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Inside: *Bioterrorism Watch*

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When it comes to disaster planning, your current plan is where to start

For most facilities, major revisions or new policies aren't needed

The concern over terrorism has centered on biological attacks since the Sept. 11 attacks and the subsequent anthrax exposures by mail, leading the Joint Commission on Accreditation of Healthcare Organizations to call for a significant improvement in the health care community's preparations. But while industrywide improvements may be needed, security experts tell *Healthcare Risk Management* that most hospitals and other providers can address the problem by shoring up existing policies.

No major revision or new policies will be necessary in most facilities, says **Lee Matthews**, CHPA, CPP, interim executive director of the International Association for Healthcare Security and Safety. The anthrax attacks in October caused a nationwide paranoia about any suspicious powders or mail deliveries, but Matthews points out that almost all of the reports turned out to be false alarms. And because anthrax is not contagious and is difficult to effectively spread, it should not be a major concern for hospitals, he says.

"There are some real concerns, but worrying about your facility getting attacked with something like anthrax is a waste of time. It's just a distraction," he says.

Reducing contagious threats

Even treating anthrax exposures should not pose a major problem to hospitals, he says. The actual substance containing anthrax spores must be contained as a hazardous material, but existing hospital policies on hazardous materials should cover such an event, he says. Treatment for those exposed involves prescribing Cipro, a common antibiotic.

Biological warfare is a serious threat, Matthews says, and other types of pathogens could pose a serious threat to the population while also challenging the health care response. The most worrisome biological threats are those that would be contagious, such as smallpox, he says. An attack with those agents could overwhelm a hospital with patients and possibly cause

a panic in the community. If the population panics, the hospital could be overrun by those seeking medications and treatment, even if they don't need it, he says.

"In those situations, controlling access to your facility becomes one of the primary concerns," Matthews says. "When your community is scared and they see you as the solution, you have to deal with crowds knocking on your door."

Existing policies should cover most scenarios

The good news is that your health care organization should already have policies and procedures in place for dealing with all of those threats, he says. They may need to be improved and re-examined in the light of the terrorist threats, but you shouldn't have to start from scratch. **(For more on how to be sure your emergency preparedness plans will cover terrorism, see *HRM*, November 2001, p. 121.)**

While he urges a calm and reasonable response, he does say that health care risk managers should look into providing more education to their staff and physicians about the nature of bioterrorism. That is one point where his advice coincides with the concerns of the Joint Commission.

On a nationwide level, the Joint Commission is calling on Congress to improve the nation's bioterrorism response capacity by developing system-wide, integrated community approaches to emergency management that are supported at the federal and state levels. And the Joint Commission wants it done quickly.

Joint Commission president **Dennis S. O'Leary**, MD, recently spoke at bioterrorism hearings before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, saying public health systems should be improved.

"We, as a nation, are not unprepared to deal with bioterrorism, but this country's public health and medical care systems could be better prepared than they are today," O'Leary said. "We need to start addressing the identified needs with all due haste."

O'Leary said one of the first priorities should be training medical professionals regarding pathogens that may be used in bioterrorism, to make them aware of the symptoms they produce, knowledgeable about their routes of transmission, and alert to the possibility of their use.

Create a surveillance team

A single, integrated system of response also should be created to effectively address a full range of diseases and rare events, whether of terrorist or natural origins, he said. O'Leary also called for community or statewide capacity analyses of preparedness that would include available medical facilities and delivery sites. A medical / public health surveillance system should be established to promptly detect naturally occurring epidemics as well as terrorist activity, he said, and issues relating to precious national supplies including vaccines and their disbursement need to be evaluated and resolved.

"If the system capabilities are appropriately upgraded, the medical care and public health systems will be able to respond effectively to massive disasters," O'Leary said. ■

Waiving the bill can be your problem solver

Compliance issues may not solve all problems

It happens in restaurants all the time: You have a problem with your meal, so management waives the bill to make up for it. More often than not, everyone walks away satisfied.

Wouldn't the same technique work in the hospital?

Some people may find the idea distasteful and crass when it comes to health care, but some risk managers say waiving the bill can be an effective strategy for making small problems go away. The key, they say, is to be very judicious in deciding how and when to comp the bill. Even those who swear by the technique

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say it is useful only in limited situations.

Steve Johnson, director of risk management for WellStar Health System in Marietta, GA, says waiving the bill is a good addition to a risk manager's toolbox. He has used the technique for years and says it can be the perfect solution for cases in which the patient or family has a relatively small complaint. One of the best uses is a situation in which a visitor claims he or she was injured on hospital property, he says. In those instances, WellStar immediately offers to waive the costs of any immediate emergency care or assessments.

A courtesy and a PR gesture

"It's a little self-serving because it gives us the opportunity to get a clinical snapshot before the person gets off our campus. That can prove useful later on if he or she decides to sue," he says. "We're not admitting liability. It's a courtesy and a public relations gesture. The incident has just happened, so that's the best time to smooth some ruffled feathers and get him or her immediate care without him or her worrying about the cost."

With some minor incidents — for example, a visitor trips and skins a knee — the immediate offer to waive the cost of care is all the patient wants, Johnson says. Those patients often are willing to sign a release saying they won't file a lawsuit.

"On the other hand, how happy are they going to be if they fall on our property and then we send them a bill?" he says. "Even if we're not talking about much money, it's those little things that can set people off."

Not for the big lawsuits

In addition to incidents happening on your own campus, Johnson says waiving the bill can be useful when you just want a minor claim to go away quickly and quietly — either because it is too small to spend time on or because you doubt the veracity of the claim. With a serious claim of medical malpractice or other wrongdoing, he doesn't even consider waiving the bill. The bigger and more substantial the claim, the less likely the plaintiff is going to drop it because you waived the bill. In those cases, offering to waive the bill can seem crass and just anger the other party if you try to settle the matter that way.

That's not to say, however, that you can't waive the bill as part of the negotiating process. The tone in which you offer to waive the bill can make a huge difference, Johnson says. In small cases, you may want to make it clear that you expect the matter to be closed entirely when you waive the bill and even get a signed release to that effect. With bigger claims, you may want to present the comp as merely a goodwill gesture, as in, "Of course we'll be taking care of all your hospital expenses here, so don't worry about that."

Then you just hope that the offer smooths the waters a bit while you negotiate the rest of the settlement.

"We find it most useful with those iffy situations where you don't think you've done anything wrong but you don't want to chew up a lot of money and time to deal with it," he says. "If we're looking at a case where we may have some true liability, I don't think it's morally or ethically right to waive the bill and expect them to sign away their rights just because you did that."

Staff's attitude also affects patients

Johnson offers the example of a patient who complains to management that a nurse was rude. If Johnson's investigation suggests that the story is true, he may think the patient deserves some sort of compensation.

"That sort of thing would not be a compensable claim, but sometimes you just think that we didn't do right by that patient and we need to do something to make it up to him," he says. "We'll go back to that person and say, 'Let us make this small gesture as a way of apologizing.'"

Another example would be miscommunication between the staff and the patient's family that did not directly affect the patient's care but nonetheless frustrated the family. Clinical matters are more difficult to judge, but Johnson says waiving the bill still can be appropriate in those. An example would be missing the call on a fractured arm.

"They go away with pain and find out later that it's fractured," he says. "We look at the film and realize we just flat out missed the call. Now the patient hasn't really suffered because the treatment is the same in the end, so I wouldn't call it a compensable claim with liability. But if the patient has some out-of-pocket and walked around in pain for a couple days, I have no trouble covering those expenses."

On the other hand, if the orthopedic surgeon says the missed diagnosis and delay caused a permanent problem with the arm, that's a different situation, Johnson says. That rises to the level

of a significant, compensable claim and he would not expect to close the claim by waiving the bill.

Insurer offers sample letter when waiving bill

Many insurers recommend waiving the bill as a way to respond to some complaints. Western Professional Insurance Co. (WPIC), for instance, advises its clients that many patients and family members will see waiving the bill as a compassionate gesture. To help you get the right tone when waiving the bill, the insurer offers a sample letter that can be used to notify the patient and document the action. This is part of the letter that WPIC recommends:

"We reviewed and investigated your billing concerns regarding your *[insert specific treatment, exam, or procedure]* on *[insert date]*. We regret that you feel the care given was not satisfactory. The anxiety and frustration you described does not represent the level of service we strive to provide our patients.

"Following a thorough review of the medical records and discussion with clinical personnel, we believe that the care you received was appropriate. *[Consider personalizing this letter by inserting specifics about the results of the investigation.]* However, in the interest of goodwill and on behalf of XYZ Medical Center / Clinic / Physician, I would like to discount / waive the charges on your account.

"The time and effort you have taken to bring these concerns to our attention is greatly appreciated. We take feedback from our patients very seriously, as it provides an opportunity for us to review and improve the services we provide.

"We hope that you are doing well at this time. Please contact me if you have further questions or comments."

More advice from WPIC can be found on its web site at www.physins.com.

Approach patient carefully

Modesty and humility are essential when making the offer, Johnson says. Avoid sounding like you're making a grand gesture and expecting the recipient to be ever so grateful.

"We really see it as a way to do right by people, not as a tool where we're trying to avoid responsibility for serious errors," Johnson says. "It can be exactly what you need in these situations because the compensation fits the level of the problem and both sides feel satisfied. Patients often just want some acknowledgment that you took their claims seriously."

There is usually a short window for deciding to waive the bill, Johnson says. This is a tool best used when the complaint is brand new and people haven't had a chance to stew over it and get entrenched with the idea that they're due a big payoff.

"Do this before it gets to the claim level," he suggests. "This is more the thing to do when they first come to you and say they're unhappy. You might end it all right there if you act quickly."

Johnson has the authority to waive health care bills with just a simple call to the billing department. It's a good idea to send the patient written confirmation that the bill has been waived, he says. The largest bill he has ever waived was about $2,000. Bills in the hundreds of dollars are not a big deal, but waiving thousands of dollars would require serious consideration.

On many occasions, however, Johnson tries to stay behind the scenes when a bill is waived. A nurse manager may call him and explain that a patient was treated poorly, for instance, suggesting that the hospital should not bill for services. If Johnson agrees, he authorizes the waiver and the nurse manager tells the patient. That can keep the patient from getting the idea that the risk manager fears a lawsuit.

No simple solutions

Even if waiving the bill is a good idea strategically and morally, there may be reasons not to, says **Leilani Kicklighter**, RN, ARM, MBA, DASHRM, president of the Kicklighter Group consulting firm in Tamarac, FL, and a past president of the American Society of Healthcare Risk Management. With the increased attention to health care fraud and compliance issues, waiving the bill may not be a simple solution.

"It used to be easier to do these things 10 years ago," she says. "Anytime you're going to do something like that in this day and age, you need to touch base with your compliance officer to make sure it's alright. These issues can get very scary when you're dealing with fraud and abuse."

Medicare regulations, for instance, prohibit billing for substandard care. So Kicklighter wonders if waiving the bill would be a form of compensation and be considered "billing" for care since that money took the place of other money you might have paid out otherwise. It's all very confusing these days, she says.

Kicklighter cautions that health care providers

may be waiving bills more than risk managers realize. Various levels of administration within the health care system may be in the habit of waiving bills without the issue ever reaching the risk manager, she says. That's dangerous, even if you would have made the same decision in the end.

"At a minimum, the risk manager should be involved in these decisions so that you know what's going on in your organization," she says. "You need to know if you're getting the same complaints from some department or if one claim represents more of a risk than the other administrator realizes. There must be some policies and procedures in place so that this is done in an organized way with input from the risk manager and compliance officer, no matter how small the sum of money in question." ■

Disclosure requires some hard choices

Disclosing unanticipated outcomes can be a dicey operation, much more difficult than you might at first imagine; and in some cases, failure to disclose can lead to charges of fraudulent concealment.

That's the cautionary advice from speakers at the recent VHA Clinical Advantage seminar on patient safety in Atlanta, sponsored by the Berwyn, PA-based VHA East. Health care providers should have a formal policy on the release of information about "unanticipated outcomes" — which includes medical errors, but also a range of other occurrences, both good and bad — but writing that policy can be a challenge, says **Grena Porto**, RN, ARM, DFASHRM, senior director of clinical operations at VHA Inc. in Berwyn, PA, and past president of the American Society for Healthcare Risk Management (ASHRM).

"What at first doesn't seem so complicated changes when you try to put it on paper," she says. "You suddenly realize you have a lot of questions."

The key to devising a policy on unanticipated outcomes is to focus on the patient's perspective, Porto says. It won't do to focus more on your needs as a health care provider than on the patient's need for information.

"Patients have really been following this patient safety debate and they're more aware than ever before that they might encounter problems with their care and that they should know about it," she says. "Unfortunately, they can have a negative impression because all they know is what's in the paper, and because we have not done a good job informing them. Remember that patients say their No. 1 problem with health care is that they can't get their providers to talk to them."

Unanticipated outcomes

New patient safety standards that went into effect on July 1 require hospitals to initiate specific efforts to prevent medical errors and to tell patients when they have been harmed during their treatment. The new standards are based both on the Joint Commission on Accreditation of Healthcare Organizations' own six-year experience in overseeing the management of sentinel events in accredited organizations, and on the opinions of a special panel that included patient safety experts as well as leaders from government, hospitals, insurance companies, universities, and consumer advocacy groups.

A new document from ASHRM can help risk managers developing a policy on unanticipated outcomes. "Perspective on Disclosure of Unanticipated Outcome Information" examines the ethical and legal context for withholding information from a patient, liability issues, and some practical concerns about how to disclose information. (The full document is available for free to ASHRM members on the group's web site at www.ashrm.org.)

The ASHRM paper does not spell out exactly how providers should address unanticipated outcomes, but it explores some of the issues and provides a framework that risk managers can use to write their own policy. Each health care organization will have to write its own policy, but Porto cautions against letting it become a bureaucratic boondoggle.

"Avoid the pitfall of trying to define all the terms. Just don't!" she says. "I once saw a disclosure policy that was pages long because they define 'unanticipated,' 'outcome,' 'sentinel event,' 'disclose' — everything. They spent a lot of time and ended up with a policy I could not understand. I told them that if I can't understand it, there's no hope for that tired nurse reading it at 3 a.m."

Porto encourages risk managers to focus on how patients would most like to receive information about unanticipated outcomes. The health care community is still figuring out what that means, but Porto says one thing is clear: Patients

don't think of the issue in the same way as health care professionals.

"This is not about just writing a policy. It's a long journey, and I think that five years from now, we will have much more literature about what patients want and how to give it to them," she says. "Far fewer physicians than patients think that they should disclose adverse events and possible complications. You're going to encounter that resistance from providers, and you should be prepared to overcome it."

One problem with devising a policy is deciding what should be disclosed. If the attendees at the VHA seminar are any indication, *everyone* has an opinion and no two are alike. Only the extreme ends of the spectrum led to consensus. Nearly everyone agreed that a serious medical error causing serious harm to the patient should be disclosed, especially since the patient or family is likely to find out, anyway. And a great many agreed that disclosure was not unnecessary when these conditions were met:

1. The error itself was so small as to be inconsequential.
2. There was no immediate harm to the patient and no possibility of future complications.
3. The patient or family doesn't know and isn't likely to find out.

Lots of gray areas to debate

Nearly everything in between those ends of the spectrum was worthy of heated debate. What if the patient or family doesn't know and isn't likely to find out? What if there was no immediate injury but complications could occur later? What if a doctor finds evidence that the referring physician committed an error but the patient doesn't seem to know?

John Banja, PhD, director of the Center for Ethics in Public Policy and the Professions at Emory University in Atlanta, says there can be some circumstances in which you are not obligated to disclose an unanticipated outcome.

"If the patient is not physically harmed or psychologically harmed, and the patient has no idea something is not right, and the patient requires no further care in response, there is no ethical obligation to disclose," he says. "But that's rare because you can't be sure the patient doesn't know and won't find out later. Remember that the person encouraging the patient to sue is often just someone who saw the error in the patient's chart later on, not an attorney."

Porto agrees that a totally inconsequential incident does not have to be disclosed, but she says those are quite rare. The slightest variation in those three factors for nondisclosure will tip the scales. She offers an example that occurred in her facility years ago. A patient was about to undergo surgery and already had been anesthetized when the OR table collapsed. Luckily, the patient was not injured in any way and was completely unaware. The surgery was rescheduled and performed later without incident.

"There was no injury, and we really thought the patient was not likely to find out," she says. "So did we disclose it? Yes we did, because it was a serious incident."

Think in terms of the patient's best interest

Porto urged the attendees to think in terms of the patient's best interest and not just instinctively seek to protect information that might harm the hospital or physician. That's simply the moral, ethical thing to do, she says, but in most cases it also is the most pragmatic solution for the health care organization.

"Disclosure does not lead to increased claims. The fear of litigation after disclosure is greatly exaggerated," she says. "But it doesn't prevent litigation, either. It's a wash in that respect."

Porto says disclosure does drive down costs by dissipating anger and encouraging a faster resolution of the case. If the circumstances are such that you will eventually have to pay the claim no matter what, denial does nothing but drive up your costs, Porto says.

There also can be a legal duty to disclose, she says. Courts have ruled that the provider/patient relationship is a fiduciary one, and failure to disclose important information could lead to charges of fraud or fraudulent concealment. Porto says she once had a physician sued for malpractice and charged with concealment because he did not disclose a medical error to the patient's family. The surgeon accidentally severed the man's pulmonary artery during a procedure for tuberculosis and the man bled out. He told the family that the patient died from "complications during surgery" but never said he had injured the man.

Eventually, a nurse decided to notify the family and the medical examiner through anonymous letters. The physician settled out of pocket because his malpractice insurance did not cover fraudulent concealment. Porto says the case illustrates two important points: First, the patient or family will

almost always find out, and more elapsed time will only make them angrier and more likely to sue. And second, fraudulent concealment will leave you standing alone at the settlement meeting. Your insurance will not cover it.

What is fraudulent concealment?

"Mere silence can be fraud. There is no need to actually speak a lie," she says. "Are you going to give them the whole truth or are you going to dance around the edges without getting your feet wet? If you ignore or deflect a patient's questions regarding possible errors, that can be fraudulent concealment. Or if you say something true like, 'He died of complications in surgery,' but don't say you caused the complications — that can be fraud."

Porto says many insurers are supportive of disclosure. COPIC, Medical Defense Associates, MMI, and Norcal all support disclosure, she says.

"Carriers are really coming around on this," Porto says. "They'll stand behind you if you do the right thing and do it the right way." **(See article, at right, for tips on how to disclose.)**

Don't focus too much on being defensive

When making a disclosure, Banja says health care providers must be careful not to choose their words so carefully that they defeat the purpose of disclosure. When in doubt, ask yourself why the disclosure is stated the way it is.

"Ethics is, by its nature, 'other-oriented,'" he says. "The ethical action is the one that does not primarily seek to protect the intents of the actor. So if you have a statement whose real function is protecting you, that's probably not the right one if you're truly interested in disclosing to the patient."

Banja also notes that harm from negligence is not covered in the informed consent process, so you still have to disclose errors even if the consent process included a warning that there could be unanticipated developments or outcomes. And if more treatment is necessary to correct the damage done by the error, you probably will need a new informed consent form unless the situation is an emergency.

"That second informed consent can be difficult to obtain," he says. "If you tell them you need it because of an error, they might hesitate to give you permission again. And if you don't disclose, it's hard to get consent again without them asking why." ■

Plan how you'll disclose unanticipated outcomes

In addition to writing a policy on the disclosure of unanticipated outcomes, you should have an actual mechanism in place for responding to an incident, says **Janice Piazza**, RN, MSN, MBA, director of advance learning workshops for VHA East in Berwyn, PA. Don't wait until the next crisis to determine how you will respond.

Sometimes there is little time to make decisions, she says. The hospital or other organization must be ready to respond even if the doctor is available to make a decision about if, when, and how to disclose, she says.

"When the nurse looks at the chart and says, 'Oh no!' on Friday night, the patient is going to ask what's wrong," Piazza says. "You can't just say, 'Let's wait until Monday when the doctor will be in.'"

You also need to decide how you will respond when not all the necessary information is available. Disclosure can be especially difficult when the outcome is dreadfully unexpected but the cause isn't completely understood yet. What do you say?

"You can say that you don't know exactly what happened, but you will inform them as soon as possible," she says. "And you explain how you are looking for an answer."

Disclosure tips

These are some more tips for how to disclose:

• **Work with the patient's and the family's needs, not your own.**

When you need to meet with them again, ask when it is convenient for them, Piazza suggests. Don't say you'll meet them with them next Tuesday at 10 a.m. because that's the only time you can get everyone together. Focus on the patient's and family's needs rather than expecting them to work around your schedule. Remember that they may need time to process the information you've given them, or maybe to get someone else to join them at the next meeting.

• **Encourage physicians to get some advice before disclosing.**

Even when disclosure is necessary, it's not a good idea for a surgeon to walk out of the OR and say, "We made a mistake." It's better for the doctor to consult with the risk manager or a peer, partly

to get some advice, but also just so there is time to calm down and decompress from the incident.

Stephen Prather, MD, senior vice president for physician leadership with VHA, says any physician, nurse, or other clinician about to disclose an unanticipated outcome should first take the time to talk to a peer. The discussion can alleviate some nervousness and fear, and the peer can help determine the best way to approach the patient or family.

"They can go through scenarios and dialogues for how to disclose," he says. "Physicians will be very open to ideas unless they're completely denying there's a problem. The peers should remind them that disclosure is always difficult, even for the most experienced and talented physician."

• **Develop a support system for clinicians who must disclose.**

In addition to developing and publishing a policy, provide resources to clinicians. The materials can include tips on how to best talk with patients and family, with possible dialogues and scenarios.

• **Avoid trying to intimidate a physician into disclosing.**

Sometimes when a physician is reluctant to disclose, the risk manager is tempted to go over his or her head to the department head or director of medicine. Bad idea, says **Grena Porto**, RN, ARM, DFASHRM, senior director of clinical operations at VHA.

"If you force a reluctant physician to disclose, he's probably going to do it badly, and that's not what you want," she says. "It's more productive to find out why the physician is reluctant and try to counter that. If he's afraid he's going to be sued, tell him that's just true and he could be saving himself some legal trouble by disclosing."

• **Pay special attention to residents.**

Residents can pose two different kinds of problems. Either they are too eager to disclose and do so without proper supervision, or they are too afraid to report an error to their attending. And if the attending physician does not know of the error, he or she can't put into motion the process for disclosing it.

• **Remember that disclosure will be stressful for the clinician.**

No matter how seasoned the provider, this moment can be extremely stressful and emotional. Patients and family can become angry with the bearer of bad news, no matter how carefully it is delivered. Be prepared to provide some assistance, perhaps by having peers ready to talk to the person afterward.

• **Don't commit your insurance company to anything.**

Insurance policies usually include a statement that you can't obligate them to pay for anything. Don't let that discourage you from disclosing, but be careful what you say.

You can say, "We amputated the wrong leg." But you can't say, "We amputated the wrong leg, but our insurance will take care of it."

• **Don't be afraid to apologize.**

Apologies are good, Porto says, and they're becoming more common. Human beings respond strongly to someone saying that he or she is sorry, so it can diffuse a lot of anger. California, Texas, Massachusetts, Vermont, and Georgia have laws or case law that prohibits an apology being introduced as evidence. Even in other states, courts are unlikely to see a simple apology as an admission of guilt.

"But sincerity is crucial," Porto says. "Don't think you can make some administrator the 'apologist' and have him or her going around apologizing for everything." ■

OIG: Site visits will work with integrity agreements

The Office of Inspector General (OIG) is offering more information about how site visits will be conducted as part of its corporate integrity agreement (CIA) billing reviews.

In a new section on its web site, the OIG explains the purpose of the site visits, who is subject to them, how entities are selected for site visits, and who at OIG conducts them. The new information also details what kinds of activities typically occur during the site visits, who is present during employee interviews, and whether claims reviews are conducted during the visit. It points out that OIG does not perform unannounced site visits and that entities are given two weeks notice prior to the visits, which are scheduled to minimize disruption to business operations.

The site visit information is part of a larger explanation by the OIG about how CIAs work. The information is available on the Internet at www.oig.hhs.gov/cia/ciafaq1.htm. These are some highlights:

• **Purpose of the site visits:** The primary

purpose of a site visit is to verify the entity's compliance with the terms of its OIG integrity agreement CIA and to provide the OIG with an opportunity to observe an entity's compliance program in practice.

• **Who is subject to a site visit:** Any provider, practitioner, or entity currently under a CIA or other integrity agreement with the OIG is potentially subject to a site visit. Additionally, the OIG occasionally conducts site visits to assess an entity's compliance program during the course of settlement agreement and CIA negotiations. Entities previously visited include hospitals, physician offices, nursing facilities, laboratories, third-party billing companies, Medicare contractors, ambulance companies, durable medical equipment suppliers, and home health agencies.

• **How site visits are selected:** Entities are chosen both at random and based on specific criteria developed by OIG. Factors considered by the OIG in determining whether to conduct a site visit include: issues raised in CIA annual reports, the reporting of deficiencies, comprehensiveness of the compliance program, size of operation, provider type, and degree of cooperation when reporting or responding to OIG requests for information.

• **Who conducts the site visits:** The visits are conducted by attorneys and/or program analysts from the Office of Counsel to the Inspector General.

• **How long a visit lasts:** The average site visit lasts between 1½ to two days. Occasionally, for large entities, site visits may last for three days or more. ■

Courts put limit on parasitic *qui tam* suits

The courts continue to fine-tune the False Claims Act (FCA) with recent rulings establishing limits on what a judge called "parasitic" *qui tam* lawsuits and establishing that such suits cannot be brought in situations in which the government did not suffer a monetary loss.

John Boese, JD, an attorney with Fried Frank in Washington, DC, monitors court developments regarding the FCA, which allows private citizens to bring suit against entities that they allege have defrauded the government. In recent years, these *qui tam* lawsuits have been brought against a number of health care organizations that cheated the government out of health care funds. The individual bringing the lawsuit can recover a substantial portion of the damages.

Inside the False Claims Act

Boese tells *Healthcare Risk Management* that recent court developments have narrowed down some of the ways in which health care providers can be threatened by the False Claims Act. A recent decision by the Ninth Circuit *(Seal 1 v. Seal A*, No. 98-56447, 2001 WL 747588 [9th Cir. July 5, 2001]) establishes "common-sense limitations on the types of suits that may be brought by private citizens under the False Claims Act," Boese says. The Ninth Circuit affirmed the dismissal, under the FCA's "public disclosure bar," of allegations that the relator learned about through the government's own investigations.

Boese says the *Seal 1* case involved two *qui tam* suits filed by the same relator. In the first suit, the relator alleged that Packard-Bell sold the government computers containing used parts while representing that the computers were new. The government declined its opportunity to get involved in the case, but the U.S. Attorney's office initiated civil and criminal investigations into the allegations. At the same time, the Air Force Office of Special Investigation also launched an investigation of Zenith, which was one of Packard-Bell's competitors at the time.

"In the course of these investigations, the U.S. Attorney's office allowed the relator to review documents obtained under a Department of Defense subpoena," Boese says. "Some of those documents implicated Zenith. The relator used information obtained from documents that he reviewed in the U.S. Attorney's office and from conversations with government lawyers to file a separate *qui tam* action against Zenith."

Some time later, the government offered to settle with Zenith, but the relator objected and demanded $8 million dollar share of that settlement. When that dispute was taken to the district court, the judge said no. In fact, the judge dismissed the relator's suit against Zenith altogether, saying that he was not the original source and had based his claims on publicly available information.

Boese explains that the Court of Appeals made an important refinement to one of its earlier public

disclosure decisions. In the earlier decision, *United States ex rel. Barajas v. Northrop Corp.,* 5 F.3d 407 (9th Cir. 1993), the Ninth Circuit held that a person is an "original" source of publicly disclosed information if the person's disclosure was the trigger, even indirectly, of the investigation that gave rise to the public disclosure. Under those circumstances, the person can still qualify to share in an FCA recovery even if it resulted from public information.

Is the relator an original source?

The Ninth Circuit imposed new limitations on the *"Barajas"* test, established earlier as the test for whether a relator is an original source. Boese explains that the court outlined several factors to use. They include looking at the degree to which the relator's information helped uncover the later allegations; the degree to which other private actors helped uncover those allegations; and the degree to which the government played a role in uncovering those allegations; and whether the later allegations are brought against the same entity as the earlier allegations.

"What is most refreshing about this decision is the Ninth Circuit's common-sense approach," Boese says. "This decision reflects this court's view, shared by other circuit courts, that the *qui tam* provisions should be used to recover fraud, not to award parasitic claims. In essence, the court saves Congress from its own poor draftsmanship."

No claim if the government didn't lose money

In another decision, a panel of the Third Circuit Court of Appeals affirmed the dismissal of a *qui tam* action based on alleged false submissions to a United States Bankruptcy Court, holding that the FCA "only prohibits fraudulent claims that cause economic loss to the government." In other words, Boese says, if the government didn't lose any money, you can't recover any damages.

The case was filed by a paralegal who accused his former employer, a law firm, of violating Section 3729(a)(1) of the FCA by submitting inflated legal bills to the Bankruptcy Court *(Hutchins v. Wilentz, Goldman & Spitzer,* Nos. 98-6248, 98-6339, 2001 WL 660936, 2001 U.S. App. LEXIS 12833 [3d Cir. June 13, 2001]). Boese says the relator alleged that the firm inflated charges for LEXIS and Westlaw research time, and billed for secretarial services performed by paralegals. The relator alleged that the submission of inflated legal bills could result in economic injury to the United States if, as a creditor to the bankrupt estate, the government was required to pay inflated legal bills.

The Third Circuit panel didn't buy that argument. That theory would have the effect of expanding FCA liability to reach any false statement made to the government, and that was not Congress's intent, the court said.

A loss to the United States?

Boese explains that the question of whether damages are required to state a claim under the FCA has taken on increasing importance because a growing number of FCA cases are based on legitimate claims submitted while the defendant may not have been in full technical compliance with federal laws or regulations.

"In such cases, it is often argued that the government suffered no injury," he says.

Courts have split on this issue in the past, but Boese says the Third Circuit panel was unequivocal in its ruling, reiterating several times that "the proper inquiry under the False Claims Act is whether the defendant made

fraudulent claims that caused economic loss to the United States Treasury."

State, local governments want to cash in, too

Boese also notes that "a growing number of state and local governments are taking note of the huge recoveries obtained every year under the *qui tam* provisions of the Federal False Claims Act" and are formulating their own state systems for recovering damages. California, Florida, Illinois, the District of Columbia, Nevada, Hawaii, Delaware, and Massachusetts each have *qui tam* false claims laws closely modeled on the federal FCA. Several other states have *qui tam* false claims laws that apply only to health care claims, Boese says.

State laws produce large recoveries

"California has recovered more than $300 million under the California FCA to date in cases involving the financial services industry, and more than $28 million has been recovered under the Florida FCA," he says.

Boese notes that Hawaii and Tennessee, which already had false claims laws on the books, recently enacted laws that build on and expand the reach of the existing laws. He says a $4 million settlement was reached only a few months after the Hawaii FCA was enacted in June 2000, with more than $750,000 paid to the two relators. He says both Hawaii laws are substantially similar to the Federal FCA, but they include some more expansive provisions than those found in the federal law. For example, each of the Hawaii False Claims Laws (like several other state false claims laws, including the new Tennessee law) impose liability upon beneficiaries of inadvertently submitted false claims who subsequently discover the falsity, but fail to disclose it to the state or county government.

Tennessee has had more limited *qui tam* false claims laws on the books that applied only to health care false claims, but Boese says the new Tennessee False Claims Act applies to any "false claim" to an agent of the state or of any political subdivision, and to contractors and grantees of the state, if any of the funds claimed were provided by the state or political subdivision. It contains seven liability provisions that are essentially the same as those contained in the federal FCA, but Boese says the Tennessee law also contains a ninth provision imposing liability on any person who knowingly "makes, uses, or causes to be made or used any false or fraudulent conduct, representation, or practice in order to procure anything of value directly or indirectly from the state or any political subdivision." ■

Handheld computers becoming popular

Experts predict that within a few years, most doctors will use handheld computing devices such as the Palm handhelds or Pocket PC as an integral part of their everyday practice. Some risk

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Editor: **Greg Freeman**, (770) 998-8455
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Coles McKagen**, (404) 262-5420, (coles.mckagen@ahcpub.com).
Managing Editor: **Lee Landenberger**, (404) 262-5483, (lee.landenberger@ahcpub.com).
Production Editor: **Nancy McCreary**.

Editorial Questions

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

managers are urging physicians to use the devices because they can reduce errors by providing more thorough documentation than traditional notes.

The devices can be used to track and update medical records for prescribing, and for billing and practice management. The trend is moving strongly in this direction, according to *Harris Interactive Computing in Physician's Practice,* a report by Harris Interactive in Rochester, NY, but the pace of change suggests that a majority of doctors will not do this for several years.

The proportion of all physicians who use handheld personal devices increased from 15% in 1999 to 26% this year. However, some of these doctors are using the devices mainly for personal activities. The number using them as an integral part of their everyday practice has almost doubled (from 10% in 1999 to 18% this year).

Tech use in the hospital

Use of handheld personal devices is higher among doctors under 45 years old (33%) than among older doctors (21%). It is also higher among those who are wholly or partly hospital-based (33% and 29%) than among those who are mostly office-based (23%). Usage also is higher among physicians in larger practices than in solo or small group practices.

Currently only a few physicians (3%) use handheld devices to track their work for billing purposes, but that is up from only 1% in 1999. Just over a quarter (27%) track their work on a computer (not including those who use handheld devices), a modest increase from 23% in 1999. Half of all practicing physicians (49%) still record their billing codes on cards or notes (down slightly from 54% in 1999). Fifteen percent use billing codes that are generated automatically as part of the clinical record-taking process.

Many physicians who don't currently use handheld devices to take notes in their practice are uncertain about when they will start to use them, but only a minority (29%) does not expect to use them in the next five years. There is clearly a great deal of uncertainty. Only 11% of those not using handheld devices expect to start doing so in the next 18 months. And further, 22% expects to do so in the next five years.

Given these expectations and the current rate of growth in the use of handhelds over the last two years, one can reasonably estimate that about half of all doctors will be using handheld devices by 2004 or 2005. However, this rate of growth could be greatly increased if payers, hospitals and/or group practices mandated their use.

The Leapfrog Group of large employers and many others believe that electronic medical records and electronic prescribing would substantially reduce medical errors and improve the quality of care, and they are pushing hard for their use. Handheld devices are likely to be used for these purposes in many hospitals and practices — so the rate of use may accelerate faster than the estimates given above.

These research findings come from *Harris Interactive Computing in Physician's Practice,* based on interviews with a nationwide sample of 834 practicing physicians surveyed in January and February 2001. For more information, go to the Harris Interactive web site at www.harris interactive.com ■

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

Anesthesia pump malfunction injures patient: $350,000 verdict plus confidential settlement

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

News: Following successful shoulder surgery, a patient was inadvertently overdosed with Demerol via a malfunctioning anesthesia pump. She was found unresponsive more than an hour later. Although she was revived, she has residual cognitive deficits, clinical depression, and post-traumatic stress disorder symptoms. A jury awarded her $350,000 in the claim against the hospital. Her case against the pump manufacturer was settled confidentially.

Background: A 34-year-old licensed practical nurse (LPN) was admitted to the hospital for minor shoulder surgery. During the post-surgery recovery period, she was placed on a Baxter PCA II anesthesia pump, a patient-controlled device for delivering medications. If the pump had operated properly, the patient would have received doses of pain medication within safe parameters. However, the Baxter PCA II unit used by the plaintiff was coupled with a Baxter model 3507 extension set, which did not incorporate an anti-siphon valve. As a result, over a period of 82 minutes, the patient was given approximately 5 cm^3 of Demerol — an overdose.

The plaintiff alleged that the hypoxic event resulted in mild damage, leaving her incapable of experiencing a full range of emotional responses and decreasing her IQ to a level where she is no longer able to function safely as an LPN.

The plaintiff alleged that if the hospital had used the Baxter PCA II pump with the appropriate extension set — one with an anti-siphon valve, costing about 40 cents per set, her injuries would have been prevented. The plaintiff also maintained that nurses incorrectly placed the syringe into the pump, allowing too much Demerol to be released.

In the case against the manufacturer, the plaintiff claimed that it was negligent for Baxter Healthcare to have manufactured and sold extension-set products that did not use an anti-siphon valve feature. The manufacturer entered into a confidential settlement agreement with the plaintiff approximately five months prior to trial.

The defendant hospital argued that Baxter Healthcare was 100% responsible and designated the manufacturer as a nonparty. The hospital denied it was negligent for failing to use extension sets incorporating the anti-siphon valve, arguing that they used the extension set that had been recommended by Baxter Healthcare. The defendant hospital went on to say that the plaintiff did not sustain any organic brain damage and that her current problems were actually caused by depression, a treatable condition.

At trial, the defendant's expert testified that the plaintiff could return to work as an LPN after approximately two months of appropriate mental health therapy. The hospital also denied that its nurses were negligent in the positioning of the

syringe into the Baxter PCA II.

The jury returned a verdict in favor of the plaintiff and awarded $350,000 ($33,000 for medical and related health care expenses, $76,000 for past lost earnings, $200,000 for post-noneconomic damages, and $41,000 for future medical expenses).

What this means to you: "This case raises a number of issues regarding the purchase, maintenance, usage, and updating of equipment used by a hospital in its operating suites, as well as in recovery and/or post-op rooms. It also raises questions relative to the monitoring of patients in post-op by nursing staff, including charting of this information by staff. There could also be some potential issues relative to the application of occurrence/incident reports in the hospital, review or investigation by risk managers of adverse events, and appropriate use of quality improvement/peer review process for enhancement of patient safety and reduction of adverse events. Additionally, this is the type of incident that could lend itself to a root-cause analysis since it appears that there could have been a breakdown in several important processes or systems within the hospital," observes **R. Stephen Trosty**, JD, MHA, HRM, director, Risk Management Consulting, American Physicians Assurance Corp. in East Lansing, MI.

"Specifically, one would first want to look into what the facility's contract was with the equipment manufacturer or vendor to see if the agreement included a hold-harmless clause," notes Trosty. "Generally, risk management should be involved in a hospital's contract review processes so that potential risk management issues may either be addressed directly in such contracts or so that the potential for repercussions can be accessed. Seemingly, there was not a hold-harmless clause; otherwise, once the case against the manufacturer was settled, this claim would have presumably been dropped. Accordingly, the risk manager in this instance should have been aware that the liability for any adverse incidents involving the use of the pump would reside with the hospital."

"Once the risk manager realizes that the facility is potentially liable for the equipment, specific protocols regarding the use of the anesthesia pump should be implemented. Actually, at a minimum, all equipment throughout a facility should be assessed prior to being used on patients. Policies and procedures should be in place to provide for initial and regular maintenance and review of all equipment employed. For instance, with equipment such as the anesthesia pump one might recommend that an equipment log be instituted. A standard usage log should include parameters such as: a) providing general instructions regarding proper use of the equipment as well as note appropriate and inappropriate attachments or extensions; b) indicating when the equipment is used so that a standard maintenance and replacement schedule can be established; and c) offering the opportunity to note any problems with the pump so that they can be appropriately addressed or at least known before the equipment is used again," adds Trosty.

"Additionally, when equipment is first purchased it should be tested and evaluated. Anesthesia pumps are widely used and accepted as customary for patients recovering from surgery, and so one wonders who at the hospital was responsible for regularly checking and assessing equipment that is routinely and regularly utilized. In this case, one questioned whether or not the facility initially evaluated the anesthesia pump to see whether it should have been independently upgraded by adding an anti-siphon value instead of depending upon the existing valve. Presumably, someone at the hospital should have been responsible for maximizing the effectiveness and efficacy of equipment to best address patient safety concerns particularly when equipment is often used. And if the pump was initially evaluated and an anti-siphon valve was not included at that time, personnel responsible for equipment oversight might be questioned as to whether or not the manufacturer issued information on the equipment suggesting that an upgrade was recommended, necessary, or required. Given the fact that the manufacturer settled prior to the case going to trial, it seems that they arguably did have some duty to supply such information and provide purchasers with data on more effective and safer use of their equipment. Further, once the pump was known to have malfunctioned, it is not clear who had the responsibility for assessing and correcting the situation and whether the specific pump was immediately sequestered and independently analyzed as should have occurred. Essentially, the key question and bottom line is why the anesthesia pump was being used with an extension set that did not have a fail-safe anti-siphon valve, particularly in light of the minimal cost involved with the seemingly simple upgrade," Trosty says.

"The equipment purchasing, assessment, and evaluation questions aside, this case raises questions as to whose responsibility it was to handle and address the consequences of an equipment

malfunction. What tests were performed on the patient, if any, to determine extent of her damages after she was found nonresponsive? And, specifically, were any tests performed to determine if the patient sustained any organic brain damage? If such tests were not performed, the risk manager would need to determine why they were not done. Given that the patient was found nonresponsive, she should have been assessed and tested to determine the extent of her injuries, if any, so that she could have been properly treated and cared for following the incident," notes Trosty.

"As for the hospital's nursing staff the following questions come to mind: What was done to determine the positioning of syringe by the nurse? Was there a notation of syringe placement in the chart? Was any notice taken of the placement after the patient was found nonresponsive? What was the training of the nursing staff relative to placement? Was there documentation of training of the nurse involved in the case relative to syringe placement? Was there any evidence that the nurse ever placed a syringe in a manner alleged by the plaintiff to have been incorrect or any evidence that this allegedly incorrect type of placement was routinely used by the hospital or nursing staff? Finally, was there any evidence that the placement of the syringe as it relates to type of extension set used in this case was or was not an issue in caring for this patient?" questions Trosty.

"Further, as to the nursing care, additional questions are raised relative to the risk manager's role in the matter. Was an occurrence report completed? If not, why not? Obviously, once a patient is determined to be nonresponsive and the apparent source is pain medication overdose due to equipment malfunction, an adverse incident report should have been issued. Once such report is issued, it should be the hospital risk manager's duty to conduct an investigation. And, if a report was not issued, the lack thereof should be investigated. Alternatively, if such a report was submitted, were any of the issues raised in this discussion looked at by the risk manager and was any relevant evidence collected during the investigation that could have responded to the allegations? If not, the root causes of the oversight should be examined whether it was because the risk manager overlooked it or because the risk manager could not obtain necessary information. Further, was this occurrence reviewed as part of the facility's quality improvement and / or peer review processes? If not, why not? The hospital and staff should attempt to review existing systems, policies, procedures, equipment usage and upgrading as well as staff training and education to determine what could be learned from this occurrence so that it would not happen again," observes Trosty.

"Specifically as to the post-operative nursing care, one wonders whether the patient was monitored during the 82 minutes following surgery. And, if in fact she was monitored, what was the patient checked for and was any of this post-surgery care charted? This includes questions regarding how often the patient was checked, conversely how often should she have been observed, whether or not the flow of Demerol was assessed as part of the routine post-operative care, and even whether her vital signs were taken, given that when she finally was found she was unresponsive at that point. Further, if the patient was not adequately monitored, the causes of that failure should be examined — was it due to overcrowding in the recovery room, was there an adequate number of staff, and was the staff present adequately trained in post-operative care?" asks Trosty.

"This case leaves many questions about the facility's routine equipment maintenance and operation as well as post-operative nursing care and general risk management practices. In retrospect, it is probably fortunate that the outcome was not even more significant given the basic malfunction of the anesthesia pump and seeming lack of hospital systems to have appropriately addressed the situation," concludes Trosty.

Reference

• *Elsie Bernice Chavez v. Parkview Episcopal Medical Center,* Pueblo County (CO) District Court, Case No. 97-CV-772. ■

No nutritional supervision: $75,000 arbitration award

News: Following gastric bypass surgery, a patient was discharged without any nutritional supervision or instruction. Because of the lack of dietary counseling, the patient was unable to keep food in her system long enough for it to be processed, causing severe malnutrition. Her malnutrition lead to the onset of peripheral neuropathy that contributed to her fracturing her foot. The patient claimed the lack of nutritional counseling and supervision fell below the standard of care and was awarded $75,000 through arbitration.

Background: The 47-year-old woman was admitted to the hospital for nonemergency, scheduled gastric bypass surgery. Neither prior to nor following her discharge from the hospital was the patient given any nutritional supervision, even though the procedure involved her stomach and intestines. While recuperating at home, her food intake was severely limited. She routinely threw up whatever food she ate, including her vitamin supplements. The patient was only able to digest a single container of yogurt a day, which did not contain the necessary vitamin B. This almost complete lack of food intake resulted in severe malnutrition and she developed severe peripheral neuropathy in her upper and lower extremities. The peripheral neuropathy contributed to the fracturing the fifth metatarsal in her right foot. Because of these setbacks, she had a six-week convalescent home stay instead of the more common one- to two-week recovery period after discharge from the hospital.

The plaintiff contended the defendant failed to provide proper nutritional supervision following her gastric bypass procedures. The patient claimed that the lack of nutritional services led to nutritional deficiency, severe peripheral neuropathy, and the fractured foot. The defendants countered that all of the patient's care was within the standard of care and maintained that the neuropathy was not the result of her nutritional deficiency. The defendants also said the patient should have recognized that her food intake level and persistent vomiting required additional medical attention that she failed to seek.

The case went to arbitration, and the patient was awarded $75,000 in damages.

What this means to you: Regardless of the particular diagnosis of any patient, nutritional status and individual nutritional needs should be addressed by the health care team as a part of total patient care. In this case nutritional education is critical to the patient's recovery because the mechanics of digestion have been permanently altered. Most weight loss procedures combine gastric restriction and malabsorption measures. The gastric restriction severely limits the quantity of food that can be consumed. Additionally, the long-term complications of imposed malabsorption include neuropathy as a result of vitamin B_{12} deficiency and osteoporosis as a result of calcium deficiency. Given the significant impact the surgery had on the patient's ability to normally consume and process food, nutritional counseling should have been provided at every step in the care continuum, notes **Cheryl A. Whiteman**, RN, MSN, CPHRM, a risk manager for Cigna Healthcare of Florida Inc., whose opinions do not necessarily reflect Cigna's.

"It is difficult to understand how the defendants could claim that the standard of care was maintained if there was no record of nutritional education. Presumably, had such a record existed, the defendants would have employed it in their defense. At the very least this patient should have received education about the procedure and the resulting digestive needs from her surgeon as part of the informed-consent process for the bypass surgery. After being admitted to the hospital, nutritional education should have been a critical part of the discharge plan. The patient and family members should have received education from the dietitian. Furthermore, reinforcement in the form of written information to refer to would normally be expected. Education regarding the signs and symptoms of dehydration, inadequate nutritional intake, and other complications should have been provided. A mechanism for both short-term and long-term follow-up should have been established. Both the initial dietary instruction and follow-up could be achieved through the physician's office, the hospital's dietitian, or a clinic. Unfortunately, it seems that each was looking to the others to provide this vital service, and ultimately no one did," she adds.

"Risk management should be involved in determining that appropriate programs are in place for services provided. In this case, the unique procedure of gastric bypass did not include the vital element of sound nutritional education and counseling. It is hoped that by correcting this patient's malnutrition, her peripheral neuropathy may be reversed or improved and that her metatarsal fracture would heal over time. Should the defendant continue to provide the service of weight-loss surgery, the facility's risk manager should be involved in determining what services should be provided to future patients to insure that positive outcomes are achieved through education, counseling, and follow-up. Further, the risk manager should not focus only on weight loss surgery. Other programs and services should also be scrutinized to assure that all aspects of total patient care are provided," concludes Whiteman.

Reference

• *Jerilyn Sassorossi v. Kaiser Foundation Hospitals, Kaiser Foundation Health Plan Inc. and Southern California Permanente Medical Group,* Orange County (CA) Superior Court; Brian K. Brandt of Uplant, CA., is the attorney for the plaintiff. ■

BIOTERRORISM WATCH

Preparing for and responding to biological, chemical and nuclear disasters

Flu or anthrax? First inhalational cases yield clues for clinicians to make the critical call

Use case history, blood work, X-rays, rapid tests

There is a postal worker in your emergency department (ED) with flulike symptoms.

That once insignificant observation about occupation and illness now triggers a detailed algorithm created by the Centers for Disease Control and Prevention (CDC) in Atlanta. **(See algorithm, p. 2.)** Is it flu or inhalational anthrax? Whether a realistic question or not, it is what many of your incoming patients may be asking — particularly if another wave of anthrax scares coincides with a nasty influenza season. Many of the initial symptoms are similar, but investigators dealing with the first inhalational anthrax cases have gleaned out key indicators that will help clinicians make the call.

"It is important to take a careful history from the [patients] when they present," says **Julie Gerberding**, MD, acting deputy director of CDC's National Center for Infectious Diseases. "If the [patients are] mail handlers in a professional environment — where they're dealing with large amounts of mail that is not their own — then the index of suspicion should be raised and more testing should be done to be sure there aren't additional clues to suggest that it is not a common viral infection."

Using the first 10 cases of inhalational anthrax as a baseline patient profile, the CDC reports that the median age of the patients was 56 years (range: 43-73 years), and seven were men.[1]

The incubation period from the time of exposure to onset of symptoms when known (seven cases) was seven days (range: five to 11 days).

The initial illness in the patients included fever (nine) and / or sweats / chills (six). Severe fatigue or malaise was present in eight, and minimal or nonproductive cough in nine. One had blood-tinged sputum. Eight patients reported chest discomfort or pleuritic pain. Abdominal pain or nausea or vomiting occurred in five, and five reported chest heaviness. Other symptoms included shortness of breath (seven), headache (five), myalgias (four), and sore throat (two). The mortality rate was 40% for the 10 patients, much lower than historical data indicated. Indeed, one of the critical reasons to recognize inhalational anthrax early is that it is far more treatable than originally thought.

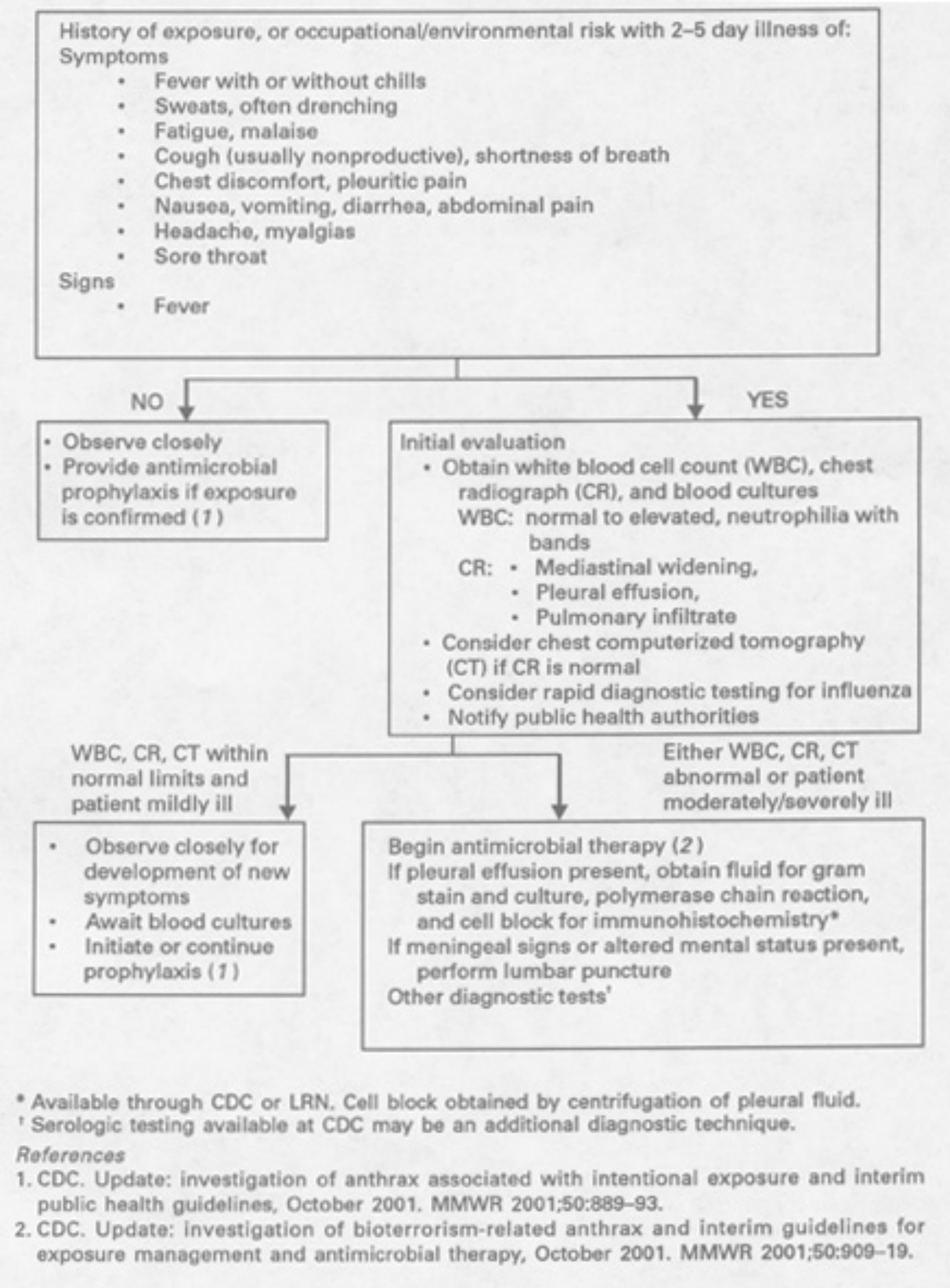
The CDC gathered comparative data on the symptoms and signs of anthrax and influenza, finding, for example, that only 20% of the anthrax patients reported sore throat.[2] Flu sufferers report a sore throat in 64% to 84% of cases. Likewise, 80% of the anthrax cases reported symptoms of nausea and vomiting. That symptom is reported in only 12% of flu cases. Shortness of breath appears to be another key distinguishing symptom, affecting 80% of the anthrax patients but seen in only 6% of flu patients.

"One of the other clues that we are noticing is that the patients with inhalation anthrax actually do not have nasal congestion or a runny nose,"

(Continued on page 3)

This supplement was prepared by Gary Evans, editor of *Hospital Infection Control*. Telephone: (706) 742-2515. E-mail: gary.evans@ahcpub.com.

Clinical Evaluation of People with Possible Inhalational Anthrax



Source: Centers for Disease Control and Prevention. Update: Investigation of bioterrorism-related anthrax and interim guidelines for clinical evaluation of persons with possible anthrax. *MMWR* 2001; 50:945.

Gerberding says. "They don't have the symptoms of an upper-respiratory tract infection. They have a more systemic chest presentation, and that may be another distinguishing characteristic."

Another finding on initial blood work is that none of the inhalational anthrax patients had a low white blood cell count (WBC) or lymphocytosis when initially evaluated. Given that, CDC officials note that future suspect cases with low WBC counts may have viral infections such as influenza. Chest X-rays were abnormal in all patients, but in two an initial reading was interpreted as within normal limits. Mediastinal changes including mediastinal widening were noted in all eight patients who had CT scans. Mediastinal widening may be subtle, and careful review of the chest radiograph by a radiologist may be necessary, the CDC advises.

Complementing the CDC's effort, are the observations of the few clinicians who have actually seen inhalational anthrax cases come into their hospital systems. Two inhalational anthrax cases, both of which survived, were admitted to the Inova Healthcare System in Fairfax, VA (near Washington, DC).

"Clinically, I think the history of the people who presented here is useful," says **Allan J. Morrison Jr.**, MD, MSc, FACP, health care epidemiologist for the Inova system. "They stutter-stepped toward their pulmonary symptoms. That had some mild symptoms and then they were sort of 'meta-stable.' They were not relentlessly progressing. Then they progressed with symptoms more aggressively. Whereas with influenza — in our experience — once you start to get sick, it just keeps on progressing with very high fevers, chills, muscle aches, and pains. As a consequence, we feel there should be a good way to differentiate the two."

Since anthrax is a realistic concern in the Washington, DC, area, what about the aforementioned scenario of symptomatic postal workers in the ED?

"We would take a very aggressive history, not only of occupation but physically where they have been," Morrison says. "If they are symptomatic and have been in or work around a 'hot zone' — a location from which anthrax has either been cultured environmentally or patients have come from there — we will err on the side of being very aggressive about working up anthrax. By that I mean chest X-rays, chemistry profile, [etc.]"

In addition, the hospital system pushed early flu vaccination programs for staff and the surrounding community. "We want to move toward herd immunity," he says. "We are also working with our local hospitals to make sure that they have access to the rapid influenza tests. So for diagnosis — for obvious reasons — it is very helpful to make that distinction early."

One such rapid test is ZstatFlu (ZymeTX Inc., Oklahoma City), which the company claims can yield a diagnosis of influenza A or B some 20 minutes after a throat swab. The test detects neuraminidase, an influenza viral enzyme. However, Gerberding cautions clinicians not to rely solely on such tests. Rather, they should use the results of tests in combination with the patient history and clinical presentation, she says.

"So it is a constellation of history, clinical findings, and laboratory tests," she says. "Hopefully, when we get these all together, we'll be able to at least reduce the anxiety among some people and help clinicians diagnose those patients who really do require the antibiotic treatment. What we don't want to have happen is for everybody coming in with the flu to get an antibiotic because that undermines a whole other set of public health issues relating to antimicrobial resistance and proper management of influenza."

Even the vaccinated can still have flu

Complicating the issue is the fact that the flu vaccine efficacy can vary annually, but is usually 70% to 90% protective, says **Keiji Fukuda**, MD, a medical epidemiologist in the CDC influenza branch. Thus, depending on how well the vaccine matches the circulating strain, a certain portion of flu patients will tell clinicians they have been immunized. But in addition to vaccine breakthrough infections, there is a plethora of other viral and respiratory pathogens that will be creating similar symptoms, he says. In a somewhat sobering reminder — given that at this writing, the total anthrax cases remained in the double digits — Fukuda notes that a typical flu season will send 114,000 people to the hospital and 20,000 to their graves.

"There has been an awful lot of attention on the [anthrax] cases, but the bottom line is that there have been few cases, and these cases generally have occurred in a limited number of communities within a limited number of groups," he says. "And so the epidemiologic message is that anthrax really has not been diagnosed in most parts of the country, whereas we expect to see millions and millions of flu cases all over the place."

If facilities are faced with an onslaught of patients with respiratory illness there are several measures they can take, he notes. Those include:

- Reduce or eliminate elective surgery.
- Relax staff-to-patient ratios within the limits of your licensing agency.
- Emphasize immunizing staff so more staff are available.
- Identify ways to bring in extra staff to help out with the patients.
- Set up walk-in flu clinics to triage the patients.

Reference

1. Centers for Disease Control and Prevention. Update: Investigation of bioterrorism-related anthrax and interim guidelines for clinical evaluation of persons with possible anthrax. *MMWR* 2001; 50:941-948.

2. Centers for Disease Control and Prevention. Consideration for distinguishing influenza-like illness from inhalational anthrax. *MMWR* 2001; 50:984-986. ■

CDC moving quickly on smallpox front

Immunizations, training, vaccine dilution studied

Though officially stating it has no knowledge of any impending use of smallpox as a bioweapon, the Centers for Disease Control and Prevention (CDC) is scrambling with conspicuous speed to be ready for just such an event.

CDC workers from a variety of specialties are not only receiving smallpox vaccinations, they are being trained to give them to others using the old bifurcated needle scarification technique. And, even as creation of a new vaccine is fast-tracked, researchers are trying to determine if the current stockpile of 15.4 million doses can be expanded fivefold by simply diluting the vaccine.

Based on such actions, it is fair to say the agency is at least highly suspicious that the known stocks of smallpox virus are not safely ensconced in their official repositories in Russia and the United States.

"CDC is putting together a number of teams, which will probably total [more than] 100 employees, that could be quickly dispatched in a moment's notice to assist state and local health departments and frontline clinicians investigate suspect cases of smallpox," **Tom Skinner**, a spokesman for the CDC, tells *Bioterrorism Watch.*

"They are Epidemic Intelligence Service (EIS) officers, laboratorians, and others. Part of this includes vaccinating them against smallpox," he explains.

But while confirming that the CDC teams are being trained to administer the vaccine, Skinner would not specify who would be vaccinated following a smallpox bioterror event. "We have a smallpox readiness plan," he says. "Issues around vaccination are covered in that plan. That plan is being finalized. It is considered an operational plan. If we have a case tomorrow, it could be implemented. It covers who should be vaccinated and when."

The general consensus among bioterrorism experts is that those exposed would be vaccinated because the vaccine can prevent infection and possibly death even if given several days out. Likewise, health care workers and their family members would want vaccine if they were expected to care for the infected. Some aspect of quarantine would no doubt come into play because, unlike anthrax, it will be critical to separate the first smallpox cases and their contacts from the susceptible population.

Another aspect of CDC preparations includes the smallpox vaccine dilution study, which is being headed up by **Sharon E. Frey**, MD, associate professor of infectious diseases and immunology at Saint Louis University School of Medicine.

The vaccine, known as Dryvax, is no longer produced, but there are 15.4 million doses left. Frey and colleagues are looking at dilution studies that could maintain vaccine efficacy while increasing the available stock by millions of doses. In a study last year, Frey tried a one to 10 vaccine dilution, which would create a stockpile of more than 150 million doses. However, the resulting vaccine had only a 70% effective rate.

"The undiluted vaccine has about a 95% take rate," she tells *BW*. "It is not perfect, but we would like to be as close to that as we could be."

The new study will include a one to five dilution, which should show greater efficacy while increasing the stockpile to more than 75 million doses.

"We are looking at a 'take' rate for the vaccine, in other words how many people actually develop a typical lesion and whether they have a strong neutralizing antibody response to the vaccine," Frey says. "We know that the vaccine is still good. We actually titered the vaccine and it is very similar to its original titer," she adds. ■

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