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.

Performance improvement

Director’s Cup rewards OR teams for moving from good to great

In November 2001, the OR leadership team of St Vincent’s Medical Center, Jacksonville, Fla, met to devise a dashboard report to quickly capture and clarify data about department efficiency and safety. During this process, it became apparent that while a great deal of data were being generated, collected, and analyzed, the implications of this data were not being considered as a whole.

A plan was developed to select and quantify key quality indicators and expand communication to the OR and medical staffs. Implementation resulted in heightened awareness, focused efforts, and improved outcomes.

Attempts at a better way

In the mid-1990s, St Vincent’s OR leadership team had developed an employee recognition and performance improvement program. This initiative, called Making a Difference, met with limited success because the criteria were too subjective, and the award was designed to recognize individual efforts. The program was dissolved within the year.

During the next few years, the OR leadership team focused on staff recruitment and retention, including expansion of the existing perioperative school. The
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**Publisher’s Note**

**The Turnover Robotic Assistant runs on 2 AAA batteries.**

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**T**

was the week before Christmas, and Santa was shopping on eBay for some last-minute gifts as he listened to his favorite holiday songs on his new iPod Nano. He was always particularly fond of “Santa Claus is Coming to Town.”

A knock on the door interrupted him. “Come in,” he called cheerfully.

“Hi, I’m an OR director, and I need some help to pick out gifts for my staff.”

“I’d be glad to help. I am so grateful for the gastric bypass a few years ago that helped me turn from a traditional tubby into a svelte Santa. (Just look at this belt size!)

“This is the year of electronic gadgets. No more scarves, neckties, gloves, or other boorrrring gifts. This year it is the gizmo, a gadget … techie toys. If it doesn’t take batteries, don’t put it under the tree … that’s my advice.”

“What would you suggest for our surgeons?”

“I have the perfect gift … the Rapid Surgical Guidance System (RSGS). Forget how to do a Whipple? Just enter the name of the procedure, radical pancreateoduodenectomy, and the RSGS will walk you through the procedure with both audio and visuals, much like the popular GPSs that help drivers find their route. The color screen tracks the surgeon’s progress, and the audio directs the progress of the procedure: ‘After you make the incision, enter the ampullary area and advance to the pancreatic head.’ If the surgeon makes a wrong move, the RSGS will say, ‘Please wait while I recalculate your route.’”

“I really like that,” the OR director said enthusiastically. “Now what about our staff? They work really hard, but one of their toughest problems is speedier turnover time.”

“I’ve got the answer—the Turnover Robotic Assistant (TRA). The TRA allows the nurses to attend to the patient while it cleans the OR. It red-bags the waste. It sends the dirty instruments and linens to central service. It mops the floor if necessary. While it is cleaning up, a second TRA sets up for the next case. And best of all, it runs on 2 AAA batteries.”

“That sounds absolutely fantastic … but I need one more gift. My assistant director does a wonderful job, but she worries about her dog who is home alone all day. How can I help her so she can devote all her attention to her job?”

“She’ll love this, and so will her pup … the Bow-Wow iPod Nano Collar (BWiPNC). Pets love listening to Dog-CatRadio.com, the Internet radio station, but the BWiPNC collar is even better. In addition to the music and talk shows your dog loves, you can record your own messages your dog can listen to while you are off at work or shopping for dog treats. For example, you might want to say this, ‘Good dog, I’ll be home in 32 minutes, and I’ll get your dinner as soon as I get home.’ I can tell you, this will be the hottest electronic item under the Christmas tree this year.”

“Thanks, Santa. You have sure given me lots of help with my Christmas shopping. I hope that I find some neat gadgets under my tree.”

“Don’t worry, I e-mailed your staff some suggestions.”

Enjoy the holidays … and don’t forget the AAA batteries.

—Elinor S. Schrader
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ASA advisory on anesthesia awareness

Brain function monitoring is not routinely indicated, either to reduce anesthesia awareness episodes or to monitor anesthesia depth, the American Society of Anesthesiologists (ASA) says in a practice advisory approved at its annual meeting in October in Atlanta.

In the works for 2 years, the advisory addresses risks and strategies for preventing anesthesia awareness.

Among the recommendations, the advisory says physicians should rely on multiple means to monitor patients for anesthesia awareness. These include clinical techniques such as checking for movement, response to commands, and opened eyes, and using conventional monitors, such as electrocardiogram, blood pressure, heart rate, end-tidal anesthetic analyzer, and capnography. The decision to use a brain function monitor should be made on a case-by-case basis.

The advisory task force concluded that the need for general use of brain function monitors to prevent awareness has not been established. It found there was not enough evidence to justify a guideline or requirement to use brain function monitors to reduce awareness not only in high-risk patients but in other patients having general anesthesia.

The advisory says preoperative evaluation may be useful in identifying patients at increased risk for awareness. If possible, a preoperative evaluation should include:

- review of a patient’s medical records for previous occurrences of awareness or other risk factors
- an interview to assess patient anxiety or previous experiences with anesthesia
- a physical exam.

Patients found to be at substantial risk for intraoperative awareness should be informed of its possibility.

Because intraoperative awareness may be caused by equipment malfunction or misuse, the task force recommends using a checklist for anesthesia machines and equipment and verifying proper functioning of IV access and infusion pumps to ensure desired drugs and doses will be delivered.

The decision should be made on a case-by-case basis whether to give a benzodiazepine prophylactically to reduce the risk of awareness or to administer a benzodiazepine intraoperatively after a patient unexpectedly becomes conscious so the patient does not remember the event.

Postoperatively, practitioners should speak with patients who report recall of intraoperative events to obtain a detailed account of the experience and to discuss possible reasons. The awareness episode should be documented in an occurrence report, and the patient should be offered counseling or psychological support.

The advisory was developed by an ASA task force that reviewed more than 150 studies and sought comments from ASA members, technical experts, and manufacturers of brain function monitors.

In a related action, ASA recommended funding further research into the usefulness of brain function monitoring in minimizing the risk of intraoperative awareness.

JCAHO’s controversial alert

The current controversy over using brain function monitoring on all patients under general anesthesia arose last year when the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a sentinel event alert on preventing anesthesia awareness.

The ASA said it did not agree with JCAHO’s timing of the alert because JCAHO was aware ASA was in the midst of its 2-year study in preparation for issuing this advisory.

The ASA practice advisory is at www.asahq.org/news/AwareAdvisoryFinalOct05.pdf

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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 safety 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.

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.
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Sharps safety

Continued from page 7

“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 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:

• scalps

You can’t just say, ‘We don’t want to use them.’

OR has highest injury rate

Where injuries occurred

<table>
<thead>
<tr>
<th>Department</th>
<th>Injury Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating room</td>
<td>33.3%</td>
</tr>
<tr>
<td>Patient room</td>
<td>27%</td>
</tr>
<tr>
<td>Procedure room</td>
<td>5.2%</td>
</tr>
<tr>
<td>ICU/CCU</td>
<td>5.4%</td>
</tr>
<tr>
<td>Other depts</td>
<td>18.9%</td>
</tr>
<tr>
<td>Emergency dept</td>
<td>10.2%</td>
</tr>
</tbody>
</table>

Types of devices causing injury

<table>
<thead>
<tr>
<th>Device</th>
<th>Injury Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposable syringe</td>
<td>31.9%</td>
</tr>
<tr>
<td>Suture needle</td>
<td>20.5%</td>
</tr>
<tr>
<td>Winged steel needle</td>
<td>7.6%</td>
</tr>
<tr>
<td>IV catheter (stylet)</td>
<td>4.3%</td>
</tr>
<tr>
<td>Scalpel, reusable</td>
<td>4.1%</td>
</tr>
<tr>
<td>Scalpel, disposable</td>
<td>4.1%</td>
</tr>
<tr>
<td>Vacuum tube blood collection needle</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

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


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/
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:

- **What kind of sharps safety items are asked were:**
  - syringe stock
  - IV catheters
  - IV tubing
  - sutures
  - wall-mounted sharps containers.

- **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.

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,
Sharps safety

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


New supply expense definition issued

A task force has issued a new definition of supply expense.

The definition is: “The net cost of all tangible items that are expensed including freight, standard distribution cost, and sales and use tax minus rebates. This would exclude labor, labor-related expenses, and services as well as some tangible items that are frequently provided as part of the service costs.”

The definition is accompanied by a list of items to be included in supply expense reporting. The definition was developed by the Association for Healthcare Resource and Materials Management (AHRMM) with support from the Healthcare Financial Management Association.

The definition and list are posted at www.ahrmm.org and www.hfma.org.

Supplemental oxygen halves infection risk

A dministering supplemental oxygen to patients during and after surgery cuts the risk of surgical site infections (SSIs) in half. These are the findings of a new study by Belda et al published in the Oct 26 Journal of the American Medical Association.

SSIs increase length of stay by an average of 1 week, and substantially increase costs. The primary defense against SSI pathogens is oxidative killing by neutrophils. Because infection risk depends on tissue oxygen partial pressure, interventions that increase tissue oxygen may reduce infection risk.

Belda and colleagues randomized 300 patients having colorectal surgery in 14 hospitals in Spain to either 30% (143 patients) or 80% (148 patients) fraction of inspired oxygen (FI02) intraoperatively and for 6 hours postoperatively.

Surgical site infection occurred in 35 patients (24.4%) administered 30% FIO2 and in 22 patients (14.9%) administered 80% FIO2. The risk of SSI was 39% lower in the 80% FIO2 group vs the 30% FIO2 group. After controlling for multiple contributing factors, the reduction in surgical site infection (SSI) risk associated with 80% FIO2 was nearly 54%.

These findings were similar to the twofold reduction reported by Greif et al in 500 patients and the study by Hopf et al, showing that infection risk is inversely related to tissue oxygenation.

In contrast, a recent study by Pryor et al with 160 patients reported that supplemental oxygen increases the risk of infection.

References


Chewing gum aids recovery after colon resection

Patients who chew a stick of gum for a few minutes a day can speed the return of bowel function and leave the hospital a day earlier after elective laparoscopic colectomy, according to research presented at the American College of Surgeons meeting in October in San Francisco.

Gum chewing could save millions of dollars a year in hospital costs by alleviating postoperative ileus, said the researcher, Harry Papaconstantinou, MD.

The study included 102 patients who were randomized to a control group limited to sips of clear liquids after surgery and an experimental group chewing 1 stick of gum for 15 minutes 4 times a day.

Postoperative ileus is the most common reason for prolonged hospitalization after abdominal surgery. If these patients were discharged a day earlier, hospitals could save $500 to $750 a patient—all for the low cost of a few packs of gum, he said.

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What OSHA says about safety scalpels

An interview with OSHA on sharps safety.

Dionne Williams, a senior industrial hygienist in the Occupational Safety and Health Administration’s (OSHA) Office of Health Enforcement, answered OR Manager’s questions about the bloodborne pathogens regulation.

Q Do you have statistics on how many OSHA inspections of hospitals in the past year have been random versus based on an employee complaint?

Williams. For the states covered by federal OSHA, which is about half of the states, in fiscal year 2004, we had a total of 195 inspections. Of those, 94 (48%) were strictly from complaints. A total of 84 were planned inspections. Those resulted either from a regional-level or an area office-level special emphasis on needlesticks/bloodborne pathogens exposure in the health care industry. The remaining inspections were of other types, such as referrals from other agencies.

Q Were more inspections conducted in some areas than others?

Williams. The regions with special-emphasis programs generally conducted more inspections than those that did not have special emphasis. There currently are 3 regions with local emphasis programs related to bloodborne pathogens and needlesticks (sidebar).

Q Would you please comment on OSHA’s expectations regarding use of safer devices in the OR?

Our readers say they have conducted trials on safer types of scalpels, such as those with retractable blades. But their surgeons will not always accept them. They document this fact, as OSHA requires. But some hospitals have been cited for failing to implement these safer scalps even though their surgeons have rejected them. Is it mandatory to use these kinds of devices? How much discretion do OSHA inspectors have in determining whether a hospital is cited for this?

Q Do you have any statistics on how many surgeons have been cited for this?

Williams. No, I don’t.

Q Some OR directors say they’re caught in the middle between OSHA and the surgeons. They are trying to comply with the bloodborne pathogens regulation, yet some surgeons say, “We are the ones who do the surgery, and we don’t want to change to a device we’re not comfortable using.” What should OR directors do?

Williams. That’s something they need to document. If the hospital has done an evaluation and determined some of these newer devices are appropriate for certain situations—obviously, no one device is going to be appropriate for every situation, particularly for surgery—you’re going to have some delicate situations where a surgeon feels comfortable using one particular type of device, and that comfort may make a difference in whether the surgery is successful or not. Those situations have to be weighed. If it’s a situation where the surgeon has determined he or she does not want to use the safer device because of a concern about patient safety, we certainly don’t expect the patient’s safety to be jeopardized. Those situations need to be documented. In cases where we might have issued citations, it’s because that documentation hasn’t been represented in the Exposure Control Plan. So it’s not just a discussion to have with the surgeons, it has to be written.

Q Is there any form this documentation needs to take? Must there be documentation for every kind of surgical procedure for which the surgeons will not use a safety scalpel?

Williams. It might come down to that because you might have some procedures where it’s accepted across the board that a safety device is appropriate and feasible to implement. In cases where they can’t use safety devices, they need to explore other measures also, such as a neutral zone for passing sharps. The bloodborne pathogens standard calls for the use of engineering controls as well as administrative controls, so it’s a combination. There are also some

Where is OSHA focusing?

OSHA has local-emphasis programs for bloodborne pathogens and needlesticks in 3 regions:

Region 2
New York, New Jersey, Puerto Rico, Virgin Islands

Region 3
Pennsylvania, Delaware, District of Columbia, Maryland, West Virginia, Virginia

Region 8
Colorado, Utah, Wyoming, North Dakota, South Dakota, Montana
Scalpels are metal; they look and feel like traditional scalpels except for the safety feature that shields the blade after use.

**Q** Would you please elaborate on the documentation OSHA expects? We have talked to one facility that was cited even though it had documentation to this effect.

**Williams.** In a lot of cases, the documentation just says the surgeons don’t want to use the safer devices. The documentation must show a real reason why surgeons aren’t using them. There needs to be more than just a blanket statement that the surgeons will not use them. That sounds like a preference as opposed to a concern about the safety of patients. There are surgeons who will not use safer devices no matter what the procedure is. That’s the kind of situation we’re trying to avoid because there’s no way we’re going to get these types of devices to become commonplace unless people actually use them when they can. Also, manufacturers will stall on advancing technology if they find surgeons are not using these devices and hospitals are accepting that fact.

**Q** Is there a specific form to use for documenting exceptions for surgeons who say they cannot use safety scalpels?

**Williams.** There is no exemption form. Each facility is required to perform an evaluation of its individual circumstances and determine whether safety scalpels (or any other safety equipment) are appropriate and/or feasible.

It is not appropriate for a facility to use a blanket exemption for safety devices (i.e., scalpels for all operations). If a facility is using patient safety as a reason for not using a safety scalpel for certain procedures, it must document this in the Exposure Control Plan, not on a blanket exemption form. No doubt there will be some cases where use is appropriate and others where it is not, especially given the fact that some newer safety scalpels are metal; they look and feel almost exactly like traditional scalpels except for the safety feature that shields the blade after use.

**Q** Regarding blade-removal devices that are mounted on the wall, is it not always possible to use these during a procedure because they are located away from the sterile field? Will you please comment on this?

**Williams.** We hear mixed things. In some cases, it might be feasible to mount the blade removal device on the tray used as a neutral zone for passing sharp devices. If a blade must be removed, it is easier and safer to have removal as close to the area of use as possible.

**Q** Our readers have questions about the neutral zone, or no-pass zone, for sharps. A no-pass zone isn’t always feasible. Surgeons may not be able to take their eyes away from the sterile field to pick up the instrument. In some cases, they may be wearing loupes for magnification. How can facilities meet the OSHA requirements and still meet the needs of the surgeon?

**Williams.** The requirement is to use engineering controls and administrative controls together. In cases where use of the neutral zone is feasible and will reduce the likelihood of injuries, we will look to see that it is being used. Situations where surgeons are unable to look away from the sterile field present concerns for the safety of assistants as well as the surgeon. This is a difficult situation, and hospitals should involve surgeons in discussions of ways to prevent injuries to workers in the OR. We do not think it’s acceptable to pass contaminated devices blindly to workers who are being stuck. Surgeons should be aware of the facility’s protocols and should be in agreement with adhering to protocols set up to avoid employee injuries. It cannot just be a policy of the hospital without the doctors being involved.

**Q** What role does a facility’s statistics on injury rates play? If a facility tracks sharps injuries and finds injuries have not been documented from passing of sharp instruments, does that affect the decision about whether to use a neutral zone?

**Williams.** Safety measures are there to prevent injuries. Even if a facility has a low number of injuries, it doesn’t mean it is exempt from using safety devices. As an example, facilities are expected to use safety syringes regardless of the number of needlesticks during use of syringes. We do not expect employers to rely on the low numbers of injuries to determine whether they are going to implement use of safety devices.

**Q** Does this mean OSHA expects ORs to implement a neutral zone even if they have a low injury rate from passing sharps?

**Williams.** That’s correct. Again, not every situation is the same. We look at it on a case-by-case basis. Feasibility is an important factor in implementing any safety measure. If it is not at all feasible, that’s one thing. But if there’s a feasible method of reducing injuries, we expect they will consider implementing that.

**Q** How often does a facility need to revisit these decisions?

**Williams.** Facilities must evaluate devices annually and must document the annual evaluation. Technology is continually advancing. Employers may find something new and better on subsequent evaluations. In cases where no new devices are selected after the annual review, employers need to document the fact that they looked at available devices and found the device they currently use to be most appropriate.

OSHA has an interpretation on use of safety scalpels on its web site at www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=25090
leadership team spent a great deal of time and energy from 1999 to 2001 engaging pride and teamwork within each specialty area. This effort was more successful than the Making a Difference initiative. Staff turnover significantly decreased, and job satisfaction increased, as measured by the staff satisfaction survey.

Given the improving climate among the specialties and lessons learned from the previous initiative, the team was ready to go one step further with improvement efforts.

**Looking for the golden opportunity**

The team wanted a program that would:
- readily identify opportunities for improvement
- recognize and reward high-performing teams
- improve MD buy-in with department goals for patient safety and system efficiencies
- act as another vehicle to keep the high-morale momentum going.

The clinical resource coordinator for surgical services proposed that harnessing competition among the teams would help drive the initiative, so an additional criterion was added to the list:
- using peer pressure and competition (rather than management nagging) to effect change.

The team spent a great deal of time deciding on the indicators that would drive quality. Indicators needed to be meaningful, measurable, and easily supported by documentation. After a thorough review, the team selected 12 indicators (sidebar).

**Getting buy-in**

The leadership team determined the general design and indicators and met with all specialty coordinators. Discussions were heated. Some coordinators initially objected to certain indicators they felt were out of their control. Only through gentle pressure did the teams eventually agree that there was indeed a role they played in case hours and case numbers. The hypothesis was that greater physician satisfaction with efficiency and patient safety would drive an increase in cases performed at our hospital rather than other venues.

As the discussions continued, it was suggested that a tangible symbol or award be rotated monthly to the winning specialty. Thus was born the Director’s Cup. The Director’s Cup is a 24-inch gold trophy presented with great ceremony at department staff meetings each month.

**Strength of peer pressure and competition**

Surgeons and OR staff are competitive by nature, and they took up the cause with enthusiasm. In the past, team members who were less engaged or less focused on safety initiatives were counseled by management with mixed results. At the same time, higher performing team members—while perhaps frustrated by their peer’s performance—were not necessarily comfortable confronting them. The Director’s Cup framework empowered staff to call their colleagues on less-than-stellar behavior. As one coordinator put it, “We’re already an elite team, but this has raised the bar. No one wants to lose points because someone else dropped the ball.” This has increased mutual accountability and esprit de corps within each specialty team.

**Involving physicians**

Each clinical specialty coordinator and team encouraged the respective surgeons and anesthesiologists to work with them to improve on-time starts for the first case of the day. This effort resulted in an increased cooperative spirit with surgeons and staff working toward mutual goals. Surgeons responded well to the shift from, “It’s your fault,” to, “What do we do to make this work?”

It is now quite common to hear surgeons ask their specialty coordinators about how well they are doing with the on-time starts and room turnaround times. No surgeon wants to be the reason that his or her specialty team loses an opportunity to win. The dog house is a lonely place to be.

**Staying focused**

In a department retreat in February 2003, staff used the framework of Jim Collins’s book *Good to Great* to examine the overall status of OR performance. Staff drew upon major points of the book to spark honest and open discussions about quality, human resources, training, market share, physician relations, and accountability. The Director’s Cup initiative was referenced throughout this day-long retreat as a tool that had been particularly energizing and helpful.

In May 2004, the department sponsored an awards dinner to honor the specialty coordinators who had achieved the greatest improvements in their quality indicators and overall excellence. The teams reflected back on the “Good to

**Director’s Cup indicators**

100% documentation. Percentage who met goal of 100% documentation. This indicator was discontinued in 2005 because on-line documentation was implemented.

Attendance. Percentage of staff not absent.

Tardiness. Percentage of staff on time.

On-time starts. Percentage of on-time starts for first case of the day.

Employee safety. Percentage of staff without injuries.

Patient safety. Percentage of patients without injury.

Case numbers. Number of cases in that month for each specialty.

Case hours. Number of case hours in that month for each specialty.

Flash sterilization. Percentage of cases in compliance with policy.

Counts. Percentage of counts correct.

Site verification. Percentage of cases in which all site verification steps were followed.

CPR. Percentage of staff who have completed CPR training.

ACLS. Percentage of staff who have completed ACLS training.

Room turnover. Percentage of cases that met specialty benchmark. Turnover is defined as the time from exit of one patient until entry of next patient. Turnover times reflect cases of surgeons who follow themselves. This indicator was added in 2004 when the advent of on-line intraoperative documentation made tracking more accurate.

Continued on page 16
## Performance improvement

### The Director’s Cup Challenge
Comparative analysis of results

![Bar chart showing performance improvement across different categories]

Source: St Vincent’s Medical Center, Jacksonville, Fla.

### Director’s Cup statistics 2005

<table>
<thead>
<tr>
<th>Year to date</th>
<th>Oral/ENT</th>
<th>General Surgery</th>
<th>Open Heart/Peripheral Vascular</th>
<th>Neuro</th>
<th>GYN</th>
<th>Ortho</th>
<th>PM Shift</th>
<th>Urology</th>
<th>Average</th>
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<td>NA</td>
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<td>99.3</td>
<td>99.08</td>
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<td><strong>Total %</strong></td>
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<td><strong>74.8</strong></td>
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<td><strong>77.9</strong></td>
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<td>100.0</td>
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<td>100.0</td>
<td>100.0</td>
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<td>76.3</td>
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<td><strong>1016.2</strong></td>
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<td><strong>1055.6</strong></td>
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<td><strong>80.5</strong></td>
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<td><strong>80.9</strong></td>
<td><strong>81.2</strong></td>
<td><strong>81.3</strong></td>
</tr>
</tbody>
</table>

*Note: Documentation wasn’t measured in 2005 because on-line documentation was implemented.*
Performance improvement

Continued from page 14

Great” retreat and made a unanimous commitment to continue the Director’s Cup program.

Outcomes

The bar chart illustrates 3½ years of data. The regular and marked improvements have been gratifying to the entire department. Clinical staff became more aware and focused and took more ownership for achieving improvements with each quality indicator. Each month, the clinical specialty coordinators and their teams could see their individual team progress or lack of progress in each indicator and could target efforts on any weak areas. The clinical specialty coordinators credited the program with improving problem-solving skills within each group.

Not only were there improvements on selected indicators, but some unanticipated collateral improvements occurred as well:

• The system of providing timely performance metrics to the clinical specialty coordinators resulted in their increased ability to deliver more positive and constructive feedback to their teams on a regular basis.

• Staff were motivated to address subpar performance of their peers in a timely manner. No longer was it acceptable to allow issues to languish and escalate into more serious problems because staff members were “uncomfortable with conflict.”

• There was an overall increase in collaboration among all levels of staff, including registered nurses and support staff. The support staff felt more a part of the team as a result of the program. Interestingly, while there was a marked increase in willingness and productivity among most of the staff, others responded to the increase in the standard of performance by opting for other career opportunities outside the OR.

Keeping the faith

The Director’s Cup has now become a fundamental component of the OR culture, and new hires are quickly socialized to its importance. In April 2005, the department celebrated with a second Annual Performance Improvement dinner and committed to carry on the Director’s Cup tradition. The clinical resource coordinator of the OR offered this thought, used as the theme for the dinner and featured in the program: “The path to greatness is a long, hard road that can only be traversed through team work, leadership, and a vision not only of what lies immediately ahead but what lies at the end of the journey.”

—Catherine C. Brandvold, RN, BSN
Director of Surgical and Outpatient Services
—Liz Bruno, RN, MSN, CS
Director of Educational Development
St Vincent’s Medical Center
Jacksonville, Fla

Reference


Monitoring cancellation rates on day of surgery

Case cancellations in the 24 hours before surgery are undesirable—they are also unavoidable. To find out if their cancellation rate is high, many facilities benchmark their cancellation rates with others. Yet the usual way of monitoring cancellation rates can result in poor decision making.

If you benchmark cancellation rates without confidence levels, there is a good chance of finding that some hospitals have higher or lower cancellation rates than others—not because they truly do but simply because of random error. That can lead to implementation of processes that waste everyone’s time.

How to monitor cancellation rates for electively scheduled cases has not been studied previously. In a recent study, my colleagues and I describe statistical methods for calculating cancellation rates.

The article demonstrates that the usual method of calculating confidence intervals, such as the Clopper-Pearson method, built into many statistics packages is not appropriate for routine monitoring of cancellation rates. The typical method is fine for estimating the percentage risk of a patient’s case being cancelled because of a medical event. In that situation, the fact that one patient’s case was cancelled does not change the probability that other patients will have their surgeries cancelled. Yet that is not the reason for most cancellations among adults. Most of these cancellations are due to administrative events, for which single cases can result in more than one case being cancelled. For example, when the cardiothoracic intensive care unit fills, several cardiothoracic cases on that day are cancelled.

The article describes a step-by-step method for measuring the cancellation rate accurately. The method uses Students t test after transformation of the data.

A summary of the study and statistical method are in the OR Manager Toolbox at www.ormanager.com

—Franklin Dexter, MD, PhD
Director, Division of Management Consulting
Professor, Departments of Anesthesia and Health Management and Policy
University of Iowa, Iowa City

More information on the science of OR management and monitoring OR performance is available at www.FranklinDexter.net.
Franklin Dexter can be contacted at Franklin-Dexter@uiowa.edu.

Reference


OR Manager’s Toolbox

Check our web site for practical help on personnel evaluation, codes of conduct, and patient assessment.

Go to: www.ormanager.com
Look under The OR Manager’s Toolbox.
How are we doing on supply cost per case? Is our program growing fast enough that we need more instrument trays? What happened to that capital equipment request?

The surgical services management team at St Joseph Hospital in Orange, Calif, can tell at a glance.

Every month, the team reviews a snapshot report that shows how each of the surgical services departments is doing on the budget, volume, and key indicators.

“The report allows managers to see trends in black and white,” says Terrence Wooten, business and materials resource manager for surgical services and endoscopy.

Before, Wooten ran reports on specific areas, but they didn’t give managers the big picture.

“I wanted to expand our reports into a monthly trending system. This gives managers a place to start. Then if they see a trend, such as a change in volume, and want to dig into it, we can do that,” says Wooten, who developed the tool, called the BOSSE—“bossy”—report, short for Business Office Surgical Services and Endoscopy.

The report is an Excel spreadsheet that is distributed to the director of surgical services and endoscopy, Joanne Stermer, RN, MBA, CNOR, as well as to managers and clinical leaders from each department in surgical services.

**Foreseeing needs**

The report has helped the department stay on budget, control costs, and plan for future needs. The instrument budget, which was overspent in the past, is now within limits. Service coordinators are able to foresee needs for their services. For example, if the neurosurgery coordinator sees an upward trend in volume, she can say, “How many trays do I need for this service? Do I have enough?”

“It’s one thing to say that a service ‘feels busy.’ It’s another to look at the trends and be able to see that it is growing,” Wooten observes. “Then we can make a decision to say, ‘OK, we need to support this service line.’”

The team can see how new programs are faring, such as those for bariatric surgery and robotics. They can see if procedures that are supposed to be moving to the outpatient surgery center are actually moving there.

If managers see hard-to-control orthopedic implant costs rising more rapidly than expected, they can examine surgeons’ practice patterns to see if the implants they are using are on contract.

**Meeting incentive targets**

The report also helps managers inform the staff about progress toward meeting targets used for employee incentives. Under the incentive program, staff can earn bonuses for meeting targets for first-case on-time starts, supply costs per unit of service, and turnover time. (See September OR Manager.) If supply costs per unit of service aren’t meeting the monthly goal, for example, managers can share that data with the staff so they will be mindful when opening supplies.

Charts on progress are posted each month so the staff can review them.

Wooten got the idea for the BOSSE from the hospital’s finance department, which generates a high-level report on financial trends for the hospital’s executive team.

He sees the report as part of his role as a business manager for surgical services.

“One of my goals and objectives is to make sure all of our clinical managers are educated on our finances and volume trends in the OR and endoscopy,” he says.

“This report is one tool for helping them in making decisions, knowing what we need to concentrate on, and knowing what our successes and losses were.”

The template for the BOSSE report is in the OR Manager Toolbox at www.ormanager.com.

---

**Surgical services trend report**

St Joseph Hospital’s tracking tool, called BOSSE, includes these categories for the 8 departments in surgical services:

- **Budget**
  - Controllable cost/unit of service (operating cost excluding benefits and depreciation)
  - Supply cost/unit of service (cost of supplies, including implants, divided by the surgical minutes for the month)
  - Labor cost/unit of service (direct labor costs)
  - Instrument purchases (dollar amount)

- **Volume**
  - Units of service for each department in surgical services
  - Cases by specialty: OR
  - Cases by specialty: Outpatient surgery center

- **Tracked data**
  - Implant cases
    - Spine
    - Total hip
    - Total knee
    - Pacemaker
    - AICD
  - — Heart valve
  - — CryoLife
  - — Implant costs
    - Costs for each of the above items
    - Implant average costs
      - Costs for each of the above items
  - — Heart cases
  - — Pain management cases
  - — Bariatric cases
  - — Robotic cases

- **Business office tracking**
  - Late charges: Encounters
  - Quality tracking
    - Wrong account number
    - Acuity/observation
    - Charges not zeroed
  - Incentive tracking*
    - First case on-time start
    - Supply cost/unit of service
    - Turnover time

- **Value analysis**
  - New products approved for use or evaluation

- **Capital**
  - Status of capital equipment requests

*Used for staff financial incentives.
Please see the ad for
CARDINAL HEALTH
in the OR Manager print version.
If your OR uses injectables mixed by an outside company, make sure the contract includes specific requirements for quality assurance monitoring and reporting.

That’s the advice of a surgical services director after her hospital discovered that bags of its cardioplegia solution prepared by an outside pharmacy were contaminated. The contaminated solution apparently was the source of respiratory complications in cardiac surgery patients at Mary Washington Hospital in Fredericksburg, Va. One of the patients died, and 2 required long hospital stays. The hospital suspended its cardiac surgery program for 2 weeks in September while it investigated the problem.

The cardioplegia solution and 11 other injectable products were voluntarily recalled Sept 16 by the manufacturer, Central Admixture Pharmacy Services Inc (CAPS), Lanham, Md (www.capspharmacy.com). The products were distributed in Maryland; Delaware; Washington, DC; and Virginia.

The company said gram-negative bacteria were identified in 3 different types of cardioplegia solutions made at its Lanham, Md, plant on 2 separate days. CAPS advised customers immediately to examine their inventory and quarantine products subject to the recall.

The recall applies only to products manufactured at the Lanham, Md, plant. CAPS said none of its other pharmacies in the US are affected.

The hospital investigates
Mary Washington suspended cardiac surgery Sept 9 when 3 patients developed systemic inflammatory response syndrome (SIRS) after coronary artery bypass surgery. The cases occurred within an 8-day period in late August and early September, according to press reports.

Though all patients on cardiopulmonary bypass have some degree of systemic response, most cases are mild, noted Donald Stern, MD, director of the Rappahannock Area Health District, who participated in the investigation. In 1% to 10% of patients, the reaction is severe. “What causes this to manifest in certain patients is not clear,” he says. In this situation, he said it is likely that the cardioplegia exacerbated the inflammatory response.

Cardioplegia solution cultured
The unusual cluster of illnesses prompted an investigation, during which the hospital’s perfusionists began looking at their process. As part of the investigation, they cultured the cardioplegia solution, which yielded the bacteria and endotoxins. The hospital had contracted with CAPS to mix the solution according to the hospital’s specifications.

Initially concerned the solutions might have been contaminated in-house, the hospital called in the Virginia Department of Health, which in turn called in the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). The agencies took unopened bags of the solution from the hospital and performed their own testing, which also found contamination.

The health department and the CDC concluded the cardioplegia solution was the most likely source of the illnesses in that cluster of patients in early September, Dr Stern said. He said the cardioplegia solution was contaminated by 3 types of gram-negative rods and endotoxins. The hospital decided to resume mixing its own cardioplegia solution, as it had before the contract with CAPS. Dr Stern said the health department recommended that the hospital could resume cardiac surgery.

Hospital officials said it was the hospital’s cardiac team, led by surgeon John Armitage, MD, that recognized the problem, identified the possible cause, halted surgery, and summoned outside help, according to the Sept 23 Free-Lance Star, a local newspaper.

The hospital’s vice president of medical affairs, Thomas Ryan, MD, said: “The FDA and the CDC cultured gram-negative bacteria out of bags that were never opened here. It was impossible for us to get anything into those bags. They took the bags away from us whole.”

A director’s advice
Based on the experience, Mary Washington’s director of surgical services, Heather Carelock, RN, MPA, CNOR, advises OR directors to make sure specific requirements for quality monitoring and reporting are included in every contract for admixtures that a facility signs with an outside firm. Specifically, says Carelock, “I would want to see a certain number of cultures on a regular basis, such as every 6 months. I would also have the hospital perform its own quality studies, such as taking cultures on these products quarterly.”

She adds: “I’m proud that we have an environment that supports and encourages staff to ask difficult questions. The investigation started with the perfusionists looking at their practice and the staff nurses looking to their leadership to follow up.” Though the decision to shut down the program and invite in the Department of Health was difficult, she says, “we did what was best for our patients and our community.”

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Remember your mentors. “How do you accomplish a vision? You can have vision and possess knowledge and skills. But you can’t achieve your goals without mentors,” said Jeanne Long, RN, as she accepted the OR Manager of the Year award at the Managing Today’s OR Suite conference Oct 19 to 21 in San Diego.

“Our mentors believe in us. They give us courage to find our strength,” said Long, urging the audience to think about their mentors—then look around and spot someone else who could use that support. Long is manager of surgical services at Clarian West Medical Center in Avon, Ind, a new hospital that she helped to create from the ground up.

The conference attracted 721 OR managers for 3 days of educational sessions and an exhibit with 80 vendors. In all, 420 managers attended 8 preconference seminars offered on Wednesday. The conference received high marks from attendees, with 94% rating it as “excellent” or “very good.”

Keynoter Quint Studer had a refreshing message for managers: “Forget the buzzwords—people want a well-balanced organization,” he said in the talk sponsored by Kimberly-Clark Health Care.

“You job as an OR manager is to help your staff and doctors know they are making a difference.

“Nurses want relationships,” Studer added. “They want someone who wants to make their unit a little better. When your staff sees you coming, is it good news or bad news?” asked Studer, founder and CEO of the Studer Group (www.studergroup.com), which is known for practical tools for building a culture of excellence.

Among tools he advocates are thank you notes to the staff and 90-day interviews with new staff to find out what is going right and what they need to succeed.

“It takes 3 compliments to offset 1 criticism,” Studer advised managers. “Unless you can harvest 3 to 1, you can’t move the flywheel”—the model he uses to explain how organizations can create momentum for change.

Courageous conversations

In a special lecture, poet David Whyte (www.davidwhyte.com) brought the audience thought-provoking observations about the meaning of conversations. His lecture was sponsored by Cardinal Health, Medical Products and Services.

One of his themes is “courageous conversations.”

“I would say most people don’t realize how foundational conversation is to their work,” he says. “You usually find mistakes are made because of a breakdown in communication—a breakdown in conversations.”

Through poetry, Whyte suggested what people need to do to stay in conversations that bring them out from behind their personal walls and help them meet on common ground.

Who speaks for Wolf?

Presenting the general session on Friday morning, Bill Moskal, veteran organizational development consultant, shared his advice for creating extraordi-
Bill Moskal shared management lessons from a Native American legend. Moskal related a Native American story, “Who Speaks for Wolf?,” about a tribe that learns the consequences when they relocate their camp without consulting one of the tribe’s seasoned members, who is off on a hunting trip.

One lesson, said Moskal, is that a “tribal council” can be as important as a formal meeting in making sure everyone gets heard.

At the Friday luncheon, a physician duo had the audience roaring with their musical revue, Damaged Care, sponsored by Advanced Sterilization Products.

Physicians Greg LaGana and Barry Levy, who first performed the revue at their medical school reunion, entertained with parodies, such as “That’s Cost Containment” and “Have a Test!”

Gail Avigne, the 2004 OR Manager of the Year, closed the conference with her inspiring message for managers and teams about the need to nurture mind, body, and spirit. Avigne is nurse manager, OR/PACU/FSC, Shands Hospital, University of Florida, Gainesville.
Please see the ad for
STERIS CORPORATION
in the OR Manager print version.
Credentialing is the process ambulatory surgery centers (ASCs) use to ensure their licensed independent practitioners, such as physicians, dentists, and podiatrists, or other health professionals, such as nurse anesthetists, physician assistants, and RN first assistants, are properly qualified.

OR Manager surveyed ASC managers for their top questions about the credentialing process.

Nancy Burden, RN, MS, CAPA, CPAN, director of health services at Morton Plant Mease Health Care in Clearwater, Fla, and Linda Haddad, a senior partner with the health care law firm of Horty Springer & Mattern in Pittsburgh, provided answers to these credentialing questions.

Managers also should review standards of the Accreditation Association for Ambulatory Health Care (www.aaahc.org) and Joint Commission on Accreditation of Healthcare Organizations (www.jcaho.org) to ensure they meet state licensing and Medicare certification requirements.

Q Should we perform our own credentialing or use a credentials verification organization (CVO)?

Burden. I strongly suggest using CVOs. First, they have the expertise. Second, the time it takes to credential is significant. If you do not have someone with dedicated time for the function at your ASC, it will be difficult to accomplish efficiently.

Q Should we perform our own credentialing or use a credentials verification organization (CVO)?

Burden. First, they have the expertise. Second, the time it takes to credential is significant. If you do not have someone with dedicated time for the function at your ASC, it will be difficult to accomplish efficiently.

Q How often must physicians be recredentialed?

Burden. For facilities accredited by JCAHO, credentials must be renewed every 2 years on or before the exact date. For example, if the physician is credentialed on Oct 22, 2004, the credentialing expires Oct 21, 2006. AAAHC standards require recredentialing every 3 years unless state law differs.

Q How often must physicians be recredentialed?

Burden. There really is no shortcut. Credentialing is a critical function of the ASC. Use an experienced CVO to do the time-consuming background checks, primary source verifications, and so forth. A local hospital may be willing to sell this service to your facility, possibly for less than commercial CVOs. It could be a revenue stream for the hospital’s credentialing department, which is generally more of a cost center. Even when using a CVO, the ASC must have someone who is responsible for the ASC portion of the process.

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Q What is the difference between credentialing and privileging?

Burden. Credentialing is verifying that physicians are who they say they are; have been adequately trained, educated, and licensed; have insurance; and have the correct abilities, according to peers. Privileging is defining exactly what procedures the physician is capable of and is allowed to perform in your facility. A physician is first credentialed to be on the staff. Then when the credentials are confirmed, the physician must

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be granted privileges for specific procedures and treatments the physician may perform.

**Q** We have a dentist who wants to bring his own assistant to work with him. Do we need to credential the assistant? What about credentialing other providers, such as physician assistants, RN first assistants, or private scrub persons?

**Haddad.** The JCAHO Ambulatory Care Standards state that ancillary health care providers who are licensed independent practitioners (LIPs) must be credentialed in order to work in an ASC. The categories of ancillary health care providers who must be credentialed may vary from organization to organization and from state to state. Dental assistants may not be considered LIPs in all states, and their role may not include duties assigned to dental hygienists. State law should always be consulted in determining whether an ancillary provider is considered an LIP.

**Burden.** You must have a method to verify the credentials of everyone who touches patients. For staff members employed by the center, you check credentials as part of the employment process. But for all others who are private assistants to a physician or come from a supplying organization, the credentialing process is nearly identical to the physician credentialing process.

**Q** What are effective ways of securing proof of experience before approving supplemental procedures for a physician? Some physicians resent that we even question their experience.

**Haddad.** Proof of experience must be obtained prior to approving supplemental procedures. A core credentialing criterion is verification of a physician’s ability to perform requested privileges. A practitioner’s ability to perform any clinical privilege must be evaluated and documented in the practitioner’s credentials file. Although JCAHO standards do not discuss specific ways of securing proof of experience for supplemental procedures, the ASC may wish to handle such requests in a manner similar to that a hospital might use to address requests for clinical privileges by low-volume practitioners. The practitioner must provide considerable additional information, such as detail about volume at other sites and office practice; copies of any quality or peer review assessments; names of physicians with whom the individual shares patients regularly, along with a clear release authorizing those physicians to respond to queries from the credentialers or authorization to conduct an office site visit and review records.

Another option is requiring that the first 3, 10, or 15 supplemental procedures involve a board-certified physician preceptor in the same clinical specialty who will assume responsibility for those patients and report to the leaders of the ASC.

**Q** How long does the entire credentialing process take?

**Burden.** It varies. The shortest time for verifying all needed information is 2

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**What do physicians need to provide?**

Documentation a physician should provide for credentialing in an ASC:

- A curriculum vitae. Some facilities provide physicians a “preapplication” questionnaire so physicians can decide if they want to pursue the application process.
- If the ASC decides the physician meets its requirements, it can give the physician an application. Don’t get caught sending someone an application, then denying privileges. This practice is reportable to the National Practitioner Data Bank (NPDB) and can become a legal and professional challenge both for the ASC and the applying physician.
- The physician submits the completed application with all pertinent background data (notify the physician if there are any blanks) and the following:
  - proof of malpractice insurance required by the facility
  - copy of doctor’s license (to facilitate background check)
  - signed permission for background check
  - signed agreement to meet legal responsibilities, such as obtaining patients’ informed consent, remaining informed about ASC bylaws and rules and state and federal regulations and agreeing to follow them, and upholding patient privacy regulations
  - signed statement about health
  - copies of education certificates required by the ASC
  - signed agreement that the physician is responsible for informing the facility if the physician does not meet any requirements in the future
  - application fee, if your facility requires one.

See also Accreditation Association for Ambulatory Health Care accreditation standards, www.aaahc.org.

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**Verify credentials of everyone who touches patients.**
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weeks, but it could be up to 4 weeks or more. The primary issue is how long it takes for reference sources—schools, residencies, peers—to get information back to you. Then add the time needed for your ASC credentialing committee to review the file and possibly interview the physician, the medical executive committee to make its recommendations to the board, and the board approval process.

Can we use information from the local hospital where the physician has privileges?

Burden. No. Your information must come from the original source.

Why do we have to check with the Health and Human Services Office of the Inspector General (OIG)?

Burden. If your facility is Medicare-certified and caring for Medicare patients, you must ensure that any physician the ASC credentials is in good standing with the Centers for Medicare and Medicaid Services and has not been excluded from the Medicare program (http://oig.hhs.gov/fraud/exclusions.html).

What are some red flags that indicate this physician might not be good for our ASC?

Burden. Some red flags are:
• poor peer reviews
• physicians listed as references who will not provide one
• known behavior or clinical care problems at another facility
• unexplained time lapses in jobs or training on application or resume
• frequent job changes
• multiple lawsuits.

What is the best way to handle recredentialing a physician who has performed only a few or no cases in the prior year?

Burden. This is a difficult issue. First, be sure your policies clearly state volume requirements, if any. You need to apply evenly any policy you make to all physicians. If you have stipulated a specific number of cases, and the physician does not meet the criteria, you can state that the physician does not meet the criteria and ask him or her to resign or perform the minimum number of cases prior to the reappointment date. If you do not have a minimum number of cases specified, you still must verify the physician’s quality during recredentialing. If you want low-volume physicians to have the option of remaining on staff, it is probably not wise to set a defined number of cases. ❖

—Leslie Flowers

Leslie Flowers is a freelance writer in Indianapolis.

Hypnosis effective for fear, anxiety before operations

Hypnosis, which causes a trance or focused state of consciousness free of distraction, was found to be effective for treating anxiety and fear before surgery in a study by an anesthesiologist from Yale. Anxiety and fear before an operation can prolong recovery and are associated with a greater need for pain medication postoperatively. Though hypnosis is common in Europe, US hospitals typically give sedatives to ease patients’ fear. But these have side effects and tend to wear off quickly, notes Haleh Saadat, MD, who conducted the study.

Dr Saadat studied a group of preoperative patients aged 18 to 65 at Yale-New Haven Hospital. Each patient was asked to rate anxiety before surgery. About one-third of patients received a 20- to 30-minute hypnotic session; a third received “attention control” care with attentive listening and support without any specific suggestions. The last third received standard care without any interventions. Patients in the hypnosis group reported significantly less anxiety than the other groups. The study was reported at the American Society of Anesthesiologists meeting in October in Atlanta. ❖
The latest battle over who should administer propofol (Diprivan) is taking place on the doorsteps of the Food and Drug Administration (FDA).

The American Society of Anesthesiologists (ASA) asked the FDA in October to turn down a petition from the American College of Gastroenterology (ACG) seeking to remove warning language from the package insert for propofol.

The package insert says propofol for general anesthesia or sedation should be given “only by persons trained in the administration of general anesthesia and not involved in the conduct of surgical/diagnostic procedure.”

ACG said the labeling is no longer warranted because there is “substantial clinical evidence” that propofol can be given safely by GI physicians and RNs working under their supervision.

ACG said the proposed change would “promote efficiency and reduce costs” by eliminating the need for an anesthesia provider when propofol is used during endoscopy. ACG says propofol induces sedation more rapidly than other sedatives, and patients recover more quickly.

ACG acknowledges propofol has risks. It is a cardiovascular and respiratory depressant. The drug is more demanding to administer than other agents because it requires more reinforcing doses. There is no reversal agent, so overdoses require assisted ventilation until the patient recovers.

“Despite these risks, the risk profile of propofol appears to be no worse than that of alternatives,” ACG says.

**ASA’s position**

ASA argues that propofol is a powerful drug with all of the risks of general anesthesia and notes responses are unpredictable. Patients may slip into general anesthesia even if only moderate sedation is intended. Those not experienced in giving general anesthesia may not be able to restore breathing or normal cardiac activity “in time to prevent a catastrophe,” ASA says.

ASA notes that the Joint Commission on Accreditation of Healthcare Organizations requires those who intend to give deep sedation to be qualified to rescue patients and be competent to manage an unstable cardiovascular system and compromised airway and respiratory system.

ASA recommends that the physician responsible for use of propofol should have the education and training to manage potential medical complications of sedation and anesthesia, including airway management, advanced life support, and an understanding of the pharmacology of the drugs involved.

ASA said: “Removal of the warning label from the propofol package insert may encourage the use of propofol by practitioners with inadequate training and experience in nonaccredited facilities where credentialing is not required, such as private offices.”


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Please see the ad for MEDICORP HEALTH SYSTEM in the OR Manager print version.
Please see the ad for TVL HEALTHCARE, INC. in the OR Manager print version.

Please see the ad for ST MARY’S DULUTH CLINIC in the OR Manager print version.
Please see the ad for 3M HEALTHCARE in the OR Manager print version.
Tissue recalled in scandal

Five tissue processors voluntarily recalled tissue from 1 tissue recovery organization, Biomedical Tissue Services (BTS) of Fort Lee, NJ. The Food and Drug Administration (FDA) notified the public Oct 26 that it is investigating BTS because some of its donors may not have met donor eligibility requirements or been screened properly.

The tissue may have been implanted from early 2004 to September 2005. The FDA advised physicians who have implanted tissue supplied by BTS to inform their patients.

A Brooklyn, NY, man sued in October, alleging his father, who died of cancer in 2003, had his tissue recovered by BTS and a Brooklyn funeral home without the family’s consent using forged documents that represented the cause of death as a heart attack. Press reports said as many as 80 cases are being reviewed in the New York area.

Tissue processors who received tissue from BTS are:
• LifeCell, Branchburg, NJ (www.lifecell.com)
• Lost Mountain Tissue Bank, Kennecott, Ga
• Blood and Tissue Center of Central Texas, Austin (www.bloodandtissue.org)
• Tutogen Medical, Alachua, Fla (www.tutogen.com)
• Regeneration Technologies Inc, Alachua, Fla (www.rtix.com).

Physicians and hospitals who obtained tissue supplied by BTS should have been notified directly by their tissue processor.

The FDA said any infectious diseases possibly related to a tissue transplant should be reported to the processing firm. Providers can also report to the FDA’s MedWatch program at www.fda.gov/medwatch.

Success found with carotid artery stents

Stents to open carotid arteries can be successfully implanted by physicians with limited experience in the procedure if they are trained, according to preliminary findings released Oct 20. Another report released Oct 19 could encourage Medicare to expand coverage for the procedure, according to the Oct 21 New York Times.

The government estimates as many as 200,000 Americans undergo carotid endarterectomy each year. Regulators approved marketing stents to a high-risk group that could include as many as 25% of these patients, but Medicare is covering fewer than 10%.

Do patients understand need to continue beta-blockers?

Beta-blockers can prevent a heart attack and even death when taken before or after surgery. Yet many patients do not understand the medication can save their life in the critical periods before and after surgery, says David M. Rosenfeld, MD, anesthesiologist at the Mayo Clinic-Arizona, Phoenix.

In a survey, he found that though 57% of patients recognized the potential benefit of beta-blockers, only 12% understood the magnitude of the benefit—decreased risk of heart attack and death during surgery. Only 10% recalled their physician mentioning the importance of beta-blockers before surgery, and only 8% said their surgeon discussed it.

When told not to eat or drink before surgery, many patients misinterpret this to include their beta-blockers, he says. The report was presented at the American Society of Anesthesiologists meeting in October in Atlanta.

Newer cell phones interfere less with medical equipment

The newest cell phones interfere less with medical equipment than those previously tested, according to the October Mayo Clinic Proceedings.

Using 6 different cell phones, researchers conducted 510 tests of 16 different medical devices and reported interference in 7, or 44%. No devices were affected at a distance greater than 32 inches, and most interference occurred with devices that display ECG or EEG waveforms and involve noise interference.

Some hospitals have banned cell phone use, some allow them to be used freely, and others, including the Mayo Clinic, ban their use in certain areas, such as ICUs, ORs, and cardiac cath labs.