

CAP TODAY

C O L L E G E O F A M E R I C A N P A T H O L O G I S T S

Sticking points: regs propel sharps safety

Karen Southwick

Exposure to bloodborne pathogens, especially since the onset of the HIV epidemic, has long been a major worker safety issue for nurses, medical technologists and technicians, and phlebotomists. So widespread is the concern that needlestick injuries, and the anguish they create, have become a staple of TV medical dramas.

Popular culture aside, the Centers for Disease Control and Prevention projects that more than 380,000 percutaneous injuries from contaminated sharps occur annually among health care workers in U.S. hospitals. Among all health care settings, the number rises to an estimated 600,000 to 800,000 injuries per year.

Last year, Congress passed a law requiring the Occupational Safety and Health Administration to update its regulations governing sharps safety. OSHA started enforcing the revised standard, published Jan. 18 in the *Federal Register*, in mid-July, although states that operate OSHA-approved programs have until Oct. 18 to adopt the federal standard or more stringent changes to their own laws.

Among the primary requirements:

◆ Safer medical devices, such as engineered sharps and needleless systems, must be used, wherever feasible, to minimize employees' exposure to blood. Employers must document in their exposure control plans

their consideration and implementation of such devices, and they must review and update those plans at least annually.

◆ In evaluating and selecting safer devices, employers must solicit input from nonmanagerial health care workers involved in direct patient care.

◆ Employers must maintain a sharps injury log that includes the type and brand of device involved in an exposure, the department or work area where the exposure occurred, and an explanation of how it happened.

Although 17 states already have regulations governing sharps safety, health care worker advocates

welcomed the new federal legislation as a way to standardize the law and drive compliance at a quicker pace.

"This law was definitely needed because there has been a disparity between the tremendous advances in needlestick technology and the slow rate of adoption in the industry," says Jane Perry, director of communications for the International Health Care Worker Safety Center at the University of Virginia.

Perry cites two main reasons for the lag in moving to safer devices. First,

"health care administrators are reluctant because of the cost," she says. Newer devices can cost up to three times as much as conventional needles and sharps. Second, workers resist moving to a device that may

continued on page 2



The lab at Presbyterian St. Luke's Medical Center, Denver, recently moved from glass tubes to plastic tubes wherever possible to increase safety, says Dr. Thomas Merrick (right), shown here with Ray Levesque.

Sharps safety

continued from page 1

seem more cumbersome and difficult to use.

"Most hospitals have probably not done what they need to," says Dennis Ernst, director of the Center for Phlebotomy Education Inc., Ramsey, Ind. The center offers continuing education services in phlebotomy for health care facilities. "Selecting devices and implementing new procedures is detailed and involved," he adds. "From the time the law was passed until [it became effective in] July, most managers have probably had their hands full figuring out how it applies to them and how to comply."



Ernst

Ernst praises the requirement for input from front-line workers. "Without that," he says, "the bulk of the decisions would have been by accountants rather than by phlebotomists," probably resulting in selection of the least expensive device.

Bill Borwegen agrees. Borwegen is the occupational health and safety director for the Service Employees International Union, which represents 710,000 health care workers in the United States. "This federal law is unique in that it requires employers to solicit the input of people who actually use the device," he says. "To me, that's the most important part of the law."

Borwegen chides the health care industry for trailing other sectors on worker safety. "We should have done this switch [to safer devices] 10 years ago," he says. "Basically, the health care industry is in a state of denial, even though it reports more occupational injuries and exposures than any other industry." The labor leader attributes the problem, in part, to health care's culture, which focuses on the needs of patients but not of workers. "But there's a synergy," he maintains. "If you make the workplace safe, it's better for patients too."

Acknowledging that switching to safer devices can be expensive, the chair of the CAP Safety Committee, Thomas Merrick, MD, calls the new law a "good idea" in view of the CDC's estimates of needlestick injuries and projections that better safety devices and procedures can prevent the vast majority of such injuries.

Dr. Merrick, director of the clinical microbiology laboratory at Presbyterian St. Luke's Medical Center, Denver, says he wrote a letter to OSHA asking if the federal agency would cite a laboratory for not using safe needle devices if there have been no documented needlestick injuries.

OSHA's response: "Citations will be issued to any employer that has not implemented engineering con-

trols where feasible. . . . Employers must institute engineering and work practice controls as the primary means of eliminating employee exposure or reducing it to the lowest extent feasible." The OSHA letter also notes that civil penalties of up to \$7,000 can be assessed for each violation.

"That reply is very definite," Dr. Merrick says. "If newer engineering controls [on sharps] are available, they must be used." Although he considers OSHA's response a bit strong, he concedes that health care institutions must move to safer devices, despite the cost.

With a variety of devices available—not just for needlesticks but also for storage and microscopic examination of blood—"who knows what the best system is out there?" Dr. Merrick questions. As part of their annual evaluation of exposure control, institutions could assess which devices are responsible for injuries, he suggests. In addition, "if you're not lowering your [worker-injury] numbers, you may want to look at other devices."

Don't focus solely on needles, Dr. Merrick adds. "All sharps are included in this new law." For example, Presbyterian St. Luke's used glass tubes in the laboratory but recently moved to plastic tubes wherever possible because the risk of shattering is lower.

Making the switch

Ernst estimates that the upfront cost for needles, syringes, and other safety equipment is probably triple that of conventional devices. For example, newer needles run \$0.25 to \$0.50 apiece versus \$0.07 to \$0.08 for conventional needles. "To get into compliance, you're probably looking at paying three or four times what you're accustomed to paying," he says, and that doesn't include training.

However, he adds, "what we would hope is that people focus on the overall savings." You might avoid spending \$250,000 for a liver transplant for a worker with hepatitis or \$500,000 for treating someone who has contracted HIV. Just to treat a wound and do postexposure evaluation costs several thousand dollars. In the long term, he and other experts agree, the cost is a wash.

A Nov. 17, 2000 report by the U.S. General Accounting Office estimated the increased purchase costs of using safety needles in hospitals to be between \$70 million and \$352 million annually, depending on whether hospitals adopted high- or low-cost devices. Those figures exclude the costs associated with training or changing work practices. Based on cost scenarios for postexposure treatment, the GAO reported that benefits in terms of prevented costs would exceed those upfront costs in many cases.

Most hospitals and laboratories are probably in the

evaluation stage for safer devices, says Sheila Dunn, DA, president and CEO of Quality America Inc., a regulatory consulting firm in Asheville, NC. The process “definitely becomes a management issue,” she notes, because workers rarely agree on what devices should be adopted. “Maybe you get three people who love a retractable device and two who say they don’t want to change.”

The experts have several suggestions for health care facilities attempting to comply with the law.



Dr. Dunn

- ◆ Select a half dozen or so products that appear to be cost-effective and give them to the staff to evaluate one at a time. “It’s important that conventional devices be removed completely during the evaluation process so workers can give their full attention to the new devices,” says the Center for Phlebotomy Education’s Ernst.

- ◆ Use written evaluation forms, which can be obtained in a number of places online, including San Francisco General Hospital’s www.tdict.org and Quality America’s Web site, www.quality-america.com, as well as from rating services like ECRI (www.ecri.org). The University of Virginia site, www.med.virginia.edu/epinet, lists safety devices and EPINet (Exposure Prevention Information Network) tracking data on their incident rates.

- ◆ Evaluate devices on their ease of use, patient satisfaction, and injury protection. The employees union’s Borwegen believes the so-called passive devices, which do not require the user to trip the safety mechanism, are preferable. Some needles, for instance, are automatically retracted before they leave the patient’s arm.

- ◆ Make sure each evaluator uses the device 10 to 20 times over a period of at least a week. “If there’s training involved, make sure you do it even for the evaluation,” Ernst says. “Otherwise, you’ll end up with ratings that are unfair to the device.”

- ◆ Once workers have evaluated the devices, administrators should make a selection. Look at more than just initial cost, Dr. Dunn advises. Retractable devices are among the most expensive to purchase but “take up one-half the amount of space in a sharps container, saving money on disposal,” she says.

- ◆ Set up an implementation schedule that includes communication and training. “It’s critical to remove all of your conventional devices because front-line workers will hoard them rather than change,” Ernst notes. Management can use the opportunity to emphasize a caring environment for employees, Dr. Dunn adds. “Instill the attitude that you’re willing to listen and you’re concerned about worker safety,” she says.

- ◆ Establish a procedure for reporting injuries that includes providing OSHA-required information. The Uni-

versity of Virginia EPINet site is one source of assistance in this area. The earlier OSHA regulations already required reporting, but the new law “is much more comprehensive and requires more specific details,” Ernst says, including the name of the device manufacturer and a description of the activity that preceded the exposure.

California leads the way

In 1998, California passed one of the more stringent safety laws pertaining to needles and other devices. (The new federal regulations are modeled in part on California’s law.) Several experts cited health care facilities in that state, including Catholic Healthcare West and Kaiser Permanente, as leaders in sharps safety.

At San Francisco-based Catholic Healthcare West, which encompasses 48 hospitals, Cynthia Fine, infection control and employee health manager, developed a centralized program to meet the state law. “We had 15 video conferencing sites” throughout the system, says Fine, who operates out of Catholic Healthcare West’s Oakland, Calif., office. Manufacturers were given five minutes to demonstrate how their devices worked. Then front-line health care workers, such as phlebotomists, participated in demonstrations using the products. The items tested included syringes and needles, scalpels, and intravenous devices.

After those videoconferenced sessions, “we picked the ones we thought were the best to pilot,” says Fine. Three or four facilities would volunteer to use each device. The operators of the devices filled out evaluation forms, which were obtained from www.tdict.org. The evaluation included user and patient experience. Among the questions: Can the device be activated with one hand? Does it interfere with the procedure? Does it hurt the patient? Is the device currently available?

A committee that included representatives from employee health, infection control, and administration made the final decision about whether to implement a product. Generally, says Fine, Catholic Healthcare West selected at least two devices in each category to make sure workers had a choice. “One of the most important things I’ve found is that people at one facility might love something, and people at another will hate it.” Of course, she had to battle materials management, which wanted to standardize on a single device.

Fine estimates it cost \$30,000 to \$100,000 more a year for each facility to move to safer devices. The costs varied based on size of the facility and the steps it had already taken to improve safety.

Catholic Healthcare West has seen a decline in exposures in about 95 percent of its hospitals. “A couple of hospitals had increases when they first switched over,” she says. “We had to look at whether they did ad-

continued on page 6

Sharps safety

continued from page 3

equate training on the devices they selected." In the short term, she cautions, "you might have increased injuries" as workers adjust to new devices.

Training was conducted primarily by manufacturers, who were eager to prove their devices in such a large health care system. In the case of IV devices, the manufacturer paid for a clinical specialist nurse to work with Catholic Healthcare West's nurses. "She spent at least a couple of months training with them," says Fine.

Another problem Fine had to address was worker resistance. "A lot of people were hiding the old devices in the cupboards. They were worried about things like hurting the patient by having an unsuccessful IV start," she recalls. At some hospitals, "we had to go around and clean up all the old devices they could find and replace them with the new ones." Switching to new safety devices takes time and effort, she adds. "It has been two years since we switched and we're just now getting to the point where people are okay with the new devices."

When Fine gets information about a new device from salespeople or the Internet, she sends e-mails to all the hospitals. "Each facility can decide if it wants to do a trial," and results are then circulated throughout the system. Both California and the federal law mandate annual re-evaluations.

Despite the hassles of compliance, Fine applauds the state and federal regulation. "Absolutely this is needed," she says, "because, unfortunately, hospitals are often in a money-losing situation and it's hard to convince them to spend more. So it takes a law to get something in place."

At the University of California San Francisco Medical Center, where phlebotomy is performed by laboratory and nursing personnel, each group chose separate safety devices. Tim Hamill, MD, director of clinical laboratories, says his phlebotomists, who handle outpatient blood draws, selected the Bioplexus, a self-blunting needle, several years ago. "At the time, we had the staff try several devices, and that was the one they liked the best," he says.

The administration initially balked at the Bioplexus because "it was significantly more expensive than some of the alternatives," Dr. Hamill says. But the phlebotomists insisted that another choice did not work as well. Eventually the cost of the Bioplexus came down, "so we started using it," he adds.

Meanwhile, the nurses, who handle inpatient draws, chose the BD Eclipse safety needle. UCSF's needlestick task force, composed of nurses, physicians, and lab representatives, evaluated safety trials and made recommendations to the institution's product standard-

ization committee, which chose the BD Eclipse.

"We're in the process of standardizing to one device throughout the medical center," which will probably be the BD Eclipse safety needle, says Ellie Lannen, nurse practitioner and chair of the needlestick task force. "The goal is to use one device so providers will be familiar with and well trained when using a phlebotomy device. This will reduce the risk of accidental exposures. We have used safety devices at UCSF since 1992, and as a result, have significantly reduced the number of phlebotomy-related exposures."

Still, Dr. Hamill says he's reluctant to impose a switch on the laboratory unless his phlebotomists acquiesce. "I'd rather leave it in the hands of the people who are using it," he says.

Implementation tales

Other institutions that have adopted new safety devices or are in the process say it's not a simple matter. Workers may not agree on a device, as in UCSF's case, or may not want to switch at all. "There's usually resistance from someone," says Ray Levesque, an employee health nurse who works on the bloodborne pathogen program at Denver's Presbyterian St. Luke's Medical Center.

Presbyterian St. Luke's is the flagship of a seven-hospital system, which about 10 months ago began converting to a safety needle. In the first phase, a joint committee of employee health and infection control nurses tested prototypes, with input from bedside nurses. At the next stage, the clinical products committee, which comprises front-line and managerial workers, looked at the test results and listened to vendor presentations. Generally, says Levesque, the products committee went along with the joint committee's recommendations.

Presbyterian St. Luke's did not standardize on a single product. Each department chose from a list of recommended items. "We are sticking with one manufacturer," Levesque says, because that allows for volume buying, which saves money.

As new devices are adopted, the manufacturer sends a clinical representative to handle training. After an exposure occurs, Levesque will do one-on-one refresher training with the worker involved in the incident and the manager.

Realizing the compliance deadline was approaching, Linda Pope, manager of outpatient laboratories and phlebotomy services at St. Joseph Mercy Hospital, Ann Arbor, Mich., decided to let her workers try a new safety needle. "We were riding in a car without our seatbelt," she says, referring to St. Joseph's use of conventional needles.

Pope met with a representative from Becton Dickinson

son and Company and obtained enough supplies of the BD Eclipse safety needle for a trial. Phlebotomists and lab technicians used the device for several months and filled out evaluation forms. "They liked it, felt comfortable with it, and that's what we adopted," says Pope. Purchasing the new needle meant about \$2,000 in added costs for the outpatient labs each quarter (\$2,550 versus \$612 for the conventional device), "but because of the safety and the need to be in compliance, that's what we have to do," she says.

Now, with the acquiescence of a new interdisciplinary task force, a sharps injury prevention committee, the BD Eclipse safety needle is being introduced in the inpatient arena for nurses. The committee will tackle sharps in other areas, such as surgery, anesthesia, and respiratory therapy.

At Children's Hospital, a pediatric care facility in Omaha, Neb., lab-directed phlebotomists try new safety devices that come on the market and that are pertinent to pediatric pathology. They fill out an evaluation form on each product. Pathology manager Karen Butler says if the phlebotomists like a device and it's readily available, Children's will add it. "There has to be a solid scientific reason for us not to use them, not just cost or the fact that it requires a change in technique,"

she says.

One problem is that devices aren't sized for Children's patients. For instance, Children's uses the 3-cc BD Vacutainer tube, which also requires a smaller than normal hub. "When you're dealing with a small child, you want to maintain as flat an entrance as possible [of the hub] to minimize discomfort," Butler explains. But the Vacutainer tubes with safety corks will only work with adult hubs. Children's has yet to find a 3-cc tube on the market with a safety cork.

The Cleveland Clinic Foundation, which includes a large hospital and an extensive outpatient network, is another system attempting to standardize on a single safety needle. The process started in clinical pathology, where phlebotomists narrowed an initial list of five devices to two.

"We tested them on patients, identified the problems, filled out evaluation forms," says Barb Kirkley, manager in clinical pathology. "They found two products they liked," she adds. Now the process is being expanded systemwide to include evaluations by nursing and the emergency department.

In each area, 10 to 12 people, representing a range of experience, are asked to evaluate the devices, says Don

continued on page 8



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Sharps safety

continued from page 7

Bianchini, training coordinator for the phlebotomy and transport services department. "We ask them to use it on different types of patients, in different settings."

The 25 questions on the evaluation form, which he culled from information on the OSHA Web site as well as ECRI and EPINet, include: Did it work on patients with fragile veins, on both thin and heavy patients? Were needles available in appropriate sizes? How easy was it to learn to use the device? Is this device compatible with other safety devices you use?

Once all the data are collected, an interdisciplinary committee, which includes phlebotomists, nurses, medical technologists and technicians, and physicians, will

make a recommendation to the executive committee. Bianchini expects that a new needle will be adopted early next year. "The difficulty I foresee is the logistics of swapping out all of the old products in a system this big," he says. "Once that is accomplished, we can readdress education and compliance."

Ernst cautions hospitals to expect compliance to be a slow process, citing the profusion of devices on the market and the time required to review products, get feedback from employees, make a selection, and do training. OSHA inspectors probably will be patient with institutions that have an implementation plan in place, he surmises, "but they will want to see progress on that plan." □

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