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OSHA may try to salvage less 'burdensome' version of TB reg for health care

But agency stumbles again on risk assessments

Scalded by critics for its rigid regulatory approach in the face of declining tuberculosis, the Occupational Safety and Health Administration (OSHA) is now considering pursuing a more flexible standard to protect health care workers from occupational TB, *Hospital Infection Control* has learned.

"If we have a final rule, it is likely to be very different from the proposed standard," says **Amanda Edens**, project officer for the OSHA TB standard in Washington, DC. "There are things that we could change if we decided to proceed with the final standard."

As a first step in that process, OSHA has reopened the rule docket to allow review and comment on the agency's revised draft TB risk assessment document. **(See related story, p. 31; chart, inserted in this issue.)** In response to criticism of the risk assessment in its original 1997 rule, OSHA updated its risk projections based in part on 1998 data. Dated July 23, 2000, the draft risk assessment apparently fell into limbo as the agency's efforts to finalize the rule were stymied by resistance from the infection control community and its political allies.

In addition, two peer review analyses of the risk assessment also are included, as is a report issued last year by the Institute of Medicine (IOM). Dealing the proposed standard a serious blow, the IOM report concluded that the regulation was inflexible

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COMING IN FUTURE ISSUES

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

because it would impose requirements that provide little additional protection in low-risk areas while adding significant costs on health care facilities. When a subsequent change in presidential administration appeared to bolster the position of OSHA's existing political opponents, most observers said the proposed standard was dead in the water. OSHA begs to differ.

"It is on the latest regulatory agenda, and it is listed as a proposed rule," says OSHA spokesman **Bill Wright**. "There were quite a few things that were in the last regulatory agenda that have been dropped. This is not one of those. It is still a major issue on OSHA's radar screen."

Thus, five years after it was originally proposed, the OSHA TB standard has been revived with the limited reopening of the docket. Infection control professionals have until March 25 to submit any comments on the risk assessment and other material placed in the docket. **(For comment information, see editor's note at the end of this article.)**

"We are looking at all the pros and cons of a standard," Edens says. "Obviously, there [are some who feel] that they are doing a really good job and there is really no need for an OSHA standard. I have talked to a lot of people, and there are people who have excellent TB programs. And there are some who don't."

The primary problem that OSHA faces in pursuing finalization of the rule is that its own peer review experts — while saying many positive things about the risk draft — concluded that OSHA overstated the threat to health care workers. Though personally in favor of an OSHA TB standard, reviewer **Mark Nicas**, PhD, professor of public health at the University of California in Berkeley, tells *Hospital Infection Control*: "In the way they did the calculation, they overstated the lifetime occupational risk of infection and they also overstated the lifetime probability of disease. Clearly, if they have mortality figures based on their disease estimates, then there was some overestimation in mortality."

Also in the docket is an analysis of OSHA's risk assessment by **Richard Menzies**, MD, professor and director of the respiratory epidemiology unit at McGill University in Montreal, Canada. He concluded, as well, that the "risk of death is overestimated. Age-specific case fatality rates are available from the literature or could be precisely calculated using national reported data from 1996-1998 that should be readily available from the Centers for Disease Control and Prevention

[CDC]. These age-specific case fatality rates should be used to calculate risk of death for health care workers who develop disease within two years following occupational infection."

According to OSHA's calculations, estimates of risk of death caused by occupationally acquired TB range from 0.1 per 1,000 for hospital workers in low-risk communities to 3.4 per 1,000 for workers in hospitals lacking enhanced controls and treating more than 100 TB patients per year. OSHA historically has used risk of mortality of one in 1,000 as a general rule of thumb for issuing regulation, says Edens. Though the one in 1,000 ratio falls within the risk estimates, the reviewers' observations and other comments will have to be considered, she says. Moreover, any decision to finalize the rule could be based as much on political considerations as risk calculations.

"The risk assessment is merely a kind of mathematical exercise, looking at the data and trying to crunch out the risk estimates," she says. "The next step is a mixture of a science and policy. We haven't gone to that stage yet, but those are the kind of determinations we will be making before the final rule. To some degree, it is a policy decision by the agency."

The agency is considering tailoring the regulatory requirements according to various levels of risk, leaving some hospitals in low TB areas with less onerous requirements.

"We are trying to look at the range of risk, and looking at the recommendations and some of the statements that were made in the IOM report about their concern that OSHA's pervious proposal was a little inflexible," Edens says. "We are open to ways to make it commiserate with the risk that exists. There was already some consideration for low prevalence or low incidence areas of TB [in the proposed rule]. But if the perception [of inflexibility] is there, we need to make it clear to people if you are in areas that don't have TB, you might have less to do."

Indeed, OSHA will have to make its whole case a lot clearer if the agency expects to meet its regulatory threshold of finding that the hazard in question represents "a material impairment of health," says **Katherine West**, BSN, MSEd, CIC, infection control consultant for Infection Control/Emerging Concepts in Manassas, VA. A longtime OSHA expert, West reviewed the risk assessment and other materials in the reopened docket for *HIC*.

"They have some tough hurdles," she says. "Their risk categories are not well defined, and they haven't accounted for different areas of risk within a facility. The [risk assessment] is based on 1998 data, and the case numbers have declined since 1998."

An additional concern is that the agency combined dissimilar types of TB in creating its occupational risk data, she says. "They talk about TB in general. The numbers reflected are not just pulmonary TB. They included atypical cases and extrapulmonary cases. Extrapulmonary cases are not communicable, and atypical TB is not a risk unless you are immune-compromised."

Risk of infection, death from TB in health care

The Occupational Safety and Health Administration (OSHA) recently reopened the docket on its proposed tuberculosis rule to allow comment on its draft final risk assessment for occupational TB. The revised draft risk assessment includes the following key elements:

OSHA divided the data into four exposure scenarios (low, intermediate, high, and very high) to describe the potential range of risk that might be experienced by workers exposed to TB. The degree to which enhanced TB control measures reduced the risk of infection was considered as the data allowed.

The weighted average estimates of lifetime occupational risk of TB infection in hospitals are presented in chart form **(See chart, inserted in this issue.)** The lifetime risk of TB infection ranged from 17.5 per 1,000 workers to 431.7 per 1,000 workers, depending on the scenario for the amount of TB exposure and the TB controls in hospitals.

Based on studies done at the very-high exposure hospitals — both before and after installation of enhanced TB controls — OSHA estimates that these controls can reduce the lifetime risk of infection by 46% to 92%.

The lifetime risk of developing active TB once infected is estimated at 10% with no treatment and 6.5% if a prophylactic treatment is given. (Practical difficulties with completing the six to nine month treatment course reduces its clinical effectiveness.) The case death rate from TB for health care workers is estimated at 7.8%. These percentages were applied to the lifetime infection risk estimates to derive health care worker active TB and death risks.

Weighted average estimates of risk of death caused by occupationally acquired TB range from 0.1 per 1,000 for hospital workers in low-risk communities to 3.4 per 1,000 for workers in hospitals lacking enhanced controls and treating more than 100 TB patients per year. ■

To avoid overstating the occupational risk, ICPs doing a risk assessment for TB in their community should ask the local health department for only pulmonary TB case numbers, she recommends.

Lacking critical medical expertise, OSHA must partner with CDC if it expects to ever issue a standard that will stand up to critical review, West says. The CDC is currently discussing modifying the frequency of skin-test recommendations and other measures in its 1994 guidelines, which formed the basis for the 1997 OSHA proposed rule. **(See related story, p. 33.)**

"OSHA should hold off and see what the CDC [revised] guidelines say," she says. "Then it can take CDC's new guidelines and put them into regulatory language."

Indeed, many critics of OSHA from the outset said they would support the agency if it stuck to enforcing CDC guidelines.

"Some hospitals need regulation," West says. "Some of them need to be told that this is important to do."

That said, the agency likely will fail if it tries to go beyond CDC guidelines because OSHA will not be able to justify a standard based on current TB trends, West says. "The numbers are continually dropping — plus, it is treatable. In Third-World countries, I believe that people get TB and die. But I don't believe that people aren't going to get picked up and treated in this country today, especially not health care workers."

'The paradox of prevention'

Issuing a final rule will be a tough sell because TB declined 7% in 2000 and has fallen a total of 39% since 1992. The early 1990s saw the nosocomial TB outbreaks that prompted the proposed rule, but now widespread public health and infection control efforts have TB on the run in the United States. But at the same time, CDC epidemiologists are well aware that the history of TB is that it resurges when prevention programs wane.

"I call it the paradox of prevention," says **Renee Ridzon**, MD, medical epidemiologist in the CDC division of TB elimination. "You do a really good job, then all the money goes away and you can't do the prevention anymore. Then it could come back. People have this concern in their minds, although I hope it wouldn't return to the state it was in the late 1980s and early 1990s."

With TB in decline, OSHA must make a case for regulatory "vigilance" if it pursues finalization of the standard. "A lot of things that we proposed are things you would still want to do even it you didn't have TB [in your community]," Edens says. For example, even in very low TB prevalence areas, ICPs would want to have referral arrangements established if they do not have TB isolation rooms. Likewise, clinicians would have to be knowledgeable in diagnosis and treatment issues should a case appear in the emergency department.

"The question is: How can we come together in a reasonable way to keep the vigilance and maybe not be so different from CDC?" Edens asks. "If OSHA had something in place, it would capture those people who have a tendency to go lax when things are going good. We could have a mechanism to make sure that we not being overburdensome, so if [hospitals] are following the CDC guidelines, which most people endorse, then following an OSHA rule wouldn't be anymore burdensome."

The standard could be written in such a way that it would enforce CDC guidelines even if they are revised, Edens notes. "Obviously, if they made huge changes in what they recommend for infection control practices, we would want to look closely at that and make sure we are both on the same page scientifically," she says. "If the only thing [the CDC] is changing is the periodicity of skin testing, that might not have a big impact on what we are doing. We could quite easily incorporate that. Some of the basic infection control procedures I don't see changing."

Currently, in addition to their own compliance documents, OSHA inspectors have a copy of the 1994 CDC guidelines for reference. Though they only can use the agency's General Duty clause for enforcement in the absence of a TB standard, there are certain things they are enforcing, Edens says. For example, OSHA currently can require that initial fit tests be done on employees using N95 TB respirators, but the agency has no authority to require annual fit-testing unless it issues a final TB standard.

"We will do an inspection," she says. "But, generally, it is part of bloodborne pathogen standard inspection or if we get a complaint. We are not scheduling them necessarily. If they don't have a TB case or have not had one in the last six months, we cannot prove a hazard exists. However, if we go into a hospital setting and they have TB patients, but are not using feasible means of abatement, then we would cite them."

[Editors' note: The recently opened TB rulemaking docket H-371 — including the peer reviewer' reports, OSHA's draft final risk assessment, and the IOM report — are available for inspection and copying in the agency's docket office in Washington, DC. The materials are not available on line, but according to Wright, the docket office will mail them to those who call (202) 693-2350. OSHA has set a postmark deadline of March 25, 2002, to receive comments on the docket items. You also may submit comments electronically to http://ecomments.osha.gov. Comments of 10 pages or fewer may be transmitted by fax to (202) 693-1648, provided that the original and one copy of the comments are sent to the docket office immediately thereafter. Comments submitted electronically or by fax must be submitted by the March 25 deadline. Send two copies of your comments to Docket Office, Docket H-371, Room N-2625, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Ave., N.W., Washington, DC 20210.] ■

CDC may drop routine TB skin testing in some areas

Testing in low TB areas leads to false positives

Reacting to declining tuberculosis, the Centers for Disease Control and Prevention (CDC) soon may drop its recommendation for annual TB skin testing of health care workers in areas of low TB prevalence.

In revising its 1994 TB guidelines for health care settings, the CDC wants to address the issue of false-positive tuberculin skin tests in areas with little TB in the community.

"For example, in Montana, which has 20 cases a year, it may be difficult to justify doing annual skin testing on every health care worker because the skin test has an inherent false-positive rate in itself," says **Renee Ridzon**, MD, medical epidemiologist in the CDC division of TB elimination. "The efficiency of the test is not really good in some settings that are using annual skin testing right now."

The system the CDC is considering going to is to test the worker at baseline (e.g., on hire) and thereafter only if there is a known or suspected exposure to TB. There would be no annual or "serial testing" for health care workers in low-prevalence areas, although the exact definition of such areas remains to be clarified.

"We are also trying to streamline the risk categories," Ridzon says. "In the old one, there were five different risk categories. Some of the feedback we have gotten is that this was very confusing for people. We are considering streamlining into just three [e.g. low, medium, and high risk]."

The CDC also is expected to address the issue of respiratory fit-testing in the revisions, but Ridzon declined comment on that aspect. The National Institute for Occupational Safety and Health (NIOSH), a branch of the CDC that certifies respirators, is participating in the guideline revision. Meanwhile, the Occupational Safety and Health Administration (OSHA) is expressing interest in duplicating the CDC revised guidelines in a TB regulatory standard. The CDC guidelines are being revised without consideration to the regulatory implications, Ridzon says.

"Given that it is not clear what is going to happen with the [OSHA] TB standard, this needs to be considered a separate publication," she says. "We consider this a document that the CDC and NIOSH are producing."

The CDC recently released a report showing TB in the United States is continuing to decline, though cases in the foreign-born are an ongoing concern.[1] During 2000, a total of 16,377 cases (5.8 cases per 100,000 population) of TB were reported to the CDC from the 50 states and Washington, DC. That represents a 7% decrease from 1999 and a 39% decrease from 1992, when the number of cases and case rate most recently peaked in the United States (26,673 cases; 10.5 cases per 100,000 population.)

Public health identification and treatment efforts, and enhanced infection control programs in hospitals are contributing factors to the decline.

"We at CDC certainly aren't receiving as much information, as in the early part of the '90s for example, of nosocomial transmission of TB." Ridzon says. "It seems like we have imposed infection control measures and that these have been effective. I think that most people in infection control in the country feel that that is the case."

Foreign-born rate seven times higher

Despite the overall decline in TB, the case rate among the foreign-born remains at least seven times higher than native U.S. citizens, according to the CDC report. Of the 16,377 cases in 2000, 8,714 cases (3.5 per 100,000 population) were reported among the U.S.-born; 7,554 (25.8 per 100,000 population) were among the foreign-born. The latter

group represents 46% of all cases.

To address the high rate in the foreign-born, the CDC is working with its public health partners to implement TB controls among recent international arrivals and residents along the border between the United States and Mexico. The CDC also is trying to assist TB programs in countries with a high incidence of TB disease, rather than just trying to catch cases at the border.

"Certainly, one of the things we have to avoid with these [revised] guidelines is saying. 'Everything is under control; forget about it,'" Ridzon says. "You don't want to create a lax sense. You need to keep vigilance up. People need to continue to be thinking about this. It's difficult, but it's sort of where we are going in a general sense with TB in the country."

The concern is the "paradox of prevention," which essentially means that the very resources that brought TB under control vanish along with the disease.

"As rates go down everywhere, even state TB control programs may lack the resources any longer to put a number of [staff] on TB only," she says. "At the same time, they still have to be equipped to deal with a cluster of cases. This is something we have to address in all aspects of TB control in the United States, not just in hospitals."

Indeed, Ridzon has firsthand experience with the phenomenon, remembering that she was told as a medical resident in the 1980s that she would probably never see a case of TB. In the following years, TB made its bold return. "Having seen that resurgence so recently, [hopefully] there won't be that much apathy," she says.

Reference

1. Centers for Disease Control and Prevention. Tuberculosis mortality among U.S.-born and foreign-born populations — United States, 2000. *MMWR* 2002; 51:101-104. ■

The big chill: Icing saline leads to LASIK infections

Pathogen source found in drain of ice machine

The apparently common practice of chilling saline solution in ice during LASIK eye surgery may lead to corneal infections in patients, researchers warn.

Eye infections in five patients were traced to an ice machine that was serving as a reservoir for the infecting pathogen: *Mycobacterium szulgai,* says **Gregory Bond**, RN, nurse epidemiologist at Scott & White Memorial Hospital and Clinic in Temple, TX. This appears to be the first investigation of an infection cluster following laser-assisted in situ keratomileusis (LASIK), and the first to link *M. szulgai* infection with an environmental source, Bond and colleagues report.[1]

After reviewing the surgeon's practice of icing the saline eye-irrigating solution, they compared the infecting pathogen with isolates taken from a nearby ice machine. A culture from the drain of the ice machine grew *M. szulgai*, which matched the outbreak strain by pulsed-field gel electrophoresis. "It was a carbon copy," Bond tells *Hospital Infection Control*.

A commonly performed procedure to correct myopia, hyperopia, and astigmatism, LASIK was added to the institution's surgical offerings in June 2000. However, in October of that year, the first infected patient was discovered. Investigators did a retrospective cohort study of all LASIK procedures between June 6 and Oct. 24, 2000, with follow-up through March 31, 2001. They found that five of 52 patients (9.6%) had confirmed postoperative *M. szulgai* keratitis. All five cases were identified among 18 patients (30 procedures) of "Dr. A." No infections were found among 34 patients (62 procedures) treated by "Dr. B."

"It took a while for the [infections] to appear, and the patients did not have optimal postoperative courses," Bond says. "They began to develop infection problems that did not respond to the usual treatment. As these [infections] went on and on, one surgeon decided to do a scraping and sent it for acid-fast studies. That is when it showed up that it was an acid-fast organism."

With *M. szulgai* identified, appropriate antibiotics could be targeted at the pathogen and all patients recovered.

"They all resolved eventually," Bond says. "Some were very slow to recover because of the difficulty in treating that type infection."

Two other patients of Dr. A had similar corneal lesions that were not cultured, but were treated as probable cases.

The surgeon's techniques differed only in his use of saline lavage that was chilled in a tub of ice. The other surgeon used saline directly from its stock bottle without chilling it.

"It's a rinse solution used as they are doing those procedures," Bond explains. "It was brought up

into a syringe with an irrigating-type tip. [Dr. A and staff] would draw up the solution and place it on a bed of ice just to chill the solution."

Though the medical benefit is unclear, the surgeon reported being taught to chill the solution when working at another hospital that did numerous LASIK procedures. There were no reported problems at the other institution, Bond says.

"This particular surgeon learned his technique in a large practice there, and that was the process that they used. I never really saw an explanation for the benefits or exactly why they were chilling the saline. He was just following the practice he had been taught. It seems to be a fairly common practice," he explains.

Transmission to the patients' eyes apparently occurred by the syringe tip becoming contaminated by the ice or possibly on the hands of a health care worker who handled both the ice and syringe.

"We don't know the exact process for inoculation, but it is linked back to the ice and to the water source," Bond says. "People just need to be aware that water sources, regardless of how potable the water is, are still going to have some type of organisms in them. Mycobacteria may be one of those that is either in the water system itself or in draining systems."

While using an unchilled solution is an obvious intervention, medical practitioners who favor the chilling technique should take some additional measures, he advises. They could chill the container of solution and then draw it into the syringe, he notes.

"[Do] something so the syringe and tip are not in such close proximity to the ice," he says. "They could put a sterile plastic sheet or something over the ice to maintain the sterility of the field."

The surgeon decided to discontinue LASIK procedures and do other types of eye surgery.

"I think that once the source was found, he wouldn't have had any additional problems with it," Bond says. "But that was his choice."

(Editor's note: We are trying to find out more about the practice described in this article. If your facility does LASIK procedures, is the saline solution chilled on ice? Have you had any problems with the practice? Please go to the forum section of your free subscriber web site at www.HIConline.com *and post a note regarding this. Information shared in the forum is for* HIC *subscribers only and is not published in the newsletter. Thanks for your input.)*

Reference

1. Holmes GP, Bond GB, Fader R, et al. A chilling experience: A cluster of *Mycobacterium szulgai* keratitis following laser assisted in situ keratomileusis (LASIK) Abstract 478. Presented at the 41st Interscience Conference on Antimicrobial Agents and Chemotherapy. Chicago; December 2001. ■

Ring wearers wed pathogens to patients

Three-fourths of workers with rings contaminated

Health care workers who wear rings are far more likely to carry pathogenic bacteria on their hands than their ringless colleagues, researchers report.

Colonization can occur in the area between the skin and the ring, creating a moist covered environment for bacteria to grow. Wearing gloves does not necessarily eliminate the problem, particularly since rings also have been associated with glove tears, says **Robert Hayes**, a microbiologist at Cook Country Hospital in Chicago.

"The study was not designed to look at that, but just as your hand can become contaminated in removal of the gloves, I am sure that a ring could also," he tells *Hospital Infection Control*.

Hayes and colleagues found that 76% of health care workers who wore a ring had bacteria-contaminated hands, compared to 29% of workers who did not wear rings. Wearing more than one ring increased hand contamination to 94%. Further, bacteria on ringed hands were more numerous than bacteria on nonringed hands.

The study was done by a multidisciplinary group from Cook County Hospital, the Atlanta-based Centers for Disease Control and Prevention (CDC), and Rush-Presbyterian-St. Luke's Medical Center, also in Chicago.[1] Samples were obtained from health care workers in the surgical intensive care unit at Rush, and laboratory work was completed at Cook County.

Using a glove juice technique, the researchers sampled 66 RNs a total of 282 times over 14 weeks. Selective media were inoculated with organisms from filtered glove juice. The researchers evaluated skin condition, dominant hand, the number and type of rings worn, nail length and applications, the number of patients cared for, and glove use during patient care. The hand cultures were processed to determine the number and type of microorganisms recovered and whether any were resistant to antibiotics. Indeed, two of the five most commonly recovered pathogens were antibiotic-resistant strains.

Pathogens cultured during the 282 assays included methicillin-resistant coagulase-negative staphylococci (201/282; 71%), gram-negative bacilli (42/282; 15%), *Staphylococcus aureus* (38/282; 14%), Candida species (33/282; 12%), and vancomycin-resistant enterococci (6/282 2%). By multivariate analysis, only ring use by the nurses remained an independent risk factor for contamination by presumably transient organisms.

Citing a lack of definitive data, the CDC left ring wearing as "an unresolved issue" in its draft hand hygiene guidelines. Whether the wearing of rings results in greater *transmission* of pathogens appears to be the key issue.

While contamination has been found, other studies document that the mean bacterial colony counts on hands after hand washing were similar among individuals wearing rings and those not wearing rings, the CDC stated in the draft. Further studies are needed to establish if wearing rings poses an increased risk of transmission of pathogens in health care settings, the agency concluded.

One problem is that studies that have looked at the issue have used different research techniques, making comparison of data difficult, Hayes says.

"There are a lot of unresolved issues," he says. "We didn't inoculate hands. In a lot of studies that have been performed, [researchers] inoculate before, then do their test. The data don't necessarily follow suit."

Reference

1. Hayes RA, Trick WE, Vernon, et al. Ring use as a risk factor for hand colonization in a surgical intensive care unit. Abstract 1333. Presented at the 41st Interscience Conference on Antimicrobial Agents and Chemotherapy. Chicago; December 2001. ■

NEWS BRIEFS

Patient safety partnership boosts medical error fight

Joint Commission links up with big business

The Joint Commission on Accreditation of Healthcare Organizations has jumped into a formal partnership with a leading patient safety advocate, The Leapfrog Group.

In the first major collaboration effort between

the two parties, the Joint Commission and Leapfrog leaders will try to identify a specific set of outcome and process measures in intensive care units. These measures eventually may be used to supplement or even replace the current Leapfrog measures, which recommend that hospitals have board-certified or board-eligible intensivists.

The new partnering arrangement relationship cements a previously informal relationship with the health care purchaser group. The Leapfrog Group is a growing consortium of more than 90 Fortune 500 companies and other large private and public health care purchasers founded by the Business Roundtable. The group launched a national effort in November 2000 to educate employees, retirees, and their families about medical errors and the importance of hospital efforts to make advances in patient safety, and to reward hospitals for their efforts in improving patient safety.

Leapfrog purchasers provide health benefits to more than 26 million Americans and spend more than $46 billion on health care annually. The group was established in the wake of the 1999 Institute of Medicine report, *To Err is Human*, which made medical errors a national issue.

Joint Commission standards issued in 1999 require the internal definition, reporting, and analysis of adverse events in accredited health care organizations, and the implementation of indicated improvements. New patient safety standards that were implemented last year encourage the creation of a culture of safety in hospitals, set forth expectations for the identification and redesign of error-prone systems, and require the disclosure of unanticipated outcomes to patients and/or their families. ▼

FDA revises reprocessing dates, seeks label input

Class II devices deadline extended to Aug. 14th

The Food and Drug Administration (FDA) is notifying hospitals and independent reprocessors of single-use medical use devices (SUDs) of some changes in enforcement deadlines of its regulations. The enforcement policy for classes I, II, and III SUDs is as follows:

• **Class II devices:** The FDA is extending the deadline for active enforcement of premarket notification submission requirements for class II SUDs until Aug. 14, 2002, provided that the reprocessor:

— submitted a premarket notification submission (also known as a "510(k) submission") by Aug. 14, 2001;

— has not received a not substantially equivalent determination;

— provides timely responses to the FDA's requests for additional information in accordance with 21 C.F.R. §807.87(l).

• **Class III devices:** The FDA may actively enforce premarket approval requirements for class III SUDs as of Feb. 14, 2002.

• **Class I devices:** The FDA may take enforcement action against any class I SUD if a 510(k) submission has not been submitted to the agency as of Feb. 14, 2002, or if the class I device does not have FDA marketing clearance by Aug. 14, 2002.

The FDA also is asking for comments and suggestions on the labeling of reprocessed SUDs with respect to the name of the original equipment manufacturer and the reprocessor. The agency is considering developing a labeling guidance.

Submit written or comments by March 20, 2002, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. ▼

Teleconferences are tops for bioterrorism training

AHRQ report addresses training effectiveness

Teleconferences are an effective way to reach geographically diverse groups and train large numbers of clinicians on bioterrorism preparedness, according to a report by the Agency for Healthcare Research and Quality (AHRQ) in Rockville, MD. Furthermore, satellite teleconferences may be as effective as classroom training, according to the report, which was produced by the AHRQ Evidence-based Practice Center (EPC) at Johns Hopkins University in Baltimore. The report, *Training of Clinicians for Public Health Events Relevant to Bioterrorism Preparedness*, reviewed 60 studies on the most- and least-effective strategies for training clinicians in bioterrorism preparedness.

CE/CME questions

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

9. What did the reviewers cited in this issue conclude about the Occupational Safety and Health Administration's recently released revised risk assessment of occupational TB in health care?
   A. It overstated some aspect of the occupational risk of TB.
   B. It was incredibly accurate.
   C. It underestimated the risk of occupational TB.
   D. It surprisingly found no link between HIV and TB infection.

10. Reacting to declining tuberculosis, the Centers for Disease Control and Prevention may soon drop its recommendation for annual TB skin testing of health care workers in:
    A. states where TB control programs have secured long-term funding
    B. areas of low TB prevalence
    C. nursing homes
    D. homeless shelters

11. Which of the following practices were linked to corneal infections in outbreak associated with LASIK eye surgery?
    A. using the same instruments on each eye
    B. warming face towels in a microwave
    C. chilling saline solution in ice
    D. all of the above

12. Despite the lingering possibility of late-onset anthrax infection, more than 8,000 people potentially exposed in the bioterrorism attacks of 2001 turned down offers of additional antibiotics and immunization with the anthrax vaccine. Which of the following were some of the possible factors in the decision?
    A. side effects to antibiotics
    B. concerns about the anthrax vaccine
    C. may have felt they were no longer at risk
    D. all of the above

Models used included infectious disease outbreaks and hospital disaster drill training.

Hospital disaster drill training appears to improve clinicians' knowledge of the disaster plan and allows them to identify problems in plan execution. However, the scarcity of studies on this type of training made it difficult for researchers to draw conclusions about the overall efficacy of disaster drills as a way to help prepare for a bioterrorist event. In fact, the report points out that very few bioterrorism preparedness training programs have been rigorously evaluated.

The report provides a framework for developing evidence-based educational programs.

"This information will help health care leaders select educational strategies for frontline professionals who are likely to be involved in the assessment and management of victims of a bioterrorist attack," says **Lisa Simpson**, MD, AHRQ deputy director. A summary of the report is available by calling the AHRQ Publications Clearinghouse at (800) 358-9295 or sending an e-mail to ahrqpubs@ahrq.gov. Copies of the full report will be available in March.

[Editor's note: American Health Consultants will present **Disaster Planning and Bioterrorism: Is Your Hospital Prepared?** *— a 60-minute audio conference that will explain step-by-step how to develop a sustainable, long-range bioterrorism and disaster plan. Scheduled for Wednesday, March 6, from 2-3 p.m. EST, the educational program will be presented by Bettina M. Stopford, RN, clinical supervisor, USPHS National Medical Response Team, and Robert E. Suter, DO, MHA, FACEP, president, Texas Emergency Physicians, PA. The facility fee is $249 for* HIC *subscribers, which includes free CE and CME for your entire staff. To register, call (800) 688-2421 or go to www.ahcpub.com.]* ■

JOURNAL REVIEWS

Bug vs. bug: NIH puts its money on the virus

VRE-infected mice live to squeak another day

Biswas B, Adhya S, Washart P, et al. **Bacteriophage therapy rescues mice bacteremic from a clinical isolate of vancomycin-resistant Enterococcus**. *Infect Immun* 2002; 70:204-210.

Pitting one microorganism against another, researchers at the National Institutes of Health are using viruses to attack antibiotic-resistant bacteria.

Working with scientists from Exponential

Biotherapies in Point Washington, NY, they have successfully used bacteriophage therapy to treat mice experimentally infected with a fatal vancomycin-resistant enterococci (VRE) infection. Bacteriophage are viruses that can attack and kill bacteria without causing disease in humans.

Renewed interest in old science

Researchers began exploring the potential of the viruses as antibacterial therapies in the early 20th century, but a combination of factors — not the least of which was the discovery of penicillin and the age of antibiotics — made that that interest short-lived.

The rise of antibiotic resistance in the 1980s and 1990s has renewed scientific interest in the development of the alternative therapies.

In the study, the researchers experimentally infected mice with a strain of VRE and injected treated them with bacteriophage at varying times after initial infection. The mice that did not receive treatment died within 48 hours. All the mice that were treated within five hours of infection and half of those treated 24 hours after infection survived.

"The emergence of antibiotic-resistant bacterial strains requires the exploration of alternative antibacterial therapies," the authors concluded.

"In the present study, we report the isolation of bacteriophage that are safe and effective as bactericidal agents for animals with lethal VRE

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

THOMSON
AMERICAN HEALTH CONSULTANTS

Editorial Questions

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

infections. The results warrant a re-examination of the potential application of bacteriophages in Western medicine." ▼

Have bug, will travel: Risk rises for transfer patients

Risk similar for incoming and moving within

Eveillard M, Quenon JL, Rufat P, et al. **Association between hospital-acquired infections and patients' transfers**. *Infect Control Hosp Epidemiol* 2001; 22:693-696.

Whether coming from another hospital or shifting wards within the same facility, the risk of having a nosocomial infection on a given day was more than four times higher in transferred patients. While clearly a risk marker, patient transfer also is independently associated with nosocomial infection, the authors found. "The origin of a transferred patient is readily known at admission. It would be useful to adopt specific measures for such patients, particularly if they have other risk factors of nosocomial infection, both to protect them and to prevent transmission of the infection to other hospitalized patients.

To assess the risk of nosocomial infection in transferred patients — and to determine whether transfer is only a risk marker or is independently associated with nosocomial infection — the researchers conducted a retrospective analysis at a 400-bed general hospital in the Paris area.

Of the 1,326 patients included in four surveys, 70 (5.3%) had been transferred from another hospital and 199 (15%) from another ward of the hospital. Transferred patients more frequently had known risk factors of nosocomial infection. Those included age more than 65 years, a length of hospital stay more than seven days, at least one invasive procedure, a recent surgical intervention, and immunosuppression.

The prevalence rate of infected patients was 6.7%. However, the risk was similar between patients transferred from another hospital (20%) and patients transferred within the hospital (17%). The multivariate analysis performed by logistic regression showed that intrahospital transfer, a length of hospital stay more than sever days, and having had at least one invasive procedure were independent risk factors of infection. ■

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. ■

OSHA Risk Estimates

Average Annual and Lifetime Occupational Risk Estimates of TB Infection, Active TB, and TB Death[a,b] per 1,000 Workers at Risk for Various Occupations. All Estimates Adjusted to 1998 TB Infection Rates.

Work Setting		Annual TB Infection Rate/1,000 Workers	Lifetime TB Infection Rate/1,000 Workers	Lifetime Active TB Case Rate/ 1,000 Workers	Death Caused by TB Rate/1,000 Workers[c]
Hospitals:	**Conditions**				
Avg. U.S. TB Risk[d]	Before 1990 CDC Guidelines	4.1	165.3	16.5	1.3
Low Risk[e]	After 1990 CDC Guidelines Good TB Controls	0.4	17.5	1.7	0.13
Average/High Risk[f]	Fairly Good TB Controls as of 1992	2.7	112.5	11.2	0.9
High Risk[g]	TB Controls as of 1995, Not Always Working	1.4	60.2	6.0	0.5
Very High Risk[h]					
JMH	Before TB Controls 1991	12.6	431.7	43.2	3.4
	After TB Controls 1992-1997	0.8	34.9	3.5	0.3
	Risk Reduction	11.8	396.8	39.7	3.1
GMH	Before TB Controls 1992	4.3	174.6	17.5	1.4
	After TB Controls 1993-1997	2.2	94.8	9.5	0.7
	Risk Reduction	2.1	79.8	8.0	0.7
Long-term Care[i]		11.8	391	39.1	3.0
Home Health Care[i]		6.6	250	25.0	1.9
Home Care[i]		1.4	60.4	6.0	0.5
Correctional Facilities[j]		0.62	27.4	2.7	0.2

a. Weighted by each state's adult population size in 1994
b. Risk estimates reflect excess risk due to occupational exposure and are expressed per 1,000 employees at risk.
c. Number of deaths caused by TB due to occupational exposure is derived based on an estimated TB case death rate of 77.85 per 1,000 cases and is computed by multiplying the lifetime active disease rate by 0.07785.
d. Based on analysis of Western North Carolina 1984 data.
e. Based on analysis of Washington state 1994 hospital data.
f. Based on analysis of SHEA-CDC 1992 data.
g. Based on analysis of Alameda and San Francisco County 1995-1997 data. Weighted average excess relative risk of 1.0.
h. Based on analysis of Atlanta's Grady Memorial Hospital 1992-1997 data and Miami's Jackson Memorial Hospital 1991-1997 data.
i. Based on analysis of Washington State nonhospital HCW 1994 data.
j. Based on analysis of NY State Corrections workers 1992 data, using average relative risk estimate of 1.6.

Source: Occupational Safety & Health Administration, Washington, DC.

BIOTERRORISM WATCH

Preparing for and responding to biological, chemical and nuclear disasters

Anthrax aftermath: Adverse drug reactions, vaccine controversy undercut CDC extended treatment offer

Some 8,000 people say thanks but no thanks

Despite the lingering possibility of late-onset anthrax infection, more than 8,000 people potentially exposed in the bioterrorism attacks of 2001 have turned down offers of additional antibiotics and immunization with the controversial vaccine, *Bioterrorism Watch* has learned.

Faced with insufficient data to truly assess the risk, the Centers for Disease Control and Prevention (CDC) in Atlanta offered the additional measures but fell short of actually recommending them.

Additional treatment offered as an 'option'

Operating on a thin margin of data about anthrax exposures, incubation periods, and subsequent infections, the CDC concluded it couldn't make a formal recommendation. The additional antibiotics and vaccine were made available as "options" to those exposed.

"The feeling was that this was the best thing we could do for people, and at least, leave it up to them to make a decision," says **Ian Williams**, PhD, medical epidemiologist in the CDC national center for infectious diseases. "We don't know what the answer is, but these are the options. We were really caught between a rock and a hard place on this one."

The 10,000 people potentially were exposed to anthrax in Connecticut, Florida, New Jersey, New York City, and Washington, DC.

They were all originally recommended to take at least 60 days of post-exposure antibiotic prophylaxis, but emerging data suggest that there has been a surprising lack of compliance.

In some preliminary surveys, fewer than half of those exposed were fully adhering to their original 60-day regimen. The CDC now has undertaken a telephone survey of all 10,000 people to identify adverse reactions and other reasons for the lack of adherence. **(See related story, p. 3.)**

The vaccine and additional antibiotic options were brought into play in part because the CDC knew it had large numbers of people who had not completed the original 60-day regimen. But the offer of additional care may have been undermined to some degree by prior adverse antibiotic reactions and fear of an anthrax vaccine that has been mired in controversy for years. Then again, many of those exposed may have felt they were no longer at risk and if their status changed, they would consult a physician.

Anthrax alive at 100 days

Though no known cases of anthrax have developed in any of the individuals who were prescribed the 60-day antibiotic course, the CDC also was aware of some disturbing data in animal studies. Traces of live anthrax spores have been detected in test animals' lungs up to 100 days following exposure, raising the theoretical possibility that the spores remaining still could

This supplement was written by Gary Evans, editor of *Hospital Infection Control*. Telephone: (706) 742-2515. E-mail: gary.evans@ahcpub.com.

cause disease. In that regard, one of the additional options offered to the exposed people was to take antibiotics for another 40 days (bringing total therapy time out to 100 days).

The other option was to take the additional drug regimen and also be vaccinated against anthrax. The latter option included three doses of anthrax vaccine over a four-week period, but antibiotics still had to be taken as the vaccine took effect.

The vaccine was not designed for post-exposure prophylaxis, but the theory is that it may provide additional protection by inducing an immune response to anthrax.

"People were unclear what the upper limit [for the onset of infection] was," Williams says. "That is what really drove both the vaccine and the antibiotic [offer]. We thought that 40 additional days to make 100 days looked sufficient based on our scant data. The vaccine was added because, is 100 days enough? I can't tell you absolutely for sure that it is enough."

Thousands took their chances

Most people were willing to take their chances that late onset anthrax will not occur.

Of the exposed cohort of some 10,000 people, 1,547 elected to receive more antibiotics after their 60-day regimen. Another 192 opted to be immunized with the anthrax vaccine and take additional antibiotics while the series of shots is given. Are the other 8,000-plus people at any real risk?

"Our feeling is that there shouldn't be any late cases of anthrax, based on what we know," Williams says.

"But that very well might be dose-dependent. We can't quantify the dose. If you go back and look at the animal studies that were done, they were actually done with probably lower doses than we have seen in the [U.S. Senate] Hart office building. But based on the data we can draw from animal models, it looks like there shouldn't be late onset cases," he explains.

If such an event occurred, the disease presumably still could be treated — provided the person seeks medical care. Still, making assumptions about anthrax can be tricky.

The CDC has been on a steep learning curve throughout the bioterrorism attack, with officials caught off guard by the ability of anthrax to disperse and spread during mail handling.

In addition, the ability to predict risk of infection in an exposed individual remains elusive, said **Julie Gerberding**, MD, director of the CDC division of healthcare quality improvement.

"We know that the exposure dose probably varies depending on how close you are to the source when it's released and how long you are in the [area] of release," Gerberding reported at a recent CDC meeting on post-exposure prophylaxis for anthrax.

> *"This is not an experiment to help us later. We don't have a control group. All we are doing is using the best science we have, which suggests that this is best way to give protection to people."*

"[But] despite our capacity to think about populations, we cannot accurately identify individual exposure, and we cannot accurately quantify individual risk," she explained.

Faced with that conundrum, the CDC put the same options on the table for all 10,000 people potentially exposed.

"The risk was probably different in different places," Williams says. "If you look at Capitol Hill, the concentration of anthrax released was probably much higher than say, Connecticut, where a letter just went through a post office. But that's group risk. Individual risk is different. [We] can't tell you exactly what your risk is. We'll give you the best available data, but you are going to have to make that decision."

Of the 190 people receiving anthrax vaccine, 80 had some political connection in Washington, DC, and 44 were postal workers in that city. Another 49 people in New Jersey were vaccinated; and the remainder were in New York City (12), Florida (four), and Connecticut (three). Of those who chose additional antibiotics only, 849 were in Washington, DC; 354 in New Jersey; 248 in New York City; 55 in Connecticut; and 41 in Florida.

A mixed message?

The CDC has drawn criticism for its approach, particularly for making a controversial vaccine available but leaving the immunization decision up to patients and their providers.

"It would have been much better if they had come out and said, 'Yes, we think in order to have as much protection as possible against the potential of developing disease, you should receive both

Side effects undermine anthrax drug adherence

More than half dropped drugs by 30 days

Amid the hype and horror of the 2001 anthrax attacks, it seemed a given that the people potentially exposed would be particularly diligent in completing their antibiotic regimens. But as time passed — and side effects continued or worsened for some — compliance fell off dramatically for many of the 10,000 people put on 60-day regimens for ciprofloxacin and doxycycline, according to preliminary data from the Centers for Disease Control and Prevention (CDC).

None of the people who started on antibiotics have developed anthrax, but the CDC wants some answers on the lack of adherence. To that end, the CDC is conducting a telephone survey project that will attempt to reach all 10,000 people for whom post-exposure antibiotic prophylaxis was recommended. The interviews began in late January and are expected to continue through March 2002. The people were potentially exposed to anthrax in Connecticut, Florida, New Jersey, New York City, and Washington, DC.

"We are making sure we get in touch with all of these people to evaluate how they did in terms of taking antibiotics," says **Ian Williams**, PhD, medical epidemiologist in the CDC national center for infectious diseases. "We have data showing adherence definitely wasn't as high as people, prior to this outbreak, would have thought it would be."

The CDC attempted a variety of methods to assess compliance prior to the phone survey, including tracking individuals who did not return to refill their medication. Other methods include giving a sample of those exposed questionnaires that were self-administered, given by a nurse, or by telephone, according to **Nancy Rosenstein**, MD, medical epidemiologist in the CDC national center for infectious diseases.

"In general, adherence has declined over the course of the [first] 30 days to as low as 45%," Rosenstein said at a recent CDC meeting on post-exposure prophylaxis for anthrax.

Some groups were more compliant than others. For example, employees who worked in the American Media Building in Boca Raton, FL, were closer to 70% compliant, she said. But only 45% compliance at 30 days was also found in a "high risk group" of mail handlers in New York City, she added.

"Adherence experts tell me that when we actually count pills, the self-reporting numbers probably overestimate real adherence by as much as 20%," Rosenstein said. "So the real estimates of adherence — taking the antibiotics every day — are obviously substantially lower."

In terms of self-reported adverse events, within two weeks of taking ciprofloxacin, 19% were reporting severe nausea, vomiting, abdominal pain, and diarrhea. At 30-day surveys, many people had switched to doxycycline, but self-reported adverse events increased to 45%.

Again, the predominant symptoms were severe nausea, vomiting, diarrhea, and abdominal pain. About 12% of the people reporting adverse events required additional follow-up with medical chart review and physician interviews, she said.

"I don't want to in any way minimize the impact of these symptoms on people's daily life, but when we actually investigated further, we were unable to identify anybody who actually required hospitalization or an emergency room visit for their adverse events," Rosenstein said.

Thus, based on Food and Drug Administration criteria, no serious adverse events have been linked to taking antibiotics for anthrax exposure. A more complete picture of the adherence problems should emerge from the CDC telephone survey of all recipients. Preliminary surveys have found that 6% to 12% of respondents reported at least missing some of their doses because of the side effects, she said. ■

antibiotic and vaccine,'" says **Phillip Brachman**, MD, a professor in the Rollins School of Public Health at Emory University in Atlanta.

The vaccine has been embroiled in a safety dispute since the military began a mandatory immunization policy several years ago, with some veterans saying it made them sick and others refusing to take it.

"A number of [the exposed people] undoubtedly read about the problems some of the military

folks claimed they had experienced after having the vaccine," Brachman says.

"They associated their problem with the vaccine. Remember, that those people in the military who have made those complaints are a very small number, considering the total number of doses given," he adds. "So there are very few voices creating a lot of concern."

Brachman did what remains the only clinical trail on the safety and efficacy of an anthrax vaccine precursor when he worked for the CDC in the 1950s.

In a study of goat's-wool workers — which was once an occupational risk group for anthrax in the United States — he found the vaccine safe and effective. He reported few side effects to vaccination and an efficacy rate of 92.5%.[1] The vaccine used in the study was a protective-antigen variety similar to the current vaccine. However, the manufacturing process has since changed and a different strain of anthrax is now used.

"There have been a few minor changes, and some people make a lot more out of it then it really should be," he says. "A different strain is being used to prepare the vaccine, but that should make no difference because the organism is not in the vaccine. It is the protein product from the organism."

Dearth of data

An Institute of Medicine committee that convened to look at the current anthrax vaccine cited a dearth of data in concluding: "The published studies have found transient local and systemic effects (primarily erythema, edema, or induration) of the anthrax vaccine.

"There have been no studies of the anthrax vaccine in which the long-term health outcomes have been systematically evaluated with active surveillance. . . . The committee concludes that in the peer-reviewed literature, there is inadequate/insufficient evidence to determine whether an association does or does not exist between anthrax vaccination and long-term adverse health outcomes. . . . To date, published studies have reported no significant adverse effects of the vaccine, but the literature is limited to a few short-term studies,"[2] the committee said.

For its part, the CDC would not have made the vaccine an option for those exposed if it had any doubts about its safety, Williams says.

"It seems to be a very safe, efficacious vaccine," he says. "[The] CDC reviewed the data with the military, which has the most experience with this."

Still, some people may have been confused because the CDC did not roll out the vaccine right after the exposures occurred. Thus, the response was somewhat tepid to a vaccine "add-on" option 60 days after the potential exposure. One problem is that the U.S. military, which controls the dispersal of anthrax vaccine, did not release any stocks in the immediate aftermath of the bioterror attacks, he says.

"One of the lessons we have learned is that if the vaccine had been available when this first started, I think the post-exposure prophylaxis would have been approached much differently," Williams says.

With the military now more amicable on the issue, if a bioterrorist strikes again with anthrax, the vaccine could play an important role from the onset, he emphasizes.

"If this should happen again, the vaccine might be used closer to day zero," Williams says. "After a series of doses over a month or so, most people will develop an antibody response, so it would obviate the need for additional antibiotics. It will be used in more of a true post-exposure fashion."

Those who have been recently vaccinated will be followed over time. Indeed, the CDC is discussing following the whole cohort of 10,000 people. It is an interesting group, having been potentially exposed to anthrax, taken prolonged antibiotic regimens, and in some cases, received a vaccine whose long-term safety is in some question.

Another curious fact — as with other post-exposure regimens for diseases — is that no one will ever know if the additional measures taken by 1,739 of these people actually prevent a late-onset anthrax infection.

"This is not an experiment to help us later," Brachman says. "We don't have a control group. All we are doing is using the best science we have, which suggests that this is best way to give protection to people."

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2. Committee on Health Effects Associated with Exposures during the Gulf War. *An Assessment of the Safety of the Anthrax Vaccine: A Letter Report*. Washington, DC: Institute of Medicine; March 30, 2000. ■