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CDC gearing up rapid vaccine response plans for smallpox bioterror

First-case contacts, front-line staff targeted

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Addressing the most feared pathogen in the potential arsenal of the bioterrorist, the Centers for Disease Control and Prevention is preparing a smallpox virus emergency response plan that calls for rapidly dispensing precious vaccine to first responders, health care workers, and first-case contacts in stricken communities, *Hospital Infection Control* has learned. An ancient scourge that has been eradicated in the wild, smallpox would be a formidable bioweapon because of waning immunity in the world population and limited stockpiles of vaccine.

The CDC response plan, which will be detailed in an upcoming report from the agency's office of bioterrorism preparedness and response, is to quickly mobilize and administer the available vaccine should the virus be released in the United States. "The way the bioterrorism program is looking at this is that there would be groups of people, including first responders who are going to take care of patients or evaluate them, who would need to be immunized," says **Michael Bell**, MD, an epidemiologist and bioterrorism specialist in the CDC hospital infections program. "If a documented case was found within a certain community, then people likely to have shared contact in that community

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COMING IN FUTURE ISSUES

■ **Once in a decade:** Complete coverage of the CDC's 4th Decennial International Conference on Nosocomial and Health-care Associated Infections
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■ **HCV in VA hospitals:** Does the prevalence of the bloodborne disease in veterans warrant more HCV prevention and efforts at VA hospitals?
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would also be vaccinated. By the same token, if a patient is [discovered] with smallpox in a hospital, then the hospital would also be receiving vaccine. Part of it is contact. Whether you are a health care worker or not, potential contact would be a reason [to be immunized]. Then the people who have to care for the patients would also need to be protected."

Highly infectious, with a 30% mortality rate and dramatically disfiguring pustules and scars, smallpox resonates beyond any other pathogen when discussions turn to potential bioterrorist weapons. **(See related story, p. 31.)** "If you consider all of the agents of bioterrorism, the reason that smallpox is particularly concerning is that the possibility of person-to-person transmission is great," Bell says. "It is a very efficiently transmitted virus. It is transmitted respiratorily, and [there is] the possibility of one person being infected but then wandering about early in their disease and exposing a lot of other people. The incubation period is [as much as] 18 days, so people can actually move quite a ways away before they manifest symptoms. The possibility of satellite spread is very great."

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Thus, as opposed to possible bioweapons such as anthrax or botulism, smallpox could create a widening circle of secondary cases that would make initial containment via quarantine and immunization critical. "Whoever inhales [anthrax] might become sick, but people taking care of that person are not likely to become sick," Bell says. "The same thing with botulism toxin. The only other real exception would be pulmonary plague — pneumonic plague. But it is less frightening to many people because of the visual manifestations of smallpox. When you are covered in purulent pox, it is fairly dramatic."

Regardless of the agent, infection control professionals could play important roles in education, surveillance, and response throughout a heath care system that is largely unprepared for bioterrorism, says **Tara O'Toole**, MD, MPH, senior research fellow at the Center for Civilian Biodefense Studies at Johns Hopkins University in Baltimore. **(See related story, p. 33.)** "[ICPs] clearly have an important role to play, particularly if the weapon were a contagious disease," she tells *Hospital Infection Control*. "I would hope

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Worst-case scenarios abound for bioterror

While there is broad consensus about the need for heightened awareness and education about the threat of bioterrorism, discussions about preparedness and response can become somewhat overwhelmed by the sheer horror of the various scenarios. "You can spin worst-case scenarios until you kind of slink away and need a glass of wine," says **Tara O'Toole**, MD, MPH, senior research fellow at the Center for Biodefense Studies at Johns Hopkins University in Baltimore.

For example, while smallpox is generally considered the worst-case pathogen, a bioweapon that aerosolized the plague bacteria *Yersinia pestis* would create pneumonic plague, an airborne transmissible disease. While antibiotic treatment would be an option, the biodefense center reports that 50 kg of *Y. pestis* aerosolized over a city of 5 million would result in 150,000 infections, at least half of which would require hospitalization, and some 36,000 deaths.[1]

"Anything contagious, obviously, would be extremely worrisome in our highly mobile society," O'Toole tells *Hospital Infection Control*. "[Smallpox] is certainly one of the scarier propositions. Inhalation plague would be no day at the beach either — probably somewhat less contagious, but it is still transmissible, and would also kill you very effectively." In addition, both plague and anthrax (*Bacillus anthracis)* would likely be easier to obtain by a terrorist group or rogue government than smallpox. While secondary infection would not be a concern with anthrax — and there is a vaccine for the military — the biodefense center cites government projections that estimate that the release of 100 kg of the pathogen over Washington, DC, would result in a minimum of 130,000 deaths. In a real-world example, when aerosolized anthrax spores were accidentally released in 1979 from a bioweapons facility in the former Soviet Union, 68 of the 79 people infected died.[1] While one could academically argue that intentional release of an infectious agent like smallpox or plague is a more dire scenario, the aftermath of mass anthrax exposure would be grim.

Those known or suspected to be exposed to anthrax would probably wait in long "Auschwitzian" lines of people waiting to get chest X-rays, says **Allan J. Morrison Jr.**, MD, MSc, FACP, health care epidemiologist for the four-hospital Inova Health System in Washington, DC. There would be little hope or medical options for those who showed radiographic evidence of anthrax infection, he says. "Basically, no resources are going to be spent on you because you are not going to make it — with a 90% likelihood. Even if you feel fine," says Morrison, a former member of the U.S. Army Special Forces. "If you have a normal chest X-ray, then you go into line 'B,' where resources would be expended and antibiotics would be used," he says. "I think most people would accept that algorithm, as fiercely horrifying as it is. That is the fact. So for a non-transmissible agent like anthrax, setting up mass radiographic screening is the first step, and managing the patients who are in the treatment cohort is really where your preparedness comes in. How can you obtain, dispense, and coordinate treatment?"

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Moreover, while the wild forms of the various bioterrorism pathogens are sufficiently nightmarish, there is, unfortunately a worst case still: genetically engineered infectious agents. For example, researchers in Moscow have created a recombinant strain of anthrax, raising the possibility that current vaccine efficacy could be undermined.[2] The advances of bioengineering will only continue, creating the possibility that scientists will find ways to create bioweapons that elude known postexposure treatments and vaccines, says O'Toole.

"The technology to make these weapons is quite available," she says. "If the will and the money and the talent come together to do evil things, then it is a real possibility. The health care community has got to awaken to this threat and figure out a responsible way of dealing with the dark side of modern biology."

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2. Pomerantsev AP, Staritsin NA, Mockov Yv, et al. Expression of cereolysine AB genes in *Bacillus anthracis* vaccine strain ensures protection against experimental hemolytic anthrax infection. *Vaccine* 1997; 15:1,846-1,850. ■

that [these issues] would put a spotlight on infection control and hospitals generally. I think there are a number of ways good preparations for bioterrorism attack would dovetail with other priorities of infection control [i.e., surveillance for emerging infections]."

Many have lost immunity

Currently, the United States has a limited stockpile of some six to seven million doses of smallpox (variola) vaccine, made from the traditional method of using cowpox (vaccinia). The supply is widely regarded as inadequate, but because mass immunization efforts ended with global eradication of the pathogen in 1980, it may take several years to gear up production and increase supplies.

Moreover, because the vaccine's efficacy has been generally estimated at some 10 years, immunity has long since waned for most of those vaccinated as children. With millions more never even vaccinated, the United States could be strikingly vulnerable should a terrorist group or rogue nation obtain and release the virus. The biodefense center at Johns Hopkins warns that an "aerosol release of smallpox virus would disseminate readily, given its considerable stability [in] aerosol form and epidemiological evidence suggesting the infectious dose is very small. Even as few as 50-100 cases would likely generate widespread concern or panic and a need to invoke large-scale, perhaps national emergency control measures."[1]

The only confirmed stocks of smallpox virus remaining in the world are reportedly in storage at the CDC and at the Russian State Research Center of Virology and Biotechnology in Koltosovo. However, the Center for Civilian Biodefense Studies warns that the former Soviet Union embarked on an ambitious bioweapons campaign with smallpox, and the pathogen may now be in the hands of other countries. "Because of the fact that many laboratories in Russia, including the one in Koltosovo, are now fiscally constrained and decreasing in size, there are growing concerns that the existing bioweapons expertise and equipment might move or perhaps have already moved to other countries," according to a World Health Organization (WHO) report posted on the center's Web site.[2]

"A number of people think Russia has worked with smallpox in terms of weaponizing it, and a lot of people fear that North Korea worked with smallpox as a weapon," says O'Toole, who recently testified before Congress on bioterrorism. "There were rumors that [North Korea] vaccinated troops, for example, some years ago." In addition to inadequate supply of vaccine, existing antiviral drugs are not thought to be an option for post-infection treatment, she adds. "They tested the available antivirals, and those don't do much," O'Toole tells *HIC*. "Those who survive it are scarred for life, and many of them are blind. It is a dreadful disease. It would be a tragedy to have it abroad on the planet again."

Indeed, the WHO Variola Research Committee is expected to formally recommend in May 2000 that the stocks of virus in the United States and Russia be destroyed no later than the year 2002. While some have argued that the virus may have research value, the threat of it falling into the wrong hands appears to be taking precedence. With military questions complicating the issue, it is important to remember that destroying the known viruses would not hinder vaccine research, O'Toole emphasizes. "One of the things that is not well-understood about the WHO decision is that destruction of smallpox really has no impact whatsoever on our ability to prepare new vaccines, which are not made from the smallpox virus [cowpox]," she stresses. "They are made from vaccinia virus, which a lot of people in the [political] policy realm don't understand. It will have no impact on our ability to develop new antiviral therapies."

Whistling in the graveyard

In that regard, the CDC is reportedly placing a high priority on increasing current stockpiles of available smallpox vaccine after a top-level, closed-door meeting last August intended to cut the red tape between the various arms of government, drug regulators, and public health officials.[3] As part of that effort, the Department of Defense Joint Vaccine Acquisition Plan has prioritized development of a new cell culture vaccinia vaccine, which would increase production capabilities and replace the traditional method of scarifying and infecting the flanks and bellies of calves.[4]

"Hopefully, we may be in a position in the next two years of ramping up a new vaccine in

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Smallpox: A single case is a medical emergency

Both airborne and contact isolation needed

The Centers for Disease Control and Prevention currently recommends the following infection control precautions for smallpox. The CDC is expected to issue a new guidance on smallpox response in the near future, and some of the information may be updated. The guidelines summarized below were developed in conjunction with the Association for Professionals in Infection Control and Epidemiology.[1]

Smallpox is an acute viral illness caused by variola virus. Smallpox is a bioterrorism threat due to its potential to cause severe morbidity in a nonimmune population and because it can be transmitted via the airborne route. A single case is considered a public health emergency. Acute clinical symptoms of smallpox resemble other acute viral illnesses, such as influenza. Skin lesions appear, quickly progressing from macules to papules to vesicles. Smallpox is transmitted via both large and small respiratory droplets. Patient-to-patient transmission is likely from airborne and droplet exposure, and by contact with skin lesions or secretions. Patients are considered more infectious if coughing or if they have a hemorrhagic form of smallpox.

Preventive measures: A live-virus intradermal vaccination is available for the prevention of smallpox. Since the last naturally acquired case of smallpox in the world occurred more than 20 years ago, routine public vaccination has not been recommended. Vaccination against smallpox does not reliably confer lifelong immunity. Even previously vaccinated persons should be considered susceptible to smallpox.

Infection control practices: For patients with suspected or confirmed smallpox, both airborne and contact precautions should be used in addition to standard precautions. Airborne precautions require health care providers and others to wear respiratory protection when entering the patient room. (Appropriate respiratory protection is based on facility selection policy; must meet the minimal standards for particulate [N95] respirators.) Contact precautions require health care providers and others to wear clean gloves upon entry into patient room and wear a gown for all patient contact and for all contact with the patient's environment. Based on local policy, some health care facilities require a gown be worn to enter the room. Gown must be removed before leaving the patient's room. Wash hands using an antimicrobial agent.

Patient placement: Patients with known or suspected smallpox should be placed in rooms that meet the ventilation and engineering requirements for airborne precautions, including door that remains closed; monitored negative air pressure in relation to the corridor and surrounding areas; and six to 12 air exchanges per hour. Health care facilities without patient rooms appropriate for isolation should have a plan for transfer of suspected or confirmed smallpox patients to neighboring facilities with isolation rooms. Patient placement in a private room is preferred. However, in the event of a large outbreak, patients who have active infections may be cohorted in rooms that meet appropriate ventilation and airflow requirements.

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Postexposure issues: Postexposure immunization with smallpox vaccine (vaccinia virus) is available and effective. Vaccination alone is recommended if given within three days of exposure. Passive immunization (i.e., for complications of vaccination) is available in the form of vaccinia immune-globulin (VIG) (0.6ml/kg IM). If more than three days have elapsed since exposure, both vaccination and VIG are recommended. Vaccination is generally contraindicated in pregnant women and persons with immunosuppression, HIV infection, and eczema who are at risk for disseminated vaccinia disease. However, the risk of smallpox vaccination should be weighed against the likelihood of developing smallpox following a known exposure. VIG should be given concomitantly with vaccination in these patients. Following prophylactic care, exposed individuals should be instructed to monitor themselves for development of flu-like symptoms or rash during the incubation period (i.e., for seven to 17 days after exposure) and immediately report to designated care sites selected to minimize the risk of exposure to others.

Reference

1. Association for Professionals in Infection Control and Epidemiology Bioterrorism Task Force and Centers for Disease Control and Prevention Hospital Infections Program Bioterrorism Working Group. Bioterrorism readiness plan: A template for healthcare facilities. 1999. http://www.cdc.gov/ncidod/hip/Bio/bio.htm. ■

unlimited supplies," says **Allan J. Morrison Jr.**, MD, MSc, FACP, health care epidemiologist for Inova Health System in Washington, DC, and a frequent speaker on bioterrorism issues at infection control conferences. "That's sort of whistling through the graveyard until we get through, come out the other side, and have all we want to vaccinate everybody or have stockpiles available. But we're not there."

Questions have been raised about using the existing vaccine to immunize some health care workers in advance of any outbreak, but determining the recipients is the problem. "I don't think you can say that one area is less likely to be [targeted] than another," Bell says. "The predictability of these things is low. So if you really wanted to [immunize health care workers], you wouldn't be able to pick and chose. Because of that limitation, the federal approach right now is to stockpile [vaccine] for emergency use. In the interim, if you don't have people with documented immunity — and by that I think the guidelines that we are releasing will say known vaccine receipt within three years rather than 10 — then we would recommend using full protective measures, including masks and gowns and so forth." **(See infection control measures, p. 31.)**

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Morrison agrees it would be a mistake to squander any of the current vaccine by immunizing health care workers in advance, even in potentially high-risk target areas like Washington, DC. For one thing, the U.S. supplies may be needed to help avert a global pandemic should terrorists or governments unleash smallpox in some other part of the world, notes Morrison, a former member of the U.S. Army Special Forces. It is estimated that some 50 to 100 million vaccine doses may be available worldwide, but there are questions about whether governments would release their limited supplies should an event occur elsewhere.

"I think [the U.S.] would have to give it up," Morrison says. "So there is a broader [reason for] holding back with the vaccine: so that you would have a resource elsewhere. If everybody in the Washington metropolitan area who is a key player in health care is vaccinated, but the epidemic is launched in Thailand, the world goes down. There's no way to stop it. Whereas, if you have the doses — if you keep your powder dry — then you might get a shot at creating a ring around a zone, cordoning it off, quarantining it, and then vaccinating those around it."

Should an exposure occur in the United States, the CDC and military will have to dispense the available vaccine quickly if they expect health care workers to stay on the job in the face of smallpox, he says. "If they can't mobilize [quickly], it may be beyond the boundaries that you can control," Morrison says. Though Bell could not say how quickly the vaccine could be delivered to a targeted area, some CDC data suggest smallpox immunization within three days of exposure may confer immunity. "We can infer some things from Department of Defense experience and from the old smallpox eradication experience at the CDC, but there were never any controlled trials, obviously," Bell says. "There was observation that seemed to say that postexposure vaccination might mitigate the number of lesions, but that is clearly soft data."

The rapidity of response may well depend on clearly established lines of communication in the affected area, he notes, adding that this issue is emphasized in a bioterrorism template prepared last year by the CDC and the Association for Professionals in Infection Control and Epidemiology.[5] "The more efficiently and quickly the facility is able to contact the right places and report the cases, the quicker the response will be," Bells says. "Having that done in advance and having a hot-list of phone numbers is something that we recommend very specifically so that we can improve the turnaround time. Now, what the actual timing and logistics would be once the FBI is notified and the stockpiles are mobilized — obviously, if it is at a big urban center that is served well with transportation facilities, that might make a difference. I really can't predict what the exact timing would be. But [rapid response] is the reason for repeatedly stressing the communications preparations."

Prepare workers by educating them

By the same token, educating health care workers about smallpox and other potential bioterrorism agents could provide reassurance in the face of an actual event, Bell adds. "Health care worker response on a personal level is something that we can help with by doing teaching ahead of time," he says. "Health care workers in our country have demonstrated in numerous different scenarios that there is a certain selflessness and professionalism that we pride ourselves on. If they are

given information ahead of time that if such a thing were to happen, this is how it is transmitted, this it how we try to protect you from it, and this is the relative risk, then each person can say this is something I can or can't deal with."

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Many hospitals unprepared for a bioterrorism event

ICPs key to gearing up readiness

Distracted by fiscal pressures and reluctant to dedicate time and money addressing a theoretical concern, many of the nation's hospitals are unprepared to deal with a bioterrorism incident in their communities, experts tell *Hospital Infection Control*. But infection control professionals and hospital epidemiologists can play vital roles in upgrading preparedness, and many are already doing so, they add.

Should a bioterrorist attack occur, hospitals would inevitably become the front-line institutions for dealing with the response, regardless of the pathogen involved, says **Tara O'Toole**, MD, MPH, senior research fellow at the Center for Biodefense Studies at Johns Hopkins University in Baltimore. But many hospitals are not well-prepared to deal with a mass casualty situation, she warns, noting that economic pressures have reduced staff, intensive care and isolation beds are scarce, and medical supplies are too often being purchased on an "as-needed" basis. While the situation has been gradually improving as the issue of bioterrorism continues to emerge as a legitimate concern, the economic climate that hospitals face does not lend itself to increased training and preparedness issues.

"Until quite recently — really until the last several months — I don't think bioterrorism was on the attention screens of most hospitals," she tells *HIC*. "Most hospitals are preoccupied with financial survival and delivering health care right now. It is a very competitive time. Secondly, the policy-making and funding efforts in the federal government that have been quite active over the last couple of years have really not addressed hospitals. It's only now that the policy-makers are really coming to understand that when you are talking about terrorism or even weapons of mass destruction, bioterrorism is a completely different kettle of fish than a chemical explosion or even a big conventional or nuclear explosion."

An unannounced bioterrorist attack would likely come to attention gradually, as health care workers became aware of an accumulation of inexplicable deaths and illness among previously healthy people, she notes. Routine infection control surveillance could provide a critical early warning sign, but communication with public health officials must follow. "One of the things that has to happen for bioterrorism preparedness is that the current gulf between the world of medicine and the world of public health — between hospitals and state health agencies — has got to be bridged," O'Toole says.

In that regard, there have been memorable cases where ICPs working with public health officials have identified and solved mysterious community outbreaks. For example, ICPs at various hospitals in the Blacksburg, VA, area alerted public health officials to an unusual increase in community-acquired pneumonias that infected 23 people and caused two deaths in 1996. Public health investigators — who tracked the outbreak of *Legionella pneumophila* to a whirlpool display at a home improvement store — credited the ICPs with sounding the alarm in the case. **(See *Hospital***

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Look for syndromes in absence of cultures

Identifying the usual bioterror suspects

Health care facilities may be the initial sites of recognition and response to bioterrorism events, the Centers for Disease Control and Prevention warns. In a preparedness document written jointly with the Association for Professionals in Infection Control and Epidemiology, the CDC emphasizes that if a bioterrorism event is suspected, local emergency response systems should be activated.[1] Notification should immediately include local infection control personnel and the health care facility administration. There also should be prompt communication with the local and state health departments, FBI field office, local police, CDC, and medical emergency services.

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Act rapidly to prevent dissemination

Rapid response to a bioterrorism-related outbreak requires prompt identification of its onset. Because of the rapid progression to illness and potential for dissemination of some of the agents, it may not be practical to await diagnostic laboratory confirmation, the CDC warns. Instead, it will be necessary to initiate a response based on the recognition of high-risk syndromes. In addition to smallpox **(see smallpox fact sheet, p. 33)**, typical combinations of clinical features of illness at presentation for other pathogens are summarized as follows:

Anthrax (*Bacillus anthracis*): Pulmonary variety would include nonspecific prodrome of flu-like symptoms following inhalation of infectious spores. Two to four days after initial symptoms, abrupt onset of respiratory failure, hemodynamic collapse, possibly accompanied by thoracic edema and a widened mediastinum on chest radiograph.

Botulism (*Clostridium botulinum*): Foodborne variety will likely be accompanied by gastrointestinal symptoms. Inhalation and foodborne will likely share symptoms of: responsive patient with absence of fever; drooping eyelids; difficulty swallowing or speaking; blurred vision; descending paralysis of arms, respiratory muscles, legs; respiratory dysfunction.

Plague (*Yersinia pestis*): Clinical features of pneumonic variety include fever, cough, chest pain, hemoptysis, purulent or watery sputum with gram-negative rods on gram stain, radiographic evidence of bronchopneumonia.

General epidemiological suspicions: Features that should alert health care providers to the possibility of a bioterrorism-related outbreak include:

- a rapidly increasing disease incidence (e.g., within hours or days) in a normally healthy population;
- an epidemic curve that rises and falls during a short period of time;
- an unusual increase in the number of people seeking care, especially with fever, respiratory, or gastrointestinal complaints;
- an endemic disease rapidly emerging at an uncharacteristic time or in an unusual pattern;
- lower attack rates among people who had been indoors, especially in areas with filtered air or closed ventilation systems;
- clusters of patients arriving from a single locale;
- large numbers of rapidly fatal cases;
- any patient presenting with a disease that is relatively uncommon and has bioterrorism potential.

[Editor's note: In addition to contacting local authorities for a suspected bioterrorist event, ICPs can call the 24-hour CDC Emergency Response Office at (770) 488-7100 or the CDC Hospital Infections Program at (404) 639-6413.]

Reference

1. Association for Professionals in Infection Control and Epidemiology Bioterrorism Task Force and Centers for Disease Control and Prevention Hospital Infections Program Bioterrorism Working Group. *Bioterrorism Readiness Plan: A Template for Healthcare Facilities*. 1999. http://www.cdc.gov/ncidod/hip/Bio/bio.htm. ■

***Infection Control,* April 1997, pp. 51-53.)** Similarly, the Centers for Disease Control and Prevention advises health care workers to look for clusters and syndromes to determine if a bioterrorism event may be unfolding.

"The sentinel manifestations of that are likely to be a couple of uncommon cases rolling into the emergency room first or perhaps [to] primary care physicians, followed by a larger cluster," says **Michael Bell**, MD, an epidemiologist and bioterrorism specialist in the CDC hospital infections program. Bell is the lead CDC author of bioterrorism guidance published in conjunction with the Association for Professionals in Infection Control and Epidemiology.[1]

The document focuses on issues of preparedness for smallpox, anthrax, botulism, and pneumonic plague. Since few clinicians have seen such infections and laboratory diagnostics are limited, the CDC / APIC document includes a list of syndromes to help identify possible infections. **(See related story, p. 36.)** If a bioterrorism infectious agent were suspected, contacting local public health authorities would be the logical next step. "But it's not as if once you call your public health department, your patients are going to disappear," Bell emphasizes. "They are still going to be sitting there in your waiting room. So if we don't in advance discuss some of the issues related to that, the scrambling at the last minute is going to be a fiasco."

As a practical matter, an influx of infectious patients (i.e., smallpox or pneumonic plague) could quickly overwhelm available isolation rooms, O'Toole adds. "It's probably not going to be necessary to make capital investments and build a lot of isolation rooms, but it would be a good idea for people to look around and see if there are certain floors or wings that could become separate areas of air flow. Most hospitals have such areas," she says. "Some advance sleuthing as to what a hospital would do if it were confronted with a whole bunch of very ill, infectious patients would probably be worthwhile."

In that regard, infection control professionals at Walter Reed Army Medical Center (WRAMD) in Washington, DC, have taken the step of creating an infection control isolation precautions matrix to instruct and educate health care workers should a bioterrorist exposure occur. **(See chart, p. 38.)** Designed to provide an easy reference for infection control precautions for the most likely agents to be used by bioterrorists, the matrix also addresses such issues as patient placement and transport, cleaning and disinfection of equipment, and discharge and post-mortem care.

Lt. Col. **Suzanne Johnson**, RN, MSN, chief of infection control at WRAMD, who designed the matrix, based it on the CDC / APIC document and materials on other biological agents from the U.S. Army's facility in Fort Detrick, MD. "This is the nation's capital. If they — whoever 'they' are — can get to the [government], I'm sure they would want to," Johnson says. "From my standpoint as the chief of infection control, I want to provide the people that work here with as much information as possible."

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Indeed, the seat of U.S. political power would be in the "top five" of virtually any assessment of bioterrorist targets, says **Allan J. Morrison Jr.**, MD, MSc, FACP, health care epidemiologist for the four-hospital Inova Health System in Washington, DC. Accordingly, Morrison stresses bioterrorism preparedness, including meetings with members of the infection control, safety, and disaster committees for discussions. "Between those three committees, there is incremental work going forward," he says, adding that he would like to conduct drills with regional law enforcement, fire, and rescue.

Mass drills shouldered aside by fiscal needs

However, it is difficult to organize the kind mass drills needed to simulate a bioterrorist event, particularly because hospitals beset by real world fiscal pressures are reluctant to give up the minimum of a half-day of down time to conduct drills, he notes. "Human nature being what it is, it is difficult to impress upon people the importance of preparing for this," Morrison says. "When you have the financial pressures that health care systems have, getting something to percolate to senior leadership — to the level it will actually be strongly endorsed — is a difficult thing compared to the realities of this fiscal quarter's budget."

Preparedness might be enhanced if accrediting organizations added a few "nudge points" regarding appropriate funding for bioterrorism response, he says. O'Toole concurs, though she notes that "paper plans" in the absence of drills will not be sufficient to address the problem. She has testified

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Source: Walter Reed Army Medical Center, Washington, DC.

before Congress to request funding for the issue, noting that only about 14% of the $10 billion currently spent on counterterrorism efforts is earmarked for biological threats.

"Some combination of incentives to get busy hospitals engaged in this issue would make sense," she says. "Exactly what those incentives should be — carrots or sticks — is something that should be worked out in the next year." As national plans continue to develop, infection control professionals and hospital epidemiologists will inevitably be called upon because of their expertise with communicable diseases, Bell says.

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"Both infection control and hospital epidemiology [professionals] are very well-placed to take a leadership role," he says. "They have a history of communications in this role — spreading the word about hand washing and cohorting, and teaching patients what it means, for example, to be on contact precautions. That is the kind of thing we are going to be needing in the event of a bioterrorism [incident]," he says.

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CDC may call for HCV screening in hemodialysis

But not likely to recommend patient isolation

The Centers for Disease Control an Prevention will soon issue new infection control guidelines for hepatitis C virus in hemodialysis settings that may recommend routine HCV testing of patients to better identify outbreaks and reinforce infection control measures, *Hospital Infection Control* has learned.

"At the current time, we are re-drawing up our recommendations for hepatitis C screening," says **Suzanne Cotter**, MD, medical epidemiologist in the CDC hepatitis branch. "We previously have not recommended routine screening. We didn't discourage it, but we have not specifically [recommended] that they should be doing it. Now it is possible, and probably likely, that that recommendation may be changed in the future. There will be a new document coming out [this] year about infection control practices in hemodialysis centers."

Developed by the hepatitis branch and the CDC hospital infections program with the consultation of experts in working groups, the new guidance is expected to be issued in the coming months for all facilities that conduct hemodialysis, she says. "Some of the centers are hospital-affiliated and some are freestanding, but our recommendations apply to all," she says. The current CDC guidelines state that "periodic [HCV] testing of long-term hemodialysis patients for purposes of infection control is currently not recommended."[1] However, the CDC recommends that all hemodialysis patients be monitored monthly for signs of elevated liver enzymes to spot signs of HCV infection and other forms of hepatitis.

HCV testing could identify clusters, guide medical interventions, and reinforce infection control measures. However, it is not currently thought that the CDC will go as far as recommending the kind of stringent isolation and cohorting measures used for hemodialysis patients chronically infected with highly transmissible hepatitis B virus. "Appropriate use of hemodialysis-center precautions should prevent transmission of HCV among chronic hemodialysis patients, and isolation of HCV-positive patients is not necessary or recommended," the current CDC guidelines state.

"We're not saying that hepatitis C patients need to be isolated, because all the studies that have been done have indicated that with good infection control practices, transmission does not occur," Cotter says.

Indeed, numerous infection control breaches were identified in an HCV outbreak at a hemodialysis center investigated by Cotter and colleagues.[2] Poor infection control practices led to transmission of HCV to seven patients who used dialysis stations after patients with chronic HCV, Cotter explains. Blood contamination of equipment and supplies was the most likely route of transmission, she notes. "Transmission in this hemodialysis center was related to following a chronically infected patient," she says. "[We also] identified that the [hemodialysis] station was contaminated. We don't know exactly how, but there was a lot of opportunity for contamination that

Strict measures needed to halt HCV in hemodialysis

ICPs must go beyond standard precautions

Intensive efforts must be made to educate new staff and reeducate existing staff regarding hemodialysis-specific infection control practices that prevent transmission of HCV and other bloodborne pathogens, the Centers for Disease Control and Prevention emphasizes.[1]

Nosocomial transmission of HCV may occur in hemodialysis centers if infection control techniques or disinfection procedures are inadequate and contaminated equipment is shared among patients. Hemodialysis-center precautions are more stringent than standard infection control precautions, which require use of gloves only when touching blood, body fluids, secretions, excretions, or contaminated items. In contrast, hemodialysis-center precautions require glove use whenever patients or hemodialysis equipment are touched.

Standard precautions do not restrict use of supplies, instruments, and medications to a single patient. In contrast, hemodialysis-center precautions specify that none of those items be shared among any patients. The CDC recommends the following routine infection control precautions for the care of all hemodialysis patients to prevent nosocomial transmission of hepatitis C virus and other bloodborne pathogens:

- Patients should have specific dialysis stations assigned to them, and chairs and beds should be cleaned after each use.
- Sharing among patients of ancillary supplies such as trays, blood pressure cuffs, clamps, scissors, and other nondisposable items should be avoided.
- Nondisposable items should be cleaned or disinfected appropriately between uses.
- Medications and supplies should not be shared among patients, and medication carts should not be used.
- Medications should be prepared and distributed from a centralized area.
- Clean and contaminated areas should be separated (e.g., handling and storage of medications and hand washing should not be done in the same or an adjacent area to that where used equipment or blood samples are handled).

Reference

1. Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. *MMWR* 1998; 47 (No. RR-19):1-39. ■

we identified. When they improved their infection control practices — they did not isolate hepatitis C patients, but they simply improved their practices — transmission ceased. That is an important message, and there have been no further cases."

Of 51 patients tested at the center, 11 were previously known to be HCV-positive. Of the remaining 40, seven (17.5%) had seroconverted to HCV. All the seroconversions occurred on the second and third shifts. During those times, case patients followed chronically infected patients on the same dialysis machine more frequently than control subjects. "So we know that they were at risk because they followed [HCV-positive patients]," she says. Moreover, numerous instances of blood contamination of environmental surfaces were identified, suggesting there were several avenues by which transmission could have occurred. For example, there were indications that staff were not regularly cleaning out and changing "priming buckets," which are used as part of the process of flushing the lines out in the hemodialysis machine.

"There is potential for that fluid to have been contaminated from the patient's blood," Cotter says. "When the next patient comes on, if that has not been emptied, it's possible that what's in that bucket can contaminate the tubing [used on] the next patient. All materials that are used for patient care should be either disposed or cleaned and disinfected prior to the next patient using them."

In addition, investigators found that a multidose vial of heparin solution may been used among patients, suggesting another route for HCV transmission. Enforcing existing hemodialysis recommendations — including prohibiting shared medications and equipment and proper cleansing and disinfection of the environment — halted the outbreak. **(See recommendations, above.)** The CDC also recommended that the patients have specific dialysis stations assigned to them and

patients be screened for HCV every three months. However, that screening recommendation was in response to an outbreak situation and will not necessarily be the policy recommended in the updated CDC guidance, Cotter notes.

References

1. Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. *MMWR* 1998; 47 (No. RR-19):1-39.

2. Cotter S, Akinbami L, Sipe K, et al. Transmission of hepatitis C virus in a chronic hemodialysis center. Abstract 460. Presented at the Infectious Disease Society of America Conference. Philadelphia: Nov. 18-21, 1999. ■

AHA: Use needle devices to comply with OSHA

OSHA action 'effectively requires' sharps safety

The Occupational Safety and Health Administration's recently revised compliance directive for its bloodborne pathogen standard "effectively requires hospitals to use [needle] safety devices," the American Hospital Association in Washington, DC, is advising. In a regulatory advisory issued to hospitals by AHA executive vice president **Rick Pollack**, the association notes that OSHA has consistently required hospitals to use engineering controls and work practices as the primary means of eliminating or minimizing employee exposures.

"In the directive, OSHA defines engineering controls as controls that isolate or remove bloodborne pathogen hazards from the workplace," Pollack notes. "OSHA uses safety devices such as needleless devices, shielded needle devices, blunt needles, and plastic capillary tubes as examples of engineering controls. OSHA has explicitly included safety devices in its definition of engineering controls. This effectively requires hospitals to use safety devices to meet the bloodborne pathogen standard."

In recently revising its compliance for inspectors enforcing the 1991 bloodborne pathogen standard, OSHA mandated that needle safety device evaluation efforts must be documented at least annually in the exposure control plan.[1] If a combination of engineering controls (i.e., shielded needle devices) and work practice controls (i.e., eliminating hand-to-hand instrument passing in the operating room) does not eliminate or minimize exposures, the employer shall be cited, OSHA determined.

Still, some infection control professionals have recommended against blindly purchasing all manner of devices to comply with the changes. **(See *Hospital Infection Control*, January 2000, pp. 1-6.)** Similarly, the AHA reminds that "rather than require the use of specific devices, OSHA's directive allows hospitals to adopt safety devices based on their own evaluation of the needs of their patients and employees." However, the AHA emphasizes that while the directive is "flexible, [it] requires hospitals to take action." To make sure hospitals are in compliance with OSHA's directive, the AHA recommends the following:

- Review your exposure control plan to ensure it meets all the requirements of OSHA's directive. Make sure there is collaboration among infection control, risk management, safety staff, clinicians, occupational health staff, and other workers to implement the bloodborne pathogen regulation in your hospital.
- Record all actions taken to comply with OSHA's directive including any future plans. Be sure to document all training and education of workers in the use of safety devices.
- Begin implementing a sharps injury prevention program if you have not already done so.
- Document steps taken to reduce injuries through the use of safety devices and work practices. Any difficulties encountered in using safety devices also should be documented.
- Document the circumstances surrounding all exposure incidents.
- In states that have OSHA-equivalent standards, contact your state enforcement agency to make sure you are also in compliance with their regulations.

[Editor's note: For more information, visit AHA's Web site at www.aha.org. The OSHA directive can be accessed on the Internet at the OSHA home page at www.osha.gov. Copies also can be obtained from the agency's publications office by calling (202) 693-1888.]

Reference

1. Occupational Safety and Health Administration. 29 CFR 1910.1030. "Occupational Exposure to Bloodborne Pathogens." OSHA instruction CPL 2.103. Field inspection reference manual. Nov. 5, 1999. ■

FDA moves to toughen hospital reuse policies

ICPs have until April 11, 2000, to comment

Hospitals that reprocess single-use devices will face more oversight and tougher regulatory hurdles if draft guidance by the Food and Drug Administration is finalized as recently proposed. While the guidelines would be phased in over time, the FDA is essentially moving to a system that will require hospitals and independent third-party reprocessors to meet the same standards.

"Although we have no data to indicate that people are being injured or put at increased risk by the reuse of SUDs [single-use devices], the results of our own research and the information provided by various stakeholders have convinced us that this growing practice needs closer scrutiny and oversight," **David W. Feigal**, MD, director of the FDA Center for Devices and Radiological Health, said in explaining the proposals to the U.S. Congress Subcommittee on Oversight and Investigations. FDA outlined the proposals in two companion draft guidance documents posted on its Web site. **(See editor's note below right for the Web site address.)** A notice of the availability of the draft guidelines and of the beginning of a 60-day comment period was published in the Feb. 11, 2000, *Federal Register.*

Devices to be classified based on risk

While hospitals that reprocess devices labeled for single use have been allowed to do so as long they assume all liability, the FDA proposes changing to a system based on the risk of reprocessing the device. Reused devices are classified as low risk (i.e., sharps containers), moderate risk (i.e. anesthesia breathing circuits), or high risk (angioplasty balloon catheters). "Based on our own studies, we have determined that cleaning and sterilizing these [high-risk] devices is very difficult," Feigal said. "Hospitals and third parties that reprocess these devices would be required to submit [premarketing notification] demonstrating that their reprocessing of these devices is safe and effective."

In a plan to phase in the requirements, FDA would enforce premarket notification and premarket application requirements within six months of issuance of final guidance if the reprocessed device is categorized as high risk; within 12 months if the device is categorized as moderate risk; and within 18 months if the device is categorized as low risk. "After receiving public comment on our draft guidance, including factors used to categorize risks and timing of our enforcement based on those risks, we will issue final guidance and begin implementation of our enforcement strategy that would regulate [original equipment manufacturers] and third-party and hospital reprocessors in the same manner," Feigal said.

Phased-in implementation recommended

However, hospitals are to be given an additional six months after the finalization of the guidelines before having to make any changes. "Possible unintended and unpredictable consequences of the agency's immediate enforcement of all requirements (e.g., potential shortages in certain hospitals) support the need for a phased-in implementation period," the FDA guidelines state. "Moreover, the agency is aware that establishments such as hospitals may be unfamiliar with FDA regulations and will need time to learn about the requirements and to develop programs to comply with these requirements."

As proposed, the FDA changes would not apply to reprocessing in non-hospital medical settings, which the agency will consider at a later date. The FDA also is considering changes to the manufacturing labeling requirements for single-use devices. "One option the agency is considering is requesting [manufacturers] who label their devices 'single-use' to provide, as part of the device's labeling, any information of which they are aware regarding the potential risks associated with reusing their [devices]," Feigal said. "This information would serve as a caution to users and reprocessors who might attempt to reprocess."

[Editor's note: Copies of the FDA draft proposals are available at www.fda.gov/cdrh/reuse/1029.pdf or CDRH Facts on Demand at (800) 899-0381 or (301) 827-0111. Specify No. 1029 when prompted for the document shelf number. Public comment on the FDA draft guidelines should be submitted to the Docket number assigned to the notice in the Federal Register, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061 (HFA-305), Rockville, MD 20852.] ■

JOURNAL REVIEWS

Unvaccinated workers pose flu risk in LTC

Deaths lower in hospitals with vaccinated workers

Carman WF, Elder AG, Wallace LA, et al. **Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: A randomized controlled trial**. *Lancet* 2000; 355:93-97

Influenza vaccination of health care workers was associated with a near 9% decrease in mortality among patients in long-term care, the authors found. However, virological surveillance showed no associated decrease in non-fatal influenza infection in patients.

The potential is high for influenza to be brought into elderly-care homes by susceptible heath care workers and for infection to be transmitted to other heath care workers and to patients, the researchers noted. In a previous study, they found that vaccination of workers was associated with a decrease in mortality of elderly patients in long-term care from 17% to 10% over a winter season. In the current paper, they did a multicenter, randomized, controlled study to find out whether vaccination of health care workers would lower mortality and the frequency of laboratory-proven influenza infection in elderly patients in long-term-care hospitals.

In a parallel-group study, health care workers in 20 long-term elderly-care hospitals were randomly offered or not offered influenza vaccine. About 50% of the workers were immunized in the facilities where vaccine was offered, as opposed to only 5% of those in hospitals where it was not. All deaths among patients were recorded over six months in the winter of 1996-97.

The researchers selected a random sample of 50% of patients for virological surveillance for influenza, with combined nasal and throat swabs taken every two weeks during the epidemic period. Swabs were tested by tissue culture and PCR for influenza viruses A and B. The mortality rate in patients was 102 (13.6%) of 749 in vaccine hospitals compared with 154 (22.4%) of 688 in non-vaccine hospitals. ▼

Give surgical patients a breath of fresh air

SSIs and costs may fall as a result

Grief R, Akca O, Horn EP, et al. **Supplemental perioperative oxygen to reduce the incidence of surgical-wound infection**. *N Engl J Med* 2000; 342:161-167.

The administration of supplemental oxygen during colorectal resection and for two hours afterward halved the incidence of surgical-wound infection, the authors found. "Because the cost of and risk associated with supplemental perioperative oxygen are trivial, the provision of supplemental oxygen appears to be a practical method

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Editorial Questions

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

of reducing the incidence of this dangerous and expensive complication," they emphasize.

Destruction by oxidation is the most important defense against surgical pathogens and depends on the partial pressure of oxygen in contaminated tissue. An easy method of improving oxygen tension in adequately perfused tissue is to increase the concentration of inspired oxygen, the authors surmised.

They randomly assigned 500 patients undergoing colorectal resection to receive 30% or 80% inspired oxygen during the operation and for two hours afterward. Anesthetic treatment was standardized, and all patients received prophylactic antibiotic therapy. With use of a double-blind protocol, wounds were evaluated daily until the patient was discharged and then at a clinic visit two weeks after surgery. Wounds with culture-positive pus were considered infected. The surgeon, who did not know the patient's treatment-group assignment, determined the timing of suture removal and the date of discharge.

The arterial and subcutaneous partial pressure of oxygen was significantly higher in the patients given 80% oxygen than in those given 30%. Among the 250 patients in the former group, 13 (5.2%) had surgical-site infections. However, 28 (11.2%) of the 250 patients given 30% oxygen had infections. "The administration of supplemental oxygen during colorectal resection and for two hours afterward reduced the incidence of wound infection — one of the most serious common complications of surgery — by half," the authors concluded. Moreover, surgical-wound infections are expensive. For example, postoperative infections in patients with cancer add an average of $12,500 per patient to the cost of care. "The one-week-longer hospitalization in patients with infection in our study is consistent with findings in previous studies and indicates that the infections were clinically important, as do the higher numbers of admissions to the intensive care unit and of deaths in the group given 30% oxygen," they emphasized.

The researchers used a sealed mask and a manifold system to deliver oxygen postoperatively so that administration could be controlled precisely. However, similar amounts of oxygen can be delivered through conventional non-rebreathing masks, they reported. The postoperative administration of oxygen through a conventional mask introduces little if any extra cost, because virtually all patients are given some oxygen after surgery, they noted. ■

CE objectives

After reading each issue of *Hospital Infection Control*, the infection control professional will be able to do the following:

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