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Hazard alert: OSHA turns its ergonomic radar on hospitals

Regional emphasis programs target hospitals and MSDs

Hospitals with high injury rates or a high proportion of ergonomic injuries will receive targeted inspections in some regions of the country under a new enforcement program for ergonomics.

Four regions have adopted a local emphasis program in at least some areas, including New England, New York-New Jersey, the Plains states of Region 7, and the Mountain states of Region 8. Each of the 14 local emphasis programs within those regions may be structured differently, but the bottom line is the same: reducing ergonomic injuries due to patient handling.

"This is a piece of the strong enforcement" as part of the four-pronged approach to ergonomics announced by Labor Secretary Elaine Chao, says **Mark Hatch**, senior industrial hygienist in the Occupational Safety and Health Administration's (OSHA) office of health enforcement. "It's not limited to just enforcement. We're also dealing with outreach as well," he adds.

The regional programs complement a national emphasis program that has targeted nursing homes for inspection. So far, 475 facilities have been inspected, resulting in three citations of nursing homes in Idaho that are owned by the same corporation. Another 60 nursing homes received "hazard alert letters" warning them of high ergonomic injury rates.

Seven hospitals have received hazard alert letters among the 253 hospitals inspected since Oct. 1.

The ergonomics enforcement failed to impress worker advocates, such as **Bill Borwegen**, MPH, occupational safety and health director for the Service Employees International Union (SEIU) in Washington, DC. Borwegen notes that many of the citations of nursing homes address building safety issues, such as electrical hazards, rather than hazards related to patient or resident care.

"They're refusing to cite employers on ergonomics, which is the No. 1 hazard these employees face," he says. "It's just breathtaking that they're

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so out of sync with the hazards that are actually threatening workers."

About 13,000 hospital workers lost at least one day of work in 2001 due to overexertion in lifting, according to data from the Bureau of Labor Statistics (BLS). Although the injuries have decreased in recent years, the health care industry still has among the highest rates of work-related musculoskeletal disorders (MSDs). Nurses who missed work due to an MSD were out for a median rate of five days.

The BLS statistics don't even reflect the full magnitude of the problem, asserts **Butch de Castro**, PhD, MSN, MPH, RN, senior staff specialist with the American Nurses Association Center for Occupational Health and Safety in Washington, DC. BLS only reports lost-time injuries.

"An OSHA standard is sorely needed in order

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to protect health care workers, as well as other types of workers, from ergonomic hazards," he says. "Workers are continuing to be injured at great rates and are being debilitated."

Without a standard, OSHA issues ergonomics citations under the "general duty" clause of the Occupational Safety and Health (OSH) Act, which requires employers to provide a workplace free of serious hazards.

"The burden of proof is higher" than with a standard, says **Rich Fairfax**, CIH, OSHA's director of enforcement.

Yet most employers will respond to OSHA's more cooperative approach, he asserts. "We'll use [the enforcement action] on the employers who are not complying and meeting their obligations under the OSH Act. There are far more employers who just need a little push. We're there with assistance and outreach and guidelines."

The push may come from the threat of inspection. Local emphasis programs may differ in details, but they all involve a focus on MSDs and ergonomic interventions.

For example, the New England (Region 1) program covers hospitals in Connecticut, Maine, New Hampshire, and part of Massachusetts. Inspectors will conduct a comprehensive inspection of hospitals that have an injury rate of eight or more lost work-time cases per 100 employees, or if more than 50% of the lost- and restricted-time cases resulted from "ergonomic stressors."

State plan states are not part of the national or local emphasis programs, but may have comparable efforts. Washington and California are the only states with an ergonomics standard.

Ergonomics expert **Guy Fragala**, PhD, PE, CSP, says he is encouraged by OSHA's emphasis on ergonomics. "This demonstrates that they are taking ergonomics seriously," says Fragala, who is director of environmental health and safety at the University of Massachusetts Medical Center in Worcester.

OSHA's strategic management plan calls for reducing occupational injuries by 20% by 2008. Reducing MSDs, the most prevalent work-related injury, will need to be a significant part of that.

Employers don't have to follow specific requirements as they address ergonomic hazards. If an employer is making an effort to apply ergonomic interventions, that is enough to avoid a general duty clause citation, Fairfax says.

To make a case, OSHA inspectors must find that four criteria apply, Fairfax says: "The employer failed to keep the workplace free of a hazard that

the employees were exposed to. The hazard was recognized — the employer knew there was a hazard. The hazard was causing or likely to cause serious injury or death. [And] there has to be a feasible method of abatement.

"If we go into a hospital and we find they have what appears to be a problem with resident handling, we have to go back and establish that all four of these elements are there," he says.

In the case of the Idaho nursing homes, any existing lifting equipment was either broken or unused. The staff had not been trained to use the equipment, and the administration had not implemented an ergonomics program, Fairfax says. The nursing home reached a settlement agreement with OSHA.

"The employer indicated to us that they wanted to correct the problems and comply, and we cut the penalties down significantly," he says. "We also worked out a penalty payment plan so they could spread it out over the course of a year."

SARS transmission among protected HCWs puzzling

CDC researchers, HCWs in Toronto wearing N-95s

Hospitals acted to improve their respiratory protection programs as new questions surfaced about protections of health care workers from severe acute respiratory syndrome (SARS). When respirators are used for SARS or any infectious disease other than tuberculosis, health care workers must be fit-tested annually, according to the U.S. Occupational Safety and Health Administration (OSHA).

Respirator use and other precautions also came under scrutiny when an infection control expert from the Centers for Disease Control and Prevention (CDC) developed possible symptoms of SARS in Taiwan.

Taiwan, which suffered from numerous hospital-based outbreaks and had more than 585 cases, has been struggling to control SARS.

The investigator had been fit-tested to use an N95 and wore the same protective equipment that CDC employees use when encountering infectious diseases, such as Ebola, CDC director Julie Gerberding, MD, said in a press briefing.

CDC investigators retraced his activities in the days before he developed a fever and slight cough in an effort to trace his exposure, although

An employer that has begun implementing an ergonomics plan but still has a high rate of injuries would likely receive a hazard alert letter with suggestions for improvement, but not a citation, says Fairfax.

OSHA administrator John L. Henshaw has stressed that "as long as the employer is exercising good faith, they are not likely to be a candidate for our enforcement efforts."

In one case, a manufacturing employer began an ergonomics program when the OSHA standard was imminent. When Congress repealed the standard, the employer halted the program. Then when OSHA inspectors appeared and began asking about ergonomic hazards, the employer renewed the program. That is not a show of good faith, says Fairfax.

"They didn't start again until we started to do an inspection," he says. "For two years, they were injuring people. They are likely to get a citation." ■

Gerberding noted, "it may be that we'll never exactly know when or where his exposure occurred," if he actually has SARS. Meanwhile, a different CDC team continued to study the transmission of SARS to protected workers in Toronto hospitals.

Was there a breach in infection control? Or is an even higher level of protection needed? Gerberding said CDC will "continue to look hard" at whether infection control precautions must be changed. But she also noted, "You have to be 100% compliant in order to be absolutely certain that there isn't an inadvertent airborne exposure."

Hospitals already are scrambling to beef up their respiratory protection programs. Some are adding to the number of employees who have been fit-tested to wear N-95s. The OSHA respiratory protection standard (1910.34) requires annual fit-testing. (**For more information on tuberculosis requirements, see box, p. 84.**)

"The misinterpretation out there is that we require fit-testing for all employees in a facility," says Amber Hogan, industrial hygienist in OSHA's Office of Health Enforcement. "We only require fit-testing for those employees who have exposure or potential exposure to those patients who have SARS."

She suggests designating clinicians in some departments, such as radiology or pediatrics, as part of a SARS care team and fit-testing those

workers — but not everyone in the department.

Hogan also noted that there likely would be an overlap between those fit-tested to care for TB patients and those who might encounter a SARS patient.

Some hospitals have turned to powered air-purifying respirators (PAPRs) as an alternative protection. PAPRs do not have to be fit-tested and can be used by more than one employee.

One thing is clear about SARS: Worldwide, hospitals have been a major focus of transmission.

In Taiwan, a six-day delay in diagnosing a hospital laundry worker with SARS led to unprotected exposure of about 10,000 patients and visitors and 930 employees. From that one chain of exposure, 137 people developed symptoms and are "probable" cases of SARS; 45 of them (33%) were hospital workers.¹

Elsewhere, hospital workers have been among the most prevalent victims. In Hong Kong, 85 of 138 cases of secondary and tertiary spread occurred among health care workers. In Toronto, 73 of 144 such cases involved health care workers.² (So far in the United States, hospital outbreaks have not occurred and two of 66 probable cases involve a health care worker.)³

In light of these hospital-based outbreaks, Bill Borwegen, MPH, occupational safety and health director for the Service Employees International Union (SEIU) in Washington, DC, called for research on the effectiveness of N-95s against the SARS virus.

"Where is the documentation that the N-95s are adequate?" says Borwegen. "All we know is that we have 15 victims in Canada" who were infected despite wearing protective equipment.

In hospitals with a large number of SARS patients, nurses have been wearing the N-95 respirators for virtually their entire shift. That may make it more difficult to continuously maintain infection control standards, employee health experts say. (**For a nurse's perspective on working amid SARS, see article, p. 87.**)

Aerosol-generating procedures, such as intubation, appear to be particularly risky. In one Toronto case, nine health care workers caring for a SARS patient while he was intubated developed suspected or probable SARS.

For hospital employee health, the specter of SARS adds a new imperative. Some facilities already are equipping additional employees with respirators to ensure protection against SARS, including security, housekeeping, and registration staff. For example, at Marshfield (WI) Clinic,

about 300 employees are fit-tested for respirators to work with tuberculosis patients. About 1,000 more may need respirators to protect against a SARS patient who could walk into an outpatient center, says **Bruce Cunha, RN, MS**, manager of employee health and safety.

"It takes about 15 minutes to do a fit test, if you're zipping right through them," he says. "[For] 1,000 people, [fit-testing] eight hours a day, it would take six weeks. If I've got to go back now and refit [the other employees], I've got another issue. I don't have even my basic core group."

If the fit tests occurred every year, Cunha says he would need to hire another employee to conduct them. "It's not feasible, and it really doesn't make any sense to have different protocols for different diseases," he says.

Hogan notes that OSHA does not have the legal authority to include SARS in the tuberculosis respiratory standard (1910.139), which was created as an interim measure while the agency was developing a tuberculosis standard.

Meanwhile, Cunha has purchased 12 additional PAPRs, which can be used by different employees after disinfecting.

Just how important is fit-testing of N-95s? That question is coming under scrutiny as the CDC investigates hospital-based outbreaks in Canada.

CDC's recommendations for HCWs exposed to SARS

The Centers for Disease Control and Prevention in Atlanta has recommended surveillance of health care workers who have contact with severe acute respiratory syndrome (SARS) patients or their environment of care. Hospitals should:

- Develop and maintain a list of all personnel who enter the rooms of SARS patients, or who are involved in the patient's care in other parts of the hospital.
- Instruct personnel who have contact with SARS patients or their environment of care to notify occupational health, infection control, or their designee if they have unprotected exposure to a SARS patient or if they develop any fever or respiratory symptoms.
- Monitor employee absenteeism for increases that may suggest emerging respiratory illness in the work force. Notify local and state health authorities of clusters or unusual increases in respiratory illness, including atypical pneumonia. ■

Several health care workers developed SARS despite the use of protective equipment, including N-95 respirators and face shields. Canada did not require respirator fit-testing. In one reported case, nine health care workers caring for a SARS-infected physician at the time he was intubated subsequently developed SARS symptoms. The primary nurse has a small beard and reported feeling air move around his N-95 mask.¹

Although SARS cases began to diminish in May, hospitals remained at high alert for potential cases. "It only takes one patient in an infectious state to slip through the cracks," noted Gerberding.

CDC is recommending a 10-day quarantine for

health care workers who have unprotected "high-risk" exposure to SARS patients. "Unprotected high-risk exposure is defined as presence in the same room as a probable SARS patient during a high-risk aerosol-generating procedure or event and where recommended infection control precautions are either absent or breached," the CDC said. (See CDC's algorithm, p. 86.)

High-risk procedures include aerosolized medication treatments, diagnostic sputum induction, bronchoscopy, endotracheal intubation, airway suctioning, and close facial contact during a coughing paroxysm, the CDC said.

Other health care workers with unprotected

Will OSHA still cite on TB skin tests, fit tests?

With no new standard, CDC guidelines reign

It's official: The tuberculosis standard is dead. The Occupational Safety and Health Administration (OSHA) withdrew the TB standard from its regulatory agenda, citing the decline in tuberculosis cases in the United States. The action had been expected; earlier this year, OSHA placed the TB rule in the "long-term action" category of the semiannual unified regulatory agenda and called future activities "undetermined."

What does OSHA expect now? Will inspectors still cite hospitals on issues related to tuberculosis?

Tuberculosis is a recognized workplace hazard that could bring enforcement action under the agency's "general duty" clause, says **Amber Hogan**, MPH, OSHA senior industrial hygienist. A 1996 compliance directive incorporated the TB guidelines of the Centers for Disease Control and Prevention (CDC) in Atlanta. So essentially, OSHA will enforce the CDC guidelines, she says. "What OSHA expects is what CDC recommends. That's the benefit of not having a standard, but having a directive. If the CDC changes their recommendation for skin testing, we can do that, too."

For example, the CDC calls for hospitals to conduct a risk assessment, which would place them in one of five categories, ranging from minimal risk to high risk. A "minimal risk" facility, which does not admit TB patients and is located in a community that has not reported any TB cases in the previous year, would not need to conduct annual skin testing. Low-risk facilities would conduct skin tests every year, those at intermediate risk would provide skin tests every six to 12 months, and high-risk facilities would perform the tests quarterly.

Positive skin tests must be recorded on the OSHA log unless there is proof that the employee

got it from a different source. "In a lot of situations, it is recordable just because it's nearly impossible to show they got it someplace else," says Hogan.

With no new TB standard, hospitals must continue to comply with the current respiratory protection standard that specifically addresses tuberculosis, 1910.139. That does not include a requirement for annual fit-testing, although it requires initial fit-testing.

Employees must be properly trained on how to wear the respirator and how to determine if it fits properly. A fit test must be repeated if any facial changes occur that could affect fit — such as weight loss, cosmetic surgery, or a change in the size or make of the respirator.

If the respirator is used for any other substance, including any other airborne pathogen, hospitals must comply with OSHA's revised respiratory protection standard (1910.134), which requires fit-testing "at least annually."

"It is strongly recommended that employers follow this same frequency for protection against tuberculosis," says OSHA spokesman **Bill Wright**.

A 1999 *Administrator's Guide*, published by the National Institute for Occupational Safety and Health, details how to conduct a fit test and states that "[f]it tests should be completed at regular, periodic intervals (e.g., annually) to ensure continued adequate fit."

Greater awareness and early detection of TB has led to a decline in cases nationwide, notes Hogan. Lower risk meant less justification for a new tuberculosis standard and few citations.

"Almost all TB [enforcement] cases are based on a complaint or [occur] if there's an outbreak," says Hogan. However, TB has been included as an inspection item in the national emphasis program that targets nursing homes with high injury rates, she notes.

(For a copy of the Administrator's Guide, go to: www.cdc.gov/niosh/pdfs/99-143.pdf.) ■

exposures should take their temperature twice a day and report to employee health each day for 10 days to check for early symptoms, the CDC advises.

Hospital workers are particularly vulnerable to "superspreaders" — patients who are highly infectious. "The transmission efficiency may vary widely from individual to individual," said **John Jernigan**, MD, MS, leader of clinical and infection control in CDC's SARS investigation team, in a webcast. In one cluster of cases in Singapore, five patients were associated with transmission to large numbers of people, while 81% of those infected subsequently infected did not transmit the virus.

"We don't understand this phenomenon and what makes a person more likely to be involved

with large numbers of secondary transmissions," Jernigan says.

So far, the United States has not encountered a superspreadер. But Gerberding cautions, "If we were unfortunate enough to have someone with unrecognized SARS be admitted to a hospital or be present in an environment where they could expose many other people, we too could have a cascade of transmission established."

At this point, there are no distinguishing features of a superspreadер. "We can't tell, up front, who's going to be infectious and who isn't," she says.

Surface contamination may be another route of infection of health care workers. In the Canadian transmission, health care workers could have

Source: Centers for Disease Control and Prevention, Atlanta.

infected themselves when they removed their personal protective equipment, CDC reported.

"Many health care workers apparently lacked a clear understanding of how best to remove PPE without contaminating themselves," investigators reported.

The proper order, according to the report, is the removal of gloves first, followed by the mask and goggles. Hand hygiene then should be performed with hand washing or alcohol-based hand rubs.

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2. Ofner M, Lem M, Sarwal S, et al. Cluster of severe acute respiratory syndrome cases among protected health care workers — Toronto, Canada, April 2003. *MMWR* 2003; 52:433-436.
3. Centers for Disease Control and Prevention. Update: Severe acute respiratory syndrome — May 28, 2003. *MMWR* 2003; 52:500-501. ■

Grace under fire: Nurse copes with SARS outbreak

'This will affect my practice forever'

On March 24, Carol Tough, RN, had to make a decision between going to work and possibly risk getting a mysterious new disease, or quitting the career she'd had for 17 years. She went to work.

The next weeks at Scarborough Grace Hospital in Toronto were surreal, as colleagues became patients. The emergency department (ED) where she worked was closed. For 10 days, she was in semi-isolation, only going to work and home. She wore an N-95-equivalent respirator at work and when she was near her husband and two children.

The ordeal began on March 24, when she was preparing for the night shift and saw a report on TV about cases of "atypical pneumonia" shutting down the hospital. She called in and was told to report to duty; she would be wearing a mask and other protective gear. Her 12-year-old daughter began to cry, "Mommy I don't want you to go; don't go to work. I don't want you to die."

"Inside, I was very frightened, but I said, 'Mommy has to go to work. I'm a nurse. This is what I do. I'm going to protect myself,'" she recalls.

At home, Tough's husband slept on the couch so she wouldn't have to wear a respirator at night.

She ate in the living room while the rest of the family ate at the dining room table. She even was advised against taking a shower because the steam could aerosolize any existing virus droplets; she took baths. At work, everyone was masked, including administrators who had no patient contact. She ate in the cafeteria, each member of the staff sitting alone at tables.

Wearing a respirator for most hours of the day was a challenge in itself. "The fit is very tight to your face," she says. "You're breathing your own air. You're constantly breathing in your own CO₂. You would have headaches, dizziness. They recommended we break at least once an hour, but sometimes it wasn't possible to do."

Everyday before her shift, Tough stepped into a parked bus where she would undergo screening — having her temperature taken, answering 12 to 14 questions. Anyone with a fever or who had unprotected exposure and another index symptom was sent to employee health.

It was impossible not to answer yes to some of the questions. "Wear a mask for 12 hours, and you'll have a sore throat, too," she quips.

Tough, 40, had trouble sleeping and started having nightmares. "The fear that I was dealing with inside would materialize in my sleep."

She saw some of her friends come down with symptoms. After an initial assessment, they were transferred to an isolation center. "All seven or six [patients] would go out to the bus in full isolation gear. The ambulance crews were in full isolation gear, so were all the staff. You could go and hug them and had no idea whether you would ever see them again. There are just no words to describe that. None. And the fear they must have felt."

Ultimately, eight members of the ED staff were hospitalized with suspected severe acute respiratory syndrome (SARS). Two actually did not have the disease. The others are recuperating.

Meanwhile, the usually bustling ED became barren. Tough and other nurses spent their time restocking shelves, updating phone lists, doing paperwork. Even when the staff were allowed to stop wearing protective gear, some nurses kept it on as a precaution. "I'm happy to be rid of mine," remarks Tough.

The experience has caused Tough to think about her chosen career and why she does it. "There's a risk every time I go to work. I've had my ribs fractured; I've been burned; I've been choked. I've had my share of back injuries after 17 years of nursing."

She had used protection against tuberculosis,

HIV, Norwalk virus, and methicillin-resistant *Staphylococcus aureus*. But SARS was different. Much still is not known about the virus and how it is transmitted. Some health care workers in Toronto developed the disease despite wearing protective equipment.

"I make \$33.75 an hour. Was it worth risking my life for that? I don't think so," says Tough. "But I don't do it for the money. In all honesty, that's not what makes me get up in the morning and go to work. It's my patients, the thrill I get in my job, and what keeps me going day to day is the hands-on. It's the laughing, the comradery with the people I work with that keeps me going."

The staff at Scarborough Grace became bonded as they faced the crisis together. "It amazes me on a daily basis to realize how these people worked, and they came together as a team. It was an amazing experience. However negative and scary it was, it sure told me what I was made of and what I can cope with," she says.

Meanwhile, Tough says she always will take infection control precautions more seriously.

"I think this will affect my practice forever. I think I'll look at a cough differently for the rest of my career, a shortness of breath," she adds. "I think I'll more readily put on isolation gear for anything that might be perceived as a risk." ■

UV light proven as new tool against TB

'Blue zone' inactivates bacteria in room

Ultraviolet (UV) light is an effective way to inactivate tuberculosis and prevent transmission in hospitals, according to a study sponsored by the National Institute for Occupational Safety and Health (NIOSH) in Cincinnati.

The use of UV light as an infection control tool has been controversial. This is the first study to demonstrate the effectiveness of UV light and to test different factors that may affect its functionality, says **Millie Schafer**, PhD, a research chemist with NIOSH who coordinated the project.

"It is an engineering control in its own right. We feel we have validated it as that," she says.

UV light may be especially useful in areas where tuberculosis patients have not yet been diagnosed and isolated, such as waiting areas, the registration area, or the emergency department.

"When you have a case that you know is TB, I think you need to have a negative pressure," says **Shelly Miller**, PhD, assistant professor in the department of mechanical engineering at the University of Colorado at Boulder. Miller was the principal investigator for the study.

Although the study focused on tuberculosis, it may have implications for preventing the transmission of other types of diseases. "Different organisms are susceptible to UV at different strengths," says Miller. "You want to make sure that the UV you're putting in the room is enough irradiation to inactivate the bacteria you're looking at. TB turns out to be a fairly susceptible to UV."

It's not known whether UV light would be effective in inactivating the virus that causes severe acute respiratory syndrome. "Very, very little has been done with using UV to inactivate airborne viruses" because it is so difficult to aerosolize viruses, says Miller. She and her colleagues are designing a study to test ultraviolet light with viruses, she says.

Although the antibacterial effects of UV light have been acknowledged for years, it wasn't easy to prove that it works. It took five years to design and conduct the study. Miller and her colleagues tested three bacteria that they could aerosolize: *Mycobacterium parafuitatum*, *Mycobacterium bovis* (a TB surrogate), and *Bacillus subtilis*.

Mark Hernandez, an environmental microbiologist at the University of Colorado, designed a method to sample and measure the inactivation of the bacteria. The researchers then created a simulated hospital room, with two to eight air changes per hour with a slight negative pressure. A manikin, heated to replicate body temperature, represented the patient. "We wanted it to be as close to a real health care room as possible," says Miller.

The UV system consisted of five lamps: one in each corner with bulbs totaling 36 watts and one in the center with bulbs totaling 72 watts. NIOSH will issue technical information on how to properly use UV light to inactivate bacteria.

Here are some factors that influence the effectiveness of the technology:

- **Placement of bulbs.** The lights must be evenly dispersed in the ceiling to create a "blue zone" where the bacteria will be inactivated, Schafer says. When they were concentrated in one part of the room, the system was less effective. The system should have a louvered fixture to allow the air to circulate near the bulbs but to protect health care workers in the room from the radiation. The ceiling

also should be at least 8 feet high, she says.

• **Mixing of air.** Researchers used a fan to make sure the air circulated and reached the “blue zone.” This can be especially important in some climates. For example, during the winter, heated air will rise and stay toward the ceiling, preventing the bacteria from reaching the UV lights.

• **Ventilation.** UV light can enhance infection control in a negative-pressure room. But the more frequent the air changes, the less effective the UV system will be in inactivating bacteria. “Sometimes, if you have a lot of ventilation, you might decide not to spend the money to put the UV in that space. You might decide to put it in a space where you’re not getting as much ventilation as you’d like,” Miller says.

• **Maintenance.** Over time, dust will build up on the lamps and decrease the effectiveness of the system. “You’ll need to check them every so often to make sure they’re still operating at an acceptable level,” she says. UV levels also should be monitored to make sure health care workers are not exposed to harmful levels.

The design of the UV system is critical, says Schafer. “Just walking in and throwing a bulb up on the wall, saying we have UV [germicidal irradiation] is not what we would be telling people to do.” UV also cannot protect health care workers while they are in close contact with patients. Personal protective equipment still will be essential, she adds.

Recommended reading

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Smallpox slowdown: Some call for halt before phase 2

Some states already vaccinate first responders

First responders and law enforcement officers began receiving smallpox vaccines in some states, even while cardiac events associated with the vaccine continued to draw scrutiny.

Myopericarditis — inflammation of the heart or the membrane covering the heart — has officially been added as a vaccine-related adverse event. In all, 21 health care workers developed the condition

after smallpox vaccination, according to the Centers for Disease Control and Prevention (CDC).¹ That includes seven vaccinees who developed dysrhythmias, which is part of the case definition of myopericarditis. Six vaccinees suffered a heart attack — including two who died — and three had angina, but the CDC has not yet determined if those incidents were related to the vaccine. If the current cardiac-risk screening tools had been in place, only three of the nine would have received the vaccine.

Only about 36,000 health care workers have received the smallpox vaccine, far fewer than the 500,000 once envisioned by the CDC. The response varied greatly around the country. For example, about 3,600 health care workers were vaccinated in Florida, but as of May 19, only 10 public health workers had received the vaccine in Nevada.

About half of those vaccinated were concentrated in eight states: Florida, Minnesota, Missouri, Nebraska, North Carolina, Ohio, Tennessee, and Texas.

“Right now, we’re considering whether or not vaccination should be expanded [to other groups],” Lisa Rotz, MD, of the CDC’s Bioterrorism Preparedness Response Program said at the American Occupational Health Conference in Atlanta in May. The conference is sponsored by the American Association of Occupational Health Nurses and the American College of Occupational and Environmental Medicine. “Some states have moved forward, and that’s OK. We just haven’t done it on a national, across-the-board basis.”

An Institute of Medicine panel had urged the CDC to evaluate the vaccination program before going ahead. A General Accounting Office (GAO) report said that not enough information was available on the program’s safety.² “Although the CDC announced that it would provide guidance for and request plans from the jurisdictions for the second stage, it has not done so,” the GAO said.

The report noted that “too few health care workers have been vaccinated and too little time has passed since their vaccination to precisely estimate rates of adverse events. Therefore, it cannot yet be determined whether the rates are the same as would have been anticipated on the basis of historical data or different enough to trigger reconsideration of how the program should proceed.”

Advocates for health care workers also urged caution, particularly while the CDC investigates whether serious cardiac events are related to the vaccine. “There needs to be a distinct period where evaluation is done and modification is done to

make sure we're moving appropriately into this next round of vaccinations," says **Cheryl Peterson**, RN, senior policy fellow with the American Nurses Association in Washington, DC. "I don't see that happening, and I think that's unfortunate."

The CDC has promoted smallpox vaccination as a critical part of bioterrorism preparedness and had advocated a smooth transition from stage one to stage two. Some states have taken that message to heart.

"This is not about a vaccination program. This is about a preparedness program — [for] health and emergency response teams to be ready in the event of a smallpox attack," says **David Miller**, coordinator of Operation Vaccinate Florida. He predicted phase two would take six to nine months as the state offered the vaccine to emergency medical workers, fire and rescue workers, and law enforcement officers in May. He didn't have an estimate of how many might eventually receive the vaccine.

In Tennessee, public health authorities began planning for phase two but put off implementation until fall. "We would like to evaluate the experience with phase one and also hope that the CDC will come forth with more about the adverse events," says **Allen Craig**, MD, state epidemiologist with the Tennessee Department of Health.

The response to phase two may be less than enthusiastic. At University Hospital in Newark, NJ, first responders were offered the vaccine as part of phase one. The hospital-affiliated emergency medical service (EMS) provides medical response for the city of Newark and the Newark International Airport. Only three EMS workers were vaccinated.

"There will not be a big outcry for the vaccine," predicted **Lawrence Budnick**, MD, MPH, director of the occupational medicine service at the University of Medicine & Dentistry of New Jersey, also in Newark. A new federal compensation program may address some concerns about compensation for adverse events. But conversely, the end of the war in Iraq may have dampened the sense of urgency and threat, he noted.

Meanwhile, some employee health professionals began wondering about the long-term maintenance of their preparedness teams — how to cope with staff turnover and the potential need for boosters. Immunity diminishes after about five years, Rotz said. "The initial goal is to get some teams vaccinated. We've got some time to work out those other issues."

(Editor's note: For a copy of the GAO report on the smallpox vaccination program, go to: www.gao.gov/new.items/d03578.pdf.)

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Hospitals fall short in preventing violence

Studies look for impact of programs

Many hospitals are failing to address the risk of workplace violence, even when state law requires prevention efforts, according to preliminary findings of a California-based study.

In California, hospitals must have a violence prevention program in order to receive accreditation by the state licensing division. But those programs often fall short, says researcher **Corinne Peek-Asa**, associate professor of occupational health at the University of Iowa's Injury Prevention Research Center in Iowa City.

She is conducting interviews in 200 California hospitals for the ongoing, three-year project, which is designed to assess violence prevention activities and the impact of the California law. The project is sponsored by the National Institute for Occupational Safety and Health (NIOSH) in Cincinnati. "Some hospitals have very good, very comprehensive security programs. It's clear that the administration is prioritizing the issue. Other hospitals have not recognized the problem. [There are some] hospitals that really do have a high level of violence but have not addressed it yet," she adds.

Peek-Asa stresses that a security plan is not the same as violence prevention. In its *Guidelines for Preventing Workplace Violence for Health Care and Social Service Workers*, the U.S. Occupational Safety and Health Administration (OSHA) outlines the components of a Violence Prevention Program: management commitment and employee involvement; work site analysis; hazard prevention and control; and safety and health training. (For more information on the guidelines, see *Hospital Employee Health*, October 2001, p. 111.)

Yet there is no single template. "It starts with a good comprehensive plan, where there's some forethought into this based on the actual environment the employee works in — how patients flow

through procedures, how information is communicated among different workers or shifts."

The need is clear: Nurses and nurses' aides have among the highest rates of workplace assault of all occupational groups. In 2000, there were 2,831 assaults in hospitals nationwide that resulted in a health care worker missing at least one day of work, according to the U.S. Bureau of Labor Statistics.

The number of nonreported assaults is far greater, says **Susan G. Gerberich**, PhD, director of the Regional Injury Prevention Research Center and Center for Violence Prevention and Control in the School of Public Health at the University of Minnesota in Minneapolis. Even verbal assaults have a significant impact. "There are numerous consequences from those physical assaults. There are even more consequences from the nonphysical — verbal abuse, sexual harassment, threats. That kind of thing should not be tolerated," she says.

'It's part of the job'

One major barrier to violence prevention comes from the nurses and other health care workers themselves: Too often, they accept violence as an expected part of their jobs.

That mindset may come from the top, at least in the workers' eyes. In one study, two-thirds of nurses who had filed workers' compensation claims related to violent assaults at work said they felt the hospital administration considered assault to be "part of the job."¹

"I think [administrators] have to make it very clear to the employees that they want to do everything in their power to prevent and control these violent events," says Gerberich. In fact, administrators may not realize the extent of the problem in their facilities, in part because of those attitudes and perceptions. "There's a great hesitancy on the part of nurses to even report some of these events." Getting reliable baseline information about violent events is an important first step toward violence prevention, she says.

Administrators could convene a multidisciplinary task force and use outside contractors to solicit information from employees. "It's an

CE questions

1. To issue a citation on ergonomics, OSHA inspectors must meet four criteria of the general duty clause enforcement. Which of the following is NOT one of those four criteria?
 - A. The employer failed to keep the workplace free of a hazard.
 - B. The employer knew there was a hazard.
 - C. The hazard caused at least 10% of the facility's lost-work-time injuries.
 - D. There is a feasible method of abatement.
2. According to OSHA, if hospitals use respirators to protect health care workers against diseases other than tuberculosis, they must:
 - A. Provide baseline fit-testing.
 - B. Provide annual fit-testing.
 - C. Give employees a choice of respirator type.
 - D. Allow respirator reuse.
3. According to CDC, if hospital employees have unprotected exposure to a SARS patient, they should:
 - A. Quarantine themselves for 10 days.
 - B. Quarantine themselves for 72 hours.
 - C. Contact the CDC.
 - D. Notify employee health or infection control.
4. Which of the following would improve the effectiveness of ultraviolet light as a method of inactivating airborne tuberculosis?
 - A. increased room ventilation
 - B. concentration of UV light in one area of the room
 - C. mixing of the room air
 - D. heating of the room air

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

extremely sensitive issue," Gerberich says.

Meanwhile, in the push for patient safety, administrators need to be careful not to send a subtle message that workers are expendable. "The new emphasis on good patient and customer relations focuses so much on the patient satisfaction and the patient experience that it leaves behind the worker experience. We believe those go hand in hand," says Peek-Asa. "You

COMING IN FUTURE MONTHS

■ Sick line: Hospital creates a tool to monitor employee illness

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can't sacrifice the worker for the patient."

Even if a hospital has addressed violence prevention, it needs to send a consistent message. Simply stating that you have "zero tolerance" for violence isn't enough, she says.

Does violence prevention work? Researchers are beginning to ask that question — and to evaluate what aspects are effective.

Last year, NIOSH awarded five grants totaling about \$1.8 million for research into violence prevention. Health care workers were among four occupations targeted by the research as high risk.

In research at the University of Minnesota, the presence of security personnel and video monitors were related to lower rates of work-related assaults.

Written policies on assault prevention and dealing with patients with repeated violent behavior also were linked to less violence. While the nurse-patient ratio wasn't a significant element, working alone or working with patients with mental illness were related to higher rates of assault.¹

"There's no one factor that is directly related," says Gerberich. "It's in concert with other factors in the environment. Patient contact is certainly very important, but that's also controlling for the environment in which they're working. You can't just look at one variable at a time." Quality leadership is also "crucial" in creating effective violence prevention, she says.

Both Gerberich and Peek-Asa say they hope further research will shed light on the essential elements of successful violence prevention.

In her research, Peek-Asa plans to compare hospital prevention programs in California with those of other states. For example, California requires all employees in the emergency department to have training in how to de-escalate growing violence. Researchers also hope to quantify the benefits of violence prevention, which include lower workers' compensation costs, less absenteeism, greater work satisfaction, and increased productivity, she says.

"One problem is that we haven't demonstrated how effective prevention can be," Peek-Asa says. "There can be extremely effective approaches to preventing violence."

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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. ■

BIOTERRORISM WATCH



Preparing for and responding to biological,
chemical and nuclear disasters

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Plague in the Big Apple: Rare cases trigger bioterrorism response

'It was pneumonic plague until proven otherwise'

When a rare and deadly infection suddenly appears out of time and place, today's clinician cannot exclude the possibility of bioterrorism. A case of plague (*Yersinia pestis*) had not been seen in New York City in more than a century. In November 2002, there appeared not one case, but two.

A couple from New Mexico, where the disease maintains a low endemic level in various animal hosts, traveled to New York City. Two days later, they developed fever and unilateral inguinal adenopathy suggestive of plague. In time, the telltale buboes — swollen lymph glands — would appear as the classic marker for bubonic plague. As the news got out, a newspaper headline warned that the "Black Death" had hit a city already deeply scarred by acts of terrorism.

Much like smallpox, plague resonates with grim historical overtones. The disease hardly needs large font headlines to invoke a visceral response. In a period of some five years in the 14th century, plague killed 25 million Europeans. Combine that with post-9/11 New York City, and you have the makings of a panic.

"New York citizens are very shaken, as you can imagine," says **Beth Raucher**, MD, hospital epidemiologist for Beth Israel Medical Center, the New York City hospital where the patients were admitted. "People are very brittle here. If you had seen some of the newspapers and web sites that published that first day — there were terrible headlines. We had to dispel a lot of that."

The couple, a 47-year-old woman and 53-year-old man, received gentamicin and other antibiotics in the hospital emergency department. Both patients were admitted and placed in respiratory isolation pending exclusion of pneumonic plague.

"We made the assumption that it was pneumonic plague until proven otherwise," Raucher says. "That is why we put both patients on strict isolation prior to finding out what their diagnosis was. I think if it is going to be used as a BT [bioterrorism] agent, it is going to be most likely in the pneumonic form."

The only form of plague transmissible from person to person,

pneumonic plague occurs when *Y. pestis* infects the lungs. Transmission can occur if someone breathes in aerosolized bacteria, either from an infected person or, theoretically, during a bioterrorist attack using aerosolized plague. The World Health Organization estimates that if 50 kg of *Y. pestis* were released over a city of 5 million, pneumonic plague could occur in as many as 150,000 people — 36,000 of whom would be expected to die. Fatality rates would depend on various factors, including time between onset of symptoms and initiation of antibiotics, access to advanced supportive care, and the dose of inhaled bacilli. The fatality rate of patients with pneumonic plague when treatment is delayed more than 24

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Editorial Questions

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hours after symptom onset is extremely high.¹

Bubonic plague — the most common form of the disease — usually occurs when an infected flea bites a person, serving as the vector between animal host (e.g., rat) and an infected human. Bubonic plague does not spread from person to person. Though bioterrorism could not be ruled out, the histories of the New York patients suggested natural causes. The couple reported being avid hikers and having a dead wood rat in their yard months earlier that tested positive for *Y. pestis*. Yet a confounding factor came with the determination that they could not have infected each other. Both people had bubonic plague.

"The issue for us was, why two infected people exactly at the same time?" Raucher says. "In our heart of hearts, I don't think we ever really felt that it was bioterrorism, but we couldn't exclude it. Bubonic plague is not transmissible from person to person. That is why this is such an unusual case. We 'guesstimate' that they both got it at the same time from the same exposure on their property, which really would be very odd. It is a very low probability."

Bioterrorism alert sounded

As health officials in New Mexico were contacted to verify the exposure history, the hospital decided to roll out its bioterrorism response plans in case the disease was of nefarious origin. The plan emphasizes communication with external agencies, education, and assuring the safety of hospital patients, visitors, and staff.

"We decided to just go for it," Raucher says. "Because: a) it is going to be picked up by the media and there is going to be a lot of craziness surrounding this; and b) we just couldn't be sure so we needed to get the health department involved."

The city health department was immediately contacted to assist with diagnostic testing, direct the public health response, and evaluate the potential that the two cases represented bioterrorism. Local health officials and the Centers for Disease Control and Prevention (CDC) were able to exclude pneumonic plague within 48 hours of the patients' admission. The health department held a televised press conference to alleviate the fears of the public and relay information regarding plague transmission.

"One of the major things we learned during this was that a quick educational response is very important," Raucher says. "We did not have any breakdown of the health care system. The hospital

went on, business as usual, because of a couple of things we did well. One was to put together an infection control newsletter very quickly on the topic. The infection control professionals did a lot

of one-on-one discussion with a lot of people in radiology, food service, and the nurses in the [intensive care units]."

In addition, a letter explaining the situation to

Plague primer: Bioterror predictors for Black Death

- Since plague (*Yersinia pestis*) was introduced into the United States in the San Francisco Bay area in 1900, there have been a total of 941 confirmed human cases recorded through the year 2000.¹ Of that total, at least 402 (42%) were fatal. An urban outbreak in Los Angeles in 1923-1924 resulted in 37 deaths in 39 cases, all in one residential neighborhood.
- The fatality rate has undergone a rapid decline since the widespread use of antibiotics beginning about 1960. By the end of the 20th century, the fatality rate declined to 15% of confirmed cases. Since 1985, there have been no more than 15 cases in the United States in any year. Only the pneumonic form of plague is transmissible from person to person. The last case of human-to-human transmission of plague in the United States occurred in the Los Angeles outbreak in 1924.²
- Worldwide, an average of 1,700 cases of plague have been reported annually for the past 50 years.
- The epidemiology of plague following its use as a biological weapon would differ substantially from that of naturally occurring infection. Intentional dissemination of plague most likely would occur via an aerosol of *Y. pestis*, resulting in a pneumonic plague outbreak. The size of the outbreak would depend on several factors, including the quantity of biological agent used, characteristics of the strain, environmental conditions, and methods of aerosolization.
- Indications that plague had been artificially disseminated would be the occurrence of cases in locations not known to have enzootic infection, among individuals with no known risk factors (e.g., animal contact), and the absence of prior rodent deaths (historically, rats die in large numbers prior to human outbreaks, precipitating the movement of the infesting flea population from the rats to humans).
- Following a deliberate attack, aerosolized inhaled *Y. pestis* bacilli would cause primary pneumonic plague, with the time from exposure to the development of first symptoms being one to six days.
- The sudden appearance of a large number of previously healthy patients with fever, cough, shortness of breath, chest pain, and a fulminant course leading to death immediately should suggest the possibility of pneumonic plague or inhalational

anthrax. The presence of hemoptysis in this setting would strongly suggest plague.

- Parenteral forms of the antimicrobials streptomycin or gentamicin are recommended. In a mass-casualty setting, intravenous or intramuscular therapy may not be possible, so oral therapy, preferably with doxycycline, tetracycline, or ciprofloxacin, should be administered

INFECTION CONTROL MEASURES

- National infection control guidelines recommend the use of disposable surgical masks to prevent transmission via respiratory droplets.
- Other respiratory droplet precautions (gown, gloves, and eye protection) also should be used by people caring for pneumonic plague cases.
- Patients with pneumonic plague should be isolated until they have had at least 48 hours of antibiotic therapy and shown clinical improvement.
- If large numbers of patients make isolation impractical, pneumonic plague patients may be cohorted. Patients should wear surgical masks while they are being transported.
- Hospital rooms should receive terminal cleaning consistent with standard precautions; clothing and linens contaminated with the body fluids of pneumonic plague patients should be disinfected per hospital protocol.
- Laboratories should observe biosafety level 2 conditions. Activities with a high potential for aerosol or droplet production (centrifuging, grinding, vigorous shaking, animal studies) require biosafety level 3 conditions. It should be noted that a plague case reported in Michigan in 1901 occurred in a lab worker who was examining infected rats from an ongoing outbreak in San Francisco.
- Bodies should be handled with routine strict precautions. Aerosol-generating procedures (bone-sawing associated with surgery or post-mortem examinations) should be avoided.
- There is no evidence to suggest that environmental decontamination following an aerosol release is warranted. *Y. pestis* is very sensitive to sunlight and heating and does not survive long outside its host.

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patients was placed on every food tray. "It said that these patients were in the hospital, they are under isolation, and it is not being spread," Raucher notes. "We're a business. If people stop coming to the hospital, that would be a big problem."

'She became a celebrity'

Still, the cases caused a media sensation, with reporters even trying to enter one of the patients' rooms for exclusive interviews. "Because the woman wasn't as sick, they were trying to get into her room," she says. "We had to place a security guard outside her room, and we had to put an extra security guard at the front door and close a lot of our entrances. She became a celebrity."

The wave of curiosity raised issues of confidentiality. The patients' charts were removed from the normal medical rack so staff would not be tempted to peruse them. "The woman was in the hospital for just under a week," Raucher says. "She did really well. He was in really critical condition for quite a long time. He ultimately was discharged after about three months."

Health officials in New Mexico found that fleas from mice and rats near the home of the Santa Fe County couple tested positive for plague.

"There were positive fleas from mice caught in a landscaped area next to the patients' home and also positive fleas from a mouse and a wood rat in an area about two miles from their home where they had hiked about a week before their onset of illness," says **Paul Ettestad**, MD, New Mexico state epidemiologist in Santa Fe. "There is convincing proof that the patients acquired plague around their home in New Mexico."

All of which raises another question — how do clinicians in New Mexico discern between naturally occurring plague and bioterrorism?

"We have a baseline level [of plague] that we are used to," says **Joan Baumbach**, MD, MPH, medical epidemiologist in the New Mexico health department in Santa Fe. "People present clinically fairly typically. In terms of hospital infection control, the chief concern is to rule out immediately any pneumonic component. We are very careful about that. We have an underlying endemic level in animals, so we have a pretty good baseline sense of activity [of animals with plague]. These people in New York had already been told about activity in their area, and they knew how it presented clinically."

That said, state bioterrorism planners still are wary of plague being used as an agent, she emphasizes. "We err on the side of including

[bioterrorism] in our thinking, but it is really not difficult to recognize fairly typical situations from something that might be atypical," Baumbach says. "We tend to see bubonic cases a lot more frequently. You take their history and look for the risk factors [e.g., exposure to animals]."

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IOM: Time to hit pause on smallpox vaccinations

'The benefits likely outweigh the risks'

The Centers for Disease Control and Prevention (CDC) temporarily should suspend its smallpox vaccination programs and conduct an evaluation and reassessment of the effort before vaccine is offered to larger groups of health care workers, a special panel of the Institute of Medicine (IOM) in Washington, DC, recommends.

"A pause is needed to evaluate the vaccination program's processes and outcomes to date, and thus ensure that expanded vaccination continues to be as safe as possible for both vaccinees and their contacts," the IOM panel reported. ". . . A break in the course of the vaccination program may help prevent vaccinating potentially large numbers of additional volunteers [e.g., health care workers, traditional first responders, and others] less safely than in the first phase of vaccinations, without adequate time to implement or update safeguards [e.g., screening, training, and education] that would be appropriate to new types of vaccinees and their contacts."

The IOM smallpox review panel was formed at the request of the CDC, and the agency is expected to carefully consider its recommendations. Issued to the CDC May 27, 2003, the IOM report praises the agency for proceeding with deliberation and caution. The screening of potential vaccinees may have played a role in preventing several of the historically expected moderate-to-severe adverse events (e.g., eczema vaccinatum, progressive vaccinia) to the vaccine in 36,217 people vaccinated in the civilian program as of May 9, 2003.

"Also, it appears that vaccinee education on the risk of vaccinia transmission to contacts and

measures taken to prevent it with appropriate bandaging and site care have worked well and may, in part, account for the absence of reported cases of vaccinia transmission from civilian vaccinees to either health care or personal contacts," the IOM noted. However, less welcome trends may emerge as the numbers increase and more occupationally diverse volunteers consider vaccination, the panel warned.

"The fact that by April 29, 2003, only 34% of vaccinees were included in the Smallpox Vaccine Adverse Event Active Surveillance System is an example of the additional work needed to help provide more data for a national view of the program," the report stated. "Some adverse events might not arouse concern on a state level, but aggregated nationally, new patterns could emerge." The recent fatal cardiac complications were unexpected adverse events, and there may be others. That is why it is important to ascertain whether the vaccine played a role in the cardiac events and rule out any other reasons for concern before vaccination is expanded to other populations, the panel advised.

In addition, the enactment of national smallpox vaccination compensation legislation is likely to remove a key barrier to vaccination, opening up the process to volunteers that heretofore may have reticent. "As this is a complex matter, the committee notes the need for additional clarification by CDC to the states on the provisions of the law, and for fact sheets or other explanatory materials for potential vaccinees," the IOM advised. Such fact sheets should explain the provisions of the legislation clearly and protections enacted and refer potential vaccinees to additional information sources.

"It is imperative that before continuing to expose individuals to a vaccine that is effective, but not without some risks, the national and state programs determine what level of pre-event vaccination is needed for preparedness," the IOM added. ". . . Although the initially expected civilian numbers have not been reached, pausing to evaluate remains an important component of the overall program of safely building smallpox preparedness. Also, by combining the safety data from both civilian and military vaccinations [totaling more than 460,000 vaccinees] a great deal can be learned, shared, and disseminated."

In advising the stoppage, the committee admitted such a move was not without risks. A pause could hinder preparedness and increase vulnerability to a smallpox attack. "However, given that the

smallpox threat level, as it is publicly described, has not changed, the committee continues to believe that the benefits of the pause likely outweigh the risks," the IOM said.

Some areas already have begun offering the vaccine to a wider population of potential vaccinees. The committee recognized that it is important for states to finish the vaccination of volunteers to complete health care and public health response teams according to state plans.

Still the committee urged CDC to "facilitate the efforts of states that wish to pause to evaluate the process and outcomes of their vaccination efforts to date, and plan for next steps before deciding whether and when to begin vaccination of new personnel." The CDC should provide states with a target date when it expects to complete a revision of materials, data systems (adding new occupational categories, etc.), and guidelines. States that have identified a need for more vaccinated volunteers to carry out specific smallpox response

IOM cites litany of reasons in urging CDC stoppage

The Institute Medicine (IOM) advised the Centers for Disease Control and Prevention (CDC) to pause its smallpox immunization efforts to permit time for the following developments:

- ✓ completion of an in-depth analysis and investigation of all known serious adverse events to date and possible risk factors;
- ✓ determination of what numbers and types of vaccinated personnel are needed to achieve preparedness;
- ✓ update of educational and training materials by the CDC;
- ✓ revision of program data systems to include new types of vaccinees and to account for differences in data entry anticipated in expanding to a wider range of occupational contexts and personnel;
- ✓ development of guidelines regarding vaccine "take" readings, vaccination site checks and site care, and other issues related to vaccination follow-up of new types of vaccines;
- ✓ establishment of communication and collaboration with other partners (e.g., first responders, security personnel, health care and hospital systems, community-based health care providers);
- ✓ revision by state and local programs of response plans that lay out clear roles and activities for teams responding to a potential event;
- ✓ strategic planning and reconciliation of the smallpox vaccination program with other bioterrorism programs and other public health priorities. ■

functions will then be able to set their own timeline for vaccinating these new groups.

A pause would allow time for CDC and the states to modify vaccination plans, data systems, and materials in response to changing circumstances (i.e., a new population of potential vaccinees). It would be helpful for many states if these changes and revisions were made before they proceeded with vaccination, in part to avoid the difficulty of implementing changes midcourse. ■

Pregnant pause: Vaccinia given despite screening

CDC forms registry to track women, babies

More than 100 pregnant women have been exposed inadvertently to smallpox vaccine since immunization programs began in U.S. hospitals, the military, and clinical trials, the Centers for Disease Control and Prevention (CDC) reports.

Women who are pregnant or who are planning to become so in the near future were warned not to be vaccinated for smallpox. While a public health investigation continues, the prevailing theory is that most of the women were in a window period in which they were pregnant but would not test positive on screening.

"There is a time period of about two weeks between the conception of an embryo and the implantation of the embryo in the uterus when the pregnancy test would not be positive," says **Joe Mulinare**, MD, medical epidemiologist in the smallpox activity branch at CDC. "We estimate that eight to 12 women per thousand — [even] if they had a pregnancy test during that period — would not know that they were pregnant."

Still there are indications the screening process worked for the most part. The rate of inadvertent exposure to smallpox vaccine among pregnant women vaccinated during the first stage of the civilian and military programs is approximately one per 1,000.¹ That rate is substantially lower than the aforementioned rate of eight to 12 per 1,000.

"In effect, what we found was about one in a thousand women vaccinated inadvertently found that they were pregnant," he says. "So in a way, we could say that we did a lot better than we would have expected. The educational programs that were being used actually didn't do a bad job. [But] we want to make sure we are doing the best

job possible. We want to determine if there are any unique qualities or characteristics of [these] women."

The CDC is working with state health departments and the U.S. Food and Drug Administration to determine how the women received the

Pregnancies missed in all immunization programs

Military, clinical trials vaccinate the pregnant

The breakdown of pregnant women inadvertently vaccinated in smallpox immunization programs is as follows:

Department of Defense: From Dec. 13, 2002, to April 22, 2003, a total of 62,222 women of reproductive age were screened for smallpox vaccination, and 52,185 were vaccinated in the military program; 85 were inadvertently exposed to smallpox vaccine during pregnancy. Of the 75 women with known vaccination status, 66 were primary vaccinees. The median age was 22 (range: 18-35). On the basis of the estimated date of conception, 62 women conceived before vaccination and 23 conceived during the four weeks after vaccination.

Civilian health care and public health workers:

From Jan. 24 to April 24, 2003, 6,174 women of reproductive age were vaccinated through the civilian program. Six were inadvertently exposed to smallpox vaccine during pregnancy. Three of the women were primary vaccinees. The median age was 31 (range: 26-38). On the basis of the estimated date of conception, two women conceived within one week before vaccination and four conceived during the four weeks after vaccination. Two of the women had miscarriages during early pregnancy. An additional two pregnant civilian women were in close contact with people recently vaccinated against smallpox. Neither of these women have had known signs or symptoms of vaccinia exposure.

Clinical studies: From November 2001 to April 24, 2003, 12 women from clinical studies who had inadvertent exposure to smallpox vaccines during pregnancy have been reported to the registry. The denominator for women of reproductive age for this population is not available. The median age was 28 (range: 18-42). Each of the women had a negative pregnancy test on the day of vaccination.¹

Reference

1. Centers for Disease Control and Prevention. Smallpox and pregnancy: Women with smallpox vaccine exposure during pregnancy reported to the National Smallpox Vaccine in Pregnancy Registry — United States, 2003. MMWR 2003; 52(17):386-388. ■

smallpox vaccine while they were pregnant or just before they became pregnant.

The CDC also has established the National Smallpox Vaccine in Pregnancy Registry. The registry will follow women during their pregnancies and their babies, after they are born, to better understand what happens to pregnant women and their babies who have been exposed to smallpox vaccine. The principal risk factor is fetal vaccinia, a rare but serious infection of the fetus.

The registry includes women found to be pregnant when vaccinated, those who became pregnant within 28 days of vaccination, and those who, while pregnant, were in close contact with a person vaccinated within 28 days. Women reported to the registry will be monitored frequently during each trimester and at the conclusion of the pregnancy to document pregnancy outcomes. Outcomes will be tabulated by trimester and reported.

The CDC recommends that all pre-event smallpox vaccination programs include pregnancy screening and education components with these elements: questioning about the possibility of pregnancy before vaccination and excluding those at risk; asking about the date of the last menstrual period; providing education about fetal vaccinia; counseling women to avoid becoming pregnant during the month after vaccination; recommending abstinence or highly effective contraception; and advising women who believe they might be pregnant to perform a first morning urine pregnancy test on the vaccination day.²

"But [testing] wasn't mandatory," Mulinare says. "For the most part women were given the same information. Dependent on the location, they would view a video and have some discussion."

Between Nov. 5, 2001, and April 24, 2003, some 60,000 women of reproductive age (18-44) were vaccinated against smallpox in three populations: military personnel, U.S. civilian health care and public health workers, and some clinical research study volunteers. (See article, p. 30.)

Overall, 103 women inadvertently received smallpox vaccine while pregnant or conceived within four weeks of vaccination.

Historically, approximately 50 cases of fetal vaccinia have been reported in the world and

CE/CME questions

For further information, refer to the CE/CME instructions box on p. 32. This procedure has proven to be an effective tool for adult learners. If you have any questions about the testing method, please contact customer service at (800) 688-2421.

1. Which of the following is the only form of plague transmissible from person to person?
 - A. bubonic
 - B. pneumonic
 - C. septicemic
 - D. A and B
2. Despite the introduction of widespread use of antibiotics, the fatality rate for plague has not declined in the United States since the disease was introduced in 1900.
 - A. true
 - B. false
3. The CDC recommends that all pre-event smallpox vaccination programs include pregnancy screening and education components that include information on which of these elements?
 - A. the role of smallpox vaccine in infertility
 - B. fetal vaccinia
 - C. the wide variety of birth defects associated with smallpox vaccine
 - D. all of the above
4. According to special smallpox review panel at the Institute of Medicine, as of April 29, 2003, what percentage of vaccinees were included in the Smallpox Vaccine Adverse Event Active Surveillance System?
 - A. 99%
 - B. 74%
 - C. 48%
 - D. 34%

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

three have been reported in the United States. In 1924, an infant was born prematurely after the mother's vaccination during a smallpox epidemic. The infant had vaccinia-like skin lesions and died

COMING IN FUTURE MONTHS

■ Table-top exercises:
What works and what
doesn't

■ Will other bioterror
vaccine programs
follow the smallpox
initiative?

■ How to rapidly
decontaminate the
chemically exposed

■ Clinical scenarios
with various agents

■ Suffer the children:
Protecting the smallest
victims

shortly after delivery. In 1968, a premature infant born at 32 weeks to a vaccinated mother had vaccinia-like scars but was otherwise healthy and developed normally. Affected pregnancies have been reported among women vaccinated in all three trimesters and among first-time vaccinees, revaccinees, and among unvaccinated close contacts of vaccinees. No validated prenatal test is available for clinical diagnosis of fetal vaccinia during pregnancy.

Except for fetal vaccinia, smallpox vaccine has not been clearly shown to cause serious birth defects or other adverse events for the fetus or neonate, including premature birth, low birth weight, or miscarriage. Among the general population, 16% to 31% of pregnancies end in miscarriages. While some miscarriages have occurred in the current group of pregnant vaccinees, there is insufficient data to know if their lost pregnancies will exceed that seen in the general population.

"The way the [smallpox] pregnancy register is set up many of the women haven't gotten even through their first trimester," Mulinare says. "So we can't really say what the miscarriage rate is relative to the general population. In a general sense, most of the [historical] studies were not able to show any increase in miscarriages. A couple of studies suggested it, but those studies may not have been well enough done to be the basis for saying there is an increase."

[Editor's note: Health care providers, state health departments, and other public health staff are encouraged to report all exposed pregnant women to the National Smallpox Vaccine in Pregnancy Registry. Civilian women should contact their health care provider or state health department for help enrolling in the registry. Clinicians or public health staff should report civilian cases through their state health department or to the CDC at (404) 639-8253 or (877) 554-4625. Military cases should be reported to DoD at (619) 553-9255. Fax: (619) 553-7601. E-mail: ode25@nhrc.navy.mil.]

References

1. Centers for Disease Control and Prevention. Women with smallpox vaccine exposure during pregnancy reported to the National Smallpox Vaccine in Pregnancy Registry — United States, 2003. *MMWR* 2003; 52(17):386-388.
2. Centers for Disease Control and Prevention. Recommendations for using smallpox vaccine in a pre-event vaccination program: Supplement recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR Dispatch* 2003; 52:1-16. ■

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CE/CME instructions

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 in November/December 2003, 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 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. ■

Hospital Employee Health

Confidential Salary Survey

This confidential salary survey is being conducted to gather information for a special report later in the year. Watch in coming months for your issue detailing the results of this survey and the overall state of employment in your field.

Instructions: Fill in the appropriate answer directly on this form. Please answer each question as accurately as possible. If you are unsure of how to answer any question, use your best judgment. Your responses will be strictly confidential. Do not put your name or any other identifying information on this survey form.

1. What is your current title?

- A. employee health nurse
- B. employee health manager
- C. employee health director
- D. infection control practitioner
- E. occupational health director
- F. other _____

3. Which certification best represents your position?

- A. RN
- B. COHN-S
- C. NP
- D. CIC
- E. FACOEM
- F. LVN
- G. CCM
- H. other _____

5. How long have you worked in health care?

- A. less than 1 year
- B. 1-3 years
- C. 4-6 years
- D. 7-9 years
- E. 10-12 years
- F. 13-15 years
- G. 16-18 years
- H. 19-21 years
- I. 22-24 years
- J. 25 or more years

7. What is your sex?

- A. male
- B. female

8. What is your annual gross income from your primary health care position?

- A. Less than \$30,000
- B. \$30,000 to \$39,999
- C. \$40,000 to \$49,999
- D. \$50,000 to \$59,999
- E. \$60,000 to \$69,999
- F. \$70,000 to \$79,999
- G. \$80,000 to \$89,999
- H. \$90,000 to \$99,999
- I. \$100,000 to \$129,999
- J. \$130,000 or more

9. On average, how many hours a week do you work?

- A. less than 20
- B. 20-30
- C. 31-40
- D. 41-45
- E. 46-50
- F. 51-55
- G. 56-60
- H. 61-65
- I. more than 65

2. Please indicate your highest degree.

- A. LPN
- B. ADN (2-year)
- C. diploma (3-year)
- D. bachelor's
- E. master's
- F. PhD
- G. MD
- H. other _____

4. How long have you worked in employee health?

- A. less than 1 year
- B. 1-3 years
- C. 4-6 years
- D. 7-9 years
- E. 10-12 years
- F. 13-15 years
- G. 16-18 years
- H. 19-21 years
- I. 22-24 years
- J. 25 or more years

6. What is your age?

- A. 20-25
- B. 26-30
- C. 31-35
- D. 36-40
- E. 41-45
- F. 46-50
- G. 51-55
- H. 56-60
- I. 61-65
- J. 66 or older

11. Which of the following best describes the location of your work?

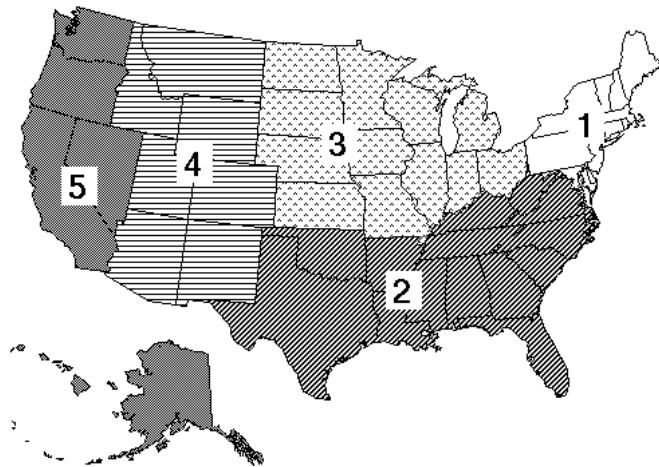
- A. urban
- B. suburban (outside large urban area)
- C. medium-sized community
- D. rural

10. In the last year, how has your salary changed?

- A. salary decreased
- B. no change
- C. 1% to 3% increase
- D. 4% to 6% increase
- E. 7% to 10% increase
- F. 11% to 15% increase
- G. 16% to 20% increase
- H. 21% increase

12. Using the map (right), please indicate where your employer is located.

- A. region 1
- B. region 2
- C. region 3
- D. region 4
- E. region 5
- F. Canada
- G. other _____



13. Which best describes the ownership or control of your employer?

- A. college or university
- B. federal government
- C. state, county, or city government
- D. nonprofit
- E. for profit

14. Which of the following best categorizes the work environment of your employer?

- A. academic
- B. agency
- C. city or county health department
- D. clinic
- E. college health service
- F. consulting
- G. hospital
- H. private practice

15. If you work in a hospital, what is its size?

- A. <100 beds
- B. 100 to 200 beds
- C. 201 to 300 beds
- D. 301 to 400 beds
- E. 401 to 500 beds
- F. 501 to 600 beds
- G. 601 to 800 beds
- H. 801 to 1,000 beds
- I. >1,000 beds
- J. I don't work in a hospital

Deadline for responses: Aug. 15, 2003

Thank you very much for your time. The results of the survey will be reported in an upcoming issue of the newsletter, along with an analysis of the economic state of your field. Please return this form in the enclosed, postage-paid envelope as soon as possible. If the envelope is not available, mail the form to: Salary Survey, Thomson American Health Consultants, P.O. Box 740058, Atlanta, GA 30374.