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INSIDE

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How to best create a plan for terrorism: 'Think of crowds of desperate people'

And don't assume anything

The threat of terrorism should prompt risk managers to conduct a thorough review of emergency preparedness plans, making it very likely that you will find that you are not adequately prepared. That's the alarming news from experts who say terrorism may strike directly at the nation's hospitals and other health care facilities.

There is reason to be alarmed, says **Lee Matthews**, CHPA, CPP, interim executive director of the International Association for Healthcare Security and Safety in Lombard, IL. He has worked in health care security for 16 years. Since Sept. 11, risk managers and security managers have flooded his office with calls asking how they can strengthen their facilities' preparations for terrorism. Matthews tells them they should get to work immediately.

"As I talk to people after the 11th, I keep emphasizing that you can't

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assume anything about your plan. Read through it with a different set of eyes," he says. "Don't say, 'That could never happen here.' Everything is different now."

Matthews says he doesn't expect health care facilities to be a primary target for terrorist attacks, but he does not discount that possibility altogether. He notes that in the Balkans and Northern Ireland, terrorists have targeted hospitals for both primary and secondary attacks. Hospital emergency rooms [ER] can be an attractive target for a secondary attack because the terrorists can be sure that they will be crowded with injured people and rescue workers.

"Everybody has to worry about terrorism in this country now, but we have to be especially concerned if we're involved with protecting hospitals," he says. "Hospitals are going to be involved, one way or another."

The good news, Matthews says, is that health care providers are not starting from scratch. The Joint Commission on Accreditation of Healthcare Organizations already requires that providers have an emergency preparedness plan for responding to a wide range of in-house and community emergencies, and effective January 2001, the Joint Commission's emergency preparedness plan (EC.1.4) was expanded and made more specific. It now requires providers to address four phases of emergency management activities: mitigation, preparedness, response, and recovery. The new rule calls for providers to conduct a "hazard vulnerability analysis" to determine how the facility might be affected by different threats. The new language in the rule also lays out specific requirements, such as identifying personnel during emergencies, but it is an all-purpose rule on emergency management that could apply to a range of disasters. Terrorism is not mentioned.

The standard lists essential elements of a plan, including an annual evaluation of its effectiveness. Matthews says risk managers should look to their existing emergency plans as the starting point when developing a response to terrorism. In fact, he doesn't necessarily even suggest that you develop a plan with the word "terrorism" in the title.

"Most hospitals don't have a specific policy on terrorism, and I'm not sure there's any need to write one up from scratch," he says. "But everyone has a policy on bomb threats, evacuation, fires. You need to focus on components like that and make sure they're the best they can be."

Many risk managers think they currently have no response plan for a terrorist attack, when in fact they have one that just needs to be improved, says **Russell Colling**, CHPA, CPPFM/LM/CM, a health care safety consultant in Salida, CO. Colling cautions risk managers that, even if they want to develop a very specific response plan for terrorism, they must first make sure they have covered the fundamentals of an overall, generic emergency preparedness plan.

"I'm telling my clients that for any kind of emergency, terrorism or anything else, you need

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- ■ HIPAA causes more focus on assessment, project planning
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- ■ Courts continue to fine-tune the False Claims Act

to look and see if you have a strong day-to-day program," he says. "There's no use in trying to throw something together quick if you don't have that foundation in place."

Access control will be a key problem

The most likely problem to face hospitals is a sudden influx of patients from an attack somewhere else in the community, he says. In that situation, the hospital would respond largely in the same way that it would respond to any other mass-casualty incident. But there could be some differences if the attack is biological or chemical or even nuclear in nature. That creates a more difficult problem with contamination and patient isolation.

A biological attack is one of the biggest fears among the public right now, but Matthews says such an incident would not cause a sudden crisis in the health care facility. The crisis might come, but it would build as people in the community realize they are infected or at risk.

"No one's going to run into your ER and throw an anthrax bomb," he says. "Instead, people are just going to start showing up with symptoms, more and more over days or weeks until you have a problem. Part of your problem could be people demanding that you give them a vaccine, whether you have it on hand or not, and even if it wouldn't help them. Your pharmacy will be at risk just because it says 'pharmacy' on it. Think of crowds of desperate people."

Colling agrees, saying about 50% of all security in a health care setting comes down to access control in one way or another. It might not be necessary to lock down the entire facility, but you will need to have a mechanism in place for reducing access points.

"It's time to address again what we did in the late '60s with all the civil unrest," he says. "The idea of auxiliary security staff should be revisited. Maintenance and housekeeping, materials management — a lot of those people should be trained to form an auxiliary security staff that could mobilize on a moment's notice to man certain posts not ordinarily manned. That idea died out after the civil disobedience abated in the '70s."

Colling says there is "not one dramatic thing you should do. It's more like shoring up everything you should already have in place." He has one specific suggestion that most hospitals could implement right away: Start conducting more thorough background checks.

"This is a good opportunity to remind hospitals that the best money you can spend on security is to find out who you're hiring," he says.

If your emergency preparedness plan already is thorough, Matthews says you might be able to just expand some of the categories to include terrorist attacks and look for details you might have overlooked before Sept. 11. But if your plan isn't high quality, and most experts say that is common, now is the time to roll up your sleeves and get to work. He offers these tips for developing or reviewing your emergency response to terrorism:

- **Include virtually every department.**

Too many emergency plans focus only on the medical care, overlooking how important support services can be. Facilities managers, for instance, can be critical — and overtaxed — in an emergency. Particularly when there are contamination issues, facilities management might be called on to alter ventilation systems or provide emergency water supplies for decontamination.

- **Use your drills to look for hidden problems.**

Your disaster drills are crucial for spotting the weaknesses that you'll never see on paper. For instance, your plan may call for setting up a decontamination site in the ER parking lot so patients can be washed before entering the facility. That's good, but during the drill you might find that there is no water hookup in that area. And even if there is a water supply, will it be ice cold? Where does the contaminated waste water go?

- **Involve local authorities.**

Your emergency plan and your drills should not be solitary affairs. Involve local police and fire departments and encourage them to provide feedback. Also be sure to solidify your relationship with these authorities because you will depend on them in a crisis.

"Go and talk to law enforcement," Matthews says. "Don't assume that you know Bob the Deputy because he drives by every night and that's your relationship with law enforcement. Reaffirm that connection and investigate what they will do if something serious happens. Can they come to help you protect the hospital or will they not have enough assets for that? Don't make any assumptions."

For instance, one of the hospitals where Matthews used to work had an agreement with the local police that they would station a patrol car at the ER whenever the hospital enacted its emergency plan. The officer provided some security, but the main goal was to ensure that the hospital had communications if its own system went out.

• **Check with vendors and consider their own limitations.**

Your emergency plan should include arrangements with vendors to expedite delivery of critical materials. But be realistic about what the vendors will actually be able to do in an emergency. Matthews tells of one hospital that had carefully arranged for a local vendor to deliver a tanker truck of diesel fuel for its emergency generator in an emergency. But when an earthquake struck, authorities declared diesel fuel an emergency provision and restricted its sale. The vendor could not deliver the fuel to the hospital without permission from state authorities despite the previous agreement.

One consultant cautions that you must not be too satisfied with your emergency preparedness plan just because it passed a Joint Commission survey. The Joint Commission requirements are rather general, and there are many ways to fulfill them, says **Cameron Bruce**, CSP, PE, a health care consultant in Orinda, CA. He says most hospitals are "woefully unprepared" for a disaster.

Hospitals and other health care organizations tended not to put much budget support behind emergency preparedness, but Bruce says that might change now that terrorism has gotten everyone's attention. That's good, because developing a good emergency plan can be expensive, especially if you use outside consultants.

"It can take you more than 1,000 hours of time to write a good emergency preparedness manual. That can cost you $30,000-$60,000 if you do it right," Bruce says. "You can slap something together in a few days before your Joint Commission survey and it might be enough to get by the surveyor. But that's nothing I would rely on in an emergency."

On a nationwide level, the U.S. health care system is ready for terrorist attacks, according to Secretary of Health and Human Services (HHS) **Tommy Thompson**. He recently spoke before an audience of manufacturers and said the federal government has eight caches containing 50 tons of medical supplies distributed around the country, ready for immediate distribution, along with a network of 81 state laboratories connected to the Centers of Disease Control and Prevention (CDC) for monitoring of anything suspicious.

Thompson says the HHS could use that network to respond within seven hours to either conventional or biological attack, Thompson said. He says he is "very confident as Secretary of Health that if a terrorist attack hits us, we are able to respond very quickly." In addition, Thompson says HHS will be improving security at places such as the CDC and NIH as well as stocking additional supplies of pharmaceuticals and vaccines.

If one arm of the American Medical Association has its way, the Joint Commission will start evaluating health care providers for their emergency plans specifically regarding terrorism. The American Medical Association's Council on Scientific Affairs issued a report in 2000 on "Medical Preparedness for Terrorism and Other Disasters," calling for substantial improvements. One of the key recommendations was to "encourage the Joint Commission on the Accreditation of Healthcare Organizations and state licensing authorities to include the evaluation of hospital plans for terrorism and other disasters as part of their periodic accreditation and licensure." The Joint Commission has not acted on that recommendation.

The Joint Commission has focused on terrorism, however. In 2001, several congressional committees explored the issue, and the Joint Commission actively participated. ■

ASHRM: Risk managers must take the lead role

The president of the American Society for Risk Management (ASHRM) in Chicago says risk managers must take a lead role in preparing their organizations for a terrorist attack or a community response to terrorism.

Geri Amori, PhD, ARM, FASHRM, risk manager with Fletcher Allen Health Care in Burlington, VT, and president of ASHRM, says health care risk managers must take a lead role and coordinate a multidisciplinary approach.

"We've always been involved in emergency preparedness and organizing the hospital's disaster response, so this is not a new area for us," she says. "But this is definitely something that needs everyone's attention more than ever, and the risk manager is the person who should be at the forefront. Take a leadership role."

Amori also expressed sympathy for the Sept. 11 victims on behalf of ASHRM and acknowledged that many members have expressed concern.

"Many of you responded with personal and professional views that were touching and reassuring during this time of national healing," Amori wrote in a letter to members on the

ASHRM web site. The ASHRM board assessed the members' concern about traveling to the ASHRM Annual Conference scheduled for Oct. 29 to Nov. 1, but determined that the conference was more important than ever.

The board unanimously voted to move forward with the conference, citing "the need to come together as an organization to support our colleagues and friends in health care risk management; the opportunity to facilitate the dialogue amongst risk managers about health care readiness and disaster preparedness; and canceling the conference would allow terrorism to prevail."

However, ASHRM arranged to step up the security already planned for the conference.

"Furthermore, I believe it behooves us all to recognize that the world, as we believed it, no longer exists. The specter of danger has been seen. It will not go away completely," Amori says. "That being said, we cannot stop living just in case we happen to be where the next event occurs." ■

Bioterror readiness plans available as a template

As hospitals and other health care organizations scramble to review and improve their emergency preparedness plans, many are seeking a template that can be used to create a terrorism response plan. There aren't a great many of those available, but risk managers may want to look at a few they might find helpful.

• The Association for Professionals in Infection Control and Epidemiology (APIC), in cooperation with the Centers for Disease Control and Prevention (CDC), offers a tool that it says can serve as a reference document and initial template to facilitate preparation of bioterrorism readiness plans for individual institutions. APIC is offering the plan for free.

The *Bioterrorism Readiness Plan: A Template for Healthcare Facilities* outlines the steps necessary for responding to the biological agents most likely to be employed in any future biological attack: smallpox, botulism toxin, anthrax, and plague. The plan provides information on the unique characteristics, specific recommendations, management, and follow-up appropriate for each of these biological agents. It covers the description, etiology, and mode of transmission of each agent and the necessary isolation precautions, patient management, and post-discharge planning associated with each. The document also provides details regarding post-exposure management, prophylaxis, and decontamination consistent with each pathogen; laboratory support and diagnosis; and protocols for the cleaning, disinfection, and sterilization of equipment and environment.

The plan outlines patient / visitor / public health precautions, and contains some discussion of the psychological and mental health aspects of a bioterrorist event. It also has appendices covering health care worker exposure fact sheets; relevant web sites for bioterrorism readiness; and other necessary information for infection control professionals to have in the event of a bioterrorist attack.

APIC says the format of the *Bioterrorism Readiness Plan* is easily adapted to suit the individual needs of institutions. "With the mounting concerns regarding threats of bioterrorism throughout the country, the timely appearance of this accessible device is meant to allow infection control professionals and health care epidemiologists in all health care facilities to prepare appropriate plans utilizing established networks to satisfy needs of unique situations," APIC wrote.

There is no charge for the downloaded version of this plan at www.apic.org / bioterror. For print and disk copies, the charge for APIC members is $10, or $18 for nonmembers to cover the shipping costs. Contact APIC at 1275 K St. N.W., Suite 1000, Washington, DC 20005-4006. Telephone: (202) 780-1890.

• When beefing up your emergency preparedness plan, consider incorporating a biological threats checklist like the one used at Alta Bates Summit Medical Center in Berkeley, CA. The checklist, prepared by emergency preparedness consultant **Cameron Bruce**, CSP, PE, in Orinda, CA, is part of the hospital's overall emergency preparedness plan. Bruce suggests that risk managers incorporate a similar checklist, modifying the Alta Bates checklist to suit your own needs. **(See the biological threat checklist on p. 126.)**

• Another source for physician education regarding terrorist attacks is an on-line presentation of lectures presented at New York University Medical Center. They are now available free on the World Medical Leaders web site at www.wml.com. In these lectures, New York University Medical Center faculty discussed hands-on experiences and emergency preparedness for potential biological and chemical attacks in the wake of the World

(Continued on page 127)

Treatment of Biological Agent Exposure

AGENT	CLINICAL SIGNS AND SYMPTOMS	TREATMENT	OTHER	SECONDARY TRANSMISSION
Anthrax (spore)	Fever, malaise, non-productive cough, progressing to dyspnea, stridor, shock. Incubation 1-6 days.	Prophylaxis/treatment: ciprofloxin, doxycycline, PCN licensed vaccine. IV therapy: ciprofloxin doxycycline, PCN licensed vaccine.	High mortality (>90%) even with treatment.	None except aerosolized body fluids.
Pneumonic Plague (bacteria)	High fever, chills, headache, hemophysis, toxemia, dyspnea, stridor, bleeding diathesis. Incubation 2-3 days.	Prophylaxis/treatment: vaccine, doxycycline, TMP/sulfamethoxazole. IV therapy: streptomycin (>1 yo), gentamicin, chloramphenicol.	Antibiotic treatment effective if begun early.	Strict isolation needed. Isolation mandatory for at least the first 48 hours of treatment.
Tularemia (bacteria)	Regional lymphademepathy, fever, chills, headache, malaise, cutaneous ulcers. Incubation 2-10 days.	Streptomycin, gentamicin. Adult prophylaxis: doxycycline.	Low mortality (about 5%).	Rare, body fluid precautions only.
Q Fever (bacteria)	Fever, cough, pleuritic chest pain. Incubation 10+ days.	Tetracycline, doxycycline.	Low mortality.	Does not require universal precautions.
Smallpox (virus)	Malaise, fever, rigors, vomiting, headache, backache; 2-3 days later lesions appear and quickly progress from macules to papules to pustular vesicles. Incubation 16-17 days.	Supportive — vaccine available from CDC. Immune globulin may be available from CDC. No antiviral medication available.	Supposed to be extinct (doubtful).	Highly contagious.
Viral Equine Encephalitis	Supportive. No antiviral medication exists.	Ribaviron, supportive care.	Isolate patients in single room with an adjoining anteroom stocked with PPE. Negative air pressure if possible.	Body fluids. Otherwise infectious by vector (mosquitoes).
Viral Hemorrhagic Fevers	Fever, malaise, myalgias, headache, vomiting, diarrhea, easy bleeding, petechiae, shock.	Ribaviron, intensive care, convalescent plasma (Argentine HF), vaccine (yellow fever), blood replacement products for DIC.	Decontaminate with hypochlorite or phenolic disinfectants.	Transmitted by bodily fluids. Strict barrier-nursing techniques. Limit patient transfers: may increase risk for secondary transmission.
Botulism (toxin)	Ptosis, weakness, dizziness, dry mouth, blurred vision, diplopia, descending paralysis. Incubation 24-36 hours.	Several antitoxins are available and effective if administered early. CDC vaccine good only for A and B.	Disinfect with hypochlorite and/or soap and water. Supportive long-term mechanical ventilation.	None.
Ricin (toxin)	Weakness, fever, cough, pulmonary edema, incubation 16-24 hours.	Supportive — oxygenation and hydration. No antitoxin or vaccine available.	Disinfect with hypochlorite and/or soap and water.	None. Derived from caster beans.
Staphylococcal Enterotoxin B (toxin)	Fever, headache, chills, myalgias, cough, nausea, vomiting, diarrhea. Incubation 3-12 hours.	Supportive — oxygenation and hydration. Ventilator support may be required.	Disinfect with hypochlorite. Most victims recover.	Use PPE.

Source: Robert Suter, DO, MHA, FACEP, Quest are Emergency Services, Plano, TX.

Trade Center disaster. The presenters stressed how essential it is for physicians to be up-to-date on key diagnostic factors, treatments, and reporting procedures. They reviewed chemical and biological agents most likely to be used in an attack. In addition, the presenters discussed what to expect in the psychological and social arenas following a terrorist attack. Speakers included Robert S. Hoffman, MD, medical director of the New York Poison Control Center, as well as leading experts on infectious diseases and psychiatry. ■

Hospital fined $22,000 in fatal MRI accident

The hospital where a 6-year-old boy died in a freak MRI accident has been fined $22,000 for 11 safety violations, according to the New York State Department of Health.

The accident happened recently at the Westchester Medical Center in Valhalla, NY. As a 6-year-old boy was undergoing an MRI exam, a staff member brought a metal oxygen cylinder into the room. The machine's powerful magnet pulled the oxygen tank through the air and into the machine, fracturing the boy's skull. The boy was sedated when he was struck, says **Edward A. Stolzenberg**, president and CEO of Westchester Medical Center.

Stolzenberg says the hospital conducted an extensive root-cause analysis and identified a wide range of systemic failures, including poorly trained staff. The hospital instituted a number of policy and procedure improvements. **(See the story in *Healthcare Risk Management*, October 2001, p. 115.)**

Robert Kenny, a spokesman for the health department, says the $22,000 fine is the maximum allowable under state law — $2,000 for each of the 11 violations. Kenny says the department hoped to bring attention to the seriousness of the safety violations by imposing the maximum fines.

The health department also criticized Westchester for not reporting or adequately investigating a similar accident in 1997. In that case, an oxygen tank struck the MRI machine but no patient was present. Kenny says a proper investigation of that incident may have prevented the fatality.

In addition to the fines, Westchester must submit a plan for correcting the deficiencies and the health department will conduct unannounced inspections. ■

AAPS doctors sue to halt HHS privacy regs

The Association of American Physicians and Surgeons (AAPS) recently announced a new lawsuit against the Department of Health and Human Services (HHS) to halt implementation of the new medical privacy regulations written under the Health Information Privacy and Accountability Act (HIPAA) of 1996.

Unlike another lawsuit filed by the South Carolina Medical Association that seeks judgment that Congress' authorization to HHS to promulgate the regulations is an unconstitutional delegation of its legislative authority, this lawsuit challenges the actual constitutionality of the regulations themselves based on the content and outcomes. The lawsuit claims that the regulations are illegal since they violate the Constitution and its amendments, as well as the Paperwork Reduction Act, explains AAPS public affairs counsel **Kathryn Serkes**, JD. The lawsuit seeks declaratory judgments based on these allegations:

- The regulations violate the Fourth Amendment by requiring physicians to allow government access to personal medical records without a warrant and authorizing the government construction of a centralized database of personal medical records with personal health identifiers.
- They are unconstitutional to the extent they govern purely intrastate activities by physicians in using and maintaining medical records for patients, and disrupt state laws.
- They violate HIPAA and lack statutory authorization to the extent they regulate medical records other than electronic transmissions.
- The regulations violate the Paperwork Reduction Act and Paperwork Flexibility Act and are unenforceable and incomplete.

Serkes says the most heavy-handed aspect of the new federal rules is the unprecedented government access to everyone's private medical records.

"While masquerading as patient protection, the rules would actually eliminate any last shred of patient confidentiality," she says. "When it comes to government prying, these rules obliterate any remote notion of patients' rights. Doctors are required to disclose all patients' records to thousands of federal bureaucrats — with or without consent. That includes handwritten notes and psychiatric records."

Law enforcement agencies will have unrestricted

access to all records — including notes about drug use, family interactions, and other confessions, Serkes says.

"But it gets worse. Doctors be not only fined for withholding records, but the feds can order them to refuse treatment to patients who won't consent to government disclosure," she says. "If patients expect the government to protect them from marketing efforts, they're in a for a rude surprise. It was government employees who sold patients medical records from government databases to HMO recruiters in Maryland a few years ago."

Serkes says the regulations are so flawed that they should be scrapped altogether and a new plan devised from scratch. ■

A tool kit is offered for reducing medication errors

The California Healthcare Foundation is offering what it calls a practical tool kit for reducing medication errors in hospitals, one of the main problems cited in the recent controversy over medical errors.

Medical errors are the eighth leading cause of death in the United States, with the number of deaths exceeding those associated with motor vehicle accidents, breast cancer, or AIDS, the foundation notes. Medication errors represent the largest single cause of errors in the hospital setting, accounting for more than 7,000 deaths annually — more than the number of deaths resulting from workplace injuries.

The Institute of Medicine report that focused on medical errors made reference to information technologies that have been shown to be effective in reducing medical errors, particularly in hospital settings, and interest in this issue has grown among health care stakeholders. Prominent examples include initiatives by the Leapfrog Group, a consortium of large private and public companies that purchase health care benefits for more than 20 million Americans and, closer to home, the California State Legislature. Senate Bill No. 1875, which requires every general acute-care hospital, special hospital, and surgical clinic in California (with the exception of small and rural hospitals) to adopt a formal plan for minimizing medication-related errors as a condition of licensure. This plan, to be implemented on or before Jan. 1, 2005, must include "technology implementation, such as, but not limited to, computerized physician order entry or other technology" to eliminate or substantially reduce medication-related errors.

In order to assist health care providers with that initiative, the California HealthCare Foundation recently published *A Primer on Physician Order Entry,* which describes computerized physician order entry (CPOE) systems and provides case studies of hospitals that have implemented these systems.

As a follow-up to that piece, the Foundation commissioned Protocare Sciences to prepare a tool kit, which hospitals can use when considering how best to proceed in choosing and applying a variety of technological solutions, including CPOE, to prevent medication errors in the hospital setting.

The tool kit consists of two parts: "A Framework for Developing a Plan" and "Ten Tools." Both are available on the California Healthcare Foundation's web site at http://quality.chcf.org/view.cfm?itemID=4194. A hard copy also may be ordered from the web site. ■

NY hospital is fined for unnecessary surgeries

The New York State Health Department has fined Parkway Hospital $32,000 for its failure to prevent and address unnecessary urologic surgeries performed on 12 patients from a home for the mentally ill.

State Health Commissioner **Antonia C. Novello**, MD, MPH, DrPH, recently announced that the department cited Parkway Hospital for deficiencies related to systemic problems concerning the lack of proper patient consent, diagnostic testing, and assessments of the health risks associated with such invasive procedures, thereby violating the rights of patients and compromising their health and safety.

"This is the final chapter in this case," Novello said. "New York State will not tolerate such cavalier actions as the ones taken by the two doctors in this case. Both doctors' knowing efforts to deceive the very patients entrusted in their care is unconscionable, and the hospital's failure to respond swiftly and appropriately after receiving staff complaints about the unnecessary surgeries is gross negligence of the worst kind."

Novello said the patients were admitted to the Parkway Hospital from the Leben Home for Adults with invalid consent forms on a Thursday

afternoon, were operated on, stayed in the hospital over the weekend, and were transferred back to Leben Home the following week. None of the patients had any prior history of illness to dictate the type of surgeries performed.

"Beyond the two doctors' calculated manipulation of these patients, perhaps the most disturbing part of this case is the fact that the hospital failed to take necessary actions in the face of staff complaints," Novello said.

The New York State Board for Professional Medical Conduct disciplined the two doctors involved in this case earlier this year. The board revoked the license of one doctor and suspended the license of the other doctor for practicing fraudulently and willfully filing a false report.

In May 2001, Novello ordered that the Leben Home for Adults' operating license be suspended and that MediSys Health Network Inc. (a not-for-profit organization that operates other hospitals) be installed as the temporary operator of the Leben Home to ensure that the residents are protected from any further endangerment to their physical and mental health.

As a result of the State Health Department's investigation, Parkway Hospital was cited for 16 violations of the State Hospital Code, resulting in a maximum fine of $32,000. Deficiencies were cited in the areas of: Governing Body, Medical Staff, Quality Assurance Program, Patients' Rights, Surgical Services, and Laboratory Services. The proposed fines amount to $2,000 per violation, the maximum monetary penalty allowable under the law.

The hospital is required to submit a Plan of Correction describing how each of the identified deficiencies will be addressed, what corrective actions will be taken, and the protocols to be implemented to insure that similar violations do not recur in the future. Parkway Hospital will also be required to submit quarterly reports to the department for a period of one year, commencing with the effective date of the stipulation and order. These reports shall detail activities undertaken to implement corrective actions and include an assessment of the effectiveness of those corrective measures.

Specifically, the department's investigation found these problems:

• The hospital failed to prevent or address unnecessary urologic surgery on patients transferred from the Leben Home despite complaints from staff about the propriety of these admissions.

• Patients arrived with signed consent forms executed at the Leben Home, even prior to being evaluated by the physician in his office. Some of the patients did not know why they were being hospitalized, and it did not appear as though they were able to provide informed consent.

• Patients received inadequate pre-surgical evaluations. There was no documented evidence that risks and benefits of the proposed procedures, and alternatives for care or treatment, if any, were disclosed to mentally incompetent patients who arrived at the hospital with signed consent forms.

• Not all records documented a review of the patients' overall conditions and health status prior to surgeries, including the identification of a patient's potential surgical and cardiac problems. There was lack of valid evidence to suggest that any of the patients were in need of the surgeries performed.

• The pathologist did not re-weigh specimens resulting from the surgeries during gross examination. In order to verify the necessity of the procedure in the first place, a certain amount of tissue needs to have been removed during the procedure for analysis. The pathologist inappropriately accepted the weight of specimens, as obtained by the operating surgeon in the operating room. ■

OIG: Copayment waiver could violate fraud rules

The Health and Human Services Office of the Inspector General (OIG) has issued a legal opinion on a practice that may be happening in your own health care organization, saying that waiving the copayment or deductible for patients could violate fraud rules, but it won't prosecute those cases when it appears the hospital does not benefit financially.

An unknown hospital requested the clarification from the OIG after there were concerns about a method that it used for promoting breast and gynecological exams. The not-for-profit hospital operates a cancer hospital at its main campus and at a satellite location. The cancer center offers an early detection program for breast and gynecological cancers "at no out-of-pocket expense" to its patients. It is financed by a series of federal and state grants, private philanthropic support and, to the extent that grant funds do not cover its annual total operating expenses, by annual grants from the hospital. The center's office space is owned by the state and provided to the center rent-free.

The Center's early-detection program includes breast and gynecological cancer screening services provided at the center, certain follow-up services provided at other hospital facilities, including the cancer hospital at the main campus, and related educational, counseling, and referral services. If concerns persist after the follow-up services, the patient is seen by one of three surgeons and scheduled for additional services (most often surgery), usually at one of three hospitals with which the attending physician has admitting privileges. These hospitals are not affiliated with or owned in any manner by the hospital in question, and the hospital receives no financial recompense for such referrals or arrangements.

Patients may elect to receive the required additional services at the original hospital. However, this happens infrequently and, when it does, all of the hospital's standard patient billing and payment policies apply, including billing patients for coinsurance, except in cases of individualized determinations of financial need.

The cancer center's outreach program targets individuals of African or Hispanic origin. To encourage use of its services, the center instituted the waiver policy, which it publicizes in connection with its community outreach program. Under the waiver policy, the center accepts reimbursement from its patients' third-party payers, if any, as payment in full for the screening services and follow-up services.

More on the waiver policy

When the cancer center asked for clarification of whether that arrangement could violate fraud rules, the OIG responded by issuing Opinion No. 01-14. **Mac Thornton**, JD, chief counsel to the Inspector General, wrote that the waiver policy may potentially generate prohibited remuneration under the civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act, for inducements to beneficiaries and under the anti-kickback statute if the requisite intent to induce or reward referrals of federal health care program business were present.

"However, the OIG will not impose administrative sanctions on [the hospital] in connection with the Waiver Policy for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act nor for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act [as those sections relate to the commission of acts described in section 1128B(b) of the Act]," Thornton wrote.

Thornton concluded that the waiver policy clearly comes within the general statutory prohibition against improper inducements to beneficiaries. The hospital waives coinsurance for the screening services and follow-up services in order to induce patients, including Medicare and Medicaid beneficiaries, to receive those services at the center. Moreover, the waiver policy does not qualify for the preventive care exception, both because the screening services are sometimes tied to the delivery of certain nonpreventive follow-up services, which also are reimbursable under Medicare and Medicaid. Also, the waiver policy applies to certain services that do not fit the regulatory definition of preventive care.

Thornton said the OIG continues to have "serious concerns" regarding the waiver of coinsurance for screening services when the waiver is tied to other services reimbursable by Medicare or Medicaid, but the OIG will not impose administrative sanctions on the hospital. He said the OIG analysis turns on two aspects of the waiver policy, which, taken together, substantially minimize any risk of fraud or abuse.

"First, the large majority of patients benefited by the waiver policy are uninsured individuals, who might otherwise receive no screening services . . . . The receipt of services by some insured patients, including Medicare and Medicaid beneficiaries, does not alter the fundamental charitable nature of the endeavor. In short, given the uninsured status of the majority of patients receiving services, it is unlikely that the screening services, in conjunction with the waiver policy, will generate substantial remunerative services for the hospital."

The second reason is that although the screening services that would otherwise qualify for the preventive care exception are tied in some cases to nonqualifying services, the nonqualifying services are limited to those necessary to confirm the initial screening results. "As such, application of the waiver policy to the follow-up services merely effectuates the initial screening services," Thornton wrote.

As is standard in all such OIG opinions, Thornton pointed out that the conclusions are valid only for the hospital in question and do not provide any protection for other health care providers. But the published OIG opinions are routinely seen as guidelines for how the OIG will interpret the law in certain situations. ■

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Limited curriculum for adverse drug events

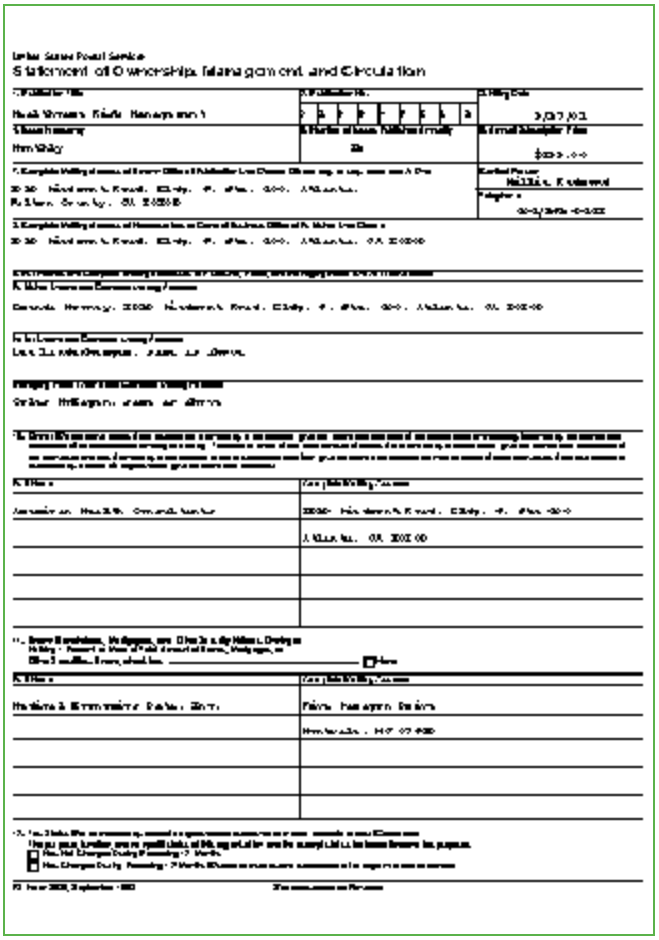
Only 16% of internal medicine clerkship programs include formal lectures about adverse drug events, according to a new study published in the Sept. 5 issue of the *Journal of the American Medical Association*. Study results indicate that medical students in the United States have little exposure to information on adverse drug events in the curriculum used during their internal medicine rotation.

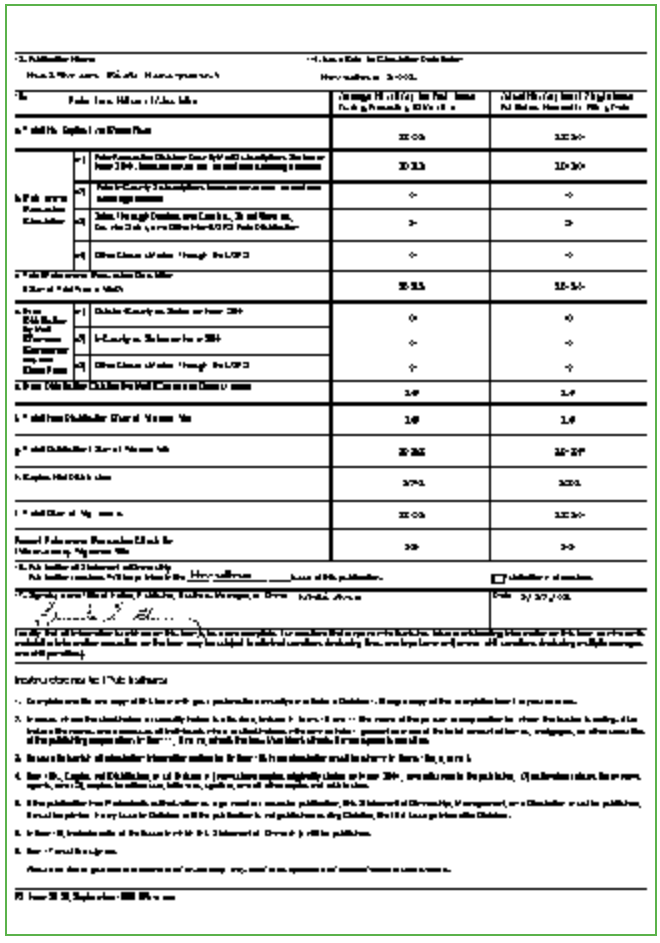
The study, sponsored by the U.S. Agency for Healthcare Research and Quality (AHRQ), with additional funding from the Food and Drug Administration, also found that 35% of clerkship directors had little or no familiarity with the 1999

Institute of Medicine report on medical errors, *To Err is Human: Building a Safer Health System.* After reading a brief summary of the report, 83% of clerkship directors said that heightened surveillance and training should occur to help decrease adverse drug events.

Sixty-five percent of the clerkship directors said that they would incorporate one or two hours of educational materials on adverse drug events if slide shows or Internet-based educational modules were available. Only 41% of clerkship directors would welcome an outside speaker to lecture on the topic.

The study was carried out by AHRQ's Center for Education and Research on Therapeutics at Georgetown University, and is based on a survey of 79 U.S. internal medicine clerkship programs that was conducted in the spring of 2000. Internal medicine clerkship programs were chosen for the survey because medical students spend an average of 12 weeks on this rotation, more than any other required clinical experience during their medical training. The study did not assess the impact of the lack of information on adverse drug events on their training overall. ■


Statement of Ownership, Management and Circulation



AMERICAN HEALTH CONSULTANTS

2001 SALARY SURVEY RESULTS

Healthcare Risk Management™

RMs' income holds steady, but career is rapidly changing

Traditional risk management roles fading away

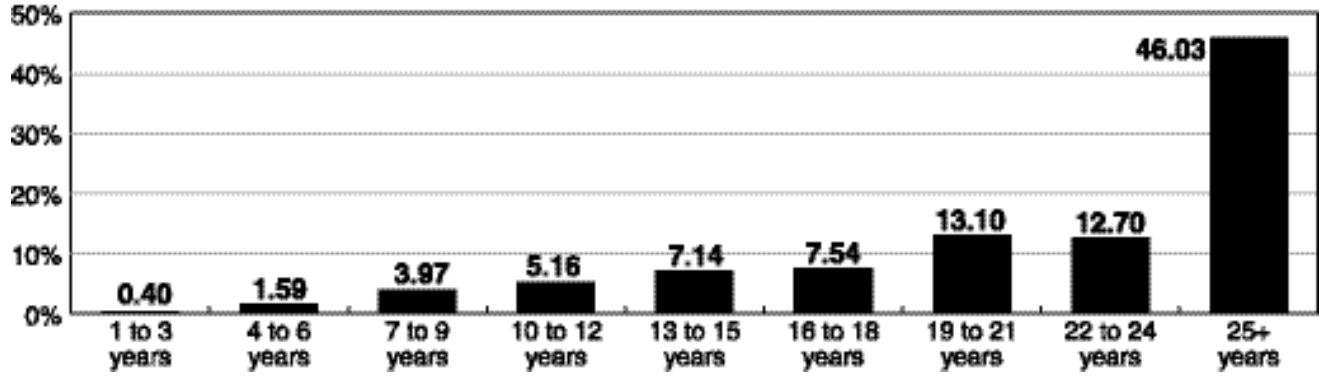
Most health care risk managers are seeing their incomes hold steady or increase slightly, but the traditional career paths are fading away. If you want to hang onto a successful career, you need to develop your skills and make yourself desirable in the new marketplace.

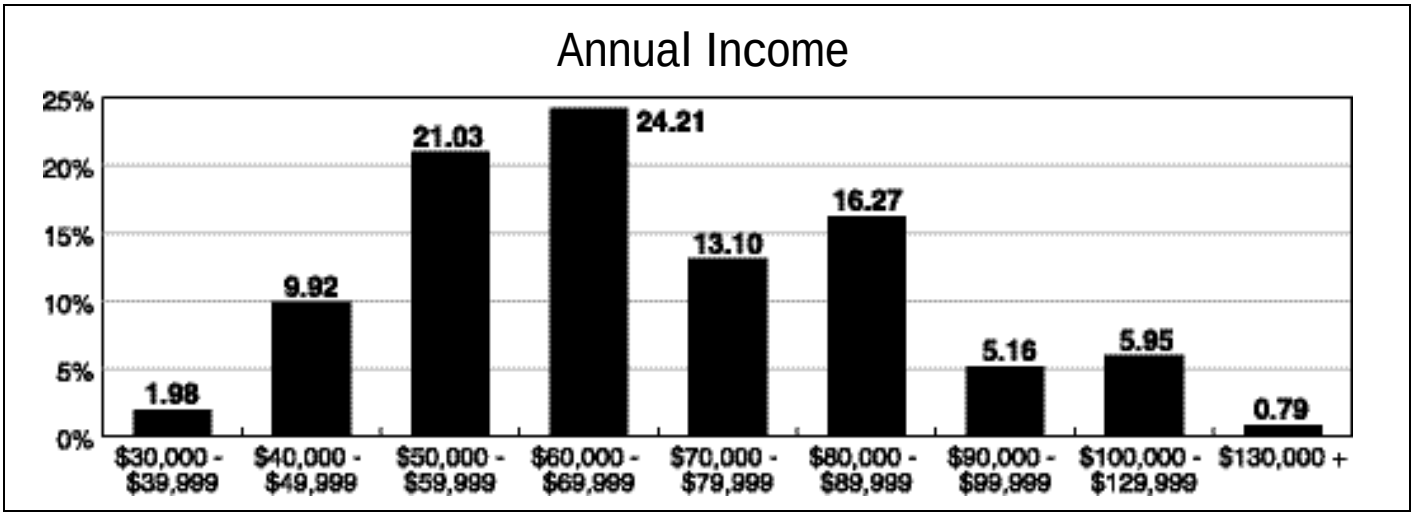
Previous years have shown an upward trend in income, but this year's results suggest that risk managers' incomes are about the same as last year's and the year before. In this year's survey, risk management directors report a median income of $65,000, about the same as last year. (Previous surveys had slightly different income brackets for respondents to choose, but the results are different only by $2,500.) Last year's median income was $62,500, the same as for 1999. In previous years, the median income for directors of risk management was in the high $50,000 range. Some of the increase in recent years has been attributed to the dramatic changes in risk managers' job descriptions.

As in most years, the survey shows that about half of the respondents reported an increase of 1%-3% in their income from the past year, though that figure is down slightly to 39%. A solid 30% reported a 4%-6% increase. About 17% reported no change, and the rest reported a decrease. Twenty-one percent report that their staff size has increased in the previous year, while 18% report that it has decreased. The rest report no change.

Risk managers still are working long hours.

How Long Have You Worked in Health Care?





Thirty-seven percent report that they work 46-50 hours per week, and 14% report that they work 51-55 hours per week. Two percent even found the time to fill out the survey while working more than 65 hours per week.

Traditional risk management is on the way out

Geri Amori, PhD, ARM, FASHRM, risk manager with Fletcher Allen Health Care in Burlington, VT, and president of the American Society for Healthcare Risk Management, says health care risk management still is a promising career, but it's not the career that many of you entered years ago. Anyone who expects to continue and thrive in the field must take heed of the dramatic changes in health care and act quickly to adapt, she advises. The changes have been heralded for years as they gradually crept into health care, but Amori says they are now here.

"Traditional risk management, as we've known it, is not a place we want to be anymore," she says. "We need to position ourselves in whatever way we can to be leaders, and particularly to participate in the patient safety arena. That means improving our skills sets, our epidemiological base, our way of thinking — everything that has to do with being proactive in risk management."

Amori expresses a certain degree of urgency when she talks about the need for risk managers to change their way of thinking and to change their position within the health care community. This message has been delivered for a long time, but she says it is no longer just a good idea. It's what you have to do if you want to keep your job.

"We are seen in many circles as being reactive, the Band-Aid people who step in when something goes wrong," she says. "That's the old style of risk management and the health care community has left that behind. Everyone wants to see a very proactive approach, and anyone who clings to the old idea of risk management is going to be undesirable to employers. Part of the problem is that we're too damned tired from all the reactive stuff we manage to spend time on being proactive, but we've got to find a way around that."

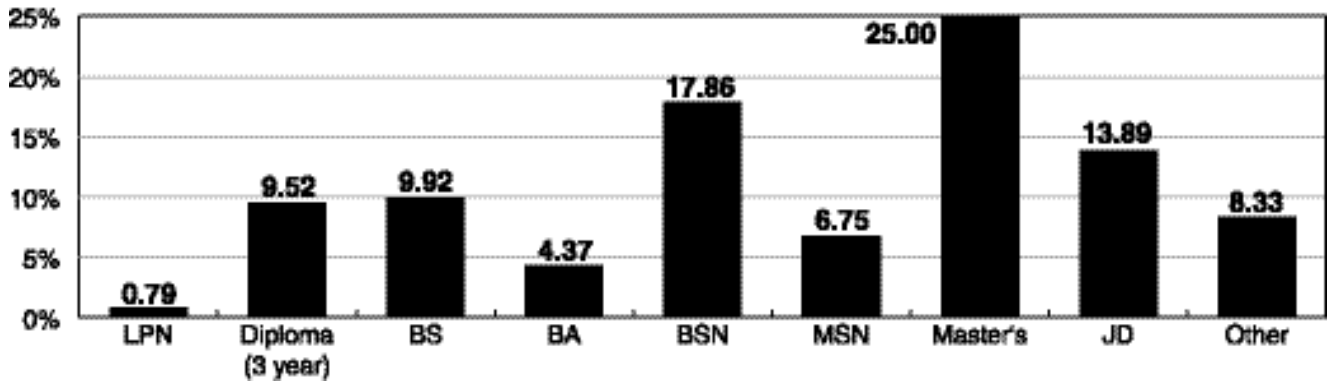
Risk managers must become leaders within the health care organization, not just middle managers, and they must seize opportunities for authority and responsibility, Amori says. The increasing focus on patient safety is a terrific opportunity, but many risk managers are being passed up, she says. Amori says risk managers are the perfect candidates to be patient safety officer but you probably won't get the position unless you lobby for it — and aggressively.

"That position rightly should go to risk management because that is what we've always done, ensure the safety of patients," she says. "But that position is going to other people, new people, and that scares me because it means we're not being seen as proactive."

Amori says that word, "proactive," seems to be the key to a risk manager's future. It is the exact opposite of the stereotype that some health care leaders have of risk managers and it fits the new attitude in the entire industry. While most risk managers aren't eager to take on yet another duty after years of having more responsibilities dumped on their desks, Amori says the patient safety manager is one role you should seek. In many ways, she says, the risk manager title is being phased out and the patient safety manager is taking over. Whether you move into that role or you wave

(Continued on page 4)

What is Your Highest Degree?



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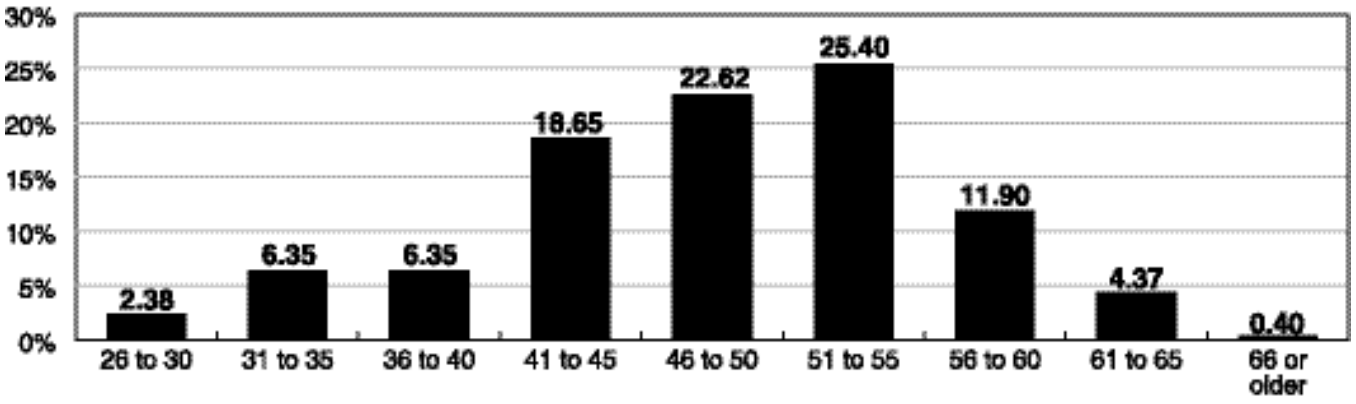
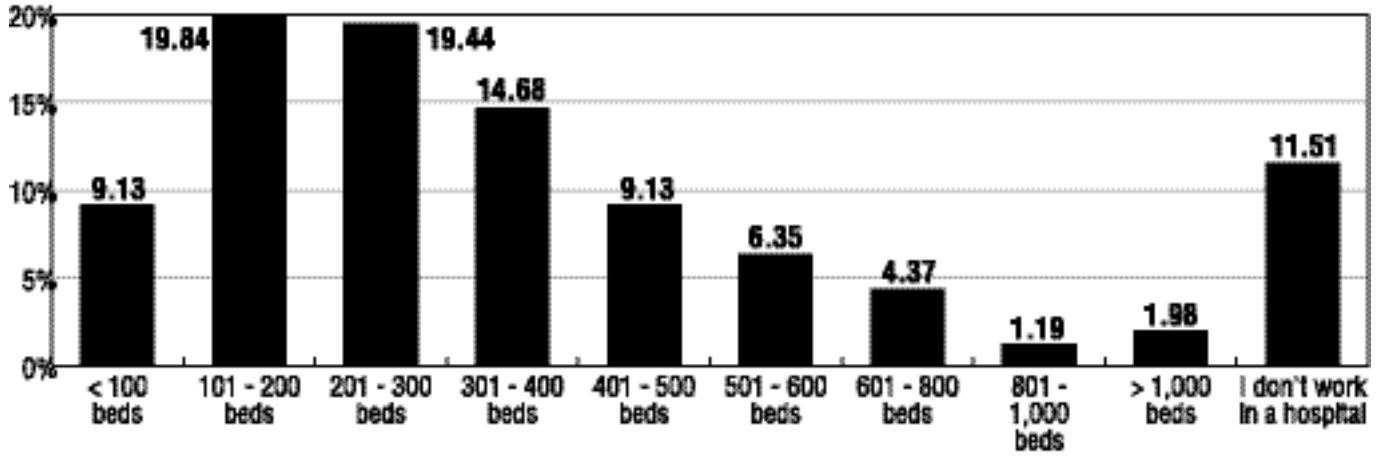


What Size Is Your Hospital?



goodbye as someone new comes in will be determined largely by how you develop new skills.

"To be really useful, you need to be seen as knowledgeable in risk and insurance financing, and you need to be able to show the correlation between proactive risk management, which is really proactive patient safety and the reduction of costs and the protection of assets of the organization," Amori says. "Cost benefits analysis needs to be something we do on a regular basis."

More opportunity to take senior positions

There is reason to be optimistic, says **Fay Rozovsky**, JD, MPH, DFASHRM, a risk management consultant in Richmond, VA. She says many risk managers are rising to a higher level in their organizations, which she calls an extremely positive trend. The higher positions give risk managers more opportunity to be a real player in the organization and have more influence. But the transition can be challenging, she says.

"It's one thing to be a middle manager, and it's another thing to be an officer in that facility," she says. "That kind of advancement is sporadic right now, and much of it is add-on work, which is a concern for those who thought they were stretched already. When you have a whole redesign of your position, that's better. You end up with a the total portfolio for risk under your umbrella, not just the clinical risk side."

The new components in that portfolio probably will include insurance purchasing, risk transfer, safety, and security. And you'll only get that position if you show that you have the skills necessary to manage those issues. Rozovsky urges risk managers to study statistics and quality management, along with insurance. She also points that out health care organizations are finding captive markets much more attractive lately, so a risk manager who can work with a captive market will find more career opportunities.

And remember, it may not be your current employer who can make it possible for you to advance in your career. If you are interested in moving up to a senior management position and taking on more responsibility, you may have to look elsewhere, Rozovsky says.

"Keep up the lifelong learning," she says. "The value that risk managers bring to the table is the knowledge they have, their ability to identify emerging risks in ways that bring value to the organization and ways that reinforce the value of having such an individual in house."

Amori says risk managers need to acknowledge some cold hard facts about their position in the health care industry. It is easy for an experienced risk manager to become complacent and feel like you are working hard, and you probably are, but that's not enough these days. Amori says you must become what the employer wants, even if that's not what you've worked so hard at all these years.

"Health care is changing, and employers are looking for something different," she says. "If we're not value-added, risk managers will be displaced."

Though it is a stereotype, many health care professionals see risk managers as the naysayer who points out what can or did go wrong without contributing much toward how to do things right. That image will sink a risk manager's career, she says.

"We can't be seen as obstreperous and difficult. Rather, we need to be seen as anxious to learn and help the organization," she says. "We need to put on a positive face."

Rozovsky agrees with that advice but emphasizes that the future is bright for risk managers who are willing to adapt. She says you have to "determine what skills you have and what skills you can acquire, then match those up with the organization in just the right way. It's not going to be a situation where any risk manager can take on any risk management job."

Though titles like "patient safety officer" are becoming more common and could one day overtake "risk manager," Amori says that day is not yet here. She does see many risk managers moving into positions like chief risk officer or a similar title, overseeing risk management for multiple facilities or networks. That kind of promotion can come with a substantial increase in income, but Amori says there are relatively few of those positions available. And even if you can snag one of those, all of the other changes in risk management still apply at that level.

"This is not a time to be complacent if you want to have a decent career years from now," she says. "We have to discourage risk managers from being the nice little person in the corner who just deals with bad things when they happen. If risk managers want to build a career for themselves, they need to become leaders — and that means getting out of your comfort zone."

The exclusive 2001 *Healthcare Risk Management* Salary Survey was mailed to about 1,500 readers in the June 2001 issue. A total of 252 were returned, for a response rate of 17%. The results were tabulated and analyzed by American Health Consultants, publisher of *HRM*. ■

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

Failure to diagnose newborn's heart-valve defect: $500,000 judgment in Indiana

By **Jan J. Gorrie**, Esq., and **Mark K. Delegal**, Esq.
Pennington, Moore, Wilkinson, Bell & Dunbar, PA
Tallahassee, FL

News: Shortly after an uneventful labor, delivery, and brief hospitalization, a young mother was discharged from the hospital with her newborn. Eleven days after the birth, the newborn was cranky. The new mother gave the child Tylenol and put him to bed. The next morning, she found him dead. An autopsy revealed that the baby died of an undetected hypoplastic heart valve birth defect. Despite a no-fault finding by a medical review panel, the jury found the hospital and its nurses negligent for not diagnosing the condition and awarded the mother $500,000.

Background: The 16-year-old was expecting her first child. The pregnancy progressed without complications, and she went to the hospital full-term for the delivery. Her labor and delivery were unremarkable. During labor and delivery, her principal caregiver was an OB/GYN resident. However, shortly after delivery, the mother reported to the medical and nursing staff that her infant's limbs appeared blue and purple, and that even when the newborn was bundled for warmth, he had a persistent discoloration.

A neonatologist was consulted. Following his evaluation, the neonatologist told the mother that there were no signs of abnormality with the newborn. Having been medically cleared the next day, the mother and newborn were discharged from the hospital to her mother's home.

Two days later, the mother and newborn were visited at the newborn's grandmother's home by representatives of the hospital's hospice. The hospital's hospice service not only provided standard hospice services but also served to make home visits on newborns delivered at the facility. The hospice personnel did not recognize any problems with the child. However, in the evening eight days later, the infant became particularly irritable. The mother gave him Tylenol and put him to bed. The next morning the mother and grandmother found him dead. The mother attempted CPR, but it was unsuccessful.

An autopsy revealed that the child died from complications from an undiagnosed hypoplastic left heart valve, a defect present at birth. Since the infant's death, the mother married the father of the deceased child and brought suit against the obstetrician, neonatologist, hospital nursing staff, and the representatives of the hospital's hospice service who examined the infant at home after discharge.

The plaintiff alleged that all of the defendants failed to properly detect the heart defect, resulting in a lack of treatment. Since the jurisdiction employs a medical review panel prior to the initiation of any medical malpractice action being taken, the panel reviewed the case. Even though the panel ruled against the plaintiff, the mother still wanted to go to trial. At trial, the young woman maintained that her repeated inquires into her infant's discoloration had been ignored, saying

that neither the nurses nor medical staff noted the queries in her medical chart or that of the child.

The defense raised multiple issues regarding the infant's condition while being cared for at the hospital and contested the mother's recollections of persistent questions regarding the infant's coloration. The defendants maintained that if it was not noted in the charts, it simply did not happen. In particular, one of the hospital's nurses charged with the care of the mother and child indicated that she had regularly checked on the infant and found nothing out of the ordinary. The defense further averred that the hypoplastic heart valve was a birth defect that would undoubtedly have proved fatal under any circumstances, and that even if the defect had been diagnosed at the time of hospitalization, it would not have changed the outcome. The defense maintained that this particular heart defect condition was difficult to detect and did not usually manifest clear signs for diagnosis until six to eight weeks after birth.

Despite the medical review panel's opinion, the jury found the hospital and its nursing staff at fault and awarded the plaintiff $500,000 in damages. The physicians and hospital's hospice staff were exonerated.

What this means to you: Once the labor and delivery are successfully completed and assuming that there is no breach of the standard of care, all eyes are generally focused on the newborn. And, just as untoward things can happen to the mother, the newborn also may call for attention. "Although many states employ one form or another of a medical review panel, this case clearly indicates that as long as juries are free to ignore the panel's rulings, plaintiffs will continue to litigate and take their chances with a jury, especially where there are multiple defendants and particularly when you have a baby in the picture," says **Ellen L. Barton**, JD, CPCU, risk management consultant of Phoenix, MD.

"This case clearly illustrates the ultimate importance of accurate as well as adequate medical records and the necessity to thoroughly explain when and why notations are made in the medical record, especially in the absence of any clearly observable signs and symptoms. Thus, if the form of charting implemented in a particular facility is 'charting by exception,' there will be a greater duty to explain that only findings that are determined to be significant to the care of a patient will be recorded.

"Therefore, when 'charting by exception,' it might be wise to include in the protocol that a patient's complaints / questions are to be noted and responded to in the medical record," Barton continues. "Even though there had been a neonatologist consultation and general charting by a nurse that there was nothing out of the ordinary, it was not sufficient enough to completely exonerate the hospital and nurses in this case. Clearly the hospital and nurses would have been in a much better defense posture if there had been notations to the effect that based on the mother's concerns, the baby had been examined and found to be not discolored. Conversely, it is interesting to note that the hospital's hospice service was absolved — perhaps this has to do with either more careful documentation or the level of care that was being provided."

"While it is stated that the jury found the hospital and its nurses negligent for not diagnosing the condition, it must be remembered that neither a hospital nor a nurse is actually competent to provide a diagnosis. This finding points out that as part of the facility's corporate responsibility, a hospital may be found to have a duty to provide appropriate staff and that such staff — such as the nurses in this case — have a responsibility to notify physicians when a patient's status so indicates," adds Barton.

"Finally, in any evaluation of a medical professional liability case, the sympathetic plaintiff factor must be evaluated. Obviously the plaintiff, despite her age, was able to elicit a great deal of sympathy even though based on the defense expert's testimony it appears that there was no breach in the standard of care. The young mother, who had to awaken to a dead newborn, which she was unable to revive, certainly fell into that category, even though there was no apparent negligence of the part of the medical team," concludes Barton.

Reference

• *Campbell vs. Methodist Hospital, et al.*, Marion County (IN) Superior Court, Case No. 49D-9710-CT-1413. ■

Share your expertise with other readers

Anyone wishing to be considered as a commentator for *Legal Review & Commentary* may contact:

• **Jan Gorrie** at (813) 639-9599 or send an e-mail to: jan@penningtonlawfirm.com. ■

4-year-old dies after diagnostic colon test

News: A 4-year-old girl was admitted to a hospital for a colonic motility study to determine the cause of her acute constipation. In preparation for the study, the child underwent a bowel-cleaning procedure and was kept without food or fluids overnight. The next morning, the procedure was performed. Afterward, the child began to vomit profusely and she lost consciousness. Her physician had left the hospital, and the nursing staff failed to closely monitor her . She had seizures and went into cardiac arrest. Although she was transferred to a children's hospital, she was declared brain dead and taken off life support.

The hospital and physicians settled prior to trial for a combined $4.5 million.

Background: The plaintiffs' 4-year-old daughter was admitted to the hospital for a colonic motility study. Because she suffered from severe constipation, the child's pediatrician had recommended that the diagnostic procedure be performed. In preparation for the test, the child underwent a bowel cleaning procedure and was not allowed to have food or liquids overnight. The next morning, she was given Versed and Fentanyl to sedate her during the procedure. During the procedure, an unknown quantity of plain water — water that contained no electrolytes — was flushed through her system.

Immediately following the test, the child began exhibiting signs of electrolyte imbalance and vomited repeatedly. The electrolyte imbalance was neither diagnosed nor treated. At the time, her physician believed that she had overreacted to the sedative, Versed. However, hours after the effects of the sedating drugs should have worn off, the child remained somnolent and the working diagnosis continuted to be overreaction to Versed. During recovery, the physician left the hospital, and although he was called with updates on her condition, he did not return to the hospital to examine to the child. Further, the staff nurse in charge of the child's first six hours of recovery took vital signs only for the first hour of her stay and failed to measure fluid intake and output.

Throughout the rest of the afternoon and evening, the child became less and less responsive. The staff caring for her felt that she was only experiencing an unusual reaction to Versed. Blood tests were not performed until late that evening. The tests revealed that the patient's sodium level (an essential electrolyte) was low and that she was in metabolic acidosis. But despite these adverse results, the medical staff on duty continued with a working diagnosis of Versed sensitivity.

The child never regained full consciousness. She eventually began to experience seizures and, shortly after 11 p.m., she went into cardiac arrest. During resuscitation, the transport team from the neighboring children's hospital arrived and determined that the child's low sodium level was the cause of her life-threatening condition. She was transferred immediately to the children's hospital where two days later, in the early morning hours, she was declared brain dead and taken off life support.

The plaintiffs claimed that the two defendant nurses and four defendant physicians were negligent when they failed to properly measure and monitor and child's fluid status and vital signs. The plaintiffs also averred that the health care professionals' failure to recognize that the child's depressed level of consciousness was due to an electrolyte imbalance (not an overreaction to sedating drugs) and failure to properly respond to the need to modify her low serum sodium level were clear breaches of the standard of care.

The plaintiffs also claimed that when the physicians and nurses failed to order brain-imaging studies after the child started seizing, they were again negligent. The plaintiffs contended that proper monitoring, diagnostic testing, and treatment would have corrected the electrolyte imbalance and avoided the child's death.

This wrongful death case settled prior to going to trial for $4.5 million with all providers contributing.

What this means to you: The medical care and treatment needs of pediatric patients are often very different than that of adults. Once the presumption was made that this child was simply reacting to the Versed, either the physician or nursing staff did not utilize physical findings and data to properly diagnose or re-evaluate the problem. As a result, far too much time elapsed before this pediatric patient's electrolytes were assessed, and even once assessed it seems that it was too late to do anything about it. This begs the question of whether the

staff of this facility was trained to handle the needs of a young pediatric patient, says **Cheryl A. Whiteman**, RN, MSN, CPHRM, a risk manager for Cigna Healthcare of Florida Inc. in Tampa, who says her opinions do not necessarily reflect Cigna's.

A bowel prep for any diagnostic procedure causes the loss of body fluid and the flushing of electrolytes. While adult are susceptible to dehydration and electrolyte imbalance, a small child runs a much higher risk of this type of systemic assault rendered by a bowel cleansing, in this case, for a motility study. An unknown quantity of plain water was flushed through the child's system during the procedure.

Staff should have noted the amount of fluid that was infused, along with the amount that was returned. Not only does water contain no electrolytes; in all likelihood, it literally flushed electrolytes from the child's system. Following the procedure, the pediatric patient's fluid and electrolyte balance was further endangered by the vomiting that she experienced. Certainly at this point, the physician and the nursing staff should have recognized the extent to which her fluid and electrolyte status had been compromised, and blood work should have been urgently drawn and reported. In situations such as this where the child remained somnolent, the physician should have ordered that vital signs and neurological assessment be done on a frequent basis.

Even though the physician didn't explicitly order this type of monitoring, the charge nurse should have recognized the need for frequent vital signs and neurological checks on a child who was not responding appropriately. To obtain one set of vital signs on a child, who is somnolent over a six-hour period post-procedure, is indefensible. While it was reported that the physician was called with updates, it would appear that the information must have been cursory, if not even updated vital signs were made available to him. He, too, should have been asking for more at this point. Further, it would have been reasonable to provide imaging studies in the face of the child's seizures. However, once the child had reached that stage, damage to her brain may have been too advanced to reverse, notes Whiteman.

In conducting a post-event investigation, the risk manager would need to determine whether the facility and its staff were capable of caring for their pediatric population. Since this was not a pediatric facility per se, particular attention to ongoing education would be necessary as would proficiency assessments of staff members caring for the small pediatric population, especially in relation to the services provided, adds Whiteman.

Bottom line: The young patient in this case was denied proper monitoring, diagnostic testing, and treatment. In the face of such poor care, there is no defense. Settlement was the only option for these providers. It would be hoped that this case was settled quickly and quietly and resulted in systemic changes in the way in which the facility handled pediatric cases, states Whiteman.

Reference

• *Parents of Deceased 4-year-old vs. Anonymous Hospital and Anonymous Physicians*, Unknown Massachusetts venue. Andrew C. Meyer, Jr. of Lubin & Meyer in Boston, represented the plaintiffs. ■

PATIENT SAFETY QUARTERLY™

PLANNING FOR NATURAL AND MAN-MADE DISASTERS

Home care poses special challenge in emergencies

Handling the worst Mother Nature has to offer

Most health care providers have an emergency preparedness plan that covers all aspects of how to run the hospital in a disaster, but there may be one glaring omission. Did you include how to care for patients in your health program?

Some home health agencies have contingency plans for providing care in an emergency, especially in severe weather. For some agencies, severe weather is a fact of life. Take New England Lifecare in Westbrook, ME, as one example. Snowstorms and rough winters are routine and require that staff and patients always be prepared for times of limited or difficult travel.

Antoinnette Pierce, RN, New England Lifecare's director of nursing, notes that she had to implement her agency's disaster plan in January when an ice storm ripped through the Northeast.

"There were people without power for up to two weeks," she says. "But we didn't have any situations that jeopardized IV patients. The storm started while we were in the office, so we called the priority patients who were going to be in a bind and gave them instructions."

It's not always the looming snowstorm or hurricane that will affect your operations, as **Kathleen Daoust**, RN, infusion coordinator for the Lee (MA) Visiting Nurses Association (VNA), can attest.

"We had a tornado, and the key is to pre-plan and have systems in place to deal with catastrophic events," she says.

Here are five steps that Pierce and Daoust recommend you take to create your own or fine-tune your existing disaster management plan:

1. Educate and plan ahead.

Every initial visit by a Lee VNA or New England Lifecare nurse requires disaster training for the patient. "When we take a patient on service, we do a lot of ancillary teaching because a lot of our patients are in very rural areas," says Pierce, noting that rurally situated patients heighten the risk of a missed or delayed visit during storms.

For Lee VNA, Daoust says the nurse conducting the initial visit takes the following steps as part of the agency's disaster management plan.

"We teach the patient to manage any problems with their therapy, identify an emergent situation, or troubleshoot a minor problem," notes Daoust. "We leave written information on how to activate assistance if they need it."

The preprinted packet contains information on the patient's specific therapy, as well as information on how to access assistance should the patient require it. The packet provides the patient with the following emergency phone numbers:

— 24 hour pharmacy support;
— home care IV nurse;
— local hospital;
— EMS;
— the patient's doctor.

Lee VNA also uses this as a marketing opportunity. The patient is given a wipe-off board and marker, on which the above emergency phone numbers are listed.

"We leave it with them so the phone numbers are immediately available to them," says Daoust. "It's a marketing tool with our logo, name, and number. It's quite convenient, and patients can write something they want to ask the nurse about so they don't forget. Also, if they have a problem in the future, our name and number is right there,

and they can call and come back into our system if they need to."

The nurse asks the patient and/or caregiver to identify any available support services in the patient's environment.

"It may be someone who lives in their home or even a neighbor or relative with a medical background," says Daoust.

The patient is also taught what to do in case of an environmental emergency, such as how to store materials and care for equipment.

Combined with similar patient education provided during the initial visit, Pierce notes that during the winter, every home infusion patient has an extra day's worth of supplies at all times. Should disaster strike where it would be impossible to visit the patients, they or their caregiver could still administer the infusion.

2. Prioritize.

For some patients, not receiving a visit for a day or two isn't a problem. But for others, the question isn't whether they need to visit but how you'll get to the patient's home. The first step in any disaster plan is to separate the patients who must be seen from those who can wait — not a task you'll want to make as Mother Nature is wreaking havoc outside. "We keep a running board of all our patients," says Pierce. "Even though we use nursing agencies, we're able to keep up to date on what each patient's condition is. We talk to our patients every week, and our agencies also keep us informed. It's according to diagnosis which patients we'll have to get to first."

Lee VNA has a similar system. "We update the IV nurses on a daily basis with a written patient roster," says Daoust, who notes that the roster includes the patient's name, vendor/referral source, current therapy and drugs, as well as any special issues or problems regarding the patient that staff should be aware of. "The roster is updated daily as needed, and we also have weekly team meetings where we discuss and update all personnel on home infusion clients."

By always having patients prioritized, there's no scrambling to review patient charts when the weather takes a serious turn for the worse. Instead, it's a simple matter of getting on the phone.

"We contact the patients who would be jeopardized should they miss a dose or if their care is interrupted," says Pierce. "We make sure they have an alternative in place or enough supplies to get them through until we can get to them." Information provided in the phone call includes:

- **Giving patients options.** In particular, Pierce makes sure patients can contact the rescue squad or a local hospital.
- **Pump education.** Patients are instructed on how to calculate drip rates, in case they lose power and the pumps run out of batteries.

Pierce notes that the above serves as a reminder to the patient education provided during the initial visit.

3. Plant a phone tree.

By having a phone tree in place, the burden of contacting all the required staff doesn't fall on the shoulders of just one or two individuals.

"Our calling tree starts with the general manager," says Pierce. "It notes who each person is responsible for contacting by phone or car phone so staff know what's going on, if there are any immediate needs patient-wise, to let the answering service know the beeper system is down, and who to contact and how to contact them," says Pierce.

4. Back up your backup plan.

The snowstorm hits, so you settle behind your desk and prepare to start the phone tree process and call patients. But when you pick up the phone, the line is dead, and your cell phones don't work. That was just the situation Pierce was faced with during the ice storm. "Our biggest hassle was when the ice brought some towers down, and our beeper system went down with it," she says.

Fortunately, the disaster plan accounted for just such a situation. "Should all communication go down, we have an assigned radio station for our staff to listen to," says Pierce. "Our general manager will contact the radio station and have an announcement made should we not be able to contact people by phone or beeper. "All we want is for them to say that they have an announcement from the GM of New England Lifecare that people who are able to go into the office should do so."

5. Be prepared to tough it out.

Pierce says that her staff are well aware of the nature of Maine winters and are thus well-prepared. "Most of our nurses have their own cell phones and drive Jeeps," she says. "When winter comes, they've got the studded tires on."

Daoust notes that you'll likely have patients who have to be seen, regardless of the patients. Then, it's up to your imagination how to get there.

"We've had nurses park a half mile away from a patient's home and walk there, and other nurses have used snowshoes," she says. "If it's a bad day and you're advised to stay at home, you can bet that any cars that go by are probably visiting nurses." ■

BIOTERRORISM WATCH
Preparing for and responding to biological, chemical and natural disasters

Clinicians must be voice of reason, reassurance now that bioterrorism battle has been joined

The threat is real, but we are far from defenseless

A new era of bioterrorism has begun with the intentional anthrax scares that have left several people dead and many more exposed as this issue went to press.

But amid the shrill coverage of the widening anthrax investigations, the scramble for gas masks and the expected hoarding of Cipro, there must be a voice of calm and reason. That voice must be your own.

Infection control professionals, hospital epidemiologists, and other key clinicians involved in health care bioterrorism readiness and response must set the tone for a panicky public and an uneasy health care work force, emphasizes veteran epidemiologist **William Schaffner**, MD, chairman of preventive medicine at Vanderbilt University School of Medicine in Nashville.

"We have to re-instill a sense of confidence for people who work in the health care system," he says. "Start with the doctors. They are the ones who are going to be more panicked than the nurses."

Restoring calm to health care community

The current situation is reminiscent of the early stages of the HIV epidemic, when there was much anxiety about the communicability of the disease and whether even casual contact would spell a death sentence for health care workers.

In that chilling time of alarmist reactions and burning mattresses, Schaffner recalls that ICPs, epidemiologists, and other clinicians, stepped into the fray to provide calming confidence and accurate risk data.

"I'm beginning to think that we may be in a similar position now," he says. "We could have a very powerful educational and reassuring effect. Everybody's anxious about this, but I think we can diminish the level of anxiety," Schaffner adds.

Infection control methods in place

Health care workers must be educated about bioterrorism agents and provided reassurance that the patient isolation precautions developed by the Centers for Disease Control and Prevention (CDC) are extremely effective, urges Schaffner.[1]

"The barrier precautions are going to work for bioterrorism. Once you get to chemical [weapons] then you get into the whole 'moon suit' issue. But for bioterrorism, we don't need that," he says.

For example, systems of barrier precautions such as gloves, gowns, and masks to isolate patients infected with all manner of infectious diseases are already in place in virtually all U.S. hospitals.

"They work," he says. "Look, we all know pulmonary tuberculosis is communicable. I'm an infectious disease doctor, have been for 30 years. I've seen a lot of patients with tuberculosis, but I have also been meticulous about my use of [face masks and respirators]. My tuberculin test continues to be negative."

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A Bioterrorism Time Line

1155 Barbarossa uses the bodies of dead soldiers to poison the wells at the battle of Tortona.

1346 Mongols catapult corpses of plague victims into the city of Kaffa to infect the defenders.

1763 British commander Sir Jeffrey Amherst ordered the transfers of blankets used by British smallpox victims to Native American tribes, ostensibly as a gesture of goodwill, with the intention of inducing illness.

1970 The United States ends its programs of developing biological agents for use in warfare. The offensive use of such weapons was forbidden by U.S. policy under executive orders of President Richard Nixon.

1972 Soviet Union signs off on Biological and Toxin Weapons Convention, but continues a high-intensity program to develop and produce biological weapons at least through the early 1990s. Hundreds of tons of weaponized anthrax spores are stockpiled, along with dozens of tons of smallpox and plague. Many of these agents are reputed to have been specifically designed to be resistant to common antibiotics.

1984 Members of the Rajneesh cult contaminated salad bars in Oregon with salmonella, resulting in the infection of 751 people. The Paris Police raided a residence suspected of being a safe house for the German Red Army Faction. During the search, they found documentation and a bathtub filled with flasks containing *Clostridium Botulinum.*

1990s Japan's Aum Shinrykyo cult plans attacks using biological agents, specifically, anthrax and botulinum toxin. While these biological attacks were not successful, cult members later implemented the release of sarin nerve gas in the Tokyo subway system.

1995 A U.S. microbiologist with right-wing ties orders bubonic plague cultures by mail. The ease with which he obtained these cultures prompts new legislation to ensure that biologic materials are destined for legitimate medical and scientific purposes.

1998 A variety of feigned exposures to anthrax spores occurred in several U.S. cities including Indianapolis, where a full-scale response by emergency services and public health occurred before the episode was found to be a hoax.

Sources

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2. Bosker G. Bioterrorism: An update for clinicians, pharmacists, and emergency management planners. *Emergency Medicine Reports* (in press) 2001. ■

And anthrax, of course, is not communicable from person to person, reminds Schaffner, who investigated a case of occupational anthrax in an animal-hide worker when he was a epidemiologist for the CDC in the late 1960s.

"The bacteria do not cause a conventional pneumonia," he says. "They replicate locally and then release toxins. Because the bacteria never replicate to very high numbers the person is not communicable. It is not so much an infection as it is an intoxication."

Inordinate fear of anthrax could cause another problem — hoarding and misuse of Ciprofloxacin and other antibiotics. That tactic eventually could contribute to emerging resistance in pathogens such as *Streptococcus pneumoniae,* Schaffner notes.

"It is one thing for a hospital and the health department to develop an inventory in the event of an emergency," he says. "I do not recommend that individuals do that. I'm quite concerned that with antibiotics in their medicine cabinets there will be a temptation to just use it now and again for inadequate reasons in inadequate doses. If there was a recipe for antibiotic resistance — that's it."

More terror than toll

While the anthrax mailing campaign now under way sends out another shock wave with every news report, the tactic will likely result in more terror than actual toll. The rapid administration of antibiotics has offset illness following exposures, the disease is not communicable from those actually infected, and everyone is now on high alert for suspicious mailings.

Indeed, if the wave of anthrax mailings continues, postal-treatment technologies may become a growth industry.

Regardless, anthrax is problematic as a bioweapon because only a certain micron size of the inhaled spore will lodge in the upper lungs where it can release its toxins, says **Allan J. Morrison Jr.**, MD, MSc, FACP, a bioterrorism expert and health care epidemiologist for the Inova Health System in Washington, DC.

"If it is too large, it won't go in," says Morrison, a former member of the U.S. Army Special Forces. "If it's too small, it goes in and moves about freely without ever lodging. This is not as easy as getting a culture, growing it in your home, and the next day having infectious microbes.

"The sizing, preparation, and ability to deliver such a weapon are extremely difficult," he adds.

The Aum Shinrykyo cult in Tokyo attempted at least eight releases of anthrax or botulism during 1990 to 1995 without getting any casualties, he recalls. **(See time line, p. 2.)** Variables such as humidity can come into play, clumping up spores even if they are perfectly sized for inhalation. Anthrax spores bound for human targets are also at the whims of ultraviolet light, rain, and wind dispersal patterns, Morrison says.

"It is a very hostile climate for microbes on planet earth." Morrison says. "The intent may be widespread, but the ability to deliver weapons grade agents is going to be restricted to a very small subgroup. And even among them, they still will require optimal climatic conditions to carry it out. There will be causalities, as in war, but the distinction here is that there has not been widespread infection."

While anthrax is the current weapon of choice, the direst scenarios usually turn to the most feared weapon in the potential arsenal of bioterrorism: smallpox.

"Invariably, I have seen smallpox described as 'highly infectious,'" Schaffner says. "It's not. That is erroneous." For example, during the global eradication efforts in the 1960s, African natives infected with smallpox were often found living with extended families in huts, he adds. "It would usually take two to three incubation periods for smallpox to move through an extended family."

"It doesn't happen all it once. This was a critical concept in the strategy to eradicate smallpox. If you could find smallpox, you could vaccinate around that case and prevent further transmission. If it had been a frighteningly [rapid] communicable disease, that strategy would never have worked," Schaffner explains.

In addition, some medical observers question the certitude of the general consensus that all those vaccinated decades ago are again susceptible to smallpox. They argue that those immunized during the eradication campaign may at least have some greater protection against fatal infection.[2]

Regardless, rather than dropping like flies, as many as 70% of those infected with smallpox actually survive and then have lifelong immunity.

While there are many other agents to discuss and prevention plans to outline in the weeks and months ahead, perhaps the greatest protective factor is the unprecedented level of awareness in the health care system. The world has changed so much since Sept. 11th that hospitals are probably more prepared for bioterrorism than they have ever been. Everywhere, lines of communication have been opened with health departments and affiliated clinics, emergency plans have been reviewed and hot-button phone numbers posted on the wall.

"We're on alert," says **Fran Slater**, RN, MBA, CIC, CPHQ administrative director of performance improvement at Methodist Hospital in Houston. "We are *all* on alert."

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Should clinicians get smallpox vaccinations?

Questions arise, stockpile expansion fast-tracked

The recent decision to accelerate production of a new smallpox vaccine is raising the complex question of whether health care workers — front-line soldiers in the war against bioterrorism — should be immunized against the disease.

As opposed to the current anthrax attacks, a biological release of smallpox would result in incoming patients with an infectious disease. Even health care workers directly exposed to anthrax could be treated with ciprofloxacin and several other antibiotics, so the anthrax vaccine is not a likely candidate for health care.

On the other hand, legitimate questions have been raised about whether health care workers will stay on the job during a smallpox outbreak unless they and their families are rapidly vaccinated. The only known stocks of smallpox virus are held by the United States and Russia, but many bioterrorism experts have warned for years that another nation or group might have secret stocks.

"I think if smallpox [vaccine] became available, we should definitely immunize all the health care workers," says **Martin Evans**, MD, hospital epidemiologist at the University of Kentucky Chandler Medical Center in Lexington. "A lot of people think [health care workers] ought to

be high on the list because they are part of the response team if there was an outbreak in the community. Not to sound self-serving, but I think we ought to immunize the medical community."

But the question currently is somewhat moot because the Centers for Disease Control and Prevention (CDC) is not wavering from its established policy of mobilizing the available vaccine only if smallpox is released. "I'm sure CDC wants to conserve its current stocks for dealing with an outbreak so it could immunize contacts," Evans says. "If [the agency has] already used [its stock] by immunizing all the health care workers in the country, then it won't be able to respond."

15 million doses stockpiled

Currently, there are some 15 million doses of the old smallpox vaccine available, according to Secretary of Health and Human Services **Tommy Thompson,** who recently announced plans to accelerate production of a new smallpox vaccine. Forty million new doses of vaccine are expected to be available by mid-to-late 2002, moving the project up considerably from its original completion date of 2004 or 2005.

The manufacturer of the new vaccine is Acambis Inc. (formerly OraVax) — based in Cambridge, UK, and Cambridge and Canton, MA. The new vaccine will be a purified derivative of the same strain of cowpox virus (vaccinia) that was used in the United States previously, because the old vaccine's efficacy was clearly demonstrated by direct exposures to those infected. While the method of immunization through scarification will be essentially the same, the new vaccine will be produced in a mammalian cell culture that contains no animal protein.

Acambis stated on its web site that it would have no other comment on the project other than to confirm it has "accelerated" its production plans. But when the project was first announced in 2000, company officials said they had the ability to scale up production well beyond the requested 40 million doses. They were even scouting for other global markets. That means the capability to produce smallpox vaccine in abundance is on the horizon, and the question of immunizing health care workers will invariably arise. *Bioterrorism Watch* was unable to get a CDC response on the question as this issue went to press, but CDC director **Jeffrey Koplan**, MD, MPH, outlined the agency's position in an Oct. 2, 2001 Health Alert posted on a CDC web site.

"Smallpox vaccination is not recommended and, as you know, the vaccine is not available to health providers or the public," Koplan said. "In the absence of a confirmed case of smallpox anywhere in the world, there is no need to be vaccinated against smallpox. There also can be severe side effects to the smallpox vaccine, which is another reason we do not recommend vaccination. In the event of an outbreak, the CDC has clear guidelines to swiftly provide vaccine to people exposed to this disease. The vaccine is securely stored for use in the case of an outbreak."

One factor in favor of the CDC's position to rapidly deploy the vaccine — rather than do widespread vaccinations — is that immunization should still be effective several days after a smallpox exposure. In the smallpox global eradication campaign, epidemiologists found they could give vaccine two to three days after an exposure and still protect against the disease. Even at four and five days out, immunization might prevent death. Still, though the new vaccine will be improved in many ways, the hazards and risk factors of introducing cowpox into the human body are expected to be roughly the same as those documented with the old vaccine.

"We are looking at probably about one death per million primary vaccinations," says **D.A. Henderson**, MD, director of the Center for Civilian Biodefense Studies at Johns Hopkins University in Baltimore. "We are looking at one in 300,000 developing post-vaccinal encephalitis — an inflammation of the brain, which occasionally is fatal and sometimes can leave people permanently impaired."

Based on those estimates, if the new stockpile of 40 million doses is eventually rolled out, approximately 40 of those immunized will die, and another 133 will develop encephalitis. In addition to those severe outcomes, the arm lesion created during inoculation can be very large and painful, serving as a reservoir to self-inoculate the eyes or even infect immune-compromised patients.

The downside is real, but as more vaccine becomes available immunization will certainly be discussed at hospitals in previously targeted areas such as New York City and Washington, DC. If they are not immunized in advance, health care workers are going to want vaccine very quickly if they are expected to take care of smallpox patients, says **Allan J. Morrison Jr.**, MD, MSc, FACP, health care epidemiologist for the Inova Health System in Washington, DC. "Forget about smallpox patients. We're talking about taking care of any patients." ■