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State systems for 'serious reportable events' will require reporting, analysis

Similar to JCAHO's sentinel events, but will be separate obligation

Now that you've gotten used to the idea of sentinel events, get ready for the state equivalent: the list of "serious reportable events" recently adopted by the National Quality Forum (NQF) in Washington, DC.

The list is similar to, but entirely separate from, the sentinel events list used by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The NQF, which developed the serious reportable events list, changed the name from "never events" because that sounded too harsh and allowed no flexibility in identifying the incidents. The NQF board recently approved the list of serious reportable events and will pass it on to other health care organizations for implementation.

Individual states will determine how and when to use the serious reportable events list, says **John Colmers**, a program officer at the Milbank Memorial Fund, an endowed national foundation in New York City that works with decision makers in the public and private sectors on issues of policy for health care and public health. Colmers worked with the NQF to develop the serious reportable events list and says the project was an outgrowth of the Institute of Medicine's (IOM) report on medical errors, *To Err is Human*. That report called for a state-based system for reporting serious medical errors.

"The IOM study anticipated a two-tiered system for reporting medical errors," Colmers says. "One would be a mandatory system for reporting the most serious and egregious events at a state level. The second, and considered by IOM the most important, is a system of voluntary reporting."

The serious reportable errors list can be used for developing both mandatory reporting requirements and encouraging voluntary reporting. The Centers for Medicare and Medicaid Services (CMS), and the Agency for Health Care Policy and Research (AHCPR) funded the research. Colmers says the NQF's job was to develop the list and then hand it over

to CMS and the AHCPR for implementation.

The list looks like another version of the Joint Commission's sentinel events but drawn up by a different committee. Critics are suggesting that the NQF's new list duplicates the sentinel event system and will only create a dual track of reporting with unnecessary and redundant work.

According to the NQF report, the core set of events are "of concern to both the public and health care providers; clearly identifiable and thus feasible to include in a reporting system; and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the health care facility." To qualify for this core list of serious reportable events, an event must be unambiguous, usually preventable, serious, and any of the following:

- adverse and/or;
- indicative of a problem in a health care facility's safety systems and/or;
- important for public credibility or public accountability.

The NQF report says that the term "usually preventable" recognizes that some of these events are not always avoidable given the complexity of health care. "The presence of an event on the list, therefore, is not a priority judgment either of a systems failure or lack of due care," the report says.

There are 27 serious reportable events that should be reported by all health care facilities as they occur. The NQF emphasizes that individual incidents should be reported, not frequencies of events. The events are organized in six categories — five that relate to the provision of care (surgical, product or device, patient protection, care management, and environmental) and one category that includes four criminal events. These latter events involve illegal acts, or acts of misconduct, and the NQF says they are included because they could be indicative of an environment that is unsafe for patients. "Although a health care facility cannot eliminate all risk of these events — *e.g.*, of assault — it can take various preventive measures to reduce that risk," the report says. **(For the list of serious reportable events, see p. 164.)**

The serious reportable events list was developed for individual state use, but there is no requirement that states adopt it or use it uniformly. The hope, though, is that many states will use the list as the basis for their reporting requirements.

"We're certainly not going to have all 50 states doing this or doing it the same way," Colmers says. "We hope states will see this list as a good starting point for developing their own reporting requirements, while realizing that their data will be more useful if they are the same as that collected by other states."

Data to become more reliable

As states adopt the serious reportable events list, Colmers says the data on medical errors will become more and more reliable, with the ability to spot trends and regional problems. The NQF's report on the issue says "the primary reason for identifying a standardized set of serious reportable events that would be mandatorily reported is to facilitate public accountability for the occurrence of these adverse events in the delivery of health care." It goes on to say that "Whether or how such data might be disclosed to the public after being reported to the responsible agency [*e.g.*, in a de-identified manner, or in aggregated regional reports naming individual health care providers, etc.] is a policy decision for the states, although at least some degree of public disclosure is recommended."

Colmers emphasizes that "public disclosure" means reporting the incident to a government body, not necessarily making the incident public.

"States and health care providers should know that this is a mechanism that requires them to be publicly accountable for serious events and do some sort of root-cause analysis," he says. "Some states already have a system like this in place, or some rudiments of mandatory reporting. The great value of having a list like the one we've prepared is that it provides some guidance to states in collecting information in a uniform fashion."

Not everyone is looking forward to the serious

COMING IN FUTURE MONTHS

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reportable events being adopted by states. **Ellison C. Pierce Jr.**, MD, executive director of the Anesthesia Patient Safety Foundation, urged the NQF not to adopt the list. Pierce wrote that his organization worries about "the nature of the bureaucracy that would be created to manage the aggregated reports from the states" and whether mandatory reporting would discourage providers from being forthright about errors. **Kenneth Aaron**, MD, medical director of Hoag Memorial Hospital Presbyterian in Newport Beach, CA, told the NQF that he and his colleagues support the goals of the list but don't see why it is any different from the Joint Commission's sentinel events program.

"The content of the list, and the express desire to employ root-cause analysis, prevention strategies, and dissemination of lessons learned to prevent recurrences either in the same or other institution, are appropriate but very similar to the requirements and philosophy of JCAHO accreditation," Aaron wrote. "If the JCAHO process is not providing the intended results, perhaps it can be modified, rather than employing another parallel system of reporting and aggregating data."

The Joint Commission insists that the new list of serious reportable events is not an effort to reinvent the wheel. **Paul Schyve**, MD, senior vice president of the Joint Commission, tells *Hospital Peer Review* that the Joint Commission participated directly in the NQF's development process and sees the new list as a way to cover areas not covered by the sentinel event process.

With sentinel events, the Joint Commission looks at two categories: certain events that result in serious harm or death and trigger a Joint Commission investigation, and other events in which no one is harmed but nevertheless represent a serious failing, Schyve explains. An example of that second category would be an infant abduction in which the child was returned safely.

All of the sentinel events that would automatically trigger a Joint Commission review are found on the NQF list as well, and everything else on the NQF list probably would qualify under the broader definition of a sentinel event, he adds. There appears to be no conflict between the two lists, though the NQF lists more specific incidents than the sentinel event list, Schyve says.

The NQF list is much more extensive than the Joint Commission's — 27 specific items vs. five incidents that automatically qualify as sentinel events. Schyve doesn't say that the NQF list expands the sentinel event definition, but adds, "I don't see anything on the serious reportable events that we wouldn't consider a sentinel event."

So why is the new list necessary? Partly because the IOM report said a state-based reporting system was necessary and no one seems eager to counter that. But Schyve says the NQF list, if it is adopted widely by states, will take the philosophy behind the sentinel event system to a wider range of health care providers.

"It's not the same as the Joint Commission's system because the sentinel event system has only those who volunteer as participants," Schyve says. "The IOM report envisioned a mandatory reporting system, and if enough states adopt some form of the serious reportable events, we'll have more providers participating than those volunteering for Joint Commission accreditation."

States must find ways to avoid duplication

Even if the two separate lists are necessary, there are legitimate concerns about duplication of efforts when a provider must report an incident, Schyve admits. Health care organizations already complain that reporting a sentinel event and conducting a root-cause analysis is burdensome, and now the NQF list suggests they might have to do it twice. That all depends on how states adopt the list, Schyve says.

"The problem of parallel tracks for reporting already has occurred in some states with mandatory reporting, and we want to work with states to avoid that," he says. "There's no reason we can't come up with systems in which the same information is reported using the same tools to satisfy the Joint Commission and the state reporting requirements."

The NQF team also worried that the serious reportable events could be a burden unless some way is found to coordinate with national requirements. "Until a standardized reporting framework is pursued, including coordination with existing voluntary and mandatory systems, the burden on individual health care providers and health care facilities to meet the requirements of divergent systems will be a source of frustration that wastes resources and diminishes the potential for public accountability and quality improvement," the NQF report says.

Multiple reporting within a state is another potential problem. In its report, the NQF says states should institute policies that permit facilities to

report an event only once to a single state entity.

Other relevant state-based reporting systems, such as state health care licensing entities, should retrieve reports from the primary receiving entity, not through a duplicate report from the facility. If this is not done, the NQF says, states should, at minimum, enact policies that allow the same data in the same form to be filed with multiple agencies.

There will be some delay before states adopt the NQF list, and some problems won't be fully understood until then. But peer review professionals should use the interim to study the NQF list, Schyve says, and anticipate how reporting those items to the state would affect them.

"Look at the list and use it as a checklist for yourself," he says. "Have you already considered all of these events as sentinel events and responded accordingly, regardless of whether you reported them? Consider how you would want that data reported to the state and influence the way the list is adopted in your state." ■

NQF's list of 'serious reportable events'

Twenty-seven "serious reportable events" are divided into six categories on the National Quality Forum's (NQF) new list, which it hopes will be adopted by states for uniform state-based reporting. These are the events that the NQF says should be reported to state bodies:

1. Surgical events

A. Surgery performed on the wrong body part: Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.

B. Surgery performed on the wrong patient: Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

C. Wrong surgical procedure performed on a patient: Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.

D. Retention of a foreign object in a patient after surgery or other procedure: Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.

E. Intraoperative or immediately post-operative death in an ASA Class I patient: Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.

2. Product or device events

A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility: Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.

B. Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended: Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.

C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility: Excludes deaths associated with neurosurgical procedures known to be a high risk of intravascular air embolism.

3. Patient protection events

A. Infant discharged to the wrong person.

B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours: Excludes events involving competent adults.

C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility: Defined as events that result from patient actions after admission to a health care facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the health care facility.

4. Care management events

A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration). Excludes reasonable differences in clinical judgment on drug selection and dose.

B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility: Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility.

E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in neonates: Hyperbilirubinimia is defined as bilirubin levels >30 mg/dl. Neonates refer to the first 28 days of life.

F. Stage 3 or 4 pressure ulcers acquired after admission to a health care facility: Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

G. Patient death or serious disability due to spinal manipulative therapy.

5. Environmental events

A. Patient death or serious disability associated with an electric shock while being cared for in a health care facility. Excludes events involving planned treatments such as electric countershock.

B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.

C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility.

D. Patient death associated with a fall while being cared for in a health care facility.

E. Patient death or serious disability associated with the use of restraints or bed rails while being cared for in a health care facility.

6. Criminal events

A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provider.

B. Abduction of a patient of any age.

C. Sexual assault on a patient within or on the grounds of the health care facility.

D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the health care facility. ■

JCAHO president calls for bioterror preparedness

The Joint Commission on Accreditation of Healthcare Organizations is urging Congress to act quickly to improve the nation's bioterrorism response capacity by developing systemwide, integrated community approaches to emergency management, with support from the federal and state levels. The nationwide improvement may follow improvements that are already underway on a smaller scale at most hospitals across the country.

At bioterrorism hearings before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, Dennis S. O'Leary, MD, president of the Joint Commission, said the health care system already has in place much of what is needed to respond to bioterrorism, but more work is needed.

"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 called for these improvements:

- Medical care workers must be trained to become familiar with pathogens that may be used in bioterrorism, aware of the symptoms they produce, knowledgeable about their routes of transmission, and alert to the possibility of their use.
- A single, integrated system of response must be created to effectively address a full range of diseases and rare events, whether of terrorist or natural origins.
- Community or statewide capacity analyses of preparedness that include available medical facilities and delivery sites must be carried out.
- A medical/public health surveillance system should be established to promptly detect naturally occurring epidemics as well as terrorist activity.
- Issues relating to precious national supplies (*e.g.*, vaccines) and their disbursement need to be evaluated and resolved.
- National funding policies, which have progressively reduced the elasticity of the medical system to ramp up to a peak demand, must be re-evaluated.

"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 added.

Cameron Bruce, CSP, PE, a health care consultant in Orinda, CA, says hospitals should review their emergency preparedness plans to ensure that they include the threat of bioterrorism. While most plans will have some mention of such a threat, plans written prior to Sept. 11 probably did not take the threat seriously enough, Bruce says.

"Now we know that just about anything could happen. The things we just barely touched on before now deserve another look," he says. "You probably won't have to start from scratch, but you'll probably have work to do."

The emergency preparedness plan should be designed with practicality in mind, Bruce advises. Think of actually using the plan and making it useful, rather than trying to just prepare something that will pass the Joint Commission's review.

"The Joint Commission's requirements aren't all that strict, and if you just do it for them, you're not going to have what you need if you have to respond to bioterrorism," he says. "Write it for yourself."

Bruce says he is encouraged by the response of hospital quality professionals so far. There was an immediate increase in interest after the Sept. 11 attacks, and Bruce says he believes many health care organizations will have greatly improved their emergency preparedness plans by the early part of 2002. **(For more on how to revise an emergency preparedness plan for bioterrorism, see *Hospital Peer Review*, November 2001, p. 149.)**

Previous improvements serve current need

In his testimony to the subcommittee, O'Leary pointed out that some of the Joint Commission's recent strengthening of its emergency preparedness requirements are paying off.

"Several years ago, in a move that now seems prescient, the Joint Commission decided to develop new standards that would broaden the ability of individual health care organizations to deal with rare events. At that time, we had become concerned that the medical system was inadequately prepared to deal with the rare threat of bioterrorism, and perhaps equally unprepared for the greater possibility of infectious outbreaks arising from an increasing global inventory of virulent infectious agents. Regardless of the source of the threat, readiness for managing biological events has certain common elements."

He went on to explain that the Joint Commission's accreditation standards were modified in three ways, all of which infused the concept of community involvement into the preparedness process. First, the Joint Commission shifted the focus of the standards from simple emergency preparedness to emergency *management*. Now health care organizations are expected to address four specific phases of disaster planning: mitigation, preparedness, response, and recovery.

"This means engaging in planning as to how an organization would lessen the impact to its services following an emergency; how organization operations might need to be altered during the heat of the crisis; and how to conduct consequency management to return the organization to normal functioning once a crisis has passed," he said.

The Joint Commission requires that when organizations are addressing each of the four phases of disaster planning, they must broaden their preparedness and their perspectives to take into account how the community around them may be affected during a rare event. The new standards, which were effective January 2001, also require accredited organizations to take an "all hazards approach" to planning.

"What this means is that organizations must develop emergency management plans that contain a chain of command approach that is common to all hazards deemed to be credible threats — an approach that also can be easily integrated into their community's emergency response structure," O'Leary said. "Hospitals must start this aspect of planning by considering a wide variety of threats that could befall their community, including terrorism.

Hospitals, for example, are now required by these new standards to do a hazard vulnerability analysis that starts with an unconstrained list of extreme events, and then critically appraises their probability of occurrence, their risk to the organization and the capacity for responding to each potential threat."

O'Leary also made one point that may be especially important in light of the nation's fears over anthrax and other threats that experts say are not likely to cause much damage. If the community fears such a threat, the hospital may have to develop a response, he says.

"Inherent in this analysis is having an understanding what the community itself, rather than just the health care organization, considers to be a realistic threat." ■

PATIENT SATISFACTION PLANNER

Poor customer service has significant impact on bottom-line results

Thinking outside the box can make huge difference

Not all factors that affect a hospital's bottom line relate directly to revenues and/or expenses. Although it may take months or sometimes even years to make its full effects known, poor customer service can be an albatross around the neck of the most well-meaning quality staff.

"Poor service with regard to patients obviously affects your market share and thus your bottom line," says **Kristin Baird**, RN, BSN, MSHA, vice president for business development at Watertown Area Health Services in Watertown, WI, and author of *Customer Service and Healthcare: A Grass-Roots Approach to Creating a Culture of Service Excellence*.[1] "While marketing and advertising can influence name recognition and even preference, once a patient and [his or her] family use your facility, they will form opinions whether to return and talk positively about you, or to not return and talk negatively."

The cost of that negative experience can be considerable, Baird notes. "Let's imagine you lose a 35-year-old woman's support. She may not be making a decision just for herself but for her spouse, her children, and possibly her parents, so there's a ripple effect."

"It's been said that one nurse in the ED [emergency department] with a bad attitude can cost you $250,000 in lost revenues," notes **Liz Jazwiec**, RN, who heads up the Oak Lawn, IL-based consulting firm Liz inc. "The ED usually gets to see between one-third and one-half of all your patients. Whether the patient is admitted or not, [he or she] can go into the community and tell other people about the experience. A negative experience can hurt you on admissions for as many as five years."

And the impact can extend far beyond admissions, she notes. "I have seen situations like the one at Baptist Hospital in Pensacola, FL, where customer satisfaction scores have helped cause bond ratings to rise from B+ to A-," she says. "That probably saved them $500,000 in interest. They also saw a tremendous reduction in claims, so from a risk management standpoint, the money they had to put aside for possible lawsuits decreased significantly."

When we think of customer service, our thoughts gravitate immediately to the patient. That kind of limited thinking can cost you money, warns Baird. "Customer service has to do with patients, physicians, and co-workers/employees; it impacts them all," she asserts.

"There is definitely a relationship between employee satisfaction and patient satisfaction," adds Kathleen Blandford, vice president of quality improvement at VHA-East Coast in Cranbury, NJ. "If employees are happy, they are that much more committed to their work and to their patients. If you have an employee morale problem, that causes turnover and makes vacancies even worse than they would be in this current shortage."

Creating a culture of service excellence has to begin from the top down as well as from the bottom up, says Baird; you can't have one without the other. "You need the support of your top administration as well as your middle management," she notes. "They have to not only believe it, but to walk the walk; they have to take an active role and work very hard at keeping the vision front and center."

Of course, different strategies must be used to address different customer groups. "With associates, the grass-roots formula is to go out and work with groups of employees to help them recognize what they can do," says Baird. "For example, we have a 'bright idea' program, a system put in place where employees can submit ideas. Little things like that make a difference."

Rewards and recognition also are important, she says. "One program we use is called 'Notable Names,' which encourages associates to catch each other in the act of being kind, or going above and beyond what is expected," she says. How does one go "above and beyond?"

"People expect good medical care and appropriate treatment," Baird says. "Beyond that, you should make sure to keep the family informed

and involved, keep the patient informed about what to expect next, and respond promptly." As one example, the nurses at Baird's hospital implemented a new policy that said everybody was responsible for answering the patient call light. "We're not all nurses, but the drapes in the patient's room might be opened too wide, or they may need the table closer, or want the door closed. This type of extra service can improve patient satisfaction scores significantly," she says.

"The way you deal with complaints — your recovery process when you react to complaints — can be very important," adds Blandford. "The more you can improve your responsiveness, the [greater the] likelihood you will reduce the number of complaints. A frustrated, angry, unhappy patient will press the issue forward all the way to a lawsuit, while one who has been treated well may not."

Blandford also recommends good, solid communication strategies — even "gimmicky stuff."

"Know if your patients are going to have a birthday while they're in the hospital and send them a card," she suggests.

Managing expectations is another critical issue in patient service, says Jazwiec. "If waiting time is going to be 45 minutes, tell the patients it will be an hour; they'll be happier," she suggests. "And acknowledge their inconvenience." Improved efficiencies also can help boost satisfaction levels. "It used to be that when we lost something belonging to a patient, we would go through the process of filling out five or six forms, which would take four or five hours," she recalls. "Now, if we lose something worth, say, $50, we apologize for losing the article and pay the $50."

Addressing the needs of physicians requires a slightly different strategy. "What makes doctors happy is knowing they have a competent staff working for them," says Baird. "They look to the staff for '24/7' care, so when their patients are happy with their care, the physician is more confident in the hospital. When they hear the patient say, 'It takes me a half hour to get my call light answered,' that's bad. But if they hear, 'I've never seen such a warm, friendly, caring staff,' that makes them want to send all their patients there."

Doctors also want to feel appreciated. "They appreciate it when we understand what they need and want, and anticipate those needs," says Baird. "So, they should not surprise you every time they come on your unit and ask for a certain protocol. That way, we're augmenting their work."

Using scripts also can be effective, says Jazwiec. These can includes lines such as, "Is there anything else I can do for you?" or "We are concerned about your privacy; should I pull the curtain closed?"

It's critical that you not jump headfirst into a customer service improvement program; you've got to know where you stand. "It's absolutely imperative to have baseline information; you wouldn't call AAA and ask how to get to L.A. if you didn't know where you were beginning your trip," says Baird.

"I have some biases about measurement," adds Jazwiec. "You need to be able to get mostly data. If you look at your budget, you need to look at it every month; to give people data four times a year and expect things to improve is very difficult. Your information has to be provided monthly, and it must be unit-specific. You also have to have something that allows you to benchmark nationally."

Baird agrees that it's critical to know your facility's specific needs. "Whenever I do a presentation, I encourage people to go back to their own organization and review their own data," she says. "Nothing hits home like that. If you go to the financial data, talk about who your most active physicians are and what their piece of the business means to your bottom line. What if you lost 15% of your business? Or 20%?"

In terms of specific survey instruments, "We use Press, Ganey, and the main reason we do is it has a large database," says Baird. "It's not enough for us to conduct our own in-house survey; we end up comparing ourselves to ourselves. We didn't know how we stacked up against other hospitals our size. How can I incentivize our associates to improve if our consistent mean score is 90%? With Press, Ganey, you may find that compared to the database, 90% is average. When this process really gets thrilling is when you stand out from the crowd, and you won't get there without comparative data."

Human nature is competitive, which works to our advantage, adds Baird. "Focus on what's important to your organization, but recognize that it's not enough to be average. Nobody seeks out health care because it is average. "When was the last time you heard a patient say, 'I'm looking for an average brain surgeon in an average hospital?'"

Reference

1. *Customer Service and Healthcare: A Grass-Roots Approach to Creating a Culture of Service Excellence*. San Francisco: Jossey-Bass; and Chicago: AHA Press; 2000. ■

Hands across the hospital: Handling internationals

Language, culture, scheduling pose challenge

In an era of managed care and federal cutbacks in health care reimbursement, international patients — who typically pay full charges for medical services — are understandably a prized part of a hospital's or health system's business.

Along with this retail rate, as it is often called, come issues and requirements that go beyond providing medical care. They present a unique set of challenges for any health system and particularly for access personnel.

"There is a need for a variety of ancillary services that are critical to providing access," notes Lesley Macherelli, embassy liaison for the Boston-based Partners Healthcare System's international program.

Some issues are remarkably the same — patients complain about wait time or question the amount of their bills — and some are decidedly different.

Guiding people through the system means not only accompanying patients to appointments, but assisting them at the airport and with housing arrangements in a city that is foreign to them, she adds.

"You're assuming a lot if you [believe] someone who doesn't speak English and has lived most of his or her life in a small town in another country can figure out which Sheraton is which," Macherelli points out.

Following Brigham and Women's example

At Brigham and Women's Hospital, one of five Harvard Medical School-affiliated hospitals for which Macherelli helps coordinate international business, the volume has grown in recent years, says Kerin Howard, manager of the hospital's international program. Residents of the Middle East make up the majority of Brigham and Women's international patients, she notes, but the business is increasing both in numbers and in countries represented.

Before Brigham and Women's established a separate office for international patients two years ago, Howard says, she worked with those patients as part of her job in the access services department, which is a 24-hour, seven-day-a-week operation. The international office, she notes, is open from 7 a.m. to 8 p.m. and has someone on call around the clock.

International patients, she says, typically make a deposit in advance of their stay of between 75% and 100% of the estimated amount of their bill.

"We do a lot with embassies, so [in those cases] we get a letter of guarantee," says Howard, who reports to Brigham's director of admitting and oversees a staff of eight. "Every patient at Brigham and Women's Hospital gets the same quality of care, but we do try to take into consideration the special needs of the international patient."

Patients can elect to pay for concierge services, she says, which the hospital outsources to a local company. "They assist with hotels, transportation, banking, grocery shopping, changing flights, and any other services that a concierge typically provides."

The Pavilion, a newly refurbished patient floor with private rooms only, was scheduled to open Sept. 4 and will be available to patients — international and domestic — willing to pay a premium for special services and amenities, Howard adds.

When it comes to scheduling the U.S. patient, "we look at length of stay in the hospital, but with the international patient, it's important to consider length of stay in the country," notes Macherelli. "Every day they're out of their country, it's costing them much more than just hospital charges. They're paying for hotels to bring family members with them, and there's the out-of-work component."

Paying attention to cultural differences

In addition to closely scheduled appointments for international patients, she explains, close attention must be paid to things that otherwise might be taken for granted.

Ensuring that the patient is there on time and follows preoperative instructions, such as not eating after midnight, is not necessarily a given, Macherelli says. Patients have been known to show up for surgery saying they really hadn't eaten, had "just had a croissant and a coffee," she adds.

Many of Partners' international patients, the majority of whom come from Arabic countries, "are not early-morning people," notes Howard. "Cultural ideas about time are not the same as here."

Such eventualities, she says, underscore the importance of "doing some education on our end." Her department uses a variety of handbooks and educational literature for international patients, Howard adds.

The importance of customer service

"One international patient is like having 10 domestic patients," she says. "It's not just language. It's cultural issues, and it's the need to have everything done in an efficient and often expedited manner. When they're leaving, they need a final bill, all their records, and their medications."

Helping Howard keep the fast pace that's required are three administrative employees who work in the office and five Arabic-speaking patient coordinators who accompany patients to their appointments and serve as interpreters, she says. Spanish is the next most frequently spoken language among international patients, Howard notes, but that language need is met by the hospital's interpreter services department or by bilingual admitting staff.

A Partners nurse stationed in the United Arab Emirates helps get patients and their records ready for the trip to Boston, she notes.

Having a good customer service program is a big advantage for any access department dealing with international patients, Howard says. Like their domestic counterparts, these patients can present a variety of scenarios that must be handled with patience and tact.

"Sometimes patients come for [a medical procedure] they think will cost a certain amount and it turns out to be more complicated," she says. "There are some common things, but you never know what to expect. They're all unusual; there's nothing straightforward."

In effect, Macherelli points out, working with the international patient sets back the clock to a time when health care providers had more time to dedicate to patients.

"Medicine is so highly specialized, we often don't have time to look at the totality of a patient's experience," she adds. "[With international patients], you have to look at the whole experience — the foods they eat, [and] the cultural and familial ramifications."

Providing access services to these patients encompasses two kinds of concerns — infrastructure and cultural — and the two categories overlap, Macherelli notes. "Critical [to the process] are triage and the scheduling of appointments, and to do that, you have to have people who can interpret and translate medical records."

With Muslim patients, there are myriad cultural issues, Macherelli explains. "To have a man come into the room and move a bedridden female patient onto another bed can be horrifying to someone," she says. "It has to happen, but there needs to be some sensitivity as to how it happens. [Providers] must be sensitive to patients' cultural mores or patients can get so distraught that the delivery of care is compromised."

Traditionally, female Muslims will only see female providers, Howard says, particularly for gynecological problems. When it makes sense clinically, the hospital will accommodate those patients, she adds. If a male physician is the best clinician in a particular field, or the only appropriate person on call during the weekend when an in-vitro fertilization needs to take place, Howard says, "usually, the patient will agree" to the care.

Devil's in the details

Simply entering the international patient's demographic data into the system can present an interesting challenge, Macherelli points out. Names are typically hard to spell and hard to pronounce, and "virtually every Arabic name begins with 'Al-,'" she notes. "If a [registrar] types in 'Al-,' hundreds of names come up. You have to take these fields all the way down to the date of birth and home address [to identify the patient]."

The date of birth also can be problematic, Macherelli adds. "I have seen the same person give a different date of birth on each of three visits."

In some cases, she says, the day and month are reversed. "It seems like a small thing, but it can cause constant confusion if the dates of birth don't match up from one year to the next on blood work. You need a thorough intake questionnaire."

Assorted challenges notwithstanding, working with international patients can be a particularly rewarding and positive experience, Howard says. "It's about making a difference in people's lives. We have a patient here from the Middle East who is pregnant with conjoined twins. She wouldn't have the same outcome if she had stayed in her own country."

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Reader Question

Report sentinel events to managed care groups

But don't disclose too much

Question: We recently had a sentinel event at our facility and responded appropriately with a report to the Joint Commission on Accreditation of Healthcare Organizations and a root-cause analysis. Now, a managed care organization (MCO) is asking for the same information and claiming that we are required to turn it over. Is that right?

Answer: Sort of. This may come as a surprise to many quality and peer review professionals, but you should report a sentinel event to MCOs. You don't *have* to, but the Joint Commission would be happier if you did.

You should be careful not to disclose too much information, but the MCO is entirely within its rights to ask for some explanation of the event.

The new *JCAHO 2001-2002 Comprehensive Accreditation Manual for Health Care Networks* has an added section on sentinel events that says, "Accredited networks are expected to identify and respond to all sentinel events occurring in the network or associated with services that the network provides, or provides for." That means that any MCO accredited by the Joint Commission is required to gather information on sentinel events in which its members are involved.

But because there are serious concerns about peer review privilege and confidentiality, the Joint Commission does not actually require providers to give that information to the MCOs, says **Lynne Bergero**, MHSA, associate project director in the division of research at the Joint Commission. In fact, the Joint Commission is planning to issue a clarification in the next month or so to emphasize that there is no such requirement.

"This question has come up a lot, so we thought a clarification was necessary, even though we're not changing the standard itself," she says. "Some providers thought they were supposed to give their root-cause analysis, and that's not what we intended. We would like to see them cooperate with the networks to promote better patient safety, but we're not saying you have to turn over a lot of sensitive information."

Many hospital peer review professionals don't know about this expectation, says **Sherry Dunn**, LMSW, ACSW, CCM, clinical quality improvement specialist with Corphealth in Fort Worth, TX, an MCO specializing in behavioral health care. Dunn says she has encountered resistance from some providers who don't understand why she is asking for information about the sentinel event. "Some wonder why we need to know and just say it's none of our business. They say they can't show us the medical records because they're confidential when they've actually been handing over other medical records all along. There's just a lack of knowledge about the requirements here."

Reporting to an MCO is a separate track from reporting the sentinel event to the Joint Commission, she explains. No one expects you to send the same information to both. And in fact, you shouldn't. Dunn has seen some providers send their entire root-cause analysis to the MCO. As someone who previously worked in quality management for a hospital, she knows that is a big mistake.

"I never would have sent that kind of information to the managed care group because then it becomes public information and you lose all your peer review privilege," Dunn says. "You expose yourself to tremendous lawsuits, and it's not even necessary. That's not the information we expect from providers."

Know what the MCO wants

So what does the MCO want to see? Most MCOs will be satisfied with a much simpler explanation of the sentinel event and the provider's response, she says. The provider should explain what happened and show that the event was treated seriously, and there was a meaningful response by the organization.

"Usually, as long as they are looking at the quality issue and can show us they are taking corrective steps, that's enough," Dunn says. "We want to see that they considered it in terms of quality improvement, that it's been through a quality committee, and they didn't dismiss it as just an isolated incident. We'll usually get a summary of the corrective action, not the specifics. They'll say that they educated the staff, changed policies, and disciplined some people, without explaining all the specifics."

According to Bergero, that sort of report would

please the Joint Commission. She emphasizes that though the Joint Commission does not require providers to give sentinel event information to the MCO, it wants the two parties to share information within the constraints of peer review and privacy issues.

In some cases in which Corphealth says patient safety is an issue, it may send Dunn or other representatives for a site visit. Remember that only the MCO whose patient was involved in the sentinel event can demand such information. Other MCOs may ask about a sentinel event in the course of accrediting your organization, but you are not obligated to provide the same information to them.

The exact mechanism for how you report the sentinel event may differ from one MCO to another. Some MCOs have a clause in their contracts that obligate the provider to volunteer the information within a reasonable time, but others like Corphealth wait until they find evidence of the sentinel event themselves. Corphealth is pleased if a provider comes forward with the information on its own, but the MCO doesn't mind if it finds out itself. In most cases, sentinel events are spotted by the MCO's utilization review staff.

Corphealth is accredited by the National Committee for Quality Assurance (NCQA), not the Joint Commission, so it reports the sentinel event information to the NCQA. Other MCOs accredited by the Joint Commission will pass on the information to that group.

Also, keep in mind that the report to the MCO serves an important purpose. The MCO will use the information to assess the quality of your organization and whether you should be accredited to treat their customers. At Corphealth, such reports are sent to the chief medical officer and the risk management committee for review. If they are not satisfied with the report, Corphealth may ask for more information.

"Ultimately, if we're not satisfied with what we're given and the provider resists giving us more information, it could threaten their accreditation with Corphealth," she says. "We would have to forward it to our credentialing committee with a recommendation for decredentialing, or at least flag it as a something to consider the next time they come up for credentialing."

Dunn saw just such a case in the past few months. A Corphealth customer committed suicide while under treatment, which constitutes a sentinel event, and then the provider would not submit adequate information. That provider already had a history of questionable care and insufficient quality improvement, so the refusal to provide adequate data about the sentinel event was the final straw. Corphealth decided not to renew the provider's accreditation. ■

HIPAA business associate agreement available soon

Anticipating the April 2003 effective date for the Health Insurance Portability and Accountability Act (HIPAA) privacy rules, the Joint Commission on Accreditation of Healthcare Organizations is preparing a model "business associate agreement" that you can use when putting together the appropriate paperwork to comply with the new rule.

The model agreement should help providers and the Joint Commission to avoid some unnecessary work, says **Margaret Van Amringe**, vice president of external relations at the Joint Commission. She tells *Hospital Peer Review* that the model agreement is necessary because the HIPAA rule considers accreditors such as the Joint Commission to be business associates of the accredited organizations.

"Given that, we would be expected to have business associate agreements with each accredited organization, and this agreement would have to delineate our own privacy and disclosure practices, and how we would handle information that is identifiable by patient name," Van Amringe says. "We have nearly 20,000 accredited organizations, so it's unreasonable to have a different agreement for each one. We don't have the resources to develop that many."

Other model business associate agreements have been written, and Joint Commission-accredited facilities are free to use those as well, she says. But the Joint Commission will encourage providers to use the model it releases to minimize the customization and the time needed to review each agreement.

"We will have the model business associate agreement out to our accredited organizations by the end of 2002, and then all of our organizations would have to sign the agreement by April 2003," she says. "We'd like everyone to use our model as much as possible." ■

NCQA, VA launch human research accreditation

The National Committee for Quality Assurance (NCQA) and the Department of Veterans Affairs (VA) have released final 2001-2002 standards for the first external accreditation program to protect humans participating in research projects. NCQA will develop and administer the new program, which will apply to more than 120 VA medical centers conducting research with human participants.

The accreditation program will set the standard for other federal agencies and private sector organizations engaged in human research, says **Jessica Briefer French**, NCQA assistant vice president in the Quality Solutions Group.

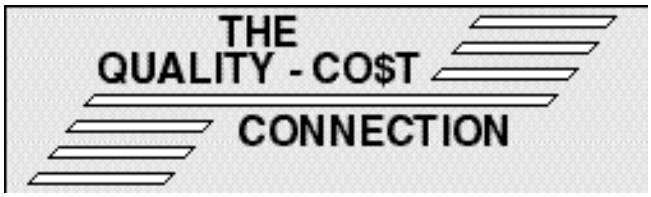
"Accreditation will enhance existing protections and help ensure that the VA can move ahead with its important research agenda," French says. "The VA is setting an example for the rest of the research community to follow."

A recent report by the Institute of Medicine cited the VA/NCQA program as the preferred model for accrediting human research protection programs. Under the new accreditation program, teams of independent experts will visit each medical center at least once every three years to certify that they are effectively managing research risks. The accreditation standards address these six major areas:

- institutional responsibilities for human research protection;
- structure and operation of institutional review board (IRB);
- IRB consideration of risks and benefits of research;
- IRB consideration of recruitment and subject selection for participation in research;
- IRB consideration of research-related risks to privacy and confidentiality;
- IRB consideration of informed consent for research participants.

Standards will be revised annually to reflect changes in VA policy and other federal regulations and, over time, to more directly emphasize outcomes of human research protection efforts. The VA last year awarded a $5.8 million, five-year contract to NCQA to develop and implement the accreditation program. In 1999, research programs at several universities and affiliated VA medical centers were suspended when federal oversight agencies found shortcomings in review procedures for protecting human subjects. VA responded with a proposal to establish an external accreditation program designed to fortify compliance with its own and other federal regulations.

The program standards are available at NCQA's VA Human Research Protection Accreditation Program web page: /www.ncqa.org.. ■



Put patient safety process changes to the test

By **Patrice Spath**, RHIT
Brown-Spath & Associates
Forest Grove, OR

Health care organizations are beginning to redesign processes to improve patient safety. Process redesign recommendations may originate from a root -use analysis or from a proactive assessment of a high-risk process. It is important to ensure that changes in patient care processes achieve the desired goal — a safer health care environment for patients. Before fundamental changes are made to a process, it is important to test the proposal. Even the most well-intentioned process changes could increase the likelihood of mistakes. Before finalizing patient safety improvement recommendations, people must understand how a change in one process might transform the entire system of care.

The Joint Commission is emphasizing the importance of analyzing and/or pilot testing a new or redesigned process. Expect surveyors to ask how you evaluated the safety of new processes prior to final implementation. Even if the process suffers from a major problem that must be solved quickly, do not neglect the testing phase. Quick fixes in one area can completely disrupt patient care activities in another.

When designing a safer patient care process, first decide on which changes to try. There may be several ideas to choose from. Everyone should

understand that process improvement is a learning activity. No one should be blamed for making the wrong suggestions. After all, even if a change doesn't work out as expected, it will suggest ways to make things better. When selecting the process redesign suggestions to try first, consider the following questions:

- Can the change be tested on a small scale?
- Will the effect be evident reasonably soon?
- Will the effect be easy to measure?
- Does the process change require new measurements or will existing measurements be sufficient to evaluate results?
- Is the change simple to do or will it take a long time to implement?
- Can the pilot test be done without disturbing other patient care processes?

Systematically test proposed changes

There are several ways of testing process changes. A pilot test may not be the first step. Construct a flowchart of the redesigned process then conduct a failure mode, effects and criticality analysis (FMECA). At each step in the process, determine what could go wrong, how significant this failure would be, and whether a mistake at one step in the process could be caught before it reaches the patient. Don't overlook the transition points in the process steps. For example, what could go wrong in the communication of information from one caregiver to the next? The results of this FMECA analysis is used to further refine what is intended to be a safer patient care process prior to formal pilot testing.

Another technique for evaluating the safety of a process prior to implementation is stress testing. Much like the stress tests done to evaluate a person's cardiac health, the subject (the process) is subjected to extreme stress (theoretical disturbances). The process redesign team hypothesizes "worse case" scenarios. For example, the process for surgical site identification prior to incision might work just fine for 99.99% of cases. But what if you have an extraordinary situation such as an emergency night surgery? X-rays are not available in the operating room; the patient is nonresponsive; after the patient is draped, the surgeon unknowingly applies a tourniquet to the patient's uninjured leg in preparation for surgery; and the operating room is short staffed. How will you prevent a wrong-site surgery in this situation? Stress testing a process can help identify where additional safeguards or revisions are needed.

CE questions

21. According to the National Quality Forum, how many types of serious reportable events should be reported by all health care facilities as they occur?
    A. 8
    B. 27
    C. 31
    D. 45

22. List the first of six categories of serious reportable events, as defined by the National Quality Forum.
    A. surgical events
    B. product or device events
    C. patient protection events
    D. care management events

23. At Congressional bioterrorism hearings, Dennis S. O'Leary, MD, president of the Joint Commission on Accreditation of Healthcare Organizations, said that a medical/public health surveillance system should be established to promptly detect naturally occurring epidemics as well as terrorist activity.
    A. true
    B. false

24. What is the effective date for the Health Insurance Portability and Accountability Act?
    A. February 2002
    B. October 2002
    C. April 2003
    D. January 2004

FMECA and stress testing are theoretical techniques for evaluating the safety of a new process. Before making changes in the process, a pilot test can be conducted. This is a preliminary test or study of the new process to try out procedures and make any needed changes or adjustments. For example, the people involved in caring for patients undergoing surgery try out new methods for identifying the correct surgical site. To minimize disruption of patient care, it may be best to pilot test the new process in only one unit or for one population of patients. Training is always important when pilot testing a process change. A training assessment should be done, especially if the change requires new skills or

competencies. Coordination will be needed to ensure the right people receive the right training at the right time to maximize the positive effects of the redesigned process.

It is also helpful to consider the risks associated with implementing change. There may be potential downsides or adverse affects associated with some changes. For example, from a staff member's perspective, changes that result in additional work may be interpreted as a burden. Plans to address these concerns and mitigate their effects should be developed. Staff reluctance to accept process changes may undermine the results of the pilot project.

Before conducting the pilot test, check to be sure all the proper approvals have been obtained. This may add time to the testing process, but it is an important component of the project. There should be a clear plan of what needs to happen and when. Issues that have the potential to unexpectedly halt the progression of the pilot project should be clearly identified on the timeline.

Pilot testing of new or redesigned processes is done for a specific purpose — to improve patient safety. But how will you determine whether or not the pilot test is a success? To achieve meaningful change, it is important to know what problems the new process was expected to fix. For example, the goals for a project involving better preoperative identification of surgery sites might include:

- The correct operative site is always marked preoperatively.
- Patient records are always available in the operating room.
- Patient X-rays are always available in the operating room.

The goals of the process redesign influence your data requirements. You'll need to design methods

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Editorial Questions

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for gathering information during the pilot project to determine the success of the process changes. Other data you may wish to collect include staff satisfaction with the new process, unanticipated outcomes, and key issues that may affect the pilot test results (e.g. staffing levels, patient satisfaction, etc.). Systematic measurements should be maintained for each stage of the pilot project. Do not rely on people's memories or intuition.

Measure success

It should first be determined if the established goals were achieved. If the goals were not achieved or were modified, then the reason(s) should be documented. Many times there are unanticipated consequences to changing a process. Whatever the outcome, it is important to document it so benefits can be attributed and/or new issues that arise can be addressed. It is important to identify the key factors that lead to success or failure of the new process. It can sometimes be difficult to document and openly share those things that did not work. However, this is important so that future process changes can be more effective in safeguarding patients from mistakes. You may need to do several pilot projects before determining the best process for improving patient safety.

When selecting the best process redesign solution there is one general principle to keep in mind. In the long run, a change that reduces variation in the process without making the process unsafe for patients is more desirable than a change that increases variation in the way people do things. This is because reduced variation makes mistakes less likely.

Share lessons learned

The knowledge gained during all phases of the process testing should be shared with others who may benefit from the lessons learned. There may be a number of closely related patient care units or people performing similar functions that can clearly benefit from the information. For example, the process of surgery site identification in the inpatient environment has implications in many other provider settings. It is important to remember that the information gained from your process testing, whether positive or negative, is valuable. Sharing lessons learned will help others improve patient safety in their environment while avoiding pitfalls. ■

CE objectives

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- Identify a particular clinical, legal, or educational issue related to quality improvement and performance outcomes.
- Describe how the issue affects nurses, health care workers, hospitals, or the health care industry in general.
- Cite solutions to the problems associated with those issues based on guidelines from the Joint Commission on Accreditation of Healthcare Organizations or other authorities and/or based on independent recommendations from clinicians at individual institutions.

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

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

The threat is real, but we are far from defenseless

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

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

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

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

Restoring calm to health care community

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

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

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

Infection control methods in place

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

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

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

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

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

A Bioterrorism Timeline

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

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

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

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

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

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

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

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

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

Sources

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

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

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

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

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

More terror than toll

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

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

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

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

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

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

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

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

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

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

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

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

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

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

References

1. Garner JS, the Centers for Disease Control and Prevention Hospital Infection Control Practices Advisory Committee. *Guideline for Isolation Precautions in Hospitals. Web site: http://www.cdc.gov/ncidod/hip/ISOLAT/isolat.htm.*
2. Bosker G. Bioterrorism: An update for clinicians, pharmacists, and emergency management planners. *Emergency Medicine Reports* (in press) 2001. ■

Should clinicians get smallpox vaccinations?

Questions arise, stockpile expansion fast-tracked

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

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

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

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

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

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

15 million doses stockpiled

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

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

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

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

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

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

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

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

Treatment of Biological Agent Exposure

AGENT	CLINICAL SIGNS AND SYMPTOMS	TREATMENT	OTHER	SECONDARY TRANSMISSION
Anthrax (spore)	Fever, malaise, non-productive cough, progressing to dypsnea, stridor, shock. Incubation 1-6 days.	Prophylaxis/treatment: ciprofloxin, doxycycline, PCN licensed vaccine. IV therapy: ciprofloxin doxycycline, PCN licensed vaccine.	High mortality (>90%) even with treatment.	None except aerosolized body fluids.
Pneumonic Plague (bacteria)	High fever, chills, headache, hemophysis, toxemia, dyspnea, stridor, bleeding diathesis. Incubation 2-3 days.	Prophylaxis/treatment: vaccine, doxycycline, TMP/sulfamethoxazole. IV therapy: streptomycin (>1 yo), gentamicin, chloramphenicol.	Antibiotic treatment effective if begun early.	Strict isolation needed. Isolation mandatory for at least the first 48 hours of treatment.
Tularemia (bacteria)	Regional lymphademepathy, fever, chills, headache, malaise, cutaneous ulcers. Incubation 2-10 days.	Streptomycin, gentamicin. Adult prophylaxis: doxycycline.	Low mortality (about 5%).	Rare, body fluid precautions only.
Q Fever (bacteria)	Fever, cough, pleuritic chest pain. Incubation 10+ days.	Tetracycline, doxycycline.	Low mortality.	Does not require universal precautions.
Smallpox (virus)	Malaise, fever, rigors, vomiting, headache, backache; 2-3 days later lesions appear and quickly progress from macules to papules to pustular vesicles. Incubation 16-17 days.	Supportive — vaccine available from CDC. Immune globulin may be available from CDC. No antiviral medication available.	Supposed to be extinct (doubtful).	Highly contagious.
Viral Equine Encephalitis	Supportive. No antiviral medication exists.	Ribaviron, supportive care.	Isolate patients in single room with an adjoining anteroom stocked with PPE. Negative air pressure if possible.	Body fluids. Otherwise infectious by vector (mosquitoes).
Viral Hemorrhagic Fevers	Fever, malaise, myalgias, headache, vomiting, diarrhea, easy bleeding, petechiae, shock.	Ribaviron, intensive care, convalescent plasma (Argentine HF), vaccine (yellow fever), blood replacement products for DIC.	Decontaminate with hypochlorite or phenolic disinfectants.	Transmitted by bodily fluids. Strict barrier-nursing techniques. Limit patient transfers: may increase risk for secondary transmission.
Botulism (toxin)	Ptosis, weakness, dizziness, dry mouth, blurred vision, diplopia, descending paralysis. Incubation 24-36 hours.	Several antitoxins are available and effective if administered early. CDC vaccine good only for A and B.	Disinfect with hypochlorite and/or soap and water. Supportive long-term mechanical ventilation.	None.
Ricin (toxin)	Weakness, fever, cough, pulmonary edema, incubation 18-24 hours.	Supportive — oxygenation and hydration. No antitoxin or vaccine available.	Disinfect with hypochlorite and/or soap and water.	None. Derived from caster beans.
Staphylococcal Enterotoxin B (toxin)	Fever, headache, chills, myalgias, cough, nausea, vomiting, diarrhea. Incubation 3-12 hours.	Supportive — oxygenation and hydration. Ventilator support may be required.	Disinfect with hypochlorite. Most victims recover.	Use PPE.

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

Hospital Peer Review
2001 Index

Continuing Education Test Questions for *Hospital Peer Review*
July – December 2001

JULY

1. Define the number of members appointed by the Joint Commission on Accreditation of Healthcare Organizations to serve on its task force to streamline standards.
   A. 16
   B. 18
   C. 20
   D. 22

2. List the last year, before 2001, that a major review of Joint Commission standards was conducted.
   A. 1994
   B. 1995
   C. 1996
   D. 1997

3. Which of the following organizations did not participate in the development of a common set of evidence-based measures for evaluating performance in diabetes care?
   A. Joint Commission on Accreditation of Healthcare Organizations
   B. American Medical Association
   C. Health Care Financing Administration
   D. National Committee for Quality Assurance

4. Define the approximate percentage of all health care expenditures in the U.S. that are lost to fraud, according to the General Accounting Office.
   A. 50%
   B. 35%
   C. 20%
   D. 10%

AUGUST

5. According to a report from the Health and Human Services Office of Inspector General, what percentage of hospitals have never reported an adverse action against a health care practitioner to the National Practitioner Data Bank?
   A. 84%
   B. 60%
   C. 71%
   D. 50%

6. One of the root causes identified for the problem of medical waste left on food trays at Part Nicollet Health Services in St. Louis Park, MN, was that overworked nurses often has to multitask and became too busy to pay attention to proper procedure.
   A. true
   B. false

7. According to its implementation schedule for ORYX, when will the Joint Commission on Accreditation of Healthcare Organization release final technical specifications for initial measure sets?
   A. September 2001
   B. November 2002
   C. October 2001
   D. July 2002

8. Which of the following organizations was not part of the coalition that sent a petition to the Centers for Medicare and Medicaid Services regarding pain management?
   A. American Academy of Pain Management
   B. American Pain Foundation
   C. Compassion in Dying
   D. American Hospital Association

SEPTEMBER

9. What is the cost of the two-day assessment portion of the Institute for Physician Evaluation program?
   A. $7,500
   B. $2,300
   C. $900
   D. $350

10. According to Patrice Spath, RHIT, a project monitoring plan should allow you to identify which of the following?
    A. differences between planned start dates and actual start dates for each activity
    B. activities performed out of sequence
    C. milestones achieved or missed
    D. all of the above

11. List one of the three “leaps” in the prevention of medical errors that the Washington, DC-based Leapfrog Group claims can save 58,000 lives per year.
    A. increased use of physician assistants in the emergency department
    B. selected strategies to reduce the incidence of patient falls
    C. computerized physician order entry
    D. lower caseloads for hospital-based case managers

12. A recent report from the Rockville, MD-based Agency for Healthcare Research and Quality identified how many best practices that represent “clear opportunities” to improve patient safety but are not being performed regularly?
    A. 3
    B. 11
    C. 15
    D. 44

OCTOBER

13. How many measures are included in the acute myocardial infarction set of ORYX core performance measures?
    A. two
    B. three
    C. six
    D. nine

14. On what date will hospitals begin collecting ORYX core measure data for patient discharges?
    A. Dec. 1, 2001
    B. July 1, 2002
    C. Sept. 1, 2002
    D. Dec. 1, 2002

15. Which of the following items is not included in the acute myocardial infarction set of ORYX core measures?
    A. smoking cessation advice/counseling
    B. aspirin at arrival
    C. length of stay
    D. aspirin at discharge

16. According to Patrice Spath, RHIT, criteria used to evaluate a health care organization's CEO can be derived from which of the following?
    A. progress toward the mission, vision, and institutional goals
    B. adherence to organizational policies and operational procedures
    C. the CEO's job description and/or the policy statement on CEO's roles and responsibilities
    D. all of the above

NOVEMBER

17. The Council on Scientific Affairs from which organization last year released the report *Medical Preparedness for Terrorism and Other Disasters*?
    A. The Joint Commission on Accreditation of Healthcare Organizations
    B. The National Commission for Quality Assurance
    C. The American Medical Association
    D. The American Hospital Association

18. List one of the top 12 mistakes in emergency preparedness plans, according to Cameron Bruce, CSP, PE, a health care consultant in Orinda, CA.
    A. contain too much multidisciplinary input
    B. inadequate drilling or testing of the plan and its components
    C. consider too many probable scenarios
    D. none of the above

19. According to Susan Mellott, PhD, RN, CPHQ, FNAHQ, a consultant in Houston, planning for a Joint Commission survey should start at least 18 months before the anticipated survey date.
    A. true
    B. false

20. On Oct. 1, 2001, the fee for querying the Healthcare Integrity and Protection Data Bank rose from $4 to what amount?
    A. $5
    B. $7
    C. $10
    D. $12

DECEMBER

21. According to the National Quality Forum, how many types of serious reportable events should be reported by all health care facilities as they occur?
    A. 8
    B. 27
    C. 31
    D. 45

22. List the first of six categories of serious reportable events, as defined by the National Quality Forum.
    A. surgical events
    B. product or device events
    C. patient protection events
    D. care management events

23. At Congressional bioterrorism hearings, Dennis S. O'Leary, MD, president of the Joint Commission on Accreditation of Healthcare Organizations, said that a medical/public health surveillance system should be established to promptly detect naturally occurring epidemics as well as terrorist activity.
    A. true
    B. false

24. What is the effective date for the Health Insurance Portability and Accountability Act?
    A. February 2002
    B. October 2002
    C. April 2003
    D. January 2004

Hospital Peer Review
Continuing Education Evaluation

Please take a moment to answer the following questions to let us know your thoughts on the continuing education program. Place an "x" in the appropriate space and return this page in the envelope with your test answer form. Thank you.

For your reference, here is the stated purpose of *HPR*:
Hospital Peer Review is a news and how-to publication for quality professionals that covers quality-related issues from government mandates through quality improvement.

Did *Hospital Peer Review* enable you to meet the following objectives*:*

yes__ no__1. Are you able to identify clinical, legal, or educational issues related to quality improvement and performance outcomes?

yes__ no__ 2. Are you able to describe how those issues affect nurses, health care workers, hospitals, or the health care industry in general?

yes__ no__ 3. Are you able to cite solutions to problems associated with those issues, based on guidelines from the Joint Commission on Accreditation of Healthcare Organizations or other authorities and/or based on independent recommendations from clinicians at individual institutions?

yes__ no__ 4. Did these objectives help accomplish the overall purpose of the program?

yes__ no__ 5. Were the teaching/learning resources effective for this activity?

_____ min. 6. How many minutes do you estimate it will take you to complete **this entire semester's** (6 issues) activities? Please include time for reading, reviewing, testing, and studying the answer sheet, which you will receive with your certificate. One nursing contact hour equals 50 minutes.

yes__ no__ 7. Were the test questions clear and appropriate?

yes__ no__ 8. Were the instructions clear and appropriate?

yes__ no__ 9. Were you satisfied with the customer service for the CE program?

10. Do you have any general comments about the effectiveness of this CE program?

_____

_____

_____