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INSIDE

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Legislative Alert: **Federal Needle Safety Regs on Horizon**

Prepare now for mandated needle safety devices in nation's hospitals

'Needlestick Prevention Act' proposed; OSHA targets regulation this fall

Infection control professionals should begin preparing now for eventual needlestick safety regulation, whether by state or federal laws, by evaluating devices designed to prevent exposures that carry a high risk of bloodborne pathogen transmission. This includes devices to start intravenous lines, IV catheters, and phlebotomy equipment, sources advise *Hospital Infection Control*.

Spurred by California's landmark needle safety law and similar legislative initiatives in some 20 other states, the United States Congress and the Occupational Safety and Health Administration (OSHA) are moving to make sharps safety requirements the law of the land.

The "Health Care Worker Needlestick Prevention Act of 1999" was introduced into Congress on May 20, 1999, by U.S. Reps. **Pete Stark** (D-CA) and Marge Roukema (R-NJ). The law would direct OSHA to amend its 1991 bloodborne pathogen standard in order to mandate needle safety devices to protect health care workers from occupational infections via needlesticks. That same day, OSHA announced it had received nearly 400 responses to its recent request for information (RFI) on the needle safety issue and will consider amending its bloodborne pathogen standard this fall.[1] **(See highlights of bill, p. 87; OSHA report, p. 89.)**

While critics fear the interference of national mandates with local clinical judgement, the needle-safety issue has become a juggernaut since California passed a bill last year requiring state hospitals to implement the devices. In addition to the aforementioned federal initiatives, a growing number of states are in various legislative stages with similar laws. **(See *Hospital Infection Control,* April 1999, pp. 45-49; February 1999, pp. 17-22.)**

"We are finding that although it is not easy, it is doable," says **Cynthia Fine**, MSN, CIC, infection control and employee health consultant for Catholic Healthcare West (CHW) in Oakland, CA. "We are progressing

with it in California, and I think in light of that it is going to roll across the United States."

Fine advises ICPs to start preparations by evaluating all devices designed to prevent exposures to bloodborne pathogens, including IV lines, catheters, and phlebotomy equipment.

"I think we all pretty much agree those are the highest-risk devices for actually transmitting disease," she says. "That's where I'm suggesting people who are just starting put their time, money, and effort."

The sudden surge in proposed needle safety legislation apparently has divided the infection control community. Some ICPs caution against legislative solutions to clinical problems, while others concede that laws are finally needed to end years of foot-dragging on the issue. Fine says the issue warrants legislation, citing her ongoing conversations with ICPs having difficulty getting the safety devices approved by cost-conscious administrators in other states.

"I just had an e-mail conversation going on with someone in another state about IV catheter devices and the difficulties they have been having implementing them," she says. "They were turned down by their CEO because they were too expensive. So it is still happening, and unfortunately I think we need the legislation."

Still, others note that federal laws and OSHA mandates may force broad adoption of more expensive needle devices that may not be appropriate for all settings.

"In some hospitals that have a high needlestick injury rate and a patient population that is likely to have bloodborne pathogens with some frequency, it might be reasonable to consider these [devices]," says **William Sheckler**, MD, hospital epidemiologist at St. Mary's Medical Center in Madison, WI. "The problem that I have is the one-size-fits-all regulatory approach either by law or by OSHA standard, which will inevitably lead to increased cost."

Modeled after the California law, the Stark-Roukema bill would direct OSHA to require that health care employers — unless they can cite one of the approved exemptions, such as concern for patient safety — use needleless systems or other engineered safety mechanisms. "The technology exists today to prevent the vast majority of these injuries," Stark says. "Safe needle devices are used in some facilities across the country, but our bill would make use of safe technology the norm rather than the exception."

The legislation also would enhance current needlestick reporting requirements and establish a national clearinghouse to collect data on safer technologies as a resource for employers. The bill drew the endorsement of health care worker unions, some health care employers and needle manufacturers, and the American Nurses Association (ANA). The bill is being given a better political prognosis than Stark's previous needlestick prevention legislation, "The Health Care Worker Protection Act of 1997," which stalled out before becoming law. For example, the current bill has bipartisan sponsorship that could mean less Republican resistance to its regulatory aspects, says **Susan Wilburn**, RN, MPH, senior specialist for occupational safety and health at the ANA in Washington, DC.

"Everyone has been stimulated by the California legislation," she tells *HIC*. "You can tell that the time has come in terms of other states that are enacting or proposing similar legislation as well as the bipartisan support of this federal legislation. There is more political momentum."

The bill is seen by some as a way of giving OSHA "legislative cover" to act on a controversial issue in much the same way that the law in California mandated regulation and enforcement by the state's Cal-OSHA program. The previous Stark legislation used possible withholding of Medicare dollars as the enforcement mechanism. Under the current bill, that threat would only be used to coerce public hospitals owned by state or local governments and thus not technically bound by federal OSHA standards. In addition, state OSHA standards, which have to be at least as "effective" as federal OSHA standards, also may apply to such hospitals, according to a spokesman in OSHA's Washington, DC, office.

The Chicago-based American Hospital Association immediately came out against the bill, describing it as "well intentioned but unnecessary" because OSHA already has the authority under its bloodborne pathogen standard to accomplish the same goals. Indeed, OSHA has "clearly signaled that it would strengthen these requirements," says **Jonathan Lord**, MD, AHA chief operating officer. "We'll continue to work with OSHA to ensure appropriate flexibility for

Needlestick Prevention Act proposed in Congress

Provisions include detailed incident reports

The "Health Care Worker Needlestick Prevention Act of 1999" that has been proposed in Congress calls for the Occupational Safety and Health Administration to amend the 1991 bloodborne pathogens standard and require employers to use needleless systems and safety-designed sharps. Other summarized provisions of bill H.R. 1899 include the following:

- All direct care health care workers shall be provided adequate training on the use of all needleless systems and sharps with engineered sharps injury protections which they may be required to use.
- Exceptions to using needle safety devices include circumstances in the employer's work facility in which the devices do not promote employee safety, interfere with patient safety or interfere with the success of a medical procedure; or if the needleless systems and sharps injury protections required are not commercially available to the employer.
- Health care employers have to include in their exposure control plan an effective procedure for identifying and selecting existing needleless systems, sharps with engineered sharps injury protections, and other methods of preventing bloodborne pathogens exposures.
- In addition to the recording of all injuries from contaminated sharps on the OSHA Occupational Injuries and Illnesses 200 log or its equivalent, the employer shall maintain a separate contaminated sharps injury log.
- The sharps injury log shall contain (to the extent such information is known to the employer) information including the date and time of the exposure incident; type and brand of sharp involved; a description of the exposure incident; job classification of the exposed employee; department or work area where the exposure incident occurred; and the procedure that the exposed employee was performing at the time of the incident. If the sharp had engineered sharps injury protections, information should include whether the protective mechanism was activated; whether the injury occurred before the protective mechanism was activated or during activation.
- If the sharp causing the injury has no engineered sharps injury protections, the sharps injury log must include the injured employee's opinion as to whether and how such a mechanism could have prevented the injury; and the employee's opinion about whether any other engineering, administrative, or work practice control could have prevented the injury. ■

caregivers when it comes to deciding what's best for patients and workers."

In that regard, the same day the federal needlestick bill was announced, U.S. Secretary of Labor Alexis Herman emphasized that OSHA was taking several steps to address the issue. Though agency officials declined requests for additional interviews, OSHA released a statement saying the agency "will take steps to amend the bloodborne pathogens standard by placing needlestick and sharps injuries on its regulatory agenda this fall." OSHA also will revise its bloodborne pathogens compliance directive later this year to reflect that newer and safer sharps technologies are now available, the agency reported.

The OSHA bloodborne pathogens standard requires engineering and work practice controls to be used to eliminate or minimize employee exposures, but the agency left something of a loophole that it now appears ready to close. For example, OSHA's compliance directive for enforcing the standard states that "employers do not automatically have to institute the most sophisticated engineering controls (e.g., needleless IV connectors, self-sheathing needles)," but it is their responsibility to continually evaluate the effectiveness of existing controls and review the feasibility of implementing more advanced devices.

However, in reviewing comments received in response to its RFI on the issue, OSHA reported that though a variety of safer devices exists to protect workers from needlesticks, "these devices are not being used widely enough to substantially reduce the hundreds of thousands of injuries each

year." Moreover, in the area of record keeping, OSHA found that many needlesticks are not being reported in the OSHA 200 logs hospitals are required to maintain. As OSHA regulations are currently written, needlesticks that do not result in medical care beyond first aid are not required to be entered into the OSHA log, but the agency is expected to now toughen those reporting requirements to ensure more injuries are recorded.

"That is critically important," Wilburn says. "If we are not collecting data about the nature of the injuries and exposures, then we have a really difficult time defining the illness for workers' compensation. We have a really difficult time saying we need to implement safer devices to prevent needlestick injuries if we can't say how many we are going to prevent."

Indeed, a by-product of all the legislative and regulatory activity may be a much clearer picture of the number and nature of needlestick injuries, as both state and federal regulations are requiring more documentation on injuries and devices.

Now that California has passed a needlestick prevention law, the Washington, DC-based Service Employees International Union (SEIU) — which represents about 650,000 health care workers nationwide — has launched a state-by-state campaign to introduce needlestick prevention legislation. The SEIU says some 20 states are now at various stages of legislative discussions. As this issue went to press, Maryland and Tennessee had passed legislation, and Texas had a bill awaiting the governor's signature.

Maryland passed a "study bill" that sets up a multidisciplinary committee to look at the issue and make a recommendation to the state legislature in January 2000. A bill signed into law in Tennessee on March 19, 1999, calls for the state health and labor commissioners to review sharps injury prevention technology and determine which work settings should implement the devices. The devices will not be required if employers can demonstrate that they are medically contraindicated or no more effective than alternative measures to prevent exposures to employees. In addition, written exposure control plans must be revised to reflect improvements in sharps technology, the law states.

"We are having to put this in our OSHA plan, identify all of our safety devices, and implement as many as we can," says **Sandy Garret**, RN, MSN, CS, CIC, infection control nurse at the Veterans Affairs Medical Center in Nashville, TN. "I think it's a good thing. But the federal VAs had already somewhat mandated that we get all sharps prevention devices that we can. We basically had implemented everything, so it is a lot easier for us. Now, for facilities that didn't have [safety devices] and are going to have to buy them without having any funds appropriated, it is going to be a lot more difficult and they probably won't be as receptive."

ICPs in Texas are finding themselves a lot more receptive to legislation there after a few critical revisions were made to a proposed law to ensure the state requirements will remain in sync with expected changes made by federal OSHA, says **Patti Grant**, RN, BSN, MS, CIC, who spearheaded the response to the bill as president of the Texas Society of Infection Control Practitioners.

"There is now a statement in the bill that states that the Texas Department of Health shall write rules that are autologous to the OSHA bloodborne pathogen standard," she says. "Texas does not have to reinvent the wheel. As federal OSHA progresses, Texas will follow. That was extremely important, because we are already accountable to too many government agencies."

OSHA action inevitable?

Though OSHA basically addressed needle safety devices from the outset — and many hospitals in Texas already have implemented devices — it appears the agency is now going to strengthen its requirements, Grant notes.

"OSHA is going to act," she says. "I can't imagine that an [agency] that large would go through the pain and effort of publishing a call for opinion in the *Federal Register* and then not do anything with it."

The Texas legislation is aimed at public or government-run hospitals that are not technically bound by federal OSHA standards, which apply to their privately owned counterparts, she explains. The Texas bill essentially requires more accountability from the hospitals, which must review the safety devices through their product evaluation committees and annually update the state regarding their implementation status or

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OSHA gets mixed message on needle mandate

But nearly all report safety devices reduce injuries

The Occupational Safety and Health Administration (OSHA) received 396 responses to its request for information (RFI) on needle safety devices, with some respondents urging broad implementation of the devices and others cautioning against blanket mandates, the agency reports.[1]

"While health care facilities did not generally comment on an appropriate course of action for the agency to take, a number of other respondents supported OSHA's interest in making safer medical devices available to employees," the report concludes. "Some respondents, however, expressed reservations about any broad mandate requiring the use of safer medical devices, maintaining that the distinctive situations and needs of particular areas of practice (e.g., dentistry, anesthesiology) must be taken into account, and that device efficacy and effects on patient care should be established prior to device adoption."

Comments were submitted by more than 300 individual health care facilities, including nursing homes, clinics, and acute care, tertiary care, rehabilitation, and pediatric hospitals. Several organizations submitted combined responses on behalf of members representing more than 130 additional health care facilities. Also responding were individual health care workers, researchers, unions, educational institutions, professional and industry associations, and manufacturers of medical devices. The OSHA findings are summarized as follows:

• The OSHA 200 log, as it is currently being maintained, does not accurately reflect injuries that may involve exposure to bloodborne pathogens in health care facilities. The criteria established for recording occupational bloodborne pathogen exposures do not require recording of all injuries that pose a potential risk of disease transmission. Only those exposure incidents resulting in loss of consciousness, transfer to another job, restriction of work or motion, recommendation for medical treatment beyond first aid, or seroconversion are currently required to be recorded. Many facilities also apparently do not correctly interpret the established recording criteria.

• Those health care facilities that responded to the RFI have almost universally adopted surveillance systems in addition to the OSHA 200 log. These alternate systems commonly record all reported percutaneous injuries involving exposure to blood or other potentially infectious materials. Information is generally recorded on the circumstances under which injuries occurred, although this information appears to vary in content and level of detail.

• Although confounding factors exist, data submitted to the docket appear to indicate that the rate of percutaneous exposure incidents is declining. An estimated 590,000 needlesticks occur annually.

• Use of safer devices appears to be increasing in limited applications. Responses indicate that most IV line access is now accomplished using safer devices. However, safer devices appear to be used much less frequently in other applications. Responses indicate that safer medical devices are an effective and feasible method of hazard control in many instances. Nearly every health care facility responding to the RFI noted that a reduction in injuries had occurred after the introduction of a safer medical device.

• Training and education in the use of safer medical devices and safer work practices were repeatedly cited by respondents as effective means of preventing percutaneous exposure incidents. In addition, anecdotal responses indicate that staff involvement in the device selection and evaluation process can play an important role in achieving a reduction in injuries. Use of safer medical devices was generally not reported to have substantially affected the delivery of patient care.

• Increased costs and staff resistance to change were the most frequently reported obstacles to adopting safer medical devices. Other barriers encountered include equipment compatibility problems, facility purchasing agreement limitations, and the unavailability of effective safer medical devices for certain applications. Safer medical devices in general are more expensive than conventional devices. The total additional cost per facility, however, appears to be a small fraction of total health care costs, and reductions in the number of these injuries may result in substantial financial benefits from reduced costs for postexposure testing and treatment as well as health benefits from a decrease in disease transmission.

(Editor's note: The report is available on OSHA's Web page at http:/www.osha-slc.gov/html/ndlreport052099.html.)

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). ■

reasons for not using the devices. Working closely with the Texas Hospital Association, ICPs launched a letter-writing campaign and participated in hearings to preserve local flexibility in selecting and implementing devices, Grant notes.

"What we have now is a win-win situation," she says. "There has been increased awareness of safety engineered devices. [The bill] allows us to use epidemiology to make institution-specific decisions about the risk and the devices used."

For example, Grant argues that for low-risk procedures like intramuscular (IM) injections, a conveniently placed sharps container probably affords the worker more protection than a safety needle that must be manipulated to activate a protection device.

"If you ask me to push, pull, twist, or turn the barrel around the needle, my hand can slip," she says. "In my opinion, it is much safer to have an excellent, top-of-the-line sharps container [for IM injections]. Now if I get stuck with a needle that I just pulled out of somebody's vein, that is a big deal. The way this law is written, it allows public hospitals in Texas to make that [device] decision, as does federal OSHA for the private institutions."

Grant recommends ICPs follow their state legislative activities through Internet legislature Web sites, generally taking a conciliatory rather than adversarial approach in trying to seek revisions to needle safety laws. "We have a lot of control," she says. "We just need to believe in ourselves, in our background in science, and our ability to affect change." Nevertheless, ICPs may be getting a bit gun-shy of the needle safety issue, as attempts to amend legislative provisions open ICPs to criticisms that they are not concerned about health care worker safety.

"One of the things that people don't always appreciate is that hospital epidemiologists and infection control professionals are health care workers too," Sheckler says. "Many of us — certainly virtually all of the hospital epidemiologists I know — see patients also and are involved in patient care. We are just as concerned about our patients and ourselves as anybody else would be."

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Agencies cite infection risk of glass tubing

OSHA, FDA, NIOSH advise alternatives

In addition to its recent emphasis on needlestick prevention, the Occupational Safety and Health Administration (OSHA) has joined with two other federal agencies in issuing a warning about possible exposure to bloodborne pathogens through breakage of glass capillary tubes.

Alternative products are available and should be considered, OSHA recommended in issuing the joint advisory with the Food and Drug Administration (FDA) and the National Institute for Occupational Safety and Health (NIOSH). Glass capillary tubes are used for collection of blood in a variety of health care settings, including hospitals, ambulatory care facilities, physicians' offices, blood donation facilities, and blood testing centers. Accidental breakage of these slender, fragile tubes has been reported when the tubes are inserted into putty to be sealed and during centrifugation.[1] Breakage of the tubes during putty insertion may result in a penetrating wound and blood inoculation to the user. One such injury resulted in the transmission of HIV to a physician who later died of AIDS.[2] Glass capillary tubes can break during centrifugation and cause blood to splatter, potentially exposing personnel to bloodborne pathogens. The broken glass fragments can injure the user, resulting in a percutaneous exposure to blood.

At one acute care facility, the injury rate associated with glass capillary tubes was 2.6 per 100,000 tubes purchased in 1992.[3] Approximately 108 million glass capillary tubes are sold each year in the United States, suggesting that approximately 2,800 injuries may occur nationwide if a similar injury rate occurs at other health care facilities. Two systems for surveillance of hospital-based health care worker injuries have reported injuries from glass capillary tubes, some of which caused blood exposure and resulted in the need for postexposure prophylactic antiretroviral therapy.[4]

To reduce the risk of injury due to capillary tube breakage, FDA, NIOSH, and OSHA recommend

that users consider blood collection devices less prone to accidental breakage, including:

- capillary tubes that are not made of glass;[5]
- glass capillary tubes wrapped in puncture-resistant film;
- products that use a method of sealing that does not require manually pushing one end of the tube into putty to form a plug;
- products that allow the blood hematocrit to be measured without centrifugation.

Although FDA, NIOSH, and OSHA cannot recommend specific products, blood-collection devices with these characteristics are currently available, and their use may reduce the risk of injury and blood exposure, the advisory states.

Copies of the advisory are available on the Internet at www.osha-slc.gov/SLTC/needlestick/.

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Can 'climate' change solve hand washing bane?

Alcohol hand gels gain favor in Europe

Changing a hospital's "organizational climate" by calling on the clout of top administrators may prove more effective at improving hand washing compliance than the myriad failed efforts that try to enact change from the "the bottom up," reported **Elaine Larson**, RN, PhD, professor of pharmaceutical and therapeutic research at Columbia University School of Nursing in New York City.

Larson previewed her findings from a study, which has been submitted for publication, at the recent annual meeting of the Society for Healthcare Epidemiology of America in San Francisco. Noting that the medical literature is rife with hand washing improvement efforts that either failed initially or saw compliance quickly revert to former levels, Larson said the new approach shows some promise in the long-running battle to get health care workers to decontaminate their hands between patients. The idea was to change a hospital's organizational culture for the purpose of increasing the frequency of hand washing and reducing nosocomial infections. The study used a framework for changing organizational climate that made hand washing a priority of top administration.

"In this study, our clients were not the individual nurses and physicians on the wards," Larson told SHEA attendees. "It was the board of directors, the medical director, the administrators of the hospital — flowing from the top down rather than from the bottom up."

A hand washing competency was developed, and hospital staff on all units were required to complete a demonstration that they knew how to wash their hands properly as part of their performance appraisal.

"Now, it sounds pretty silly, but people took it very seriously, and they couldn't continue to work unless they had passed this competency," she said. "All new hires received a letter from the CEO and medical director welcoming them, telling them that this was the hospital that did the hand washing — this is what we were known for, this is what we believe in."

The 300-bed hospital was compared with a similarly sized facility in the same city with comparable infection control staff. The intervention was conducted over some six months, and then the researchers did a follow-up evaluation six months later. The hypothesis was that hand washing compliance would not jump, but would gradually increase to a higher level that would be sustained. Indeed, follow-up indicated that the baseline level of hand washing compliance had tripled in the intervention hospital based on data collected from 500,000 hand washes recorded by undetectable counting mechanisms on soap

dispensers. Moreover, infection rates with MRSA and VRE also declined after the intervention. Interestingly, the change occurred without feedback to workers or other follow-up interventions, she explained.

"At follow-up, after we stopped doing anything, the [new climate] had taken it over," she said. "We weren't doing anything. We just came back and counted hand washes."

> "All new hires received a letter from the CEO and medical director welcoming them, telling them that this was the hospital that did the hand washing — this is what we were known for, this is what we believe in."

Hand washing studies have found rates of compliance after touching patients generally in the range of 20% to 40%. Efforts to change hand washing behavior through motivational and educational posters may show an immediate improvement in hand washing but actually very little sustained effect. Similarly, engineering devices like automated sinks and paper towel dispensers may fail to sustain improved compliance, perhaps partially because some health care workers resent "losing control over their hand washing behavior," Larson noted. However, bringing in an administrative component has demonstrated efficacy in behavioral studies in other areas besides infection control, she noted.

"You see the theme here . . . get to the leaders, don't try to work on all the individuals in the units; achieve agreement with the leadership group; implement changes administratively; do an educational blitz after deciding what's going to work; and then ride out the reactions because people will be unhappy," she said. Eventually, a shift may occur from an individual focus on changing behavior to an organizational focus, she added.

"'Do I value hand washing?' That's individual," she said. "'Is our unit committed to reducing infections with hand hygiene practices?' That's organizational. We need to move ourselves from individual valuing to organizational valuing."

Looking at another aspect of hand washing at the same SHEA session, another clinician noted that even if health care workers comply, they may only wash hands briefly. Reviewing 10 studies that addressed duration of washes, **John Boyce**, MD, noted that six of them found that workers washed hands for less than 10 seconds. Most laboratory evaluations of soap and detergent products call for 30 seconds or one minute of hand washing time in their protocols, he added.

"I think this is an important point that has not been addressed," said Boyce, hospital epidemiologist at the Miriam Hospital in Providence, RI. ". . . Based on my cursory review of the literature, at this point I don't know what the efficacy is of soap and detergent preparations under the actual conditions they are used by health care workers."

An alcohol gel alternative

Acceptability of the products may be a factor in use and duration of use, and Boyce said concerns about skin damage may be hindering wider acceptance of alcohol-based products by health care workers in the United States. In a study presented at SHEA, Boyce and colleagues conducted a prospective, randomized trial to determine the frequency of skin irritation and dryness associated with alcohol hand gel vs. standard soap and water hand washing.[1] The study followed 29 nurses on three wards. Skin irritation and dryness were evaluated using self-assessment by study participants, visual assessment by a study nurse, and estimation of epidermal water content (to determine dryness) by using electrical capacitance measurements. Nurses were randomized to use one of the two regimens for two weeks; then after a two-week rest period, each nurse switched to the alternate regimen for two weeks. Nurses were instructed not to use hand lotion during trial periods.

"When nurses used standard soap and water hand washing during their ward activities, their hands became progressively drier during the two-week period," Boyce told SHEA attendees. "In contrast, when they were using the alcohol-gel

regimen, their hands did not become dry, and in fact there was a slight improvement. This small study suggests that alcohol gel regimens that contain emollients actually do not result in more irritation and dryness, and may be tolerated better than a lot of the soaps and detergents."

The practice of using alcohol-based hygienic hand rubs has largely replaced hand washing as the standard of care in Northern Europe, added **Andreas Widmer**, MD, MS, a clinician at the University Hospital in Basel, Switzerland. Speaking at the same SHEA session on hand washing, Widmer said his hospital is using hand disinfection rather than hand washing more than 90% of the time that hand washing is indicated and hands are not visibly soiled. An alcohol dispenser is available between all beds, at each nurse's desk, and two at each ICU bed, he said. A database of 4,500 workers has not identified a single case of documented allergy to the commercial alcohol compound in use. Studies indicate that hand disinfection is much more effective in killing bacteria and most viruses than hand washing with a medicated soap, he noted.[2,3]

However, there are no sound epidemiological data demonstrating that a certain level of killing is needed to have an impact on the incidence of nosocomial infection. Regardless, studies indicate that hand disinfection by alcohol can be done in about one-quarter of the time it takes to achieve the same results by hand washing.[4,5] In addition, sinks are expensive and cannot be installed at necessary locations as easily as disinfectant dispensers, he added.

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Reporting surgeon SSI rates reduces infections

Reduced SSI rates yield $375,000 two-year savings

Enhanced surveillance of surgical site infections (SSIs) — including confidentially reporting individual infection rates to surgeons — dramatically reduced SSIs and saved a hospital more than $187,000 annually, an epidemiologist reported recently in San Francisco at the annual meeting of the Society for Healthcare Epidemiology of America.

Edward Smyth, MD, FRCP, epidemiologist at the Royal Hospitals in Belfast, Northern Ireland, analyzed 6,256 surgical procedures from January 1995 to June 1997.[1] Surveillance methodology and patient risk index were based upon the Centers for Disease Control and Prevention's National Nosocomial Infections Surveillance (NNIS) system. The researchers established an SSI rate during the first six months of the study and made the assumption that this rate would continue in the absence of infection control interventions.

> The "$64,000 question" is to determine exactly how telling surgeons their infection rates results in lower rates.

"Over the study period, the number of surgical procedures didn't vary much," Smyth told SHEA attendees. "Using the first six-month period as the baseline, we then calculated an expected SSI rate. The main intervention that occurred at the end of the first six-month period was confidential surgeon-specific rates."

At the end of the first period and for each subsequent six-month period, surgeons received confidential SSI rates regarding their own practice. Over a period of four consecutive six-month intervals, Smyth observed a downward trend in the SSI rate from the initial baseline of 4.7% to 2.3% over the ensuing two years. Over the 24-month

Potential Savings Achieved Due to a Reduction in Surgical Site Infections Over 24 Months

Time Period	Surgical procedures	Actual SSI	Expected SSI[1]	Reduction In SSI[1]	Potential savings ($)[2]
Jan 95 -Jun 95	1,364	64	-	-	-
Jul 95 - Dec 95	1,282	28	60	32	106,240
Jan 96 - Jun 96	1,250	26	59	33	109,560
Jul 96 - Dec 96	1,147	35	54	19	63,080
Jan 97 - Jun 97	1,213	28	57	29	96,280
Total	**6,256**	**117**	**230**	**113**	**$375,160**

[1] assuming first six months SSI rate of 4.7% was representative of hospital's SSI rate.
[2] based on extra inpatient costs of $3,320 per SSI.

Source: The Royal Hospitals, Belfast, Northern Ireland.

intervention period, the researchers recorded 117 SSIs, but that figure would have been a projected 230 SSIs had the rate of infection prior to the interventions continued. **(See chart, above.)**

Thus, the intervention resulted in a 49% reduction in expected SSIs. The 113 infections prevented translated to substantial savings by slashing lengths of patient stay. Investigators calculated that development of an SSI in patients with no apparent risk factors for infection resulted in a median of 11 additional days of hospital stay.

"Based on an additional cost [estimate] of $3,320 per SSI, we appeared to achieve a potential savings of $375,160," Smyth told SHEA attendees. The results confirm the positive value of SSI surveillance and will be invaluable when negotiating his next infection control budget with hospital administration, Smyth added.

The cost estimate is generally in line with a 1992 U.S. analysis that found that an SSI resulted in 7.3 additional hospital days and added $3,152 in extra charges.[2] Another study presented at SHEA in 1997 estimated that the total excess cost of an SSI, including hospital readmission, was approximately $5,000 per infected patient. **(See *Hospital Infection Control*, June 1997, p. 87.)**

Smyth conceded that "the $64,000 question" is to determine exactly how telling surgeons their infection rates results in lower rates. He said the process of providing continuous feedback seems to improve the surgeon's technique. In addition, the process raised general awareness about preventing infection among both surgeons and nursing and surgical support staffs who were aware that such data were being collected, he noted.

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COMING IN FUTURE MONTHS

- Complete coverage of the APIC conference in Baltimore
- Future directions for infection control professionals in a changing system
- Joint Commission update: Is IC still a critical standard?
- Analysis of new CDC surgical site infection guidelines
- After the sound and the fury: the OSHA TB guideline

Staph vaccine the answer to vancomycin resistance?

Animal studies hopeful; human trials to come

Researchers have developed a vaccine that protects mice against multiple strains of *Staphylococcus aureus*, the most common cause of nosocomial infections and a much-feared "superbug" in strains that show emerging resistance to vancomycin. While current research is based solely on animal studies, the findings are encouraging because the vaccine protected the mice from infection with both methicillin-resistant *S. aureus* (MRSA) and strains with intermediate resistance to vancomycin.[1-4]

"Our findings suggest that this vaccine has the potential to provide immunity to the multidrug-resistant *S. aureus* 'superbug' that we have heard alarming reports of in the last year or so," says **Gerald B. Pier**, PhD, who directed the research team at the Channing Laboratory at Brigham and Women's Hospital in Boston. Pier and colleagues at Harvard University Medical School developed the vaccine with research support from the National Institute of Allergy and Infectious Diseases (NIAID) in Bethesda, MD. NIAID has made development of a staph vaccine a priority since the appearance of the first strains with emerging vancomycin resistance in Japan and the United States.[2-4] **(See *Hospital Infection Control*, October 1997, pp. 145-152.)**

"This is an intriguing finding and a hopeful step against a very worrisome pathogen," says **Anthony Fauci**, MD, director of NIAID. "Within the last two years, *S. aureus* has become increasingly resistant to antibiotics. Most troubling is the emergence of strains that are partially resistant to vancomycin, our last line of defense against *S. aureus*. New treatments — and, ideally, an effective vaccine — are urgently needed."

The new vaccine is the first to be made from a bacterial molecule produced primarily during infection rather than in laboratory culture. The researchers used animal and human clinical isolates, including lung tissue from two cystic fibrosis patients infected with *S. aureus*. The researchers found that although tissue from humans and mice infected with *S. aureus* contained a staph polysaccharide molecule known as PNSG, few *S. aureus* strains produced PNSG when cultivated in the laboratory.

"Presumably, these products are critical for infection and disease progression, and would therefore be logical targets for new therapeutics or vaccines," Pier says.

Researchers injected the molecule into rabbits, who produced large amounts of PNSG antibodies. The researchers then injected the PNSG antibodies into mice and exposed them to eight different strains of *S. aureus*, including strains resistant to methicillin and partially resistant to vancomycin. None of the animals developed an infection.

"It looks like a great vaccine candidate for staphylococci in general, both *S. aureus* and *S. epidermidis*," says **Stephen Heyse**, MD, medical bacteriology and antibacterial resistance program officer at NIAID. Indeed, the researchers note that the PNSG molecule is also produced by another common nosocomial pathogen, coagulase-negative staphylococci (CNS).

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Editorial Questions

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

"Together, *S. aureus* and CNS account for 40% to 60% of bacterial blood isolates from hospitalized patients," Pier says. "An additional potential advantage of a PNSG vaccine might be protection against the spectrum of clinically important CNS [infections]."

The team hopes to move the PNSG vaccine into human trials within the next year or two, and they currently are negotiating licensing rights for the vaccine. If borne out in human trials, the vaccine eventually could have an impact in reducing the estimated 500,000 nosocomial staph infections acquired annually by patients in U.S. hospitals. *S. aureus* also is a common source of community-acquired infections, ranging from minor skin infections and abscesses to life-threatening diseases such as severe pneumonia, meningitis, and bloodstream infections.

Even as the vaccine initiative continues, researchers are aggressively pursuing ways to preserve antibiotic efficacy against *S. aureus.* NIAID recently awarded a seven-year contract to MRL Pharmaceutical Services in Herndon, VA, to establish a network for tracking antibiotic resistance in the pathogen. The Network on Antimicrobial Resistance in *S. aureus* is designed to enhance communication and collaboration among investigators and clinicians. Plans call for establishment of an Internet Web site so researchers can evaluate and compare methods for testing antibiotic susceptibility. The network also will establish a repository of antibiotic-resistant *S. aureus* isolates for distribution to researchers. Meanwhile, efforts continue to sequence the genomes of two *S. aureus* strains in order to pinpoint the specific genes that select for resistance to antibiotics. Researchers at the Institute for Genomic Research in Rockville, MD, are sequencing an MRSA strain, while a research team at the Oklahoma (City) University Health Science Center is sequencing a strain that remains sensitive to antibiotics.

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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. ■