting feedback. They tend to be more responsive and responsible."

Baldwin says his research also has suggested that orthopedic surgeons who spend more time on the initial visit with a patient are less likely to be sued.

Those physicians who score well on tests of moral reasoning also are less likely to be sued, but Baldwin found that a superior medical education does not necessarily improve a doctor's moral reasoning.

"Medical education, in fact, tends to inhibit moral reasoning," he says. "It tends to train people to think in terms of right and wrong rather than thinking out issues. You want someone who is aware that there sometimes are degrees of right and wrong, and that you have to consider each case on its own."

While physicians may come out of medical school without that kind of moral reasoning, Baldwin says risk managers can change that with about 20 hours of case-based, small group discussions of morally problematic issues. He suggests that risk managers could use these measures to screen physicians when they are first hired or granted privileges.

"If I saw someone with a low score on these tests, you might go to that physician and say, 'You need training in communication and conflict resolution,'" he says. "You could use these measures to determine where to focus your resources, who is most in need of your attention. Above all else, watch out for the loner rather than the physician in a group." ■

Medication bar codes can work but problems persist

Researchers have found that a new computer system that uses bar codes to safeguard patients' medications can work successfully, but not without creating new, serious problems for nurses charged with patient care.

Emily Patterson, a research specialist in The Ohio State University's Institute for Ergonomics in Columbus, says the Veterans Health Administration (VA) recently designed a drug dispensing system called Bar Code Medication Administration (BCMA) and asked her to evaluate it.

"In general, we viewed the system as successful," she says. "There are no magic-bullet solutions to human error in any setting, and even the best systems will require constant maintenance and flexible redesign after implementation."

At issue is whether bar codes could enable health care professionals to verify that a patient is receiving the right drug, at the right dose, at the right time. Patterson conducted the research with the VA Midwest Patient Safety Center of Inquiry in Cincinnati, along with Marta Render, director of the center and adjunct associate professor of internal medicine at the University of Cincinnati, and Richard Cook, director of the Cognitive Technologies Laboratory at the University of Chicago. The Department of Veterans Affairs funded the study.

With BCMA, hospital pharmacies label medications with bar codes, and patients wear barcoded wristbands. Nurses scan a patient's wristband, and a laptop computer on the medication cart displays that patient's prescriptions. Before giving the medicine, the nurse scans the medicine bottle or other container, and BCMA records the drug as delivered. If the nurse accidentally scans the wrong medicine or dosage, or tries to give medicine at the wrong time, a warning pops up on the computer screen.

Patterson followed the activities of 26 nurses at three VA hospitals as they dispensed medication with BCMA. She also watched as doctors entered new prescriptions into the electronic medical record and pharmacists labeled prescriptions. Then she interviewed these people as well as hospital computer support personnel and nurse managers to gauge everyone's opinion of the system.

The study did not specifically examine errors caught or prevented by BCMA, but focused instead on the interaction of users with the system in order to find ways to make the system work better.

Nearly all VA hospitals are now using BCMA software version 2.0, and Patterson and her colleagues are helping create version 3.0, which will address some of the problems found during the study. After that, Patterson and her colleagues will continue to help the system evolve over time.

Patterson cites a 1999 study at Brigham and Women's Hospital in Boston and Harvard Medical School that found medication errors fell 86% when doctors began entering their prescription orders via computer. When computer systems are optimized for taking human factors into account, errors can decrease even further, she says.

The new Ohio State study found these five unanticipated negative side effects of introducing BCMA to hospitals:

- Sometimes the computer automatically removed medications from a patient's prescription list. For example, one patient could not receive his dose of a drug on time because he had been away in another part of the hospital when he was supposed to receive it. When the patient returned to the ward and the nurse administered his medications, BCMA no longer displayed the medication because it was dropped when a time window had elapsed. In most cases, the nurses

Smallpox handbook

(Continued from cover)

staffing and screening issues that will affect your entire facility as well as crucial questions about liability and other legal concerns.

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knew to administer the medication and asked a pharmacist to add it back to the prescription list.

• There was less coordination between doctors and nurses, compared to a paper-based system. Doctors reviewed patient's medication orders less often because doing so through the BCMA computer was more difficult or time consuming than the old procedure, which involved simply reading the nurses' notes on a paper medical chart. That means doctors and nurses were less likely to know if a patient's medication needed to be changed.

• During the busiest parts of the day, nurses had to ignore some of the required BCMA procedures to save time. For instance, bar codes didn't always scan properly on the first try. To avoid rescanning a patient during crunch periods, nurses would often enter the seven-digit bar code number manually.

• Nurses became anxious about delivering medications on time. The computer required the nurses to type an explanation when medications were given even a few minutes early or late, and nurses were concerned that the late administrations would reflect badly on their job performance. As a result, nurses tended to make just-on-time administration of medicines a high priority, compared to other duties.

• The computer didn't easily accept unusual dosage orders. While the system streamlined the administration of consistent dosages of drugs, it wasn't set up to accept dosages that increased or decreased over time. For example, pharmacists had to enter 14 separate daily doses for a patient whose medicine was supposed to taper off over a two-week period. ■

Single-use devices have their fair share of doubters

The Center for Patient Advocacy recently released a survey of surgeons, operating room nurses, and consumers, which suggests that health care professionals have serious concerns about the reuse of single-use medical devices and their impact on patient health and safety.

The majority of doctors and nurses oppose the use of reprocessed single-use medical devices, according to the survey. The survey also shows that most consumers are unaware of the practice of reprocessing, says **Neil Kahanovitz**, MD, president and founder of the Center for Patient Advocacy. According to the results of the survey, three out of every four surgeons believe that reprocessed single-use only medical devices pose a health and safety risk to patients, including the potential spread of hepatitis and HIV. In addition, the survey found that 74% of surgeons felt that single-use only medical devices should not be reprocessed and 79% of nurses believe that the use of reprocessed single-use devices should be discontinued.

"Clearly, this is a safety issue for patients," Kahanovitz says. "The fact that surgeons and nurses are overwhelmingly concerned that the reuse of single-use devices poses a threat to product quality as well as risk of infection and the spread of disease should raise red flags."

Eighty-two percent of nurses and 71% of

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surgeons surveyed say they would be uncomfortable if a reprocessed single-use device were used on themselves or a family member.

"How can we expect patients to feel safe with these reused devices if surgeons and nurses clearly would not want the devices used on them?" asks Kahanovitz.

Sixty-five percent of consumers are unaware that these surgical devices may have previously been used, often multiple times, in other patients. A recent FDA survey indicates that approximately 25% of U.S. hospitals use reprocessed single-use-only devices.

"It is unacceptable that hospitals and other medical institutions do not routinely inform patients that these devices will be used in their surgery," Kahanovitz says. "It seems to me that they should have a moral obligation to inform patients about this practice and provide them with an opportunity to accept or reject the use of these devices in their surgery."

By a 2-to-1 ratio, patients surveyed said they would expect to be informed about the practice before surgery. And of those aware of this practice, nearly 70% were unaware they had the right to request that such devices not be used in their surgery. The Center for Patient Advocacy has created a consent form for patients to complete before undergoing surgery to reject the use of reprocessed single-use devices in their treatment. The form is available at the center's web site, www.patientadvocacy.org. ■

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. ■

United States Postal Service

Statement of Ownership, Management, and Circulation

1. Publication Title	2. Publication No.	3. Filing Date
Healthcare Risk Management	1 0 8 1 - 6 5 3 4	10/09/02
4. Issue Frequency	5. Number of Issues Published Annually	6. Annual Subscription Price
Monthly	12	$499.00

7. Complete Mailing Address of Known Office of Publication *(Not Printer) (Street, city, county, state, and ZIP+4)*
3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, Fulton County, GA 30305

Contact Person: Willie Redmond
Telephone: 404/262-5448

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not Printer)*
3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do Not Leave Blank)*

Publisher *(Name and Complete Mailing Address)*
Brenda Mooney, 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

Editor *(Name and Complete Mailing Address)*
Greg Freeman, same as above

Managing Editor *(Name and Complete Mailing Address)*
Lee Landenberger, same as above

10. Owner *(Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual. If the publication is published by a nonprofit organization, give its name and address.)*

Full Name	Complete Mailing Address
American Health Consultants	3525 Piedmont Road, Bldg. 6, Ste 400 Atlanta, GA 30305

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box → ☐ None

Full Name	Complete Mailing Address
Medical Economics Data, Inc.	Five Paragon Drive Montvale, NJ 07645

12. Tax Status *(For completion by nonprofit organizations authorized to mail at nonprofit rates.) (Check one)*
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☐ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months *(Publisher must submit explanation of change with this statement)*

PS Form **3526**, September 1998 *See instructions on Reverse)*

13. Publication Name: Healthcare Risk Management
14. Issue Date for Circulation Data Below: October 2002

15. Extent and Nature of Circulation			Average No. of Copies Each Issue During Preceding 12 Months	Actual No. Copies of Single Issue Published Nearest to Filing Date
a. Total No. Copies *(Net Press Run)*			1719	1863
b. Paid and/or Requested Circulation	(1)	Paid/Requested Outside-County Mail Subscriptions Stated on Form 3541. *(Include advertiser's proof and exchange copies)*	1384	1400
	(2)	Paid In-County Subscriptions *(Include advertiser's proof and exchange copies)*	9	7
	(3)	Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Non-USPS Paid Distribution	27	81
	(4)	Other Classes Mailed Through the USPS	0	0
c. Total Paid and/or Requested Circulation *(Sum of 15b(1) and 15b(2)*			1420	1488
d. Free Distribution by Mail *(Samples, Complimentary and Other Free)*	(1)	Outside-County as Stated on Form 3541	17	20
	(2)	In-County as Stated on Form 3541	0	1
	(3)	Other Classes Mailed Through the USPS	0	0
e. Free Distribution Outside the Mail *(Carriers or Other Means)*			0	21
f. Total Free Distribution *(Sum of 15d and 15e)*			17	0
g. Total Distribution *(Sum of 15c and 15f)*			1437	1509
h. Copies Not Distributed			282	354
i. Total *(Sum of 15g, and h.*			1719	1863
Percent Paid and/or Requested Circulation *(15c divided by 15g times 100)*			99	99

16. Publication of Statement of Ownership
Publication required. Will be printed in the February issue of this publication. ☐ Publication not required.

17. Signature and Title of Editor, Publisher, Business Manager, or Owner: Publisher — Date: 10/09/02

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CE instructions

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

CE Questions

Please review the text, answer the following questions, check your answers against the key below, and then review the materials again regarding any questions answered incorrectly. To receive credit for this activity, you must return the enclosed CE evaluation in the enclosed envelope at the end of each semester. For further information, refer to the "CE Instructions."

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5. The CDC's Advisory Committee on Immunization Practices recommended smallpox immunization for 510,000 health care workers, saying each hospital should designate ____ "smallpox care team" members who will be immunized first.
A. 10 B. 20 C. 30 D. 40 E. 50

6. Choose the statement that accurately reflects the fee-based consultation e-mail guidelines released by the eRisk Working Group on Healthcare:
A. On-line consultations should occur only within the context of a previously established doctor-patient relationship that includes a face-to-face encounter when clinically appropriate.
B. On-line consultations can occur without a previous relationship or a face-to-face encounter.
C. On-line consultations require a previously established doctor-patient relationship or face-to-face encounter only for life-threatening conditions.
D. On-line consultations require a previously established doctor-patient relationship or face-to-face encounter only for prescriptions.
E. On-line consultations should be completely prohibited.

8. According to research by DeWitt C. Baldwin Jr., MD, determine the accurate statement regarding the likelihood of a surgeon be sued for malpractice.
A. Those in group practices were less likely to be sued.
B. Those in group practices were more likely to be sued.
C. Being in a group practice or a solo practitioner had no bearing on the likelihood of being sued.
D. Those who majored in academically challenging subjects were less likely to be sued.
E. Those who were members of Alpha Omega Alpha were less likely to be sued.

8. According to research by Emily Patterson, which statement is true?
A. Medication bar codes eliminate errors with patient medications and have no significant drawbacks.
B. Medication bar codes do not have any effect on errors with patient medications.
C. Medication bar codes may decrease errors somewhat but the expense is too high to justify the improvement.
D. Medication bar codes can decrease errors in administering patient medications, but not without creating new, serious problems for nurses charged with patient care.
E. Medication bar codes do not decrease errors in administering patient medications.

Answers: 5-D; 6-A; 7-A; 8-D.

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

Infant's undiagnosed tuberculosis leads to brain damage: $3 million settlement

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

News: After several visits to its family physician, an 11-month-old child was taken to a hospital emergency department (ED). The child was then transferred to a children's hospital, where a test for tuberculosis (TB) was positive. While the TB had gone undiagnosed and untreated, the child developed meningitis, which eventually led to brain damage. The children's hospital, its pediatrician, and the initial hospital settled for about $3 million. A favorable verdict for several of the treating physicians followed.

Background: On April 2, an 11-month-old infant was taken to his family's general practitioner with complaints of cough, cold, and diarrhea. After examining the child and finding nothing alarming, the parents were told to return if there was a change in the child's condition. Later that day they did return as the child had developed a fever in addition to the other symptoms.

Early that evening the child was admitted to a local community hospital with an admitting diagnosis of bronchitis and enteritis, which is inflammation of the intestine. During this hospital admission, a chest X-ray was performed that the plaintiff later alleged indicated hilar adenopathy, which could have suggested primary pulmonary tuberculosis. However, the family physician was not told of this finding and released the child from the hospital without having a TB test performed.

On April 7, the child was taken to his primary pediatrician because he still was complaining of the same symptoms. The pediatrician prescribed medications to treat the diarrhea. The next day the child began having seizures and his parents took him to a different community hospital ED, where he was diagnosed as having meningitis. After four days of hospitalization at the community hospital, the child was transferred to a children's hospital.

Shortly after being admitted to the children's hospital, a TB skin test was performed and found to be positive. Ten days had elapsed between his first seeking care and the TB diagnosis. For the next month, anti-TB medications were administered until the child developed liver toxicity to the medication. The toxicity was probably due to the viral etiology of the compounding meningitis. However, it was not until the child's third admission to the children's hospital that tuberculosis meningitis was diagnosed. The child eventually developed hydrocephalus, which required the insertion of a shunt.

He ultimately suffered severe neurological injury and cerebral palsy. The child now requires 24-hour medical care.

The plaintiff alleged that if the TB test had been administered during the first hospitalization, anti-TB medications could have been initiated much sooner and all the subsequent injuries could have been avoided. The plaintiff claimed that if the appropriate diagnosis of tuberculosis

meningitis had been made sooner at the children's hospital the child would not have sustained brain damage. In each instance, the plaintiff maintained that the physicians and hospitals violated the standard of care.

The defendants contended that the child did not have tuberculosis as the initial pathogen, that his meningitis was viral not bacterial, that the chest X-ray was not indicative of TB, that TB tests at the children's hospital were negative, and that all tests results at the children's hospital were consistent with viral meningoencephalitis.

The first community hospital settled for $150,000. The children's hospital and treating pediatrician settled for $2.87 million. Trial proceeded against the family practitioner and primary pediatrician, as well as the ED physician at the second hospital; all were found to be not at fault.

What this means to you: According to the World Health Organization (WHO), TB is a communicable disease affecting the respiratory system and is most commonly spread by coughing and sneezing. Each year, 2 million people worldwide die from this curable disease. Many cases in the United States are found in prisons and among those who are HIV-positive.

"This case is unusual in that it involves an illness that rarely occurs or is rarely seen today in most parts of the United States and it involves a diagnosis that is not often made. Although we have seen some reoccurrence of specific strains of TB in the last one to two years, not even that has been very frequent. Therefore, TB is not something that most physicians would readily think about or consider in today's world, especially in an 11-month-old baby. However, as this case indicates, physicians have to again give consideration to the possibility of TB, even in an infant, if a patient presents with symptoms that could be an indication of possible TB. TB has to go back onto the physician diagnostic radar screen for adults as well as children," says **Stephen Trosty**, JD, MHA, CPHRM, director, risk management consulting, APAssurance Corp. in East Lansing, MI.

Though TB has nearly been eliminated, "physicians have to be aware of the causes of TB and of factors that can increase the likelihood of its occurrence. In the case of children, practitioners have to know what questions to ask parents. The questions to determine high-risk category for TB include: 1) exposure to, or contact, with an adult case of TB; 2) living in a household in which a case of TB has occurred; 3) children of immigrants or refugees from high-incidence areas including Africa, Asia, Latin America, the Caribbean, and most of the Middle East; and 4) children who are living in areas with higher levels of TB, such as some inner-city populations, and some native communities. These questions can indicate potentially increased risk exposure for the infant/child," notes Trosty.

"If an infant or child has been in contact with an infected adult or falls into one of the four high-risk categories listed above, he/she should have a clinical assessment for TB and a tuberculin skin test should be done as soon as possible. This means that the physician has to be aware of the potential for TB and has to ask the noted questions and obtain the information relative to high risk. This is especially true if the child has a cough, bronchitis, and a fever that gets worse and will not go away. If the answers indicate high risk or there is a concern about the possibility of TB, a tuberculin skin test should be done immediately. Physicians have to be aware of appropriate tests to order for infants that can help detect the presence of TB. They also have to be aware of the limitations of the tests as they relate to infants and know what additional tests might be appropriate in order to make a diagnosis. Specifically, additional screening/testing that can and should be done on infants/children if TB is suspected or if they fall into a high-risk category include: 1) a chest X-ray to detect mediastinal or hilar adenopathy and/or pleural effusion, and 2) gastric or sputum smears or cultures to see if they are positive for mycobacterium tuberculosis," Trosty says.

"If, as the plaintiff alleged, the chest X-ray indicated hilar adenopathy, additional tests for TB should have been performed before releasing the child from the hospital in the first instance. A chest X-ray indicating hilar adenopathy is one of the important indications of possible TB. At that point, a gastric or sputum smear/culture should have been performed to determine if mycobacterium TB existed. In addition, a Mantoux tuberculin skin test should have been performed as part of the diagnostic effort. The Mantoux skin test is the recommended skin test for diagnosing TB, especially in infants and young children," adds Trosty.

It appears that neither the benchmark questions were asked nor the telling indicator discovered, all of which delayed the diagnosis.

"Timely diagnosis of TB is extremely important, almost critical, in infants because infants are far less likely to be able to contain the infection than are adults. TB infection in infants will progress to serious disease in 43% of those who are under

1 year of age and will do so relatively quickly. That is why accurate and timely diagnosis of TB is so important in infants, especially those who are symptomatic as appears to have been true in this case," Trosty says.

Once left untreated, TB can manifest itself in other ways.

"Common diseases that occur in undiagnosed and untreated infants who have TB include meningitis and osteomyelitis. And the infant in this case contracted one of the severe, complicating diseases — meningitis — that frequently occurs in infants with TB who go undiagnosed. The failure of the series of practitioners to recognize the potential symptoms of TB, to order a skin test, to accurately read and interpret the X-ray indicating hilar adenopathy, to order a gastric or sputum smear/culture, to keep the infant hospitalized, and to begin treatment for TB were all errors or breaches of the standard of care that occurred in this case. Although it can be difficult to make a conclusive diagnosis of TB in an infant as young as the child in this case, the infant did present with symptoms that could have been indicative of TB. However, no diagnosis of TB was made and there is no indication that any of the physicians or emergency room personnel asked the key questions to determine if the infant could be in a high-risk category for TB. There is nothing to indicate that TB was seriously considered as a possible diagnosis. The chest X-ray indicating hilar adenopathy does not seem to have been correctly interpreted as indicating the possible presence of TB; and, therefore, no gastric or sputum smears/cultures appear to have been ordered, to better determine if TB existed. The infant was released from the community hospital without any of the follow-up TB tests [i.e. skin test, gastric/sputum culture] after the telling X-ray result," Trosty says.

Time and again documentation proves to be a critical factor in medical malpractice cases.

"It is very important to remember that all of the steps noted above should be documented when they are occur. If TB had been considered but ruled out, it is very important that documentation exist to indicate the thinking/reasoning behind this decision. This could be critical in a subsequent legal action if there is an attempt to justify why the decision/reasoning had been correct at the time. There were several opportunities for physicians and hospital personnel to identify the existence of the TB or to order additional testing to help make the correct diagnosis but none of this occurred as it should have. Thus, there was a delay in diagnosis with serious consequences. It can be helpful to have documentation that substantiates the thinking, reasoning and process used to rule in or rule out potential or actual diagnoses," adds Trosty.

"It is important to know, and to not overlook, diagnoses or diseases that do not occur often; to know the primary symptoms of these diseases; to know the appropriate tests that can assist in making the diagnosis; to know the importance of making a timely diagnosis as it relates to the likelihood of serious illnesses or problems occurring from a delay in diagnosis. Unfortunately, the delay in this instance was compounded, and the undiagnosed infant developed serious corollary illnesses," states Trosty.

Even though most people probably do not know anyone who has contracted, let alone died from TB, TB still is a household word. So, familiarity probably contributed to the substantial settlement.

"In addition, the award in this case probably resulted from the location/jurisdiction of the case, namely Chicago or Cook County, which is known for large awards in malpractice cases. Further, the severity of the damages suffered by the infant are another contributing factor to the sum. The delay or failure in diagnosis ultimately resulted in the infant developing meningitis, hydrocephalus, severe neurological injury and cerebral palsy. This is an infant that would require comprehensive, total and expensive care for the rest of its life, and whose quality of life was drastically minimized; all of which was the result of undiagnosed TB," concludes Trosty.

Reference

• *Daniel Banderas-Mendosa, minor v. Dr. Flordeliza Villafuerte, Dr. Henry Munez, Dr. Alfredo Rumilla, Dr. Howard Lopata, Children's Memorial Hospital, Dr. Donald Wharton, St. Mary of Nazareth Hospital,* Cook County (IL), Circuit Court Case No. 94L-15894. ■

Scalding sitz bath leads to severe burns, $1.5M

News: A nursing home patient developed a cyst on her labia, and her treating gynecologist ordered a sitz bath to relieve the condition.

However, the nurses administering the bath thought they were to treat the affected area with steam and the patient was burned with steam and scalding water. She died seven months later, and the family brought suit against the owner and operator of the facility. After extensive negotiations, the operator paid a $1.5 million settlement.

Background: The patient was a resident of a nursing home/rehabilitation facility when she developed a cyst on her labia. To alleviate the pain and shrink the cyst, her treating gynecologist ordered a bath for her.

Evidence produced by the plaintiff showed that the nurses thought they were supposed to steam the decedent's vaginal area as opposed to simply place her in lukewarm water. The nurses obtained the water for the bath from an industrial coffee urn and filled the tub with water that was 185° F.

The patient sustained second- and third-degree burns as a result of the contact with the steam rising from the water and/or contact with the water. Her buttocks were burned in the areas of the anus and outward covering approximately half of each buttock as well as a portion of her perineum.

The patient's estate brought suit against the nursing home operator, nursing home owner, and treating physician. The plaintiff claimed that it took about four months for the patient to recover from the incident. Three months later, she died of congestive heart failure. According to the defense, the estate also alleged that her untimely death was related to the burn incident. This action never made it to a jury. Instead, it was settled for $1.5 million. After extensive negotiations, the nursing home operator paid the entire amount.

What this means to you: "This case is so severe that the first thing that comes to mind is to do a root-cause analysis to see where the process fell down. The occurrence is so bizarre that it makes one think that this might be a symptom of a much bigger systemic problem," says **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, CHt, director, risk management services, of the Miami Jewish Home and Hospital for the Aged.

"The cardinal issue in this case is one of standard of care — basically, that you do not do a procedure unless you have been trained to do it. The assigned caregivers should have gotten instructions from the supervisory staff on how to give a sitz bath if they were unfamiliar with what one was let alone how to give one," notes Kicklighter. "In this case, we don't know if the facilities procedure manual had a policy and procedure describing this treatment. If there were one, at the very least the caregivers should have checked that procedure to verify the correct process.

"Nursing homes typically have more certified nurse assistants than registered nurses, licensed professional nurses than acute care facilities, and some states may not require a RN on all shifts. However that is no excuse for residents/patients to receive less than the standard care. What this incident raises to the forefront is training, or lack thereof. Furthermore, there is a need to reemphasize to all staff their obligation to advise their supervisor when they are not familiar with an assignment.

"Further, administration should undertake an assessment of all staff to identify who has experience and competence to do certain procedures/treatments. Those who are not experienced/competent to do those treatments or procedures commonly ordered to do so in the facility should be trained to perform them as appropriate for their professional level. The nursing office and each unit where the employee is assigned should have a copy of who has been signed off to do which procedures or treatments," Kicklighter says.

"In addition, all the staff should be trained regarding thermal burns. In particular, all staff should be educated that no liquid of any type that is used on a resident/patient should be over a certain temperature, and proper thermometers should be appropriately placed throughout the patient care units for easy access," she notes "The same holds true for liquids and foods administered orally. If it's too hot for the health care provider, it is definitely too hot for the patient.

"Bottom line: Supervisors and managers should be trained to question staff about assignments to validate that staff are experienced in doing the procedure or treatment. Finally, as an aside, it would be of interest to know if this incident was reported to the Illinois Department of Health and what the feedback was from that venue," Kicklighter says.

Reference

• *Marilyn Pease, as special administrator of the estate of Elizabeth Jawor, deceased, vs. Brentwood North Nursing and Rehabilitation Center Inc., Riverwood Associated, and John D. Gailbraith Jr.,* Cook County (IL) Circuit Court, Case No. 00L 10804. ■