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INSIDE

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California needle-safety law: Is it a prelude to a national regulation?

Exceptions, cost factors are unresolved issues in new California law

In what many suspect is a preview of national regulatory action, infection control professionals in California are scrambling to comply with a landmark state law requiring use of needle-safety devices to prevent bloodborne infections in health care workers.

The first law of its kind in the nation, the California legislation requiring implementation of needle-safety devices was signed into law Oct. 1, 1998. The statute directs the state division of Occupational Safety and Health (Cal-OSHA) to enforce the law by amending the bloodborne pathogen standard, the state version of the 1991 federal OSHA bloodborne regulation. Cal-OSHA issued an emergency amended standard on Dec. 17, 1998. That regulation still is subject to review and revision prior to issuance of a final enforcement standard, but health care facilities in California essentially have until Aug. 1, 1999, to come into compliance by implementing the use of needle safety devices.

Special Report: ICPs Respond to Needle-Safety Regs

After years of emotionally charged debate on the issue of needlesticks and protecting health care workers from bloodborne infections, 1998 saw California pass the first state law requiring implementation of sharps safety devices. There is growing sentiment that the situation in California is a prelude to other regulatory efforts nationally. In this issue of *Hospital Infection Control,* we feature a special report on the ongoing efforts by infection control professionals in California to comply with the new law in the most cost-effective manner. We also present some of the comments submitted by ICPs and other concerned clinicians to officials weighing the need for similar federal requirements. ■

As a result, observers report that health care purchasing departments in California are being inundated with safety products that include such designs as self-sheathing needles, retractable devices, blunting devices, and needleless connectors for intravenous lines. That makes it all the more important for ICPs to get involved in the evaluation process and determine the most appropriate method of compliance for their facility, says **Marguerite Jackson**, RN, PhD, CIC, FAAN, administrative director of the medical center epidemiology unit at the University of California in San Diego.

"The purchasing people are being bombarded with widgets," she tells *Hospital Infection Control*. "It is absolutely critical that the ICP be a key player in this process."

The Cal-OSHA regulation does not require specific safety devices by brand name, but calls for use of needleless systems or sharps with engineered injury protection designs. In effect, the regulation requires that health care employers replace conventional needle devices with such designs unless they can cite one of Cal-OSHA's regulatory exceptions, which are market availability of the device, patient safety, safety performance, and availability of safety performance information. **(See box, at right.)**

"There are four exceptions, and you can use your own data to support decisions you make," Jackson says. "Obviously, no one can afford to buy everything that is out there."

While heading up a task force at her facility to respond to the law, Jackson also has participated in several state meetings with other ICPs in her role as infection control advisor to the California Healthcare Association. She is stressing the importance of forming multidisciplinary evaluation committees that allow front-line health care workers, union representatives, and other key players to participate in the process of device evaluation.

"The first thing that [committees] need to do is assess their need for safety devices for hollow-bore needles that are blood-filled," she says. "That is where the major exposure risk is, so everybody needs to develop an action plan to systematically evaluate the classes of devices that are available, and then determine whether there is efficacy data for these devices that is not manufacturer-derived."

Indeed, data from the EPINet surveillance system in Charlottesville, VA, indicate that many hospitals nationally have implemented needleless intravenous systems, for example, to prevent needlesticks. But the IV line injuries being prevented are generally considered at relatively lower risk for transmission of bloodborne pathogens, while protective devices for prevention of higher-risk exposures during phlebotomy or IV catheterization have not been as widely used. **(See related story, p. 22.)**

Cal-OSHA device reg cites four exemptions

A Cal-OSHA regulation to enforce California's new law designed to protect health care workers from bloodborne infections via needlesticks cites the following four exceptions to requirements to implement needle-safety devices (engineering controls):

1. Market Availability: The engineering control is not required if it is not available in the marketplace.

2. Patient Safety: The engineering control is not required if a licensed health care professional directly involved in a patient's care determines, in the reasonable exercise of clinical judgement, that use of the engineering control will jeopardize the patient's safety or the success of a medical, dental or nursing procedure involving the patient. The determination shall be documented.

3. Safety Performance: The engineering control is not required if the employer can demonstrate by means of objective product evaluation criteria that the engineering control is not more effective in preventing exposure incidents than the alternative used by the employer.

4. Availability of Safety Performance Information: The engineering control is not required if the employer can demonstrate that reasonably specific and reliable information is not available on the safety performance of the engineering control for the employer's procedures, and that the employer is actively determining via objective product evaluation criteria whether use of the engineering control will reduce the risk of exposure incidents occurring in the employer's workplace. ■

Similar findings were reported by **Cynthia Fine**, MSN, CIC, infection control and employee health consultant for Catholic Healthcare West (CHW) in Oakland, CA. Fine is heading up a comprehensive evaluation and compliance program for some 50 CHW hospitals. She has developed an overall action plan and is working with individual ICPs at the other hospitals to bring the CHW system into compliance with the new state law. Tools used to implement the plan include a checklist of criteria for device selection and sharps evaluation forms, which Fine created from various sources. **(See checklist, below; form, p. 20.)**

"We've been trying to pull in the front-line workers to look at these devices and give us their feedback," she says. "Then we evaluate them using the standard criteria. Those that meet our criteria are going to trial. We have selected five or six hospitals that are interested in working with us on [trials]. We are going to trial them, and then we will make recommendations to business services."

The effort began with a survey of 39 CHW hospitals to collect baseline data as Fine launched the program. Of the 30 facilities that responded, 100% have implemented a needleless or needle-safety device for IV fluid / medication administration. But when looking at devices designed to prevent exposures that have a higher risk of transmission of bloodborne pathogens, Fine found that only 53% of the facilities had implemented safety devices for IV catheter insertions, and 40% reported use of safety-designed phlebotomy devices. Devices to prevent exposures during phlebotomy and insertion of IV catheters are among those that will be trialed under the program, she adds. Though no decision on the issue has been made yet, such findings raise the question of whether hospitals can defer some of the money spent on IV line safety systems to purchase devices designed to prevent injuries with a higher risk of transmission, Fine explains.

"We are focusing on the high-risk devices for IV starts, phlebotomy, and the hollow-bore syringes,"

15 sharps criteria are key to product selection

Cynthia Fine, MSN, CIC, infection control and employee health consultant for Catholic Healthcare West (CHW) in Oakland, CA, lists 15 criteria, summarized as follows, for sharps safety product selection in her program to comply with a new state law:

1. The manufacturer must be willing to work with and contract through business services departments.

2. Manufacturer must have adequate product and supply capability to service CHW system without delays or shortages.

3. Manufacturer must supply adequate free product for pilot projects.

4. Devices that reduce high-risk exposures will be given priority.

5. Product representatives must be available around the clock to educate and demonstrate devices at all CHW facilities.

6. The product must meet all regulatory requirements.

7. The device must minimize or eliminate the risk of needlestick injury to the user and others before, during and after use.

8. Safety mechanism activates easily and requires only one hand to operate. Devices that require no activation are preferred.

9. Minimal changes in technique during use of product are required:

— The product does not require more time than the non-safety device.

— The device is easy to use and does not require extensive training to be operated correctly.

— The safety device does not interfere with the product's intended use.

10. User can easily tell if safety feature is activated / locked.

11. The device has a minimal failure rate and consistently functions as intended.

12. Patient discomfort is not increased:

— Additional punctures are not routinely required.

— The safety feature does not interfere with ability to puncture skin.

13. A minimal number of parts / pieces is required to use the system / device.

14. Product is available in typical size ranges.

15. The device is compatible with other vendor's supplies. ■

she says. "My hope is that [Cal-OSHA] would be understanding if a facility put its money into high-risk devices and saved it on IV tubing. We'll see."

Indeed, compliance cost issues are critical as the California health care system begins a large-scale implementation of devices that often are much costlier than conventional needles. According to one industry estimate, for example, a phlebotomy device that demonstrated a 76% reduction in injuries costs about 22 cents more per unit than

User Sharps Products Evaluation Form

Name _____ Date _____

Dept/Unit_____ Phone # _____

1. How would you rate this product compared to other similar products you have used?

CRITERIA	Better than most	Same as most	Worse than most
Easy to open package			
Ease of assembly			
Ease of intended use			
Comfortable feel for user			
Length of time required for use			
Activation of safety feature			
Safety feature can't be defeated			
Has minimum failure rate and functions as intended			
Good for use with different patient populations			
Safe for healthcare workers			
Safe for patients			
Patient will like it			
Doctors will like it			
Ease of disposal			
Compatibility with other products			
WIll reduce risk of needlestick before use			
Will reduce risk of needlestick during use			
Will reduce risk of needlestick after use			
Reasonable number of parts			
Available in the sizes you need			

2. Would you recommend purchasing this device? ☐ Yes ☐ No

3. Is there a device you would rather use? ☐ No ☐ Yes_____

4. Comments: _____

_____

_____

_____

Source: Catholic Healthcare West, Oakland, CA.

APIC targets injuries at highest risk

Collaborative efforts needed to implement devices

Trying to strike a balanced position on an emotionally charged issue, the Association for Professionals in Infection Control and Epidemiology (APIC) in Washington, DC, recommends a collaborative approach targeting the injuries at highest risk of transmission in order to accomplish cost-effective implementation of needle-safety devices.

"This information makes it easier to choose which of these safer, but more costly, devices to purchase with limited funds," APIC states in a recently published position paper.[1] "To date, many institutions have purchased expensive needleless IV systems to reduce sharps injuries related to IV therapy. Although these systems appear to reduce injuries, such injuries are less likely to transmit bloodborne pathogens than injuries associated with devices used in directly accessing the bloodstream."

Despite data showing fewer injuries in areas where safety devices have been used, cost is frequently cited as a reason for not using them, APIC says. Noting that the replacement of unsafe devices will take a concerted effort by individual institutions, researchers, manufacturers, government agencies, and professional organizations, APIC recommends that the collaborative efforts should encourage:

- timely FDA safety alerts related to the use of conventional needles in high-risk settings to facilitate removal of unsafe devices;
- all institutions to develop active surveillance of device-related sharps injuries and to develop risk-reduction strategies;
- manufacturers to standardize design of sharps devices allowing for universal usage;
- epidemiologic studies to examine the effects of safety devices on risk reduction;
- the transfer of new technology into the workplace through funding for research, consortia study, professional publication of clinical evaluations, and presentations at meetings;
- the formation of coalitions or joint task forces to keep issues in the forefront between and among industries, government, and the health care community;
- the establishment of a central clearinghouse to develop device-specific criteria and to eliminate unsafe products;
- the creation of a nationwide repository for product information, evaluation, and compatibility;
- the development of cost-effective strategies for the implementation of safety technologies.

Reference

1. Association for Professionals in Infection Control and Epidemiology. APIC 1997 and 1998 Guidelines Committees. APIC position paper: Prevention of device-mediated bloodborne infections to health care workers. *Am J Infect Control* 1998; 26:578-580. ■

a conventional blood-drawing needle, resulting in an estimated overall increase of $14,500 annually for a 350-bed hospital.[1] **(See related story in *Hospital Infection Control*, February 1998, pp. 20-21.)** Of course, ICPs trying to justify the purchase of such equipment often factor in cost savings due to reduced exposures and worker follow-up, which has become more expensive with the new postexposure prophylaxis regimens for HIV. It also is hoped that the opening up of such a large state health care market will contribute to mass production, competition, and lower device prices.

"It's going to be expensive and difficult, but it is something that we are supporting as an industry," says **Roger Richter**, senior vice president of professional services at the California Healthcare Association. "We think it is realistic when [the] exceptions are allowed. . . . Cost is the big change. We are just hopeful that the vendors will start bringing their prices down, since they will be selling more products."

Fine notes she has been instructed to ignore cost when selecting devices for use in CHW facilities, and business and administrative officials will work out the purchasing contracts.

"We have contracts currently, but if we find devices that meet our needs better, we can go outside of our contracts," she says.

While costs and impact will vary, there is some question of whether the regulation will translate to budget crunching and pared-down clinical and support staffs at some facilities in California. The costs will be borne by institutions rather than through patient reimbursements, Jackson notes.

"I'm quite sure — since California often leads the way — that this will be reviewed very carefully [nationally]," she says. "What is going to be important is whether there are any outcome data that suggest it makes a difference. Because it is going to have a substantial financial impact on an industry that is already very stressed financially."

Again, the best way to protect workers in a cost-effective manner is to target high-risk exposures for needle-safety devices, emphasizes **Julie Sellers**, RN, CIC, chairperson of the governmental affairs committee at the Washington, DC-based Association for Professionals in Infection Control and Epidemiology (APIC). APIC has followed the California situation closely and recently issued a position paper on the issue of needle-safety devices in light of such state and national efforts.[2] **(See related story, p. 21.)** But Sellers says the exceptions are so narrowly written in the California law that it will "be very difficult for a facility to opt out."

To head off a similar situation occurring on a national scale, APIC has offered to assist federal OSHA in educational efforts to help facilities conduct appropriate epidemiological assessments to enable them to target needle-safety devices toward prevention of high-risk injuries.

"That's the approach we want to advocate: a smart approach instead of a blanket approach," Sellers says. "We know the sticks that are risky — hollow-bore needles that have been deep in tissue and have visible blood."

Regardless, in the wake of the California law and a recent request for information on needle-safety devices by OSHA, there is a growing consensus that regulatory action nationwide will follow.

"I don't know that it is necessarily going to be like the California regulation in terms of content, but I do believe OSHA is going to develop some type of revision to the bloodborne standard that might provide them with more enforceable language in the section about engineering controls and specifically sharps devices," Sellers says.

Despite the cost issues, even some ICPs — a group traditionally opposed to legislative solutions to clinical problems — see benefits of regulatory action in light of the longstanding problem of needlesticks and foot-dragging on the part of some facilities in purchasing safety devices.

"Even amongst our ranks, there is concern because there are facilities that have not responded responsibly," Sellers says. "There are practitioners who feel the need of regulations in order to get accomplished what they know needs to be done."

Indeed, Fine prefers to look at the challenge as "an opportunity," noting that many ICPs have been trying for years to prevent needlesticks and implement safer devices. Still, the situation has created a difficult balancing act in which legitimate safety concerns of workers must be weighed against real-world issues of cost and compliance.

"If we advocate for the use of funds foolishly, we recognize that there are other programs within institutions that might not get funded that could also impact worker safety," Sellers reminds. "We have to look at the big picture. We are absolutely advocates of safety, but we are also agents of our facilities and we have to be fiscally responsible."

References

1. Centers for Disease Control and Prevention. Evaluation of safety devices for preventing percutaneous injuries among health-care workers during phlebotomy procedures — Minneapolis-St. Paul, New York City, and San Francisco, 1993-1995. *MMWR* 1997; 46:21-25.

2. Association for Professionals in Infection Control and Epidemiology. APIC 1997 and 1998 Guidelines Committees. APIC position paper: Prevention of device-mediated bloodborne infections to health care workers. *Am J Infect Control* 1998; 26:578-580. ■

EPINet, ICPs respond to OSHA needlestick request

Surveillance network urges adoption of devices

The most well-established surveillance network on needlestick injuries and exposure prevention devices in the United States has come out in favor of a "complete transition" from conventional sharps to safety devices, *Hospital Infection Control* has learned.

The Charlottesville, VA-based International Healthcare Worker Safety Center at the University

of Virginia takes this position in comments to the Occupational Safety and Health Administration. With increasing calls for the required use of needle-safety devices designed to prevent blood exposures to health care workers, OSHA recently published a request for information (RFI) that could be a prelude to regulatory action.[1] **(See *Hospital Infection Control,* November 1998, pp. 164-165.)**

"The [center] is in favor of measures that would result in a complete transition from conventional to safety devices in the U.S. health care workplace," the comments state. "We very much hope that this RFI will result in OSHA's taking concrete steps to bring this about, thus creating a safer work environment for American health care workers in every state."

The comments also provide a detailed overview of the needlestick problem and implementation of devices based on data compiled from approximately 70 hospitals in the Exposure Prevention Information Network (EPINet), the largest database of its kind in the United States. Based on 1997 EPINet data, 78% of injuries from hollow-bore needles fall into a "potentially preventable" category.

"This figure clearly indicates that the health care industry is far from achieving the best possible level of injury reduction among health care workers," the comments state. "At the Center, we believe a national goal must be to rapidly implement effective protective technology which, like a universal vaccine, can prevent transmission of all bloodborne pathogens. With more than 1,500 patents issued in the last decade for devices designed to prevent needlesticks, safety devices are now available in every major device category."

Needleless IV systems have found the widest acceptance, with more than 65% of hospitals purchasing this equipment. But the device categories that pose the greatest risk for transmission of bloodborne pathogens lag far behind this mark, with only 28% of hospitals switching to safer devices for IV catheters and less than 10% of hospitals switching for blood-drawing needles, the center notes in its comments.

In addition, EPINet data underscore the following statistical highlights:

• The average rate of reported sharp-object injuries is 30 injuries per 100 occupied hospital beds per year.

• The total annual percutaneous and mucocutaneous exposures to blood or at-risk biological substances in the United States, based on 1996 EPINet data, was 786,885.

• Before the widespread implementation of needleless and protected-needle IV systems, 26% of needlesticks involved IV infusion equipment with needles. Now they account for only 3%.

• A shielded stylet safety IV catheter reduced IV catheter-related needlesticks by 83%.

• Injuries associated with recapping needles have declined dramatically over the past decade, from about 25% of hollow-bore needle injuries to about 4% today.

• Overall, 25% of percutaneous injuries fall into the high-risk category (injuries from blood-filled needles). Of these, about 74% are related to blood drawing, and 26% to IV catheter placement.

In additional comments gleaned from the OSHA docket on the needlestick prevention RFI, individual infection control professionals detailed their experiences with the devices.

Kathy M. Henderson, RN, employee health coordinator at Columbia Augusta (GA) Medical Center, said she received approval recently to implement new engineering controls after implementing some needleless devices three years ago. She underscored the variety of sharps injuries that can occur in telling OSHA that the facility recorded 28 needlesticks in 1997 and 22 as of Nov. 20, 1998. Those injuries involved needles, knife blades, patient's staples, scissors, a glass slide, and a small sliver of glass from a laboratory tube.

Overcoming financial implications

Henderson and colleagues have instituted new engineering controls in the form of safety needles and phlebotomy devices. However, she said the effort took a "labor-intensive" year of presentations to various hospital committees.

"I feel that the most difficult obstacle to overcome is the financial aspect associated with implementation," she states in the OSHA comments. "These devices are considerably more expensive to purchase and until you implement them you can't prove that savings will be recognized in treatment cost for post exposure. It's difficult to prove . . . that you're trying to be proactive and avoid the extravagant cost that can result from an HIV seroconversion or a hepatitis C [virus] seroconversion."

Success can be achieved, however, through perseverance, use of objective data, and having health care providers involved in the financial decisions, she says. After educating employees about the use of safety devices, continued noncompliance should result in disciplinary action, she adds.

In additional ICP comments, **Bridget Farrell**, RN, director of infection control and employee health services at Burdette Tomlin Memorial Hospital in Cape May Court House, NJ, told OSHA that a significant reduction of exposures occurred after the implementation of a safety-designed IV catheter system and a secondary IV "piggy-back" protection system. Requests for all new products are submitted to a hospitalwide products committee that has multidisciplinary representation, she explained.

"Very high product costs may delay the decision to purchase the products," she states in the comments. "Historically, the purchase of costly products is more likely to occur if [the] product is already part of a group purchasing contract."

Staff input in the choice of products is important because the device must be readily available and user-friendly for successful implementation, she adds. Initial and follow-up education is the key to acceptance and use, Farrell notes.

"It takes longer initially to deliver patient care when using a number of safety devices," she told OSHA. "Over time, this does not have a negative impact once [the] learning curve is achieved."

Cost remains an important issue, and assessing the compatibility of new products to existing systems adds another challenging dimension to the decision-making process, she told OSHA.

"The arguments for prevention, the right thing to do, and the potential for the acquisition of serious illness or death are incalculable," Farrell states in the comments. "It is difficult to translate these risks into a measurable bottom line that facilitates the hard financial decisions that must be made in health care today."

Doris Wuensche, RN, CIC, director of infection control at Citizens Medical Center in Victoria, TX, reports favorable results following the purchase of safety-designed lancets for fingerstick blood sampling.

"This was our most stunning success and occurred about five or six years ago," she states in the comments to OSHA. "We have only had one or two exposures from this source in the last five or six years, and both of those were from improper use of equipment."

But every new device that is adopted requires a "maximum effort" to get it accepted because most require changes in technique, she adds. In some cases workers have refused to use the safety equipment, and may continue to do so as long as conventional alternatives are available, she says.

"Prices on the safety devices must come down before they can be universally used; under the current cost-containment climate, nobody can afford everything they need," she says.

Reference

1. Occupational Safety and Health Administration. Occupational Exposure to Bloodborne Pathogens: Request for Information. 63 *Fed Reg* 48,250-48,252 (Sept. 9, 1998.) ■

Mask study likely spells fit-testing in final TB reg

But annual refitting requirement not expected

A recently published government study all but ensures that respirator fit-testing programs will be required in the final version of the federal tuberculosis standard, *Hospital Infection Control* has been advised.

During the protracted debate on the TB standard proposed by the Occupational Safety and Health Administration, the Association for Professionals in Infection Control and Epidemiology questioned the need for fit testing and objected to the costs associated with such programs — particularly if retesting is required annually. The TB standard is still being finalized after months of hearings and comments. However, a recent study by the National Institute for Occupational Safety and Health (NIOSH), which documented the benefits of fit-testing, very likely means the requirement will be in the final standard, says **Julie Sellers**, RN, chair of the APIC governmental affairs committee.[1]

"The findings clearly show in their view the continued necessity to require fit testing," she says. "One of our big issues has been the need for that. I guess we can say that we will inevitably see the continued requirement for fit testing."

A branch of the CDC, NIOSH is the government agency charged with testing and approving respirators. At the height of the TB mask debate in the mid-1990s, it appeared that health care workers might be required to don high-efficiency industrial respirators whenever they treated TB patients. As a result of the ensuing controversy, NIOSH introduced a new classification scheme for respirators and developed criteria for the less expensive and restrictive N95 particulate respirators that many health care workers now use to prevent occupational transmission of tuberculosis. The question of whether N95 respirators needed to be fit-tested in respiratory protection programs to ensure worker protection was raised. According to the NIOSH study, fit testing is a procedure used to evaluate how well a given respirator fits a given person by assessing leakage around the face seal. Fit testing can either be qualitative (i.e., relying on a subjective response of the wearer) or quantitative (i.e., using a measurement of actual leakage).

NIOSH evaluated the performance of 21 N95 respirator models on a 25-person panel. The panel comprised 15 women and 10 men with face lengths and widths similar to the general population. For each test, the person donned the respirator and performed a user seal check (i.e., pressure-tightness test, fit check, or negative / positive pressure check) according to the manufacturer's instructions. Each person then performed a series of exercises to simulate facial movements during normal use. Quantitative tests also were performed to assess mask leakage.

"The findings in this report indicate that fit testing N95 respirators is essential in programs employing these respirators and can eliminate poorly fitting respirators, ensuring at least the expected level of protection," NIOSH concluded.

Without surrogate fit testing, average exposure for the 25-person panel was reduced to 33% of the ambient level, which is much less protection than expected of the N95 class of respirators. However, when fit-tested first, the panel received substantially greater protection than normally expected (the average exposure was reduced to 4% of the ambient level), the agency reported. Without fit testing, people unknowingly may have poor face seals, resulting in excessive leakage and exposure, NIOSH concluded.

However, while the more elaborate quantitative testing was done to verify findings in the study, it appears that the less rigorous qualitative testing will suffice to ensure worker protection, Sellers noted. Also, the study addressed the efficacy of initial fit testing but did not emphasize any need to refit workers annually.

"So we have the feeling that we will not be doing annual fit testing," Sellers says. "We don't have to now, and we don't think we will have to change and begin to when the final rule comes out. But our hope that we wouldn't have to fit-test at all, I think, is down the drain."

Reference

1. Centers for Disease Control and Prevention. National Institute for Occupational Safety and Health. Laboratory performance evaluation of N95 filtering face piece respirators, 1996. *MMWR* 1998; 47:1,045-1,049. ■

ABSTRACT & COMMENTARY

Antibiotic controls: One step up, one step back

Synopsis: Control of virtually all cephalosporin use at one hospital was associated with a significant reduction in the prevalence of resistant *Klebsiella* containing extended-spectrum beta lactamase. This was accomplished, however, with an increased use of imipenem, as well as an increased prevalence of imipenem resistance in *Pseudomonas aeruginosa*.

Sources: Rahal JJ, et al. **Class restriction of cephalosporin use to control total cephalosporin resistance in nosocomial *Klebsiella*.** *JAMA* 1998; 280:1,233-1,237; Burke JP. **Antibiotic resistance squeezing the balloon?** *JAMA* 1998; 280:1,270-1,271.

An outbreak of *Klebsiella* producing an extended-spectrum B-lactamase (ESBL) occurred in Rahal and colleagues' hospital in 1990. Over the next five years, the prevalence gradually increased despite restrictions upon the use of third-generation cephalosporins. In 1995, there were a total of 150 isolations of ESBL-producing *Klebsiella*, representing 19.6% of all *Klebsiella* isolates. Approximately 40% of the resistant isolates were resistant to cephamycins (cefotetan, cefoxitin) as well.

Prior to 1996, use of third-generation cephalosporins or imipenem required approval by the infectious disease service. Beginning in 1996, the hospital adopted new antibiotic use guidelines, requiring approval for use of all cephalosporins and cephamycins with few exceptions, such as the use of ceftriaxone for the treatment of meningitis or gonococcal infections. Restrictions on the use of imipenem continued.

Rahal et al measured the effect of the new restriction by comparing the isolation of ceftazidime-resistant *Klebsiella* in 1996 with that noted in 1995. They also compared the isolation of imipenem-resistant *Pseudomonas* during the two-year period. Surveillance methods and infection control practices were identical during the two years. Cephalosporin use hospitalwide decreased 80%, from 5,558 g / month in 1995 to 1,106 g / month in 1996. However, imipenem use increased by 141% (197 g / month in 1995 to 474 g / month in 1996). During 1996, there was a 44% reduction in nosocomially acquired ceftazidime-resistant *Klebsiella* compared with 1995 (150 vs. 84 isolates, respectively). The reduction was most apparent in the ICUs. There was a concomitant 69% increase in isolation of imipenem-resistant *Pseudomonas*.

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

ESBLs of *Klebsiella* are typically plasmid-mediated and confer high-level resistance to ceftazidime and aztreonam, and variable, often less marked, resistance to cefotaxime. Many, but not all, of these ESBL-producing strains remain susceptible to cephamycins. The plasmids often contain resistance determinants to other, unrelated antibiotics such as aminoglycosides. ESBL-producing *Klebsiella* (as well as other members of the Enterobacteriaceae) are widespread in hospitals and long-term care facilities throughout the world.

Efforts to control resistant microorganisms generally have consisted of a two-pronged approach: prevention of transmission by isolation practices and control of antibiotic use. The reported results of control measures have been, to put the best possible face on the situation, decidedly mixed.

Rahal et al took a novel approach and hypothesized that restriction of the entire cephalosporin class, including the related cephamycins, would lead to withdrawal of the selective pressure favoring ESBL-producing *Klebsiella*. They were remarkably successful in reducing cephalosporin use, and, indeed, there was a marked and statistically significant reduction in resistant *Klebsiella* that was most apparent in the ICUs. Unfortunately, there was an increase in the frequency of isolation of imipenem-resistant *Pseudomonas*, no doubt in response to the increased use of imipenem during the period of intervention. In an accompanying editorial, Burke compares the result to "squeezing a balloon — constraining one end causes the other end to bulge."

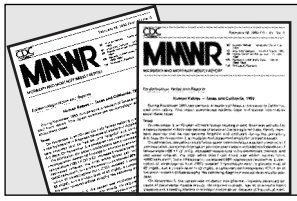
It is difficult to judge the overall effect of the intervention by the authors, who do not provide outcome information in terms of infection rates or deaths due to infection. It also would be important to know what effect the change in antibiotic prescribing had on other resistant flora in the hospital, particularly other potentially cephalosporin-resistant agents such as *Enterobacter* and *Serratia*. One might surmise that a decrease in cephalosporin use might have led to a decrease in isolation of methicillin-resistant *Staphylococcus aureus* and resistant *Enterococcus*, for example. It also would be important to know the changes in the use of alternative agents such as ciprofloxacin, and the effects of these changes upon the frequency of resistance to these agents. Likewise, it would be important to know what happened to the total use of antibiotics and any changes in drug expenditures.

Hospitals can be likened to complex ecosystems, in which one change or perturbation is likely to have not only its intended effect but also multiple secondary effects that may not be predictable. It's not surprising that the ecologic niche occupied by resistant *Klebsiella* would be taken over by something else that might be just as objectionable. It is, undoubtedly, overly optimistic to expect that changing the usage pattern of a single class of antibiotics will solve the problem of drug

COMING IN FUTURE MONTHS

- Protecting low-birth-weight infants from nosocomial infections
- Pros and cons of patient culturing on admission for resistant bugs
- Assessing the efficacy of building antimicrobial agents into biomaterials
- Advising patients and workers on HCV testing, precautions

resistance. But the experience of Rahal et al demonstrates that antibiotic usage patterns can be changed in a rational way over a prolonged period of time, and that at least some of the effects of the intervention can be quantified. Such studies are an important stepping stone if we hope to devise comprehensive control strategies to reduce the threat of antibiotic resistance. ■



MMWR Update

What price beauty? SSIs are linked to liposuction

After assisting in investigating an outbreak of surgical site infections (SSIs) following cosmetic surgery in Caracas, Venezuela, the Centers for Disease Control and Prevention reminds that all surgical instruments used in liposuction or liposculpture procedures should be cleaned carefully and sterilized after the procedure.

Providers should sterilize the equipment in accordance with a validated reprocessing protocol provided by the medical device manufacturer. The exclusive use of low- or intermediate-level disinfectants to reprocess surgical instruments between patient procedures is inconsistent with Food and Drug Administration guidance and recommended standards of practice, the CDC emphasized.

During October 1996-March 1998, nine patients in eight hospitals in Caracas, Venezuela, acquired SSIs caused by rapidly growing mycobacteria (RGM). All episodes of RGM infection occurred within two months after liposuction or liposculpture. All case patients were previously healthy women aged 28 to 49 years. Eight surgeons and surgical teams performed the cosmetic surgery on the women. The median time from surgical procedure to onset of infection was 15 days (range: four to 45 days). Clinical findings included fever, local inflammation, microabscesses, purulent drainage from the wound, or fistulae.

All hospitals cleaned liposuction and liposculpture cannulae with tap water and soap followed by low-level disinfection with a commercial quaternary ammonium solution, the CDC reported. The epidemiologic investigation did not reveal other risk factors such as exposure to certain persons, cleaning solutions, medical supplies, or contaminated quaternary ammonium compounds. Following the outbreak, two of the surgical facilities modified their reprocessing procedures for surgical instruments used in cosmetic surgical procedures by replacing quaternary ammonium compounds used for low-level disinfection with either high-level disinfection using 2% glutaraldehyde or ethylene oxide gas sterilization. No further cases of RGM infections complicating cosmetic surgical procedures were reported.

"The underlying mechanism for the cluster of SSIs described in this report was not determined," the CDC concluded. "However, potential causes included contaminated tap water used in cleaning cannulae during liposuction or liposculpture or contamination of the quaternary ammonium solution used to disinfect these instruments."

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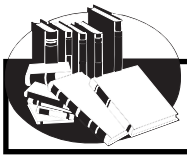
Nosocomial infections associated with contaminated quaternary ammonium compounds that were used to disinfect patient-care supplies or equipment have been reported, but none of these infections were caused by RGM. National Nosocomial Infections Surveillance system data indicate that among 5,652 integumental surgical procedures performed during 1986-1996 in the United States, only 1.4% had SSI. SSI caused by RGM following aesthetic surgical procedures is rare. Prior reports include infection following face-lift and augmentation mammoplasty procedures that implicated contaminated gentian violet skin-marking solution as the source of infection, the CDC concluded.

Reference

1. Centers for Disease Control and Prevention. Rapidly growing mycobacterial infection following liposuction and liposculpture — Caracas, Venezuela, 1996-1998. *MMWR* 1998; 47:1,065-1,067. ■



JOURNAL REVIEW

French AL, Welber SF, Dietrich SE, et al. **Use of DNA fingerprinting to assess tuberculosis infection control.** *Ann Intern Med* 1998; 129:856-861.

Because it illustrates genetic relatedness among strains of *Mycobacterium tuberculosis*, DNA fingerprinting has been used to confirm outbreaks of disease and laboratory cross-contamination. The authors hypothesized that routine DNA fingerprinting, done by using restriction fragment length polymorphism analysis, could be used to enhance hospital infection control surveillance for patient-to-patient transmission of TB.

The authors used DNA fingerprinting to analyze 173 TB isolates over a one-year period. Analysis revealed that five isolates represented false-positive cultures and that 91 (54%) of the remaining 168 isolates were in 15 DNA fingerprinting clusters, which ranged in size from two to 29 isolates. However, retrospective epidemiologic analysis of inpatient and outpatient visits by the 91 patients who had clustered isolates revealed only one possible instance of patient-to-patient transmission.

"However, these results did not lead to changes in infection-control practices or in clinical care," the authors note. "The study findings do not support the use of DNA fingerprinting for nosocomial tuberculosis surveillance, but they suggest that compliance with the CDC tuberculosis infection-control guidelines may control patient-to-patient transmission in high-risk urban hospitals." ■

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. ■