

BIOTERRORISM WATCH

Preparing for and responding to biological, chemical and nuclear disasters

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Fatal heart attacks rock CDC smallpox vaccination efforts

If cases linked to vaccine, national effort will surely suffer

(Editor's note: A 55-year-old man in the National Guard suffered a fatal heart attack following smallpox vaccination as this issue of Bioterrorism Watch went to press. That case is not reflected in the seven cases described in the story below, which all occurred in hospital or public health workers.)

Two fatal heart attacks following smallpox vaccination of health care workers threaten to further derail a struggling government immunization program already suffering from a striking lack of hospital participation.

Though a direct cause and effect has yet to be established in an ongoing investigation, the reports do not bode well for a program that has vaccinated only about 5% of the 500,000 hospital workers it originally projected.

A female nurse at Peninsula Regional Medical Center in Salisbury, MD, died of a heart attack on March 23, 2003, five days after being vaccinated. She reportedly was in her 50s. On March 26, 2003, a 57-year-old health care worker in Florida died 10 days after suffering a heart attack that occurred a week after being vaccinated for smallpox.

Those cases and reports of five other heart-related adverse effects among vaccinees prompted the Centers for Disease Control and Prevention (CDC) to declare a history of heart disease as a new contraindication for receipt of smallpox vaccine. Health care workers should not receive smallpox vaccine if they have a history or a diagnosis of coronary artery disease, myocardial disease such as angina, heart attack, congestive heart failure, or any kind of cardiomyopathy. Health care workers who already have been vaccinated should immediately consult a physician if they have any symptoms of heart disease, such as shortness of breath or chest pain, the CDC advises.

There is some concern that the effect on the program may ripple out beyond the specifics of that contraindication. The new heart disease contraindication may give pause to workers — or their personal physicians — with any peripheral concerns about, for example, diabetes or blood pressure, says **William Schaffner**, MD, chairman of the department of preventive medicine at Vanderbilt University

Medical Center. Beyond that — even if the deaths are later ruled entirely unrelated to the smallpox vaccine — a certain amount of “re-education” will be necessary to reassure health care workers about the program, he adds.

“Clearly, if we look at all known risk factors for coronary artery disease, we would potentially get to very, very large numbers of the population, and it would, in essence, be very difficult to enhance our preparedness,” conceded **Walter Orenstein**, MD, chief of the CDC national immunization program. “What we’ve tried to do is pick out people with the very highest risk factors, in the absence at this point, of any known causal relationship.”

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Editorial Questions

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

The CDC is determined to forge on, particularly with the threat of bioterrorism related to the war in Iraq. (See related story, p. 19.)

“Certainly, we are at a time in the history of our country where the potential for terrorism has probably never been higher,” says **Julie Gerberding**, MD, MPH, director of the CDC. “And we recognize that we must continue to be prepared to deal with a threat of smallpox in our nation.

“We are going to continue the program. But we’re also going to continue the program with the caveat that safety still is a high priority for us. And every time we put something on the list of medical conditions that constitutes a basis for deferral, we recognize that it does decrease, to some extent, the population of people who are willing to volunteer. But it’s a balance. And I think, again, we want to err on the side of safety,” she explains.

Two deaths after 25,000 vaccinated

The CDC discovered the seven cases of heart-related problems among the 25,645 health care and public health workers who have been vaccinated in the civilian program. The seven cases include three cases of myocardial infarction (heart attack), two of which resulted in the aforementioned deaths; two cases of angina (chest pain); and two cases of myopericarditis (inflammation of the heart muscle or sac surrounding the heart).

Issuing the contraindication is a clear case of erring on the side of caution, because a definitive link to smallpox vaccination has not been established in any of the cases.

“I think the first hypothesis is that this is not causally related,” Gerberding says. “That’s the null hypothesis in this case that we’re working from. But I think there is also at least the biological plausibility that when you have a viral infection — which is basically what happens when you issue the vaccine — that there could be inflammatory response that in some unidentified way exacerbates pre-existing coronary artery disease or inflammation.”

The CDC convened a panel of expert cardiologists and immunologists to review the cases to determine if the problems are vaccine related. Investigators also will look at comparable populations in other studies to assess the incidence of cardiac problems in unvaccinated people.

The CDC also is trying to determine if the heart problems may occur at a higher rate in females,

which comprise the majority of health care workers being vaccinated for smallpox.

"The five patients who have had the coronary artery disease-related complications — the three with MI, and the two with angina — all have very clear defined risk factors for coronary artery disease," she says.

"That is known in their medical history, and these are people who would medically be considered to be at perhaps increased risk of these conditions, based on their past medical history," adds Gerberding.

Smallpox vaccination and cardiac problems have not firmly been linked in the historical smallpox literature, but more older people are being vaccinated now than during the childhood immunization programs prior to smallpox eradication. The three workers who had heart attacks were all women in their 50s. In all seven cases,

the time lag between vaccination and cardiac problems varied from five to 17 days. No adverse reactions were noted at the time of vaccination.

"We don't have a lot of epidemiologic or scientific information about the relationship between vaccine and cardiac illness in persons who are older and who were not involved in the childhood immunization program where we had the most experience in the '60s." Gerberding says.

The problem is that older staff members who have been previously immunized have been considered at lower risk of adverse effects. Might the CDC begin discouraging senior staff to be inoculated for smallpox?

"I don't think that we are prepared to take that step at this point in time," she says. "We'll defer to the expert input that we anticipate receiving from people who are the most credible in the world of cardiac risk assessment." ■

Fear of airborne smallpox is behind push to vaccinate

Warning of scientist echoed by health officials

As previously reported in *Bioterrorism Watch*, top government health officials are pushing mass smallpox vaccinations in the health care system because they fear that Iraq possesses smallpox virus with "bioengineered . . . transmission" characteristics.

A top U.S. bioweapons scientist told *BW* last year that the former Soviet Union developed a method to spread a vaccine-resistant strain of the deadly virus through the air over large areas. Iraq and other rogue governments and terrorist groups may possess the technology, warned **Alan P. Zelicoff**, MD, senior scientist in the Center for National Security and Arms Control at Sandia National Laboratories in Albuquerque, NM. (**See *BW*, September/October 2002, p. 9.**) Raising the specter of airborne smallpox dashes most contingency plans for controlling an outbreak, which typically assume the virus would spread by conventional person-to-person transmission.

While some dismissed the warning as unfounded, top public health officials appear to share the same concern in a recent conference call with Michael Tapper, MD, president of the Society for Healthcare Epidemiology of America (SHEA). Here is a summary of the discussion that was posted on the SHEA web site:

"Dr. Michael Tapper, SHEA president, represented SHEA on a conference call on March 7 with **Tommy Thompson**, secretary of Health and Human Services, undersecretary Jerome Hauer, and **Julie Gerberding**, MD, director of CDC. The call was

organized on short notice to request support from health care organizations for increased voluntary participation in the first phase of the smallpox vaccine program. Thompson expressed his concern about the relatively poor acceptance to date of the voluntary smallpox immunization by health care workers. He cited concerns about the possibility of imminent military activity in the Middle East and suggested that the U.S. government strongly suspected that the Iraqi government had access to smallpox, perhaps bioengineered. Gerberding emphasized that the issue of bioengineered smallpox more likely applied to its virulence or transmission characteristics and not to the utility of the current smallpox vaccine."

Though Zelicoff's analysis of a formerly secret Soviet report has elements of speculation, he made a provocative argument that a 1971 smallpox outbreak in the city of Aralsk can be traced to airborne smallpox experiments on the island of Vozrozhdeniye in the Aral Sea. The outbreak was never officially reported to the outside world by the Soviet government. Though ascribing it to natural causes in its internal medical report, the former Soviet Union suppressed reports of the outbreak to protect the secrecy of its bioweapons research program on the island, he noted.

Zelicoff reviewed the official Soviet report and interviewed some of the outbreak survivors, including the index case. Now 54 years old, she was a fisheries biologist on a ship that sailed near the island of Vozrozhdeniye in July 1971 to conduct research on the declining marine environment in the Aral Sea. Though she had been immunized against smallpox and the ship was some 15 km from the island, the biologist developed smallpox and subsequently spread it to nine others on her return to the mainland. ■

Health care system falling back into complacency?

Lack of funding leaves communities vulnerable

Despite 9/11 and its anthrax aftermath, the majority of hospitals and their surrounding communities have slipped back into “complacency” and are dangerously unprepared for bioterrorism or other mass casualty events, according to the Joint Commission on Accreditation of Healthcare Organizations.

A recently released report by a panel of experts convened by the Joint Commission warned of a “brewing cataclysm” of underfunding, inexperience, and unpreparedness of emergency response capabilities across America’s communities. This vulnerability, the report stressed, must be urgently addressed by local, state, and federal authorities.

“The events of Sept. 11 and the subsequent anthrax attacks provided a startling wake-up call about this country’s emergency preparedness shortcomings,” **Dennis O’Leary, MD**, Joint Commission president, said at a press conference held to release the findings.

“But across the country, people today seem to be slipping into a comfortable complacency about emergency preparedness,” he added. “In most of America’s communities, there has been no mobilization, nor have the funds and resources been provided by the federal and state governments truly at the local level to make this possible.”

O’Leary was asked specifically by *Bioterrorism Watch* whether that “complacency” was evidenced in the reluctance of many hospitals to immunize workers against smallpox. “Complacency is probably too strong a term in this context,” he replied. “But I do think if you are a caregiver — a doctor or nurse and you are looking at this issue — what you’re weighing in your head is what is the risk of vaccination vs. how real do I think this smallpox risk is. That’s human nature. I think that there is some feeling that this smallpox risk is not really that great. It kind of typifies the general feeling. It’s a hard commentary that until something else happens it’s hard to get peoples attention. One smallpox case; it’s a different story.”

The report was prepared in consultation with a 28-member panel, which included representatives of various federal and state agencies, frontline emergency care providers, emergency preparedness planners, and public health and hospital

community leaders. Noting that virtually all disasters, including intentional terrorist events, will be experienced at the local level, the report emphasizes that many communities will be on their own for the first 24 to 72 hours.

The response that must be mobilized will, at a minimum, require the active involvement of emergency medical services, fire, police, hospitals, public health agencies, and municipal and county leaders. This is no task for a single hospital or agency, the report said.

“Many of our large metropolitan areas, such as New York City and Washington, DC, are far better prepared to deal with terrorist attacks and other disasters than they were before Sept. 11,” O’Leary said. “However, most of America’s communities are at the stage of waiting for someone to call the meeting.”

The report urged community leaders to convene that meeting, calling together local emergency management agencies, public health agencies, hospitals, and municipal and county leaders. The report goes on to detail the critical elements of good emergency management programs, and goes so far as to urge the creation of a federal program to hold communities “accountable” for such plans. **(See recommendations, p. 21.)**

“The potentially involved players today do not, in most communities, work with or even talk with each other on a regular basis,” O’Leary said. “Most are lone rangers that are used to being simply in control.” Beyond the lack of communication and cooperation, there is a problem getting adequate funding to individual communities. Securing promised federal funds at the local level has been an historic problem, but the fiscal barriers were supposed to be torn down after 9/11, he said. “The federal government needs to feel a little more pressure and heat about making this happen. We are advised that the money kind of moves to the state levels and it gets hung up there in the budget allocation processes.”

Complacent or cash-strapped?

Panel member **Mark Ackermann**, senior vice president and chief corporate services officer of Saint Vincent’s Catholic Medical Centers in New York City, stressed just how expensive it is to prepare for bioterrorism and natural disasters.

“Of the preparedness we are doing in our health care system — which is seven acute care hospitals — we anticipate we are going to need to

(Continued on page 22)

JCAHO: Local communities will be on their own

The Joint Commission on Accreditation of Health-care Organizations has released an expert panel report: *Health Care at the Crossroads: Strategies for Creating and Sustaining Communitywide Emergency Preparedness Systems*.

The report recommendations include the following:

I. Enlist the community in preparing the local response .

- Initiate and facilitate the development of community-based emergency preparedness programs across the country.
- Constitute community organizations that comprise all of the key participants — as appropriate to the community — to develop the communitywide emergency preparedness program.
- Encourage the transition of community health care resources from an organization-focused approach to emergency preparedness to one that encompasses the community.
- Provide the community organization with necessary funding and other resources and hold it accountable for overseeing the planning, assessment, and maintenance of the preparedness program.
- Encourage the pursuit of substantive collaborative activities that also will serve to bridge the gap between the medical care and public health systems.
- Develop and distribute emergency planning and preparedness templates for potential adaptation by various types of communities.

II. Focus on the key aspects of the preparedness system that will preserve the ability of community health care resources to care for patients, protect staff, and serve the public.

- Prospectively define point-in-time and longitudinal surge capacity at the community level.
- Establish mutual aid agreements among community hospitals and other health care organizations.
- Ensure a 48- to 72-hour stand-alone capability through the appropriate stockpiling of necessary medications and supplies.
- Fund and facilitate the creation of a credentialing database to support a national emergency volunteer system for health care professionals.
- Make direct caregivers the highest priority for training and for receipt of protective equipment, vaccinations, prophylactic antibiotics, chemical antidotes, and other protective measures.
- Support the provision of decontamination capabilities in each hospital.

- Maintain the ability to provide routine care.
- Make provision for the graceful degradation of care.
- Provide for waiver of regulatory requirements under conditions of extreme emergency.
- Adopt incident management approaches that provide for simultaneous management involvement by multiple authorities and fluidity of authority.
- Make provisions for accommodating and managing the substantial acute mental health needs of the community.
- Directly address the fear created by terrorist acts through targeted education, application of risk reduction strategies, and the teaching of coping skills.
- Provide public education about emergency preparedness.
- Actively engage the public in emergency preparedness planning.
- Anticipate information needs of the community.
- Create redundant, interoperable communications capabilities.
- Develop a centralized communitywide patient locator system.
- Engage the mass media in the emergency preparedness planning process.
- Regularly test, at least yearly, community emergency preparedness plans through reality-based drills.
- Assure the inclusion of all community emergency preparedness program participants in the plan tests.

III. Establish accountabilities, oversight, leadership, and sustainment of community preparedness systems.

- Develop and implement objective evaluation methods for assessing the substance and effectiveness of local emergency preparedness plans.
- Provide funding at the local level for emergency preparedness planning.
- Explore alternative options for providing sustained funding for hospital emergency preparedness activities.
- Initiate and fund public-private sector partnerships that are charged to conduct research on and develop relevant, scalable templates for emergency preparedness plans that will meet local community needs.
- Disseminate information about existing best practices and lessons learned respecting existing emergency preparedness initiatives.
- Clarify the applications of EMTALA, HIPAA, EPA and other regulatory requirements in emergency situations.
- Coordinate domestic and international emergency preparedness efforts. ■

spend about \$10 million," he said. "Our board has already committed \$2.5 million of that, which has been spent. We have received a total of \$40,000 thus far from the federal government. I think that gives you an example of the timing issues here and the magnitude of the money."

Given those kinds of dollars, the \$500 million earmarked by the federal government for emergency preparedness next fiscal year is not going to go very far. Hospitals are particularly vulnerable because the system has shrunk capacity to remain viable over the past two decades, the report stated.

"This has translated into the closure of many hospitals and even more emergency departments, despite the escalating demands for services," the Joint Commission panel said. "In addition, many hospitals now are experiencing severe shortages of nurses and other essential health care personnel. This is further reducing the capacity of these hospitals to deliver care, including emergency care. Today's hard reality is that hospital emergency departments across the country are overcrowded and, even absent any external disaster, likely to be diverting patients on any given day."

Mind games: Turn terror into a more realistic fear

Assessing the psychological impact of terrorism

Much discussion has centered on the physiological signs and symptoms of the various weapons of mass destruction, but what about the psychological state of the public after an attack?

Three scholars recently looked at that question at a special session on the topic at a bioterrorism symposium sponsored by the Johns Hopkins University Center for Civilian Biodefense Strategies in Baltimore. The message was somewhat mixed, with the experts indicating that overall panic was unlikely, but noting that many people may present at medical centers with imagined ills.

"The one take-home point I really want to make is that our goal as leaders, as health care providers is — to prevent ideally — or to convert terror to a realistic fear in the wake of these sorts of events," said **Ann Norwood**, MD, Col, MC, associate chairman of the department of psychiatry at Uniformed Services University in Bethesda, MD.

Why are psychological responses important? "In the first place, they affect our physiological responses, and that can directly impact health

Exacerbating the situation are several other factors, including soaring liability insurance premiums for physicians, state reductions in the number of people on Medicaid rolls, threatened Medicare cuts, and increasing demands for care of the uninsured.

Health care and community planners can stretch dollars by overlapping disaster plans where appropriate, taking an "all-hazards" approach that covers both bioterrorism and natural disasters, says panel member **Edward J. Gabriel**, M.P.A., EMT-P, deputy commissioner for preparedness at the New York City Office of Emergency Management. "You can use any of the pieces of preparedness for any particular kind of attack," he said. "For example, if you are getting a large hurricane into a particular area, you are going to need evacuation routes. So you can use the same framework by which you do an all-hazards planning drill for most of the major pieces of a terrorism-related drill."

(For a complete copy of the report, see Health Care at the Crossroads: Strategies for Creating and Sustaining Communitywide Emergency Preparedness Systems, at www.jcaho.org.) ■

care seeking behaviors," she said. "People take themselves to a health care provider or a hospital to get checked out because they are worried that they might have whatever [agent] it is."

Such "worried well" were reported after the 9/11 attacks, particularly by Pentagon employees who thought some biological or chemical weapon may have been used there. The problem is multifactorial, but begins with the body's classic response to fear — the fight or flight syndrome.

"You can imagine if you start to feel these kinds of things that might just reinforce your concern and fear that you have been infected with something, so that there is a real true physiological response that can play into this health-seeking behavior and fear," Norwood said. "There's a certain amount of hypersuggestibility right after something that kind of stuns us. Risk communication will be a critical factor in determining outcome to one of these events."

The smell (or lack thereof) of fear

Many bioterror and chemical agents are invisible and odorless. That taps into deep-rooted human fears of being invaded and destroyed by an invisible force, she said. Also, there is a delayed onset between exposure and illness, a lag that

produces tremendous anxiety and uncertainty in those fearing they may have been infected.

Moreover, because most biological weapons produce diseases that are rarely seen in American medical practice, there is limited knowledge about diagnosis, treatment, and outcome, said Norwood.

"As we saw with the anthrax, these agents may behave differently than we anticipated based on prior experience in terms of their infectivity, and ability to be aerosolized and so forth. Because of this uncertainty, physicians and patients really are in the same boat," she added.

All the more feared are agents such as smallpox that produce a grotesque appearance in the afflicted. The totality of these factors can result in "overwhelming emotions [that] can disrupt realistic problem solving," Norwood said. "Panic really is when people do what we don't want them to do, and don't do what we want them to do."

But the stereotypical "widespread panic" is actually a rare phenomenon in disaster and mass casualty situations, said **Lee Clarke**, PhD, professor of sociology at Rutgers University in New Brunswick, NJ.

"We look at the World Trade Center, of course, and there we see very little panic. People were scared out of their minds, but that's a perfectly

rational thing to do. One of the reasons there wasn't a higher death toll in New York is indeed that people generally responded well, but this is not surprising to those of us in disaster research. They did not rush, pushing people out of the way to get out of the building. They helped each other. They helped complete strangers."

If there's a silver lining to 9/11 and the anthrax

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, you must complete the evaluation form, that has been provided in this issue, and return it in the reply envelope to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME questions

9. Heart-related adverse effects among smallpox vaccinees prompted the CDC to declare which of the following as a contraindication for receipt of smallpox vaccine?
 - A. high cholesterol
 - B. diabetes
 - C. heart disease
 - D. all of the above
10. Julie Gerberding, MD, CDC director, said the five patients who have had coronary artery disease (CAD)-related complications (three with heart attacks and two with angina), all had:
 - A. very clear defined risk factors for CAD
 - B. no risk factors for CAD
 - C. unknown risk factors for CAD
 - D. none of the above
11. According to Edward J. Gabriel, deputy commissioner for preparedness at the New York City Office of Emergency Management, health care and community planners can stretch dollars by overlapping disaster plans where appropriate, taking an "all-hazards" approach that covers both bioterrorism and natural disasters.
 - A. true
 - B. false
12. According to Lee Clarke, PhD, professor of sociology at Rutgers University, widespread public panic following disaster and mass casualty situations is:
 - A. very common
 - B. rare
 - C. beneficial due to social venting
 - D. A and C

Answer Key: 9. C; 10. A; 11. A; 12. B

COMING IN FUTURE MONTHS

■ Keys to the new all-hazards mentality

■ Rapid decontamination of the chemically exposed

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■ Take me to your leader: Should one person be in charge, and should it be you?

■ Smallpox and heart attacks: Connected or not?

aftermath, it's to some extent, our "imagination have been stretched," and our worst fears nearly realized, Clarke said.

"It used to be that we advised people not to imagine the worst cases. We would tell them that it was against their interest, and against good reason to concentrate on the risk, as opposed to the outcomes. We would tell them it was unreasonable, that perhaps we would even be prone to panic if we focused on worst-case possibilities, rather than the likelihood of an occurrence. But of course, we live in a worst-case world now, and I don't think our imaginations are going back." ■

Hospital safely provides smallpox vaccine shots

A detailed review of start-up to follow-up

Significant planning and organization is necessary to accomplish an efficient hospital-based smallpox vaccination program, but it can be done successfully, reports **Kathy Lynn Emanuelsen**, RN, Med, director of occupational health at Hartford (CT) Hospital.

The hospital was one of the first facilities to begin immunizing workers for smallpox, and Emanuelsen's account of the careful planning required and lessons learned along the way can provide critical guidance for those considering a program in the future.

"Assigning the responsibility for your overall smallpox program to one person or one group of individuals with the expertise to develop programs is essential," she says. "Focused education is the key to a successful program. Flexibility is essential on the part of the vaccinating team."

Emanuelsen recently reviewed her program — from start-up, to immunization, to follow-up for adverse events — as part of a special audio conference, **Smallpox Vaccinations of Health Care Workers: The Real-World Experience**, sponsored by Thomson American Health Consultants, publisher of *Bioterrorism Watch*. As of March 3, 2003, 75 health care workers have been vaccinated at Hartford Hospital, she reports. While no serious adverse events have occurred, she reviews the thorough screening and follow-up procedures down to the most unusual questions (e.g., the safety or lack thereof of household pets in the home of vaccinees).

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William Craig, MD, Tennessee state epidemiologist, joined her on the program. Craig describes all aspects of the comprehensive statewide smallpox vaccination program.

In addition, **William Schaffner**, MD, chairman of the department of preventive medicine at Vanderbilt University Medical Center in Nashville, TN, serves as the program's moderator and expert commentator on the recently reported cardiac problems among vaccinees and new infection control guidelines to protect patients.

To order a CD of the audio conference, call (800) 688-2421. The price is \$299 and offers CE, CME, and critical care credits for your entire facility. When ordering, please refer to **effort code #80041**. ■

CE/CME objectives

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

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