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Congress halts the enforcement of annual tuberculosis fit-test rule

Long-awaited TB guidelines skirt fit-test issue

Federal enforcement of the annual fit-testing requirement has been halted for at least a year, as Congress intervened in the tuberculosis-related rule. Meanwhile, new draft federal TB guidelines leave some ambiguity by recommending periodic fit-testing, while acknowledging regulations that require annual fit-testing.

A provision in the huge federal appropriations bill that passed in late November prohibits the U.S. Occupational Safety and Health Administration (OSHA) from spending federal funds to enforce the General Industry Respiratory Protection Standard annual fit-testing requirement as it applies to TB. It only applies to FY 2005, which runs to Oct. 1, 2005, and actually does not revoke the rule, which went into effect July 2.

The action doesn't resolve the contentious debate over the fit-testing rule. In fact, it actually will have little effect, says **Bill Borwegen**, MPH, health and safety director of the Service Employees International Union (SEIU). "There's going to be a lot of confusion. People are going to think the respirator rule doesn't apply. That's not the case."

State plan states will be able to use state money to enforce the annual fit-testing rule, he notes. And as it is an existing regulation, the Joint Commission on Accreditation of Healthcare Organizations will expect hospitals to follow it, Borwegen says.

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"If it's still a regulation, the Joint Commission will still require compliance with all applicable law and regulation," acknowledges **Mark Forstneger**, JCAHO spokesman.

The Association for Professionals in Infection Control and Epidemiology (APIC) and the American Hospital Association sought congressional relief from the annual fit-testing rule, which they contend places a great burden on hospitals but provides little benefit in employee protection.

Jennifer Thomas Barrows, APIC's director of government and public affairs, notes that the halt in enforcement is just a stop-gap measure.

"This was designed to hopefully provide an important window of time during which we can continue to work with our public health and health care partners to ensure effective strategies for addressing health care worker protection from airborne pathogens from infectious patients," she says. "APIC wholeheartedly supports scientifically proven methods for protecting workers and will continue to advocate for measures that are both necessary and effective."

Industrial hygienists assert that fit-testing is necessary to ensure respirators continue to provide the proper level of protection — and health care workers are not treated differently from employees of other industries.

Hospitals have been scrambling to fit-test hundreds of employees since OSHA revoked the TB-specific respirator standard Dec. 31, 2003, and stated that hospitals must comply with the General Industry Respiratory Protection Standard.

The ban on enforcement may have little effect for another reason: OSHA had not cited any employers in the first five months after the annual fit-testing rule went into effect. **Richard Fairfax**, OSHA director of enforcement programs, also notes the congressional action only applies to tuberculosis. Annual fit-testing still is required to protect health care workers from exposure to other airborne infectious diseases.

"If you're a hospital worker and there's a SARS [severe acute respiratory syndrome] outbreak, you would still be covered completely under 1910.134 [the General Industry Respiratory Protection Standard]," he says.

Meanwhile, the Centers for Disease Control and Prevention (CDC) released its long-awaited draft TB guidelines, which are available for public comment on its web site (www.cdc.gov). The draft guidelines took three years to develop and were delayed for months by a lengthy internal review at the CDC.

The most contentious issue is fit-testing. The National Institute for Occupational Safety and Health supports annual fit-testing, while other CDC divisions do not. The draft guidelines recommend periodic fit-testing based on a risk assessment, but note that OSHA requires annual fit-testing. They do not define periodic.

"There's not a sufficient scientific base to make a recommendation," explains **Michael Iademarco**, MD, MPH, associate director for science in the CDC's Division of TB Elimination. "Our final decision was to lay out the facts. . . . We're giving infection control programs all the data and saying, 'You need to make a decision.'"

The CDC convened a workshop on fit-testing

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and respiratory protection in Atlanta with dozens of experts in industrial hygiene, infection control, epidemiology, and occupational health. Information from that meeting may lead to changes in the draft TB guidelines, he adds.

"The job of CDC is to look at the public health science and make the best public health recommendation possible," Iademarco says. "We'll take this information and come up with the best recommendation possible."

He notes the guidelines also cover administrative controls, engineering controls, and other aspects of a respiratory protection program. "This contentious issue is only one small aspect of the third strategy [respiratory protection]."

The draft guidelines also address the use of the new QuantiFERON-TB blood test for testing health care workers and as a diagnostic tool.

With a revised risk-assessment protocol, it changes recommendations for the frequency of TB screening of health care workers and defines health care workers who need periodic TB screening. For many hospitals, the draft guidelines may decrease the screenings. For example, facilities at low-risk for TB should conduct baseline TB screening of employees but do not need to perform any further screening unless there is an exposure to TB, the draft guidelines state.

Hospitals with more than 200 beds would be considered low risk if they encounter fewer than six TB patients in the past year. Hospitals with fewer than 200 beds would be low risk if they encounter fewer than three TB patients in the past year.

California works toward consensus

Amid the controversy over fit-testing, a group in California is working toward a consensus on an airborne infectious disease standard.

Representatives of labor unions and hospitals found common ground by looking beyond tuberculosis and fit-testing, says **John Mehring**, health and safety educator with the SEIU Education and Support Fund in San Francisco. "We're trying to take a more holistic approach and look at the whole spectrum of diseases," he says.

For example, at a recent meeting, the group discussed influenza vaccination and whether health care workers should be required to sign a declination if they don't want the vaccine, as they do with hepatitis B. They talked about respiratory hygiene and whether that might be incorporated into a standard.

Even in the area of fit-testing, the committee found some areas of agreement. Too many people are included in the annual fit-testing at many hospitals, Mehring notes.

"In part, it's because the nature of staffing in acute-care facilities today requires a great degree of flexibility on the part of management and workers," he says. "Perhaps, there needs to be a two-tiered approach. If we understand that the universe [of fit-testing] is artificially too large, how do we break that down into something that's more realistic?"

The group will review the OSHA's proposed tuberculosis standard, which the agency withdrew last year, and consider whether there are low-risk circumstances that would not require annual fit-testing.

Some California hospitals support the idea of a comprehensive standard on airborne infectious diseases, Mehring adds. Yet fit-testing still may prove to be a stumbling block. The creation of a standard will depend on the ability of the group to work out its differences. ■

No OSHA citations for hospitals on ergo

You're OK if you're making progress

Enforcement related to ergonomic hazards remains light more than two years after the U.S. Occupational Safety and Health Administration (OSHA) trained inspectors to recognize and document those hazards. More than 1,000 inspections of nursing homes generated only 10 citations related to ergonomics. They were among only 16 employers nationwide who received such citations.

No hospitals have been cited for ergonomic hazards, although overexertion in lifting is the leading cause of injury in the industry.

"The burden of proof is much higher than if we had a standard," says **Richard Fairfax**, OSHA director of enforcement programs. "We have to establish a number of elements [for a general duty clause violation]. If the employer is working toward abating, that takes them out of [range] of the general duty clause."

The general duty clause of the Occupational Safety and Health Act requires employers to keep workplaces free of hazards that could cause serious injury. To cite employers based on the clause,

inspectors must show "the employer failed to keep the workplace free of a hazard to which employees were exposed, the hazard was causing or likely to cause death or serious physical harm, the hazard was recognized, and a feasible means of abatement for that hazard exists," OSHA has stated.

When OSHA inspectors identified hazards that didn't meet the general duty clause criteria, they sent hazard alert letters suggesting safety improvements. Of 376 hazard alert letters sent to employers, 181 were to nursing homes. None were sent to hospitals.

"When [Labor Secretary Elaine] Chao told us they were going to kill the ergonomics standard, OSHA told everyone that they were going to unleash a much more aggressive general duty clause campaign on ergonomics," notes **Bill Borwegen**, MPH, health and safety director of the Service Employees International Union (SEIU).

"Clearly, that has not happened. Clearly, it was simply a ruse to deflect criticism that OSHA was eliminating the standard that would have addressed the leading cause of workplace illness and injuries," he explains.

State legislators and regulators and workers' compensation insurers ultimately may take greater action on ergonomics, Borwegen says.

Fairfax contends the nursing home ergonomics guidelines, outreach and education programs, and hazard alerts have led to safer working conditions. "We're seeing more and more nursing home establishments that are doing something [about ergonomic hazards]," he notes.

OSHA asserts that by targeting its enforcement activities to high-hazard industries and the most egregious employers, it is making significant progress in improving worker safety.

In November, **John L. Henshaw**, CIH, OSHA administrator, touted the agency's "strong, fair, and effective" enforcement program, which focuses on high-hazard workplaces.

"OSHA's balanced approach in worker safety and health, in our mind, is succeeding; and it's validated by the workplace injury and illness rate, which is decreasing, even as our work force continues to expand," he said at a news conference.

The targeting of certain industries is an important part of that, says Henshaw. "It's an effort to focus our energies where they are needed most," Henshaw notes.

Both hospitals and nursing homes have an injury and illness incident rate that's significantly higher than the general industry average: 9.7 per 100 full-time workers at hospitals, 12.6 at nursing homes, and 5.3 for general industry.

The bloodborne pathogen standard continued to be the No. 1 standard cited by OSHA inspectors in hospitals. From October 2003 to September 2004, OSHA issued 115 citations at 37 hospitals, with fines totaling about $100,000. The nature of those citations has changed since the passage of the Needlestick Safety and Prevention Act, says Fairfax.

"Ten years ago, most of our violations were for not having a bloodborne pathogen program at all," he says. "Now our citations are for deficiencies."

The respiratory protection standard was the fifth most frequently cited, although OSHA has not cited any hospitals for failing to conduct annual fit-testing, Fairfax says. **(See cover story.)** ■

Absenteeism may hit hospitals this flu season

One-third reported flu-linked shortages last year

Brace yourself for a tough flu season. Absenteeism could become an issue for many hospitals as unvaccinated employees with respiratory symptoms miss days of work.

Health care worker influenza vaccination rates typically are dismal, with only 38% receiving the vaccine, according to the National Health Interview Survey. No one knows how many health care workers will be vaccinated nationally this year, but the rates likely will vary widely based on the vaccine supply available to individual hospitals.

With fewer people immunized in the general population, unvaccinated health care workers could be more vulnerable to the illness, employee health experts say. The result may be significant staffing shortages.

"We, of course, are concerned about the quality and intensity of flu this year because that will influence our absenteeism," stresses **William Schaffner**, MD, chair of the department of preventive medicine at Vanderbilt University in Nashville, TN, which had ordered from Chiron Corp. of Emeryville, CA, and found itself scrambling for available doses.

"Our fingers are crossed that we'll have a milder than usual flu season. If that's true, we'll get through this OK," he says.

Many hospitals had planned campaigns to increase their employee vaccinations — only to discover they had little or no vaccine. Even those with adequate supply are following recommendations of the Centers for Disease Control and Prevention (CDC) and limiting vaccination to health care workers in direct patient care or with other risk factors, such as chronic illness.

Last year, a CDC survey found that 35% of health care facilities reported staffing shortages due to influenza. The greatest impact was in the western United States, where 47% of health care facilities reported shortages. Those facilities actually had reported higher than average vaccination rates, with an average of 53%. The CDC will conduct a similar survey this year to determine the impact of the vaccine shortage.

"We have never been well-positioned to prevent absenteeism because of the low rates of vaccination among health care workers," says **Raymond Strikas**, MD, medical officer in the CDC National Immunization Program. "So hospitals have dealt with this in the past."

Sick HCWs and a flood of patients

This was to be the year for a major push for health care worker vaccination. The CDC made vaccination of health care workers a priority, as did the Association for Professionals in Infection Control and Epidemiology (APIC). Hospitals created slogans and strategies to get the shots to employees.

With those campaigns now cut short, hospitals will need to rely on other methods to minimize the risk of nosocomial spread of influenza.

Health care workers with a cold or cough will be expected to follow respiratory hygiene: using alcohol-based hand rubs or washing hands frequently, wearing a mask if there are respiratory symptoms, and coughing into a tissue. Health care workers also should wear surgical masks if they have close contact with patients with respiratory symptoms, according to CDC recommendations.

But here's a worst-case scenario: limited vaccination with virulent flu in the community. You won't want your health care workers to come to work if they have symptoms, but you need as many as possible to report for duty to care for patients.

You also don't want health care workers staying home every time they get a runny nose. "How do you define sick?" Schaffner asks.

The presence of a fever is a key factor, as it may indicate that the worker is contagious. "Once they're afebrile, they can probably go back to work," Strikas adds. "For most people, that should be two or three or four days."

Using antivirals to treat infected health care workers can shorten the course of illness if they're used within two days of onset. Because the medications have potential adverse effects, employees would need a health screening, Schaffner says. In fact, concern about adverse effects may make employee health professionals reluctant to use antivirals among this otherwise healthy population, he adds.

If there already is an influenza outbreak in the facility, the CDC recommends the prophylactic use of antivirals among health care workers who care for patients at high risk of complications from influenza, such as HIV/AIDS patients. (Vaccinated workers only would need the antivirals for two weeks after receiving the vaccine.) Health care facilities can consider using antivirals as chemoprophylaxis in health care workers who have direct patient care responsibilities and have been unable to obtain the vaccine, the CDC says.[1]

If influenza is spreading throughout the community, your hospital likely will feel the impact even with vaccine and antivirals. If the situation becomes severe, you may want to initiate parts of your pandemic influenza plan to cope with an onslaught of patients and staffing shortages due to influenza-stricken workers.

That is what Vanderbilt did last year when the emergency department was overwhelmed with influenza patients, Schaffner notes. Physicians assessed patients and determined which ones could be safely discharged.

That opened up enough beds to handle the overflow, and the hospital didn't need to move to Phase 2 of the plan, which would have included curtailing some elective procedures, he says.

Not everyone is struggling to vaccinate health care workers this year. Ironically, for those hospitals with adequate supply, the shortage may raise the demand and inspire better vaccination rates among health care workers with direct patient care. In fact, the shortage may help hospitals raise their vaccination rates next year.

"Four years ago, when there was never a shortage, we had a hard time giving it away," explains **JoAnn Shea**, MSN, ARNP, director of employee health and wellness at Tampa (FL) General Hospital. She had ordered extra doses from Aventis Pasteur and had started her Flu Challenge program in mid-September, a few weeks before the Chiron news broke.

The Flu Challenge targeted high-risk units, such as the burn unit, transplant, critical care, and intensive care, to raise their health care worker vaccination rates by 20%. If they succeeded, the staff won wellness prizes, including a chair massage.

Employees began to respond to the challenge. For example, the cardiac surgery unit went from seven employees vaccinated last year to 32. There are 71 employees in the unit.

But even with a full order of vaccine, the hospital ran out. Physicians and medical residents who usually received the vaccine elsewhere got it from Tampa General. The hospital also followed the CDC recommendations and limited the vaccine to health care workers with direct patient care and to high-risk groups.

"Without a doubt, we have a lot of people who still want it," Shea points out. "If we were able to do our Flu Challenge program like we had planned, I think we would have well surpassed these numbers."

And even with better vaccination rates, Shea is wary about the flu impact on her employees — and staffing. "A shortage is going to affect everybody because you're going to have more chance of exposure in the community," she says.

With so much publicity and concern about the flu and the flu vaccine, Shea hopes employees will be more receptive to vaccination in the future. "All it takes is to get the flu once, and people will become flu vaccine believers."

Reference

1. Centers for Disease Control and Prevention. Influenza antiviral medications: 2004-05 Interim chemoprophylaxis and treatment guidelines. Nov. 3, 2004. Web site: www.cdc.gov/flu/professionals/treatment/0405antiviralguide.htm. ■

Slow flu start helps the vaccine effort

Doses will be available through January

In a bad-news year for influenza vaccination, public health authorities are glad for some good tidings: The flu season began slowly and the vaccine promised to be more effective than last year's mismatched version.

As of mid-November, only Delaware had reported widespread flu activity. New York state and New York City reported regional activity, and elsewhere, influenza remained only sporadic. So far, the influenza vaccine is well-matched with the circulating viruses, A/Fujian/411/2002-like (H3N2) and B/Shanghai/361/2002-like.

Meanwhile, the Centers for Disease Control and Prevention (CDC) continues to redirect flu vaccine supply to the nation's high-priority populations, including health care workers. Some 2.6 million doses will be available in January, the CDC said.

If vaccine is imported from other countries, it would likely become available in December, said **Raymond Strikas**, MD, medical officer in the Immunization Services Division of CDC. "We are well aware that the challenges have been very difficult for all of us," he said in a web conference.

In November, CDC began apportioning 7.2 million doses of vaccines to states based on a formula that takes into account the estimated number of people in high-priority categories and the number of doses already shipped to the state. The CDC advised health care providers to contact their state or local health departments if they still have unmet vaccine needs.

Vaccine shortages occurred throughout the country, but within a community, the impact varied greatly. "We've had reports of practitioners being next door to each other, one having all the vaccine they expected to get and the other having no vaccine," said Strikas, noting that 33 million doses of Aventis Pasteur's vaccine already had been distributed when Chiron Corp. announced that it would be unable to provide vaccine this year.

In a worst-case scenario — not enough vaccine and an outbreak of influenza — unvaccinated health care workers can use antivirals — amantadine, rimantadine, and oseltamivir — as chemoprophylaxis, said **Tim Uyeki**, MD, MPH, of CDC's influenza branch. They are 70% to 90% effective at preventing influenza illness although they will not necessarily prevent influenza infection, he said. Amantadine and rimantadine only are effective against influenza A viruses, while oseltamivir is effective against both influenza A and B.

"For persons caring for high-risk individuals in an outbreak in a hospital, the duration [of prophylaxis] should be at least for one week following the end of the outbreak," he said.

The CDC will monitor supplies of the antivirals, but "at this time, antiviral supplies are estimated to be adequate," Uyeki noted.

The CDC also is reminding health care workers to use droplet precautions when treating patients with respiratory symptoms and fever, including

wearing a mask when they are in close contact with the patients. Droplet precautions should be maintained for five days in otherwise healthy patients and for the duration of their illness with immunocompromised patients.

Rapid antigen diagnostic tests may be falsely negative in up to 30% of cases, the CDC cautioned.

(Editor's note: More information on influenza vaccine supply and chemoprophylaxis is available from the CDC flu web site: www.cdc.gov/flu.) ■

CMS to approve hand-rub dispensers in hallways

Hospitals must meet NFPA conditions

Hospitals soon will get a green light from the Centers for Medicare & Medicaid Services (CMS) to install dispensers of alcohol-based hand rubs in hallways.

Last year, the National Fire Protection Association (NFPA) amended its 2000 and 2003 Life Safety Code to allow the convenient use of dispensers and set criteria for their installation, but CMS rules still prohibited the use.

CMS is expected to publish an interim final rule allowing the dispensers in the Dec. 23 *Federal Register*. The same rule is expected to require battery operated smoke detectors for patient sleeping rooms in existing nursing homes that do not have sprinklers. CMS then will issue a notice of proposed rulemaking to require sprinklers in all nursing homes, a CMS official said.

The CMS sanctioning of alcohol-based hand-rub dispensers removes a barrier to hospitals that were concerned about regulatory issues but wanted to use the dispensers to encourage hand hygiene. Hospitals still must follow the rules of state and local fire marshals, which means some still could be restricted from using the dispensers.

Employee health and infection control experts say the dispensers make the use of hand rubs convenient for health care workers. "[W]e consider these wall-mounted dispensers absolutely critical for assuring improved access and compliance with recommended hand-hygiene practices," the Association for Professionals in Infection Control and Epidemiology said in a statement.

The NFPA allows the dispensers in corridors with these conditions:

- The corridor width must be 6 feet or greater and dispensers must be separated at least 4 feet apart.
- The maximum individual dispenser fluid capacity is 1.2 liters for dispensers in rooms, corridors, and areas open to corridors, and 2 liters for dispensers in suites of rooms.
- The dispensers may not be installed over or directly adjacent to electrical outlets and switches.
- In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces are permitted only in sprinklered smoke compartments. Each smoke compartment may contain a maximum aggregate of 10 gallons of alcohol-based hand-rub solution in dispensers and a maximum of 5 gallons in storage. ■

Hospital finds wellness is an EH way of life

New clinic treats non-occ health needs

An employee comes to employee health with blood pressure that's out of control. Another has diabetes and isn't good at managing her diet. Another has a headache from a sinus infection. Is that your problem?

It is at the University Health Systems (UHS) of Eastern Carolina. The six-hospital system based in Greenville, NC, has had a wellness center with educational and exercise programs for the past nine years. And this summer, a wellness clinic opened at Pitt County Memorial Hospital, the system's largest medical center, to provide employees with everything from minor sick visits to comprehensive physical exams.

"You can't call this a frill," says **Pat Dalton**, RN, COHN-S, occupational health project specialist and a key player in the establishment of the program. "Sooner or later, you've got to say, 'If we don't take care of our employees and their health, it's going to cost us megadollars'" in workers' compensation claims and medical costs.

Actually, it wasn't a hard sell to promote wellness among the system's employees. "It starts from the top," says **Mary Chatman**, RN, MSN, vice president for specialty services and president of the ViQuest subsidiary, which runs the wellness programs. "Our president is very much wellness-oriented and has been all his life. We

have always had support for wellness."

The benefits are both direct and indirect, in lower costs and more productive employees, says Chatman. "We have tried to corral things like absenteeism and presenteeism," she adds, noting that employees now can visit the clinic and immediately return to work.

Managers, too, take more responsibility for their employees' health. And employees enjoy the perks, which include a wellness incentive program that allows them to earn points for time off, gifts, and bonuses.

Wellness focus evolves over time

A focus on wellness isn't an instant mindset change. The program has evolved over many years, Dalton points out. "This didn't happen overnight. We recognized the need for a cultural change that would emphasize the health of our own employee population."

The wellness program began in 1985 with a wellness coordinator who reported to employee health. Initially, the gym in the rehabilitation unit was used for aerobics classes. They offered personal health-related education sessions in available meeting rooms and often took health-related information to the various departments during the work shifts.

Eventually, the health system built a 52,000 square foot, $8.2 million facility at Pitt Memorial. A smaller version serves the system's regional hospitals. The wellness center has about 5,000 members, half of whom are employees or their family members, who pay a reduced rate, Chatman notes. The center also attracts members from the community.

"We built it on the medical model so there's a focus on identifying the current health of each participant and assisting them along the continuum to optimal health," she says.

The hospital also maintains an in-house wellness program, offering sessions and activities to employees who don't belong to the wellness center. The wellness assessment also has been integrated into the occupational health department.

UHS took a big step in its commitment to wellness with the ViQuest Clinic, which opened in July to take care of the ongoing health needs of employees and dependents age 16 and older who are covered on the UHS Medical Plan.

Employees immediately embraced the concept. ViQuest clinic director **Debra Thompson**, RN, MSN, APRN-BC, CDE, had projected that the clinic would have 45 visits during the first month. There were 142. The top three conditions: upper respiratory complaints, urinary tract infections, and contact dermatitis.

The clinic offers a variety of services, including minor sick visits, annual physicals, sports physicals, comprehensive chronic disease management, pharmacotherapy services, and referrals

Hospital employees answer the 'Fitness Challenge'

Competition boosts morale and health

It was a challenge issued to the beat of a step class, the pace of a race walk, the strength of a stream of push-ups. The reward for the team who won the Fitness Challenge at DeKalb Medical Center in Decatur, GA: $1,000 to split and a paid day off.

The Fitness Challenge drew 660 hospital employees to the two-month effort. About half (318) completed both the pre- and post-assessment.

The overall results were impressive. Employees collectively lost 671 pounds, gained 482.75 inches in flexibility, increased their number of push-ups by 2,854, and improved their heart rate on a cardio step test by 1,247 beats per minute.

"These are things you can't fake. People really had to work to increase their cardio endurance like this," marvels **Gail Winston**, RN, MSN, director of health promotion.

DeKalb Medical Center has had a wellness center, with an indoor track, cardio and weight equipment, swimming pool, and classrooms, for almost 20 years. Employees receive a reduced rate to join. But this is the first year the hospital encouraged them to get fit with a challenge.

Winston promoted it through newsletters, fliers, and e-mails. "Then the word just spread," she says. "People were very excited about it." Even the CEO joined a team.

"Results R Us," from the Rehab Results unit, won first place, beating out "Overnight Celebrities," the night-shift team, which won $500.

Winston also gave out third place ($250) and an individual award ($100 and a paid day off) in addition to door prizes. Teams had five to 10 members.

The prizes were an appealing incentive, but then employees became hooked on the competition and fitness goals, Winston says. It contributed to morale and team-building, she adds.

"Everyone knows that a healthy employee has less sick days, less injuries on the job, and more satisfaction," Winston notes. ■

within the local community and UHS resources. Services are filed to insurance and the employees pay a $20 copay.

The staff include Thompson, who is a nurse practitioner; a receptionist who handles billing and scheduling; and a part-time clinical pharmacist practitioner. The start-up costs were $22,000, and the clinic's initial budget was $200,000. Within months of opening, Thompson already was hiring another nurse practitioner and planned to add additional staff. The clinic also made plans to expand from three exam rooms to seven.

The clinic doesn't compete with local physicians but fills in gaps to meet employee health care needs, Thompson says. "We are not here to provide primary care, although many employees have requested us to do that," she says.

For example, if an employee has uncontrolled hypertension, the ViQuest clinic may provide an initial work-up and medication management. The employee then would receive a referral to a private physician. The ViQuest clinic also could provide regular monitoring of the employee's blood pressure.

"The clinic is not only a benefit to our employees and their dependents, but also can reduce rising health care costs," says Thompson. Some 28% of employees seen by the clinic didn't have a primary care provider, and if they became sick, they would have visited the hospital's walk-in emergency department, she adds. "The ViQuest clinic can provide consistent, comprehensive care and follow-up until a local provider can provide ongoing care," she says. ViQuest also has a wellness case management program geared toward high-risk and high avoidable risk clients.

Meanwhile, employees who come to work with nagging symptoms, or who begin to feel sick, can be evaluated at the clinic. They can be quickly treated and sent back to work, or if necessary, sent home to avoid infecting patients and co-workers.

"The cost avoidance is going to make a tremendous difference — reducing absenteeism, increasing productivity, and identifying undiagnosed conditions," Thompson says.

If the success of the clinic continues, the concept will be rolled out to other UHS facilities in the future, Dalton explains.

Employees view the clinic as a new benefit, Thompson adds. But the wellness program offers some tangible perks, as well.

Employees don't have to be members of the wellness center to participate in ViQuest Rewards. They receive incentive points for varied health activities, including taking a health-risk appraisal, exercising regularly, attending classes, or even eating a balanced diet with five fruits and vegetables a day.

They build up points to earn a variety of awards from a T-shirt or pedometer to a day off with pay. "It's a motivator for the employee to show them that all of their efforts are paying off," Dalton adds.

ViQuest also has an on-line product employees can use to track their health and get information.

The health system is offering the ViQuest clinic and wellness model to local businesses, but the primary focus remains on its own employees, she says.

"We can't ignore this [aspect of employee health], because if we ignore this, we're ignoring our bottom line," Dalton adds. "I really feel that strongly about it." ■

Getting unstuck: Hospital finds safe zone in the OR

Sharps injuries decline, but challenges remain

Never let up. That is what Greenville (SC) Hospital System learned about reducing sharps injuries in the operating room. It takes a sustained effort to keep rates down.

The three-hospital system has been on the forefront of sharps safety, implementing safety devices in 1991, about 10 years before the Needlestick Safety and Prevention Act provided a national mandate. When other hospitals were evaluating safety products, Greenville Hospital System was monitoring compliance.

But one challenge remained. The operating room still had consistently high rates of blood and body fluid exposure. "Because the safety devices have reduced injury in other areas, the OR stands out," says **Connie Steed**, RN, CIC, director of infection control.

So an action team created a new objective: "To decrease OR health care worker exposures by implementing a hands-free neutral zone during surgery and ensuring the appropriate use of safety devices and personal protection equipment.

Easier said than done.

The hospital placed an emphasis on maintaining a neutral zone for the passing of sharps. They

should no longer be passed directly between a surgical technician or nurse and the surgeon.

"It took more than a year to get compliance," says clinical nurse specialist **Sue Seitz**, RN, MSN, CNOR. "We faced several barriers. We educated about the neutral zone policy; we educated about hepatitis C and the devastating effects it can have. Despite the education, there was not any behavioral change."

Monitoring behavior in the OR and providing feedback on sharps injuries eventually made the difference, she points out.

Rounds focus on safety hazards

Seitz continually relayed information to the OR staff and physicians about who was being stuck, how were they being stuck, how it could have been prevented, and what it was costing the hospital.

Infection control staff made rounds in the OR and noted safety hazards. For example, they recommended that fewer people hover around the OR table, which meant some students needed to step back a few paces and provide more room for safe maneuvering.

Nurse managers made rounds and reminded staff about the neutral zone. They use "award" and "alarm" sheets to give feedback about compliance.

Meanwhile, the hospital system's vice president of medical affairs offered his strong commitment, which was the key to surgeon support of the changes. The hospital brought in Marc Davis, MD, a former surgeon who has become a national champion of sharps safety in the OR, to speak to medical staff.

The hospital purchased special relay trays for passing suture needles and gave surgeons four options for the neutral zone: a magnetic pad, a folded towel, an emesis basin, or the tray. "We set up a display for our surgeons outside of their lounge so they could see examples of what they could expect [from surgical technicians]," says Seitz.

From 2002 to 2003, the OR exposures declined from 5.55 to 3.73 per 1,000 procedures. By 2003, the rate climbed again, to 4.72. **Margaret Baker**, RN, the hospital system's exposure control nurse, tracked the quarterly rates and investigated why the exposures went up. Nurse managers told her they had slacked off on rounds.

The rounds started up again, and Seitz reminded the OR staff to keep up the neutral zone. The rate dropped back down to 3.48 in the second quarter of 2004.

CE *questions*

1. In late November, Congress included a provision in the appropriations bill impacting OSHA's enforcement of annual fit-testing for TB. How does the action affect hospitals?
   A. They no longer need to conduct annual fit-tests.
   B. OSHA will not enforce the annual fit-test rule for TB for FY 2005.
   C. OSHA will draft a new rule governing fit-tests and TB.
   D. The federal government will provide money to hospitals for fit-tests.
2. According to public health experts, absenteeism due to flu may be greater this year among health care workers because:
   A. There are overall staff shortages.
   B. The flu season is more virulent.
   C. Vaccine supply shortages make unvaccinated health care workers more vulnerable to flu.
   D. Health care workers aren't complying with respiratory hygiene.
3. According to Mary Chatman, RN, MSN, vice president for specialty services and president of the ViQuest subsidiary at University Health Systems of Eastern Carolina, the benefits of a wellness program and wellness clinic include:
   A. reduced absenteeism and greater productivity
   B. employee retention
   C. new contractual arrangements with physicians
   D. fewer work-related injuries
4. To reduce sharps injuries in the OR, Greenville (SC) Hospital System focused on what safety measure?
   A. glove and goggle use
   B. required use of blunt suture needles
   C. needless IV
   D. neutral zone for passing of sharps

Answer Key: 1. B; 2. C; 3. A; 4. D

"After three years [of effort], we have a success story," says Seitz.

Suture needles remain a challenge

Challenges remain in the OR, as they do for hospitals around the country. Surgeons have resisted using blunt sutures, saying the devices change their technique and affect patient care.

"Two or three years ago, I talked to the surgical groups to facilitate interest," she notes. "We had a lot of surgeons volunteer to try it. Some

of them tried it and didn't like it."

Nationally, suture needles are the second greatest source of sharps injuries, accounting for 18% of injuries, says **Jane Perry**, MA, director of communications for the International Healthcare Worker Safety Center at the University of Virginia Health System in Charlottesville.

The center collects sharps injury data from hospitals participating in its EPINet network. The EPINet database, established in 1993, now includes more than 25,000 sharps exposure incidents.

"Our data show that sharp-tip suture needles continue to be a significant source of injury to health care workers, but there's been very little change in the injury rate for this device over the last 10 years because safer technology and techniques haven't been widely adopted," she says.

A 1997 study by the Centers for Disease Control and Prevention showed blunt suture needles were effective in reducing sharps injuries in gynecologic surgery without impacting outcomes,[1] Perry notes.

"I think manufacturers of blunt suture needles need to do a better job of promoting this technology as a safety measure for surgeons and those who work with them," she says. "Surgeons need to be educated about what this technology is and how it can be used."

Greenville Health System will continue to try to educate surgeons about blunt suture needles and other safer technologies. "We're not going to give up," Steed explains.

Here are some of the lessons that were learned at Greenville about reducing sharps injuries in the OR:

- Track your rate, not your numbers. If your sharps injuries go up, you need to know whether your procedures or patient population went up as well.
- Your past performance is your best benchmark. If you compare your rates to those of other facilities, you may not know if you're calculating your injuries in the same manner. "Some hospitals don't [include nonemployees, such as surgeons], so it looks like they have lower rates," says Baker. "We decided not to compare ourselves with others."
- Collect your data monthly but analyze it quarterly. On a month-by-month basis, you may have a lot of fluctuation that can be confusing, says Baker.
- Look at sharps injuries by occupation. For example, Greenville Health Systems noticed sharps injuries were going up among medical residents, which prompted a closer look at that group.

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Readers Write

To the Editor:

Following the death of a Virginia hospital nurse from tuberculosis, an article in *The Virginian-Pilot* (Simpson E, Hardy K. Aug. 1, 2004) raised questions regarding the nurse's case.

Specifically, how could her illness have gone undetected in a hospital, and should anything be changed to keep such cases from occurring again?

As stated in the article, the Centers for Disease Control and Prevention established guidelines in 1994 to ensure the safety and health of workers and stem the spread of TB in hospitals.

A key safeguard is annual employee tests for TB. But until the widely used tuberculin skin test (TST or Mantoux) is laid to rest, the Virginia hospital nurse will not be an isolated case.

The TST was developed in 1890 — the decade that saw the invention of the gas-powered automobile — and suffers from a high rate of false-positive, as well as false-negative, results.

COMING IN FUTURE MONTHS

- Fit-testing: Where do we go from here?
- Should influenza vaccination be mandatory?
- How to deal with ergo vendors
- Improving sharps injury prevention training
- A better collaboration between employee health and infection control

In addition, interpretation of the TST is highly subjective, not reproducible, and requires two patient visits. On average, more than 30% of patients do not return to have their TST results read.

The U.S. Institute of Medicine has regarded the failings of the TST for TB infection as the single largest problem for TB control in the United States, as discussed in its seminal report *Ending Neglect*. It is time to begin using accurate TB tests such as QuantiFERON-TB GOLD, a simple blood test currently under review with the Food and Drug Administration that is more accurate and reliable for detecting TB.

In addition to its integral role in the control and spread of TB, a simple, one-step blood test should yield dramatic cost savings in terms of medical staff time and the elimination of common false-positive results, the latter involving costly follow-up testing and unnecessary TB therapy.

For hospitals, such a test would relieve the huge administrative and cost burden associated with maintaining testing compliance.

Old habits may die hard, but knowing an alternative TB test exists that could have prevented this tragedy is even harder. The time has come to relinquish the TST to history.

Lee B. Reichman, MD, MPH
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Preventative Medicine and Community Health
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New Jersey Medical School
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Newark ■

CE objectives

After reading each issue of *Hospital Employee Health*, the nurse will be able to do the following:

- identify particular clinical, administrative, or regulatory issues related to the care of hospital employees;
- describe how those issues affect health care workers, hospitals, or the health care industry in general;
- cite practical solutions to problems associated with the issue, based on overall expert guidelines from the Centers for Disease Control and Prevention, the National Institute for Occupational Safety and Health, the U.S. Occupational Safety and Health Administration, or other authorities, or based on independent recommendations from clinicians at individual institutions. ■

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Supplement to *Hospital Infection Control* and *Hospital Employee Health*

BIOTERRORISM WATCH

Preparing for and responding to biological, chemical and nuclear disasters

THOMSON
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IN THIS ISSUE

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Bioengineering smallpox: Rethinking the unthinkable

Widespread immunization urged — but would it make a difference?

While the United States has taken steps to prepare for smallpox bioterrorism event, the nation remains starkly vulnerable to a genetically engineered strain of the deadly virus. Indeed, if a smallpox attack occurs, a genetically altered strain that could be more virulent or elude the current vaccine actually may be the most likely choice of weapons, the author of a provocative new report argues.

"Most of the literature treats smallpox as a natural disease," says **Martin Weiss**, MD, professor of medicine at the University of California, Los Angeles. "We have to consider any new smallpox event as being man-made and therefore essentially being a weapon. It will be improved upon because man tends to improve on his weapons. It will not be a natural event. It will be an unnatural, man-made event. We have to assume that someone will try to expand the transmissibility of smallpox."

The former Soviet Union was known to have engaged in an active program to aerosolize bioweapons, including smallpox, Weiss and co-authors of the report note.[1] If modified or attached to the appropriate carrier, modified variola virus possibly could remain suspended and infectious for a much longer period than wild smallpox.

"The concern is that [the virus] could be bioengineered so that it could evade our vaccines," Weiss tells *Bioterrorism Watch*. "Another concern is that it could be made more virulent. Either way would be a problem." He acknowledges the threat may not be immediate, noting that the smallpox genome is complex and its DNA requires the activity of associated proteins to be infectious. However, "it may not be long in coming," Weiss adds.

Indeed, not only is bioengineering possible with smallpox, it apparently is moving from heresy to accepted science. Recently, an advisory committee to the World Health Organization (WHO) recommended scientists be approved to insert genetic markers in the virus to expedite the search for effective drug treatments. The marker would glow under florescent light if a trial drug were ineffective

against the pox virus. Weiss says he backs the recommendation, but reaction in the scientific community has been decidedly mixed.

According to published reports, **Ken Alibek**, MD, PhD, DSc, a former researcher in the Soviet Union's biological weapons program who defected to the United States in 1992, called it "absolutely the right decision. The bad guys already know how to do it. Why prohibit legitimate researchers to do research for protection."[2]

Others were aghast at the implications. "We have seen no evidence of a threat that would justify this research," says **Sujatha Byravan**, executive director of the Council for Responsible Genetics in Boston. "A decade ago, the WHO was planning to destroy the world's last remaining samples. Today, it is proposing to tinker with the virus in ways that could produce an even more lethal smallpox strain. This is a devastating step backward."

Likelihood vs. plausibility

But as Weiss points out, such genetic engineering of pox viruses already is occurring. Australian researchers increased mousepox virulence by splicing a mouse gene into a laboratory strain.[3] Similar constructions might be assembled using human smallpox virus or another pox virus (e.g., monkeypox virus) and human genes.

"We tend to underestimate our enemies," he adds. "It could be an aerosolized virus, a bioengineered virus that we have no vaccine for, or there could be several attacks at once. I don't want to be overly pessimistic, but I think we should be prepared for any eventuality. If the question is one of likelihood, it is probably unlikely. But the issue is not one of likelihood, it is plausibility. Is such an attack plausible? If it is, the common-sense thing to do is try to [reduce] the risk as much as possible."

Yet Weiss casts a critical eye on many of the assumptions that have guided the nation's smallpox preparations. Such considerations could prove to be overly optimistic because they do not take into account the many uncertainties regarding transmission and infectivity of the smallpox virus. For example, another misnomer in current thinking on smallpox is that the virus is not a highly infectious disease, he notes. Indeed, review of outbreaks in India and Pakistan in the 1960s showed that each case of smallpox gave rise to not more than three new cases, he found. However, a factor not emphasized in those reports is the extent of existing immunity in the affected population.

"The smallpox [transmissibility] studies were on populations that already had, in effect, herd immunity," Weiss says.

Though emerging data indicate smallpox immunity may last many years after vaccination, those never immunized would be strikingly vulnerable to infection. The immune status of never-vaccinated people (generally younger than 37) probably resembles that of the New World populations that were devastated by smallpox. "The younger population is naive to this virus," he warns. "It would be much like the Aztecs or the American Indians among people under age 36 or 37."

According to U.S. Census Bureau data for 2000, there are some 140 million people younger than 35 in the United States. Though almost 40,000

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Editorial Questions

For questions or comments, call **Gary Evans** at (706) 742-2515.

health care workers have been immunized in recent years, Weiss says the health system could not deal with a competent smallpox attack.

"I think it would be overwhelmed," he says. "If it was natural smallpox, we could probably handle it. But if it is going to be an unnatural event that is amplified by man, I don't think [the health care system] could handle it."

More vaccinations needed

A great unknown is what level of protection the existing vaccine would afford against a smallpox virus designed to elude it. Nevertheless, the bottom line to many pro-vaccine advocates is that widespread smallpox vaccination of the public and health care community would yield more benefit than risk. The thinking, in part, is that it certainly would protect against wild virus and may at least minimize the impact of a bioengineered strain.

"We would like more widespread vaccination," Weiss says. "I don't think it should be imposed on the public. There is a long history of people of being resistant to vaccinations. It would create a big political turmoil that is unnecessary. It should be voluntary for people who would like the vaccine. They could judge for themselves, and they can choose if they want it or not."

The risk of side effects and deaths is real, but adverse reactions were relatively few in the recent round of vaccinations among the military and health care workers. In recent data from an ongoing Department of Defense (DoD) study, there was one case of encephalitis reported among 623,244 vaccinations.[4] The patient recovered. Fifty cases of contact transfer of vaccinia occurred, primarily in spouses and adult intimate contacts. The lower-than-expected incidence of adverse events may reflect more-careful screening of vaccination candidates, the generally healthy status of the population being vaccinated, the previous vaccination in up to two-thirds of vaccine recipients, and covering of the vaccination site to reduce inadvertent inoculation, Weiss theorizes. Still, there were unexpected coronary problems during the recent round of smallpox vaccinations in both the civilian and military populations.

Ongoing research to improve smallpox vaccine could mitigate the risk, but mass inoculation inevitably would result in fatalities. Depending on the percentage of the population vaccinated, the number of deaths is estimated to be in the range of 125 to 500, Weiss reports.[5-7]

In addition, a long-forgotten smallpox drug called methisazone should be back on the radar screen given the current threat of bioterrorism, he emphasizes. The agent fell into disuse with the eradication of smallpox, but could be used as prophylaxis to reduce the incidence of smallpox by 30% to 40%.

"It would be better than nothing. I suspect it would be very inexpensive to produce. They used it in India in the 1960s, so it can't be that expensive. It has no patent protection; it's in the public domain. I don't know how expensive it would be to produce it, but it can't be very much. It would be like a backup insurance policy. In case disaster struck, we would have something available."

On a chillingly practical note, Weiss also recommends stockpiling respirators so that society could continue to function in the aftermath of a smallpox attack. The smallpox virus is 200-300 nm in size, meaning $7 N-100 respirators would be very efficient in preventing inhalation, he notes. The N-95 respirators commonly used in health care settings would be less effective, but still provide some protection. If masks were distributed to the public, it might lessen paralysis of cities and allow continuation of essential services.

"I don't want to overplay that, because if there is a smallpox attack, no one is probably going to be aware of it for seven or eight days," he says. "So a mask isn't going to prevent the initial consequences of attack. But once the attack is recognized, if people are wearing masks, they can go out in public with some relative degree of assurance and plus, they would be able to take care of the people who are sick."

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Instant hospital aims to meet bioterror surge

Portable hospitals from the ground up

From a large-scale bioterror attack to extreme natural disasters, we're constantly reminded of looming safety threats and the U.S. infrastructure's need to respond. And perhaps no industry has taken the threat more seriously than health care.

Doing its part, Blu-Med Response Systems in Kirkland, WA, has developed an advanced-care instant hospital structure that can be quickly deployed at various cites in the event of a large-scale disaster or bioterror attack exceeding a hospital's normal surge capacity.

Blu-Med is a division of Alaska Structures of Seattle, which has 25 years of experience developing similar structures for military use. The U.S. military currently uses the company's portable hospital buildings throughout the world, including Afghanistan, Iraq, and Kuwait.

"These shelters have really served the military well as portable hospitals, and people have wanted to know if we would make a civilian model of that," says **Gerrit Boyle**, executive vice president for Blu-Med and Alaska Structures. "We have taken the proven concepts for military use and adapted them for homeland security and other disaster-response scenarios."

Each hospital complex is composed of six interconnected shelters to create a 50-bed, 4,000-square-foot facility. The structures are Quonset hut-shaped, with a lightweight aluminum frame, and covered with a tension vinyl cover system. The units come complete with floors, windows, doors, heat, and air conditioning and electrical systems. To differentiate the civilian model from military applications, the buildings have been altered slightly to come in bright safety colors, such as a combination of blue, white, and orange.

The first organization to purchase one of these temporary hospitals was the Nevada Hospital Association (NHA) in Reno, which recently conducted the first assembly demonstration of its new system.

The association has purchased multiple units, according to **Christopher Lake**, PhD, director of hospital preparedness for NHA.

He says components for these instant hospitals would be stored with the air-conditioning units, hardware, and electrical equipment in a warehouse in a rapidly deployable manner.

"Essentially, if a disaster was declared, and it was recognized as a biological terrorism event where hospitals needed immediate surge capacity capabilities, we will be able to get these facilities anywhere in the state of Nevada, on the ground, set up and operational, with personnel and equipment in 24 hours," Lake explains.

The units can be configured to fit different needs, including triage, emergency department, surgery, intensive care, and other isolation requirements. He says the warehouses are geographically located so the temporary facilities can be deployed anywhere in Nevada in five or six hours. "The concept really is a 50-bed hospital, where and when [it is] needed," Lake adds.

The recent demonstration was the first test to see how long it would take to assemble one of the structures, with all components, using an uninitiated crew of people. "We needed a facility that was very easy to set up because you never know who will be available in a disaster," he explains. Lake said response from medical personnel has been very positive.

"One of the concepts with any event — pandemic disease, bioterrorism, nuclear explosion or natural event — is these patients are going to be long-term," he says, explaining why NHA chose the Blu-Med system as opposed to other alternatives. "We needed something for large numbers of patients who will not be able to be simply treated and then moved."

The No. 1 factor was that the facility needed to be able to last, Lake says. "We needed surge capacity not for two, three, or four days. We needed it for months or a year."

A nonmilitary look and feel also was important, because the public must know where the facilities are and how to reach them, he adds. In addition, because the structures have been tested for fire, heat, snow, wind, and other extreme weather, they can provide a controlled, clean environment.

"We looked all over — including other structures such as tractor-trailers and basic tents," Lake says. "This is a better long-term solution."

Boyle said Blu-Med is in the process of talking to other states and hospital associations about its new product. Each basic 50-bed unit — configured similarly to Nevada's — costs roughly $350,000. And Blue-Med is able to accommodate clients, based on need, such as the level of equipment required, medical supplies, and other hardware, he adds.

Nevada's program is supported through funding from the National Hospital Bioterrorism Preparedness Program. ■

Bioterror mail threats continue to be reported

Feds outline action steps for local response

Public health and law enforcement officials recently declassified a report that reveals ongoing biological threats through the mail. A large number of potentially suspicious letters and packages continue to be reported to federal, state, and local law enforcement and emergency response agencies nationwide, the Nov. 2, 2004, report states. In some instances, these letters or packages may include powders, liquids, or other materials.

Since there often is an articulated threat, it is likely the substance was intentionally introduced into the package in an effort to validate that threat. An articulated threat itself (with or without the presence of a suspicious substance) is a federal crime and also may constitute a violation under state and local statutes.

According to the report, these are some of the key steps to take for a letter/container with unknown powderlike substance and a threatening communication (with or without illness in the recipient):

- **Request the assistance of the nearest certified hazardous materials response team** to conduct risk assessments, field safety screening, sample (evidence) collection, decontamination, and other mitigation activities. Any sample (evidence) collection must be coordinated with law enforcement.
- **Notify appropriate law enforcement when a potential threat is identified.** Do not touch, move, or open any suspicious package until an initial hazard risk assessment of the package can be performed in coordination with HAZMAT personnel and law enforcement.
- **Contact your local public health department** (who should in turn notify state authorities and the Centers for Disease Control and Prevention) if there is a threat of public health exposure or environmental contamination exists.
- **In coordination with law enforcement, always notify the U.S. Postal Inspection Service,** whenever it appears the threat was delivered through the U.S. mail. Assist with ensuring the origin and tracking information is obtained from the package (ideally, photographs of the front and back).
- **Treat the scene as a crime scene.** Preserve evidence in coordination with law enforcement and ensure materials are packaged safely. Take steps to retain enough suspicious material for laboratory analysis and forensic examination of criminal evidence, regardless of whether the threat ultimately is determined to be accompanied by a hazardous material.
- **Transfer custody of evidence to a law enforcement officer as soon as possible.** Maintain chain of custody by obtaining a record of names and signatures every time custody of a suspicious material or sample for laboratory analysis changes hands.
- **In coordination with public health and law enforcement, identify and list names and contact information for anyone who may have been exposed to the suspicious substance** so they may be contacted when the lab test results are available or if there is other additional information. If positive results are obtained, state and local public health departments will need to contact those potentially exposed as soon as possible to provide appropriate assistance (e.g., antibiotics, education, additional testing, vaccination, and surveillance/symptom reporting). ■

New bioterror vaccines are getting in the pipeline

All aimed at 'Category A' agents

The federal government has awarded $232 million to fund research and development of new vaccines against three potential agents of bioterrorism: smallpox, plague, and tularemia. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), will administer the contracts.

The funding responds to a key objective of the NIAID biodefense research agenda, which emphasizes the development of new and improved medical products against "Category A" agents — those considered by the Centers for Disease Control and Prevention (CDC) to pose the greatest threat to national security.

The smallpox awards continue advanced development work that began in February 2003 on two modified vaccinia Ankara (MVA) vaccine candidates. These contracts will support larger scale manufacturing of the vaccines as well as further safety and effectiveness studies in animals and humans. The tularemia and plague awards will fund early-stage product development of the respective vaccines, which will include dosage formulation, pilot batch production, and initial clinical assessment. All four contracts are for purchases of vaccine lots intended for research use. Any future purchases of additional vaccines for stockpiling in the event of an emergency will depend on the results of the research currently under way.

NIAID awarded two contracts totaling up to $177 million for advanced development of MVA vaccines against smallpox. The three-year contracts were awarded to Bavarian Nordic A/S of Copenhagen, Denmark, and Acambis Inc. of Cambridge, MA, and Cambridge, England. MVA is a highly weakened form of the vaccinia virus that cannot replicate in human cells.

Previous NIAID research has demonstrated that MVA is nearly as effective as the standard smallpox vaccine, making it a promising candidate for use in children and pregnant women as well as people with weakened immune systems or skin conditions such as eczema. The new contracts will allow the companies to continue the work they began under contracts awarded in February 2003.

For the plague vaccine, NIAID awarded a contract to Avecia Biotechnology Ltd. of Manchester, England. The three-year, $50.7 million contract covers the manufacture of a new plague vaccine as well as animal testing and initial human trials. There currently is no licensed plague vaccine, and the pneumonic form of the disease, which infects the lungs and can spread from person to person through the air, is nearly always fatal unless antibiotic treatment is started within 24 hours of infection.

NIAID also modified an existing contract with DynPort Vaccine Company LLC of Frederick, MD, to include the manufacture of a pilot batch of live, attenuated tularemia vaccine. The three-year, $4.5 million contract modification also covers stability testing of the vaccine. Tularemia is a highly infectious bacterial disease most often transmitted by ticks and insects.

In humans, illness is characterized by intermittent fever, headache, and swelling of the lymph nodes. This live, attenuated vaccine contains a weakened form of the tularemia bacterium, enabling the immune system to recognize and produce neutralizing antibodies against the bacterium if it is encountered again. ■

Anthrax vaccination policy dropped after court ruling

Court rules against forced military vaccinations

The Department of Defense (DoD) has halted mandatory anthrax vaccinations of military personnel after a ruling by the U.S. District Court for the District of Columbia. The injunction cited a congressional "prohibition on forced inoculations with investigational drugs" in issuing a permanent injunction.

Until the Food and Drug Administration (FDA) certifies that the vaccine is safe and effective, the DoD "may no longer subject military personnel to involuntary anthrax vaccinations absent informed consent," the court ruled. Six plaintiffs, known as John and Jane Doe No. 1 through No. 6, brought the action to challenge the lawfulness of the government's anthrax vaccination program.

They all are military personnel and civilian contract employees of the DoD who have submitted or have been instructed to submit to anthrax vaccinations without their consent. The ruling also cited an expert panel on finding that "no meaningful assessment of the [the vaccine's] value against inhalation anthrax is possible."

Moreover, interested parties who originally were invited to comment on the vaccine in 1985 "could not have anticipated that FDA would permit the vaccine to be used for inhalation anthrax as a result of exposure through a biological attack," the court found. "Now for the first time, 18 years later, FDA's Final Rule and Order asserts the FDA 'does not agree with the panel report,' and believes that 'the vaccine is indicated for active immunization against [anthrax], independent of the route of exposure,' and that the vaccine will 'protect humans against . . . inhalation anthrax.'"

The court ruled that the FDA position was a significant post-comment expansion of the scope of the original inquiry and it deprived the public of a meaningful opportunity to submit comments and participate in the administrative process mandated by law.

In a press release, the DoD pointed out that the ruling does not question the safety and effectiveness of the anthrax vaccine.

"The injunction centered on FDA procedural issues stating that additional public comment should have been sought before the FDA issued its final rule in December of 2003," the DoD stated. "DoD remains convinced that the anthrax immunization program complies with all the legal requirements and that the anthrax vaccine is safe and effective." ■

ABSTRACT & COMMENTARY

B. cereus mimics anthrax infection

Could be used to confound attack response

Synopsis: A patient with a disease resembling anthrax led to the identification of anthraxlike virulence factors in an isolate of *Bacillus cereus*.

Source: Hoffmaster AR, et al. **Identification of anthrax toxin genes in a *Bacillus cereus* associated with an illness resembling inhalation anthrax.** *Proc Natl Acad Sci USA* 2004; 101:8,449-8,454.

A previously healthy patient presented with a two-day history of nausea, vomiting, hemoptysis, shortness of breath, and fever. His chest X-ray was abnormal, and his WBC on admission was 12,000/mm^3, subsequently rising to a peak of 22,400/mm^3.

Cultures of sputum and of blood yielded a gram-positive bacillus identified using traditional phenotypic characteristics, including biochemical reactions, as *Bacillus cereus*. The patient required mechanical ventilation for 44 days but eventually recovered.

Sequencing of the organism's 16S rRNA confirmed its identity as *B. cereus* while multilocus sequence typing found that it was closely related to, but distinct from, *Bacillus anthracis*.

The patient's isolate, however, contained a circular plasmid, named by Hoffmaster and colleagues as pBCXO1, that had 99.6% similarity with the *B. anthracis* toxin-encoding plasmid, pXO1.

In addition, a polysaccharide capsule cluster was encoded on a second plasmid, pBX218, thus providing an analog to the *B. anthracis* capsule genes encoded on its other plasmid, pXO2.

CE/CME *questions*

1. Some of the concerns about bioengineering smallpox virus included the possibilities of making the pathogen:
   A. capable of spreading in a suspended aerosol
   B. impervious to current vaccines
   C. more virulent
   D. all of the above
2. An advisory committee to the World Health Organization recommended that scientists be approved to insert genetic markers in smallpox to expedite the search for:
   A. transmission enhancers
   B. effective drug treatments
   C. ways to render it noninfectious
   D. rapidly conferred immunity
3. The so-called "instant hospital" complex is composed of six interconnected shelters to create a 50-bed, 4,000-square-foot facility.
   A. true
   B. false
4. During an investigation of a letter containing a suspicious powder and a threatening note, whose names and contact information should be collected on a list?
   A. likely suspects
   B. customers, patients who were turned away due to the incident
   C. anyone who may have been exposed to the suspicious substance
   D. all of the above

Answer Key: 1. D; 2. B; 3. A; 4. C

COMING IN FUTURE MONTHS

- Early signs of foodborne botulism
- Syndromic surveillance for flulike illness
- Ill wind revisited: The Sverdlovsk anthrax outbreak of 1979
- Public Health Emergency Response Guide
- Laboratory Response Network

The virulence of the patient isolate was confirmed by mouse inoculation experiments.

Comment by Stan Deresinski, MD, associate chief of infectious diseases, Santa Clara Valley (CA) Medical Center.

B. cereus, a cause of food poisoning, is an uncommon cause of invasive infection. These infections mostly occur in immunocompromised patients, and have included post-traumatic or post-cataract surgery endophthalmitis, prosthetic valve endocarditis, native valve endocarditis in injection drug users, and meningitis in neonates and hematopoietic stem-cell recipients.[1] Other reported infections include those of cerebrospinal fluid shunts and of vascular access. *B. anthracis*, on the other hand, is a highly virulent organism that causes potentially fatal disease regardless of precipitating events or immunocompromise.

The virulence is the consequence of the presence of the expression of genes carried by 2 plasmids, pXO1 and pXO2, which encode the lethal toxin complex and the poly-g-D-glutamic acid capsule, respectively. The virulent *B. cereus,* isolated from the patient had acquired a plasmid encoding the anthrax toxins and a second plasmid capable of encoding polysaccharide capsular material.

As indicated by Hoffmaster, et al, in a comment on the evolutionary plasticity of the microbial world, "depending on the number extent of lateral gene transfer, nature could produce an unlimited number of variations and combinations." Thus, when using standard clinical laboratory techniques, notions such as "anthrax bad, cereus not so bad" potentially are dangerous over simplifications that may have a number of important clinical and other implications, and that potentially apply to other organisms.

Thus, in some instances, the identification of an isolate such as *B. cereus* may lead to its being inappropriately disregarded as a contaminant.

The lack of association of severe virulence with such an isolate may lead to unnecessary searches for other etiologies of a patient's perilous clinical state. Finally, an engineered bioterrorism agent that clinical laboratories identify simply as *B. cereus* could lead to significant delay in the identification of a sinister attack.

Reference

1. Drobniewski FA. *Bacillus cereus* and related species. *Clin Microbiol Rev* 1993; 6:324-338. ■

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Physicians and nurses participate in this CE/CME program by reading the issue, using the provided references for further research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to answer key to test their knowledge.

To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this semester's activity, you must complete the evaluation form that will be provided and return it in the reply envelope to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME objectives

After reading each issue of *Bioterrorism Watch*, the infection control professional will be able to do the following:

- identify the particular clinical, legal or educational issue related to bioterrorism;
- describe how the issue affects health care providers, hospitals, or the health care industry in general;
- cite solutions to the problems associated with bioterrorism, based on guidelines from the federal Centers for Disease Control and Prevention or other authorities, and/or based on independent recommendations from clinicians and bioterrorism experts. ■