OR Manager Inc

**OR Manager**
Vol. 21 No. 12
December 2005

Sharps safety

# OSHA is pressing ORs to adopt safety scalpels but surgeons resist

Frustration. That's the word OR directors use to describe their experience with trying to implement use of safety scalpels in their ORs. In several regions, the Occupational Safety and Health Administration (OSHA) is pressing facilities to adopt safety scalpels as part of compliance with the bloodborne pathogens regulation.

Many facilities have evaluated safety scalpels. But OR directors say surgeons often will not accept them. In some cases, facilities have been cited and fined because surgeons refused.

Safety scalpels are engineered to prevent sharps injuries. For example, they have a retractable blade or a sheath that locks in place to cover the blade.

To date, in acute care, less than 5% of the market for reusable scalpels has converted to safety devices, according to BD, a leading scalpel manufacturer. For disposable scalpels in acute care, it's about 59%.

The directors say they want OSHA to be clearer about its expectations: Are safety scalpels required? If surgeons refuse to use them, how should that be documented?

The bloodborne pathogens regulation requires facilities to have an exposure control plan. The plan must be updated at least annually. As part of the update, facilities must involve front-line workers in evaluating new technology that eliminates or reduces exposure to bloodborne pathogens.

About half the states are covered by federal OSHA. The rest have OSHA-approved state programs, which must have standards at least as strict as federal OSHA's.

## Mixed experience

OSHA has leaned on hospitals in the Pittsburgh area to adopt scalpels with safety features. OSHA's Pittsburgh office is conducting a special project on bloodborne pathogens. Over the past 2 years, the 20-hospital University of Pittsburgh Medical Center (UPMC) system has had 29 inspections, says William Smith, director of environmental health and safety.

UPMC has had mixed experience with safety scalpels. Initially, surgeons were reluctant to adopt them, he says. After evaluations, surgeons seemed to find an acceptable model with a metal handle.

But as more surgeons began using it, there was a revolt. Some surgeons saw a patient safety issue because they said the scalpels are not rigid enough and might bend during some deep tissue incisions, he says.

One surgeon said he found the sheath covering the blade awkward to use. He said it did not retract or slide back over the blade easily.

If surgeons complain they can't use safety scalpels, the OR documents an exception stating the surgeons are not able to use them for patient safety reasons. The documentation is included in the exposure control plan.

"OSHA is very precise," Smith says. "You can't just say, 'We don't want to use them.'" There must be a patient safety rationale.

In addition, as an alternative, OSHA requires the facility to adopt other safe work practices to protect employees. For UPMC hospitals, that usually is a neutral zone for passing sharps in the OR.

But before adopting an alternative, "you still have to conduct that upfront process to evaluate the safety devices," he says.

Facilities also have to stay up-to-date on safety devices coming on the market and do thorough review. You can't just take a quick look and say, "There's nothing new," Smith cautions.

### A visit from OSHA

A hospital in Tennessee had a thorough review by OSHA in January. The hospital was cited for 14 violations, including 10 violations of the bloodborne pathogens rule. The total penalty stood at $7,100 in September. The hospital appealed but lost. OSHA has said it will return. If the inspector finds the hospital is not in compliance, the fine could be much stiffer, the OR director says.

Safety scalpels were a big issue with OSHA, she says. "We do use them, but not 100%. There are certain times when it is not appropriate," she says. Plus, most surgeons don't like them.

Surgeons seem to be more willing to use trays for no-hands passing of instruments. Some physicians want to use the passing trays as an alternative to safety scalpels, but the director is concerned the OSHA inspector will not agree.

### Employees at risk

Some OR directors wish OSHA would be clearer about what it wants. "It would be easier if OSHA just told us we have to use safety scalpels," one OR director says.

But that's not the way the regulation is written, explains Gina Pugliese, RN, MS, vice president of the Premier Safety Institute.

"This is a performance-based standard. That means it tells you what the goal is—to prevent injuries," she says. "OSHA can't tell a facility how to meet that goal. That is the facility's decision, and you want the flexibility to tailor your program."

The reason OSHA can cite facilities when surgeons do not use safety scalpels, even though the surgeons usually are not employees, is that the facility allowed surgeons to put its employees at risk, she notes.

Pugliese suggests that implementing safer devices is like any other change process in the OR—"you need to get a group together and find a surgeon champion." Then map out a plan for improving the process (see sidebar, page 10).

### What's an acceptable exception?

OSHA says it will grant exceptions to use of a safer device if the device would compromise patient safety.

OSHA addressed the question of safety scalpels in a June interpretation letter posted on its web site. The letter clarifies that scalpels and blades are included in OSHA's definition of regulated sharps.

In the letter, OSHA says surgeon preference generally "is not an excuse for failure to use engineering controls" (such as safety scalpels). Then it says, "In some surgical procedures, the 'feel' of a device in the hands of the surgeon may be crucial to properly executing the surgical technique." That could affect the outcome of the procedure and safety of the patient.

"OSHA recognizes there might be unique circumstances where the safety of the patient or the integrity of a procedure might be best served with the use of a device that is not a safety device," the letter continues.

"In those situations, it is important that good work practice controls, such as hand-to-hand instrument passing in the operating room, be implemented to provide protection to employees who are at risk of getting injured by an unprotected device." (The letter is at www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=25123.)

If surgeons do not want to use safety scalpels because of the "safety of the patient" or "integrity of the procedure," how should that be documented?

The letter says the documentation should be part of the facility's annual review of its exposure control plan but is not specific.

### Data may not reflect injuries

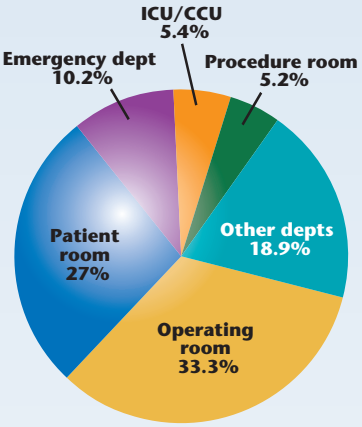
Under the OSHA regulation, the types or numbers of injuries a facility has does not affect which safety devices should be considered.

"The lack of recorded injuries on the sharps injury log or OSHA 300 log does not exempt the employer from use of engineering/work practice controls," OSHA says in its compliance directive for inspectors.

In any case, a facility's data probably is not an accurate reflection of injuries that

## OR has highest injury rate

### Where injuries occurred




*Note: Other departments include outpatient clinic/office, labor and delivery, clinical laboratories, service/utility area, venipuncture, outside patient room, autopsy/pathology, dialysis facility, home care, blood bank, and others.*

### Types of devices causing injury

**Most common devices causing injury:**

| | |
|---|---|
| Disposable syringe | 31.9% |
| Suture needle | 20.5% |
| Winged steel needle | 7.6% |
| IV catheter (stylet) | 4.3% |
| Scalpel, reusable | 4.1% |
| Scalpel, disposable | 4.1% |
| Vacuum tube blood collection needle | 3.8% |

*Note: Data are from 48 facilities that reported 1,708 total injuries.*

*Source: Needlestick and Sharp-Object Injury Report. US EPINet Network, 2003.* Advances in Exposure Prevention. *2005;7(4):44-45.*

*The EPINet Network is coordinated by the International Health Care Worker Safety Center, University of Virginia. More information is at www.healthsystem.virginia.edu/internet/epinet/*

occur. Research shows as few as 30% to 40% of injuries may be reported by surgeons, according to Mark Davis, MD, surgeon and author of *Advanced Precautions for Today's OR*, a handbook for preventing sharps injuries.

"This really is a tough issue," Dr Davis adds. He thinks it will get better as companies refine their products. "It's just a matter of ingenuity, engineering, and more education."

## What do surgeons think?

"The products just aren't there. Unfortunately, it's hard to be compliant when we don't have good technology," says Maria Allo, MD, FACS, chief of surgery at Santa Clara Valley Medical Center, San Jose, Calif. "We have trialed some and did not feel there was a product that made it worth replacing the ones we are using."

The hospital has been tracing sharps injuries and has not identified scalpel injuries as a problem in the OR, she adds.

William Schecter, MD, FACS, chief of surgery at San Francisco General Hospital, who has been involved in the bloodborne pathogens issue since the 1980s, says he thinks that once new, easier-to-use safety scalpels emerge, surgeons will adopt them more readily.

"The first generation of safety scalpels was difficult to use, and surgeons weren't enthusiastic," he says. "The second generation was better. I think when we get the next generation, it will improve."

"Let's face it," he adds, "if OSHA didn't put up a fuss about this, it would not happen. But it takes time for industry to come up with improved designs."

## Advice from an OR director

In complying with the OSHA regulation, administrators and medical executives must back the OR manager and staff, stresses Lowell Price, RN, CNOR. He is surgical services coordinator at a small community hospital inspected by OSHA in 2002. OSHA cited the hospital for a number of violations. Among them were 2 serious violations of the bloodborne pathogens standard in the OR—using standard stainless steel scalpels and an absence of blunt suture needles available to use "where appropriate." The total fine for these 2 violations was $4,500.

In the surgery department, Price says the compliance officer wanted to see all engineering and workplace controls that dealt with sharps. During a walkthrough, the officer examined:

- scalpels
- syringe stock
- IV catheters
- IV tubing
- hypodermic needles
- sutures
- wall-mounted sharps containers.

The officer also conducted a one-on-one interview with employees, especially those who had been injured with needles or blades. Among questions the officer asked were:

- What kind of sharps safety items are used? Examples are sharps containers, needle counters, and shielded scalpels.
- Are they always used? "The answer had better be yes," says Price.
- What does the facility do when someone is injured? The answer: Send the employee to the emergency department and fill out the OSHA Form 300.
- How often are the sharps containers checked? "Ours are checked daily," Price says. "Have a policy to document what you are doing. Our containers are transparent and have a label that says, 'Do not fill above this line.'"

## A form for exceptions

During the visit, Price showed the officer a file on an evaluation of a shielded scalpel, documenting that the surgeons found it unsuitable. He says the officer told him: "It doesn't make any difference what the surgeons like. You must use the shielded disposable scalpels or continue to be fined."

After the hospital was fined, "My administration said, 'Pull every traditional scalpel and blade,'" he says. Now traditional scalpels can be used only if there is a specific exception. Since surgeons have been using the safety scalpels, "they actually like them," he says.

For any exceptions, the surgeon must complete and sign the hospital's Patient Safety Exception Form. The forms are kept on file. The form applies only to a specific type of procedure, such as open heart.

Price's comment to OR directors whose surgeons do not want to use the safety scalpels: "The hospital administration has to make up its mind whether it wants to pay a fine to OSHA or please the surgeons."

His other recommendations:

- "Bring in every safety product you can identify for a trial," he says.
- Keep a folder documenting product trials and outcomes.
- Make sure front-line staff have input into evaluations of safety devices. Document who participated and what input they gave. Give the documentation to the person in your organization who is responsible for the exposure control plan.
- Have a specific form to document exceptions to the use of safety devices and require physicians to sign it. OSHA says a specific form is not required, but Price recommends using one anyway.
- The CEO must communicate to the chief of surgery and chief of medicine that any physician who wants an exception must fill out the exception form.

"It used to be we could evaluate products and say they were not acceptable. Now we have to use them or fill out the Patient Safety Exception form," he stresses.

- Implement a policy for neutral zones for passing of sharp devices in the OR.

### What about other sharps?

The OR director in Tennessee faced another big issue with OSHA. The compliance officer wanted the facility to examine every sharp object used in surgery and document if there was no alternative. OSHA defines a sharp as "any contaminated object that can penetrate the skin."

"Practically everything we touch in the OR can cut or perforate," she says. She was reviewing an 82-page inventory list to identify every sharp for which there was not a safer option. That included Steinmann pins, K-wires, saw blades, and trocars, among others. She said the OSHA officer had told her there must be a process to review all sharps and if there is no safety alternative, document that the facility still finds them acceptable.

Smith at UPMC said their OSHA office has a similar expectation. In UPMC, each OR has its own exposure control plan, which is an attachment to the hospital's plan.

The OR's plan lists all sharp devices by category and whether there is an alternative, for example: "Device X: No alternative."

Given OSHA's approach, OR directors will continue to play a balancing act until scalpel technology is refined and surgeons find it more acceptable. ❖

## Resources

Davis M. *Advanced Precautions for Today's OR.* Atlanta: Sweinbinder Publications, 2001. www.orprecautions.com/contact.html

EPINet. Exposure Prevention Information Network, University of Virginia. www.healthsystem.virginia.edu/internet/epinet/about_epinet.cfm

OSHA. Bloodborne pathogens and needlestick prevention. www.osha.gov/SLTC/bloodbornepathogens/index.html

Premier Safety Institute. Sharps safety resources. www.premierinc.com/safety/sharps-safety/

# Top 3 OSHA citations

These are the top violations of the bloodborne pathogens regulations OSHA cites hospitals for:

1. **Paragraph (d)(2)(i).** Engineering and work practice controls are required to eliminate or minimize employee exposure to bloodborne pathogens.
2. **Paragraph (c)(1)(iv).** The Exposure Control Plan shall be reviewed at least annually and whenever necessary. The update shall among other things:
   — reflect changes in technology that eliminate or reduce exposure
   — document that safer medical devices have been considered and implemented as appropriate.
3. **Paragraph (d)(4)(iii)(A)(2).** During use, sharps containers shall be:
   — easily accessible
   — maintained upright
   — replaced routinely and not allowed to overfill.

*Source: OSHA. Data are for 2004.*

# A change strategy for safety scalpels

Persuading surgeons to try safety scalpels is like any other change process in the OR, advises Gina Pugliese, RN, MS, vice president of the Premier Safety Institute.

Here are some steps she suggests:

- OSHA requires, as part of the facility's annual update of its exposure control plan, a review of innovations and new technology that eliminates or reduces exposure to bloodborne pathogens.
- OSHA requires you to involve front-line workers in this annual review. Include at least one surgeon in this evaluation. Ideally, this will be a surgeon who is an opinion leader.
- As part of the annual review, consider polling surgeons anonymously to ask them how many times they have been stuck by a scalpel and what the circumstances were. OSHA does not consider the lack of injuries to be a reason not to use safety devices. But the survey might raise consciousness among the surgeons about how safety scalpels could prevent some injuries.
- Have companies bring in safety scalpels that are currently on the market. Line up the scalpels and ask surgeons to try them. Suggest they take samples and spend time handling them. "You might actually find some who will say, 'This one is not so bad,' or 'I like this one,'" she says.
- If the surgeons say the safety scalpels still are unacceptable, document specifically which devices they tried and the specific reasons for rejecting them. Remember that OSHA considers the "safety of the patient" and "integrity of the procedure" might be reasons for not using a device with safety features.

*Information about the Premier Safety Institute is at www.premierinc.com/all/safety.*