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INSIDE

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The mission of smallpox transmission: Risk managers seek to minimize trouble

Education about risk is important; thorough planning needed

The federal government's plan for vaccinating key health care workers against smallpox immediately set off warning bells for risk managers. Though it appears the risk for health care providers won't be as bad as some initially feared, that doesn't mean you can take the smallpox vaccinations lightly.

The first concern for many risk managers is the scale of the vaccination plan; few hospitals will be exempt from the recommendations. The Centers for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP) recently recommended smallpox immunization for 510,000 health care workers. All hospitals should designate a smallpox care team that will be immunized first, the committee says. That team should include about 40 health care workers per hospital, including the epidemiologist, infection control staff, 15 emergency department (ED) physicians and nurses, eight intensive care unit (ICU) nurses for adult patients, eight pediatric ICU nurses, one infectious disease consultant, one dermatology consultant, four respiratory therapists, four radiology technicians, two engineers, and selected staff from the security and housekeeping departments.

With that core team vaccinated, the hospital should be able to respond to the first cases of a smallpox outbreak without exposing health care workers unnecessarily, says **Jane Siegal**, MD, who advised ACIP on the issue as a member of the CDC's Healthcare Infection Control Practices Advisory Committee. The exact makeup of the team will be left to the individual hospital to decide, she says.

Treat it like other vaccinations, but still some problems

Risk managers should approach the smallpox vaccination plan like any other vaccinations for health care workers, but with a few exceptions, says **Michael Seitz**, vice president for risk management with Fairview Healthcare Services in Minneapolis, and a board member of the American Society for

Healthcare Risk Management. Many health care workers already receive vaccinations for various diseases, so Seitz suggests you use the same framework as the smallpox vaccinations. There's no need to start from square one just because smallpox is a high-profile, particularly scary disease now, he says.

"I don't see the smallpox vaccination plan being an additional risk for health care employers right now, if you do some things right," Seitz says.

Similar assurances come from risk manager **Gina Pugliese**, RN, MS, vice president of the Premier Safety Institute in Chicago. Though there is no reason to panic, she cautions risk managers that the smallpox vaccination plan will be a major program for each hospital, and one in which the risk manager should be play a significant role. Most health care providers will set up a multidisciplinary committee to make all the key decisions about who will be vaccinated and how. She says the risk manager must sit on that committee.

Employee furloughs were one of the first potential problems that sprung to mind for risk managers. Initial reports suggested that, because employees might spread the virus to others for up to 19 days after vaccination, they would have to be sent home for that time. With staffing shortages already threatening patient safety, the furloughs were considered a genuine threat. But now the CDC reports that, while health care workers who receive smallpox vaccine should keep the vaccination site covered until the scab separates, they would be allowed to care for patients immediately after vaccination.

John Modlin, MD, chairman of the ACIP, says the vaccination site should be covered with absorbent material such as gauze, and "at least a single layer of impermeable acoustic dressing" until the scab separates. But he says the committee recommends against placing health care workers on leave after receiving smallpox vaccinations unless they develop symptoms from the vaccination or do not adhere to infection control precautions.

In a press briefing at the CDC, Modlin stressed that, "The very close contact required for transmission of vaccinia to household contacts is unlikely to occur in the health care setting."

Risk managers should note, however, that not everyone can receive the vaccine. The ACIP recommends that health care workers with eczema, atopic dermatitis, or other skin conditions not be vaccinated. Between 2% and 5% of adults have eczema or atopic dermatitis, Modlin says. Other skin conditions mean that the vaccine may be contraindicated for up to 10%-20% of people.

The vaccine also is contraindicated for pregnant health care workers, those with HIV/AIDS, and other immunocompromised individuals. Modlin says female health care workers should be counseled not to become pregnant for four weeks after vaccination and that health care providers should offer HIV testing before vaccination.

The CDC also announced recently that a network of experts will be available for consultation at any hour in case of bad reactions to the vaccination.

Liability possible if you don't screen workers

Seitz says those contraindications could be the biggest concern for risk managers. If you don't properly screen workers and prevent transmission of the virus to others after vaccination, the

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hospital could be sued, he says. For instance, risk managers may need to think in terms of a wide circle of people the vaccinated employee will contact. The CDC says employees can work after vaccination, but what about those in the workers' homes who might be susceptible to the virus? If anyone in the employee's household has eczema or is immunocompromised, for instance, the CDC says the employee should be excluded from the vaccination program. To properly screen out such situations, the hospital might need to be especially attentive to educating employees about the risk of transmission, Seitz says.

He also raises the issue of how much vaccinated workers should be restricted in the days soon after receiving the vaccine. Should they be prohibited from certain areas in which patients or others are more vulnerable?

"There is a potential liability if we didn't make the proper assessment and caused some additional exposure," he says. "What if someone goes from the emergency department to the obstetrics ward and exposes a father there in the waiting room? He exposes the wife and his newborn, and then people ask why you allowed that employee to spread the virus."

Let's talk immunity

Federal officials are discussing the possibility of providing some type of immunity for health care providers for vaccination-related claims, but Seitz says it is far too early to know if that protection will be available. The publicity over smallpox has heightened the public's awareness and could lead to more lawsuits than those prompted by less sensational infections in the hospital. But he says the risk really comes into play only if you don't take the appropriate precautions. If there's an outbreak of smallpox and people flood the hospital, that's probably less of a liability exposure because that's a community disaster in which transmission is hard to control, he says.

"For the vaccination plan, the community standard will be what everyone else had in place to prevent these accidental transmissions. You will be compared to other hospitals in the area," he says. "If we have a hospital that just wants to close its eyes and not do anything, that's the one that's going to have major problems because they haven't been responsible in getting ready for this." ■

On-call physicians pose a potential EMTALA risk

Two of a risk manager's constant worries can become one major problem if you don't set up your on-call program correctly, cautions an attorney who has seen hospitals run afoul of the Emergency Medical Treatment and Labor Act (EMTALA) because doctors refused to come to the hospital when called.

The problem is that physicians have the right to refuse unless you carefully structure your program to eliminate that risk.

Risk managers have long struggled with the pitfalls of EMTALA, and it's not uncommon to find that physicians won't respond when they are on call. Put those two together and you could have a serious EMTALA violation, according to **Lowell Brown**, JD, a partner with the law firm of Foley and Lardner in Los Angeles. Under EMTALA, hospitals have the obligation to ensure that the physician arrives to care for the patient. But the same law gives the doctor the right to say no.

The statute provides that a hospital must have an on-call panel representing the specialties available on the medical staff to treat patients who

come to the emergency department. EMTALA has always saddled the hospital with more responsibility than the physician, but changes recently proposed by the Centers for Medicare & Medicaid Services (CMS) will only worsen the risk for hospitals, Brown says. The changes were intended to address persistent questions about whether calls should be mandatory or voluntary, but Brown fears they will only reaffirm the doctors' idea that they can refuse calls.

CMS is pushing for a change that would includes the statement that "physicians, including specialists and subspecialists, are not required to be on call at all times." The change also would state "the hospital must have written policies and procedures in place to respond to situations in which a particular specialist is not available or the on-call physician cannot respond because of circumstances beyond the physician's control."

Hospital left with most, but not all, risk

Those additions to EMTALA probably would be welcomed by physicians but they will make the situation worse for hospitals, he says. They will reinforce the physicians' idea that they can turn down calls without extraordinary reasons.

"The law is written in a strange way from the perspective of public policy and getting things done," he says. "The onus is placed on the hospital to make sure call coverage is provided, and hospitals with a Medicare provider agreement are required to have call panels. This is probably one of the biggest problems facing hospitals now. I see it all over the country."

But most hospitals have no actual control over physicians, who are members of the medical staff with privileges though they're not employees of the hospital. When push comes to shove, most hospitals can't force the physician to take a call.

"EMTALA is all about the hospital. The physician can decide whether to take calls or not and the EMTALA violation is going to be on the hospital," Brown says. "That's the bedrock of the problem. They doctor can say no, I don't want to come in, and they know the hospital will be left holding the bag."

The only way to counter that dilemma is by effectively removing the physician's ability to refuse calls, usually through explicit requirements in the medical staff bylaws. Many hospitals don't have that protection in place, Brown says, and the results can be terrible if you get caught in an EMTALA violation. By then, it's too late to put the safeguards in place.

Medical staff can get around bylaws

Medical staff membership and privileges are the only leverage a hospital has over physicians, Brown says, but simply enacting a rule requiring physicians to take calls isn't enough. That's because in most health care organizations the medical staff pretty much governs itself.

"So you could have hospital bylaws saying you have to take calls, but then that will be subjected to political pressures until the medical staff changes it to say calls mandatory only if you're an 'active' staff member. And 'active' staff member will mean the doctor makes a certain number of contacts at the hospital per year," Brown says. "The next thing you know, they will cut their contacts down to get under that threshold and work more at the hospital across town where calls aren't mandatory."

Risk managers must do something to correct the problem because the hospital is the one at risk, Brown says.

"They are the deep pocket," he says. "The EMTALA law says the patient can sue the hospital if he's injured by an EMTALA violation. It says nothing about suing the doctor."

Physicians can be subject to a $50,000 fine and exclusion from Medicare if the violation is flagrant or repeated, but Brown says that is difficult to prove in most cases. Unless the physician is already working at the hospital and just refuses to treat a patient for no good reason, the EMTALA violation can be hard to prove. When a physician is at home or otherwise away, it's much easier to claim that he or she couldn't come to the hospital — or at least make it sound plausible enough to avoid the EMTALA fine.

Remind physicians about their EMTALA risk

So is the situation hopeless for risk managers? Not quite. Brown says a health care risk manager is most definitely at a disadvantage with this problem, but that's no reason to just give up. He recommends a few strategies:

- **Educate physicians about their risk from an EMTALA violation.** While most of the risk lies with the hospital, physicians don't get off scot free when EMTALA is violated. The $50,000 fine might be difficult to pin on physicians, but you don't have to tell them that. You can emphasize

to them that a $50,000 fine is possible, that it would fall entire on their shoulders, and that their insurance probably won't cover it.

• **Remind doctors that their name is attached to a call refusal and EMTALA violation.** "If you have to refuse a patient and transfer him or her, the hospital is required by law to send with the patient the name and address of the call panelist who didn't show up," Brown says. "Make sure they know this and you can even have your staff remind them on the phone when they refuse to come in. People have a harder time refusing the call if they know their name and address will be right there with the patient's chart that shows why they shouldn't have been transferred."

• **When possible, write medical staff bylaws in a way that requires on-call service.** "Medical staff bylaws should require that if you're an active member of the medical staff, you must be available for call service," Brown says. "If it's not in there already, you're going to have a hard time getting it in, in any substantive, effective form, unless the physicians are feeling generous."

If the bylaws are not yet written in the most desirable way, look for every opportunity to improve them. If you must negotiate with physicians over other terms, keep the on-call requirements in mind as something you always want to improve.

• **If your bylaws already are strict about requiring on-call service, never change them.** The Joint Commission requires that medical staff bylaws be set up so that they cannot be altered without agreement between the medical staff and the hospital. Once you have bylaws that make it difficult for physicians to refuse calls, consider those bylaws a tremendous asset and never consider weakening them in that regard. No matter what else you might consider negotiable, the terms for on-call service are off-limits if they already are strict.

"Resist any effort to make call service voluntary," Brown says. "Resist it *very* strongly."

• **Be reasonable and compromise on other points to maintain good relations with physicians.** Because the physicians ultimately have control over whether they will accept calls, it is to your advantage to maintain a good relationship between the hospital and the medical staff. When the hospital and the physicians start to fight over every detail of their relationship, on-call requirements are one of the first targets. Before you know it, the physicians can water down the requirements or interpret them loosely enough to pose EMTALA risks.

"If you get to the point that you're making demands and they're making demands for exorbitant pay for on-call service, it's a no-win situation," Brown says. "Everyone loses. The hospital has the bigger risk, so it has the bigger motivation to avoid that situation."

And don't get overzealous about placing physicians on call. CMS leaves significant discretion for hospitals to devise call schedules that are not overly burdensome to physicians, so Brown says you should try to minimize — without threatening patient safety — how many physicians are on call and how much any one physician is put on call. ■

Joint Commission surveys will change in a big way

It appears the Oakbrook Terrace, IL- based Joint Commission on Accreditation of Healthcare Organizations has heard all the wailing by hospitals across the country and is announcing a major overhaul of the survey process. Under the new system, the accreditation process is supposed to be more relevant to actual patient care and less of a hassle.

The Joint Commission's Board of Commissioners determined that "now is the time for the Joint Commission to take bold action" and "radically revamped the accreditation process," says **John Noble**, MD, board chairman. The new plan, called "Shared Visions — New Pathways," goes into effect January 2004.

Dennis O'Leary, MD, president of the Joint Commission, says the new survey process will be more continuous and eliminate much of the "ramp up" before a scheduled survey. A task force is continuing its efforts to review all Joint Commission standards and eliminate those that are redundant or unnecessary, he says.

"We're consolidating, saying things in a lot fewer words and moving standards to the most appropriate sections," O'Leary says. "We have reduced the number of scorable elements, and that has a significant impact in terms of the burden on accredited organizations."

The new-and-improved system includes these components:

• Streamlined standards and a reduced documentation burden, with more focus on critical patient care issues.

• A self-assessment process intended to support an organization's continuous standards compliance

while freeing up survey time to focus on the most critical patient care issues.

• A system for focusing surveyors on specific areas that need attention during their visit. Organization-specific data are used to highlight those areas.

• A new survey system with six basic components that will replace the standard triennial survey format. The system starts with an opening conference between surveyors and hospital leaders, which is followed by a leadership interview, validation of self-assessment results, a focus on actual patients as the framework for assessing compliance with selected standards, discussion and education on key issues, and a closing conference.

• More training, requirements, certification, and an enhanced role for surveyors. Surveyors will have to be certified and recertified every five years.

• Revised decision and performance reports providing more meaningful and relevant information.

• The use of ORYX core measure data to identify critical processes and help organizations improve throughout the accreditation cycle.

• Better engagement of physicians in the new accreditation process.

• A new approach to surveying complex organizations.

The self-assessment, in which you look for much of what the surveyors would have looked for in the triennial survey, could be the biggest change for health care providers. An accredited organization will complete the self-assessment at the 18-month point in its three-year accreditation cycle, rating its level of compliance with all standards applicable to that organization.

If you find that your organization is not compliant in any standards area, you must detail the corrective actions that you have taken or will take to comply. Once the information is submitted, a Joint Commission representative will contact you to review the findings, approve the corrective actions, and provide advice on taking those actions. At the 36-month point, the time for the triennial survey, surveyors will visit the site to verify that the corrective actions have been taken. The surveyors also will validate the self-assessment by reviewing specific critical areas.

Providers that are at the midpoint of their accreditation cycles or beyond as of January 2004 (meaning they are due for a survey in July 2005 or after) will receive the self-assessment tool in July 2003 or thereafter. Once you receive the self-assessment tool, you will have three to six months to complete it and plan any corrective actions.

The biggest change during the on-site survey involves what the Joint Commission calls "tracer methodology." In short, surveyors will trace the experience of actual patients through your system to determine compliance with Joint Commission standards instead of quizzing staffers and studying representative documents. That system will focus the survey process much on actual patient care rather than theoretical compliance with standards, says **Russell Massaro**, MD, executive vice president for accreditation operations with the Joint Commission.

"In the past, surveyors might have asked what steps you take to prevent wrong-site surgery and the organization would talk about procedures, education, and other steps," he says.

"In the future, we'll get at the same information but in a different way. We will choose at random from open records a patient who has just had surgery, and we'll trace that patient through the process. The surveyor will go to the ER [emergency room] and ask how they X-rayed the patient, how they obtained consent, and so on. Then if the patient went to a unit, the surveyor will go there and talk about preoperative preparation. Then they'll go to the OR and say, 'When this patient came up, was the site marked? Did you have a time out before you began surgery to discuss whether this was the right patient and what procedure you were doing?'"

All of the questions will be derived from the actual patient's chart, Massaro concludes. ■

GUEST COLUMN

Back to basics: Revisit ED fundamentals to lower risk

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Reducing the risks in an environment as complex as the emergency department requires the support and involvement of decision makers at all levels of the organization. Despite the complexity

of emergency department (ED) liability, sometimes a review of the basics can greatly reduce your risk and improve patient safety.

In my role as a risk management consultant for a health care professional liability insurance company, I am often asked to brief new risk managers, administrators, and clinical managers about the risk management issues in the emergency department. This risk management briefing focuses on some selected troublesome systems, processes, and especially the underlying dynamics that contribute to risk and short-circuit risk-management efforts.

Everyone can benefit

With so many lawsuits and other liabilities stemming from emergency care, any emergency department could benefit from a review of the fundamentals of clinical risk management. The following self-assessment is intended to serve as a guide for discussion among risk managers, frontline and midlevel management, and physician and executive leadership:

- **Management Practices and Support**

Talk with the professional and support staff about their concerns about patient safety, barriers to safe and effective care, and potential solutions. Issues to consider may include space constraints, lack of trained staff, poor communication or substandard equipment.

Ask staff what happens when they are involved in a near miss or adverse outcome. Do they report near misses and is there an effort to learn from the near miss to prevent a repeat? What happens when they are involved in an adverse outcome? Is there a systems-based, root-cause analysis approach, or is the involved staff blamed and admonished? Does a debriefing follow an emotionally charged event?

Explore thresholds for involving administration and risk management. Some EDs have a tendency to sometimes evolve into rather independent entities. It is important to discuss and set expectations regarding when to involve administration and risk management. For example: Does the ED team know and follow the hospital's plan for a coordinated approach to managing adverse outcomes and disclosure? Have ED staff and physicians testified at regulatory or legal proceedings without notifying risk management or administration? Do they report episodes of violence in the ED? Handling violent outbreaks has become a matter of daily practice and may not be reported to risk management, until a serious injury occurs.

Look into oversight

- **Professional Staff**

What are the mechanisms of oversight of the emergency physicians' practice? Emergency physicians are often members of a group practice that contracts with the hospital. Credentialing, peer review and reappointment often are deferred to the contracting group, and the hospital and medical staff may have involvement or oversight.

What is the process used to evaluate the credentialing and oversight practices performed by the contract group? Does anyone review the physician's medical records for quality of care and documentation? Is emergency physician practice evaluated through hospital medical staff quality and peer review processes? What are the physicians' attitudes regarding standardizing care?

In the complex environment of the ED, error reduction will require standardizing practices across the entire health care team. Physicians vary in their acceptance of standardization. Some physicians have adopted clinical protocols for local use, while others voice disdain for standardization. Interim steps include the development of standardized physician orders for common presentations such as chest pain or, at a minimum, discussions about best practices. The expectation and support for standardizing practices has to come from leadership.

How is the on-call physician panel functioning? Many EDs have one or more physicians who are listed on their on-call panel, but who may actively or passively resist this role. These physicians may refuse to respond or may insist that a patient be transferred to an ED that is more convenient for the on-call physician. This is an issue that requires prompt resolution by administration and medical staff leadership. The risks of failing to resolve this issue include avoidance of contacting the on-call physician, perhaps to the detriment of the patient. The organization also may be in violation of federal EMTALA regulations and could be subject to significant fines. A caution is that some ED physicians and nurses will take out their frustration about this issue by complaining to patients and their families, reporting to regulatory agencies or by airing this conflict in the medical record.

Talk to the nurses and physicians, especially those that work nights and weekends, about the availability of any problems related to the on-call

physician panel. Refer problems with the on-call physician panel to the medical staff process and be prepared to provide and seek counsel. Review your medical staff bylaws to be sure they clearly describe the expectations of the on-call physician.

Explore the process for assessing and documenting nurses' competency. Nursing care provided in the ED can be viewed as care provided before or after the emergency physician assesses the patient. The quality of the nursing assessment and decision making that occurs before physician involvement, in the triage process and while the patient is waiting for physician assessment, can make a difference between prompt or delayed diagnosis of a serious condition. Yet, some emergency departments assign less-experienced nurses to the triage function because it has been viewed as a less-desirable position, and because the importance of the nursing assessment and decision making is not understood or optimized.

Talk with the ED nurse manager and ask her or him to describe and show documentation of the requirements for nursing staff experience, training and competency for the various ED nursing roles and functions, and the standardized process for assessing and documenting competency.

Spot-check triage assessment to check quality

- **Triage**

An important goal of nursing triage is to prevent serious delays in diagnosis and treatment. There are several functions that can play a significant role in reducing delays. These include the triage assessment, nursing protocols that allow the nurse to initiate the ordering of selected tests while the patient awaits the availability of the physician, and the reassessment of patients while they await an exam by the physician.

How comprehensive is the triage assessment? A spot-check triage assessment is designed to identify patients with obvious compromise of the airway and breathing, circulation, and other obvious emergent findings. It is important to realize that in some EDs, patients may be sent to the waiting room based only on a spot-check triage assessment, and they may have to wait a variable amount of time for the ED physician to examine them. Some of these patients will have self-limiting minor conditions, but some will have an occult or atypical presentation of a serious condition such as myocardial infarction (MI) or meningitis. The delay may contribute to a critical deterioration in their condition while they are waiting.

What tests may nurses order or perform prior to the physician's assessment of the patient? Many EDs have protocols that allow nurses to initiate tests based on the patient's characteristics, and this can play a role in preventing delays. For example, a pregnancy test conducted as a part of the triage process for selected patients may contribute to a more prompt recognition of an ectopic pregnancy.

Are patients reassessed while waiting for physician assessment? A failure to continue to monitor patients while they await assessment by the physician is a common factor in deterioration of their condition. There should be a method for observation and reassessment of patients who are awaiting physician assessment, whether they are in the waiting room or in the treatment area. It is helpful to review the medical records for evidence of this reassessment.

Participate in a discussion about the emergency department's triage process, nursing protocols for ordering tests and reassessment of the patient. Refer nursing leaders to the article "Potential for Risk Reduction through ISO 9000-based Redesign of Emergency Triage" in the spring 2002 issue (vol. 22, no. 2) of the *Journal of the American Society of Healthcare Risk Management.* This article describes a triage process and provides a sample form that is designed to prompt the triage nurses to assess for and identify patterns of high-risk clinical indicators. Also refer to the Joint Commission on Accreditation of Healthcare Organization's *Sentinel Event Alert*, "Delays in Treatment" (issue 26, June 17, 2002).

Discharge and documentation

- **Discharge Practices**

Is there a documented discharge assessment that reflects resolution or stabilization of the patient's problem? A common finding in claims involving patients whose condition deteriorated after leaving the ED is that problems were not followed to resolution. For example, abnormal vital signs, neurologic problems, difficulty breathing or severe pain were identified, but no further entries documented resolution of the problem. Whether this reflects an actual failure to resolve or stabilize the problem, or just a failure to document the resolution, these cases can result in tragic outcomes and are difficult to defend.

Are the discharge plans and instructions adequate? Discharge instructions should be printed (not handwritten) and legible, and should clearly

state what symptoms should prompt a return to the ED. Any assessment conducted to assure that a responsible adult will be available to assist the patient after discharge should be documented. In some cases a phone call several hours after discharge is appropriate to assess the patient's ongoing status and also serves an important risk management function of connecting with the patient.

Does the ED follow a standard practice for notifying the patient of test results that return after the patient has left the ED? Notification of the patient's private physician may not be considered adequate follow-up. The ED should follow and document a standard process for contacting the patient regarding abnormal test results and necessary follow up. This includes having a process for radiologist review of X-rays initially read by the ED physician, and for notification of the patient as indicated.

Ask for a record review to determine if the records reveal resolution of abnormal findings prior to discharge. Discuss the practices for providing discharge instructions and following up with patient after discharge.

- **Medical Record Documentation**

Review of medical records can be an effective risk management intervention, as the defensibility of claims is contingent on the strength of the documentation. Unfortunately, considerable effort is often involved in conducting medical record reviews that focus on the mechanics of documentation rather than on the content. Medical record review should focus on documentation pertinent to the high-risk practices described in this article and on the common, high-risk emergency conditions such as MI, meningitis, stroke, pulmonary embolism, and appendicitis, among others.

There are also several general issues that need to be considered as important to developing defensible medical records. A key consideration is that the notes should portray a clear picture of how the available subjective and objective data was interpreted to reach a diagnosis and a plan of care. Another issue, addressed previously, is the need to "close the loop" to indicate that abnormalities have been stabilized or resolved prior to discharge.

Putting it all together

It is clear that there is no shortage of information about how to reduce risk and improve patient care and safety in the ED. Evidence-based clinical protocols for managing high-risk conditions are widely available. Information technologies allow nearly instant access to diagnosis support and treatment references. We have learned to examine our adverse events and near misses for risk management lessons. Studies have researched teamwork and communication patterns in the ED. So, why are some EDs more successful at identifying and controlling risks?

Clearly, what is lacking is not information, but an established framework for using the available information to change practice behaviors in a manner that leads to lasting risk reduction. Become familiar with error reduction and teamwork techniques. Consider how high- and low-tech tools can support and standardize changes. For example, while electronic medical records may be the answer to standardizing ED practices, they are not yet widely used. A low-tech solution, such as modifying the ED forms, can be used to prompt nurses to collect specific information and to document the information in a consistent manner. When developing a change in practice, develop a few key audit criteria to support monitoring to be sure the change occurs and continues.

A detailed explanation of an effective framework for continued improvement is available from the Institute for Healthcare Improvement. Check its web site at www.ihi.org, under the tabs Resources and Quality Improvement, for a simple but powerful model that describes a step-by-step process for creating lasting change in the health care environment. ■

OSHA will inspect nursing homes with unusual rates

The Occupational Safety and Health Administration (OSHA) says it soon will begin targeted inspections of nursing and personal care facilities experiencing injury and illness rates higher than the industry average.

OSHA will first target 1,000 facilities that have 14 or more injuries or illnesses resulting in lost workdays for every 100 full-time employees. Then inspectors will move on to facilities with eight or more lost workdays. The nursing home industry has an injury and illness rate more than 2.5 times higher than that of general industry. In 2000, the last year for which data are available, there were almost 75,000 injuries or illnesses resulting in lost workdays among nurses' aides

and orderlies, for an average of almost eight workdays lost due to illness or injury for every 100 full-time employees. The average for general industry is three days.

The Bureau of Labor and Statistics reports that, in 2000, only truck drivers and nonconstruction laborers lost more workdays than nurses' aides and orderlies. OSHA's announcement comes at the end of a 60-day outreach initiative supporting the new National Emphasis Program begun in July, which focused inspection efforts on the hazards most common in nursing and personal care facilities. OSHA data indicate that staff are most frequently injured while moving or handling a resident, or by slips, trips, and falls. Exposure to blood and other potentially infectious materials, or to TB, is a leading cause of illness.

The National Emphasis Program is expected to last until the end of September 2003 unless it is renewed. ■

Survey: Quarter of docs drink alcohol while on call

While most doctors are against drinking any alcohol while on call, nearly one-quarter of the 135 doctors surveyed in a recent study from Hamilton County, TN, admitted to drinking alcohol while on call. Sixty-four percent reported having encountered colleagues whom they suspected had used alcohol, and 27% thought they had seen physicians impaired by alcohol while on call.

Jimmy Wallace, a 1999 graduate of The University of the South in Sewanee, TN, who now is a graduate student in public health at The University of North Carolina in Chapel Hill, received a Tonya Foundation grant for the research through Erlanger Medical Center, which is affiliated with the Chattanooga Unit of the Department of Medicine at the University of Tennessee College of Medicine. He joined **James Peterman**, PhD, professor of philosophy at The University of the South and others to conduct the study (*BMJ* 2002; 325:579-580).

"I think the subject of this study has not been an issue that's been discussed previously. That, in itself, is surprising," Peterman says. "There is no standard rule about what is acceptable (for doctors drinking alcohol while on call), so people then make up their own rules, and there are no rules then for medical students on this. There is ambiguity in doctors minds as to whether on-call time is private time or work time. That's, in a way, the question that needs to be brought out in people's minds, so a decision can be made on it."

The researchers developed a survey with 10 questions to probe doctors' perceptions about their own and their colleagues' use of alcohol while on call. They obtained a list of all doctors in Hamilton County from The American Medical Association, and sent their survey to a 20% random sample from each listed specialty. Of the 206 surveys sent, 135 (65%) responses were returned.

Fourteen percent of the respondents felt that social drinking while on call was acceptable, and one-fourth thought that in their specialty, some alcohol use is safe. Twenty-four percent reported consuming alcohol while on call, but only half of those doctors responded that they report their alcohol use to the patients they treat during that time. In response to asking how many drinks a doctor in their specialty could safely drink while on call, 73% answered zero, 9% answered one, 4% answered two, 5% answered three, and 13% answered four or more. Almost all doctors (98%) believed that patients care whether they use alcohol while on call, but were divided about their obligation to inform patients before seeing them. While sex and specialty were not associated with doctors' responses, older doctors were more likely to report encountering doctors whom they suspected had used or were impaired by alcohol while on call.

"More data need to be obtained about these issues, and the medical profession and society need to discuss the balance between personal freedom and professional obligation to patients," Peterman says. "Medical societies need to include stronger declarations about drinking alcohol while on call in their ethical codes, before the issue is decided for them. There are clear rules and regulations about alcohol use in the aeronautical industry, so there should be in the medical profession, too." ■

Most health providers say patient safety is improved

Despite a work force shortage that contributes to medical errors, 90% of poll respondents at a national gathering of hospital patient safety

experts said they believe their organizations have made a credible effort to improve patient safety. More than a third of the respondents said that hospital pharmacies are addressing patient safety the best within their organizations.

According to 27% of respondents, emergency departments still need the most improvement dealing with patient safety and medical errors. The assessment comes from the patient safety leaders and innovators from health care organizations across the country attended the recent Partnership Symposium 2002: Smart Designs for Patient Safety in Washington, DC. The symposium was the third annual event to bring the patient safety community together with experts from diverse fields to share best practices, approaches and solutions to the patient safety crisis in health care. Of the more than 400 people in attendance, 94 responded to the poll, says **Nancy Wilson**, MD, MPH, chief medical officer of VHA Inc.

"Remarkably, just a year ago, 92% of the attendees said health care wasn't moving fast enough to reduce medical errors," Wilson says. "The results of this poll are truly a positive sign that hospitals are elevating the issue of patient safety and are getting traction."

Patients also are adding to the safer environment. Seventy-seven percent of the respondents indicated that patients have taken a more active role in their care by marking surgical sites and asking more questions.

"The increase in patient involvement is quite reassuring," says **Martin Hatlie**, JD, president of the Partnership for Patient Safety. "There is a lot of rhetoric in the patient safety movement about making the health care system patient-centered, but we cannot achieve that goal until patients become actively involved as partners in adopting a systems approach to ensuring safety. Health care systems need to invite and encourage patients and their families to play that role, and these poll results suggest progress in doing that."

Sixty-four percent of attendees responding to the poll indicated that in addition to a committed effort to improve patient safety, health care organizations have embraced technology as a tool to facilitate improvements. According to the survey, the most commonly used tools include bar coding, bedside computer stations, robotic pharmacy carts, and on-line error-reporting mechanisms. ■

Smallpox vaccinations imminent for hospitals

Know the consequences for your facility

The Atlanta-based Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recently approved a plan that calls for smallpox immunization of 510,000 health care workers.

The plan suggests that all hospitals should designate a "smallpox care team" that will be immunized prior to any release of the virus. The committee recommends that the team include a minimum of 40 health care workers per hospital, with some hospitals vaccinating 100 or more, including emergency department physicians and nurses, infection control professionals, intensive care unit nurses, infectious disease consultants, radiology technicians, respiratory therapists, engineers, security, and housekeeping staff.

To help you prepare for sweeping procedural changes, American Health Consultants offers **Imminent Smallpox Vaccinations in Hospitals: Consequences for You and Your Facility**, a 90-minute audio conference Wednesday, Dec. 11, 2002, from 2-3:30 p.m., EST. This session is designed to help you and your staff answer serious questions and prepare your facility for the inevitable. How will being vaccinated affect you? How do you protect yourself, patients, and family? What are the logistics of implementing a smallpox care team? How do you deal with vulnerable populations? How do you minimize side effects?

This panel discussion will be led by **William Schaffner**, MD, chairman of the department of preventive medicine at Vanderbilt University Medical Center in Nashville, TN. A veteran,

award-winning epidemiologist who has seen actual cases of smallpox and currently oversees a volunteer smallpox vaccine study at Vanderbilt, Schaffner began his distinguished medical career as a medical detective in the CDC's Epidemic Intelligence Service. He also is a liaison member of ACIP. Schaffner and an expert panel of emergency and infection control professionals will help you prepare for this critical task.

The second speaker, **Jane Siegel**, MD, is a professor of pediatrics at the University of Texas Southwestern Medical Center in Dallas. The author of several books on infection control issues, Siegel has emerged in recent years as a key CDC advisor. As a member of the CDC Healthcare Infection Control Practices Advisory Committee, she is on a bioterrorism working group that reviewed the critical issues regarding smallpox vaccine. Showing a clear knowledge of the pros and cons of the various options, Siegel presented the working group's research to ACIP.

The program's third speaker, **Joseph J. Kilpatrick**, RN, NREMT-P, is an adjunct instructor with the Texas A&M University Texas Engineering Extension Service in College Station, where he develops courses and provides training on weapons of mass destruction and emergency medical services (EMS) courses to EMS professionals throughout the United States. Trained as an emergency department and flight nurse, he also recently has worked as an independent nursing contractor, providing critical care, flight, and emergency nursing services to various health care and corporate organizations.

The cost of the program is $299, which includes 1.5 hours of free CE, CME, and critical care credits. ACEP Category I credit approval for the conference is pending. You can educate your entire facility for one low fee. The facility fee also includes handout material, additional reading and references, as well as a compact disc recording of the program for continued reference and staff education.

For more information, or to register, call customer service at (800) 688-2421. When ordering, please refer to effort code **65341**. ■

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

Drug abuse leads to nerve damage, and the settlement is substantial

By **Jan Gorrie**
Buchanan, Ingersoll Professional Corp.
Tampa, FL

News: An orthopedic surgeon with a history of cocaine abuse operated on a patient and severed a nerve root. During the patient's recovery from surgery, the orthopedist's drug use became public knowledge, and he resigned from the medical staff. No other physician was assigned to the patient until follow-up surgery was performed.

Prior to trial, the matter settled with all parties contributing a substantial, yet confidential amount.

Background: the Oklahoma Board of Medical Examiners disciplined the orthopedic surgeon in 1988 for cocaine abuse. After attending rehabilitation, he practiced in Texas for eight years and built a substantial medical practice. To maintain his license, he participated in random drug testing. He was tested on Jan. 12, 1998. On Jan. 21, he performed a multilevel decompressive laminectomy at L5-S1, L4-L5, and L3-L4 on the plaintiff. A positive test result for cocaine came back Jan. 26. He voluntarily reported the result to the hospital. He was suspended from practicing at the hospital.

At this point, the woman still was an inpatient at the hospital, recovering from surgery. A hematoma had developed on her spine. On Feb. 2, the hematoma was surgically removed.

The plaintiffs claimed that the orthopedic surgeon performed surgery that was not necessary, that procedure was negligently performed, that he was under the influence of cocaine and impaired during the time he treated her, and that he severed a nerve root in her back during surgery. The plaintiffs contended there was a good deal of evidence — he had tested positive to a drug test and a toxicologist testified that, based on the physician's own testimony regarding his history of drug usage and the amount that he habitually used over an extended period of time, that his nervous system was more likely than not permanently damaged, rendering him unable to perform surgery properly. In addition, the plaintiff claimed that the orthopedic surgeon's assistant, a general surgeon, was negligent in providing the closure of surgical wound. As a result, they claimed, the patient developed a hematoma resulting in partial paralysis, loss of bladder control, loss of sexual function, and chronic severe pain. She suffered from cauda equina syndrome, a condition caused when blood compresses the nerves and results in nerve death. Plaintiffs claimed that during surgery, she lost 2,200 cubic cm of blood because a drain was not used, causing cauda equina syndrome.

In their lawsuit, the plaintiffs alleged that the hospital was grossly negligent in its postoperative care as well as wrongfully credentialing the surgeon. They contended he should not have been allowed to practice at the hospital, even when initially credentialed because the hospital knew the Oklahoma Board had disciplined him.

In their defense, the physicians and hospital

claimed that an initial MRI showed postoperative changes, but that the hematoma was not detectable at that time. Defendants contended the orthopedic surgeon's care and treatment were appropriate and that surgery was necessary. Further, the hospital maintained that an appropriate postoperative team participated in the plaintiff's care after the orthopedist withdrew from practice.

The patient's past medical expenses were $265,000, including rehabilitation. She was unable to return to work. A loss-of-future-earning claim was made; the amount is unknown. The patient's husband also filed a loss-of-consortium claim.

All defendants participated in a substantial yet confidential settlement prior to trial.

What this means to you: Health care practitioners with a substance abuse problem may often be given a second chance. But that second chance should be accompanied by heightened monitoring, particularly in the credentialing and reappointment processes commensurate with the nature of the health care providers vocation.

"Criteria should be in place for increased monitoring or supervision of a known substance abuser physician. This is one of the questions on the original application for hospital privileges and is also included in the reappointment process; therefore, this person is known to the chief of the particular medical specialty department," states **Joan Bristow**, vice president of risk management for The Doctors Company in Napa, CA. "Either the credentialing or executive committees can make the decision to monitor or supervise and also assign who will actually perform these tasks. Reports should be generated as proof of performance. With a substance abuse history, the physician might be periodically checked for use, by blood or urine testing, as a part of the credentialing and reappointment processes. Just as there is a responsibility to give one a second chance, there is also the primary responsibility to ensure patient safety."

Again, given the nature of the practitioners work, the results of the critical monitoring lab tests should be made as expeditiously as possible. "Although it does take time to run drug screens, there are shorter flash results that are available, similar to 12-hour culture results while waiting for the completed culture of 24-48 hours. While it may not be as accurate as wanted, it would give an alarm to he who receives the results. Another issue here is the question of where the lab results were sent? If the tests were only sent to the physician in question, there is potentially a big gap in follow-up," she observes.

Once an issue is discovered, hospitals, health facilities, and the physician's practice should have mechanisms in place to appropriately handle both the impaired practitioner and their patients. "The critical next step for this hospital might be to determine who should have taken what action and when, then build it into the rules and regulations of the medical staff. In particular, there was a significant period of time — from Jan. 26 until Feb. 2 — when this woman was an inpatient without an attending physician. This is an absolutely unacceptable situation. Every charge nurse, if not the direct-care nurse, has a responsibility to communicate with the attending physician at regular intervals. Most medical staff rules and regulations contain language that addresses the frequency of physician visits to their patients. When more than 24 hours pass without a physician visit, the nurse must first call the attending, and if no response, should go up the chain of command until satisfaction is achieved. This is a nursing responsibility. Of course the out-going physician also has responsibilities. He must replace his care with another physician of the same medical specialty, should give notice to the patient or her family, and document in the medical record that the transfer of patient care goes from himself to the newly assigned physician," remarks Bristow.

As for the medical care provided in this instance, "there are usually standard operating procedures for positive radiology interpretations. When the interpreter recognizes a positive result he/she is obliged to notify the physician who ordered the test and convey those positive findings. There may be a need for additional radiological studies or at least correlation with the patient's physical and current condition that will verify or not the value of the findings. If no policies or procedures address positive interpretations, it might be time to develop these. In addition, it is always interesting to note whether the surgical procedure was emergent, urgent, or elective, and often practitioners do not agree on this. Here it might be wise to develop preoperative criteria that could be applied to orthopedic and neurosurgical patients to justify a need for spinal surgeries. Then when Murphy's law kicks in, and there was an emergent or even urgent need for the procedure, defense is enhanced by alluding to the dire consequences without surgery. This is also an informed consent process issue, to make the patient and family aware of the risk and complications that are associated with the surgery," she concludes.

Reference

• *Loleta Horner and Clarence Horner v. Garland Community Hospital, Ltd., Bruce Hinkley, MD, and Ross Curtess, MD.* Dallas (TX) County District Court, Case No. 00-00748-A. ■

Lidocaine-induced seizures lead to $5.6 million verdict

News: A woman underwent elective breast augmentation and, in addition to general anesthesia, was given lidocaine as a local anesthetic. After surgery, in the recovery room, a nurse on duty noticed the patient was unresponsive and twitching. The surgeon and nurse anesthetist, joined by a cardiologist and a neurologist, saw the patient suffer a grand mal seizure and cardiac arrest. The patient never recovered and now requires around-the-clock medical care. The patient brought suit against all the physicians, the surgicenter, and the nurse anesthetist. After settling with two physicians, a jury awarded an apportioned verdict of $5.6 million.

Background: The 28-year-old patient underwent elective breast augmentation surgery at an outpatient surgical center. Surgery was performed by a plastic surgeon and anesthesia was administered by a certified registered nurse anesthetist (CRNA). Lidocaine, in addition to the general anesthesia, was administered during the procedure. The surgery was uneventful, and the plaintiff was moved to the recovery room.

After a few minutes in the recovery room, a nurse observed the patient twitch and realized the patient was no longer responsive. The recovery room nurse called the surgeon and nurse anesthetist into the room. A blood level for lidocaine was drawn; however, the medical records did not reflect any findings. The surgeon asked a cardiologist, whose office was in the same complex as the surgicenter, to see the patient on an emergency basis. The cardiologist's recommendation was later disputed, but the cardiologist claimed he told the surgeon to intubate the patient and immediately transfer her to the hospital.

The surgeon countered that the cardiologist told him the patient had a neurological problem but was otherwise stable, and called a neurologist.

The neurologist arrived at the outpatient facility 30 minutes later. As he entered the recovery room, the patient had a grand mal seizure and went into cardiac arrest. Paramedics were called and, after 10 minutes of applying multiple medications and electric countershocks to her heart, the patient was resuscitated. The patient was taken to a nearby community hospital, where she was diagnosed with hypoxic encephalopathy.

The plaintiff spent 2½ months in the hospital. She then was transferred to a skilled nursing facility. Her medical condition deteriorated — she suffered pneumonia, decubitus skin ulcers, and pyelonephritis. Eventually, she was moved to a private, specialized neurocare facility. Her condition stabilized and improved somewhat, but she remains at a Rancho Level III (minimally responsive) condition.

The a plaintiff claimed the CRNA failed to recognize and treat her lidocaine-induced seizures, and that she experienced intermittent seizures for more than an hour before she went into cardiac arrest. The plaintiff also added that the attending nurses failed to recognize her increasing heart rate and respiration. Further, she averred that the surgicenter staff and physicians failed to appropriately intervene on her behalf and delayed in calling 911 to transfer her to the hospital.

The plastic surgeon settled prior to trial for a confidential amount. The cardiologist settled during trial for his policy limits, which also were confidential. The jury was told of the separate settlements, but not the amounts. The jury, awarding $5.6 million, found the plastic surgeon 40% negligent, the CRNA 35% negligent, the surgicenter 20% negligent, and cardiologist 5% negligent.

What this means to you: The facility staff seems to have been at complete odds on how to deal with an emergency situation.

"This is the type of situation in which the risk manager should become involved immediately. A patient who begins to twitch and then loses consciousness within minutes of her arrival in the post-anesthesia recovery unit [PACU] following an elective, cosmetic procedure should not have been allowed to languish while specialists were called. The gravity of the circumstances and outcome command review and investigation by risk management," states **Cheryl A. Whiteman**, RN, MSN, CPHRM, a risk manager for Cigna Healthcare of Florida Inc. Her opinion does not necessarily reflect Cigna's.

"The first step in the risk-management investigation would be an evaluation of the pre-operative and postoperative documentation. Was the patient

questioned about allergies, and was her response documented? Assuming that she did not have any known allergies to lidocaine or related drugs, the amount of local lidocaine administered by the surgeon should then be evaluated. As part of the routine in the operating room, the amount of a drug administered locally should be documented. The risk manager should also attempt to retrieve the vials that were used during the case. Having the actual vial[s] would confirm that the correct medication and dosage was administered. This would be a critical part of the investigation as lidocaine-induced seizures can be caused by sensitivity to the drug or by injecting more than the manufacturer's recommended dosages. Patient safety dictates that limiting the amounts and concentrations of a drug available to the practitioner can prevent overdoses. Appropriately, postoperative orders were given to test her blood level for lidocaine. These results would have been helpful in determining whether or not she had a experienced an overdose or sensitivity. However, there is no documentation as to the findings, which raises additional issues regarding the facility's documentation processes and/or cover-up measures. Either way, the indications are not positive," notes Whiteman.

"Second, the risk manager would evaluate whether there were any findings that would have alerted the nurse anesthetist to early seizure activity. A careful review of the vital sign flow sheet for unfavorable trends, regardless of how subtle, should be conducted to determine if there were any indications that should have alerted the CRNA to cardiac and/or neurological compromise," she adds.

"The record as to patient's clinical course over the next 30 minutes is unclear. Documentation should again be reviewed and involved staff members should be interviewed as soon as possible. The report indicates that a nurse observed the patient twitch and subsequently realized the patient was no longer responsive. While the surgeon was called back to the PACU and both cardiology and neurology consults were requested, no medical treatment during the next 30 minutes was reported. The patient's condition and corresponding interventions must be scrutinized. Apparently, the neurologist arrived 30 minutes after the patient initially lost consciousness, but unfortunately his arrival coincided with the patient's grand mal seizure and cardiac arrest," states Whiteman.

"It appears that emergency rescue was summoned when the patient arrested. The activities during the 10-minute interval before their arrival also requires careful investigation. Did the surgicenter have a well-supplied 'crash cart'? Did the staff initiate cardiopulmonary resuscitation? Did the surgicenter have a team capable of providing advanced cardiac life support? The standard of care dictates that these emergency measures be available in a center that administers general anesthesia," she adds.

"Finally, if the risk manager was not immediately involved in the situation, then a retrospective review should be initiated. This situation would lend itself well to a root-cause analysis. Likewise, any facility in which surgery is performed could utilize this case to conduct a failure modes effects analysis exercise in order to identify potential problems within its organization. Regardless of the methodology used for appraisal, every aspect of the situation should be carefully reviewed. Appropriate actions to prevent recurrence need to be undertaken urgently," concludes Whiteman.

Reference

• *Monique Thompson and Brett Thompson v. Richard Bruck, MD, Keith Mathahs, CRNA and Upland Outpatient Surgical Center*, San Bernardino County (CA) Superior Court, Case No. RCV 34534. ■

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2002 Index

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