

# The monthly publication for OR decision makers

December 2008 Vol 24, No 12

# Ambulatory Surgery Centers

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## **Patient safety**

# Taking steps to protect patients from specimen-handling errors

An OR specimen was transported to the laboratory. The lab called to say there was no specimen in the container. The specimen was a completely excised ovarian mass.

A patient had two specimens excised from her breast. The specimens were sent to radiology for x-ray. The lab reported that only one specimen was received. Unable to locate the other specimen.

hese incidents, reported by the Pennsylvania Patient Safety Authority, are examples of what can go wrong in specimen handling. Specimen errors have huge implications for patient safety because they can mean a missed diagnosis or delayed treatment.

Managing specimens in the OR involves multiple steps and handoffs that are vulnerable to errors. Staff education is critical because of the many types of specimens and preparations required.

How common is the problem?

Little has been published on the incidence of specimen errors. A study of specimen identification errors at The Johns Hopkins Hospital found the rate was low. Examining errors in 21,351 specimens from all patients who had inpatient or outpatient surgery over 6 months, the researchers led by Martin Makary, MD, MPH, found the error rate was 4.3 per 1,000 surgical specimens. The rate was 0.5% for the outpatient set-

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## **Technology for surgery**

# New scanners bring high-tech imaging to operating rooms

ew high-tech scanners, once seen only in major medical centers, are making their way into more hospitals. The rapid 3-D imaging takes the OR far beyond fluoroscopy. Surgeons say they can improve results and make surgery safer. Before the patient leaves the OR, they can scan the brain to make sure they have removed all of a tumor. They can see that a pedicle screw is properly placed while the patient is still in surgery.

ORs are starting to see mobile Oshaped CT scanners. The first OR with an MRI in a community hospital that does double duty for surgery and diagnostics opened this fall at Sacred Heart Hospital in Eau Claire, Wisconsin.

"What is happening is a one-way

change—we are not going back," predicts neurosurgeon Kamal Thapar, MD, director of Sacred Heart's Brain & Spine Institute. �

#### **Special focus: Imaging**

Three articles plus a special insert in this issue look at the new technology.

- Page 9: Sacred Heart's MRI OR.
- Page 10: O-shaped CT scanner: The benefits and costs of this new device.
- Page 12: Brushing up on radiation safety.
- Special insert from ECRI Institute: O-Arm scanner for spinal surgery.

Please see the ad for MEGADYNE in the *OR Manager* print version.

# **Upcoming**

# Spine: Advice on a costly specialty

Tips to help in getting a handle on spinal surgery, with its biologics and other costly components.

#### **Curbing bad behavior**

What the Joint Commission will be looking for and help from colleagues on effective policies.



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# Publisher's Note

As Santa Claus and Mrs Claus sipped a refreshing cup of green tea and discussed the upcoming holidays, the door of the workshop blew open. Elaine the Accounting Elf slammed the door behind her.

"I have bad news," she announced. "We are facing a holiday meltdown. The cost of reindeer feed is out of sight. Our supply costs are up. The elves are worried about the meltdown of their 401(k)s. We may need a holiday bailout."

"Banks, car manufacturers, investment firms may get bailed out by the government, but I think we can enjoy the holidays without a bailout." Santa set down his cup of tea. "This is going to be a difficult holiday season for many people. Many parents are not going to be able to buy the expensive presents that their children want."

Mrs Claus glanced at the lists in her lap. "You're right. I have lots of requests for Wii, Playstation 3, xBox 360. Teenagers are requesting iPods and iPhones. The lists go on."

"This will be time to rediscover what is important during the holidays," Santa said. "Gifts are an important part of the holidays, but they don't need to be expensive. Skip the diamond stud earrings from Tiffany's and go for the plastic ones at Target. Stir up your creativity in the kitchen and make edible gifts

"Invite your friends and neighbors over for Ritz crackers and Cheese Whiz instead of a fancy feast. Your Christmas dinner may be meatloaf instead of tenderloin. Wrap your gifts in brown paper and tie them with string. Frugality is the trend this year. Conspicuous consumption is out. What is important is being with family and friends and sharing good times."

"What about our friends who work in health care? Remember the nurses and doctors in the OR who took care of us when we had the bariatric surgery a few years ago?" asked Mrs Claus. "Every day they work hard to help those who are ill or disabled and in need of surgery to restore their health."

Santa mused. "The election of Barack Obama as president brought celebration and excitement, but now the president-



elect faces many challenges. Certainly health care is among those challenges. Some 60% of those who voted for him expect something big will be done about our health care system, but of course they don't agree on what that something big should be.

"I have a special gift for our friends in health care. It is the gift of a voice. A loud voice. To be specific, it is a Thunder-Power megaphone. In politics, interest groups speak with money and loud voices. There are many vested interests that will be involved as we talk about how to reshape our health policy, and they have lots of money in their pockets to make their voices heard. They will donate to politicians who represent their point of view. They will buy television ads that will misinform and scare you. But the voices of those in the trenches—the nurses, doctors, and other health care providers—should also be heard loud and clear."

"Do you want help wrapping that megaphone?" volunteered Mrs Claus. "I've got the Sunday comics right here."

"Yes, but first let me use this ThunderPower megaphone to shout a wish for happy holidays to one and all from *OR Manager*—holidays that won't require a bailout in January." •

—Elinor S. Schrader

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Please see the ad for SPECTRUM SURGICAL INSTRUMENTS in the *OR Manager* print version.

# Tough times force look at supply costs

ealth care facilities like other businesses face tough economic headwinds. Tightening credit, plummeting investment values, and the prospect of less philanthropic giving make for a difficult financial climate. There's also likely to be more uncompensated care as unemployment rises, and state Medicaid programs cut back.

OR directors and business managers, no strangers to cost cutting, are going to be challenged anew. Supply and equipment prices aren't going down despite the tough times.

Premier, the alliance of hospitals and other facilities, is asking for suppliers' help. In a letter to about a thousand of its suppliers in October, Premier urged suppliers to hold the line on prices and assist in other ways to save on supply expense.

A survey by Premier of its contracted suppliers found estimated price increases of 3% to 40% through December 2009. Some examples were:

- capital equipment: 3% to 8%
- OR laparoscopic supplies: 3% to 10%
- orthopedic implants: 4% to 8%
- materials management: 3.5% to 40%. Such price hikes would be hard to absorb even without current economic



pressures, Mike Alkire, president of Premier Purchasing Partners, said in an interview. "Many hospitals are already operating on razor-thin margins. We wanted to send a message that hospitals couldn't continue to absorb these increases."

What's been the response?

"Actually, it's been quite positive," he says. About a dozen suppliers have contacted him saying they have special offerings or are willing to work more closely with hospitals on costs.

#### **Pricing not enough**

Attacking pricing isn't enough. It may be time to take a new look at the whole supply chain from beginning to end. Suppliers are also under severe cost pressure. They face higher raw material costs, and many haven't passed on fuel-cost increases from earlier this year. Harsh economic conditions are an opportunity for providers and suppliers alike to go back to basics like improving inventory turns and limiting overnight shipping.

Alkire said supply chain efficiencies are part of Premier's plans.

"There's a huge interest in inventory turns at hospitals to be sure products are being used in a timely manner," he said.

Other strategies he said Premier plans to pursue are greater supply standardization with some sole sourcing for some members; standardization on distributors; and a continuing effort to manage costs and use of expensive items like orthopedic implants.

#### Better alignment with MDs

Implants have been one of hospitals' biggest cost issues, and better alignment with physicians is needed.

"We've been seeing much more of this," Alkire noted, "including hiring physicians directly into hospitals and more joint ventures."

He expects momentum to pick up as new global-payment arrangements are introduced that pay hospitals and physicians a single fee for certain procedures. Medicare is conducting a demonstration project on global payment for cardiac and orthopedic surgery.

Taking physician alignment a step further, he said Premier plans to roll out a registry to track outcomes of some implant procedures not only in the hospital but also after discharge. The aim is to be able to compare outcomes and costs of different treatments and implants. "We have great data from our acute care hospitals," says Alkire. "What we really need are the physicians' office data so we can begin to track clinical effectiveness." He said a group of physicians is working with Premier on the project.

Tracking outcomes is part of a trend toward value-based purchasing, which pays hospitals a little more in exchange for improvement on outcome indicators. Premier has been participating in a value-based payment demonstration project with Medicare since 2003. �

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## **Patient safety**

## A clean, orderly specimen area

As part of Swedish Medical Center's improvement project, lead by the pathology department, the OR staff reorganized areas where specimens are placed for pathology pickup. Carrie Stout, RN, BSN, was the OR's representative on the project. The project used Lean, a quality improvement method based on the Toyota Production System that Swedish has adopted.

In cleaning up the work areas, the OR used a Lean method called 5S. The S's stand for 5 Japanese words that apply to a clean, orderly workplace. The 5S's applied to the OR work areas are:

#### Sort

Decide what is necessary and what isn't necessary in the work area.

#### Straighten

Make it clear where items need to go. Make sure items are labeled, and it's clear what should happen to them.

#### **Standardize**

Standardize the process and terminology so these are clear to the surgical and pathology staffs and to the couriers.

#### Sweep

Clean the area. Remove equipment that is no longer used.

#### Sustain

Make sure the area is kept orderly, and the process is followed consistently.

Standardizing was important, says Stout, because the hospital has 4 surgical sites: an eye center, an orthopedic center, the main OR, and a same-day-surgery area. All sites now use the same A, B, C, D system to identify the order of specimens obtained from the patient. Specimens are placed in bins labeled so the newest ones are at the top. The pathology staff then knows in what order the specimens should be processed.

"One key thing we did was to put up clear, laminated instructions in each area," she says.

At first, Stout says she wondered how relevant the pathology RPI would be to the OR. But she found the project enlightening.

"As OR nurses, we tend to be unit centered," she says. "Understanding the courier process and what happens to the specimen when it gets to pathology was eye-opening. You see what information they need. I was glad to see another department I worked closely with so I could better understand the process."

for download at www.psa.state.pa.us/psa.

Among steps recommended:

- flowcharting the process and interviewing staff members about what actually occurs during specimen handoffs
- placing specimens in sterile containers and labeling them immediately after they are handed from the sterile field
- reducing reliance on memory with checklists, requisition forms, and charts with proper handling procedures
- using "forcing functions" such as bar coding, read back of patient identification and specimen type, and handoff protocols for specimen transfer
- developing a chain of custody to track specimens from collection through transfers to their final disposition
- standardizing language and tasks
- incorporating quality monitoring, for example, by reviewing documentation, double-checking that specimen logs agree with the specimens received in pathology, and investigating discrepancies
- configuring the physical environment where specimens are stored to reduce errors.

#### **Building a stronger process**

Swedish Medical Center, a 3-hospital system based in Seattle, has strengthened its specimen handling process in several ways. Its specimen handling policy was revised recently after a lost specimen. The OR also participated in a pathology department rapid-process improvement project (RPI) at the flagship First Hill campus (related article). As an added level of safety, specimen documentation is being added to Swedish's new Epic perioperative information system.

#### **Updated policy has safeguards**

Swedish's revised policy builds in a number of safeguards. Coincidentally, Renae Battié, RN, MN, CNOR, the recently hired director of intraoperative services who took the lead on the revision, also served on the AORN Recommended Practices Committee during the 2006 revision of the specimen handling recommended practice.

Safer handoffs are one aspect of Swedish's new policy:

The scrub person verifies the specimen

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must be checked during the "sign out" before the patient leaves the OR. (See August 2008 OR Manager.)

The Joint Commission's National Patient

Safety Goal 1 addresses specimen handling, saying 2 patient identifiers are required when collecting blood samples and other specimens.

#### Creating safeguards

To improve the process, the Pennsylvania Patient Safety Authority in a 2005 advisory on lost specimens recommends shifting from a focus on individual performance to a systems approach with built-in safeguards. The advisory is free

no and 0.4% for the OR. Frrors were

Continued from page 1

ting and 0.4% for the OR. Errors were most common in breast procedures, followed by skin and colon surgery. The majority of errors (59%) were associated with a biopsy. All incidents were resolved without patient harm.

# Specimens included in briefings

One strategy for reducing the risk of errors is to include specimens in OR briefings and debriefings. Johns Hopkins includes specimens in its OR debriefings, Dr Makary noted. The debriefing includes the question, "Has the surgical specimen been verified?"

The World Health Organization (WHO) includes specimen-labeling verification in its model surgical safety checklist introduced in June 2008. Specimen labeling

## **Patient safety**

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by confirming with the surgeon the name of the specimen, inquiring which tests are to be performed, and checking with the surgeon before passing the specimen to the circulating nurse.

- The circulating nurse, when handed the specimen by the scrub person, reads back the patient's name, name of the specimen, and test to be performed.
- The circulating nurse documents the name of the specimen, tests to be run, the destination, and name of the transporter in the perioperative record.
- At the end of the case, the surgeon verifies how many specimens were taken and received by the nurse.

The policy states that all material removed from the patient's body must be sent to the pathology lab, except for a specific list of items that can be discarded. The policy also spells out how to handle special types of specimens such as amputated limbs, culture samples, cytology specimens, tissue for chromosomal analysis, and explants requested by the patient or surgeon.

(The College of American Pathologists has a policy on specimens to be submitted to pathology. www.cap.org.)

As Swedish implements Epic for the ORs, the software will include specimen documentation and order forms, Battié notes. That will add a layer of safety because the nurse must complete certain fields for the order forms to print. Epic will automatically assign an order number for tracking.

#### **Chain of custody**

Having a chain of custody for specimens is recommended by both AORN and the Pennsylvania Patient Safety Authority. If a specimen is missing, a chain of custody provides a way to track back to see where the error occurred.

Christiana Care, a 2-hospital system based in Wilmington, Delaware, took steps to improve its chain of custody 3 years ago after several specimens were lost. Thomas Zeidman, RN, BSN, CNOR, made that one of his first projects after becoming manager of surgical services for one of the 2 main OR departments at Wilmington Hospital. Since the new system was introduced, there has been only 1 specimen that could not be accounted for, and an additional step has helped to close that loophole, he notes.



Under the old process, the OR nursing staff filled out a specimen request form and placed the specimen in the refrigerator, where the pathology staff picked it up. But there was no handoff or tracking mechanism.

Zeidman developed a new 2-part form that collects more information: the type of specimen; a code for where the specimen is taken (OR refrigerator, to the lab by courier) and spaces for initials of the person receiving the specimen; signature of the OR nurse, and signature of the surgeon verifying that the specimens listed on the form are the ones taken from the patient.

## New chain of custody process

This is the chain of custody process:

- The circulating nurse places one copy of the form in the patient's chart. The circulator places the specimen in the OR refrigerator and puts the specimen form in a binder near the refrigerator.
- The pathology staff member who picks up the specimens looks in the binder to see what new forms have been added, initials the forms, and takes the specimens. If a form is in the binder but no matching specimen is in the refrigerator, the lab staff member calls the OR charge nurse so the specimen can be tracked down immediately.
- When a courier takes a specimen to the lab, the courier gets a sticker from the pathology lab signed by the staff member who received the specimen. The courier brings the sticker back to the OR and places it on the specimen form in the OR binder.

"This way, we have a record of everyone along the chain who had custody of the specimen," Zeidman notes. "The system seems to work well. I think we have closed the loopholes as best we can."

#### **Staff education**

The variety of specimen types and the

special handling methods make staff education challenging. Common methods are regular in-services and laminated charts listing specimen types and preparation requirements.

Perhaps the best patient safety measure is open communication between the OR staff and pathology lab staff, says Matthew A. Zarka, MD, director of cytopathology in the Department of Pathology and Laboratory Medicine at the Mayo Clinic in Scottsdale, Arizona.

"We stress to the OR staff that if there is any question, it is better to call us," he says. "No one should be embarrassed or nervous about asking how a specimen should be handled."



The Swedish specimen handling policy is in the OR Manager Toolbox at www.ormanager.com.

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# Intraop MRI in a community hospital

ophisticated intraoperative imaging suites, with their special facility needs and high cost, are usually found in academic medical centers. But a community hospital in Wisconsin has installed an intraoperative MRI and is helping to support it by also using it as a diagnostic imaging facility.

The MRI equipment is located at one end of the operating room so it can be accessed by separate entrances. The MRI scanner, ceiling mounted on a motorized

#### **Special focus: Imaging**

track, is separated from the rest of the room by sliding stainless steel doors, which are opened for surgery and closed for diagnostic use. The OR walls and doors are copper lined.

The sophisticated imaging system allows for large-scale data display.

"The OR walls serve as information billboards," says Marshfield Clinic neurosurgeon Kamal Thapar, MD, describing the new advanced neurosurgical suite at 340-bed Sacred Heart Hospital in Eau Claire, Wisconsin.

Formerly an academic surgeon in Canada, he came to Sacred Heart 6 years ago to start a neurosurgery program that has had an effect on all of the specialties. Sacred Heart has 9 conventional ORs, the MRI OR, and will soon open a CT OR for spinal procedures. The hospital performs more than 600 spinal procedures annually.

The high-tech suite takes surgery to the next level, Dr Thapar says. A physician can access the applications, housed in the operating suite, from workstations in the clinic. The seamless data integration and transmission are particularly useful for imaging and preoperative planning, he notes.

"Some would call an intraoperative MRI scanner just another trendy piece of equipment. But it is not," he says. "An MRI OR is an entirely different environment configured to try to make surgery as safe and effective as possible. We've found this view to be easy to justify to our board of directors."

As director of the Brain & Spine Institute and director of tertiary care services at Sacred Heart Hospital, Dr Thapar was instrumental in setting up



Sacred Heart Hospital's new MRI-equipped OR. Stainless steel doors enable the scanner also to be used for diagnostics.

the suite, which integrates IMRIS's intraoperative MRI magnet with BrainLab's navigation and image-data management.

#### Leaps beyond

Intraoperative MRI is several leaps beyond fluoroscopy and intraoperative ultrasound. Fluoroscopy is 2-dimensional and provides limited information on whether an implant has been properly placed, he notes. Fluoroscopy cannot be used for soft tissue imaging. As a result, he says, surgeons and manufacturers have been looking for ways to bring the best of digital imaging technology into the OR, including intraoperative MRI and CT scanning, and integrating these with navigational guidance.

Preoperative MRI alone was not sufficient. "When I look at a brain tumor on an MRI scan, that tumor exists in a virtual-digital world. It doesn't tell me where that tumor is in the patient's head," Dr Thapar notes. The old way was to make a large incision and explore the brain, which carries substantial morbidity.

The next advance was to take preop MRI imaging data into the OR and integrate it with a global positioning system, allowing the surgeon to know exactly where the tumor was and where to operate.

But this software-guided imaging still had limitations. During surgery, the data set can change as the brain shifts, and by the end of the procedure, the original imaging data is no longer accurate. Surgeons then asked: "Why can't we configure an operating room with the same tools as a radiology suite?" That would provide real-time imaging, allowing surgeons to scan the brain both during and at the end of surgery to make sure they had completely removed a tumor.

"The most common question a patient's family asks following removal of a brain tumor is, 'Did you get it all?'" he says. "Now, with this technology, we can answer with certainty, because the procedure only concludes when we have radiologic confirmation that the tumor is entirely removed."

#### Changing the playing field

Dr Thapar says his goal has been to take these powerful technologies and apply them to common procedures in community hospitals.

"Whereas MRI and CT were once diagnostic tools, we now regard them as therapeutic tools that guide the surgeon in the operating room," he says. "We

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# O-scanner: Real-time imaging in the OR

magine scrubbing in for a spine case without lead aprons. Imagine taking a scan of the spine at the beginning of surgery that gives images so precise further imaging isn't needed during the case. These are advantages of the new Oshaped portable computed tomography (CT) scanners, which provide real-time 3-D imaging in the OR.

These include the O-Arm Imaging System from Medtronic, the only such device cleared for marketing by the Food

#### **Special focus: Imaging**

and Drug Administration (FDA), and the Dominion Vi 3D Imaging Scanner from Imaging3, which is investigational. An older technology is the Arcadis Orbic 3D by Siemens.

Donald Myers, MD, chief of neurosurgery at Community Regional Medical Center, Fresno, California, who has used the O-Arm for about a year, told *OR Manager*, "It is the next-generation advance—it provides intraoperative CT scanning with the convenience and mobility of a C-arm."

Traditionally, spinal surgery patients have had preoperative imaging procedures such as CT scans, MRIs, and x-rays to provide diagnostic information to the surgeon. Conventional x-rays taken during surgery with a C-arm verify placement of surgical implants such as pedicle screws. But x-rays show only one-dimensional views, which means the trajectory of the screw could be off in 2 other planes. The O-Arm shows 3 planes during surgery and can verify accurate placement before closing.

"There is nothing else like the view we get of the spine in the OR with the O-Arm," says Dr Myers. "There is no way to duplicate it with previous technology."

#### **O-Arm with navigation**

The O-Arm can function in a standalone mode but is most useful when linked with a computerized navigation system, such as the Medtronic Stealth, which functions like a global positioning system (GPS). The navigation system converts the 3-D image from the O-Arm into a computerized image, which is projected onto a monitor to guide the surgeon in placing instruments and implants in real time.

Using reflective spheres as markers on drills and other instruments, the navigation system can generate images to show the surgeon exactly where the instruments extend inside the patient's body. This enables the surgeon to insert pedicle screws precisely, for example.

"If a pedicle screw is inserted in a suboptimal manner in a 4 mm pedicle, it may crack or break," says Dr Myers. "We get one good shot at putting a screw in exactly the right spot. There's nothing like the O-Arm to help us do it."

#### Clear, accurate image

One O-Arm can be used in multiple cases at the same time, but if navigation is also needed, it requires 2 navigation systems, notes Julie Blatnik, RN, BSN, CNOR, program director for spine care for HealthEast Care System, Maplewood,

Continued from page 9

want to know how we can use this new technology to reduce the size of incisions, the length of stay, and postoperative pain and overall make surgery safer."

He predicts surgeons will rely more and more on intraoperative imaging.

"Surgeons want to know that a pedicle screw is appropriately placed, and a tumor has been removed in its entirety while the patient is on the OR table, not the following day when postoperative imaging is performed."

#### **Cost considerations**

Despite the power of the imaging, most hospitals don't perform enough neurosurgery to justify the cost of an intraoperative MRI suite. The MRI OR suite at Sacred Heart, which includes the scanner plus an integrated navigation system and monitors, cost \$6.4 million, including:

- room construction: \$880,000
- equipment: \$51,000
- MRI magnet: \$3.1 million
- MRI navigational system: \$2.3 million.
   To provide a greater revenue stream,

the MRI OR was built to be used both for surgical and diagnostic purposes without violating OR access restrictions.

"When we initially designed the MRI OR suite, we thought about how we were going to utilize the square footage and the MRI because there are only so many brain tumors you can resect," says Loren Lortscher, RN, BSN, director of surgical services at Sacred Heart.

The motorized track, stainless steel doors, and positioning of the suite allows dual access to the adjacent intensive care suites so intraoperative MRI can be used for diagnostic purposes when it is not being used for surgery.

#### **CT OR is next**

Next for Sacred Heart Hospital will be a CT OR by BrainLab, which is under construction and expected to open in 2009.

The intraoperative CT scanner is less expensive than an MRI, at about \$1 million. The configuration of the CT OR is not only less expensive than the MRI OR, but it will be used daily for spinal and ENT surgeries. The CT scanner will also be on rails so surgeons can roll it up to the

patient, take the scan, and roll it back. The CT scanner will be permanently placed in the room, but unlike the MRI scanner will not be used diagnostically.

#### **Dedicated team**

A dedicated neurosurgical team composed of 4 RNs and 4 surgical technologists was created to work with these new technologies. Dr Thapar says a dedicated team is essential. The technology alone without the needed skills would keep the technology from providing a return on investment.

The neuro team has had a "dramatic impact" on reducing the length of surgical procedures, he says, with the average procedure time reduced by 20% since the team was launched. This has been true regardless of the complexity of the surgery or the neurosurgeon performing the procedure.

"The team working together has decreased the preoperative and intraoperative inconsistencies," Lortscher says. �

-Judith M. Mathias, RN, MA

Watch a video of the Sacred Heart MRI OR at www.sacredhearteauclaire.org/smartor

Minnesota. Medtronic recommends cases start about 45 minutes apart, but the O-Arm is mobile and can be moved from room to room for scans at the beginning and ending of cases.

HealthEast purchased an O-Arm last spring.

"The image is very clear and accurate up to 0.3 millimeter," says Blatnik.

Some surgeons use the O-Arm alone without navigation just at the end of surgery before closing to confirm screw placement, spine decompression, alignment, and any surgical changes before leaving the OR. According to Medtronic, about 80% are using it with Stealth navigation.

There is also potential to use the O-Arm linked to navigational guidance at the skull base and in the brain. Medtronic anticipates that within the next year it will have algorithms and new software that might allow using it in the head, says Dr Myers.

The O-Arm is not cleared as a diagnostic imaging CT device, and the patient cannot be charged for it from that standpoint. The FDA submission is expected in 2009 or 2010, notes Blatnik.

#### **Surgeons work faster**

In addition to accurate imaging, Blatnik says the O-Arm allows surgeons to work faster and have the patient under anesthesia a shorter time. The O-Arm with Stealth can reduce a minimally invasive 2-level spinal fusion from 2 to 3 hours to about 1½ hours. This is after training is conducted, and staff are comfortable with the equipment.

Dr Myers says the O-Arm doesn't necessarily save him a great deal of time, but it allows him to be more accurate.

The big advantage for the OR staff is they don't need to wear lead aprons for the entire case. Usually, only 1 or 2 spins are done at the beginning and end of the case. The staff can step behind a lead shield or leave the room for the spins. In contrast, with a C-arm, images are taken throughout the case, which requires the staff to wear lead aprons. The anesthesiologist can don a lead apron for the spin.

#### Draping the O

Draping for the O-shaped scanner is similar to the C-arm. The device is shaped like a C-arm when open and can be draped similarly before closing it over the patient.

Though Dr Myers notes this draping

technique is adequate, he worries about contamination when the O-Arm is opened again and removed from the field. The area where the O-Arm closes is not draped.

He places an extra drape over the patient for the spin, cutting the drape down the middle and letting it fall to each side after the O-Arm is taken from the field.

If the O-Arm stays in place for the entire procedure, the usual clear plastic drape is enough, he says.



Before purchasing an O-Arm, find out what surgeons intend to use it for, cautions Blatnik. Some surgeons want to use it as a glorified C-arm, though it is not designed to be used in that way. This exposes the patient to large amounts of radiation. A single spin of the O-Arm entails significantly higher radiation exposure for the patient and staff than a standard C-arm, though a standard C-arm typically involves multiple shots during a case.

The technology is expensive at nearly \$1 million for the O-Arm and Stealth together, and \$20,000 should be added for marketing and education, Blatnik advises.

Minimally invasive instrumentation will add another \$89,000 to the price, in addition to disposables such as percutaneous leads and dilating tubes. A reusable set of dilating tubes is about \$20,000.

Use of this high-tech scanner does not bring additional reimbursement. In fact, some payers question its necessity. Blatnik recommends working with the hospital's contracting department and payers to establish guidelines or pass-throughs for use of the device.

"The only thing your organization can gain financially is market share or increased volume," she says. "If use of the device isn't going to expand volume or market share, are you willing to spend a million-plus dollars just to have a new technology?"

Dr Myers sees the O-Arm as a technology whose time has come, saying, "The time is right for intraoperative and



The Medtronic O-Arm portable CT scanner.

small mobile CT scanners. All the major neuro and spine programs either have this technology, or they're planning to acquire it."

#### **Training for staff**

Radiologic technologists are trained by Medtronic to operate the O-Arm. Dr Myers has a radiologic tech to perform the spin even though he and the other surgeons have fluoroscopy operator supervisor licenses and technically don't need to.

At HealthEast, radiologic techs set up the O-Arm and perform the spin. HealthEast surgeons receive training on how to use the O-Arm, but it is not a certification course, says Blatnik. Typically, Medtronic staff are in the room for support. HealthEast is looking into separate physician credentialing for this technology if used with navigation for minimally invasive spinal procedures.

#### The scanner market

The Medtronic system currently is the only O-Arm with FDA clearance. The Dominion Vi Imaging Scanner by Imaging3 received FDA approval for investigational use in April 2008 and anticipates full FDA clearance by the end of the year, notes Jennifer Van Pelt, MA, senior research analyst and strategic technology planning specialist with Hayes Incorporated, a health technology research and consulting company (www.hayesinc.com).

The Dominion is described by Imaging3 as a multifunction device that can cross over to other modalities such as mammog-

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raphy and digital radiography.

"The fact that there may be a competing system introduced to the market soon is important for OR managers and administrators to know," says Van Pelt. "They need to look at both systems to see which system will fit their needs best in terms of the clinical application they are going to use it for."

Though the O-shaped devices may have more advanced features, they haven't been proven to improve patient outcomes, she notes.

The Siemens Arcadis Orbic 3D is also a C-arm with 3-D imaging capabilities, notes Jason Launders, senior project officer, medical physicist for ECRI Institute, an independent nonprofit organization (www.ecri.org). The Orbic is slower in generating an image than the O-Arm, taking up to a minute compared with less than 30 seconds for the O-Arm.

The Orbic is equipped with a multimodality workstation but does not include a surgical navigation system, which is where Medtronic has the advantage, says Launders

A third-party system can be integrated with Orbic via Navilink, he says.

"The spine is the best use for the O-Arm because that is where you can do the most harm. The 3-D data set is a huge advantage for the O-Arm, even though it takes more radiation to create the 3-D image," he says. •

— Judith M. Mathias, RN, MA

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Holly L T, Foley K T. Image guidance in spine surgery. *Orthop Clin N Am.* July 2007;38:451-461.

#### Resources

#### **O-Arm Imaging System**

**Medtronic,** Minneapolis, Minn www.medtronicnavigation.com/ procedures/intraoperative/o-arm.jsp

#### **Arcadis Orbic 3D**

Siemens, Munich, Germany www.medical.siemens.com Look under Healthcare, Products & Solutions, Detection and Diagnosis, Surgery Systems, C-arms, Arcadis Orbic.

#### **Dominion Vi Imaging System**

Imaging3 Inc, Burbank, Calif www.imaging3.com

# **Keeping it low: Protecting teams from radiation during surgery**

ith more minimally invasive surgery, the C-arm has become a regular resident in the OR. Surgeons rely on imaging during cases to guide implant placement and other critical aspects of surgery.

How much radiation are OR teams being exposed to, and what safety measures should they be taking?

Safety pointers were offered by 2 radiology managers: Jeff Palmucci, CRA, director of radiology services at Children's Hospital of Wisconsin,

#### **Special focus: Imaging**

Milwaukee, past president of the American Healthcare Radiology Administrators (AHRA), and Debra Lopez, CRA, FAHRA, RT(R), president-elect of AHRA and director of diagnostic imaging at Santa Clara Valley Medical Center, San Jose, California.

Radiation use in health care is regulated by federal, state, and local agencies. The Nuclear Regulatory Commission (NRC) has regulations for radiation and safety, which are typically carried out by the states.

AORN's Recommended Practices for Reducing Radiological Exposure in the Perioperative Practice Setting provide specific advice for OR staff.

A good resource is your radiation safety officer (RSO), who is responsible for the facility's radiation safety program.

#### How low can you go?

A key concept in radiation safety is ALARA—"as low as reasonably achievable." The idea is that you can never have zero radiation exposure because of natural background radioactivity, so the best you can do is to keep exposures ALARA.

Radiation safety organizations recommend that adults working with radioactive material not receive more than 5 rems (5,000 millirems, or mrem) of exposure per year. Americans average about 0.3 rems (300 mrem) a year just from natural radiation

Fluoroscopy with a regular C-arm exposes a patient to about 1,200 to 4,000 mrem/minute. Exposure from a mini-C-arm is 120 to 400 mrem/minute, according



to a review article by Gordon Singer, MD.

Surgeons are the most exposed team members because they are nearest the source. An orthopedic surgeon using a regular C-arm without protection is exposed to as much as 20 mrem/minute to the torso and 30 mrem to hands. For a 5-minute fluoroscopy, this would be about 100 mrem to the torso and 150 mrem to the hands per case, notes Dr Singer. The recommended exposure limit for hands is 50 rem (50,000 mrem) a year.

Exposure for spine surgeons is estimated to be 10 to 12 times the dose of other surgeons who use fluoroscopy.

There have been few studies of exposure to the rest of the OR team. A 1997 simulation study found a first assistant 2 feet away received 6 mrem/minute to the body. No exposure was detected for the scrub person 3 feet away or anesthesiologist 5 feet away.

#### **Protection principles**

"Distance and shielding are two of the biggest safety measures," Lopez says.

Protection centers on 3 principles:

- **Time:** Minimizing exposure time reduces the dose.
- **Distance:** The farther from the radiation source, the less the exposure.
- Shielding: A solid material, such as lead, between a person and the source greatly reduces the dose.

Raising awareness about radiation safety is probably the best step a manager can take, Palmucci emphasizes.

#### Distance reduces exposure

Make the staff aware of the distance rule. Doubling the distance from the source reduces exposure by a factor of 4,

for example. Stepping back from the surgical field even a step or two can greatly reduce exposure.

#### **Shielding for staff**

Have lead aprons available whenever radiation is used.

"When our x-ray technologists go into the OR, they check to make sure everyone who needs to is wearing lead aprons," Lopez notes.

Are there any solutions for the ergonomic stress lead aprons place on the body?

"We try to buy the lightest aprons we can but still maintain safety with the appropriate thickness of lead," Palmucci notes.

Two-piece lead garments (skirt and vest) are available for staff who work around radiation all day, but these are not as easy to put on and take off, Lopez notes.

Glasses, gloves, and thyroid shields are available to protect extremities, eyes, and thyroid.

#### **Monitoring exposure**

Under NRC rules, persons who have potential to receive 10% (500 mrems a year) of the maximum permissible dose must wear a dosimeter badge.

Children's Hospital doesn't issue badges to employees receiving less than 500 mrems. Because OR staff are under that amount, they do not routinely receive badges unless they request one. Orthopedic surgeons and anesthesiologists wear badges, as do radiologic technologists and cath lab employees.

"We have measured exposure in the OR for many years, and no one has come close to 500 millirems," Palmucci says. "However, if an employee requests to wear a badge, we provide it at no cost."

Santa Clara provides dosimeter badges to some OR personnel, but exposure is minimal, Lopez says.

"We are a Level 1 trauma center and do a lot of x-rays in the OR, but I can't think of a time when anyone in the OR came close to the limit," she says.

Both hospitals provide pregnant employees with an additional "baby badge" to monitor exposure in the abdominal area.

Badge exposure results are reviewed by the hospital's RSO. Once the reports are reviewed, the RSO speaks to any employee who has had a noteworthy



dose to determine the reason and review procedures.

Make sure the RSO or someone reviews badge reports, Lopez adds. "The Joint Commission has specifically asked to see our radiation dosage reports because they want to be sure someone is reviewing them."

#### **Education and awareness**

At Children's Hospital, radiation safety is part of annual mandatory staff safety education. Additional education is required for employees who work around radiation and those who wish to wear a dosimeter badge.

Raising awareness is a key safety strategy. "The less you know, the more you worry," Lopez says. •

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# **News from ASA**

News reported at the American Society of Anesthesiologists meeting in October in Orlando, Florida.

# Nausea, vomiting decrease when kids allowed to eat

A liberal eating and drinking policy for children after surgery improves recovery and does not increase postop nausea and vomiting (PONV), according to a study from the University of California, San Francisco.

Previous studies have shown PONV increased when kids were mandated to eat and drink.

The researchers, led by Christian C. Apfel, MD, expected delaying oral intake might merely delay the time until PONV was triggered. But eating and drinking didn't increase the incidence at all at any time.

"This is a new finding that has not been studied before," he said.

#### Deep sedation with nursedelivered sedation

In all, 78% of patients who received nurse-delivered sedation reached sedation levels consistent with general anesthesia, a study from Duke University found.

That means patients lost consciousness sometime during the procedures, increasing the possible risk to the patient, explained lead author Tong J. Gan, MD.

Adverse events occurred in 6% of patients, including episodes of oxygen saturation, difficulty to arouse, pain, hyper- and hypotension, and restlessness.

The study included 595 patients who had procedures such as colonoscopies, upper GI endoscopies, and bronchoscopies.

# Monitors don't prevent anesthesia awareness in study

Brain-wave (BIS) monitors were not found superior to traditional anesthesia monitoring in preventing long-term psychological symptoms related to anesthesia awareness in study findings.

Of 2,000 patients in the trial, 4 experienced definite awareness, and 5 experienced possible awareness. Of these, 6 were part of the BIS-monitor group, suggesting the BIS protocol was not superior in this study in preventing awareness. Of 2 patients with long-term negative effects, such as recurrent nightmares and depression, both were part of the BIS protocol, noted Michael S. Aviden, MD, the study leader. ❖

## **Patient safety**

# Minnesota's retained object protocol

work group of Minnesota hospitals and health systems has developed a step-by-step protocol for preventing retained foreign objects. The protocol includes a detailed flow sheet with recommendations for each step. Processes are spelled out for performing and recording counts and taking x-rays, among other things.

The protocol is based on professional guidelines, including those from AORN, the American College of Surgeons, and



others. It is also based on experience with adverse events reported as part of Minnesota's mandatory reporting system. In the state's latest report, re-

leased in January 2008, 25 retained objects were reported in 2006-2007, down from 42 the previous year.

The evidence-based protocol was developed by a multidisciplinary group facilitated by the Institute for Clinical Systems Improvement (ICSI), Minneapolis, an independent nonprofit collaboration of medical groups, hospitals, and health plans.

The work group included representatives from nursing, surgery, radiology, patient safety and quality, and obstetrics and gynecology, plus a human factors consultant who has worked with OR teams. A separate protocol was developed for labor and delivery.

#### Seeking a balance

"We needed to balance patient safety with practicality, efficiency, and cost," notes Dana Langness, RN, BSN, MA, a member of the work group and senior director of surgical services at Regions Hospital in St Paul.

Among the recommendations are:

- recording the count on a whiteboard in each OR
- conducting a room survey before the baseline count
- keeping distractions and interruptions to a minimum during the count process.
- establishing "red rules," a few key



rules to address situations that pose the highest risk.

The intent of red rules is to develop solid habits so the rules are followed consistently and accurately each time. Suggested red rules include:

- 1. Sponges/soft goods and sharps will be counted for surgical procedures.
- Baseline counts are accurately performed and completed before the incision starts.
- 3. If the count cannot be reconciled, imaging must be done appropriate to the patient's condition as outlined.

#### **Room survey**

The protocol recommends that the circulating nurse perform a room survey before the baseline count.

"The nurse methodically goes around the room, making sure nothing has been left in the room from the previous patient," Langness explains.

The nurse verifies that the whiteboard and other recordkeeping documents are clean and don't have information left from the previous case.

If the room survey or baseline count can't be performed, the protocol states, the count is considered compromised. If the count is compromised, the regular count process should still be followed, but an x-ray should also be taken.

#### **Baseline count**

A baseline count is done before the patient is brought into the OR. If parallel processing is used—that is, room setup activities are carried out simultaneously—the protocol advises that 2 circulators be assigned to the room, one dedicated to the count process and the other for setup and patient care. If extra staff are not available, the protocol says the

# Root causes of retained items

Root causes of retained items reported by Minnesota hospitals:

- Process relied on provider's memory to check for retained sponges
- Staff reluctant to voice questions or concerns to surgeons
- Differences in staff practice for counting lap sponges individually or in groups of 5
- Staff moving in and out of OR during procedure may miss some items placed in cavity if not verbalized by surgeon and written on whiteboard
- Staff felt rushed to prepare for next case, so sponge count was not consistent with policy
- Radiologist doing postop x-ray was not told to look for a potential foreign object
- Policy was not in place to do sponge counts after vaginal deliveries.

Source: Minnesota Department of Health. Adverse Health Events in Minnesota. January 2008.

www.health.state.mn.us/patientsafety

baseline count must be performed before the patient arrives in the OR.

#### Whiteboard records count

The protocol advises using a preformatted whiteboard in each OR as the primary record for the count. Also, when possible, only one source of count information should be used during a case.

The advantage of a whiteboard is that every team member can see it, Langness notes. The board helps reinforce the importance of the count and serves as a memory aid. If the whiteboard is close to where the count is performed, the circulator can mark directly on the board rather than using a count sheet.

If the OR is too small for a whiteboard, the protocol recommends using a standardized, formatted count sheet. A sheet can also be used as a supplement to

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## **OR Business Management**

# Managing an endomechanical conversion

R managers making a major conversion such as an endomechanical or a suture manufacturer change, face as much pressure as an Olympic athlete. Setting up for a successful conversion begins with understanding a simple equation.

"You have to look at 2 components when doing conversions—logistics, or the supply chain side, and the clinical side of the equation. The supply chain and the clinical people need to work together," says Mary Kaye Van Huis, RN, MSN, director and clinical field specialist for the Premier health care alliance, Charlotte, North Carolina.

In March 2008, Premier released guidelines for successful conversion of endomechanical and suture products for its members. The guidelines include a step-by-step tool for conversions.

Whether or not you have access to a formal tool, Van Huis and Simon Wajnblom, MBA, business manager for surgical services at CoxHealth, Springfield, Missouri, say a process is key to a successful conversion.

"You need to have a plan and do every step of that plan," says Walters.

#### **Organized process**

CoxHealth, which has 23 ORs and a surgical volume of 21,300 cases per year, converted from Covidien to Applied Medical trocars this year. Wajnblom says the conversion was handled through the organization's established processes.

At CoxHealth, all requests for conversions are presented to the surgery products committee (SPC), which Wajnblom and the director of purchasing co-chair. Representation on the committee includes nursing, materials management, the VP of clinical services, and the administrative director of surgical services.

At the monthly SPC meetings, the committee reviews surgeon requests, in addition to suggestions committee members have researched. The surgeon is asked to explain the clinical reasons why the requested product would benefit the department. Wajnblom is responsible for addressing the financial piece. Smaller trials may be approved on the spot. But trials that involve several surgeons or have a large financial impact are presented to the Surgical Executive Committee (SEC) for



feedback and approval. The medical director of the OR chairs the SEC, with support of the VP of clinical services and the administrative director of surgical services. Members include representatives from all surgical specialties, anesthesia, and the OR department, including nurses and clinical coordinators.

Once a request is approved, a subgroup of the SPC, which includes Wajnblom, the clinical team coordinator for the specialty, and other key players, plan the trial. If it's successful, an implementation plan is put into action.

#### Analysis and more analysis

Perhaps the most time-consuming part of a conversion is the data analysis. "Just getting all the information together takes a lot of time," says Wajnblom. "Although the vendor can help, you need to double-check their information."

He says to obtain information from purchasing and the warehouse supplier to match products. Van Huis adds to be sure the conversion doesn't conflict with other contracts or projects.

"You have to have the data to determine if there's a financial case for conversion," says Wajnblom. "Double-check all your information. If you make a mistake, those reviewing the report will pick it apart, as they should." The trocar conversion analysis showed an estimated savings of \$260,000 from what was currently in use.

"You can't always do just a line-item analysis," adds Van Huis. "In some instances, such as bariatrics, a cost-percase model is appropriate to determine total cost." Products can also be part of custom packs. Here is where clinicians' knowledge of what's needed for each type of surgery comes into play. Van

Huis says the biggest mistake organizations make is to look only at the financial piece without considering all of the clinical components.

Value analysis teams are helpful, as long as there is proper representation.

#### **Conversion on trial**

Once the decision was made to consider converting to a different trocar manufacturer, the hospital set up a 4-week trial period. Each step for the trial of a new product needs to be planned. Wajnblom says during the first week, the company's representatives provided education for staff and physicians during all shifts. The next 3 weeks (Monday through Friday) were allotted for using the product. A cross-reference tool of equivalent products was posted in each OR to avoid confusion. Sales reps were on hand to answer questions.

Before the trial, surgeons received letters explaining the process and how they could contact a product representative if they needed additional education.

"We didn't force the pilot on surgeons," Wajnblom says. If surgeons didn't choose to participate, the nurse administrative director of the OR contacted them to see why. Surgeons who don't participate in a trial are many times unable to weigh in on the final decision.

It's best to get comments from the surgeons throughout the pilot, so there aren't any big surprises at the end.

"Compile results from each surgeon," Wajnblom says. "This helps you learn who supports change and identify those who don't like the product sooner rather than later"

Physician champions or OR nurse leaders can talk with surgeons who are unhappy with the product to address their concerns. Wajnblom adds it can help to explain the financial impact: "A surgeon may say, 'I like this [current] product better, but not to the tune of X dollars."

#### Who makes the final decision?

"Who makes the final decision needs to be set early on in the process so that the decision doesn't get delayed," says Wajnblom.

Getting physicians involved helps build engagement, and the administration can help. For example, the COO could bring

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#### **Conversion**

Continued from page 15

together a physician group for dialogue and feedback.

Once a decision is made to move forward, it's time to plan the change. Wajnblom suggests asking the company for help. "Many of them have their own checklist they can modify for you." If you already have a checklist, ask the company's representative for theirs so you can develop a common one. "You don't want to be working off of 2 different checklists," he says.

The key for a successful conversion is communication. "You need one person to do all the communication such as drafting letters so the message is always the same," says Van Huis. "That person is the hub of wheel." An effective communication plan extends to administrators. It helps to have talking points for administrators so there is a consistent message.

Multihospital systems tend to phase in hospitals rather than convert all at once. One of the hardest decisions is whether to start with hospitals you believe will be most or least receptive to change. It's important to work with the culture of each organization and consider each one's typical reaction to change.

"Monitor the conversion on a day-today basis," advises Van Huis. One strategy is to have suppliers and key internal personnel email the communication point person daily with positive feedback and areas that aren't going as well.

#### **Timing a conversion**

How long does a conversion take? At CoxHealth, the trocar conversion started in April 2008, with the initial in-services for the clinical trial. The trial ended on May 9, and the conversion, including changes in specialty procedure packs and related stock, was completed in June 2008.

Van Huis says if a hospital already has a strong value analysis team, implementation can take as little as 4 to 6 weeks, but in some cases a full quarter is needed. It's better to work within a realistic time frame rather than rush the process.

"You never want to convert and then have to go back," Van Huis says. "If it's unsuccessful, physicians and staff have a very long memory." If possible, avoid making 2 major changes at the same time. For example, you wouldn't want to implement a new information system and do a product conversion at the same time.

#### **Following up**

Once the conversion is completed, it's tempting to sit back and rest on your achievement. Don't.

Van Huis recommends assessing savings 3 to 6 months after conversion and letting surgeons know if expected outcomes were met.

Conversions may seem like a Herculean task, but understanding the process and having a plan will help you come out a winner.

—Cynthia Saver, RN, MS

Cynthia Saver is a freelance writer in Columbia, Maryland.

### **Retained objects**

Continued from page 14

the whiteboard for procedures, such as cardiac cases, where there are a large number of items. (The protocol includes a sample count sheet.)

For ORs that have electronic displays, the count could be posted on the electronic display, Langness notes.

#### **Wound exploration**

A methodical wound exploration should be performed with the count process, the protocol states. If this isn't possible because of the patient's condition, the exception should be documented and an x-ray taken as soon as possible based on the patient's condition.

#### "A sacred time"

The protocol recommends keeping distractions and interruptions to a minimum during the count process.

Counting is "basically a sacred time, and all other distractions need to be minimized," Langness comments.

#### When to take an x-ray

The protocol says x-rays are not a substitute for counts and wound exploration. Langness says that after much discussion, the work group decided not to recommend that every patient have an x-ray to ensure nothing has been left behind.

The protocol advises that an x-ray be taken in the OR with portable equipment when:

- counts are off and cannot be reconciled
- the patient's condition did not allow the count process to be followed, for example, when the count was rushed or incomplete
- a member of the surgical team has concerns about the accuracy of the count process
- before final wound closure for wounds previously intentionally left open or packed.

A postop x-ray with fixed equipment and moving grid is recommended when:

- the patient's condition did not allow for an x-ray in the OR with portable equipment
- the entire anatomic area was not included in the x-ray
- a portable x-ray failed to locate a retained foreign body, and the count could not be reconciled
- the surgeon could not verify that portable x-ray equipment provided adequate anatomic coverage of the operative site.

The protocol includes recommendations for managing the x-ray process, including who should review the x-ray, timing, and communication issues.

#### Implementing the protocol

Langness says her hospital is implementing the protocol in 3 phases.

"We've done a lot of work on preventing retained foreign objects here, but we're starting over and taking it to a deeper level," she says. "We have a strict process for how people are to count. We're making sure people understand the correct process, as defined by the protocol. We're making that a competency so everyone is on the same page."

The first phase involved revising the count sheets so terminology and items counted are consistent with the protocol, standardizing the counting sequence, reeducating the staff, and standardizing placement of sharps and sponges on the Mayo stand and back table. The second phase will be to implement the room survey, use of 2 circulators during parallel processing, consistent wound exploration, and use of x-rays as recommended. The last phase will be to include the count documentation in Epic, the information system used for OR nursing documentation.

"Our vision is to have an electronic whiteboard some day where the nurse can enter the count, and it will go up on a screen for everyone to see," Langness comments. •

The protocol is at www.icsi.org. Look under Guidelines & More, then Patient Safety & Reliability.

#### **Sterilization & Disinfection**

# A mighty weapon: Steam sterilization

n the war against microbes, one of the mightiest weapons is the steam sterilizer. Steam, considered the ideal sterilant, is recommended for sterilizing devices that are heat and moisture stable. Steam is nontoxic, readily available, and low in cost relative to other technologies. With the exception of prions, the particles responsible for Creutzfeldt-Jakob disease, steam sterilization readily kills microorganisms, including bacteria (including those in a spore state), viruses, and fungi responsible for life-threatening infections. Assuming all of the processes leading up to the sterilization process, such as cleaning, drying, packaging, and cycle selection, are carried out correctly; the steam quality is appropriate; and the sterilizer is working properly, there is every reason to have high confidence in the sterilization process.

This is a refresher on basics of steam sterilization.

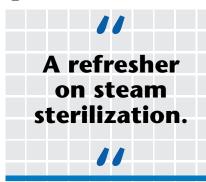
#### The sterilization standard

The standard for sterilization is expressed mathematically as  $10^{-6}$  and as a sterility assurance level (SAL). Stated simply, this means that at the end of the sterilization cycle, there is  $\leq 1$  chance in 1 million that there are any remaining viable microorganisms.

To test whether a sterilizer is capable of achieving this standard, a biological indicator is placed in the sterilizer, and the cycle is run. The biological indicator for a steam sterilizer contains roughly 1 million spores of *Geobacillus stearothermophilus* bacteria. These bacteria are the most resistant to steam sterilization, and bacterial spores are more difficult to kill than vegetative bacteria.

#### Cleaning makes a difference

In real life, devices placed in a sterilizer contain far less than a million microorganisms, and the bacteria are most likely be in a vegetative state, not the more resistant spore state. Several studies have demonstrated that the amount of bioburden on instruments after cleaning is actually quite low. Chan-Myers et al found the bioburden associated with rigid lumened devices before cleaning was low—approximately 132 CFU (colony forming units) per device—and after cleaning, 83% of devices had less than



10-2 (100) CFU. Rutala found that after 50 general surgery instruments were cleaned, 72% had 0 to 10 CFU, 14% had 11 to 100 CFU, and 14% had more than 100 CFU. The bioburden on flexible endoscopes such as colonoscopes is higher because the bacterial count in the colon is naturally high. But after cleaning, even these devices have been shown to contain well below a million microorganisms.

#### A margin of safety

In short, the sterilizer must demonstrate the ability to kill far more microorganisms than normally would be found on a surgical device, especially after cleaning. There is no commonly accepted standard in the US for "clean." Whether an item is clean is typically determined through visual inspection.

Before the Food and Drug Administration (FDA) clears a sterilizer for market, the sterilizer manufacturer must demonstrate that the sterilizer can achieve an SAL of 10<sup>-6</sup> in half the cycle time for which it is programmed. For example, if the sterilizer is programmed for a cycle time of 4 minutes at 270° F (132° C), the actual kill must occur in 2 minutes. The extra 2 minutes is considered "overkill" and provides an additional—and tremendous—margin of safety. The sterilizer is designed so the operator cannot adjust the cycle to less than the time required for overkill in this cycle.

# Understanding the sterilization cycle

At the end of the sterilization cycle, the operator should check the sterilizer printout to determine if the proper time and temperature were achieved and whether the exposure time was sufficient. Knowing what those values should be is critical, but it is also important to understand their significance.

#### Steam quality

Proper steam quality is a key factor in preventing wet packs. When water is heated at atmospheric pressure, a temperature of 212° F (100° C) is achieved, and water will boil. When the water and the water vapor are the same temperature, the steam is termed saturated steam. The saturated steam temperature of 212° F (100° C) at atmospheric pressure is not high enough to kill heat-resistant microorganisms. A pressure vessel or sealed container—ie, the sterilizer chamber—is required to increase the saturated steam temperature to 250° F (121° C), the lowest temperature required for sterilization. Steam is said to be 100% saturated when there is no liquid present. Steam quality is generally recommended to be at least 97%, meaning there is less than 3% liquid present. Steam quality can be determined by the sterilizer company service personnel or an in-hospital engineer.

#### Three critical factors

The 3 critical factors in steam sterilization are time, temperature, and moisture.

#### Time

Microorganisms exposed to saturated steam at a constant temperature do not all die at the same time. Their death is typically expressed in a straight-line survivor curve. In the example below, the initial number of microorganisms to be killed is 1 million (the same number that might be contained in the biological indicator). One million microorganisms is expressed as  $10^6$  (not to be confused with  $10^{-6}$ ).

As exposure to the sterilant occurs, the microorganisms begin to die. When 90% of the microorganisms die, 100,000 will have survived. This is considered a 1 log reduction. When 90% of the remaining 100,000 microorganisms die, 10,000 will have survived. This is considered a 2 log reduction. Progressive 90% or 1 log reductions will result in 1,000 survivors, followed by 100 survivors, followed by 1 survivor. At

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#### Sterilization & Disinfection

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this point, a 6 log reduction will have been achieved.

In a 4-minute cycle at 270° F (132° C), a 6 log reduction will have been achieved at 2 minutes. For all practical purposes, all of the microorganisms should have been killed at this point. As the cycle progresses, 90% or 1 log reductions continue until 0.000001 of microorganisms will have survived, or a 12 log reduction (an SAL of 10<sup>-6</sup>), will have been achieved.

Another term used when discussing the survivor curve is the D value. The D value is the amount of time it takes for a 1 log reduction to occur. D values vary according to the microorganism in question. The more resistant the organism, the greater the D value.

#### Why extended cycles?

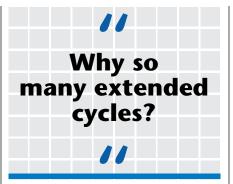
You might ask why so many newer devices require an extended cycle, an exposure time longer than the more common 4 minutes. Reasons include complexity of the device, lumen size, or dense configuration of a set. Some materials used in containment devices, such as certain plastics or a combination of plastic and metal, may also require a longer exposure time. When device manufacturers validate sterilization instructions for their devices they inoculate the devices with 10<sup>6</sup> Geobacillus stearothermophilus bacterial spores, placing theses spore populations in the least accessible areas of the devices, and determine how long it takes for the spores to be inactivated, or half the exposure time required to achieve an overkill. The overkill time is the exposure time provided in the instructions.

When a device exposed to prions is sterilized, the cycle time is also extended. The recommended time is 18 minutes at 270° F (132° C). In this instance, the extended cycle time relates to the resistance of the organism.

#### **Temperature**

The lower the temperature, the longer the time required for sterilization to occur. For example, if it takes 12 minutes to kill 1 million spores of *Geobacillus stearothermophilus* at a temperature of 250° F (121° C), raising the temperature to 270° F (132° C) decreases the time required to less than 1 minute.

It is important to note that if the steam is not saturated, the microorgan-



isms may not be killed even though the time and temperature are appropriate. Increasing the exposure time in the event of a failed biological indicator is not the proper corrective action because it does not ensure the presence of saturated steam—one of the requisites for steam sterilization.

#### Moisture

One reason dry heat is rarely used for sterilization in health care facilities is the time required for sterilization. What requires 6 hours to sterilize at 250° F (121° C) in dry heat may require only 15 minutes at 250° F (121° C) in moist heat. Moisture reduces the time necessary to denature or coagulate proteins, which causes microorganisms to be killed in steam.

One impediment to adequate moisture is trapped air. Air and steam do not mix well, and air can prevent steam contact with a device. In health care facility sterilizers, air is removed from the chamber either by the force of gravity (a gravity displacement sterilizer or a gravity cycle), a vacuum (prevacuum sterilizer or cycle), or pulse pressure (a series of steam pressure pulses).

Positioning of devices in a gravity displacement sterilizer or cycle is critical. Medicine cups and other concave devices should be inverted to prevent air entrapment. In a vacuum cycle, concave items are inverted to prevent pooling of condensate.

#### Testing for residual air

Residual air in the chamber can be the result of an air leak caused by a faulty gasket or other defect. A Class 2 indicator, commonly referred to as a Bowie-Dick test, is used to assess the efficiency of air removal in a cycle where air is removed by vacuum. A Bowie-Dick test may be user assembled, but most facilities employ a commercially prepared test. The Associa-

tion for the Advancement of Medication Instrumentation recommends performing this test each day the sterilizer will be used before the sterilizer is used to sterilize devices.

To standardize test procedures and reduce the potential for error, the test should be performed at the same time each day. In the operating room, it may be most convenient to have the night staff perform the test just prior to the end of the night shift and the start of the day shift. The Bowie-Dick test is run in an empty chamber. To properly heat the sterilizer, a cycle should be run omitting the dry time prior to performing the Bowie-Dick test.

#### **Ensuring a safe process**

Understanding the basic function of a steam sterilizer and correctly interpreting the printout are part of quality monitoring and facilitate processes that have a major impact on patient safety. Processing of surgical instruments is a complex process. Though starting a cycle may require only the push of a button, sterilization is not magic. An excellent process and outcome require in-depth knowledge and critical thinking skills. Sound knowledge of the principles of steam sterilization will help ensure a consistent and safe process. �

-Cynthia Spry, RN, MA, MSN, CNOR Independent Clinical Consultant

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# **Managing Today's OR Suite**

# OR leaders converge on Washington, DC

n an election year, Washington, DC, is the focal point for leadership, so it's fitting that from Oct 29 to 31, it became a hub for OR nurse leaders from across the US and as far away as New Zealand.

Nearly 800 OR managers and directors attended the 21st annual Managing Today's OR Suite conference, sponsored by OR Manager, Inc. This year, the AORN Leadership Specialty Assembly participated for the first time.

The attendees chose among 8 all-day seminars and 28 breakout sessions and networked with vendors from the 101 companies exhibiting. Experts spoke on topics ranging from health care policy to OR briefings and debriefings as a tool for safer care.

In her keynote address, Emily Friedman, independent health policy and ethics analyst, said, "It's been 15 years since the demise of the Clinton health care plan. It's time to gird our loins and do it again." She acknowledged that predicting the future is dicey: "Nobody really knows what's going to happen. If I did, I'd be on Dr Phil or in Las Vegas."

Still, Friedman, whose presentation was sponsored by Kimberly-Clark Health Care, drew on her years of public policy experience to discuss 7 areas of change that might make this attempt at health care reform more successful: population changes, public and patient attitudes and expectations, the push for improved quality, the structure of the system/work force, financing and coverage, politics and policy, and "wild cards" such as national disasters and pandemics.

#### **Big changes**

Friedman said the 3 main areas of demographic change are an aging population (the fastest growing age group is those older than 100 years), the high percentage of women living alone (higher than men from 66 to over 85 years), and increasing diversity (by 2050, 1 of every 3 persons older than 65 will be a member of a minority group).

Minority patients deserve particular attention, Friedman said. "Language and culture are major determinants of everything from patient satisfaction to clinical outcomes," she said as she called for action. "I don't know how many more studies we need to tell us that. Let's do something about it instead."





"We have a sacred trust to deliver better quality," said Sr Mary Jean Ryan, FSM, of SSM Health Care.

"We could afford it if we wanted to," said policy expert Stuart Altman about universal coverage.

There was time to meet with vendors at the trade show.

The changing population has changing expectations, too. "There is impatience with the unequal patient-provider relationship and a desire for self-determination," Friedman said.

Despite the national election, Friedman expects more local than national action in health care reform. "The states are the ones to watch,"

she said, pointing out efforts to insure children and provide universal coverage.

#### **Ready for reform**

Stuart Altman, dean and Sol C. Chaikin professor of National Health Policy at The Heller School for Social Policy and Management, Brandeis University, Waltham, Massachusetts, continued the theme of health care reform in his presentation, sponsored by Cardinal Health.

Altman, whose experience in health care dates back to the Nixon White House,





gave a brief historical overview and said 3 issues dominate health care reform policy today: create universal coverage, reduce the rate of health care spending, and improve quality of care.

Altman recommended reforms in employer-sponsored health insurance combined with universal coverage and dismissed concerns that coverage and cost control must happen simultaneously. "We could do it (provide universal coverage) if we wanted to do it," he said. "We could afford it if we wanted to afford it. Why

## **Managing Today's OR Suite**

don't we go to the same store that bailed out the banks?" He said the cost of covering the uninsured is reasonable, estimated at 5% to 7% of additional spending (\$100 billion to \$140 billion).

Altman admitted controlling spending isn't as easy as providing coverage, citing several powerful forces that work against cost control, including providers, insurers, patients, politicians, and suppliers. He ended on an optimistic note, saying, "Health care reform has the best shot it has had in my lifetime."

#### An exceptional journey

A recurring theme through the conference was a dedication to quality. The leaders at SSM Health Care have been strong advocates for quality. The system was the first in health care to receive the Malcolm Baldrige National Quality Award in 2002.

"Transformation and quality improvement are explicitly linked," said Sister Mary Jean Ryan, president and CEO of SSM Health Care, a 20-hospital system based in St. Louis.

Ryan chronicled the system's journey to the Baldrige award, an organizational transformation that began with an awakening: "We realized we weren't nearly as good as we could be, should be." SSM made the decision to tackle Baldrige.

Ryan emphasized ongoing commitment to quality and shared 2 sides of the quality coin with participants. First, a patient had the wrong kidney removed — an incident that created shock waves throughout the organization. There was "a feeling of intense shame at the hospital," said Ryan.

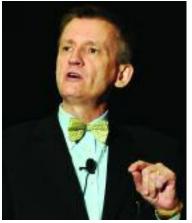
On the other side of the coin was the

# Your evaluations of the conference

Of the 346 attendees who evaluated the conference, 95% rated Managing Today's OR Suite as "excellent" (55%) or "very good" (40%), while 5% ranked it as "good." For 98%, the conference met expectations, and 99% thought the content valuable and would recommend it to a colleague.

Most (75%) liked having the handouts available for printing before the conference.

Some 86% found the exhibits an integral part of the educational process, and 84% agreed that it helped with their purchasing decisions.





story about the surgical technologist who spoke up, getting the team's attention and preventing a wrongsite surgery. "Now that's exceptional," Ryan said.

She admitted that the path to quality is long and difficult. "There are no shortcuts," she said. "You must have faith that you

will reach your vision." She recommended leaders "define, measure, monitor, and improve."

Empowering everyone in the organization to lead is an important component of success.

#### **Keep your nurses for life!**

Brian Lee, CSP, CEO/founder of Custom Learning Systems Group, Ltd, Calgary, Alberta, Canada, told participants, "The single greatest asset is your staff."

Lee's dynamic presentation, sponsored by Advanced Sterilization Products, was packed with practical strategies for retention, based on KEEP: The Key is culture, Empowerment is the way, Education and engagement, and Physician acceptance.

"Change your culture or be doomed to repeat the past," Lee said, who recommended striving to become an employer of choice for nurses. That includes understanding the types of employees: superstars, winners, grinners, sinners, and slugs. In most organizations, the slugs are put in the same group as everyone else, but Lee said, "The slugs have to go yesterday. They are counter-productive."



Clockwise from above, left: "Your single greatest asset is your staff," said speaker Brian Lee.

OR Manager of the Year, Barbara McKinnon (center), with colleagues Kathleen Sliney and Gail Sebet of New England Baptist Hospital, Boston.

Attendees at the Thriller Night Gala sponsored by Integrated Medical Systems.

Lee said education keeps staff engaged. "When your people are learning, they're not leaving." He suggested tapping staff to lead customer satisfaction efforts, using a train-the-trainer approach.

Physician acceptance includes zero tolerance for bad behavior.

Lee said people forget what they hear at a conference within 14 days if they don't take action. He advised participants to "commit to using one idea." •

—Cynthia Saver, RN, MS

Cynthia Saver is a freelance writer in Columbia, Maryland.



# Medicare issues long-awaited ASC CfCs

he Centers for Medicare and Medicaid Services (CMS) published the long-awaited final revision of the ambulatory surgery center (ASC) conditions for coverage (CfCs) on Oct 30, 2008. The CfCs spell out the rules for ASCs participating in Medicare. They were issued as part of a larger rule that includes updates to the ASC and hospital outpatient payment systems and changes to the ASC list of covered procedures. The rule was scheduled to appear in the Nov 18, 2008, Federal Register.

The changes are effective Jan 1, 2009. Comments on designated parts of the final rule will be accepted until Dec 29, 2008.

This is the first major overhaul of the CfCs since the original ASC rules were adopted in 1982. Since then, the number of ASCs participating in Medicare has mushroomed to 5,100.

Compliance with the CfCs is checked either by state survey agencies or 1 of the 4 national accrediting bodies: the Joint Commission, American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), or American Osteopathic Association (AOA).

The final CfCs have some notable revisions from the proposed rule published in August 2007. The ASC Association, which plans to issue a detailed analysis, pointed

A less restrictive definition of ASCs.

in particular to a less restrictive definition of ASCs than was in the proposed rule issued in August 2007.

#### **Definition of an ASC**

The revised more flexible wording defines an ASC as a "distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which services are not expected to exceed 24 hours following admission."

This definition will allow patients to stay in the ASC for 23 hours and 59 minutes starting at the time of admission. That will create a 24-hour rolling clock that will allow ASCs to perform procedures later in the day or to perform procedures that require a longer recovery time.

In contrast, the proposed rule would have defined an ASC as caring for patients who do not require an "overnight stay," defined as a stay past 11:59 pm on the day of surgery that required "active monitoring" by "qualified medical personnel."

#### Strengthening patient rights

The CfCs strengthen patient rights regarding physician disclosure of financial interests in the ASC, advance directives, the grievance process, and confidentiality of clinical records. CMS is retaining proposed requirements that:

- patient rights be posted in the ASC
- patients be informed of their rights orally and in writing.

In addition, CMS kept the proposed requirement that patients be notified about physician ownership in the ASC in advance of the date of their procedure. ASCs said this would be burdensome because patients often don't come to the ASC before their day of surgery. CMS said it was not specifying how the notice must be given. For example, the notice could be included in the information packet patients receive before their procedure. The packet might have a form with a check box to indicate whether the patient's surgeon has a financial interest in the facility.

CMS also kept the requirement about giving patients information about advance directives, even though ASC patients have elective surgery. "We believe ASC health care personnel

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#### Ambulatory Surgery Centers

should discuss the use of advance directives with patients and their designated family members," CMS says, because this is becoming a standard of practice.

Regarding patient complaints, the final rule requires ASCs to report only complaints or grievances that are substantiated to state and/or local authorities. The proposed language would also have required reporting unsubstantiated complaints.

CMS did decide to do away with a separate CfC for confidentiality of clinical records, referring instead to the privacy rules in HIPAA (Health Insurance Portability and Accountability Act).

# Quality assessment and improvement

The final CfCs for quality improvement are basically the same as proposed. These rules impose stronger obligations on ASC governing bodies to oversee the quality assessment and performance improvement (QAPI) program, while allowing ASCs flexibility to use their own information to assess and improve patient services, outcomes, and satisfaction. CMS notes that these requirements bring the CfCs up to date with what the accrediting bodies already require.

The QAPI standards require ASCs to have an ongoing program that would:

- be able to show measurable improvement in quality outcome and safety indicators
- collect and analyze data to identify PI opportunities
- set priorities for PI activities
- reflect the scope and complexity of the ASC's services and activities.

The ASC's governing body would be responsible and accountable for the QAPI program. One change makes the final rule more specific, saying ASCs must allocate adequate "staff, time, information systems, and training" to the QAPI program, rather than using the more general term "resources."

# Patient admission, assessment, and discharge

With the expansion of procedures being performed in ASCs, CMS said it believes stronger requirements are needed for patient assessment and recovery. Core objectives of these requirements are to ensure:

- the patient can tolerate surgery
- the patient's anesthesia risk and recovery are properly evaluated
- the patient's postoperative recovery is adequately evaluated
- the patient receives effective discharge planning
- the patient is successfully discharged from the ASC.

#### Admission and assessment

This section says a patient must have a comprehensive history and physical not more than 30 days before the scheduled surgery. On admission to the ASC, each patient must have a presurgical assessment that includes, at a minimum, an update documenting any changes in the patient's condition, including documentation of any allergies to drugs and biologicals. The history and physical must be in the patient's medical record prior to the surgical procedure.

In one change, CMS dropped the requirement that the assessment include the patient's "mental ability" to undergo surgery because this may be beyond the scope of the surgical team.

#### Postsurgical assessment

The final language says RNs with postop experience, in addition to physicians or other qualified practitioners, can assess and document the patient's postoperative condition.

On discharge orders, the final language states the ASC must: "Ensure each patient has a discharge order signed by the physician who performed the surgery or procedure in accordance with applicable state health and safety laws, standards of practice, and ASC policy." Dropped was additional language, which would have required that "the discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery."

In addition, the ASC must: "Ensure all patients are discharged in the company of a responsible adult, except patients exempted by the attending physician."

CMS did not make the proposed

requirement that ASCs must ensure "the patient has a safe transition to home and that the postsurgical needs are met." The agency agreed with commenters who said the language was too broad and might be interpreted to mean the ASC had responsibility after the patient left the facility.

#### **Radiology services**

In response to public comments, CMS decided to scrap onerous requirements for radiology services. ASCs had been concerned that the proposed changes would severely restrict their ability to perform procedures that require imaging and impose other impractical requirements.

CMS instead decided to keep the existing radiology services requirements applying to ASCs that are in the hospital conditions of participation. These include requirements for safety, equipment maintenance, and personnel qualifications.

#### Infection control

The final CfCs emphasize the importance of infection control practices, requiring ASCs to maintain an infection control program. In a wording change, CMS added the requirement that the infection control program must include documentation that the ASC has implemented "nationally recognized infection control guidelines," such as those of the Centers for Disease Control and Prevention.

#### Disaster plan

The final CfCs require ASCs to adopt a disaster preparedness plan, as proposed. ASCs will need to coordinate the plan with state and local agencies, conduct annual drills, and "promptly implement" (rather than "immediately implement," as proposed) any changes needed to improve the plan. •

The ASC Association will be providing an analysis on its website at www.ascassociation.org.

Please see the ad for CARDINAL HEALTH in the *OR Manager* print version.

# ASC payment plan updated for 2009

edicare issued its final 2009 policies and payment rates for ambulatory surgery centers (ASC) Oct 30, 2008. The changes issued by the Centers for Medicare and Medicaid Services (CMS) are part of a large rule updating hospital outpatient and ASC payments and finalizing the ASC conditions for coverage (related article, p 22). The changes take effect Jan 1, 2009.

Next year will be the second year of transition of the new Medicare ASC payment system launched in 2008. The new system pegs ASC facility payments to the hospital outpatient department (HOPD) rates, though ASCs receive less than HOPDs for the same services. For 2008, ASCs were paid 63% of what hospitals received for the same services. For 2009, it's estimated ASCs will be paid 59% of HOPD reimbursement for the same services, according to the ASC Association.

By law, ASC payments will not receive an inflation update for 2009.

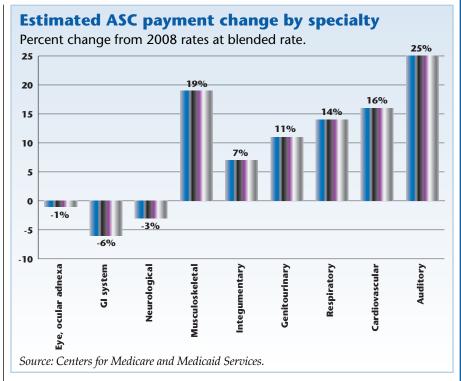
#### **Payment rate updates**

As in 2008, the impact of the payment updates on your ASC will depend on the specialties you perform. Eye procedures—the highest volume ASC procedure—will see a 1% decrease. Orthopedics on the whole will see a 19% rise. But some lower volume procedures, such as ear surgery, will see payments go up in the aggregate (chart).

#### **Changes to ASC list**

In all, 27 surgical procedures are being added to the list of procedures Medicare will pay for in an ASC. These include 13 procedures with new CPT codes and 14 that were previously excluded.

As part of the new payment system, CMS adopted a new approach to the ASC list. The only procedures now excluded from ASC facility payment are those CMS determines pose a significant safety risk or would typically require an overnight stay. Formerly, procedures had to be added to the list by CMS to be eligible for payment, and updates lagged. The ASC list is now updated annually along with the HOPD payments.



Among ASC procedures added are:

- CPT 34490 (Thrombectomy, direct or with catheter; axillary and subclavian vein, by arm incision)
- CPT 36455 (Exchange transfusion, blood; other than newborn)
- CPT 49324 (Laparoscopy, surgical; with revision of previously placed intraperitoneal cannula or catheter, with removal of intraluminal obstructive materials if performed)
- CPT 49326 (Laparoscopy, surgical; with omentopexy).

CMS decided not to add CPT 31293 (Nasal/sinus endoscopy, surgical; with medial orbital wall and inferior orbital wall decompression). The agency decided this is similar to 2 other nasal/sinus endoscopy codes, 31292 and 31294. Because CMS thinks all 3 pose safety risks in an ASC, it believes they should continue to be excluded.

In response to comments, CMS did add 4 codes for acellular dermal grafts (15170, 15171, 15175, and 15176) because

these don't pose a significant safety risk or require an overnight stay.

Some knee arthroscopies with grafts (CPT 29867 and 29868) were not added because of the postoperative care they require. Also not added, despite requests, was CPT 37205 for stent placement.

Eight procedures were added to the list of office-based procedures. These are paid the lesser of either the amount paid to physicians under their office fee schedule or the standard ASC rate. The purpose is to prevent Medicare from paying more for procedures performed in an ASC that are mainly done in the office.

In all, 12 codes were added to the list of device-intensive procedures because these procedures require use of a high-cost implant or other device. These include, among others, several codes for reconstruction of the elbow or wrist joint and knee joint revision. •

More information on the payment updates is on the ASC Association website at www.ascassociation.org. Look under the Medicare tab. Please see the ad for DIGITELL in the *OR Manager* print version.

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Please see the ad for INTEGRATED MEDICAL SYSTEMS in the *OR Manager* print version.

#### At a Glance

# Laminar airflow shows no benefit in new German study

In an unexpected finding, OR ventilation with laminar flow showed no benefit and was even associated with a significantly higher risk for severe surgical site infection after hip replacement surgery. The large study from Germany, published in the Annals of Surgery, compared turbulent ventilation with HEPA-filtered air to HEPA-filtered laminar flow. The study involved 63 surgical departments and more than 99,000 operations. The authors said they controlled for many patient and hospital variables, such as duration of the surgery, endoscopic approach, and academic status of the hospital.

> —Brandt C, Hott U, Sohr D, et al. Ann Surg. 2008;248:695-700. www.annalsofsurgery.com

# FDA: Surgical mesh linked to complications

Surgical mesh used to repair pelvic organ prolapse and stress urinary incontinence has been linked to rare but serious complications, according to an Oct 20 notice from the Food and Drug Administration (FDA). The FDA has received more than 1,000 reports in the past 3 years of problems with mesh from 9 surgical mesh manufacturers. Complications include erosion of the mesh through vaginal tissue, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. Contributing factors may include estrogen status, overall health, mesh material, size and shape of

mesh, and surgical techniques. The mesh is usually placed transvaginally with minimally invasive tools.

-www.fda.gov/cdrh/safety/ 102008-surgicalmesh.html

# Beta-blockers linked to postop heart attacks, mortality

A new study finds noncardiacsurgery patients given perioperative beta-blockers have higher rates of postoperative myocardial infarctions (2.94% vs 0.74%) and postoperative mortality (2.52% vs 0.25%) than control patients.

The beta-blocker patients who died had significantly higher preoperative heart rates (86 vs 70 beats/min). None of the deaths occurred in patients with a high cardiac risk. The researchers conclude that administration of beta-blockers should be carefully monitored in patients who are not at high cardiac risk.

- Kaafarani H M A, Atluri P V, Thornby J, et al. Arch Surg. 2008;243:940-944.

# Study looks at costs of technology for preventing retained sponges

A new study presented at the American College of Surgeons meeting in October found new technologies can reduce the incidence of retained surgical sponges at an acceptable cost. The study compared routine counting, x-ray, barcoded sponges, and radiofrequency-tagged sponges.

Routine counting prevented 82% of retained sponges, and bar-coding prevented 97.5% for an additional \$95,000

per event averted. Radiofrequency would prevent from 97.5% to 99.7% of retained sponges at a cost of about \$600,000 to \$700,000 per event averted. X-ray is more costly and less effective—preventing 95.5% at more than \$1 million per event averted. Medical and liability costs are over \$200,000 per retained sponge, the authors say. The researchers say each organization needs to decide what is best based on its priorities, ease of use, cost reduction, and ensuring retained sponges are "never events."

-Regenbogen S E, Greenberg C C, Resch S C, et al. J Am Coll Surg. 2008;207 (3)Suppl:S73-S74. www.journalacs.org

# DVT guidelines have new surgery chapter

The American College of Chest Physicians dedicates a full chapter in its updated thrombosis prevention guidelines to perioperative management of patients on long-term antithrombotic therapy who require surgery or other invasive procedures.

The guidelines recommend balancing the risk of DVT when therapy is interrupted for surgery against the risk for bleeding. The guidelines include routine use of prophylaxis for patients having major general, gynecologic, or orthopedic surgery as well as bariatric and coronary artery bypass surgery. •

-Hirsch J, Guyatt G, Albers G W, et al. Chest. 2008;133:110S-112S. Download is free at www.chestjournal.org/ cgi/content/abstract/133/6\_suppl/110S.

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