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ICPs are urged to join unprecedented national patient safety network

CDC's ambitious network based on proven systems

In a move that may push infection control professionals to the fore of the patient safety movement, the Centers for Disease Control and Prevention (CDC) is launching a nationwide Internet-based network on infections and adverse events occurring in both patients and health care workers, *Hospital Infection Control* has learned.

The creation of the CDC National Healthcare Safety Network (NHSN) was announced in Nashville, TN, at the annual conference of the Association for Professionals in Infection Control and Epidemiology. ICPs were encouraged to join the network, sharing infection rates and other adverse outcomes within a confidential system that eventually will include a wide variety of health care settings. The CDC will collect and analyze the data, much as it does with its current sentinel networks.

"There will be no limit on hospital size or type of institution," said **Teresa Horan**, MPH, CIC, an epidemiologist in the CDC division of healthcare quality promotion. "If you are a legitimate facility and we have a category for you, we want you to join. If we don't have a category and you are a legitimate entity, talk to us and we will make one. We would like everybody."

The NHSN will replace three existing CDC surveillance systems, including the highly regarded National Nosocomial Infection Surveillance (NNIS) system.

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Debate: Screen and isolate or standard precautions?
Rather than special measures such as screening and isolating patients, ICPs should focus their limited resources on improving compliance with standard precautions to battle multidrug-resistant organisms. On the contrary, another expert argued, the only way to prevent nosocomial spread of resistant pathogens is to identify the colonized patient reservoir and place them in contact isolation 85

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2002 Infection Control Innovation Awards

Prevention pays for reader innovations

Don't forget to enter our second annual Infection Control Innovation Awards. Sponsored by *Hospital Infection Control*, the 2002 awards focus on a single theme: Prevent Pays! A first prize of $1,000 will be awarded to the reader who applied something learned in *HIC* or its supplements to prevent infections or otherwise protect patients and health care worker. See the entry form at your free subscriber's web site at *www.HIConcline.com*. ■

In addition, the CDC's National Surveillance System for Health Care Workers (NaSH) and the Dialysis Surveillance Network (DSN) will be folded into the network. Data from such systems typically are used as a benchmarking tool for ICPs, and the new network should eventually generate much more comparative data than are currently available. NNIS, for example, primarily provides data on infections in intensive care units or high-risk nurseries, Horan said.

"The difference here is that you will be able to choose events you want to monitor and then choose the location where you want to study that event," she said. "There will be a lot more flexibility for the users. We anticipate and hope — everyone keep your fingers crossed — that we can actually deploy the NHSN in the first quarter of next year."

In addition, the network is expected to ultimately include noninfectious adverse events such as medication errors and patient falls. "We can add noninfectious adverse events as we develop the definitions and the protocols," Horan said.

In that sense, the move is more an expansion, as the CDC brings proven infection control methods to other settings and disciplines, said **Patti Grant**, RN, BSN, MS, CIC, director of infection control at RHD Memorial Medical Center in Dallas.

"They are designing a system that we know works," she said. "They are expanding it for use for other disciplines without reinventing the wheel." The development of use of standard definitions for noninfectious events will generate exciting new data, she added. "In the same way that we all have definitions for a central-line bacteremia, I'm sure they are going to have a definition for a medication error or what is a patient fall. And once we know it, it won't take too long

Network to create a vision of patient, worker safety

BSIs tracked, noninfectious outcomes to follow

The Centers for Disease Control and Prevention's (CDC) planned National Healthcare Safety Network will include the following general outline and three specific components for data tracking and analysis.

VISION. Create a web-based knowledge system for accumulating, exchanging, and integrating relevant information and resources among private and public stakeholders that support local efforts to protect patients and promote health care safety. Users are providers of care, hospitals, clinics and outpatient settings, long-term care facilities, health plans, and consumers of care.

GOALS. Improve patient and health care worker safety by providing protocols for monitoring adverse events associated with devices, procedures, and medications. Provide feedback of comparative data for performance improvement. Provide a way to access prevention tools, lessons learned, and best practices.

PREMISES. Share data in a timely manner while maintaining data security, integrity, and confidentiality. Confidentially and security exist between the user and the public health agencies to which they are reporting and also between users. Minimize user burden by streamlining data-reporting protocols. Increase the capacity for including data from existing electronic sources. Build ways for users to access their laboratory information systems, admission, discharge, transfer system, operating room, pharmacy, and clinical data system records. All health care delivery systems are allowed to participate.

PATIENT SAFETY. This component will be based on the National Nosocomial Infection Surveillance system and the Dialysis Surveillance Network. It will include reporting and analysis of central bloodstream infections in any patient population; hospitalization or an IV antimicrobial start in a chronic dialysis outpatient; ventilator-associated pneumonias; and catheter-associated urinary tract infections. Noninfectious adverse outcomes also may be added. The patient safety component also will include reporting and analysis of post-procedure associated pneumonia in both inpatients and outpatients; and surgical-site infections after operations. Antimicrobial use and resistance will be tracked, and this aspect may be expanded to include medication errors.

HEALTH CARE WORKER SAFETY. The health care worker safety component will be based on the CDC's National Surveillance System for Health Care Workers (NaSH) system. This aspect of the network calls for reporting and analyzing worker exposures, including administration of post-exposure prophylaxis after HIV bloodborne exposures. It also will include TB exposure data, vaccine history, and exposures to vaccine-preventable diseases.

RESEARCH AND DEVELOPMENT. As the data are reported to CDC, the agency will conduct studies and do demonstration projects with partners. The data will also be published in aggregate form. ■

to stratify it. It's going to be cool."

The aforementioned three CDC sentinel networks will link up and trial the program for about six months, then the network will be expanded to affiliated institutions and sister hospitals of the original members.

"Then, the third step will be to open the membership to all comers," Horan said. "The enrollment process will be totally on-line, and when we are ready to announce it for everyone to join, we will put the information out everywhere we can. I hope you'll join us when the time is right."

The plan was well received by the APIC audience, and individual ICPs favored the move in interviews with *HIC.*

"It is the natural next step," said **Elaine Larson**, RN, PhD, a longtime infection control researcher and professor of pharmaceutical and therapeutic research at Columbia University School of Nursing in New York City. "We have had NNIS for more than a decade. It's the world model for surveillance of infections. I see this as just expanding the same surveillance techniques beyond health care-associated infections to other kinds of adverse events and complications. It is very promising."

With ICPs already moving strongly into the patient safety movement, participation in the new CDC system could further solidify their patient safety roles.

"It certainly could," Larson said. "It could also expand the cadre of professionals that are reporting to the CDC on adverse events. Either way, I think it's great."

A major benefit of the proposed system will be the collection of data that essentially have been unavailable, as CDC sentinel systems have been focused on a limited number of facilities and procedures, she noted. "If the network were able to provide data and protect the confidentiality of the institutions, there would be the possibility of having a large enough sample size that you really

could look at interventions that wouldn't be possible [previously]," she said. However, the voluntary nature of the program will create some misrepresentation in the data, as the facilities that usually participate in sentinel systems have high-quality programs, Larson added.

"I think that will always be a problem," she said. "No matter what the numbers are, it represents only those that are willing to give the data. But I think that's the way it should be. I would not be supportive of requiring, at least initially, [participation]. I don't think we would get honest reporting."

In that regard, Horan strongly emphasized the confidentiality of the data and the protection of participating institutions. The CDC will issue digital certificates to members, and the data will be encrypted during transmission, she said.

"We will also provide each facility with control of who can access the data," she said. "If someone is responsible for selecting surgical-site infection data, you may not want to them to be able to enter and add records on device-associated infections. You can control the access of who gets what data and how they can manipulate it."

Asked whether the data will be reported to patient safety groups or regulatory agencies, Horan said, "Not by us. Currently, we are collecting the data for aggregate purposes. We would never, for example, give a single hospital's data to some other entity."

More than a data repository, the NHSN will provide information and tools for patient safety interventions, Horan emphasized. The network will include prevention tools, lessons learned, and best practices. "Who but you are better to give them to us?" she asked APIC attendees. "You all have success stories, and at meetings like this, we have a chance to share them. Well, wouldn't it be great if we could share and access them on-line anytime?"

The network is seen as a way to achieve an ambitious set of CDC goals, including reducing catheter-associated infections by 50% over the next five years.

"We hope that we will be able to make at least that much in terms of reduction," Horan said. "On the other hand, there is going to be lots of data that we are collecting that we have never had before. So for some areas, it will be a time of collecting baseline data and then we will have to make appropriate targets for reduction in the future."

The network will be a source for performance measurement data and national comparative rates and ratios. Ideally, reports could be created easily, leaving more time for infection prevention efforts.

"One of the things that we think is very important is that it is critical for you to have the data at your fingertips and have the tools to analyze the data," Horan said. "Because you can't do your work if you can't analyze the data. There is no use in collecting it if you can't analyze and use it for prevention. We recognize that you have a great need for data analysis so we will have line listings, tables, graphs, control charts that can easily created, printed, and exported."

Likewise, hospital systems can form their own groups to compare data among affiliated facilities. Beyond surveillance and analysis, the network also will be used to sound alerts for adverse events such as recalls. In light of confusion about a recent bronchoscope recall, many observers have said such a broad-based sentinel system could be useful in getting the word out about important developments.

"The system can be programmed so that when a sentinel event occurs it sends a signal that [says] an immediate response and perhaps a root-cause analysis should be undertaken." Horan said. "Also this should be proactive, built on algorithms where unusual events might be identified and tagged as a signal of preventable threats to patient safety. You could initiate steps ahead of time to prevent the bad outcome from happening." ■

Is endoscopy getting out of (infection) control?

Rapid growth in physician offices alarming

An increasing number of gastrointestinal endoscopy procedures are being performed in physician's offices and outpatient clinics without adequate assurance of appropriate infection control measures, clinicians warn.

"As this [procedure] goes out more into private offices and into endoscopy centers, there are less people involved in making sure everything is being followed carefully," says **Gerald Isenberg**, MD, assistant professor of surgery at Jefferson Medical College in Philadelphia.

Representing the American Society for Colon and Rectal Surgeons, Isenberg recently joined other experts in Atlanta to discuss infection control

Reviewing gold standards for processing endoscopes

Staff must receive device-specific training

Endoscopes are classed as semicritical items because they come into contact with mucous membranes or nonintact skin. Semicritical items minimally require high-level disinfection using wet pasteurization or chemical disinfectants, according to the Centers for Disease Control and Prevention's (CDC) *Draft Guideline for Disinfection and Sterilization in Healthcare Facilities, 2003*.

The recommendations for high-level disinfection listed below were all ranked "IA" in the draft guidelines. The ranking indicates the strongest level of clinical evidence in support of the practice, suggesting that none of the following recommendations will undergo much revision:

- Meticulous cleaning of the endoscope with an enzymatic detergent recommended by the endoscope manufacturer should be performed immediately after use. Cleaning is essential before the use of currently available automatic endoscope reprocessors.
- All of the channels should be flushed and brushed, if accessible, to remove all organic (e.g., blood, tissue) and other residue. Clean the external surfaces and accessories of the devices by using a soft cloth, sponge, or brushes.
- Reusable accessories (e.g., biopsy forceps or other cutting instruments) that break the mucosal barrier should be cleaned (e.g., ultrasonic clean biopsy forceps) and then sterilized between each patient.
- Endoscopes and accessories that come in contact with mucous membranes are classified as semicritical items and should receive at least high-level disinfection after each patient use.
- A Food and Drug Administration-cleared (FDA) sterilant or high-level disinfectant should be used for sterilization or high-level disinfection.
- The FDA-cleared label claim for high-level disinfection should be used unless scientific studies demonstrate an alternative exposure time is effective for disinfecting semicritical items. For example, if > 2% glutaraldehyde is used, scientific data show that all immersible internal and external surfaces should be in contact with this high-level disinfectant for not less than 20 minutes at 20 degrees C.
- After high-level disinfection, endoscopes (including channels) must be rinsed with sterile water, filtered water, or tap water, followed by a rinse with 70% to 90% ethyl or isopropyl alcohol.
- Personnel assigned to reprocess endoscopes must receive device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilization. Competency testing of personnel reprocessing endoscopes should be done on a regular basis (e.g., commencement of employment, annually). ■

issues in endoscopy and review draft guidelines by the Centers for Disease Control and Prevention (CDC). The comment period closed June 14, 2002, for the CDC's *Draft Guideline for Disinfection and Sterilization in Healthcare Facilities, 2003.*

The recent meeting concluded with options being discussed in a closed session that included endoscopy experts, epidemiologists, and public health officials.

"We talked about whether it will be necessary to convene a task force to look at this [concern] and try to find out what the best approach would be — to monitor the offices or just to ensure that they are doing the right procedures," Isenberg tells *Hospital Infection Control.* "You never like to have additional regulatory agencies, but that might be something [to consider]."

Other possibilities include getting the industry more involved in infection control education and working with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), he adds. There is little controversy about the CDC recommendations themselves, but experts fret over the rapid expansion of endoscopy in settings with little regulatory oversight.

"Currently, the office endoscopy setting is the least-regulated setting, but federal reimbursement actually favors doing endoscopy in that setting," says **Douglas Nelson**, MD, staff gastroenterologist at the Veterans Affairs Medical Center in Minneapolis. "So the federal government — through its reimbursement policy — is actually encouraging office endoscopy, which has the least regulation, rather than ambulatory endoscopy centers or hospitals where there is probably the most regulation."

Individual states primarily regulate endoscopy in the office setting, says Nelson, who represented the American Society for Gastrointestinal Endoscopy at the meeting.

"The issue is really how do we implement [guidelines] to make sure everyone does them," Nelson says.

"I think [compliance] is good, but obviously we are shooting for 100%. I can verify the compliance in the hospital because there are JCAHO standards.

JCAHO does not regulate office practice," he adds.

Nelson emphasized that there are no data suggesting that more infections and adverse events are occurring in office-based endoscopy as opposed to institutional settings. "Overall, infection is an extremely rare event. There was a very broad consensus that current practices are safe. However, [endoscopy is] vulnerable to human error no matter what system you use. We want to make sure that people are cleaning endoscopes according to the right guidelines."

The problem is ensuring infection control safety for office endoscopy without scaring the public away from critical diagnostic procedures, Isenberg adds. "Then we're not going to be picking up polyps and cancer, and that would be far worse."

While rare, infections related to any procedure can be subject to underreporting in outpatient populations not under the watchful eye of an infection control professional. "There probably is an underreporting," says **Cathy Nutter**, MS, a microbiology expert at the Food and Drug Administration (FDA). The FDA has voluntary and mandatory reporting programs, one of which requires facilities to report to the manufacturer and the FDA all device-related patient deaths and injuries. The problem is that those regulations do not apply to physician offices. Expanding the regulatory authority would require nothing less than an act of Congress, she says.

"That would have to come from Congress under the Safe Medical Devices Act," she says. "It did not cover physicians offices, I guess, because they are a way too numerous. It's hard enough trying to get [reports] from hospitals."

Reviewing the available data, Nutter says, "there really weren't that many directly related to GI endoscopy." Since 1992 there have been nine reports to the FDA regarding gastrointestinal endoscopy, including two deaths and three reports of infection. According to the FDA, one patient developed peritonitis two days after colonoscopy and died. An autopsy revealed death due to acute peritonitis associated with perforation of the colon. The patient had a history of diverticulitis.

The other death occurred in an 82-year-old patient who cultured positive for *Klebsiella s*pecies one day after an endoscopy procedure. The duodenoscope used also cultured positive for the pathogen. The patient was administered antibiotics, but died 11 days after discharge. Other reports of infections include a 66-year-old patient who was infected with *Pseudomonas* species following endoscopy. The patient recovered after antibiotic treatment.

Three other FDA reports involved patients who complained of GI bleeding and cramping one day after undergoing sigmoidoscopy in a physician's office. The patients were treated with prophylactic antibiotics and symptoms subsided within one day. The culture results and cause of symptoms were unknown.

While the office setting remains a concern, the clinical content of infection-control recommendations is fairly well defined.

"There is no dearth of endoscope reprocessing guidelines," Nelson says. "If you look at them, since 1977, basically they have only changed in very small increments."

One change that was recommended in the CDC guidance was the inclusion of endoscopes with disposable components, he said. Instead of trying to reference specific products, the guidelines may state that users should follow FDA label guidelines and manufacturer's cleaning instructions on any new device.

"A guideline that addresses every new widget that comes out is going to have a very short shelf life," Nelson says. "[Including] FDA labeling is so the manufacturers will have to prove their claims. We think that is adequate." ■

APIC focus: Pediatric IC

$350,000 outbreak hits hospital NICU

Think prevention is expensive? Try infection

The cost of a single nosocomial outbreak was recently broken down into staggering detail by an economically minded clinician at Columbia University Hospital in New York City. The message to administrators: Think prevention is expensive? Try infection.

"A four-month outbreak — a third of a million dollars," said **Patricia Stone**, PhD, RN, a health services researcher at Columbia. "This outbreak costs the hospital $350,000, and that is a conservative estimate."

The expensive pathogen behind the outbreak was extended spectrum â-lactamase *Klebsiella pneumoniae*, which often is linked to hospital-acquired infections occurring in intensive care units. In this case, the setting was a neonatal

intensive care unit (NICU), which had eight infected and 14 colonized neonates over a four-month period. The persistent outbreak ultimately resulted in closing the unit, bringing lost revenues into the economic picture on top of all the other expenses.[1]

"There were 14 infants who were not admitted to the unit during the outbreak period," she said recently in Nashville at the annual meeting of the Association for Professionals in Infection Control and Epidemiology (APIC). "We looked at the lost revenue to the hospital in terms of those lost beds and the NICU closure."

The closed beds resulted in a revenue loss of $110,000. The infected babies who were admitted had a mean length of stay of 85.5 days, 48 days longer than a similarly risk-adjusted patient group using comparative data. At $590 a day, the attributable cost of increased stay for infected neonates totaled $229,000. Of course, costs associated with fighting the outbreak pushed the total higher, but the efforts revealed two NICU nurses with persistent hand-carriage *K pneumoniae* due to long or artificial fingernails. The hospital has now banned fake and long nails.

"Economic evaluations like this increase understanding of the burden of outbreaks," Stone said.

"Evidence such as this may encourage more effort and resources to be put in [infection] prevention. You start to be able to make evidence-based arguments," she added. But will the cost figures be used to lobby administration for an enhanced investment in infection control resources? "It's being done as we speak," she told APIC attendees at a special session on pediatric infection control.

HCW linked to outbreaks years apart

Another study presented at the same session featured a similar case of a colonized worker, but with an unusual twist. A nurse with recurrent carriage of a strain of methicillin-resistant *Staphylococcus aureus* was linked to separate outbreaks two years apart.

Between Dec. 17, 1999, and Jan. 5, 2000, 13 infants in an NICU at Virginia Commonwealth University (VCU) Health System in Richmond were infected or colonized with MRSA. The index case was an 800 g infant delivered in an ambulance.[2]

"The first four cases were within 10 days of one another," said **Lynn Reynolds**, RN, infection control professional at VCU. "There were two deaths; one related to the [MRSA] bacteremia."

Eight babies were asymptomatically colonized in the umbilicus and/or nares. Before the source was discovered, the infection control team went to great efforts to prevent further spread.

"Our interventions initially for the first two cases included placing infected infants on contact precautions," she said. "The infected infants were moved to the back row of the unit away from the main traffic stream. We cohorted staff and infants; we reinforced the wearing of gowns and gloves for staff and visitors. And of course, [we did] education of staff. Unfortunately, despite our early interventions, we continued to have more cases of MRSA bacteremia."

Additional interventions included weekly surveillance cultures of the nares and umbilicus of all babies in the NICU. MRSA-positive infants were treated with intranasal mupirocin.

Thorough cleaning of the unit was done daily to prevent environmental contamination. Access to the unit was limited to one entrance, which was through the scrub area. Underscoring the severity of the situation, a security guard was placed at the entrance to ensure hand washing. Employees were cultured for the outbreak strain. "We were able to identify more cases of infected and colonized babies even after our additional interventions were instituted," she said. "If nosocomial transmission continued, there was discussion that we would close the unit."

Nares swabs were obtained on 140 hospital workers and the two EMS workers who delivered the index case. All cultures were negative except for one taken from an NICU nurse. Her isolates were identical to the outbreak strain by molecular typing. Control strains from other units were different from the outbreak strain.

"Further investigation of the colonized health care worker revealed that she was also positive for MRSA [during] a 1997 NICU outbreak," Reynolds said. "At that time, she was treated with intranasal mupirocin and had a follow-up culture that was negative."

The colonized nurse directly cared for eight of the 13 infants who were infected or colonized in the outbreak. She had no underlying medical conditions. Interestingly enough, this health care worker's colonizing strains from the 1997 outbreak and the 2000 outbreak were genetically identical. She was removed from the unit, retreated with intranasal mupirocin, and successfully decolonized. She was reassigned to a non-NICU unit. "Once the heath care worker was removed, we had no new cases of MRSA infection or colonization

[in] the two months that followed," Reynolds said.

However, the story doesn't end there. The NICU nurse — one of the best on the unit — eventually left the hospital after the reassignment. "[One] argument was that we should allow her to return to the unit because she was considered one of the best nurses in the unit," Reynolds said. "She was highly trained and skilled, and deeply committed." But the risk of subsequent infections — and the morbidity, mortality, and costs they could entail — compelled the hospital to ban the nurse from the NICU. "This outbreak illustrates the controversy that arises when health care workers are found colonized with multidrug-resistant organisms," she said.

In other research presented at the pediatric session, an ICP detailed the development of a successful policy for preventing seasonal outbreaks of nosocomial respiratory syncytial virus (RSV).[3]

"There are various conditions that increase the risk of a person having severe or even fatal RSV infection," said **Elizabeth Fuss**, RN, MS, CIC, an ICP at Johns Hopkins Hospital in Baltimore. "[Those include] congenital heart disease, underlying pulmonary disease in children, and prematurity — and immunodeficiency and immune suppression at any age. Nosocomial transmission of RSV is very well described, and if you look in the literature among reported outbreaks, you can find mortality rates as high as 44%."

ICPs at Johns Hopkins started tracking nosocomial transmission of RSV in 1989.

"It's a good think we did, because in the 1990-1991 [season], we had a terrible [rate]: 20.2% of all RSV cases were acquired nosocomially," she said.

The two-stage control measures that were originally put in place in 1991 have continued to evolve in the hospitals 140-bed pediatric unit. Stage 1 begins when the first case of RSV is admitted each fall. The protocol requires obtaining RSV antigen testing and viral cultures on all children under age 6 who have been diagnosed with bronchiolitis or pneumonia. Stage 2 begins when five patients have been admitted with RSV and expands RSV antigen testing and viral cultures to all children under 6 with any respiratory symptoms. They stay under RSV precautions until the antigen is negative, which sometimes is only a few hours with the rapid testing, she said. A nosocomial case is defined as a child who develops RSV at least four days after admission. Stage 2 stays in effect until 10 days have passed without admission of a community-acquired case or discovery of nosocomial transmission.

Though a private room is preferable, roommate arrangements may be necessary in peak RSV season. Roommates of RSV patients cannot be high-risk patients, including those with any immune disorder, congenital heart disease, or chronic lung disease. Another addition to the policy is that all newly admitted children with presumptive HIV infection — whether or not they have respiratory symptoms — have an RSV antigen test. "That is primarily because HIV [positive] children may shed the virus when they are not actually symptomatic," she said.

Health care worker and parent education continues as an ongoing process.

"Primarily due to Joint Commission [on Accreditation of Healthcare Organizations'] concerns about confidentiality, we no longer call it RSV precautions," Fuss said. "It is now pediatric droplet precautions. Gloves only are required to enter the room and then gown and mask for direct patient contact. Parents are educated about strict enforcement about hand hygiene and to restrict their care to their own child. They are not required to wear all the [isolation] garb."

While, ideally, workers with upper-respiratory symptoms would not care for patients, staffing needs sometime dictate that they continue to work with a mask and gloves on. "[We] give consideration to their assignments to avoid high-risk patients," she added. "A big part of the whole program, of course, is communication and education," she said. "We learned along the way that we needed to do some training on how to obtain an effective nasopharyngeal aspirate. We primarily do that through a video, and multiple copies are on every unit."

What do all the measures mean for nosocomial RSV rates? "It came down nicely and basically has stayed down," Fuss said. "[For] the season that just ended, we had a 3% nosocomial case [rate]. That was three nosocomial cases out of a little [more than] a 100 children with RSV admitted this year. We really do believe that ongoing RSV surveillance can help to provide effective isolation and detect outbreaks early."

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Screen and isolate or standard precautions?

The challenge to control drug-resistant bugs

Rather than special measures such as screening and isolating patients, infection control professionals should focus their limited resources on improving compliance with standard precautions to battle multidrug-resistant organisms such as vancomycin-resistant enterococci (VRE) and methicillin-resistant *Staphylococcus aureus* (MRSA), a veteran nurse educator recently argued.

"There is evidence that standard precautions, when practiced consistently and correctly, can prevent transmission of VRE, MRSA and other organisms," said **Marguerite Jackson**, RN, PhD, CIC, FAAN, director of education, development, and research at University of California in San Diego Health Care.

On the contrary, another infection control expert argued, the only way to prevent nosocomial spread of resistant pathogens is to identify the colonized patient reservoir and place them in contact isolation (i.e., gowns for patient contact).

"Nosocomial spread accounts for almost all of the patients with these pathogens," said **Barry Farr**, MD, epidemiologist at the University of Virginia (UVA) Hospital in Charlottesville. "The reservoir for spread is usually colonized patients. Actively identifying this reservoir for spread and implementing contact precautions offers more effective control than do standard precautions."

Such were the positions taken as two well-known members of the infection control community squared off in an interesting, educational debate on multidrug-resistant pathogens recently in Nashville, TN, at the annual conference of the Association for Professionals in Infection Control and Epidemiology (APIC).

Jackson is a past president of APIC, and Farr is the current president of the Society for Healthcare Epidemiology of America (SHEA). In general terms, the respective membership of each group is primarily composed of doctors (SHEA) and nurses (APIC). With that professional difference as a subtext, Jackson pointed a finger at physicians who inappropriately prescribe antibiotics.

"Why is there so much emphasis on interrupting transmission rather than other strategies?" Jackson said. "One [reason] is because it is very difficult to control antimicrobial prescribing behavior of physicians. It is almost impossible to make those people behave! There is the belief that you can make the nurses and the other folks behave better by telling them what to do [rather] than by making doctors do what they ought to do about antibiotics. It's a whole lot easier to write rules and to make the nurses behave because the health care organization can control the paychecks of the nurses [rather] than the physicians, who are free agents. That is a perception. I haven't had a double-blind clinical trial evaluate that, but I think that perception is probably shared by many of you."

Rather than attempting to identify patients colonized with VRE and MRSA and place them in contact isolation, Jackson argued for strict adherence to standard precautions with all patients. Standard precautions (formerly called universal precautions) primarily emphasize hand hygiene and appropriate glove use with all patients to prevent transmission of recognized and unrecognized sources of infection.

"The principle on which standard precautions is based theoretically makes a great deal of sense," she said. "However, the second part of this principle is that consistent observance offers the greatest potential for decreasing transmission of infectious agents. . . . The key to success here is health care worker compliance."

There is substantial evidence that consistent adherence to standard precautions is poor, she said. "The increasingly serious international nurses shortage adversely affects correct and consistent compliance with standard precautions and other transmission precautions," she added.

By that same token, trying to adopt more rigorous measures, such as screening, isolating, and gowning for colonized patients, is likely to fall afoul of poor compliance.

"The busier the nurses are, the less they wash their hands," Jackson said. "If you're a nurse, it does not take rocket science to figure that out. That is what happens. When nurses are busy, they wash their hands and comply with other recommendations less frequently. If the compliance is poor for hand washing, would compliance with

other infection control recommendations — be it standard precautions, contact precautions, or whatever — [be any better]?"

Rather than emphasize transmission-driven guidelines for individual pathogens, Jackson said she favors marshalling efforts to improve compliance with standard precautions.

Jackson is serving as a consultant to the Centers for Disease Control and Prevention's Healthcare Infection Control Practices Advisory Committee (HICPAC), which is in the process of updating patient isolation guidelines. Those guidelines are being finalized, but one draft discussed at a recent HICPAC meeting states that that "in acute care, an overemphasis on additional transmission-based precautions . . . can diminish the adherence to standard precautions." **(See *Hospital Infection Control*, April 2002, under archives at *www.HIConline.com*.)**

While both speakers cited a wealth of research to support the efficacy of their positions, Farr added an ethical appeal. "We take TB seriously, actively looking for contagious patients and using transmission-based precautions that work much better than standard precautions for this," he said. "By contrast, we don't usually actively look for antibiotic-resistant infections even though they cause far more deaths — 130,000 to 150,000 over the past decade, with MRSA and VRE undoubtedly contributing heavily to this toll. Is it OK to just look the other way while hospital contagion claims thousands of lives?"

MRSA accounted for one-third of nosocomial *S. aureus* infections in Denmark before health care professionals started taking effective action, he noted. "They controlled it over the next decade and have kept it less than 1% now for a quarter of a century using active surveillance cultures and contact precautions the whole time."

Infection control programs in the United States were born in the early 1970s when penicillin-resistant *S. aureus* exploded through the health care system, he reminded. The programs were formed because "we might not always be able to cure antibiotic-resistant infections so we should figure a way of preventing them," Farr said. "We have failed to control nosocomial MRSA infections, which almost doubled in rate between 1989 and 1999. We are clearly failing to control nosocomial VRE infections as well."

Patients with positive clinical cultures for VRE or MRSA represent the tip of a figurative iceberg, Farr said. They are the reservoir for spread to other patients because they go unrecognized and unisolated without active surveillance cultures. Health care workers then spread the pathogens on transiently colonized hands, clothes, and equipment.

"[Research] has shown that when we examine a patient with MRSA or VRE, we frequently end up with it on our clothes if we're not wearing a gown," said. "Two-thirds of the time, gown, gloves, and/or stethoscope were contaminated whether the patient was infected or colonized."

Detractors of the screening/isolation approach

CE/CME questions

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

1. Which existing surveillance system will be incorporated into the Centers for Disease Control and Prevention's new National Healthcare Safety Network?
   A. National Nosocomial Infection Surveillance System.
   B. National Surveillance System for Health Care Workers
   C. Dialysis Surveillance Network
   D. all of the above

2. According to **Douglas Nelson**, MD, current federal reimbursement policy encourages gastrointestinal endoscopy in which setting?
   A. physician offices
   B. teaching hospitals
   C. nursing homes
   D. A and B

3. According to **Marguerite Jackson**, RN, PhD, CIC, FAAN, rather than special measures such as screening and isolating patients, infection control professionals should focus their limited resources on improving compliance with which type of currently recommended CDC precautions?
   A. body substance
   B. universal
   C. standard
   D. transmission-based

4. A $350,000 nosocomial outbreak at Columbia University Hospital was traced to what cause?
   A. long fingernails
   B. artificial fingernails
   C. persistent dermatitis
   D. A and B

often cite the expense of such measures, but Farr argues that it is cheaper than treating infected patients. "It is cheaper to use active surveillance cultures and contact precautions to control MRSA and VRE than it is to use standard precautions and just let it spread," he said. ■

ABSTRACT & COMMENTARY

Resistant infections cost $30,000 more a case

Synopsis: Emergence of antibiotic resistance in *Enterobacter* species results in increased mortality, hospital stay, and spiraling hospital charges.

Source: Cosgrove SE, et al. Health and economic outcomes of the emergence of third-generation cephalosporin resistance in *Enterobacter* species. *Arch Intern Med* 2002; 162:185-190.

Abstract: Emergence of cephalosporin-resistance among *Enterobacter* species during therapy is a well-recognized phenomenon. Cosgrove and colleagues examined a cohort of 477 patients with initial clinical cultures yielding *Enterobacter* species susceptible to third-generation cephalosporins by microbroth dilution assay. In 46 patients (10%), subsequent cultures yielded an *Enterobacter* isolate resistant to this class of beta-lactam antibiotics. These case patients were matched to 113 control patients by anatomic site of isolation and duration of prior hospitalization. The outcomes of interest were mortality, length of hospital stay, and hospital charges.

The crude mortality rate among cases was 26% compared with 13% among controls. The median hospital stay for cases was 29.5 days and 19 days for controls. Median hospital charge for cases was $79,323, compared with $40,406 for controls. After adjusting for confounding by multivariable analysis, emergence of resistance had a significant association with mortality. Hospital stay for cases was significantly prolonged (1.5-fold), and hospital charges were significantly greater (1.5-fold). The increased length of stay attributable to emergence of resistance was nine days, and the attributable increase in hospital charges was $29,379.

Comment by Robert Muder, MD, hospital epidemiologist, Pittsburgh VA Medical Center.

Cephalosporin resistance in *Enterobacter* species is typically mediated by beta-lactamases of the *AmpC* type.[1] These enzymes are chromosomally encoded and widely present in *Enterobacter* spp., *Serratia* spp., *Citrobacter freundii*, and *Morganella morganii*. They are produced in minute quantities, but production can be increased by exposure to beta-lactam antibiotics, including third generation of cephalosporins.

High levels of enzyme production after such exposure lead to dramatic increases in MIC and in vitro resistance of previously susceptible strains.

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Editorial Questions

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More important is the selection of depressed mutants, reported to be present in *Enterobacter* spp. at a frequency of approximately 10^{-7}. These strains are resistant to third-generation cephalosporins, extended-spectrum penicillins, and aztreonam. *AmpC* beta-lactamases are not subject to inhibition by beta-lactamase inhibitors such as clavulanate, sulbactam, or tazobactam. *AmpC* producing Enterobacteriaceae are nearly always susceptible to imipenem and meropenem. The clinical importance of induction of resistance by exposure to beta-lactamase was demonstrated by Chow and colleagues[2] in a study of *Enterobacter* bacteremia.

Of those patients treated with a third-generation cephalosporin, 19% had subsequent isolation of a third-generation cephalosporin-resistant *Enterobacter*. Only 1% of patients treated with aminoglycosides had subsequent isolation of an aminoglycoside-resistant *Enterobacter*. Emergence of resistance was not encountered among patients receiving other classes of beta-lactam antibiotics.

The study by Cosgrove, et al shows that emergence of in vitro cephalosporin-resistance is associated with adverse clinical outcomes and increased costs. They did not report details of antimicrobial therapy and thus did not relate emergence of resistance or outcome to use of cephalosporins. However, based on the data available from this report and Chow's prior study, it is clear that third-generation cephalosporins are poor choices in the treatment of serious infections due to *Enterobacter* spp., and by extension, *Serratia* spp. If they are used at all, a second agent to which the isolate is susceptible, such as a quinolone or aminoglycoside, should be added, but this may not always prevent the selection of resistant mutants. Indiscriminate use of third-generation cephalosporins increases the likelihood of emergence of resistant strains. Although originally chromosomally mediated, *AmpC* beta-lactamases are now encoded on a number of plasmids that can be transferred to species that don't normally carry these enzymes, such as *E coli* and *Klebsiella*. Thus, the widespread dissemination of these enzymes, with major adverse clinical and economic consequences, is a real possibility.

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1. Livermore DM. Beta-lactamase-mediated resistance and opportunities for its control. *J Antimicrob Chemother* 1998; 27(Suppl 1):S100-106.

2. Chow JW, et al. Enterobacter bacteremia: Clinical features and emergence of antibiotic resistance during therapy. *Ann Intern Med* 1991; 115:585-590. ■

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. ■

SPECIAL NEWS ALERT
HOSPITAL INFECTION CONTROL
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Some ICPs, epidemiologists likely will be on smallpox response teams

Bioterror fears drive decision to break out vaccine

Infection control professionals — particularly those already working with public health or in hospitals designated for smallpox patients — may be asked to join a smallpox response team in the coming months. If you join, you will be among a new wave of people receiving vaccine for smallpox, a disease that has been completely eradicated in the wild.

But in a historic concession to the new age of bioterrorism, the Centers for Disease Control and Prevention (CDC) on June 20 recommended that state-based teams of health care workers and public health officials be immunized against smallpox. However, the vaccine will not be offered to the public or health care workers in general, as the potential side effects of the vaccine outweigh the risk of exposure. The landmark decision, coming three decades after broad-scale smallpox immunizations were discontinued in the United States, was made in a unanimous vote by the CDC's Advisory Committee on Immunization Practices (ACIP).

ACIP recommended smallpox vaccination "for people predesignated by the appropriate bioterrorism and public health authorities to conduct investigation and follow-up of initial smallpox cases that would necessitate direct patient contact."

The smallpox response teams might include medical team leaders, public health advisors, medical epidemiologists, disease investigators, diagnostic laboratory scientists, nurses and other trained vaccinators, and security/law enforcement personnel, ACIP recommended. "Such teams may also include medical personnel who would assist in the evaluation of suspected smallpox cases." In that regard, the panel voted to vaccinate "selected personnel in facilities predesignated to serve as referral centers [so-called 'type C' hospitals] to provide care for the initial cases of smallpox. These facilities would be predesignated by the appropriate bioterrorism and public health authorities, and personnel within these facilities would be designated by the hospital."

ACIP's decision essentially delegates the formation of the teams to bioterrorism planners in individual states. The total number nationwide who will opt for the voluntary vaccine is estimated at 10,000 to 20,000. In making the decision, ACIP emphasized that much planning and implementation remains to be done at national and state levels. The recommendations should "catalyze" the public health and clinical response to bioterrorism, said **William Schaffner**, MD, a nonvoting liaison member of the committee. Either extreme — offering vaccine to all or holding it back until an attack — was a flawed strategy, said Schaffner, chairman of the Department of Preventive Medicine at Vanderbilt University in Nashville, TN.

"This is the direction I was hoping the committee would go," he said. "It knits together the public health response and clinical care. That is very important. This will oblige the public health network and the major hospitals to collaborate, to have conversations. And that's a great thing."

The committee recommended that each state establish and maintain at least one smallpox response team. Consideration for additional teams should take into account population and geographic factors. The recommendations await final approval by the Dept. of Health and Human Services. The vote came after a workshop meeting, where the CDC solicited advice and opinion. **(For debate on this issue, see *Bioterrorism Watch*, July/August 2002, p. 1, which was published earlier. Also, get updates at *www.HIConline.com.)*** ■

PATIENT SAFETY ALERT™

A quarterly supplement on best practices in safe patient care

Poor supervision can contribute to a higher rate of errors

When focusing on systems, don't forget human factor

The current focus on systems when exploring the cause of medical errors overlooks one important fact: People still are interacting with those systems.

"There are two things you have to remember," says **Anthony F. Grasha**, PhD, professor of psychology at the University of Cincinnati. "Strong systems build strong people — and vice-versa. You have to work at both ends at the same time. You will be successful in minimizing errors if you can do what's right for the system *and* for the individual."

The other thing you must remember, Grasha says, is the critical role of the supervisor within the system — and the need for supervisors to be well trained in psychosocial skills. "Administrative and technical skills work great for the system, but you need psychosocial skills for employees to perform at their best," he says.

The impact on errors

Grasha has conducted extensive research into the cause of errors, particularly with pharmacists, and he has found a direct link between errors and the way his subjects perceived their supervisors. Those who made fewer errors had a supervisor whom they perceived as helpful in setting task goals and who allowed them appropriate autonomy.

What's the connection? "We've known for a long time that positive nurturing and more democratic approaches work better than micromanaged people, particularly professionals," Grasha says.

"By definition, a professional is someone who's obtained a high standing through independent work. When they then find themselves in a position where someone hovers over them, the net result is it creates tension and stress," he says.

In Grasha's work, the pharmacists who made the fewest mistakes and were most satisfied with their jobs also rated the quality of their supervision higher.

Generally, these pharmacists had supervisors who allowed them to "do their jobs as they saw fit" and worked with them rather than constantly telling them what to do, he explains. Supervisors who made demands for people to meet high performance standards in a more controlling manner (i.e., directing vs. working with people, using negative incentives vs. encouraging) had staff with higher levels of job dissatisfaction — and who also tended to make more mistakes.

"One of the things I've found is that accuracy, productivity, and job satisfaction [form] a triangle, with supervision in the middle of the triangle," he continues. "It affects all of them through the vehicle of stress and tension and mental distractions that make a job less fun. Stress sets up a process where you work faster than you should and take shortcuts, and are mentally distracted at times you should be focused. This leads to errors of commission as well as omission."

This same dynamic works among nurses, physicians, and pharmacy teams. "People who report more problems with their supervision report fewer errors and intercept fewer errors," he observes. "The basic principals apply, the examples just differ; it just so happens the vehicle I've studied has been the pharmacy."

"I don't think we perceive as much of a link between supervision and errors as we could in health care," adds **Judy Smetzer**, RN, vice president of the Institute for Safe Medication Practices (ISMP), based in Huntingdon Valley,

Pharmacy Supervisor Skills Checklist

The following checklist of pharmacy supervisor skills, created by Anthony F. Grasha, PhD, professor of psychology at the University of Cincinnati, can readily be applied to other areas of health care as well:

- ✔ Set clear goals and directions for the work people do.
- ✔ Help establish a climate for excellence and professionalism.
- ✔ Be clear but not overbearing when discussing expectations.
- ✔ Encourage people to enhance their level of performance.
- ✔ Delegate appropriately the freedom to do a job.
- ✔ Be able to "work with people" rather than "always telling them what to do."
- ✔ Ensure that the reasons why something is done are stated clearly.
- ✔ Set high standards for performing tasks.
- ✔ Be able to help people set priorities for completing multiple tasks.
- ✔ Promote critical thinking about how to work effectively.
- ✔ Be able to motivate and get people excited about their jobs.
- ✔ Be able to get people to identify and solve problems as a group.
- ✔ Provide sufficient answers to questions.
- ✔ Be able to fix responsibility for getting tasks accomplished.
- ✔ Hold people accountable for doing their jobs properly.
- ✔ Adjust your supervisory style to accommodate differences among people.
- ✔ Make people feel involved and important.

PA. She says that supervisors who instill fear are likely to have employees who hide errors.

Smetzer notes the example of a nurse in a long-term care facility who received an order from a physician to reduce the dose of warfarin for a patient. However, as an LPN, she was not permitted to accept the order. She also forgot to note the order in the patient's medical record, so the warfarin continued at the same dose.

Later, when the physician called to discontinue the warfarin, the nurse falsified the records to show that the patient had received the lower dose as ordered previously, Smetzer adds. The patient later died, and court records show the death could have been prevented if the nurse had revealed her mistake immediately.

Many work environments are punitive, she says. "Even counseling can be very punitive, depending on how it is carried out," Smetzer explains. "At the lowest end of the scale, perhaps the supervisor goes through all the things that were allowed to happen. And to this day, there are people who are fired for an error if the patient is harmed."

Too much control

Perhaps the supervisors who have the greatest impact on errors are the ones who exercise too much control. Grasha talks in terms of control modes ("I get good performance by controlling you"), as opposed to working with modes ("People do better work if they are committed").

"One of the biggest predictors for making more mistakes on prescription double-checks was micromanagement," he notes.

This can take many forms. The supervisor may give instructions on how to do something you already know how to do. Or he or she can tell you to do something a certain way and then not follow up. "It's their way of saying, 'Here's how I want to control you,'" Grasha explains.

In an interdisciplinary team setting, the team may make a decision about the most appropriate medication to give a patient, then the supervisor comes by and says, "Why did you bother doing that when you could have actually done nothing and waited to see what happens?"

"If you control frontline workers like a parent would a child, there's no room for creativity, autonomy, or teamwork — those skills that can really help curtail errors," Smetzer says. **(What supervisory skills work best? See checklist, at left.)**

Training can help

Proper training of supervisors can help improve staff attitudes, and at the same time, help reduce errors, Smetzer says. "If you look at any health care training program — medicine, nursing, pharmacy — you usually have a course in management. They teach hierarchy and theory but not [psychosocial] skills. There's not a lot of that going on in health care. Some of the best teaching needs to be about how and why we make mistakes."

Smetzer points out the "high-reliability" approach being taken by large organizations outside of the health care industry to produce

good safety records. "Why do the nuclear industry and the chemical industry have lower error rates than we do? They have better training programs," she asserts.

"If you look at what's happening in pharmacy generally, there's no training, no [continuing education] CE offerings," adds Grasha. "People graduate one day, and they're in charge of a pharmacy the next. In the hospital environment, human resource development staff and funding are being cut."

This approach is penny-wise and pound-foolish, he argues. "People need a chance to role-play, to do case studies, to get their hands dirty. It's not the kind of stuff we can learn by just reading," Grasha says. "We need to be coached."

Smetzer says that mentoring also can be effective. "I would think mentorship is the best way to go," she says. "You have people who already have good supervisory skills; usually the staff can tell you who the best supervisors are."

The bottom line is that these important skills can be taught, Grasha says. "A good book on supervision can be helpful, as is taking a management-training course or CE seminar, or beginning company-sponsored work in this area."

One good resource, he adds, is CRM Learning (www.crmlearning.com), which offers a range of educational/training materials.

He also recommends a book by Bill Catlette and Richard Heddon, *Contented Cows Give Better Milk*, which describes companies that attract and keep good people, as well as an article by Amy Edmundson, "Learning about mistakes is easier said than done," in the *Journal of Applied Behavioral Science* (1996; 32:5-28).

The price we pay for failing to train supervisors properly is high indeed, Grasha reminds us. "Organizations put people into positions without much training. They become anxious, and they drop into control mode."

In conclusion, Smetzer offers this caveat about a systems-only approach to errors: "We in health care are very focused on a system-based approach, which we definitely need to be, but with a total emphasis on systems, we can forget about the people, and we need to remember them — not to punish them, but to realize they are the ones who interact with the system. And there are clearly things we can do with people to improve performance."

[For more information, contact:

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- ***Anthony F. Grasha**, PhD, Professor of Psychology, University of Cincinnati. Telephone: (513) 556-5543.]*

Recommended readings

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Injury prevention model broadens safety scope

Create situations where human error can't happen

Traditional approaches to patient safety that focus exclusively on errors may be missing significant opportunities for improvement, argues a group of researchers from the Injury Research Center at the Medical College of Wisconsin, Milwaukee.

Writing in the April 17, 2002, edition of the *Journal of the American Medical Association (JAMA),* they assert that "The error-oriented approach includes mistakes that do not harm patients such as near-misses."[1] Conversely, they write, "The injury-oriented approach includes patient harm arising from a diagnostic or therapeutic intervention, including those that are not associated with any identifiable error."[1]

What they are proposing is an injury-prevention model, rather than an error-prevention approach. This broadens the approach of identifying medical injuries and developing strategies to prevent them, rather than limiting discussions to the errors that may have been made.

"The main issue related to this approach is not that we are ignoring error, but that we are not making it the sole centerpiece," explains **Stephen W. Hargarten**, MD, MPH, director of the Injury Research Center and one of the paper's authors. "It's similar to what happens when you drive a

car; people make errors in driving. Some don't result in any harm. But if an error does result in a crash, you want to reduce the frequency and the harm of these events. If you do crash, you have a seat belt on and an airbag. This protects you, regardless of how well or how poorly you and others drive. In our case, we are trying to reduce errors, but we recognize that if they are occurring, we should try to reduce the event or reduce our reliance of addressing medical injuries solely by addressing human error."

In summary, the authors assert that by focusing solely on errors, we actually are looking at a relatively small percentage of all medical injuries and missing the majority of them.

A paradigm shift

The paradigm shift of the injury prevention model, Hargarten explains, is that a prevention strategy may circumvent human error by creating a situation where it *can't* happen.

Human error is a challenge in and of itself, he notes, but it can be overcome by technology. "Take needlesticks, for example," he says. "We teach people not to commit the error, but the most complete strategy is to make needles where you really can't stick yourself. This is a very important aspect of our approach."

The injury prevention approach is represented graphically in a table called Haddon's phase-factor matrix, derived from the public health profession's agent-host-environment vector model of injury causation. It was first used in the study of automobile injury, but has proved useful in preventing injuries in a variety of settings.

In its simplest form, it is a two-dimensional chart. Down the left-hand side are three categories:

- Pre-event: Underlying risk factors predisposing to injury.
- Event: What causes an injury to occur? Will an injury result from this event?
- Post-event (outcomes): The final severity is determined here. How severity is minimized or maximized depends on these factors.

Along the top of the matrix are agent, host, vector/vehicle, and environment (with three subsets: physical, social, biological).

In a real-world example, the pre-event may be the reversal of X-ray film, which leads the physician to interpret it incorrectly. The event then could be putting a chest tube in on the wrong side, and the post-event would be the outcome. "A post-event may be that nothing happened," Hargarten explains. "For example, the event may be the prescribing of an incorrect antibiotic."

At present, researchers from the Injury Research Center are conducting studies that implement the injury prevention approach in different settings.

"In applying injury control science to the broad class of issues of medical injuries, we can look at a variety of ways we can have impact using these tools in specific areas like the [emergency department (ED)], ICUs, and so forth," Hargarten says.

How might this unfold in a practical setting in a hospital? "The first and most fundamental part of this is, we are looking at what happens to patients when they enter into, [for example], the ED, and the outcomes of those interactions that are from interventions from a variety of sources — from devices to medications," Hargarten observes. "With these interventions, some outcomes are adverse reactions to medications, or devices put in the wrong place. These are medical injuries, but we do not start trying to identify names and blame."

Rather, he says, they also will look at effects from accepted therapies — for example, reactions to penicillin. "A certain percentage of patients get a reaction," he says, noting they may be asked about an allergy, but respond in the negative. "How do we move forward to reduce this likelihood? Do we want to explore and see if there are other therapies for the same conditions? This is a more productive approach."

Previous studies note that even agreeing that an error took place in a specific case is sometimes difficult to determine. "We are already starting out with the potential for disagreement, but the bottom line for the patient is that there was an adverse reaction, an untoward outcome that no one desires. That's why we should not limit our explorations to those adverse events that occurred as the result of error," Hargarten concludes.

[For more information, contact:

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Reference

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BIOTERRORISM WATCH

Preparing for and responding to biological, chemical and nuclear disasters

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CDC weighs vaccinating now or waiting until first smallpox attack

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

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

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

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

Welcome to the new *Bioterrorism Watch!*

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

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

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

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

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

David Liebershach, one of the CDC advisors and the state director for the Alaska division of emergency services, made it clear he would not be lining up for voluntary immunization for any reason.

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

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

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

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

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

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

(Continued on page 4)

COMING IN FUTURE MONTHS

- Lessons of Chernobyl
- Treating patients exposed to radiation
- CDC smallpox vaccine recommendations
- Bioterrorism field kits
- Diagnosing the exotic agent

CDC mulls smallpox vaccination scenarios

Questions and options on a difficult decision

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

Background

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

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

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

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

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

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

Option 2. Continue current recommendations for not vaccinating in the general population in the absence of a smallpox bioterrorist attack, but allow permissive or voluntary use of the vaccine for people in the general population who desire to be vaccinated despite the recommendation.

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

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

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

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

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

Potential groups for immunization:

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

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

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

Vaccine reactions and the use of immune globulin

Most deaths from encephalitis, progressive vaccinia

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

Details about these reactions include:

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

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

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

Approximately 15% to 25% of vaccinees who develop post-vaccinal encephalitis die, and 25% have permanent neurological sequelae.

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

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

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

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

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

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

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

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

However, Bicknell warns that there is a "pre-eruptive period" as the incubation phase wanes when the self-inoculated terrorist could be infective without obviously having smallpox. Even as disease progresses, he adds, "If you are motivated, you can feel pretty terrible and move around." Moreover, a mass smallpox immunization in Yugoslavia in the 1970s began with an atypical index case that had no rash, he reminds.[2]

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

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

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

College of Emergency Physicians at the meeting.

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

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

"Think about an outbreak of smallpox and what would happen to emergency services and those emergency responders out there picking people up off the street," he said. "This is the only source of federally mandated care. Any patient for any reason that shows up at a hospital in America that has an operating ED [must be treated] by federal law." There are some 9 million first responders when you add ED clinicians, paramedics, police, and firefighters, he said.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A series of public focus groups and interviews with physicians revealed current attitudes on the smallpox situation, he said.

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

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

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

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

CE/CME questions

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

1. Some medical consultants and advisors cautioned about a host of potential side effects from smallpox vaccine, which could be particularly hazardous to the 300,000 people in the United States who do not know they have:
   A. hepatitis C virus
   B. tuberculosis
   C. HIV
   D. variola

2. William Bicknell, MD, PhD, argued that which group of people are much less likely than first-time smallpox vaccinees to have any adverse reaction:
   A. dairy workers
   B. those who have been previously vaccinated for smallpox
   C. those already immunized with other live vaccines
   D. all of the above

3. Progressive vaccinia, a potentially fatal complication of smallpox vaccination, has occurred almost exclusively among:
   A. immunocompromised people
   B. women
   C. those infected in sub-Sahara Africa during the 1960s
   D. those vaccinated under poor sanitary conditions

4. The American Hospital Association stated that the Centers for Disease Control and Prevention's smallpox response plan could substantially increase confusion or promote misinformation at a time when implementation of standard procedures would be critical.
   A. true
   B. false

possible rather than as few people."

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

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

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

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

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

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

"One of my colleagues thinks I am a complete nut case on this," Bicknell told *Bioterrorism Watch.* "He says, 'It will never happen.' His assessment of the risk of attack is different than mine. His is infinitesimal; mine is low, but real. Therein lies the difference."

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AHA strongly questions CDC smallpox plan

Agency inconsistent with other standards

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

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

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

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

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

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

The [CDC] recommendations call for the use of buildings *other than* hospitals for "contagious patients, such as nursing homes and hotels." Yet hospitals are the only buildings *likely* to have negative pressure rooms with 100% exhausted air (or recirculated air through HEPA filters). Further, the complexity of equipment needed to care for critically ill persons is also unlikely to be readily available in a facility that does not provide health care.

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

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

CE objectives

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

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