AMERICAN HEALTH CONSULTANTS®

HOSPITAL INFECTION CONTROL®

FOR 29 YEARS COVERING INFECTION CONTROL AND PREVENTION

FOR 29 YEARS THE LEADING SOURCE OF NEWS AND COMMENT IN HEALTH CARE EPIDEMIOLOGY

IN THIS ISSUE

FEBRUARY 2003

VOL. 30, NO. 2 (pages 13-28)

Will 'dropout fever' spread? Hospitals opting out of smallpox offer draw fire

'We come down on the side of above all, do no harm'

Deciding that the risk of smallpox vaccine outweighs the current benefit of immunization, an increasing number of hospitals are refusing the government's offer to vaccinate key health care workers. Though public health authorities still are expecting widespread compliance, the move has raised concerns that the nonparticipants will undermine bioterrorism preparedness.

The declinations were branded as "deplorable" in an editorial in *The New York Times* that warned that "the refusal to participate raises needless suspicions about the nation's smallpox preparations and could, if dropout fever spreads too widely, undermine efforts to prepare for bioterrorism."[1]

Richard Wenzel, MD, professor and chairman of the department of internal medicine at the Medical College of Virginia in Richmond, defends the hospital's decision to opt out of the voluntary program. "It's not an issue of patriotism," he says. "This issue is purely one of medical risk and benefit. As we looked at the risk and benefit of vaccination and potential transfer [of vaccinia] to vulnerable populations, we thought there was substantial risk."

Smallpox vaccination handbook available now

Call today for your copy of *Hospital Handbook on Smallpox Vaccination*, a facilitywide resource containing all the information you need about smallpox vaccination in most health care facilities and environments. Learn about possible side effects and adverse reactions and how to protect your staff, patients, and family members against this most controversial vaccine. Read about the challenges of implementing a smallpox care team plus critical staffing and screening issues that will affect your entire facility as well as crucial questions about liability and other legal concerns.

(Continued on page 17)

The institutional decision was welcomed by **Randy Smith**, RN, MS, CIC, an infection control professional at the Virginia hospital.

"I'm in agreement with the policy," he tells *Hospital Infection Control*. "I am not going to go out on my own and get immunized. I have a 2-year-old. Unless it is mandatory, I wouldn't do it. I am not going to subject him to possibly being exposed to the virus in the vaccine."

It is concern for others, particularly, immune-compromised patients, that has some hospitals balking at the bioterrorism response plan recommended by the Centers for Disease Control and Prevention (CDC). After the Bush administration gave the green light to CDC's recommendation to immunize 500,000 hospital workers nationwide, hospital clinicians and administrators began weighing the pros and cons. Issuing one of the first declinations was the Grady Health System in Atlanta. The hospital said it will not immunize workers at this time, but would act quickly if a case appears or there is clear imminent danger. Grady issued a statement citing concern for the "safety and health of our patients and our health care workers." The hospital added — somewhat oddly, given that this is a national effort — that there was no evidence of the "capacity of any enemy to launch an attack on Georgia with smallpox."

Patients take precedence

Factored into such decisions is the low but potentially serious risk to the person vaccinated, and beyond that, to any immunocompromised (e.g., HIV) or otherwise contraindicated (e.g., atopic dermatitis) potential contacts of vaccinees.

"We are a center hospital for HIV and have many transplant patients, both solid organ and bone marrow," Wenzel explains. "We have a number of people who are on steroids or immune suppressors."

Paul Offit, MD, infectious disease chief at the Children's Hospital of Philadelphia, cites similar reasons for declining, saying any rush to immunize workers runs counter to the old admonition, "don't test the water with both feet." Offit is a member of the CDC's Advisory Committee on Immunization Practices (ACIP), which approved the hospital vaccination plan last year. However, he cast the lone vote against the recommendation. Now his hospital has followed suit and declined the vaccine offer. Will such defections undermine the ACIP effort?

"I don't think ACIP would see it that way," he says. "Individual hospitals have to make a decision for what they think is right for their hospital. It's a voluntary program. This is not mandatory. We all believe that in case of an event, there will be time to respond. We're not prepared to recommend the vaccine for our frontline health care workers at this time."

Despite the defections, **Julie Gerberding**, MD, MPH, CDC director, says the agency expects about 3,600 of the nation's estimated 5,000 hospitals to participate. "This is a voluntary program,

Hospital Infection Control®, including **Infection Control Consultant**™ and **Healthcare Infection Prevention**™ (ISSN 0098-180X), is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Hospital Infection Control**®, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291. Hours of operation: 8:30-6. Monday-Thursday, 8:30-4:30 Friday EST. World Wide Web: http://www.ahcpub.com. E-mail: customerservice@ahcpub.com.

Subscription rates: U.S.A., one year (12 issues), $429. Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $343 per year; 10 to 20 additional copies, $257 per year. For more than 20 copies, call customer service for special handling. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. **Back issues**, when available, are $72 each. (GST registration number R128870672.)

This continuing education offering is sponsored by American Health Consultants®, which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. American Health Consultants® is an approved provider by the California Board of Registered Nursing for approximately 18 contact hours per year (provider #CEP10864).

American Health Consultants® is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians. American Health Consultants® designates this continuing medical education activity for approximately 18 credit hours in Category 1 of the Physicians' Recognition Award of the American Medical Association. This activity was planned and produced in accordance with the ACCME Essentials.

In order to reveal any potential bias in this publication, and in accordance with Accreditation Council for Continuing Medical Education guidelines, we disclose that Drs. Joseph (consulting editor) and Schaffner (editorial advisory board) report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Editor: **Gary Evans**, (706) 742-2515.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Coles McKagen**, (404) 262-5420, (coles.mckagen@ahcpub.com).
Senior Production Editor: **Ann Duncan.**

THOMSON
AMERICAN HEALTH CONSULTANTS™

Editorial Questions

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

and we know from our long experience in working with the public health system that implementation varies from jurisdiction to jurisdiction," she says. "So, it's really not surprising that some hospitals would have chosen not to vaccinate.

"We know that we're going to be far more prepared with the response teams that are stepping up to the plate," she adds.

Once the first group of hospitals demonstrates that the vaccine can be administered safely, other facilities will likely follow, adds **William Bicknell**, MD, PhD, professor of international health at Boston University. "If the double semipermeable membrane dressing, which the CDC recommends

JCAHO sounds alarm about deadly nosocomial infections

If 90,000 a year die, why are so few reported?

The Joint Commission on Accreditation of Healthcare Organizations has sent out a sentinel alert to all accredited facilities calling for them to report fatal nosocomial infections. The Jan. 22, 2003, alert follows an earlier direct appeal for the information by **Dennis O'Leary**, MD, president of the Joint Commission. The request for data has raised concerns among infection control professionals, who argue that ascribing deaths to infections is a complex matter confounded by underlying illness and a host of other variables. **(See our new Joint Commission supplement, inserted in this issue.)**

The Joint Commission bulletin argued that "the deaths of patients from hospital-acquired infections are being seriously underreported across America." The *Sentinel Event Alert*, sent to nearly 17,000 JCAHO-accredited health care facilities, also urges compliance with new guidelines from the Centers for Disease Control and Prevention (CDC) that advise health care professionals to use alcohol-based hand rubs to prevent nosocomial infections. The CDC estimates that more than 2 million patients annually develop infections while hospitalized for other health problems and that nearly 90,000 die as a result of these infections. Despite these high figures, the Joint Commission's 7-year-old patient safety reporting database includes only 10 such reports that cover 53 patients, the alert stated. "We are receiving a disproportionately low volume of reports on the number of patient deaths from infections acquired in the health care setting, possibly because many health care organizations do not view these events as 'errors' under the definition of a sentinel event," O'Leary wrote in the alert. "However, in view of the importance and high visibility of such occurrences, we are urging health care organizations to share this information with the Joint Commission, just as they might share information about other types of sentinel events with us."

Due to the nature of such events, the Joint Commission said in the alert that it is likely that health care facilities will have already conducted the related in-depth analyses required as part of the accreditation standards. Increased reporting will lead to greater understanding of the factors that lead to their occurrence and effective strategies for prevention.

In a related development, the Joint Commission has formed a infection control panel to review infection control standards. As previously reported in *Hospital Infection Control*, the expert panel will consult with the Joint Commission about infection control standards as the organization continues sweeping revisions in the accreditation process.

Slated to meet for the first time in February, the panel members include:

- Mary Alexander, CRNI, Infusion Nurses Society
- Judene Bartley, MS, MPH, CIC, American Hospital Association
- Marianne Billeter, PharmD, American Society for Health-System Pharmacists
- John Boyce, MD, FACP, Hand Hygiene Task Force
- John D. Christie, MD, PhD, FCAP, College of American Pathologists
- Georgia Dash, RN, MS, CIC, Association of Professionals in Infection Control and Epidemiology
- Loreen A. Herwaldt, MD, American Society of Microbiology
- Elaine Larson, RN, PhD, FAAN, CIC, American Nurses Association
- John Molinari, PhD, American Dental Association
- Gary Overturf, MD, Pediatric Infectious Disease Society
- Gina Pugliese, RN, MS, American Society for Healthcare Risk Management
- Jeffery Roche, MD, MPH, American Public Health Association
- Matthew Samore, MD, American College of Physicians
- William E. Scheckler, MD, University of Wisconsin School of Medicine
- Steve Solomon, MD, Centers for Disease Control and Prevention
- Bryan Simmons, MD, Methodist Health System
- Keith St. John, Certification Board of Infection Control and Epidemiology
- Michael Tapper, MD, Society for Healthcare Epidemiology of America
- Jeremiah G. Tilles, MD, American Medical Association
- Robert Weinstein, MD, Infectious Disease Society of America
- Dale Woodin, CHFM, American Society of Healthcare Engineers ■

Pox plan raises concerns for HIV-infected workers

Risk to health and threat of disclosure

Confidentiality and testing concerns about HIV-infected health care workers are starting to surface as the government moves ahead with its plan to offer smallpox vaccine to hospital staff. Those with HIV would be at risk of dangerous complications, including potentially fatal progressive vaccinia, if they receive smallpox vaccine.

While the process is designed to be voluntary and confidential, smallpox immunization programs in hospitals threaten the health and confidentiality of HIV-infected health care workers, warns **Larry Gostin**, JD, LLD, director of the Center for Law & the Public's Health at Johns Hopkins University in Baltimore.

"This really puts them in a dilemma," he says. "First of all, there is the problem of those who don't know they are infected and will be placed at risk [if vaccinated]. Secondly, hospitals — either because they fear liability or for policy reasons — may be much more aggressive at uncovering people with undiagnosed HIV infection, either by asking pointed questions or testing. Thirdly, for those who are known to be HIV-infected, the chances of that information being spread more widely across the hospital are significant. There is real potential for concern about health, discrimination, and breaches of confidentiality. It's a real worry."

In addition, the American Hospital Association (AHA) in Chicago is asking the government to clarify its position on HIV testing for smallpox vaccination. Clarification is needed about whether pre-vaccination tests are necessary to screen out health care workers who should not receive the vaccine, **Roslyne Schulman**, AHA senior associate director for policy development, said recently at a smallpox meeting of the Institute of Medicine in Washington, DC.

"The Advisory Council on Immunization Practices has recommended against the need for mandatory screening tests prior to vaccination as long as a thorough medical history and interview are completed and people are informed of the risks," she said. "However, the Department and Health and Human Services has not officially adopted these recommendations. Further, the [Bush] administration has indicated that those persons who might have a contraindication for the vaccine should be referred to the local public health department or another health care provider for testing. However, there remain questions about who will pay for such testing. Again, clarity is needed." ■

for hospitals workers is used [to cover the vaccine site], and if people are rotated off burn units and transplant units, I think there really isn't any significant danger," he says. "Some hospitals will opt out, but many will opt in. I think we will see that if it is done carefully, the risks are going to minimal and very acceptable. I think that the hospitals that [vaccinate] are being responsible to patients, the general public, and their staff. The hospitals that don't are understandably cautious, but I would say overly cautious."

Though liability issues have not been given for the declinations, that is clearly an issue that is making some hospitals reticent, he adds. The American Hospital Association (AHA) in Chicago has raised liability concerns on its web site, but nonetheless, says it is encouraging hospitals to participate.

A question of risk

"This is a voluntary effort, and we have supported it all along the way," says **Rick Wade**, AHA spokesman. "We urge our members to cooperate if they possibly can. We are still trying to solve the liability issue. We have not urged anyone to drop out for that reason. We hope to get that cleared up so that will not be a barrier to anyone's participation. Hospitals are on the front lines as first responders. We have to prepare ourselves. This is not going to be something that it is going to be easy for any hospitals to opt out of."

Still, another factor that has dogged the situation from the onset is that — despite months of theoretical discussions — the actual threat of a smallpox attack remains largely undefined, or possibly more to the point, undisclosed.

As a result, like the proverbial elephant to the blind men, the risk appears differently to different observers. Many were waiting for some kind of definitive statement when the Bush administration approved the plan. Instead, to some the offer of vaccine with little emphasis on the threat of smallpox appeared counterintuitive.

"President Bush said on Dec. 13 that we had no imminent threat of smallpox bioterror," Wenzel says.

"If there is a credible risk, you wouldn't immunize a small portion of the health profession [anyway]; you would do widespread immunization. I think there is a lack of logic with the current policy." Indeed, with the last known cases occurring decades ago, should smallpox appear anywhere

(Continued from cover)

This newly released handbook confronts the implications that departments face throughout the hospital, including infection control, the ED, critical care, employee health, and risk management.

Order your copy today of this comprehensive resource guaranteed to provide you with the knowledge you need to manage this unprecedented response to a bioterrorism threat. The cost is just $99 for subscribers who will receive a discount off the original price of $149. To order, call customer service at (800) 688-2421. When ordering, please refer to the effort code: **76991**. ■

in the world the likely national response would be large-scale immunizations — not hospital teams, he notes.

"We're very flexible," Wenzel says. "We would change our mind under any one of several scenarios, one of which is a single case of smallpox anywhere in the world."

In addition, the hospital would quickly begin immunizing if a vial of smallpox was reported in a country outside the two known repositories in Russia and the United States.

"If the intelligence community said that this was truly a high-risk situation and had credible information, that would completely change [our decision]," he says. "But for the time being, as we look at the risk and benefit medically, we come down on the side of above all, do no harm."

Another critical factor is that stocks of smallpox vaccine have been steadily increased. With vaccine readily available, protection against smallpox infection still would be possible several days after an exposure to an incoming patient, Wenzel argues. "Even if I had direct contact today, I have four days to get vaccinated and be protected," he says. "I think the government has done a good job of increasing the supply [of vaccine]. To me, that is the most important thing."

Thus, Wenzel concludes that a small-scale attack (e.g., infected terrorists trying to expose others) could be contained without pre-event immunizations.

On the other hand, having small groups of health care workers immunized will be of little import in a worst-case scenario of a massive attack. "If somebody drops an aerosol over the city of Atlanta, certainly a handful of immunized physicians will have no impact," he says.

"We would be no different if we immunized a small fraction of our health care workers than where we are now. It's a drop in the bucket. The only thing that protects you from that kind of exposure is widespread, pre-event vaccination," Wenzel says.

Reference

1. Ducking Smallpox Vaccinations. Editorial. *The New York Times*, Dec. 22, 2002; 4:10. ■

New TB test can be used for baseline HCW testing

Role less clear for routine surveillance

A recently approved tuberculosis test can be used to diagnosis latent TB infection in health care workers without generating false positives due to "boosting" effects of the traditional TB skin test, the Centers for Disease Control and Prevention (CDC) reports.

The new test (QuantiFERON-TB or QFT; manufactured by Cellestis Limited, Carnegie, Victoria, Australia) measures the release of interferon-gamma in whole blood in response to stimulation by purified protein derivative (PPD). Tuberculin skin testing (TST) has been used for years as an aid in diagnosing latent tuberculosis infection. TST includes measurement of the delayed type hypersensitivity response 48 to 72 hours after intradermal injection of PPD.

The new diagnostic test requires phlebotomy, but it can be accomplished in a single visit because the worker does not have to come back to have the results read. The QFT assesses responses to multiple antigens simultaneously and does not boost anamnestic immune responses. Compared with TST, QFT results are less subject to reader bias and error, the CDC notes.[1]

"Lot's of people prefer it because it might also give you some advantage to distinguish people who are BCG-positive [due to previous Calmette-Guérin TB vaccination], and you cannot get that out of the skin test," says **Margarita E. Villarino**, MD, medical epidemiologist in the CDC division of TB elimination. "It's not very expensive, and you don't have the person back to have the test read. It doesn't boost. You wouldn't get a false-positive skin test if you test after using quantiferon. The opposite is not recommended. It is not recommended that you do a QFT after you test with a skin test because the skin test does boost the quantiferon test response," she says.

TST and QFT do not measure the same components of the immunologic response and are not interchangeable. Assessment of the accuracy of the tests is further limited by lack of a standard for confirming latent TB infection.

"In the studies that were done, it had about the same sensitivity and specificity of the skin tests," Villarino says. "It measures different parts of the immune response, so they are not completely comparable. That said, it is considered to be screening test that is as good, specific, and sensitive as the skin test."

The new test is indicated for initial employment of health care workers, but its role for periodic surveillance is less clearly defined. The key variable is the risk of TB in the work environment the worker is going to be exposed to. Routine TST testing in populations with little or no TB has been discouraged because it primarily yields false positives. "We don't really know what the recommendation should be for serial testing of somebody who is at low risk of TB exposure," she says.

"If they are going to a high-exposure setting, then they could be more equivalent to serial testing [recommended for] high-risk groups. Then the facility might choose to use the [QFT test]. We don't know exactly how it will function in a surveillance system for periodic surveillance of health care workers. But it is indicated for the initial evaluation — their pre-employment screening — before they get exposed to a situation of high-risk TB," she says.

Interim CDC recommendations for QFT remind that the highest priority of targeted tuberculin testing programs is identifying people at increased risk for TB who will benefit from treatment for latent TB infection.

Following that principle, targeted tuberculin testing should be conducted among groups at risk for recent infection with *M. tuberculosis* and those who, regardless of duration of infection, are at increased risk for progression to active TB. QFT can be considered for screening for latent TB infection (LTBI) as follows:

- initial and serial testing of people with an increased risk for LTBI (e.g., recent immigrants, injection-drug users, and residents and employees of prisons and jails);
- initial and serial testing of persons who are, by history, at low risk for LTBI but whose future activity might place them at increased risk for exposure, and others eligible for LTBI surveillance programs (e.g., health care workers and military personnel);
- testing of people for whom LTBI screening is performed but who are not considered to have an increased probability of infection (e.g., entrance requirements for certain schools and workplaces).

Confirmation of QFT results with TST is possible because performance of QFT does not affect subsequent QFT or TST results. The probability of LTBI is greatest when both the QFT and TST are positive. Considerations for confirmation are as follows:

- When the probability of LTBI is low, confirmation of a positive QFT result with TST is recommended before initiation of LTBI treatment. LTBI therapy is not recommended for people at low risk who are QFT-negative or who are QFT-positive but TST-negative.
- TST can also be used to confirm a positive QFT for people at increased risk for LTBI. However, the need for LTBI treatment when QFT is positive and the subsequent TST is negative should be based on clinical judgment and perceived risk.

Negative QFT results do not require confirmation, but results can be confirmed with either a repeat QFT or TST if the accuracy of the initial test is in question.

Reference

1. Centers for Disease Control and Prevention. Guidelines for using the QuantiFERON®-TB test for diagnosing latent *Mycobacterium tuberculosis* infection. *MMWR* 2002; 51: Dispatch. ■

West Nile a new threat to laboratory workers

Two cases result from sharps injuries

West Nile virus is emerging as a new threat to laboratory workers as its presence grows in the United States. Infection control precautions should be reemphasized in light of two occupational cases of West Nile virus infection in research laboratorians, the Centers for Disease Control and Prevention (CDC) emphasizes.

"Both of these laboratory workers were working with materials that had high concentrations of West Nile virus in them, whereas people who are working in clinical labs are dealing generally with

(Continued on page 23)

JCAHO Update for Infection Control

News you can use to stay in compliance

'Flip-flop' flap: Joint Commission urges ICPs to report fatal, impairing nosocomial infections as 'sentinel events'

ICPs 'back on their heels' as JCAHO reinvents itself

In an unusual direct appeal to health care facilities, the chairman of the Joint Commission on Accreditation of Healthcare Organizations is asking for reports of nosocomial infections that result in patient deaths or permanent loss of function.

"We have until recently believed that the [Joint Commission] database is representative of the broad universe of sentinel events," **Dennis O'Leary**, MD, said in an open letter to all accredited institutions.

"Now, in retrospect, it appears that we are receiving a disproportionately low volume of reports on [deaths and impairment due to infections]. In view of the importance and high visibility of such occurrences, we urge you to share this information with the Joint Commission, just as you might share information about other types of sentinel events with us," he wrote. "Given the nature of these events, we believe it likely that you will have already conducted the related in-depth analyses anticipated by Joint Commission standards."

However, reporting to the JCAHO Sentinel Event Database continues to be voluntary, he said. O'Leary acknowledged that such events are often already being reported to various government agencies and confidentiality is no small concern. "While the Joint Commission has thus far been able to maintain the confidentiality of all sentinel event information reported to it to date, we do understand that confidentiality concerns limit the number of cases actually brought to our attention," he explained.

The request comes as the Joint Commission continues a dramatic process to reinvent itself in an age of patient safety. Scalded by criticisms in the press that it is lax on infection control, the Joint Commission recently warned that it was going to become more aggressive in the area.

"If a patient dies in a hospital or has a permanent disability as a result of a nosocomial infection, the hospital really should think about that as a sentinel event and treat it and evaluate as such," says **Paul Schyve**, MD, Joint Commission senior vice president.

In addition, the Joint Commission is scheduled to convene the first meeting of a special task force on infection control in late January or early February. The agency decided to form the panel after ICPs protested a proposal to consolidate and reduce the number of infection control standards in 2004, when the commission plans to implement its ambitious Shared Vision/New Pathways accreditation program. The whole series of events is befuddling to some ICPs.

"First of all, they tell us they are going to cut infection control regs — [making us] a less important part of the survey process," explains **Susan**

New supplement to solve your accreditation problems

In response to reader interest, we are adding a new quarterly supplement covering accreditation issues. We're here to answer your most pressing questions, solve your most difficult problems, and share your best tips. Contact: Gary Evans, American Health Consultants, P.O. Box 740056, Atlanta, GA 30374. E-mail: gary.evans@ahcpub.com. ■

Kraska, RN, CIC, an ICP at Memorial Hospital of South Bend, IN. "All of the ICPs ask, 'What are you guys thinking?' Now, we have the opposite end of the spectrum, wanting us to report fatal or life-impairing infections. Wait a minute, either they are important or they are not," she continues. "It just doesn't seem to be very well thought out on the Joint Commission's part. I think they really have ICPs back on their heels right now because of this flip-flop."

That said, ICPs certainly view such serious nosocomial infections with deep concern, she emphasizes. "I am working every day to prevent those things from happening," she says. "To add additional reporting, I guess I want to know to what end? Is this going to improve patient outcomes by reporting it? What are they looking for — are they just looking for data so they can tell folks their survey process is [thorough]?"

William Scheckler, MD, one of the recently appointed members to the Joint Commission's infection control task force, says in informal discussions with JCAHO officials, he has strongly disagreed with interpreting nosocomial infections as sentinel events. Traditionally, nosocomial infections have been regarded as "complications" rather than sentinel events, he explains.

"[Sentinel events] are supposed to be limited to "unexpected serious injury or disability," says Scheckler, hospital epidemiologist at St. Mary's Hospital in Madison, WI. "Hospitals do not have to report these directly to the JCAHO as long as they keep track of them and do the proper analysis of such events and demonstrate they are doing so when their accreditation visits occur. I hope this new advisory panel can discuss this issue at some length."

Such infections are probably not reported to the Joint Commission as sentinel events very frequently because it is actually quite rare that a nosocomial infection is the obvious sole reason for a patient death, adds **Patti Grant**, RN, BSN, MS, CIC, director of infection control at RHD Memorial Medical Center in Dallas. Patients frequently have multiple underlying diagnoses across the broad spectrum of disease, from diabetes to pulmonary hypertension, she stresses. In contrast, a wrong-site surgery or medication error is 100% external to the patient.

"A nosocomial event is rarely 100% external, and involves the patient's internal ability to fight infection, their colonization with endogenous pathogens, the invasive procedures required to save their life," Grant says. "Calling a wrong-site surgery a catastrophic sentinel event is obvious, and correct, and must be reported if patient safety is ever to improve. But in my 12 years of infection control, I can honestly say that I have seen very few black-and-white [cause/effect] deaths from a nosocomial infection."

Even with morbidity associated with a nosocomial infection, there are often many extraneous variables that confuse the issue, she notes. "Which came first, the chicken or the egg? The patient's intrinsic risk factors for infections are fluid and complicated — making such a 'call' for a sentinel event reckless. We must be responsible to our professionalism, JCAHO included, and not be cavalier about requesting, or supplying, such potentially misguided information."

Pushing for such data could cause a chill factor on open discussions in the medical literature, she adds. "My overall fear of this type of reporting, and for that matter most 'external' benchmarking of nosocomial infection surveillance, is that it will stifle our openness with publication in peer-review journals of outbreaks and [hinder our] success with process improvement." ■

ICPs won't push JCAHO for new staffing formula

Study shows ratio of 1 ICP to 250 beds outdated

Though recent research supports the need for more infection control staffing than traditionally allotted, ICPs are not expected to press for a specific staffing requirement from the Joint Commission on Accreditation of Healthcare Organizations.

The guideline for staffing infection control programs has traditionally been one ICP for every 250 licensed beds, but a recently published study indicates the ratio should be approximately one ICP per 100 licensed beds under current conditions in health care.[1] The longstanding benchmark of one ICP per 250 occupied beds was recommended by the Centers for Disease Control and Prevention's Study on the Efficacy of Nosocomial Infection Control (SENIC) project[1] The SENIC data were gathered in the 1970s.[2]

"That study was what was appropriate for that time in history," says **Carol O'Boyle**, PhD, RN, assistant professor at the University of Minnesota School of Nursing in Minneapolis. "I think we

need to question the appropriateness of the guidelines that people derived from that in today's contemporary health care."

O'Boyle is lead author of the new staffing study, which involves the Delphi method — time and task surveys and re-surveys of 32 participating ICPs. It is well known that ICPs are stretched thin over an increasing array of responsibilities. Infection control has expanded into a variety of different health care settings, including physicians' offices, affiliated clinics, and long-term care. All the while, additional functions, including bioterrorism, patient safety, employee health, and management of central services have been added to the traditional ICP program.

Data were obtained from the ICPs in 20 states through a series of 10 surveys. Competing responsibilities and lack of adequate resources were the most frequently cited reasons for nonperformance of essential infection control tasks. A ratio of 0.8 to 1.0 ICP for every 100 occupied acute care beds was suggested as adequate staffing by the Delphi panel. However, the findings need to be confirmed through subsequent research, O'Boyle says.

"One needs to be careful in looking at these recommendations, in that these were made by a panel of 32 [people]," she says. "The advantages of using this Delphi method are that they did not meet each other and did not see what others were writing to me. So the value of a Delphi is that you are able to get recommendations without having panel members influence each other."

The Joint Commission has emphasized in its standards that infection control programs should be adequately staffed, but has never required a specific ratio or formula, "One of the issues that we always have to take into account is the differences in organizations and patient mix," says **Paul Schyve,** MD, Joint Commission senior vice president. "That's one reason why we have concluded that hard-and-fast staffing ratios — say for nurses — are not the best way to approach staffing effectiveness."

Indeed, ICPs would be asking the Joint Commission to codify a ratio or formula that is not drawn out for any other medical profession.

"I can't think of any other standard that says thou shalt have this number of people to do anything," says **Candace Friedman**, MT (ASCP), MPH, CIC, manager of infection control and epidemiology at the University of Michigan Hospitals and Health Centers in Ann Arbor.

"The staffing standards of the Joint Commission imply that an institution needs to evaluate all of its staffing and be staffed appropriately. If there are data that support a particular type of staffing, then that is what should be brought forward if there are issues within a particular institution. I don't think it should be a specific number because there may be instances where an institution may need to be better staffed than that for other reasons. I wouldn't want to be held to any specific requirement."

References

1. O'Boyle C, Jackson M, Henly SJ. Staffing requirements for infection control programs in US health care facilities: Delphi project. *Am J Infect Control* October 2002.

2. Haley RW, Culver DH, White J, et al. The efficacy of infection surveillance and control programs in preventing outbreaks of nosocomial infections in U.S. hospitals. *Am J Epidemiol* 1985; 121:182-205. ■

JCAHO looking at timing of surgical drug prophylaxis

Research may lead to new quality indicators

The Joint Commission on Accreditation of Healthcare Organizations is partnering with the University of Tennessee, the Centers for Disease Control and Prevention, and the Society for Healthcare Epidemiology of America to conduct a four-year study under an Agency for Healthcare Quality and Research-funded grant project titled "Trial to Reduce Antibiotic Prophylaxis Errors" (TRAPE). The study will examine hospitals' timely use of antibiotics before and after cardiovascular, joint replacement, and hysterectomy surgeries to effectively reduce post-surgical infection.

It is estimated from one-third to one-half of surgical patients do not receive antibiotics or receive them in such a way as to leave them relatively unprotected from infection, says principal investigator **Stephen B. Kritchevsky**, PhD, professor of the department of preventive medicine at the University of Tennessee in Knoxville.

"If you split the difference, about 35% or 40% of patients are getting suboptimal prophylaxis," he says. "It is quite widespread. Most antibiotics should be given about an hour before surgery. If they are given before that or after the incision, it is really not optimal. So [this study] is really a 'process' focus — here's a target, that if people could hit, patient care quality would be improved. What is stopping people from hitting this target and

what can they do to do a better job?"

As ICPs are well aware, post-surgical infections can lead to readmission, extended hospital stays and even death. "Patients who don't get prophylaxis or get it very late are somewhere on the order of four to six times more likely to get infections," Kritchevsky says.

The study will start early this year, as 40 hospitals will enroll in the randomized trial for six months. Half of the hospitals will receive feedback on their error rates. The other half will receive feedback plus intensive assistance in identifying and implementing solutions to improve the appropriateness and timeliness of preventive antibiotics. While 20 hospitals will only get baseline and summary information, another 20 selected at random will receive much more detailed feedback.

"We have a few interventions — innovations, we hope — that we are trying to validate," says Kritchevsky. "We will be doing a process assessment of how each of the hospitals in our study provide antibiotic prophylaxis. We'll relate that to the timing problems and hopefully identify a list of best practices."

The Joint Commission is serving as coordinator of the study, but is participating through its research — as opposed to regulatory — branch. That means, essentially, that the study is not being done with an eye on changing Joint Commission requirements, though that could be the result somewhere down the road. ■

Surveyors checking for new patient safety goals

Be advised that accreditation surveyors now are looking for signs of implementation of the six patient safety goals established for 2003.

Effective Jan. 1, 2003, all Joint Commission Accreditation of Healthcare Organization organizations will be surveyed for implementation of the recommendations or of an acceptable alternative. Alternatives must be at least as effective as the published recommendations in achieving the goals. Failure to implement any of the applicable recommendations or an acceptable alternative will result in a single special Type I recommendation (citation).

Surveyors will look for evidence of consistent implementation of the recommendations, but you don't need to do any special documentation for the Joint Commission that you wouldn't be doing already to implement the recommendations.

"The surveyors will look at whatever documentation you have that is relevant and will interview the organization's leaders and direct caregivers to determine whether the recommendations have been implemented and how consistently they are being done," the Joint Commission stated in a patient safety advisory. "It's the actual performance we are interested in, not the paperwork."

The 2003 patient safety goals are:

1. **Improve the accuracy of patient identification.** Use at least two patient identifiers (neither to be the patient's room number) whenever taking blood samples or administering medications or blood products. Prior to the start of any surgical or invasive procedure, conduct a final verification process, such as a "time-out," to confirm the correct patient, procedure and site, using active — not passive — communication techniques.
2. **Improve the effectiveness of communication among caregivers.** Implement a process for taking verbal or telephone orders that requires a verification "read back" of the complete order by the person receiving the order. Standardize the abbreviations, acronyms, and symbols used throughout the organization, including a list of abbreviations, acronyms, and symbols not to use.
3. **Improve the safety of using high-alert medications.** Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride >0.9%) from patient care units. Standardize and limit the number of drug concentrations available in the organization.
4. **Eliminate wrong-site, wrong-patient, wrong-procedure surgery.** Create and use a preoperative verification process, such as a checklist, to confirm that appropriate documents (e.g., medical records, imaging studies) are available. Implement a process to mark the surgical site, and involve the patient in the marking process.
5. **Improve the safety of using infusion pumps.** Ensure free-flow protection on all general-use and patient-controlled analgesia intravenous infusion pumps used in the organization.
6. **Improve the effectiveness of clinical alarm systems.** Implement regular preventive maintenance and testing of alarm systems. Assure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit. ■

(Continued from page 18)

samples that have a very low likelihood of having high concentrations of West Nile virus," says **Roy Campbell**, MD, PhD, medical epidemiologist in the CDC vector-borne infections branch.

"But the message for clinical laboratory workers is that you can get West Nile virus from laboratory accidents. They are uncommon, and your risk is much lower than the two laboratory workers that we describe, but it is not zero," he says.

West Nile virus, a mosquito-borne flavivirus introduced recently to North America, is a human, equine, and avian neuropathogen. The majority of human infections with West Nile virus are mosquito-borne.

Lab infections documented

However, laboratory-acquired infections with West Nile and arboviruses have occurred historically. The most recent reports came late last year in two separate incidents.

"One of them was a needlestick, and one was a scalpel injury," Campbell says. "One was working on an infected bird, and the other was working on infected mice. We didn't conclude that there was any particular break in procedure."

In the first case, in August 2002, a microbiologist was performing a necropsy on a blue jay submitted as part of a state's West Nile virus surveillance program. The microbiologist — working in a Class II laminar flow biosafety cabinet under biosafety level 2 conditions — lacerated a thumb while using a scalpel to remove the bird's brain.

The superficial cut was cleansed and bandaged. Four days later the lab worker had acute symptoms of headache, myalgias, and malaise followed by chills, sweats, dysesthesias, recurring hot flashes, swelling of the post-auricular lymph nodes, and anorexia. Two days later, the microbiologist noted a maculopapular rash that began on the face. The rash extended to the trunk, arms, and legs during the next three days; and then disappeared gradually. The microbiologist continued to work during illness and had intermittent chills, sweats, dysesthesias, and hot flashes for approximately one week before recovering fully, the CDC reports.

The second case occurred in October 2002. A laboratorian who was harvesting West Nile-infected mouse brains in a Class II laminar flow biosafety cabinet under BSL-3 conditions punctured a finger with a contaminated needle. The wound was cleansed and bandaged. Three days after injury, the lab worker had upper respiratory infection symptoms without fever or chills. The next day, symptoms continued with malaise, fatigue, chills, and a low-grade fever.

Although the worker missed only one day of work, respiratory symptoms, dry cough, and hoarseness continued for more than a week.

"We didn't recommend any changes in lab workers based on these two cases. Both of these case involved laboratories following proper procedures. Sometimes, these things happen regardless of how many precautions you take.

Lab workers handling fluids or tissues known or suspected to be infected with West Nile virus should minimize their risk for exposure and should report injuries and illnesses of suspected occupational origin to their supervisor. Illnesses in both laboratory workers were mild and self-limited, which is typical of illnesses in WNV-infected persons. But the cases confirm that laboratory workers are at risk for occupationally-acquired WNV infection, including West Nile meningoencephalitis.

"There have been 18 cases [of lab-acquired West Nile virus] in the literature summarized in various review articles, the most recent of which was in 1980," Campbell says.

Other cases may be on the horizon, because the number of laboratories and laboratory workers involved in arboviral diagnostic and reference activities has increased dramatically since West Nile emerged in the United States.

"More laboratories — be they clinical, research, or reference laboratories — are dealing with West Nile virus than ever before," Campbell says.

"There is an unprecedented number of laboratories and laborationians working with West Nile virus in the United States," he says. "So it is not surprising to find a few cases like this. We don't know if this is a trend or whether these cases will be very few and far between."

A universal or standard precautions approach with all specimens is the best protection for clinical lab workers, Campbell adds.

"Anybody who is dealing with clinical lab specimens has to assume that those are infected with any number of agents, and West Nile virus would be one of the least of their worries, he says. "Every sample needs to be treated as if it were infectious."

Laboratory workers involved in necropsies or other procedures involving materials potentially infected with the virus should use every precaution

to minimize their risk for exposure to fluids or tissues during handling, including standard droplet and contact precautions; using and disposing of needles, scalpels, and other sharp instruments safely; and minimizing the generation of aerosols.

Reference

1. Centers for Disease Control and Prevention. Laboratory-acquired West Nile virus infections — United States. *MMWR* 2002; 51(50):1,133-1,135. ■

Group A strep strikes 24 health care workers

Are standard precautions adequate?

Source: Kakis A, et al. An outbreak of group A streptococcal infection among health care workers. *Clin Infect Dis* 2002; 35:1,353-1,359.

Abstract: A patient with group A streptococcal respiratory and soft tissue infection was the source of an outbreak involving 24 health care workers.

A previously healthy 43-year-old woman presented to the emergency department with bullae involving her left breast. She had had the onset of fever and upper respiratory symptoms three days earlier. Over several hours, the lesions of the breast began to coalesce and spread, followed by sloughing. She developed vomiting, diarrhea, renal failure, and respiratory distress. Chest X-ray showed pulmonary infiltrates.

The woman was admitted to the critical care unit and underwent nasotracheal intubation. Group A streptococci (GAS) were isolated from blood, respiratory secretions, and soft tissue. She was treated with vancomycin, piperacillin-tazobactam, clindamycin, intravenous immuglobulin, and hemodialysis. On the sixth hospital day, she underwent mastectomy; there was extensive tissue necrosis along with multiple abscesses. The patient ultimately died on hospital day 17.

On hospital day 4, three intensive care unit nurses complained of sore throat and fever. Initial surveillance identified 20 symptomatic staff who had direct patient contact.

Of these, a total of 10 had positive pharyngeal cultures for GAS. Expanded culture surveillance of asymptomatic staff who had patient contact identified a total of 24 culture-positive individuals, and one symptomatic physician who treated himself with penicillin before undergoing culture (he was included as a case). Isolates from the culture-positive staff were compared with the source patient's isolates by DNA typing.

Twenty-three had a DNA pattern identical to that of the patient. The employee with a different pattern had two children at home with GAS pharyngitis; her isolate was identical to that of her children. Thus, there were 24 nosocomial cases of GAS infection among hospital staff. All infected staff had had contact with the patient within the first 25 hours after presentation.

All staff received treatment with penicillin or a macrolide. There were no secondary cases among patients or families.

Commentary by Robert Muder, MD, hospital epidemiologist at the Pittsburgh VA Medical Center.

This outbreak of GAS infection is unusual in that it involved a large number of hospital staff exposed over a relatively short period of time. One contributing factor may have been the streptococcal isolate. It was M type 1, and produced NADase. These factors have been associated with invasiveness and transmissibility.

The extensive nature of the patient's infection was no doubt a contributing factor, as well. In addition to extensive skin and soft tissue infection, she also had GAS pneumonia and underwent nasotracheal intubation shortly after admission. Thus, there would have been ample opportunity for both contact and respiratory droplet transmission.

In a survey of compliance with infection control procedures done after the outbreak, staff caring for the patient nearly always wore gloves, but rarely wore gowns or masks. Although none of the staff involved in this outbreak had serious sequelae, a large number of employees required antibiotic therapy and a minimum of 24 hours of exclusion from work. Had there been secondary cases among patients, additional morbidity or even mortality might have occurred.

The most recent Centers for Disease Control and Prevention (CDC) guidelines for isolation procedures in hospitals recommend droplet precautions (e.g., private room and masks) for pediatric, but

not adult, patients with GAS pharyngitis or pneumonia. Although one hesitates to draw sweeping conclusions, this report indicates that standard precautions may be inadequate for patients with pneumonia or very extensive soft tissue infection due to GAS.

Given the potential seriousness of an outbreak of GAS in a hospital, I would recommend that such patients be managed with both contact and droplet precautions until at least 24 hours after institution of effective antibiotic therapy. ■

Program takes aim at drug-resistant bugs

CDC launches major initiative to aid detection

The Centers for Disease Control and Prevention (CDC) plans to distribute some 10,000 copies of a new training tool designed to assist laboratorians in selecting and using appropriate testing methods to detect antimicrobial-resistant strains of bacteria. The new tool, an interactive CD-ROM-based training course, provides the most extensive compilation of information on antimicrobial-resistance testing available to date.

"Antimicrobial susceptibility testing has become more complex in recent years as new drugs have become available and resistance has emerged," says **Steve Solomon**, MD, acting director of CDC's healthcare quality promotion program.

"This CD-ROM will help microbiologists on the front lines to better detect this emerging problem, which significantly impacts public health across the United States," he adds.

The CDC estimates that more than 70% of the bacteria that cause hospital-acquired infections are resistant to at least one of the drugs most commonly used to treat those infections.

"Accurate antimicrobial susceptibility test results not only help physicians choose the best therapy for their patients, but guide infection control efforts to the most serious infections," says **Fred Tenover**, PHD, a CDC expert on antimicrobial susceptibility testing and one of three coauthors of the CD-ROM.

Upon completion of the course, scientists can receive up to eight hours of continuing education units (CEUs), marking the first time the agency has offered CEU credits for programs designed to help in identifying antimicrobial-resistant bacteria.

The target audience for this course includes microbiology laboratory directors, supervisors, and medical technologists who perform or interpret the results of antimicrobial susceptibility tests in clinical or public health laboratories. Others who are likely to benefit from this program include physicians, pharmacists, and medical students.

This training tool complements other CDC resources for microbiologists including CDC's multilevel antimicrobial susceptibility testing educational resources (MASTER) web site and a series of national training programs. This web site is intended to keep microbiologists informed of antimicrobial susceptibility testing issues related to clinical microbiology laboratory practice. Go to: www.phppo.cdc.gov/dls/master/default.asp. ■

Congressional watchdog asked to jump on JCAHO

Plans to allow self-inspections criticized

Continuing to face withering criticism from diverse corners, the Joint Commission on Accreditation of Healthcare Organizations has now drawn the ire of a powerful member of Congress.

Rep. **Pete Stark**, (D-CA) ranking Democrat on the House Ways and Means Health Subcommittee, has formally requested the Office of the Inspector General of the Department of Health and Human Services to take a hard look at some of the Joint Commission's planned accreditation changes.

"JCAHO recently announced that in 2004 they would be converting to a self-assessment-oriented hospital survey protocol," Stark stated in a letter requesting the action. "This protocol appears even more collegial and less regulatory in nature than the current survey. In addition, its reliance on extensive self-assessment activities is particular cause for concern."

The action comes on the heels of several controversial developments, including strong criticism by ICPs of the Joint Commission's recent request for reports of fatal or life-impairing nosocomial infections.

Scalded by criticisms in the press that it is lax on infection control, the Joint Commission had

warned that it was going to become more aggressive in the area. **(See new supplement in this issue.)** Stark's pointed attack also falls under the general umbrella of quality, particularly the Joint Commission's plan to allow 18-month institutional "self-assessments" as part of its Shared Vision/New Pathways accreditation program.

In the most recent Centers for Medicare & Medicaid Services report to Congress, validation studies indicated that JCAHO was least reliable in assessing Medicare Conditions of Participation (CoPs) when self-assessment activities were a primary component of the monitoring process, Stark emphasized.

"Now, it will be the predominant component of the entire survey," he stated. "I am requesting that you investigate whether the proposed new procedure can effectively assess compliance with the Medicare CoPs and assure quality and safety in Medicare participating hospitals."

In addition, JCAHO business practices appear fraught with potential for conflict of interest because it has been aggressively pursuing and obtaining consulting contracts with the very institutions it is surveying, Stark charged. "There is a specter of undue influence eroding the impartiality of the surveying process," he warned.

In response, the Joint Commission said it welcomed an evaluation by the Office of the Inspector General at any time.

"The self-assessment is an additional accreditation requirement and does not in any fashion substitute for the on-site evaluation by the survey team; neither the survey length nor the size of the survey team are to be reduced," the Joint Commission responded in a statement posted on its web site.

"The principal purposes of the self-assessment

CE/CME instructions

Physicians and nurses participate in this CE/CME program by reading the issue, using the provided references for further research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to answer key to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this semester's activity in June 2003, you must complete the evaluation form that will be provided and return it in the reply envelope to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME *questions*

Effective with this issue, *Hospital Infection Control* is changing its testing procedure. You no longer need to return a Scantron answer sheet to earn credit for the activity. Please review the text, answer these questions, check your answers against the answer key, and then review the materials again regarding any questions answered incorrectly. To receive credit for this activity, you must fill out the CE/CME evaluation that will be included in the June 2003 issue and return in the envelope that will be provided. For further information, refer to the CE/CME instructions box. This procedure has proven to be an effective learning tool for adults. If you have any questions about the new testing method, please contact customer service at (800) 688-2421.

5. In declining the government's offer of smallpox vaccine, Richard Wenzel, MD, cited the fact that that stocks of smallpox vaccine have been steadily increased. Why is that important?
   A. The vaccine is now so inexpensive that people will pay out of pocket.
   B. The vaccine still provides protection against smallpox several days after an exposure.
   C. The new stocks of vaccine cause no side effects.
   D. all of the above

6. Larry Gostin, JD, LLD, cited which of the following as concerns for HIV-infected health care workers as the government moves ahead with its plan to offer smallpox vaccine to hospital staff.
   A. health
   B. discrimination
   C. confidentiality
   D. all of the above

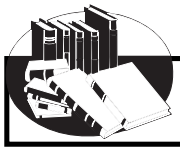
7. A new test for latent tuberculosis infection requires drawing blood, but the person being tested does not have to return to have the results read like a traditional tuberculin skin test.
   A. true
   B. false

8. In light of transmission of Group A streptococcus (GAS) to 24 medical workers from a single patient, Robert Muder, MD, recommended using which type of isolation for patients with pneumonia or very extensive soft tissue infection due to GAS?
   A. standard
   B. contact
   C. droplet
   D. a combination of B and C

Answer Key: 5. B; 6. D; 7. A; 8. D

are to increase organization awareness of the importance of continuous standards compliance and to promote organization ownership of the self-assessment findings and the improvements that it should expect of itself. Self-assessment methods have long been used successfully by other accrediting bodies and evaluators, including government agencies."

Concerning the conflict of interest charges, the Joint Commission said a "firewall" exists between its consulting and accrediting entities and all activities meet U.S. Securities and Exchange Commission separation criteria. ■



JOURNAL REVIEW

EDs best way to deliver pneumonia vaccine?

Husain S, Slobodkin D, Weinstein R. **Pneumococcal vaccination: Analysis of opportunities in an inner-city hospital.** *Arch Intern Med* 2002: 262;1,961-1,965.

Emergency departments (ED) in inner-city hospitals appear to be the best site within the facility to offer pneumococcal vaccine to high-risk patients, the authors found.

Pneumococcal vaccination rates in the United States are reported to be 28% to 47%, well below the desired 90% levels, with the result that many patients are denied effective protection against a major cause of morbidity and mortality. This study demonstrates that an ED-based vaccination strategy would protect most patients at risk for pneumococcal bacteremia in an inner-city public hospital, with a best-case scenario showing cost savings.

There were more than 100.4 million ED visits in the United States in 1998, the authors said. The ill, the elderly, the poor, and members of ethnic minorities are overrepresented in that group. These patients are at higher risk of respiratory disease and of undervaccination, the authors concluded.

"Pneumococcal bacteremia is a major cause of morbidity and mortality in the United States, with a yearly incidence estimated to be 15 to 30 cases per 1000,000 population," they emphasized. "This vaccine-preventable disease kills more Americans than all other vaccine-preventable diseases combined, in large part, because of inadequate rates of vaccination among populations at risk."

Various sites within the hospital — inpatient medicine wards (IMW), general medicine clinics (GMC), and emergency departments (ED) have been previously suggested as venues for administering vaccination.

The authors sought to compare the potential coverage of at-risk patients and cost of pneumococcal vaccination delivered in an ED, GMC, and IMWs.

They studied a retrospective cohort of 300 patients with pneumococcal bacteremia who had been hospitalized at Cook County Hospital in Chicago from January 1994 through December 1998. Researchers measured the presence of risk factors, as defined by the Centers for Disease Control and Prevention, for developing pneumococcal disease prior to index admission for bacteremia. They also looked at patient use of ED, GMC, and IMWs from four weeks to five years before index admission; size of target population for vaccination in each site; and cost benefit of a pneumococcal vaccination strategy at each site.

In the four weeks to five years before index admission, risk factors were present in 209 patients; 182 (87.1%) of the 209 had been in the ED, 104 (49.7%) in an IMW, and 64 (30.6%) in a GMC. The ED showed the greatest potential vaccine coverage, at a cost savings in a best-case scenario. The IMWs showed the best cost-benefit ratio but would provide access to fewer at-risk patients.

A program in the GMC would reach the fewest at-risk patients, with a cost-benefit ratio similar to that of the ED. ■

COMING IN FUTURE MONTHS

- Can of worms: Opening up the liability question for hospitals and smallpox vaccine
- Asleep at the wheel: Does your anesthesiologist reuse needles?
- Rap on the knuckles: New education materials for alcohol-based hand rubs
- Getting the point: FDA moves to have needle safety at the product submission stage
- SHEA in DC: Complete coverage of this important conference

United States Postal Service

Statement of Ownership, Management, and Circulation

1. Publication Title	2. Publication No.	3. Filing Date
Hospital Infection Control	0 0 9 8 - 1 8 0 X	10/09/02
4. Issue Frequency: Monthly	5. Number of Issues Published Annually: 12	6. Annual Subscription Price: $429.00

7. Complete Mailing Address of Known Office of Publication *(Not Printer) (Street, city, county, state, and ZIP+4)*: 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, Fulton County, GA 30305 — Contact Person: Willie Redmond; Telephone: 404/262-5448

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not Printer)*: 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do Not Leave Blank)*

Publisher *(Name and Complete Mailing Address)*: Brenda Mooney, 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

Editor *(Name and Complete Mailing Address)*: Gary Evans, same as above

Managing Editor *(Name and Complete Mailing Address)*: Coles McKagen, same as above

10. Owner *(Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual. If the publication is published by a nonprofit organization, give its name and address.)*

Full Name	Complete Mailing Address
American Health Consultants	3525 Piedmont Road, Bldg. 6, Ste 400 Atlanta, GA 30305

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box → ☐ None

Full Name	Complete Mailing Address
Medical Economics Data, Inc.	Five Paragon Drive Montvale, NJ 07645

12. Tax Status *(For completion by nonprofit organizations authorized to mail at nonprofit rates.) (Check one)*
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☐ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months *(Publisher must submit explanation of change with this statement)*

PS Form **3526**, September 1998 *See instructions on Reverse)*

13. Publication Name: Hospital Infection Control — 14. Issue Date for Circulation Data Below: October 2002

15. Extent and Nature of Circulation			Average No. of Copies Each Issue During Preceding 12 Months	Actual No. Copies of Single Issue Published Nearest to Filing Date
a. Total No. Copies *(Net Press Run)*			2741	3100
b. Paid and/or Requested Circulation	(1)	Paid/Requested Outside-County Mail Subscriptions Stated on Form 3541. *(Include advertiser's proof and exchange copies)*	2167	2213
	(2)	Paid In-County Subscriptions *(Include advertiser's proof and exchange copies)*	10	9
	(3)	Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Non-USPS Paid Distribution	27	77
	(4)	Other Classes Mailed Through the USPS	0	0
c. Total Paid and/or Requested Circulation *(Sum of 15b(1) and 15b(2)*			2204	2299
d. Free Distribution by Mail *(Samples, Complimentary and Other Free)*	(1)	Outside-County as Stated on Form 3541	28	27
	(2)	In-County as Stated on Form 3541	2	2
	(3)	Other Classes Mailed Through the USPS	0	0
e. Free Distribution Outside the Mail *(Carriers or Other Means)*			33	400
f. Total Free Distribution *(Sum of 15d and 15e)*			63	429
g. Total Distribution *(Sum of 15c and 15f)*			2267	2728
h. Copies Not Distributed			474	372
i. Total *(Sum of 15g, and h.*			2741	3100
Percent Paid and/or Requested Circulation *(15c divided by 15g times 100)*			97	84

16. Publication of Statement of Ownership
Publication required. Will be printed in the February issue of this publication. ☐ Publication not required.

17. Signature and Title of Editor, Publisher, Business Manager, or Owner: Publisher — Date: 10/09/02

I certify that all information furnished on this form is true and complete. I understand that anyone who furnishes false or misleading information on this form or who omits material or information requested on the form may be subject to criminal sanctions (including fines and imprisonment) and/or civil sanctions (including multiple damages and civil penalties).

Instructions to Publishers

1. Complete and file one copy of this form with your postmaster annually on or before October 1. Keep a copy of the completed form for your records.
2. In cases where the stockholder or security holder is a trustee, include in items 10 and 11 the name of the person or corporation for whom the trustee is acting. Also include the names and addresses of individuals who are stockholders who own or hold 1 percent or more of the total amount of bonds, mortgages, or other securities of the publishing corporation. In item 11, if none, check the box. Use blank sheets if more space is required.
3. Be sure to furnish all circulation information called for in item 15. Free circulation must be shown in items 15d, e, and f.
4. Item 15h., Copies not Distributed, must include (1) newsstand copies originally stated on Form 3541, and returned to the publisher, (2) estimated returns from news agents, and (3), copies for office use, leftovers, spoiled, and all other copies not distributed.
5. If the publication had Periodicals authorization as a general or requester publication, this Statement of Ownership, Management, and Circulation must be published; it must be printed in any issue in October or if the publication is not published during October, the first issue printed after October.
5. In item 16, indicate date of the issue in which this Statement of Ownership will be published.
6. Item 17 must be signed.

Failure to file or publish a statement of ownership may lead to suspension of second-class authorization.

PS Form **3526**, September 1999 *(Reverse)*

CE/CME 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. ■

AMERICAN HEALTH CONSULTANTS®

BIOTERRORISM WATCH

Preparing for and responding to biological, chemical and nuclear disasters

IN THIS ISSUE

MARCH/APRIL 2003

VOL. 2, NO. 2 (pages 9-16)

Israel reports 4 hospitalized among 18,000 smallpox immunizations

Data may foreshadow more adverse smallpox reactions in U.S.

In emerging findings that will fuel more debate about immunizing U.S. health care workers for smallpox, a similar program in Israel has resulted in four hospitalizations — including the immunocompromised wife of a vaccinee, *Bioterrorism Watch* has learned.

No deaths have been reported after immunizing some 18,000 health care workers in Israel, but the hospitalizations suggest the rate of serious adverse reactions may be somewhat higher than historically seen in the smallpox medical literature. Is the glass half empty or half full?

"I don't want to get superstitious; I may get the next telephone call that we have another side effect," says **Ido Hadari**, spokesman for the Israeli Ministry of Health in Jerusalem. "But considering what is known in the medical literature, these 18,000 are getting very well right now without side effects or problems. We are very [thorough] in selecting those to receive vaccination."

Currently, about 15% of health care workers are being screened out due to contraindications. For the most part, those workers who have been immunized have not missed work in Israeli hospitals, he says. "After they get the vaccination, they get dressed and go back to their positions," he says. To some degree, the hospitalizations following immunization in Israel reflect err on the side of caution, he adds. "We have had four cases we decided to hospitalize, even though three of them were fine," Hadari adds. "One case was a person who got vaccinated and developed a slight fever and an inflammation of the muscles of the heart. But we are still checking [the link] between the [condition] he had, which can be caused by many things, and getting the vaccination."

The most serious adverse reaction was in the wife of a health care worker who had recently been vaccinated. "If the husband had read the [informed consent] sheet, he would have known he shouldn't have gotten vaccinated," he explains. "He is living in the same home with a

person who suffers from a weakened immune system and takes steroids. She developed general vaccinia, and her condition was not good."

However, the woman responded to treatment with vaccine immune globulin and has completely recovered, he says.

Still, the fact that four people were hospitalized — despite a screening effort that included selecting those previously immunized for smallpox — suggest the U.S. health care workers will see more serious adverse reactions than recorded in the medical literature.

"The Israelis were also using a milder vaccine," says **Brian L. Strom**, MD, MPH, director of the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania School of Medicine in Philadelphia. "I would be very surprised if we did not see higher rates than the published rates."

Historic estimates based on passive reports

The typically discussed risk of one death per million and some 40 serious reactions is based on old passive surveillance systems, says Strom, chairman of an Institute of Medicine committee that recently issued a cautionary report on the Centers for Disease Control and Prevention's (CDC) smallpox immunization plan. **(See related story, p. 13.)** "They are almost surely underestimates of the real risk," he says.

The CDC is sending a team to Israel to take a firsthand look at its smallpox immunization program. In the most recent information posted on its web sites, the CDC estimates that for every million people vaccinated, 1,000 will have non-life-threatening, serious reactions; between 14 and 52 will have life-threatening reactions; and one or two will die.

A rough extrapolation of the initial Israeli report projects out to 150 to 200 hospitalizations per million vaccinations.

According to the CDC, the statistical information about smallpox vaccine adverse reactions is based on data from studies conducted in 1968. Adverse event rates in the United States today may be higher because more people are immune-suppressed from cancer, cancer therapy, organ transplants, and HIV. On the other hand, the patient outcomes following adverse reactions may be better because of advances in medical care. The CDC has created an algorithm to track adverse reactions and distinguish those that are mild from those that are life-threatening. **(See algorithm, p. 12.)**

Given the possibility of severe reactions, the programs in both Israel and the United States are voluntary. As has been seen stateside, there has been reluctance among Israeli health care workers to be vaccinated since the program began last August. "We have 150,000 people working in health care," Hadari says. "We expected to get more compliance from the health workers, and it was a big disappointment for us."

A contributing factor was that the program was launched right before national holidays in Israel, and people who planned to travel or have guests were reluctant to be immunized, he says.

"Then after the holidays ended, we suffered

Bioterrorism Watch (ISSN #1543-0243) is published bimonthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Bioterrorism Watch**, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291. Hours of operation: 8:30-6. Monday-Thursday, 8:30-4:30 Friday EST. World Wide Web: http://www.ahcpub.com. E-mail: customerservice@ahcpub.com.

Subscription rates: Free to subscribers of *Hospital Infection Control* and *Hospital Employee Health*. For nonsubscribers, the price is $149. U.S. possession and Canada, add $30 plus applicable GST. Other international orders, add $30. (GST registration number R128870672.) Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. **Back issues**, when available, are $48 each.

This continuing education offering is sponsored by American Health Consultants®, which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. American Health Consultants® is an approved provider by the California Board of Registered Nursing for approximately 6 contact hours per year (provider #CEP10864).

American Health Consultants® is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians. American Health Consultants® designates this educational activity for approximately 6 hours in Category 1 credit toward the Physicians' Recognition Award. Each physician should claim only those credits that he or she actually spent in the activity This activity was planned and produced in accordance with the ACCME Essentials.

In order to reveal any potential bias in this publication, and in accordance with Accreditation Council for Continuing Medical Education guidelines, we disclose that Patrick Joseph and William Schaffner (both on editorial advisory board) report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Editor: **Gary Evans**, (706) 742-2515.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Coles McKagen**, (404) 262-5420, (coles.mckagen@ahcpub.com).
Senior Production Editor: **Ann Duncan.**

THOMSON
AMERICAN HEALTH CONSULTANTS

Editorial Questions

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

Smallpox Vaccine Alert

Use only three needle sticks for first-time vaccinees

CDC cites liability issue in shifting gears

Health care workers receiving their first lifetime vaccination for smallpox only should be stuck three times with the bifurcated immunization needle — not the 15 skin pricks previously recommended by the Centers for Disease Control and Prevention (CDC).

In an untimely glitch just as some programs were getting under way, the CDC's Advisory Committee on Immunization Practices (ACIP) cited liability issues in revising the prior recommendation. ACIP had recommended 15 needle sticks for both "naïve" never-vaccinated people and those who had been previously immunized.

The idea was to enhance the number of "takes" conferring immunity and give out a uniform recommendation for vaccination. However, that recommendation was not in harmony with the original package insert by Wyeth Pharmaceuticals in Madison, NJ.

"Because this is a federally executed program, the use of the vaccine must conform with the package insert," says **William Schaffner**, MD, a liaison ACIP member and chairman of the department of preventive medicine at Vanderbilt University School of Medicine in Nashville, TN.

"And Wyeth obviously has old data submitted to the Food and Drug Administration that support two to three pokes for naïve people and 15 with people who have been previously vaccinated. The question now is whether we will see fewer takes."

To ensure three needle insertions are sufficient for first-time vaccinees, smallpox vaccinators should look for a trace of blood to appear at the site of vaccination. If no blood is visible within 15 to 20 seconds, an additional three insertions should be made using the same bifurcated needle without reinserting the needle into the vaccine vial, ACIP recommends.

The change means some additional training for screeners and vaccinators because they must be aware of the new information to immunize health care workers. If it not clear whether people being immunized have been vaccinated previously, the current thinking is that they should be treated as revaccinees and given 15 needle insertions, Schaffner says. ■

from [poor] momentum," he adds.

Scores of U.S. hospitals similarly have opted out of the program here, but the CDC still expects to have immunized teams in thousands of facilities. As of Jan. 29, 38 states had requested a total of 195,700 doses of vaccine.

"The goal of this program is not to ensure that every hospital in the country has vaccinated employees," says **Julie Gerberding**, MD, MPH, director of the CDC. "The goal is to ensure that we have the public health response teams that can go out and assess initial cases and that we have health care personnel in a facility in that jurisdiction that would be able to take care of the first cases. We have 3,000-plus hospitals that have indicated that their personnel will be participating in the program. We never expected every hospital to participate, and we still remain confident that we will have the level of preparedness we need."

Connecticut takes U.S. lead

Connecticut was among the first states to join the U.S. effort, immunizing public health vaccinators in late January. They were, in turn, scheduled to offer the vaccine to hospital workers beginning Feb. 10, 2003.

"At this point, we have about 40 people who have volunteered," says **Louise Dembry**, MD, epidemiologist at Yale-New Haven (CT) Hospital. However, the hospital is not offering the vaccine to infection control professionals in the first round of immunizations. "We are trying to get a group of people who are willing to then become vaccinators," she says. "We didn't include infection control or hospital epidemiology because we didn't feel these were going to be people giving hands-on care to cases of smallpox. If there are cases of smallpox, they would probably be doing other activities related to infection control, so I excluded them as vaccinators."

The hospital will conduct daily vaccination site monitoring for immunized workers, whose "take" sites will be covered with semipermeable gauze dressing as recommended by the CDC.

"We are emphasizing the importance of hand hygiene," Dembry says. "We won't allow people to work who can't have the site contained by the bandage, have too much itching so that they are always touching their vaccination site, or have satellite lesions."

Regarding adverse effects and lost time, workers in the three-hospital Yale-New Haven system will

(Continued on page 13)

Legend
Morbidity and Mortality Risk based on clinical presentation.

Low

Moderate

High

Clinical Evaluation Tool for Smallpox Vaccine Adverse Reactions
Dermatologic Reactions/ Localized to Vaccination Site (2-07-2003 Version)

Tool 1

www.bt.cdc.gov/agent/smallpox/vaccination/clineval

Vaccine Recipient?

NO → **Close Contact of Vaccine Recipient?**

YES → **Go to Dermatologic Reactions/ Nontoxic Appearance, Distant from Vaccination Site (or in a Contact) Clinical Evaluation Tool.**

YES

Normal Vaccination Reaction

Typical reaction timeline

Day	Description
0	Vaccination
3-4	Papule
5-6	Vesicle with surrounding erythema - vesicle with depressed center
8-9	Well-formed pustule
12+	Pustule crusts over and becomes a scab
17-21	Scab detaches revealing scar

Timeline may be accelerated in persons with history of prior smallpox vaccination.

Major reaction. Area of definite induration or congestion surrounding a central lesion that may be a scab or ulcer 6-8 days after vaccination.
Equivocal reaction. Any reaction or response other than a "major reaction."

Common signs/symptoms after vaccination
- Pruritus
- Soreness at vaccination site
- Intense erythema ringing the vaccination site
- Small papules or vesicles around vaccination lesion (satellite lesions)
- Headache
- Local lymphadenopathy
- Malaise
- Myalgia
- Fever

Provide supportive care. Use antihistamines and NSAIDs PRN; avoid topical/ systemic steroids.

Erythematous Vaccination Reaction of Concern

Erythema present along lines of adhesive tape and no or mild systemic symptoms?

YES → **Tape sensitivity**
Try different tape. Change bandage frequently, rotate bandage, or take a judicious bandage "holiday" remembering to use other means (e.g. long sleeves) to prevent contact transmission. Use antihistamines PRN; avoid topical/ systemic steroids.

NO → Erythema with induration, warmth, and pain. May also have regional lymphadenopathy and fever.

Range of normal reactions, including Robust take (>3 inches or ~7.5 cm of redness with swelling, warmth and pain at vaccination site):
- Symptoms expected to peak at 8-10 days post vaccination.
- Symptoms typically improve within 24-72 hours of peak inflammation.

Provide supportive care. Use antihistamines and NSAIDs PRN; avoid topical/ systemic steroids. Observe & rest affected limb. Observe vigilantly until improvement noted.

Consider **Bacterial infection** if:
- Honey-crusted lesions (impetigo) or fluctuance is present at vaccination site.
- Symptom onset is within one week of vaccination or >15 days post vaccination.
- Symptoms are not improving within 72 hours after onset.
- Other concerning clinical features are present.

Streptococcal or staphylococcal infection is the most likely etiology, however other bacterial sources are possible. Obtain cultures of skin/ blood, other lab tests (including gram stain) and administer empiric antibiotics as indicated. Use infection control precautions; lesions may contain vaccinia virus.

Severe Vaccination Reaction

Rapid progressive painless extension of central vaccination lesion or progression without apparent healing after 15 days. Lesion often necrotic. Initially little or no inflammation. May present with few or no systemic symptoms.

Early Progressive vaccinia (Vaccinia necrosum, Vaccinia gangrenosum)
Go to Clinical Evaluation Tool for Dermatologic Reactions/Toxic Appearance, Distant from Vaccination Site (or in Contact). See Consultation and Reporting Information.

Differential diagnosis for localized smallpox vaccine adverse reactions
Consider conditions not related to smallpox vaccine such as:
- Acute contact dermatitis
- Furuncle/ carbuncle
- Pyoderma/ ecthyma
- Herpes simplex virus (HSV)
- Anthrax
- Atypical mycobacteria
- Molluscum contagiosum and other pox viruses
- Pyoderma gangrenosum
- Brown recluse spider bite

Laboratory testing
Consider use of licensed diagnostic tests to rule out etiologies not related to vaccina virus contained in smallpox vaccine.

Consultation and Reporting Information

Civilian health care providers who need clinical consultation with or without release of Vaccinia Immune Globulin (VIG) (first line agent) or Cidofovir (second line agent) for potential smallpox vaccine adverse reactions should contact their state/ local health department or the CDC Clinician Information Line at (877) 554-4625. Military health care providers should call (888) USA-RIID or (301) 619-2257.
Health care providers should report smallpox vaccine adverse events to their state/ local health department and to the Vaccine Adverse Event Reporting System (VAERS) at http://www.vaers.org/ or (800) 822-7967.

Please call (888) 246-2675 (Español (888) 246-2857, TTY (866) 874-2646) or visit http://www.bt.cdc.gov/agent/smallpox/index.asp for general public information about smallpox vaccination. Persons experiencing urgent or life-threatening medical events should seek immediate medical assistance.

be covered by workers' compensation, she says. "We recognize at that point, it is a very individual decision that each person has to make," Dembry says. "We are not going out trying to recruit people and cajole them into being vaccinated. We are here to present what the vaccine is, what the risks are, and what the contradictions are."

(Editor's note: For a wealth of materials on smallpox immunization programs, go to the CDC web site at www.bt.cdc.gov/agent/smallpox/index.asp.) ■

IOM: Set trigger before a vaccine death occurs

CDC urged to track reactions, explain liability

With its smallpox immunization plan now under way in the nation's hospitals, the Centers for Disease Control and Prevention (CDC) must decide how many adverse reactions and deaths are acceptable before modifying or halting the program, told a special smallpox review panel formed at the Institute of Medicine (IOM) in Washington, DC.

The CDC should develop and communicate criteria — such as a threshold number of adverse events — that would trigger midcourse changes to the agency's current guidance on issues such as screening, contraindications, and administrative leave policies, the IOM panel recommended.

"It is not an easy decision, that it why we are saying it should be made [beforehand]. It should not be made in the heat of battle," says **Brian L. Strom**, MD, MPH, chairman of the IOM panel and director of the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania School of Medicine in Philadelphia.

The IOM report was sponsored by the CDC, which is taking the suggestions seriously and reviewing its smallpox plans.

"Obviously, there has been a decision that [approximately] one per million deaths and 40 per million serious side effects is tolerable, given the risk seen by the government," Strom says. "Presumably, if you were talking about one per hundred deaths, it would not be tolerable. Where is the boundary in between? Decide that up front, not after the first or second death comes in. Then it is going to be under a political microscope, and it is going to be very hard to make a decision."

The CDC is addressing such concerns with the formation of a Data Safety Monitoring Board, which consists of experts who will assess the program as it goes forward.

"We have made a commitment to monitor this program in real time so that we can detect at the earliest possible moment any emerging, unexpected, or expected-but-rare problem," says **Julie Gerberding**, MD, MPH, CDC director. "Keep in mind that we used this vaccine for decades successfully. This is the vaccine that was involved in eradicating smallpox. And so I don't think we anticipate we'll be finding unusual complications, but we are very concerned that the program is administered safely, and so in real time, we'll be watching very carefully. We are also working very carefully with the Department of Defense so that we can understand any complications that are occurring there [in military personnel], and we'll be able to use that information as well."

The IOM committee commended plans to establish the safety monitoring board, but questioned the board's independence if it is too closely tied to government. Fail-safe mechanisms for independent review, analysis, and reporting should be established or the proposed organizational arrangement should be reconsidered, the IOM advised.

Estimating that about 30% of the population is contraindicated for the smallpox vaccine due to various conditions, the IOM panel questioned whether the CDC will catch all reactions and adverse events using the existing Vaccine Adverse Event Reporting System (VAERS).

"It serves a critical role, but its purpose is not to quantify adverse reactions," Strom says. "Its purpose is to discover new reactions that we might not otherwise know about. There is vast underreporting. People don't report their reactions to VAERS."

Instead, the committee strongly urged the agency to use a "pre-event vaccination system" to actively collect information on adverse events. Under that plan, adverse reactions would be reported into a secure data system by every immunization site.

"Then we will truly have definitive information — yes or no — about whether a person had an adverse reaction. I know CDC is, in fact, making that change because [the agency] asked us specifically about the program it is implementing," Strom says.

There was some confusion when the IOM report recently was released, with initial reports suggesting the panel was asking the CDC to stop the

immunization effort until concerns are addressed. "Proceed with caution" is more to the point of the IOM's recommendations.

"We never said they should not move ahead," Strom says. "What we said was that it shouldn't be implemented until it can be done safely. Recognize that this is a national campaign being done locally. So CDC can implement nationally, but the real question is when it is implemented by each locale; it shouldn't be initiated until the [local] programs think they are ready."

The CDC has clarified that each vaccination site should move ahead only when everything is in place to safely provide immunizations.

This caution is important because any complications experienced during the initial phase of the immunization campaign could lessen willingness to participate in the program, the IOM stressed.

In that regard, the panel did ask for a pause in the process after the smallpox care teams are immunized in hospitals. The data collected from that effort should be thoroughly analyzed before the vaccine is offered to other health care workers, first responders, and public safety officials.

"The second phase shouldn't be mounted until the analysis of the first phase is done," Strom says. "The decisions made in the first phase are based on data that are decades old. That needs to updated and corrected on a real-time basis. . . ."

It goes without saying that cumulative data should be scrutinized before the so-called "third phase" begins by offering the vaccine to the general public. In all cases, the process should be paused and restarted based on collected data rather than an arbitrary time line, Strom adds.

Liability issues clouded

Currently, some health care workers and many members of the public understandably are confused about several aspects of the program, the IOM noted. For example, many potential vaccine recipients may falsely assume that the provisions of the Homeland Security Act of 2002 would reimburse them for medical expenses or lost income resulting from complications of vaccination. However, the act covers only injuries that result from vaccine that was negligently manufactured or administered, the IOM panel reminded.

Other vaccine injuries might be covered under workers' compensation laws, which vary by state, and by individuals' health insurance plans. However, without clear means of compensation for losses that may occur even if the vaccine was carefully administered, some — perhaps many — health workers may decline vaccination, which would undermine the program's effectiveness, the committee warned.

"[Liability issues] need to be made transparent, and that has to be part of the informed consent," Strom says. "Otherwise it is not truly voluntary. People need to know the medical and economic risk they are taking, given that there is limited liability or injury protection now build in. That is going to require the CDC working with the state health departments on a state-by-state basis because there are relying to a substantial degree on workers' compensation, and that varies from state to state."

Gaps in coverage

For example, one of the current "gaps in coverage" concerns adverse reactions in contacts of people who volunteer for vaccination, Gerberding concedes. A number of steps are being taken by the CDC and other government agencies to clarify the situation, she says.

"We've advised the states to get a very firm assessment of what workers' compensation programs in their state will and will not cover, and we're advising that various employers collaborate in this process," she says.

That said, the CDC is determined to move forward and clarify the issues as the program proceeds. "Even though the states may vary in the kinds of coverage or the programs that are available, we are certainly not going to delay this program because of concerns about compensation," Gerberding says.

"The president's decision to recommend this vaccine to the response teams was really based on the fact that we need urgent and efficient action. We live in a dangerous world these days, where a

terrorist attack with smallpox is possible. Even though the president reassured us that an attack was not imminent, we all know that this is now a possibility, and we must be prepared," she adds.

Indeed, the risk of a vanquished disease being intentionally loosed on a largely vulnerable population is the great unknown that makes this the most unusual vaccine campaign in history.

"Presumably [the risk of an attack] is not zero, or the campaign wouldn't have been done to begin with," Strom says.

"Basically, our judgment was we don't have that information; we can't have that information; and to some degree, it is probably not even knowable even from a [government] security point of view. The central issue is: This is not the normal public health vaccine campaign. You normally would not give a vaccine that will kill people for a disease that doesn't exist," he adds.

(Editor's note: The complete IOM report is available at http://national-academies.org.) ■

How not to run a bioterror immunization campaign

GAO blasts military's anthrax effort

Harsh lessons learned from the government's forced anthrax vaccination campaign in the military include poor communication, driving people out of the service, and massive underreporting of adverse reactions among those immunized, according to a report by the General Accounting Office (GAO).[1]

Reasons given for not reporting adverse reactions included the possible effect on a military or civilian career, fear of ridicule, and lack of awareness of the Vaccine Adverse Events Reporting System (VAERS).

Echoing concerns already expressed about the fledgling smallpox campaign in health care, the GAO recommended that the Department of Defense (DOD) establish an active surveillance program instead of using the Food and Drug Administration's VAERS.

Though they were initially underreported, the GAO report reveals that adverse events experienced by personnel who had received the anthrax shots were considerably higher than those published in the vaccine manufacturer's product insert in use at the time of the survey. The insert has now been amended.

"For example, an estimated 84% of the personnel who had had anthrax vaccine shots between September 1998 and September 2000 reported having side effects or reactions," the GAO found. "This rate is more than double the level cited in the vaccine product insert."

The DOD considers inhalational anthrax as one of the greatest bioterrorism threats to U.S. military

CE/CME *questions*

For more information, see CE/CME instructions box, p. 16. This procedure has proven to be an effective tool for adult learners. If you have any questions about this testing method, please contact customer service at (800) 688-2421.

5. The most serious adverse reaction thus far in Israel's program to immunize workers was in the immune-compromised wife of a health care worker who recently had been vaccinated.
   A. true
   B. false

6. According to Julie Gerberding, MD, MPH, the number of hospitals expected to participate in the CDC's smallpox immunization plan is about:
   A. 1,000
   B. 2,000
   C. 3,000
   D. 4,000

7. The CDC is addressing concerns about adverse reactions to the smallpox vaccine by formation of a panel of oversight experts called the Data Safety Monitoring Board. What concerns did the IOM panel raise about this board?
   A. its independence if it is too closely tied to government
   B. if adverse effects are few, making vaccination mandatory
   C. its dismal track record with the anthrax vaccine
   D. all of the above

8. In a report by the General Accounting office, harsh lessons learned from the government's forced anthrax vaccination campaign in the military include:
   A. poor communication
   B. driving people out of the service
   C. underreporting of adverse reactions
   D. all of the above

Answer Key: 5. A; 6. C; 7. A; 8. D

forces. To counter this threat, DOD officially established the mandatory vaccination program in August 1998 to inoculate all 2.4 million service members, including active duty and reserve component personnel, along with some DOD civilian and contractor employees. This major undertaking involved scheduling and administering more than 14 million shots to satisfy the vaccine's initial dosage requirements of six shots per individual over an 18-month period, followed by an annual booster.

The anthrax vaccine campaign featured high-visibility education efforts that included information about the threat of anthrax and the safety of the vaccine via a web site, a toll-free hotline, and a speakers' bureau of experts. To assess the effectiveness of the program, the GAO surveyed a random sample of 1,253 people from DOD's list of Air National Guard and Air Force Reserve personnel. These included pilots, flight engineers, loadmasters, navigators, and crew chiefs.

"Our findings suggest that DOD's communications efforts were largely unsuccessful in convincing most [respondents] that the anthrax threat was as serious as alleged," the GAO concluded. "Overall, there was a general and pervasive degree of dissatisfaction about the completeness and accuracy of most of the information DOD provided."

Respondents strongly questioned the battlefield effectiveness of the anthrax vaccine, its history and past usage, its short-term and long-term safety risks, and the possible side effects from the vaccine. The program forced some personnel out of the service, as 16% survey respondents cited the required anthrax vaccine as a prime factor in their decision to leave the military or reduce their level of participation.

"The actual losses and expected losses as a result of this program represented some of the most experienced and highly trained individuals in these services and are people not easily replaced," the GAO warned. "It takes time and a great deal of money and other resources to develop trained, experienced pilots and other aircrew members to support the important missions of these reserve components, particularly in light of the current battle against terrorism."

Reference

1. General Accounting Office. *Anthrax Vaccine: GAO's Survey of Guard and Reserve Pilots and Aircrew.* GAO-02-445. Washington, DC; 2002. ■

CE/CME instructions

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

To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this semester's activity in May/June 2003, you must complete the evaluation form that will be provided and return it in the reply envelope to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE objectives

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

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