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IN THIS ISSUE

Infection control moves out across the continuum
In revising its 1996 isolation guidelines, the Centers for Disease Control and Prevention is trying to broaden the recommendations across the continuum of care. The old guidelines focus almost exclusively on acute care settings, but a new draft under discussion tries to extend infection control by emphasizing standard precautions for all patients in all settings . . . . . cover

CDC drafts performance measures for IC programs
In revising patient isolation guidelines, the CDC and its advisors have drafted infection control performance measures for administration, process, and outcomes 43

Outbreak interventions for drug-resistant bugs
Caveats and controversies dog many approaches to deal with a suspected or confirmed outbreak of multidrug-resistant pathogens. The CDC's new draft infection control guidelines include a review of the pros and — more often — the cons of current strategies 44

Fear a consideration in an age of bioterrorism
In conversations that would have not likely occurred prior to Sept. 11 and its aftermath, the CDC and its advisors wrestle with the clinical and psychological implications of bioterror infection control 45

In This Issue **continued on next page**

A first: Infection control draft guidelines emphasize 'performance measures'

CDC also revising approach to resistant bugs

The Centers for Disease Control and Prevention (CDC) is revising its patient isolation guidelines to add new "performance measures" that may be adopted as national quality indicators by patient safety groups, *Hospital Infection Control* has learned.

The CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) reviewed a draft of the new guidelines at a Feb. 25-26 meeting in Atlanta. In updating the 1996 patient isolation guidelines, the CDC and its advisors discussed and revised the second draft of a new *Guideline to Prevent Transmission of Infectious Agents in Healthcare Settings*.[1,2]

There was much discussion of the proposed performance measures, particularly since patient safety groups such as the National Quality Forum in Washington, DC, are beginning to work with HICPAC to add such measures to their quality indicators. The proposed infection control performance measures include administrative directives such as conducting "an annual review of effectiveness of [the] procedures to prevent transmission of infectious agents." **(See list of performance measures, p. 43.)**

The measures, in part, are an effort to reinforce "administrative support for implementation and deployment of these particular recommendations," said **Emily Rhinehart**, RN, MPH, CIC, CPHQ, a consultant to the HICPAC committee and vice president

In This Issue **continued from cover page**

Lab workers face risk of deadly meningitis
Although the exact mechanism of transmission is unclear, failure to use a biosafety cabinet during manipulation of sterile site isolates of *Neisseria meningitidis* threatens lab workers with occupational infections 46

Two patient deaths linked to bronchoscopy
A nationwide recall of bronchoscopes is under way because the equipment has a loose port that may act as a reservoir for *Pseudomonas aeruginosa* infections. 49

Does VRE matter? You bet your life
Vancomycin-resistant enterococci bacteremia is an independent predictor of death, and appropriate antibiotic therapy is associated with improved survival, researchers found. The study unequivocally answers a central question about VRE, the answer to which had previously remained uncertain: Does VRE matter? 50

A nasty strain of VRE transmitted to patients
The authors report the discovery and subsequent nosocomial transmission of a 'superbug' — a strain of linezolid-resistant, vancomycin-resistant *Enterococcus faecium* that was isolated from seven patients. 52

Bioterrorism Watch

Bridging the abyss: Will bioterror close the gap? 1

Was anthrax mailer a bioweapons researcher? 3

2002* HIC *Reader Survey

Patient Safety Alert

COMING IN FUTURE ISSUES

There's the rub: One pathogen poses big problem for alcohol-based hand hygiene

Teach your children: A novel program may start a children's crusade on antibiotic resistance

Smallpox plan reaction: Is CDC using outdated methods?

SHEA hits the slopes: Complete coverage of the annual meeting from Salt Lake City

APIC goes country: Complete coverage from Nashville of the Association for Professionals in Infection Control and Epidemiology

of AIG Consultants in Atlanta. In addition, by breaking out such measures for possible adoption by other quality groups, the guidelines may further solidify the role of the infection control professional in the national patient safety movement.

"Certainly, nosocomial infection is a [patient] safety issue, and this adds one more piece to that puzzle," said **Jane Siegel**, MD, professor of pediatrics at the University of Texas Southwestern Medical Center in Dallas, the HICPAC member spearheading the new guidelines. "[This] picks out the recommendations that we think are the most important to monitor and use as quality indicators. We are really picking out what we think are the three to five most important, high-impact things and then having a measure for that to see if institutions are doing that."

There was some discussion of letting individual facilities select from a list of performance measures, but the prevailing argument was that there should not be an option of selecting some measures and opting out of others.

"[I] thought that this was a distilling of the document to those things — that if you do nothing else — you should be doing to make sure that you're getting the most out of the guidelines," said **Robert Weinstein**, MD, HICPAC chairman and epidemiologist at Cook County Hospital in Chicago. "I think that having a large menu and saying, 'Choose some of these,' really defeats that purpose. This is the first set of guidelines where we are doing this, so I think we will learn as we go."

In revising the 1996 CDC isolation guidelines, HICPAC is trying broaden the recommendations across the continuum of care. The old guidelines, for example, focus almost exclusively on acute care settings. "Accordingly, the revised guideline addresses the entire spectrum of health care delivery sites: acute care settings, special care units within hospitals, long-term care facilities, ambulatory clinics, medical offices, and private residences," the draft guidelines state.

The guidelines strongly underscore the concept of standard precautions for all patients in all settings. With its emphasis on hand hygiene and appropriate use of gloves and other protective equipment, standard precautions form "the essential foundation" for infection control during patient care. Beyond that, additional measures include droplet precautions (e.g., wear mask within 3 feet of patient with pertussis); contact precautions (e.g., place patient with *Clostridium difficile* in private room if possible); and airborne precautions (e.g., tuberculosis patient placed in

CDC drafts performance measures for IC programs

Big three: Administration, process, outcomes

In revising patient isolation guidelines, the Centers for Disease Control and Prevention (CDC) and its advisors have drafted infection control performance measures for health care facilities. While there is some discussion indicating that the measures may be picked up by patient safety groups as quality indicators, the following list from the second draft of the document is expected to undergo further revision and reduction.[1] As currently proposed, the performance measures under discussion include these categories:

A. Administrative Measures
1. Organizational structure that provides for a designated person(s) or group/committee to manage the development, selection, implementation, and monitoring of patient care procedures to prevent transmission of infectious agents.
2. Process that requires an annual review of effectiveness of procedures to prevent transmission of infectious agents including review by an executive committee, senior management, or administration.

B. Process Measures
1. Provision of education and training via orientation and/or annual inservice education to 95% of employed patient care staff.
2. Provision of education and training via orientation and/or annual inservice education to 95% of contracted patient care staff.
3. Standardized observational studies comparing required activities for adherence to standard precautions vs. observed activities. Apply to selected high-risk areas at least annually.
4. Concurrent record review to determine the identification and documentation of the need for enhanced precautions and documentation of the implementation of enhanced precautions in appropriate patients/residents.
5. Retrospective record review, using ICD-9 codes, to determine the identification and documentation of the need for enhanced precautions, and documentation of the implementation of enhanced precautions in appropriate patients/residents.
6. Assessment of availability of waterless hand hygiene products and monitoring amounts purchased for intensive care units.

C. Outcome Measures
1. Use of Occupational Safety and Health Administration (OSHA) 200 logs to identify occupational exposures to airborne infections including tuberculosis. Exposure investigation should determine if lack of diagnosis, lack of implementation of appropriate precautions or lack of compliance contributed to the exposure.
2. Use of OSHA 200 logs to identify occupational exposures to infections spread via the droplet route. Exposure investigation should determine if lack of diagnosis, lack of implementation of appropriate precautions, or lack of compliance contributed to the exposure.
3. Use of health care-associated infection data to identify potential patient-to-patient transmission of infectious agents and multidrug-resistant organisms.

Reference

1. Strausbaugh L, Jackson M, Rhinehart, et al and the Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee. *Guideline to Prevent Transmission of Infectious Agents in Healthcare Settings 2002*. Draft # 2. Feb. 15, 2002. ■

negative-pressure room vented to outside). While very similar to the 1996 recommendations for "transmission-based" precautions, the additional measures now are called "enhanced" precautions. The change involves more than semantics, as the draft document states that "in acute care, an overemphasis on additional transmission-based precautions . . . can diminish the adherence to standard precautions."

Indeed, the emphasis on standard precautions extends to multidrug-resistant organisms, (MDROs), some of which have been treated under contact precautions at many hospitals. The new draft de-emphasizes the necessity of that, stating that contact precautions may be required for drug-resistant infections "in settings with outbreak, unusually vulnerable patients or wounds that cannot be contained with dressings."

In its new view of resistant infections, the CDC is trying to go to a more generic infection control approach instead of issuing guidance for individual pathogens such as the 1995 recommendations for vancomycin-resistant enterococci.

"One of the biggest changes is the way we are trying to present management of [MDROs]," Siegel told *Hospital Infection Control*. "We think it should have practical application, and we are hoping that

Outbreak interventions for drug-resistant bugs

Caveats and controversies dog many approaches

The Centers for Disease Control and Prevention's new draft infection control guidelines include a review of the pros and cons of control strategies to deal with a suspected or confirmed outbreak of multidrug-resistant pathogens.[1] The list includes the following summarized highlights:

Surveillance Measures

1. Screening cultures: patients/residents, including new admissions; health care workers if implicated in transmission or carriage.
   - expensive, time-consuming, and requires laboratory support
   - utilized to define scope of problem and reservoir as well as candidates for enhanced precautions and/or decolonization therapy
2. Molecular typing of isolates from colonized/infected (C/I) patients.
   - technology may not be available
   - results may not be timely
   - expensive, but offers best evidence for presence of an outbreak

Control Measures

1. Contact precautions for C/I patients.
   - necessitates screening to identify all candidates
   - uncertain benefit without timely recognition of C/I patients
   - logistics often difficult
   - difficult to achieve adherence
2. Contact precautions for all C/I new patients entering health care setting and all newly recognized carriers.
   - often impractical
   - requires space, screening, and possibly additional staffing
   - adverse effect of desired socialization in some settings
   - most useful for control of hyperendemic and/or clinically problematic pathogens
3. Cohort C/I patients.
   - necessitates screening to identify all candidates
   - logistics often difficult
   - impractical when multidrug-resistant organism (MDRO) prevalence rates are high
4. Establish isolation areas or wards.
   - seldom practical
   - implies commitment to screening cultures for all new arrivals
   - requires space, additional staffing
   - adverse effect of desired socialization in some settings
5. Cohort health care workers.
   - difficult in most settings;
   - may require screening cultures of all staff
   - increases staffing requirements
6. Enhanced environmental decontamination.
   - considered for management of vancomycin-resistant enterococci (VRE) cases in acute care
   - benefit in reducing transmission unproven

Reduction of Reservoir

1. Exclusion of C/I patients from facility.
   - strategy used by some long-term care facilities
   - not widely recommended
   - may negatively impact care and create hardships for patients
2. Early discharge of C/I patients.
   - may provide benefit in acute care facilities but unproven
   - not applicable in other care settings
3. Decolonization therapy of patients/residents, new admissions, and staff.
   - no agent for VRE or highly resistant gram-negative bacilli
   - not 100% effective for methicillin-resistant *Staphylococcus aureus* and development of resistance to agent(s) used common
   - screening cultures required

Reference

1. Strausbaugh L, Jackson M, Rhinehart, et al and the Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee. *Guideline to Prevent Transmission of Infectious Agents in Healthcare Settings 2002*. Draft #2. Feb. 15, 2002. ■

it will help people to make decisions for their [individual] settings. When we broadly recommended very strict precautions for certain organisms in all settings, it was very difficult to implement and they didn't always control the organisms."

The draft notes that "the experiences of health care facilities with specific MDROs span a spectrum that ranges from no prior isolations on one end to full-blown outbreaks on the other." A wide variety of other facilities fall between these extremes, making a single approach to the problem very difficult.

"We realized that there is not the same solution to the MDRO problem in every setting with every organism," she said. "So [this guideline] gives people some principles upon which they can walk through the process and make decisions as to how they will manage the patients in their setting."

The generic approach represents a "breakthrough" in how the CDC views special pathogens, said **Julie Gerberding**, MD, director of the CDC division of healthcare quality promotion. At the same time, however, she reminded the committee that new and emerging organisms such as vancomycin-intermediate *Staphylococcus aureus* (VISA) warrant special attention and enhanced communication between clinicians and health departments.

"We are not breaking [VISA] out and giving it specific recommendations," Siegel said. "But I think what we will include in response to her comment is some discussion about the fact that when one has a new pathogen for which the epidemiology has not been clearly defined, then it would be prudent to use contact precautions until we know more about that pathogen."

In general, ICPs should have a high index of suspicion and a low threshold for investigation to contend with drug-resistant pathogens, the draft recommends. For example, frequent monitoring of susceptibility patterns for problem pathogens may indicate a problem when the percentage of methicillin-resistant *S. aureus* (MRSA) isolates rises from less than 10% to more than 30%. "Similarly, two or three infections during the course of a month on certain patient care units may signal the advent of an outbreak in some settings, as would even a single infection when colonization rates are known to be increasing," the draft states.

The guidelines acknowledge — but do not really embrace — the myriad additional efforts ICPs are using to combat drug-resistant pathogens. **(See control measures, p. 44.)** For example, attempts to identify and decolonize asymptomatic patients are "controversial because there are no controlled trials to evaluate the benefit of one strategy vs. another," the draft states. "Given the uncertainty about the optimal strategy, individual facilities must select approaches that address their specific problem within the context of their overall goals, available resources, and standards promulgated by state and national organizations."

Despite calls for the CDC to recommend routine patient screening to better identify and control resistant organisms, the HICPAC draft does not endorse the practice.[1] **(See *HIC*, December 2001 under archives at *www.HIConline.com*.)** A key section of the draft guidelines states that "because of their expense and the consequences of their use, e.g., stigmatization of carriers, most authorities would limit their use to problematic situations where their results will dictate a different course of action, e.g., use of contact precautions or cohorting schemes."

And with the guideline trying to extend recommendations across the spectrum of care, the committee is concerned that any recommendations for routine screening will require the resources and the availability of hospital epidemiologists and ICPs to resolve key issues. Those include which patients should be cultured, how should the tests be done, and at what intervals should they be given. "Because of these complexities, routine recommendations for surveillance cultures cannot be issued at this time," the draft concludes.

References

1. Strausbaugh L, Jackson M, Rhinehart, et al, and the Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee. *Guideline to Prevent Transmission of Infectious Agents in Healthcare Settings 2002*. Draft #2. Feb. 15, 2002.

2. Garner JS, Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. *Infect Control Hosp Epidemiol* 1996; 17:53-80, and *Am J Infect Control* 1996; 24:24-52.

3. Farr BM, Salgado CD, Karchmer TB, et al. Can antibiotic-resistant nosocomial infections be controlled? *Lancet Infect Dis* 2001; 1:38-45. ■

Fear is a consideration in an age of bioterrorism

IC policy goes beyond purely clinical concerns

The hair-splitting difficulties of crafting new health care infection control guidelines in an age of bioterrorism were underscored at a recent meeting of the Centers for Disease Control and Prevention's (CDC) Healthcare Infection Control Practices Advisory Committee (HICPAC).

In conversations that would have not likely occurred prior to Sept. 11 and its aftermath, the CDC and its advisors wrestled with the clinical and psychological implications of bioterror infection control. HICPAC is revising patient isolation guidelines and, in doing so, must consider anew the agents of bioterror.

For example, the traditional wisdom is that anthrax cannot spread from person to person. However, there are rare reports of cutaneous anthrax being spread, particularly under Third World conditions when antibiotics may not have

been administered, the committee discussions revealed. Given that, the committee debated whether those infected with cutaneous anthrax should be treated with standard precautions or the more rigorous contact precautions.

But the issue was left unresolved at the meeting, in part, because the purely medical concerns were clouded by the psychological implications.

"My main concern here is not so much whether standard or contact precautions would work," said **William Scheckler**, MD, HICPAC member and epidemiologist at St. Mary's Hospital in Madison, WI. "But [it's] the notion that the public might get, that anthrax can spread willy-nilly from cutaneous lesions. I am more concerned about the fear epidemic than anthrax exposures if we start saying that it requires contact precautions."

In addition, there is the issue of dealing with the incoming patient who reports exposure to a possible anthrax powder. Though, again, the traditional view is that anthrax is not communicable, there is the issue of a health care worker inhaling spores off the person's clothing. Thus, the committee discussed wearing respiratory protection while getting such patients to an area where they can remove their clothes and shower**.** The committee may add a "decontamination section" to the document to address such issues, which must be addressed in the new age of bioterrorism.

"One of the [lessons] that we learned is that you can't tell if a powder is aerosolized or not," said **Julie Gerberding,** MD, director of the CDC division of healthcare quality promotion.

Similar discussions based on threadbare data occurred regarding Ebola. The natural outbreaks in Africa have included cases that suggest the disease can be spread by the airborne route in its latter stages. There are accounts of family members of victims being infected without coming into contact with them. The committee discussed whether to stay with its current recommendations for contact and droplet precautions or recommend airborne precautions (e.g., tuberculosis).

"It seems like this is going to be so rare in the United States that being extreme in terms of the isolation would be reasonable," said **Robert Weinstein**, MD, HICPAC chairman and epidemiologist at Cook County Hospital in Chicago. "If this is a U.S. document [only], I have no problem being more extreme."

While such an approach appears reasonable given the rare natural occurrence of the pathogen, the specter of bioterrorism complicates making such a recommendation.

"You may actually have a situation where it may not be possible to implement airborne precautions on a broad scale," Gerberding reminded.

Thus, despite a strong body of data suggesting that droplet precautions are sufficient, the more rigorous — and difficult to implement — airborne precautions may work their way into bioterrorism documents if the CDC made such a recommendation. ■

Lab workers face risk of deadly meningitis

Lack of biosafety cabinet is a major risk factor

Although the exact mechanism of transmission is unclear, failure to use a biosafety cabinet during manipulation of sterile site isolates of *Neisseria meningitidis* threatens lab workers with an occupational infection that has a 50% mortality rate, the Centers for Disease Control and Prevention (CDC) reports.

"What we found that in nearly all of these cases involved manipulation of the isolate outside of a biosafety cabinet," says **Jim Sejvar**, MD, medical epidemiologist in the CDC's meningitis and special pathogens branch. "We don't understand enough about the transmission to say definitively that this is what causes the laboratory-acquired infections. But it certainly suggests that by manipulating these isolates outside of those enclosures, the laboratorians are putting themselves at greater risk."

Despite the deaths of two lab workers in Michigan and Alabama two years ago, the CDC decided not to officially recommend routine immunization of lab workers for *N. meningitidis*. While urging laboratorians to make "an informed decision" about immunization, the CDC is emphasizing laboratory safety measures with generated aerosols and droplets as the best method to prevent future cases.[1]

The primary problem is that the vaccine does not cover *N. meningitidis* serogroup B, which caused half of the fatal cases recently reviewed by the CDC. The vaccine currently available in the United States covers groups A, Y, and W-135 and C, the type of meningitis that killed the two laboratorians in 2000. **(See case reports, p. 48.)** In its recently published official report of the cases, the CDC concluded: "Although primary prevention should focus on laboratory safety, laboratory

Schedule for Administering Chemoprophylaxis Against Meningococcal Disease

Drug	Age group	Dosage	Duration and route of administration*
Rifampin†	<1 month	5 mg/kg every 12 hours	2 days
	≥1 month	10 mg/kg every 12 hours	2 days
	Adults	600 mg every 12 hours	2 days
Ciprofloxacin§	Adults	500 mg	Single dose
Ceftriaxone	<15 years	125 mg	Single intramuscular dose
Ceftriaxone	Adults	250 mg	Single intramuscular dose

* Oral administration unless otherwise indicated.
† Not recommended for pregnant women because the drug is teratogenic in laboratory animals. Because the reliability of oral contraceptives may be affected by rifampin therapy, consideration should be given to using alternative contraceptive measures while rifampin is being administered.
§ Not generally recommended for persons aged <18 years or for pregnant and lactating women because the drug causes cartilage damage in immature laboratory animals. However, ciprofloxacin can be used for chemoprophylaxis of children when no acceptable alternative therapy is available.

Source: Centers for Disease Control and Prevention. Laboratory-Acquired Meningococcal Disease — United States, 2000. *MMWR* 2002; 51:143.

workers also should make informed decisions about vaccination. The quadrivalent meningococcal polysaccharide vaccine . . . will decrease but not eliminate the risk for infection. Research and industrial laboratory scientists who are exposed routinely to *N. meningitidis* in solutions that might be aerosolized also should consider vaccination. In addition, vaccination might be used as an adjunctive measure by microbiologists in clinical laboratories."

Two cases lead to 16 others

As previously reported in *Hospital Infection Control*, the unrelated cases shocked medical communities in Huntsville, AL, and Lansing, MI, because two experienced and highly regarded laboratorians died after occupational exposures to the pathogen**. (See *HIC*, April 2001 under archives at *www.HIConline.com*.)** The CDC found in investigating the two deaths that 16 previously unreported cases of probable *N. meningitidis* infection occurred in laboratories over the prior 15 years.

Of those, nine (56%) were caused by *N. meningitidis* serogroup B, and seven (44%) were caused by serogroup C. Overall, eight cases (50%) were fatal, three from serogroup B and five from serogroup C, the CDC reported.[1]

"[The vaccine] does not protect against serogroup B, which in this [report] was responsible for half of the laboratory-acquired cases," Sejvar says. "I think as opposed to focusing on vaccination as the primary method of prevention, we need to be focusing on laboratory safety. Anecdotally, of the laboratorians I have talked to, most of them are choosing to receive the vaccine. I think that is a very wise decision, but we felt that the more reasonable approach was to emphasize the laboratory safety issues and not the vaccine issues."

The identification of the previously unreported cases suggests that either cases of laboratory-acquired meningococcal disease are underreported or on the increase, the CDC concluded. In addition, the case-fatality rate of 50% is substantially higher than that observed among community-acquired cases. That might reflect underreporting of mild cases or might be a result of the highly virulent strains and high concentration of organisms encountered in the laboratory setting, the CDC speculated. Is there another group out there of less serious, unreported laboratory infections?

"We have no idea," he says. "That's partially the issue. If anything, this is probably an underestimation. In general, where you do passive surveillance like this, you are going to catch the severe cases because they come to people's attention."

In 15 of the 16 cases, the laboratory workers reportedly did not perform procedures within a

Occupational infection fells two lab workers

CDC case reports of fatal meningitis infections

The Centers for Disease Control and Prevention (CDC) recently issued detailed case reports of two fatal laboratory infections due to *Neisseria meningitidis*. The case reports are summarized as follows:

CASE 1. On July 15, 2000, a 35-year-old Alabama microbiologist presented to a hospital emergency department with acute onset of generalized malaise, fever, and diffuse myalgias. The patient was given a prescription for oral antibiotics and released. On July 16, the patient returned to hospital A, became tachycardic and hypotensive, and died three hours later. Blood cultures were positive for *N. meningitidis* serogroup C.

Three days before the onset of symptoms, the individual had prepared a Gram's stain from the blood culture of a patient who was subsequently shown to have meningococcal disease. The microbiologist also had handled and subcultured agar plates containing cerebrospinal fluid (CSF) cultures of *N. meningitidis* serogroup C from the same patient. Co-workers reported that in the laboratory, aspiration of materials from blood culture bottles was performed at the open laboratory bench. Biosafety cabinets, eye protection, or masks were not used routinely for this procedure. Results of pulsed-field gel electrophoresis (PFGE) and multilocus enzyme electrophoresis testing at the CDC indicated that the two isolates were indistinguishable. The laboratory at hospital A infrequently processed isolates of *N. meningitidis* and had not processed another meningococcal isolate during the previous four years.

CASE 2. On Dec. 24, 2000, a 52-year-old Michigan microbiologist had acute onset of sore throat, vomiting, headache, and fever. By the next day the patient had developed a petechial rash on both legs, which quickly evolved to widespread purpura. The patient presented to a hospital emergency department and died later that day of overwhelming sepsis. Blood cultures were positive for *N. meningitidis* serogroup C. The patient was a microbiologist in the state public health laboratory and had worked on several *N. meningitidis* serogroup C isolates during the two weeks before becoming ill. That laboratory had handled a median of four meningococcal isolates per month during the previous four years. Co-workers reported that the worker had performed slide agglutination testing and recorded colonial morphology using typical biosafety level 2 (BSL 2) precautions, which do not entail the use of a biosafety cabinet. PFGE was performed at the state public health laboratory and at CDC on all four specimens handled by the microbiologist. The isolates from the worker and from one of the recently handled laboratory samples were indistinguishable.

Reference

1. Centers for Disease Control and Prevention. Laboratory-Acquired Meningococcal Disease — United States, 2000. *MMWR* 2002; 51:141-144. ■

biosafety cabinet. It appears that exposure to isolates of *N. meningitidis* — and not patient samples — increases the risk for infection. Nearly all the microbiologists were manipulating isolates and performing subplating with an inoculation loop on an open laboratory bench. *N. meningitidis* is classified as a biosafety level 2 organism.

Current lab guidelines do not recommend the routine use of a biosafety cabinet for isolate manipulation. A biosafety cabinet is recommended for mechanical manipulations of samples that have a "substantial risk" for droplet formation or aerosolization such as centrifuging, grinding, and blending, the CDC notes.

The nation's major lab groups such as the Washington, DC-based American Society for Microbiology will discuss possible guideline revisions based on the findings, according to the CDC. In light of the cases, the CDC currently recommends that "if a biosafety cabinet or other means of protection is unavailable, manipulation of these isolates should be minimized, and workers should consider sending specimens to laboratories possessing this equipment."

The CDC recommends also that lab workers' percutaneous exposure to an invasive *N. meningitidis* isolate from a sterile site should receive treatment with penicillin. Those with known mucosal exposure should receive antimicrobial chemoprophylaxis. **(See table, p. 47.)** Microbiologists who manipulate invasive *N. meningitidis* isolates in a manner that could induce aerosolization or droplet formation (including plating, subculturing, and serogrouping) on an open bench top and in the absence of effective protection from droplets or aerosols also should consider antimicrobial chemoprophylaxis. The CDC continues prospective surveillance for laboratory-acquired meningococcal disease. Hospitals, laboratories, and public health departments that are aware of suspected cases should report these cases through their state public health department to the CDC at (404) 639-3158.

Reference

1. Centers for Disease Control and Prevention. Laboratory-Acquired Meningococcal Disease —- United States, 2000. *MMWR* 2002 51:141-144. ■

Two patient deaths linked to bronchoscopy

Faulty scopes recalled by U.S. manufacturer

A nationwide recall of bronchoscopes is under way because the equipment has a loose port that may act as a reservoir for *Pseudomonas aeruginosa* infections, the Centers for Disease Control and Prevention (CDC) reports.

Investigators at Johns Hopkins University in Baltimore notified the CDC of *Pseudomonas aeruginosa* infections and colonizations that may be associated with the defective bronchoscopes. On Nov. 30, 2001, Olympus America Inc. issued a voluntary recall of defective Olympus bronchoscopes with the loose port. The recall involved these models: BF-40, BF-P40, BF-1T40, BF-3C40, BF-XP40, BF-XT40, BF-240, BF-P240, BF-1T240, BF-6C240, BF-160, BF-P160, BF-1T160, BF-3C160, and BF-XT160.

A group of approximately 410 Johns Hopkins patients underwent bronchoalveolar lavage between June 1, 2001, and Feb. 4, 2002. Many of the patients were critically ill at the time of their procedures, all of which took place in the same endoscopy lab in the hospital. Bacterial contamination was confirmed in three of seven bronchoscopes used for examining these patients. In early February, officials at Johns Hopkins became aware of a national recall notice sent out earlier by Olympus to hundreds of hospitals. The notice was prompted by a report from another medical center of bacterial contamination in its bronchoscopes.

In its recall notice, Olympus noted that a loose port on certain bronchoscopes might have permitted the contamination to occur. *(See www.olympusamerica.com.)* Four of the seven scopes used by Johns Hopkins, including the three in which contamination was found, were subject to this recall.

Preliminary findings indicate that about 100 of the approximately 410 patients in the group have tested positive for exposure to pseudomonas, a two- to three-fold greater incidence than expected for this organism in this group of patients.

Infections related to the contaminated scopes may have contributed to the deaths from pneumonia of two already critically ill patients, according to a statement issued by Johns Hopkins. ■

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ABSTRACT & COMMENTARY

Does VRE matter? You bet your life

A 'Rodney Dangerfield' bug finally gets respect

Synopsis: VRE bacteremia is an independent predictor of death, and appropriate antibiotic therapy is associated with improved survival**.** **(See related journal review, p. 52.)**

Source: Vergis E, et al. Determinants of vancomycin resistance and mortality rates in enterococcal bacteremia. A prospective multicenter study. *Ann Intern Med* 2001; 135:484-492.

Abstract: The authors performed a prospective observational study of patients with enterococcal bacteremia at four academic medical centers and one community hospital in order to determine whether vancomycin resistance is an independent predictor of death as well as whether outcome is affected by appropriate antibiotic therapy.

Sixty percent of the 398 bloodstream isolates were *Enterococcus faecalis* and 37% *E. faecium*; 35% of the 398 were vancomycin-resistant (VRE; MIC ³ 32 µg/mL), while 2% were intermediate (MIC 8-16 µg/mL). Eight percent of *E. faecalis* and 80% of *E. faecium* were vancomycin-resistant. Eighty-seven percent of *E. faecium* were resistant to ampicillin, 60% had high-level gentamicin resistance, and 22% had reduced susceptibility to quinupristin/dalfopristin. Linezolid was not tested in the study.

Thirty-eight percent of the 147 patients with VRE bacteremia and 49% of those with susceptible enterococcal bacteremia had more than one organism recovered in blood culture. Infection at an abdominal site other than the biliary tract was four times more common (20% vs. 4%) in the patients with VRE bacteremia compared to those with susceptible isolates.

Vascular catheters were the most common site of infection in the former group and the second most common site in the latter. Endocarditis was present in 3% of patients in each group.

Multivariate analysis found that the independent risk factors for VRE bacteremia were receipt of vancomycin within the previous 14 days, receipt of glucocorticosteroids within the previous 14 days, and the severity of illness (APACHE II score). Risk factors for death within 14 days were the presence of an underlying hematologic malignancy, vancomycin resistance, and severity of illness.

Bacteriological failure was more common with

CE/CME questions

Save your monthly issues with the CE questions in order to take the two semester tests in the June and December issues. A Scantron sheet will be inserted in those issues, but the questions will not be repeated.

13. In revising its patient isolation guidelines, the CDC has drafted new guidance that:
    A. adds new performance measures
    B. broadens the recommendations across the continuum of care
    C. takes a more generic approach to multidrug-resistant organisms
    D. all of the above

14. The guidelines strongly underscore the concept of which kind of precautions for all patients in all settings?
    A. standard
    B. contact
    C. droplet
    D. airborne

15. Despite the deaths of two lab workers in Michigan and Alabama two years ago, the CDC decided not to officially recommend routine immunization of lab workers for *Neisseria meningitidis*. The primary problem is that the vaccine does not *cover N. meningitidis* serogroup:
    A. W-135
    B. A
    C. Y
    D. B

16. Researchers reported the nosocomial transmission of a strain of vancomycin-resistant *Enterococcus faecium* that was resistant to six drugs. Which of the following antibiotics was the VRE strain susceptible to?
    A. linezolid
    B. ampicillin
    C. quinupristin/dalfopristin
    D. streptomycin

VRE infection (12/16 vs. 4/16). In a multivariate analysis restricted to 208 patients with monomicrobial VRE bacteremia, APACHE II score was a risk factor for 14-day mortality, while receipt of appropriate antibiotic therapy within 48 hours of the initial positive blood culture was protective.

Comment by Stan Deresinski, MD, FACP, associate professor of medicine, Stanford (CA) University.

This study addresses a central question related to VRE, the answer to which had previously remained uncertain: Does VRE matter? Previous studies have resulted in varying answers. For instance, a case control study identified VRE bacteremia as being associated with greater all-cause mortality than was bacteremia with vancomycin-susceptible strains.[1]

However, other studies have found that, although patients with VRE bacteremia do, indeed, have greater overall mortality, vancomycin resistance is not an independent predictor of mortality and is more likely simply a marker of the severity of comorbidity.[2]

The paper under review authoritatively answers the question of the relevance of VRE bacteremia in the affirmative. They have demonstrated that VRE bacteremia and lack of effective antibiotic therapy active against VRE in patients with bacteremia are each independent risk factors for mortality.

These observations have important implications. First, vigorous attempts to prevent patient acquisition of VRE are warranted. This means implementation of effective infection control practices to limit the spread of VRE and control of use of relevant antibiotics that predispose to colonization with VRE, especially vancomycin. It also means that strong consideration be given to screening of high-risk patients for colonization with VRE.

The results of this study also demonstrate that a low threshold for administration of antibiotics likely to be active against VRE must be maintained in the appropriate settings. Thus, in institutions in which VRE are prevalent, the presence of organisms morphologically compatible with enterococci observed on Gram staining of blood culture should trigger the use of an antibiotic likely to be effective against VRE, at least until definitive microbiological data are available. This is likely to be a policy unpopular with those responsible for the pharmacy budget, since the antibiotic most reliably active against VRE is linezolid.

In 2000, the average wholesale cost of a 600 mg vial of linezolid was $72 and that of a 600 mg tablet was $53.[3]

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1. Bhavnani SM, et al. *Diagn Microbiol Infect Dis* 2000; 36:145-158.
2. Lautenbach E, et al. *Infect Control Hosp Epidemiol* 1999; 20:318-323.
3. *Medical Letter* 2000; 42:45-46. ■

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JOURNAL REVIEW

A nasty strain of VRE transmitted to patients

DNA mutation enables resistance to six drugs

Herrero IA, Issa NC, Patel R. **Nosocomial spread of linezolid-resistant, vancomycin-resistant *Enterococcus faecium***. *N Eng J Med* 2002; 346:867-869.

The authors report the discovery and subsequent nosocomial transmission of a "superbug" — a strain of linezolid-resistant, vancomycin-resistant *Enterococcus faecium* that was isolated from seven patients. All isolates carried the vanA gene and were resistant to linezolid (minimal inhibitory concentration [MIC], 16 µg per ml), ampicillin, penicillin, gentamicin, streptomycin, and vancomycin. Fortunately, the strain was susceptible to quinupristin/dalfopristin and the investigational agents oritavancin and tigecycline.

The multidrug-resistant strain was first identified in a liver-transplant recipient whose course was complicated by hepatic-artery thrombosis and an intra-abdominal infection with vancomycin-resistant enterococcus, for which he received linezolid. The strain was subsequently nosocomially transmitted to six other patients, none of whom had overt linezolid-resistant, vancomycin-resistant enterococcal infections or had been treated with linezolid.

Five of the six patients were hospitalized in the same transplantation unit as the index patient. Only private rooms were available in this unit, and all health care workers entering the patients' rooms were required to wear gloves. After the identification of carriers of vancomycin-resistant enterococci, all personnel entering the patients' rooms were required to wear gloves and gowns.

In preclinical studies, linezolid was active against all enterococci tested. In the isolates the researchers identified, resistance to linezolid was associated with a DNA mutation that previously had been described in linezolid-resistant, laboratory-derived mutant strains of *E. faecalis* (but not *E. faecium*). "The emergence of linezolid-resistant, vancomycin-resistant *E. faecium* as a result of selective pressure is of concern," the authors conclude. "The spread of this multidrug-resistant organism in health care settings is of even greater concern. Our results suggest that the susceptibility of vancomycin-resistant enterococci to linezolid should be determined if the use of linezolid therapy is anticipated, that linezolid should be used prudently, and that there is an ongoing need for the development of agents that are active against vancomycin-resistant enterococci." ■

CE objectives

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

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

BIOTERRORISM WATCH

Preparing for and responding to biological, chemical and nuclear disasters

Building a bridge over the abyss: Will bioterrorism help bring disjointed health system together?

Getting in same boat as 'tsunami' of money builds

Diverse and disjointed, the nation's public health and clinical settings have education needs and communication gaps that must be bridged if the system is to improve its response to bioterrorism, a group of consultants recently told the Atlanta-based Centers for Disease Control and Prevention (CDC).

The CDC's national center for infectious diseases is holding a series of meetings to assess the lessons of last year's anthrax attacks and begin to close the long-standing breach between public health and clinical medicine.

The gap may stem from differences between the private and public health care systems, both of which are fragmented and highly variable by geography and urban vs. rural settings, according to a CDC draft summary of the Jan. 7, 2002, consultants' meeting, which was obtained by *Bioterrorism Watch.*

Seeking collaboration

"There was lot of [discussion] about the gap between public health, private practices, and hospitals and how to bridge that gap and make things more collaborative," said **William Scheckler**, MD, a consultant at the meeting and hospital epidemiologist at St. Mary's Hospital in Madison, WI. "[We need] to reduce some of the redundancies in the systems both in terms of preparing and education."

Scheckler also is a member of the CDC Healthcare Infection Control Practices Advisory Committee (HICPAC), which met Feb. 25-26, 2002, in Atlanta.

Scheckler gave a report on the consultants' meeting, telling HICPAC members that the CDC had input from a broad range of bioterrorism groups and clinical specialties. There is a wealth of information scattered among these groups and on numerous web sites, he noted. For example, a dermatology group at the meeting has photographs of skin lesions that could be a good resource in an investigation of cutaneous anthrax.

"When an outbreak occurs, the same questions [arise]: What do people need to know? What is the best way to get out the information?" he said. "There should be one best-practices web page that you can go to."

The CDC currently operates several different clearinghouses for information as well as different public inquiry numbers. The agency now is considering the possibility of centralizing its clearinghouses and public inquiry services, the CDC report states.

"During the anthrax crisis, the CDC public inquiry system was overwhelmed, and therefore the agency set up a new system during the outbreak," the CDC report continues.

In addition, the CDC found that "during the attacks, the amount of information on anthrax increased from virtually nothing to an overwhelming number of e-mails, web sites, printed

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documents, and other materials. Much of this information and work was duplicative."

The consultants suggested that the CDC devise a strategy to centralize information development activities and then distribute the product, rather than having so many individuals working independently. **(See CDC action items, below right.)**

Linking the data base

Regarding public health and clinical partnerships, a relatively simple system of linking health departments with hospital emergency departments (ED) was described by HICPAC member **Alfred DeMaria Jr.**, MD, state epidemiologist at the Massachusetts Department of Public Health in Jamaica Plain.

Under the program, participating hospitals in the Boston area report their daily number of ED visits to the health department. The numbers are compared against emergency visits a week earlier and on the same date a year prior to detect surges that might suggest a bioterrorism event, he said.

The information is easily obtainable by the hospitals and can be submitted electronically to the health department without extra work. That is important because bioterrorism surveillance systems that are labor-intensive will likely falter as vigilance inevitably wanes, DeMaria noted.

The system has provided the secondary gain of improving communication between public health and clinical sectors. The threshold for investigation occurs at two orders of magnitude above baseline, which thus far has occurred with influenza ED visits and those associated with a large trauma event such as a bus crash, he said.

Sometimes, the threshold will be reached simply out of random chance, as ED visits increase for no single reason. "The question is, we don't know how big an event has to happen [to be detected]," DeMaria said.

The CDC is interested in such bioterrorism surveillance systems, and also may seek to apply its existing hospital sentinel networks, including the National Nosocomial Infections Surveillance system, said **Steve Solomon**, MD, chief of special studies activity in the CDC division of healthcare quality promotion.

National concerns about patient safety and bioterrorism have created a "tsunami of money" to address such issues, Solomon told HICPAC members.

"We have a lot of concerns about the surveillance and response needs," he said. "We are seeking a small trickle of that tidal wave of funds."

Ultimately, the CDC may help shape a national system or contribute to a "mosaic" of systems that track surrogate markers such as severity of illness in "real time," he said.

The research and development needs for such a system are in the ballpark of $120 million to $180 million, which may be available in the current climate over the next four or five years, he said. There is considerable interest being expressed from health care-related industries in partnering with the CDC on such efforts.

"They are standing in line," Solomon told HICPAC members. "The phone is ringing off the hook. We are trying to figure out who is the best partner." ■

CDC gets plenty of advice for action

Clarify roles, make info user-friendly

A recent consultants' brainstorming session on education and communication needs for bioterrorism resulted in numerous suggestions to the Centers for Disease Control and Prevention (CDC) in Atlanta. Some of the points of information and recommended items for action included:

- ✔ Strengthen the CDC Health Alert Network e-mail notification system to ensure that all state and local health departments are involved.
- ✔ Make surveillance and reporting as automatic as possible, and do not depend on the clinician to initiate the report quickly.
- ✔ Because the CDC is recognized as an authoritative source for information provided through *Morbidity and Mortality Weekly Report* and press releases, the CDC web site should be changed to make it more user-friendly.
- ✔ Ruling out disease is the most important clinical issue, rather than identifying new cases of disease.
- ✔ Clarify roles when a criminal investigation is going to occur during a public health emergency.
- ✔ Develop a prototype disaster plan for use by communities and make it readily available.
- ✔ The cacophony of information is a problem. For clinicians, an appropriate tool would be a page of bulleted information necessary for the

clinical setting. This should be provided in addition to baseline information.

✔ The CDC smallpox plan is a good model for allowing outside review during the development phase.

✔ Identify additional ways for using communication technology, particularly e-mail, to link local resources together. ■

Was anthrax mailer a bioweapons researcher?

'This has military lab stamped all over it'

Given the difficulty of creating high-quality anthrax in a civilian research lab, the original source of the *Bacillus anthracis* that killed five people last year was likely a U.S. bioweapons facility, the president of the American Society of Microbiology (ASM) tells *Bioterrorism Watch*.

"Given the high quality of the preparation that was used, this has military laboratory stamped all over it," says **Abigail Salyers**, PhD, ASM president and a professor of microbiology at the University of Illinois in Urbana-Champaign.

The U.S. bioweapons program was formally disbanded as part of a global treaty in the early 1970s, but many military labs remained open for "biodefense" research to counter bioterrorism, she says. "These anthrax spore preparations last for decades," Salyers says.

Anthrax mailer is 'criminal, but not stupid'

The atmosphere of a university research lab is too open and freewheeling for someone to produce anthrax undetected, she says. Salyers' personal theory is that someone who worked in a military bioweapons laboratory stole the anthrax, possibly years ago.

"It's anybody's guess as to what is going on here, but I would be astounded if this came out of a university laboratory," she says. "[This person] is crazy, criminal, but not stupid. I can't imagine that anybody who was going to do that would take the trouble and risk of trying to do that in a university laboratory environment."

In a related matter — despite a published report to the contrary — the Federal Bureau of Investigation denies it has narrowed its anthrax investigation to a former scientist in a U.S. bioweapons lab.

A FBI spokeswoman at the agency's national office in Washington, DC, told *Bioterrorism Watch* that the agency has not identified "a prime suspect" in the hundreds of interviews it has conducted in the investigation.

A story that was published in the Feb. 25, 2002, *Washington Times* reported that the FBI's search was focusing on a former U.S. scientist who worked at a government bioweapons laboratory. The government's chief suspect, the article reported, is believed to have worked at the U.S. Army Medical Research Institute of Infectious Diseases at Fort Detrick, MD, which has maintained stores of weapons-grade anthrax. No charges had been filed as this issue of *Bioterrorism Watch* went to press.

Do you know this person?

Salyers described her theory on the case — before the newspaper report was published — when the FBI openly solicited help from the ASM in the investigation. In a message appealing for help from ASM members, **Van Harp**, assistant director of the FBI's Washington, DC, field office, said "a single person" is most likely responsible for the mailings. "It is very likely that one or more of you know this individual," he told ASM members.

A $2.5 million dollar award is offered to anyone providing information that leads to an arrest of the bioterrorist. The FBI profile describes a socially withdrawn person who has "a clear, rational thought process" and is very organized. "The perpetrator might be described as 'standoffish' and likely prefers to work in isolation as opposed to a group/team setting," Harp told the ASM. It is possible the mailer used off-hours in a laboratory or may have even established an improvised, concealed facility to produce the anthrax, the FBI profile noted.

"The person is experienced working in a laboratory," Harp told the ASM. "Based on his or her selection of the Ames strain of *Bacillus anthracis,* one would expect that this individual has or had legitimate access to select biological agents at some time. This person has the technical knowledge and/or expertise to produce a highly refined and deadly product."

Indeed, the Ames strain used in the attacks has been used in bioweapons research both in the United States and worldwide, Salyers says. In

addition, given the elaborate research protocol required, it is unlikely a university laboratorian creating anthrax would go undetected no matter how "standoffish" he or she was.

"I'm just telling you what you have to go through if you were crazy enough to be a bioterrorist," Salyers says. "If a deranged scientist tried to do this in a university laboratory, red flags would be going up all along the way."

Recipe for disaster

The first step — cultivating the bacteria and producing spores — is something that almost any microbiologist could do, she says.

"But you get this slush, and that is not going to hurt anybody," she says. "There are people who will tell you that you can do this the hard way with a mortar and pestle and grind it up in the laboratory. But it is clear that the powder that was in the letters was a much higher quality than that."

The anthrax "slush" must be ground into a fine powder to be capable of getting past human respiratory defenses. "The machinery for doing this is mostly in military research laboratories," Salyers says. In addition, sophisticated treatment of the spores must be done to defeat their general property of clumping and sticking together.

"You would want to treat the spores so that they don't stick together and also so that you get a preparation that is very volatile — goes into the air and stays in the air," she adds.

Regardless of whether the mailer worked in a military lab or other facility, there is growing consensus that the attacks were not the work of foreign terrorists.

"The current thinking among many people is that this is a domestic event that kind of occurred in the slipstream of 9/11," says **William Schaffner**, MD, ASM member and chairman of preventive medicine at the Vanderbilt University School of Medicine in Nashville, TN.

"The [FBI profile] characteristics don't seem terribly surprising. They seem akin to the kind of characteristics that were part of the picture of [the Unabomber] Ted Kaczynski — a disgruntled person who is very bright, and in this instance, has a substantial amount of professional and technological expertise in order to carry this off."

[Editor's note: Those who think they may have information relevant to the case can contact the FBI via telephone at (800) CRIME TV — (800) 274-6388 — or via e-mail: Amerithrax@FBI.gov.] ■

Bioterrorism forensics: The burden of proof

If bug does not fit, you must acquit?

Already asked by federal investigators to assist in finding the anthrax mailer, the American Society of Microbiology (ASM) is taking the next step and discussing the emerging science of bioterrorism forensics.

Despite an impressive array of scientific methods, primarily used in health care epidemiology and outbreak investigations, linking a pathogen to a terrorist will not be easy.

"You want to trace it back to the 'smoking gun,' says **Abigail Salyers**, PhD, ASM president and a professor of microbiology at the University of Illinois in Urbana-Champaign. "We know how to tell what bullet came from what particular gun. But when it is bacteria, viruses, or other microorganisms we really don't have established forensics for that."

To address the issue, the ASM will hold meetings later this year that may result in a booklet on how to use molecular epidemiology techniques to establish a chain of evidence rather than identify the source of an outbreak, she says.

The methods typically used by outbreak investigators include DNA fingerprinting and pulsed-field gel electrophoresis. But using such methods to link a bioterrorist to a biological weapon would be unprecedented, Salyers notes. "Suppose they find somebody [who] might have perpetrated the [anthrax attacks], and they find some spores on that person or the immediate environment."

"Trying to prove that that is the [exact strain] will be unprecedented. It is not just a question of finding the person. It is a question of what are going to be the legally binding types of evidence," Salyers explains.

Another problem in the anthrax attacks is the separation of act and outcome, she says. As opposed to a bomb exploding and leaving an immediate impact, the anthrax mailer had time to dispose of evidence after the mailings.

"You have a perpetration of an act and the consequences of the act separated by nearly a month," she says. "There has been a lot of time for the perpetrator to cover up tracks. This is very different from putting nerve gas into a subway system, where the cause and effect are very close together," Salyers adds. ■

PATIENT SAFETY ALERT™
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Early results of Leapfrog hospital survey promising

Nearly half of institutions contacted provided replies

In mid-2001, a total of 525 hospitals in six regions around the country were invited to complete a web-based patient survey by the Business Roundtable's The Leapfrog Group in Washington, DC.

Now, the first returns are in, and The Leapfrog Group's top official says she is encouraged by what she sees.

"Overall, the results are very promising," said **Suzanne F. Delbanco**, PhD, executive director, during a press briefing held Jan. 17, 2002. "Nearly half of the hospitals that we invited to take the survey submitted responses (241, or nearly 48%). That's an enormous achievement."

53% meet standards

What's even more exciting, she added, is that of the hospitals that responded, 53% already met at least one of Leapfrog's standards for three key safety practices: The use of computerized physician order entry (CPOE); staffing intensive care units (ICU) with intensivists; and evidence-based hospital referral.

By practice, the results broke down as follows:

- Of the responding hospitals, 3.3% have instituted CPOE.
- About 10% of the responding hospitals have fully implemented the intensivist model, and another 18% indicated plans to enlist intensivists by 2004.
- In terms of specific volume recommendations, 12% meet Leapfrog's recommended level of annual experience for coronary artery bypass graft; 31% for coronary angioplasty; 21% for abdominal aortic aneurysm repair; 20% for carotid endarterectomy; 15% for esophageal cancer surgery; and 22% have neonatal ICUs that meet Leapfrog's recommendations.

The six targeted regions include urban hospitals in Atlanta, California, East Tennessee, Minnesota, St. Louis, and Seattle-Tacoma-Everett. Three of the six regions (California, East Tennessee, and Minnesota) reported having at least one hospital with a fully implemented CPOE. Five of the six (California, East Tennessee, Minnesota, St. Louis, and Seattle) have at least one hospital that has fully implemented the ICU physician staffing or intensivist practice.

The greatest impact

The three standards were selected because, according to Leapfrog members, the greatest impact could be made on patient safety in the shortest period of time. If implemented, nearly 60,000 lives could be saved each year and more than half a million serious medication errors could be prevented, the group claims.

"CPOE has been shown to reduce serious medical errors by more than 50%. Staffing intensive care units with intensivists has been shown to reduce the risk of patients dying in the ICU by more than 10%. Appropriate referrals for high-risk procedures and conditions can reduce the risk of a patient dying by at least 30%," Delbanco declared.

Private industry is an integral part of this effort, and companies have their own incentives for participating, noted **Charles R. Lee**, chairman and co-CEO of New York-based Verizon Communications.

"We have two standpoints. First, we care about our employees and our retirees, and their

dependents, and their families," he said.

"The other one is the whole matter of quality. Quality is a never-ending journey. You're never satisfied with the current results; you always want to get better and do better. It's a standard practice in big corporations. We hope that we can, over time, develop relationships with some of the institutions that are involved in the medical profession to move them forward."

Sharing the information

Now that Leapfrog has this survey information, the next step is to share it with specific stakeholders. "Our members are going to share it with their employees, retirees, and dependents, through internal communications like newsletters, benefits materials, and corporate web sites," Delbanco said.

She also noted that Leapfrog, with the help of the Portland, OR-based Foundation for Accountability, has created a consumer test and tool kit that members, health plans, physicians, and others can use and customize to educate consumers. The hospital information is being made available to the public on the group's web site www.leapfroggroup.org.

Delbanco noted that sharing these results fulfills a commitment not only to consumers but also to the hospitals that took the time to complete the survey.

"Sharing this information is only part of what we're doing with hospitals," she added.

"In some cases, our members will offer financial incentives to hospitals to implement the Leapfrog practices, as well as other types of reward and recognition," Delbanco said.

Such strategies are, of course, intended to engender change at the institutional level, which is critical to the success of Leapfrog's efforts. The survey information "is only significant if people change behavior," noted **John Rother**, director of policy and strategy for the Washington, DC-based American Association of Retired Persons (AARP).

"It's only significant if the hospitals respond not only to a request for information but start to implement these changes to save lives." **(Some institutions and health care organizations already have; see article, at right.)**

It's also important for all of us, as patients and family members, to pay attention to the information and make decisions based on it, Rother noted.

"Do not send your parent to a hospital that's refusing to give this kind of information," he warned. "Do not send a family member to a hospital for an operation where we know that another hospital in your area does it better — a lot better. These choices are life and death decisions."

[For more information, contact:

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Putting safety principles into practice

Incentivizing safety efforts

When it comes to safety, theory is nice but results are better. Two panelists at the Leapfrog Group press briefing reported how they have given teeth to safety principles with transformative initiatives.

Michael A. Stocker, MD, MPH, CEO of Empire Blue Cross and Blue Shield in New York City, described an innovative incentive program being undertaken in his area.

"We represent about 100,000 employees and dependents in the New York City area," he said.

Making it worth the effort

"Those hospitals that meet the computerized physician order-entry (CPOE) standard and the enclosed ICU [intensive care unit] standard will receive a 4% bonus on all income that we provide to them if, in fact, they fulfill these standards. We are actually going to send a check quarterly to the CEO to make the point to the hospitals in the area." In the second year, a 3% bonus will be provided, and a 2% bonus will be paid in the third year, he added.

Why is Empire Blue Cross and Blue Shield doing this? "From its inception, what we really

liked about The Leapfrog Group's standards is the fact that they are evidence-based," Stocker noted.

"The evidence is simply overwhelming; one large company estimates that one or two of their employees died because of medical errors every day, including retirees and dependents," he said.

Because the standards are evidence-based, he continued, "Everybody can intuitively understand what it means if you have a volume standard, what enclosed ICUs mean, if you have intensivists [who] are available and [CPOE]. Second, it can be done anywhere. You could do this all across the country, and our hope, of course, is that's what's going to happen."

CPOE implementation

At Cedars-Sinai Health System in Los Angeles, CPOE is about to become a reality. "We've been working on it for about two years, and it's set to go live in May of this year," reported **Michael L. Langberg**, MD, FACP, chief medical officer and senior vice president for medical affairs.

The medical executive committee at Cedars-Sinai passed a motion in January that basically would suspend a physician's ability to practice in the institution if the physician was not certified competent in his or her ability to use the CPOE system by the time it goes live.

"The reason for doing this is not punitive," Langberg explained. "It's a very strong belief in the marriage of a physician order-entry system with clinical decision support. So at the time physicians submit an order to the hospital, they will have available to them all the important information to make the best judgment or choice for their patients.

"Once we establish that standard, all patients and all physicians will have to be involved in that kind of support in real time," he said.

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Safety tool stresses education and action

Tragedy transforms facility into industry model

Two tragic medication errors seven years ago prompted Dana-Farber Cancer Institute in Boston to undertake what CEO **Jim Conway** calls "a journey of change."

That journey has led to industrywide praise and recognition, including the recent awarding to Conway of one of the two inaugural Individual Leadership in Patient Safety Awards from the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance.

Among Conway's most notable accomplishments was the development of a patient safety self-assessment tool that encourages executives to initiate improvements proactively rather than to wait for the occurrence of adverse events to force action.

In early 1995, Dana-Farber discovered that two patients had received massive chemotherapy overdoses. As one of those patients was Betsy Lehman, a well-known health reporter for the *Boston Globe*, the events received extensive media coverage, including 28 front-page stories in the *Globe*. The question on everyone's lips seemed to be, "How could such a bad thing happen at Dana-Farber, and to such an informed patient?"

This led to what Conway calls "a journey of change for our leadership and staff." Naturally, he says, Dana-Farber carried the burden of these events, but that was not enough.

"It was also our responsibility to learn all we could about why our system failed," Conway says. The events, he says, took on significant power, driving health professionals across the country to learn about medical errors.

"It's mentioned in the first sentence of the executive summary of the [Institute of Medicine] report [*To Err Is Human*]," Conway notes. "It was not only a sentinel event, but a seminal event."

The development of the safety tool grew out of the ongoing process of change. "Myself, the chief of nursing, the staff, the directory of pharmacy, the director of risk management, and others have all spoken on the subject extensively," Conway notes.

"We get two common questions from health care leaders. The first is, 'In the absence of high-profile events, how do you create the tension for

change?' The second issue we hear is something like this: 'You would never catch my boss standing in a public forum and talking about *our* stuff!' We have talked a lot about the gap between excellence and perfection," he explains.

It was not surprising then that last November, the Joint Commission asked Conway to give a talk at its annual meeting on leadership and patient safety. "In preparation for that talk, we had conversations with our trustees and executive leadership, as well as with our staff," he says.

"We asked ourselves, 'What are the things we do that work and seem to make sense, and that lead to success?'" Conway then put up a posting on the National Patient Safety Foundation listserv, asking if health care professionals believed their organizations' leaders "got it" when it came to patient safety.

"We got a number of comments from people who said they did, and they told us what they do," Conway reports. "Then we went and looked in the literature. We spoke with people like [the Institute for Healthcare Improvement's] Don Berwick and [Harvard University's] Lucian Leape, and asked what they thought."

Dana-Farber also consulted two other groups: a state coalition of 20 organizations dedicated to improving patient safety, and their patients.

The result was the patient safety tool, which has been given the title, "Strategies for Leadership — Hospital Executives and Their Role in Patient Safety."

It is divided into four basic sections:

- **Personal Education.**

How do you educate yourself? What books and articles have you read? Do you take courses? Do you understand the facts of your organization?

- **Call to Action.**

What are you doing to establish a framework for safety in your facility? What policies and procedures have you put in place?

- **Practicing a Culture of Safety.**

How do you do this every day?

- **Advancing the Field.**

What do you do outside of your institution to support others?

The tool is presented in the form of a questionnaire, with "Y" and "N" boxes next to each of the 42 questions. The American Hospital Association in Chicago has put its imprimatur on the tool and has distributed it to hospital executives. In the cover letter, Conway notes: "To be sure, having a number of checks in the 'Yes' column of the self-assessment is far more significant than having none. But identifying a plan to move some checks from 'No' to 'Yes' could be equally significant."

Clearly, he says, some "Y's" are more important than others, but that can vary from institution to institution.

"The question to ask is, 'How can I move in my organization from No to Yes?' It is an opportunity to step back and reflect," Conway says. "We propose that you not only reflect with yourself, but with a group of other people before checking off the box."

The Dana-Farber program actively involves patients and family members at all levels of institutional planning; this is what helps keep safety at the forefront of all Dana-Farber activities, he adds.

"We have patient and family advisory councils in both adult and pediatric care," he says. "They sit on most of our operational committees — at the board level on our quality committee. [They leave if the board goes into executive session.] We share error rates with patients, and slips and falls. When we go through the Joint Commission survey, they are involved."

Nearly instant feedback

By actively engaging patients and families in the process, Dana-Farber can get almost instant feedback. "We can implement a new system today, and the next day a patient can say, 'The infusion room is too crowded,' or 'The construction project is making the staff uncomfortable,' or 'When I was admitted they couldn't find my records,'" he explains.

"Our patients are experiencing care in ways that none of us do, and to the extent our processes are not working, they can tell us — and quickly. Sure, we do statistical surveys, but the results often come in two or three months later. We want our patients to pick up a phone and give us a call."

Out of a tragedy have come some very good things indeed. Today, Dana-Farber sees nearly three times as many patients as it did in 1995.

"Not only has our volume grown, but our research has grown; the center is vibrant," Conway says. "Our story is the story of how an institution took a tragic situation and used what it learned to leverage the whole organization to a better place."

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