

# BIOTERRORISM WATCH

*Preparing for and responding to biological, chemical and nuclear disasters*

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## CDC weighs vaccinating now or waiting until first smallpox attack

*Would you take smallpox vaccine? A pox on both your choices*

If smallpox vaccine were made available by the government, would you bare your arm for that tattoo of skin pricks with the little pitchfork needle, hoping that the live cowpox virus entering your bloodstream would do you more good than harm?

That's what it may come down to: individual choice. Because whatever the Centers for Disease Control and Prevention (CDC) recommends about the controversial smallpox vaccine, it certainly will be voluntary (at least for nonmilitary personnel). The CDC recently called together a working group of clinicians and experts in Atlanta to solicit advice and opinion about possibly immunizing people with vaccinia (cowpox) against variola (smallpox), one of the more dreaded potential weapons of bioterrorism. The group will forward its analysis of a set of options — without making a consensus recommendation — to the CDC's Advisory Committee on Immunization Practices. That committee and the CDC will hold a series of meetings in the coming months and decide whether to resurrect voluntary smallpox immunization programs in the United States. (See options, p. 3.)

The disfiguring infectious disease that killed millions worldwide for ages was eradicated case by case decades ago in one of the greatest public health achievements of all time. The last smallpox immunization programs in the United States were disbanded in 1972. The last known stores of smallpox virus in the world are officially in Russia and the

## Welcome to the new *Bioterrorism Watch!*

Welcome to our expanded, bimonthly publication, *Bioterrorism Watch*, your source for cutting-edge information on bioterrorism and the health care delivery system. In this issue, we feature a special report on smallpox, as public health officials seriously weigh whether to hazard the vaccine risks or hold off until the first attack. ■

United States, but the increasingly broad consensus is that the dreaded pox could be in the hands of rogue nations and/or terrorist groups. It is known that smallpox was developed as a weapon in the sweeping bioweapons program in the former Soviet Union. With a new vaccine under production and dilution studies showing that existing vaccine supplies can be greatly expanded, mass immunizations are a possibility again.

In that regard, some of the consultants at the meeting called for action, urging the CDC to recommend voluntary immunizations for health care workers and the public. Others cautioned about a host of potential side effects and the fact that there are some 300,000 people in the United States who do not know they are HIV-positive. Vaccinating them and other immune-compromised people could lead to one of the worst complications of cowpox: fatal, progressive vaccinia. (**See related story on adverse vaccine reactions, p. 4.**) In addition, a Food and Drug Administration (FDA) official at the meeting warned the CDC that widespread use of the live virus vaccine could imperil the blood supply because those immunized must wait one year before donating blood.

"Currently in the country, there are about 13 million blood donations donated by 9 million blood donors," said **Allan Williams**, PhD, director of the FDA division of blood application. "The current industry standard for a blood donor vaccinated with live virus is a one-year deferral. That's very conservative, but [it is] really unknown what duration of viremia may be associated with vaccinia immunization. If large scale vaccination were considered, a fairly large number of blood donors would be deferred and this could potentially create shortage problems in what is really a very fragile blood supply."

The margin is so thin that cutting the blood supply by 10% could result in serious morbidity and mortality in blood-product recipients, Williams said. Before large-scale immunizations are undertaken, he said it might be necessary to first recruit and vaccinate a large group of repeat, dedicated blood donors.

**David Liebershach**, one of the CDC advisors and the state director for the Alaska division of

emergency services, made it clear he would not be lining up for voluntary immunization for any reason.

"I don't want smallpox vaccination," he told the work group. "I have a 12-year-old child and a 5-year-old child, and I don't want them vaccinated pre-attack. That's speaking from one person from a state where the [likelihood of attack] is probably pretty low. And if it does occur, it is cold and dry up there and your population is about one [person] per square mile density, so the face-to-face contact would be minimized quite a bit."

Again, individual choice is the key. Having been immunized as a child and later in life after joining the Peace Corps, **William Bicknell**, MD, PhD, professor of international health at Boston University, made one of the more compelling arguments for voluntary mass immunization.<sup>1</sup>

"The primary argument is that it should be up to the people to decide, with appropriate guidelines," he told *Bioterrorism Watch*. "Don't immunize [pre-attack] little babies and people with organ transplants and AIDS. But otherwise, let's say, 'Here's what we know about the vaccine; here is what we know about the risk: Make your choice.'"

While risk groups should be screened out, there are also some 157 million people in the United States who were immunized as children, he notes. Whether they have any immunity left is an open question, but they are much less likely than first-time vaccinees to have any adverse reaction to the vaccine, Bicknell argues.

"If you look at the people who already have been vaccinated, the complications are much lower of all types and there are virtually no deaths in that group," he said. "Then if you eliminate [immunizing] people under 5, that cuts about half the deaths and half the complications. Suddenly, you have almost no complications. It's much less dangerous than driving to work in the morning."

The CDC's current draft smallpox plan hinges on "ring" vaccination, which requires rapid mobilization of vaccine to immunize the first reported smallpox cases and their contacts. The ring approach was used to successfully eradicate

(Continued on page 4)

## COMING IN FUTURE MONTHS

■ Lessons of Chernobyl

■ Treating patients exposed to radiation

■ CDC smallpox vaccine recommendations

■ Bioterrorism field kits

■ Diagnosing the exotic agent

# CDC mulls smallpox vaccination scenarios

*Questions and options on a difficult decision*

The smallpox working group at the recent meeting held by the Centers for Disease Control and Prevention (CDC) reviewed a series of issues and questions in a draft document on smallpox vaccination options. Highlights of the document are summarized as follows:

## Background

If vaccination were provided pre-event, the rate of adverse events likely would be much lower as vaccination could be deferred for people who have contraindications. People who are immunocompromised because of cancer or its therapy, who have known HIV infection, or who are receiving immunosuppressive therapy can be identified readily and vaccination deferred.

People who are unaware that they are infected with HIV may be identified by questions regarding risk factors and serological testing. A history of eczema may be difficult to obtain because the prevalence is highest among infants and decreases rapidly during the preschool years; however, risk of severe reaction in an adult with a history of eczema only as an infant is likely lower than for other at-risk groups.

Deferring vaccination for household contacts of people at high risk and instructing vaccines regarding care of the vaccination site would decrease the risk of adverse reactions in contacts. Estimates of the rate of severe adverse reactions to smallpox vaccination are subject to substantial uncertainty.

Other, unpublished estimates have ranged from about < 40 to > 200 reactions per million vaccine doses administered. Population denominators for some high-risk conditions (e.g., eczema) are imprecise and the risk of severe reactions among people with the current range of immunocompromising conditions may differ from the risk experienced during the past.

**Question 1.** *With no known cases of smallpox worldwide, should routine smallpox vaccination be re-introduced into the United States? That is, should there be any change in the current recommendation for not vaccinating people in the general population unless a smallpox bioterrorism event has occurred?*

**Option 1.** There should be no changes in the current recommendation.

**Option 2.** Continue current recommendations for

not vaccinating in the general population in the absence of a smallpox bioterrorist attack, but allow permissive or voluntary use of the vaccine for people in the general population who desire to be vaccinated despite the recommendation.

**Option 3.** There is no positive or negative recommendation. The committee is neutral but recommends that vaccine be available for individual choice.

**Option 4.** Routine vaccination is recommended, but there is a provision to opt out of taking the vaccine.

**Question 2.** *Are there other occupational groups at the federal, state, or local level who should be vaccinated in a pre-attack setting in order to enhance preparedness?*

**Option 1.** At the present time, there should be no vaccination of additional people at the state or local level. That is, the current recommendations as outlined in the Advisory Committee on Immunization Practices statement on the use of vaccinia vaccine published in June 2001 remain valid.

**Option 2.** Vaccination would be done from the smallest number of personnel to the largest number of personnel, and thought of as being done in an additive fashion. One needs to consider the likelihood of being exposed to smallpox, the importance of the occupation in dealing with smallpox, and the risk of vaccination to the individual.

### Potential groups for immunization:

- pre-designated public health and medical personnel (including emergency department staff) who would be called upon to care for and treat smallpox patients in designated facilities;
- smallpox-response teams at the federal, state, and local levels who would be called upon to investigate smallpox cases, and contain outbreaks;
- selected first responders who would play a critical role in the control of an outbreak of smallpox;
- pre-designated personnel to maintain essential services;
- all health personnel;
- other first responders;
- others.

**Option 3.** State and local public health authorities are given a fixed amount of vaccine, and they determine who should be vaccinated within their state for preparedness and response enhancement.

*(Editor's note: The CDC options assume that there is a clear understanding of the risks; vaccines take appropriate care of their vaccine site; the product is available for use; there is sufficient vaccine immune globulin available; there is sufficient security; vaccines must be used under investigational new drug procedures until mid-2003; and there is appropriate screening for contraindications.) ■*

# Vaccine reactions and the use of immune globulin

*Most deaths from encephalitis, progressive vaccinia*

According to materials distributed at the smallpox working group meeting recently held by the Centers for Disease Control and Prevention (CDC), reactions to smallpox vaccine range from mild to moderate to severe. (See charts, pp. 5 and 6.)

Details about these reactions include:

Historically, people being vaccinated for the first time (primary vaccinees) experienced adverse reactions at higher rates ( $> 10x$ ) than those being revaccinated; rates are higher in infants than in older children or adults.

Inadvertent inoculation at other sites is the most frequent vaccine complication, accounting for nearly half of all complications of primary vaccination and revaccination. Most lesions heal without therapy; vaccine immune globulin (VIG) may be useful for cases of ocular implantation.

Progressive vaccinia, a potentially fatal complication of vaccination, has occurred almost exclusively among immunocompromised people.

Approximately 15% to 25% of vaccinees who develop post-vaccinal encephalitis die, and 25%

have permanent neurological sequelae.

Most deaths caused by vaccination are the result of post-vaccinal encephalitis or progressive vaccinia: approximately one death/million primary vaccinations and 0.25 deaths/million revaccinations.

Approximately 5% to 20% of vaccine adverse events occur in the contacts of vaccine recipients. Inadvertent inoculation is the most frequent adverse event occurring in contacts of vaccines (60%). In the 1963 and 1968 national surveys, approximately 20% of VIG recipients were contacts; most frequently with eczema vaccinatum. Eczema vaccinatum can be more severe in contacts than in actual vaccine recipients.

Based on the data from the 1963 and 1968 state and national surveys, it appears that at least 10 times more mild adverse events (including mild eczema vaccinatum, generalized vaccinia, and inadvertent inoculation) occur than events that need VIG.

Generalized vaccinia, vaccinia necrosum, eczema vaccinatum, and some accidental implantation can be treated with VIG. CDC has developed estimates of the frequency of adverse events requiring VIG therapy as a basis for establishing a stockpile.

In addition, vaccination would result in — 0.5 to one death per million persons vaccinated — primarily from post-vaccinal encephalitis, which cannot be treated with VIG. ■

smallpox from the world, but the demographics of the disease are strikingly different today because most people in the world are susceptible. The ring concept was effective when many people already were immune due to vaccination or past infection. "There were growing levels of immunity in the population," Bicknell said.

"They were working in remote areas with small numbers. Ring vaccination is great for that, but not if you have a malicious exposure," he explained.

While there have been various scenarios about how such an attack would occur, some have dismissed the likelihood of self-inoculated terrorists moving about the country to infect the populace. That is because smallpox is not infective in its incubation period and presumably terrorists with onset of fever and pustules would be noticeably ill and incapable of much widespread movement.

However, Bicknell warns that there is a "pre-eruptive period" as the incubation phase wanes when the self-inoculated terrorist could be infective without obviously having smallpox. Even as disease progresses, he adds, "If you are motivated, you can feel pretty terrible and move around." Moreover, a mass smallpox immunization in

Yugoslavia in the 1970s began with an atypical index case that had no rash, he reminds.<sup>2</sup>

Indeed, given the possibility of a well-organized release of smallpox over a broad area, the CDC immediately should begin immunizing first responders and medical personnel, advised Steven Christianson, DO, MM, medical director of the Visiting Nurse Service of New York City. "If an attack is credible, it will possibly come in multiple areas and multiple sites within those areas," he said. "It will be designed to overwhelm the public health system and the medical system. Our perspective is that voluntary vaccination of first responders and medical people should be encouraged even while the vaccine is still unlicensed."

However, Christianson recommended against routine mass immunizations of the public due to adverse effects and deaths. One recent study estimated that vaccinating people ages 1 to 65 years would result in 4,600 serious adverse events and 285 deaths.<sup>3</sup>

But if there is an attack and mass public immunization has not been done, will emergency departments (EDs) be overwhelmed? They are practically overwhelmed right now, pointed out Thomas Terndrup, MD, who represented the American

College of Emergency Physicians at the meeting.

"If you expect the emergency departments in America to supply [surge] capacity you are seriously mistaken," he said. "Our emergency departments are already operating to capacity. On Sept. 10th, the day before the World Trade Center bombings, there was an article outlining this in *Time* magazine. We continue to see significant increases in patient visits to the emergency departments. The CDC estimates that in 2002, something like 108 million visits will be made to emergency departments."

Though Terndrup left it to the CDC to decide who to immunize, he underscored the chaotic impact a smallpox release would have on emergency workers and departments.

"Think about an outbreak of smallpox and what would happen to emergency services and those emergency responders out there picking people up off the street," he said. "This is the only source of federally mandated care. Any patient for any reason that shows up at a hospital in America that has an operating ED [must be

treated] by federal law." There are some 9 million first responders when you add ED clinicians, paramedics, police, and firefighters, he said.

"Should first responders be immunized?" Terndrup said. "I don't have any answers."

Whatever policy is adopted, the CDC better have answers for the AIDS community, cautioned **John Bartlett**, MD, HIV expert, and clinician at Johns Hopkins University School of Medicine in Baltimore. "The AIDS community is a very cohesive group," he said. "It's loud and well-organized. Whatever is decided, [you] need to work with that group and get buy-in. If the decision here is that we ought to give people the vaccine, and there is not buy-in from the AIDS care community, it is not going to happen."

There are about 900,000 people living with HIV infection in the United States, and about one-third of them do not know they are infected, he said. HIV patients are contraindicated for live vaccines, and that should probably remain the rule for smallpox as well, he said. Bartlett cited a case in the literature of an HIV-positive patient who died of progressive

## Rates of Reported Complications Associated with Vaccinia Vaccination (Cases/Million Vaccinations)\*

Age (yrs) and status	Inadvertent Inoculation	Generalized Vaccinia	Eczema Vaccinatum	Progressive Vaccinia	Post-vaccinal Encephalitis	Total†
<b>Primary</b>						
<1	507.0	394.4	14.1	—§	42.3	<b>1549.3</b>
1-4	577.3	233.4	44.2	3.2	9.5	<b>1261.8</b>
5-19	371.2	139.7	34.9	—	8.7	<b>855.9</b>
>/20	606.1	212.1	30.3	—	—	<b>1515.2</b>
<b>Overall Rates</b>	<b>529.2</b>	<b>241.5</b>	<b>38.5</b>	<b>1.5</b>	<b>12.3</b>	<b>1253.8</b>
<b>Revaccination</b>						
<1	—	—	—	—	—	—
1-4	109.1	—	—	—	—	<b>200.0</b>
5-19	47.7	9.9	2.0	—	—	<b>85.5</b>
>/20	25.0	9.1	4.5	6.8	4.5	<b>113.6</b>
<b>Overall Rates</b>	<b>42.1</b>	<b>9.0</b>	<b>3.0</b>	<b>3.0</b>	<b>2.0</b>	<b>108.2</b>

\* Adapted from Lane JM, Ruben FL, Neff JM, Millar JD. Complications of smallpox vaccination, 1968: Results of 10 statewide surveys. *J Infect Dis* 1970; 122:303-9.

† Rates of overall complications by age group include complications not provided in this table, including severe local reactions, bacterial superinfection of the vaccination site, and erythema multiforme.

§ No instances of this complication were identified during the 1968 10-state survey.

Source: Centers for Disease Control and Prevention, Smallpox Work Group, Atlanta.

vaccinia after being immunized for smallpox.<sup>4</sup> But trying to screen out people who are HIV-infected as part of a smallpox immunization program could open up a legal quagmire of testing and confidentiality issues.

Complicating the issue further is the possibility that the HIV-infected person may be a health care worker or one of the other groups recommended for immunization. While the vaccine poses a possible danger to the HIV-infected, how would they fare in a smallpox attack?

"What might happen if somebody with HIV gets smallpox?" Bartlett said. "I don't think any of us know. It might be universally lethal." Co-infection with tuberculosis for example, speeds the progression of HIV, he said. In a worst-case scenario, where vaccinating the HIV infected was considered necessary, there would still be a question of whether they could mount an immune response, he added.

"A number of vaccines have been tested on individuals with HIV infection, and they show that the cleave point for response and non-response . . . risk and no risk is a CD4 count in adults of about 200," Bartlett said. "Below 200, there will probably not be an immune response."

Comparable populations exist of other immune compromised groups, including organ transplants and those under chemotherapy treatment for cancer, meaning vaccinia immune globulin must be available in sufficient quantities.

If the choice is to immunize, a massive education effort will be necessary to influence physician attitudes and explain the reasoning of the program, said **Glen Nowak**, PhD, CDC, associate director for health communications in the CDC national immunization program.

A series of public focus groups and interviews with physicians revealed current attitudes on the

### VIG Doses Needed by Population Vaccinated Post-Event at a Rate of 80 per Million

Population vaccinated	VIG doses need for vaccines	VIG doses needed for contacts	Total VIG doses needed
3,000	0	0	0
30,000	2	0	2
300,000	19	5	24
3,000,000	192	48	240
30,000,000	1,920	480	2,400
300,000,000	19,200	4,800	24,000

Source: Centers for Disease Control and Prevention, Smallpox Work Group, Atlanta.

smallpox situation, he said.

"We found that many — again the younger ones more than the older physicians — thought that ring vaccination was a counter-intuitive strategy," Nowak said. "[Their thinking was] if we do vaccinate we should try to vaccinate as many people as

## CE/CME questions

Please save your bimonthly issues with the CE questions in order to take the two semester tests in the May/June and November/December issues. A Scantron sheet will be inserted in those issues, but the questions will not be repeated.

1. Some medical consultants and advisors cautioned about a host of potential side effects from smallpox vaccine, which could be particularly hazardous to the 300,000 people in the United States who do not know they have:
  - A. hepatitis C virus
  - B. tuberculosis
  - C. HIV
  - D. variola
2. William Bicknell, MD, PhD, argued that which group of people are much less likely than first-time smallpox vaccinees to have any adverse reaction:
  - A. dairy workers
  - B. those who have been previously vaccinated for smallpox
  - C. those already immunized with other live vaccines
  - D. all of the above
3. Progressive vaccinia, a potentially fatal complication of smallpox vaccination, has occurred almost exclusively among:
  - A. immunocompromised people
  - B. women
  - C. those infected in sub-Saharan Africa during the 1960s
  - D. those vaccinated under poor sanitary conditions
4. The American Hospital Association stated that the Centers for Disease Control and Prevention's smallpox response plan could substantially increase confusion or promote misinformation at a time when implementation of standard procedures would be critical.
  - A. true
  - B. false

possible rather than as few people."

It was also evident that the anthrax experience has engendered skepticism regarding containment strategies. "Many of these physicians said that during the anthrax experience recommendations were changing on a frequent basis," Nowak said. "What was true on Monday may not have been true on Wednesday. So they wanted to know how could we know that the current medical and public health assumptions regarding ring vaccination are valid today?"

Likewise, the ring vaccination approach is not something you want to explain one on one to patients besieging an ED in the wake of a smallpox attack.

"There was still was some confusion [among the public] about what ring vaccination was," he said. "It is a difficult concept to explain to the public. They tend to view vaccination in terms of broad or mass vaccination. The public also raised some questions about whether such a policy — because it was selective in nature — would limit access among minority groups or groups with [low socioeconomic status] if there was an outbreak. They saw ring vaccination as a selective vaccination strategy."

In additional findings of the project, physicians expressed concern about their personal liability if they were asked to give the smallpox vaccine. They also felt they did not know enough to discuss the risk and benefits of vaccination with their patients, he added. If there is a recommendation to immunize physicians, they are going to want a lot more information on the rationale behind such a move, he said.

"From the physicians and the public, basically, the message was if there was an outbreak, they would prefer broad, rapid access to smallpox vaccine," Nowak said. "Most of [the physicians] wanted to know why should they be vaccinated [pre-attack]? You couldn't just put them in a group and say get vaccinated. They wanted to know why."

Indeed, risk — some specific probabilities that smallpox will be used as a weapon — was the great unknown that held sway over every scenario at the meetings. Some are sufficiently convinced that the risk is real if only because the CDC has already immunized some of its own staff and is now considering reintroducing a potentially dangerous vaccine for a disease that has been vanquished in the wild.

"One of my colleagues thinks I am a complete nut case on this," Bicknell told *Bioterrorism Watch*.

"He says, 'It will never happen.' His assessment of the risk of attack is different than mine. His is infinitesimal; mine is low, but real. Therein lies the difference."

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Editor: **Gary Evans**, (706) 742-2515.

Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, [brenda.mooney@ahcpub.com](mailto:(brenda.mooney@ahcpub.com)).

Editorial Group Head: **Coles McKagen**, (404) 262-5420, [coles.mckagen@ahcpub.com](mailto:(coles.mckagen@ahcpub.com)).

Senior Production Editor: **Ann Duncan**.

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## Editorial Questions

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

# AHA strongly questions CDC smallpox plan

Agency inconsistent with other standards

The Centers for Disease Control and Prevention's (CDC) smallpox response plan is not consistent with its existing standards and those set by other authoritative groups, the American Hospital Association (AHA) warns.

"Some of the recommendations could substantially increase confusion or promote misinformation at a time when implementation of standard procedures would be critical," the AHA stated in comments to the CDC.

The CDC released the *Interim Smallpox Response Plan and Guidelines* as a working document subject to comment and revision.

Dated March 8, 2002, the comments sent to the CDC by the AHA and the other aforementioned hospital groups included the following points:

The current version of the plan's recommendations appears to draw heavily from experiences from outbreaks in Europe in the early 1970s. However, review of primary references that described these outbreaks reveals physical facility and ventilation designs that differ dramatically from contemporary U.S. health care facilities. Descriptions of the smallpox outbreak investigations, particularly the numerous reports concerning the outbreak at the Meschede hospital in Germany, reveal that the air supply was shared and ventilation was accomplished by opening windows and doors.

By contrast, U.S. hospitals today require the use of more effective procedures, such as airborne infection isolation rooms (AIIRs) that supply negative air pressure at 6-12 air changes/hour. According to current standards, exhaust from AIIRs is either direct to the outside or, if recirculated, passed initially through HEPA (high efficiency particulate air) filters. This design is deemed effective for tuberculosis and chickenpox, and therefore, also likely effective for the less hardy smallpox virus.

The [CDC] recommendations call for the use of buildings *other than* hospitals for "contagious patients, such as nursing homes and hotels." Yet hospitals are the only buildings *likely* to have negative pressure rooms with 100% exhausted air (or recirculated air through HEPA filters). Further, the complexity of equipment needed to care for critically ill persons is also unlikely to be readily

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available in a facility that does not provide health care.

The plan should not limit recommendations regarding medical waste treatment to incineration and/or autoclaving. Instead, CDC should consider other methods of waste disposal that reflects newer technologies and alternatives to managing medical waste in a manner that is consistent with local, state and federal regulations.

We do not believe fogging the facility with formaldehyde as a means of "disinfecting the facility," as described in the draft plan, is warranted based on the known mode of transmission and evidence demonstrating susceptibility of related orthopox viruses to a broad range of chemical disinfectants applied to surfaces. ■

## 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. ■