

Ambulatory Surgery Centers

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Human resources

Survey shows assigning extra staff to OR cases is widespread

The standard staffing pattern for a surgical case is one scrub person and one circulating RN. But there are many situations for which ORs assign additional personnel. A surgeon may expect the hospital to provide an assistant, robotic-assisted surgery with its complex setup requires an additional person, additional help may be needed for patients who are morbidly obese, and so forth.

To learn more about how ORs assign additional personnel, *OR Manager* conducted an online survey in September 2010. *OR Man-*

ager subscribers were polled about staffing patterns for 12 types of procedures as well as for other situations.

In all, 353 responses were received, with 69% of the responses from community hospitals, and 31% from academic hospitals with surgical residents.

The diversity in staffing patterns was striking. For bariatric surgery and total joint replacements, for example, community hospitals were evenly split on whether they use 1 scrub person or 2. For vaginal hysterectomies,

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Patient safety

Preventing retained items: Time to consider technology?

Technology is starting to take its place as a supplement to manual counts in the effort to prevent retained surgical items (RSIs). RSIs persist despite the emphasis many ORs have placed on tightening their manual counting

methods. Recent reports from California are an example of the challenge ORs are up against (sidebar, p 18).

Though rare, RSIs take a heavy toll. Patients with retained items had a rate of death 2.14% higher than controls, excess hospital stays of 2.08 days, and excess costs of \$13,315, in a report by Zhan et al. They also increase liability costs.

Four companies now offer technologies to help in accounting for instruments and sponges. The newest, ORLocate, which entered the market in August 2010, is the first that can account for instruments. The other companies are upgrading their systems.

Continued on page 18



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Upcoming

Dashboards: Usable tools

How can you make your data work for you? Lessons and examples.

Scheduling: The next level

Read how ORs are taking this critical role to the next level.



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Editorial

How do you decide how many personnel to assign to a surgical case? When is an additional person needed beyond the usual one scrub person and one circulating RN? To what extent do you provide hospital-employed first assistants to surgeons?

The survey reported in this issue examines how *OR Manager* readers assign staff for 12 types of surgical procedures as well as for other situations like laparoscopic and robotic-assisted surgery. You can read, for example, how many assign additional staff for abdominal aortic aneurysms and total hip and knee procedures.

The idea for the survey grew out of a conversation we had with a perioperative director at our OR Business Management Conference in May 2010 in San Francisco.

She asked whether we knew of any criteria for assigning additional personnel beyond the usual one scrub person and one circulating RN.

It seems that her hospital participates in a labor productivity benchmarking program that is based on 2 direct care staff for a case. But her OR, like many, often assigns an additional person—for example, a person to operate the laser during a laser case.

Using extra staff pushes her facility over the benchmark.

"Then we're over budget, which is a big deal," she said.

She had discussed the matter with the CEO. Though he seemed to understand the rationale, he wanted to see independent literature documenting the need for additional staff.

As far as we know, there isn't any, beyond professional guidelines that apply to specific situations. Two of these are the AORN recommendations calling for a laser operator and a nurse to monitor patients having moderate sedation.

When is an additional person needed?

Thinking others might be facing similar questions, we decided to conduct an online survey. In all, 353 of you took time to respond to indicate how your facility staffs for the selected procedures and situations. The results indicate there is considerable variation.

Big drivers

The big drivers are technology and surgeon requests. Robotic surgery and laparoscopic surgery involve more equipment and setup. Many surgeons, faced with rising practice expenses and falling reimbursement, no longer employ their own assistants and expect hospitals to provide them. Some surgeons insist on a second scrub for laparoscopic surgery or an extra person for their orthopedic cases.

Hospitals don't want to turn down surgeon requests, particularly for surgeons who are important to their business.

Judging from the survey and respondents' comments, facilities that assign additional personnel are far from alone. If your facility has found a way to meet aggressive labor productivity benchmarks, our readers would like to hear how you've done it. Please contact me at editor@ormanager.com. ♦

—Pat Patterson

For 2011, the OR Business Management Conference will be held in conjunction with the Managing Today's OR Suite Conference September 28-30 in Chicago.



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Term 'flash sterilization' to go away

The term "flash sterilization" is going away. The new term is "immediate use sterilization."

The new term better describes the process employed to steam sterilize items intended to be used immediately and not stored, say those who have worked on a joint position statement on immediate use sterilization. The statement, developed by 13 professional societies and agencies, is expected to be issued soon.

"We all agreed that the term 'flash sterilization' is antiquated and was contributing to confusion," says Ramona Conner, MSN, RN, CNOR, manager of standards and recommended practices for AORN, which endorsed the statement in October.

The statement notes that immediate use sterilization is safe and efficacious as long as users understand the principles of steam sterilization, make sure their personnel are well educated, and are well informed about manufacturers' requirements for sterilizing particu-

**'Immediate use'
is the
new term.**

lar items.

The statement addresses elements required to perform immediate use sterilization.

"It emphasizes the key steps of cleaning, decontamination, and rinsing prior to sterilization and emphasizes the importance of aseptic transfer of the sterilized product from the sterilizer to the point of use," Conner says. Shortcuts, particularly in cleaning, are what have given flash sterilization a bad name.

Guidelines unchanged

The joint statement doesn't change current steam sterilization guidelines

of either the Association for the Advancement of Medical Instrumentation (AAMI) or AORN, she notes. AORN will update its sterilization recommended practices in 2011 to reflect the term "immediate use."

Other organizations that had endorsed the statement by press time are the ASC Quality Collaboration, the International Association of Healthcare Central Service Materiel Management (IAHCSMM), and the Accreditation Association for Ambulatory Health Care. The statement was awaiting a vote of the AAMI standards board, having been approved by AAMI's hospital steam sterilization working group in November. The final document will become an interpretive statement to AAMI's ST79 steam sterilization standard.

Looking at the whole process

"The Joint Commission has given us verbal acknowledgment that they will recognize the statement, as has the Centers for Medicare and Medicaid Services (CMS)," says Conner. (Federal agencies and accrediting bodies don't endorse statements; they recognize them, she explains.)

Conner says she thinks the discussions have already helped surveyors better understand immediate use sterilization and the key areas they need to look for in a survey, "specifically looking at the whole process rather than just the number of cycles that are run."

Other organizations involved are the American Dental Association, the American Society of Cataract and Refractive Surgery, the Association for Professionals in Infection Control and Epidemiology, the Centers for Disease Control and Prevention, the Food and Drug Association, and the American Association for Accreditation of Ambulatory Surgery Facilities. ♦

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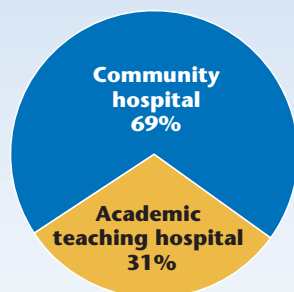
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Human resources

What is your facility type?



Number of scheduled ORs

	Community hospitals	Academic hospitals
1-4 ORs	26%	10%
5-9 ORs	42%	19%
10+ ORs	32%	71%

Continued from page 1

while 57% use 1 scrub, 43% use 2 or 3 persons in the scrub role.

Comments reflected the differences. One person wrote, "Our staffing model rarely allows for only 2 staff in a room." Another said, "We rarely assign 3." Yet substantial numbers reported using additional personnel for common types of surgery, such as major abdominal surgery and complex spine cases. (See p 10.)

It's not just complex surgery that drives staffing needs. A couple of respondents noted the demands placed by computerized charting.

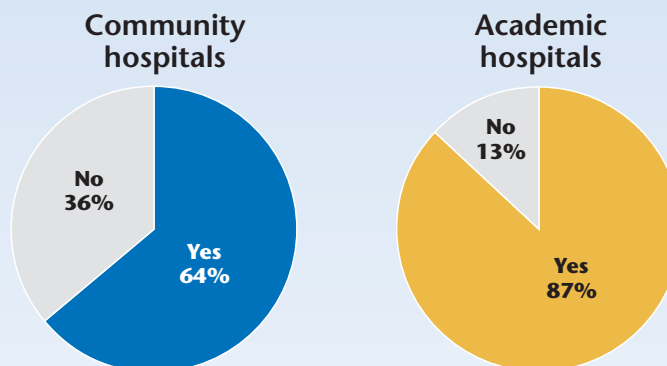
"E-charts take longer to do than the procedures," said one respondent. "Other OR staff have complained that the computer takes up too much time for just 1 circulator on many cases." But "administration does not feel that way," this person added.

First assistants

Use of hospital-employed first assistants is widespread, the survey found.

First assistants are defined by the American College of Surgeons

Does your OR have specialty teams; ie, staff assigned regularly to certain specialties?



Most common specialty teams

	Community hospitals	Academic hospitals
Cardiac surgery	56%	77%
General surgery	37%	NA
Orthopedics	84%	82%
Neurosurgery	43%	75%
Other	94%	53%

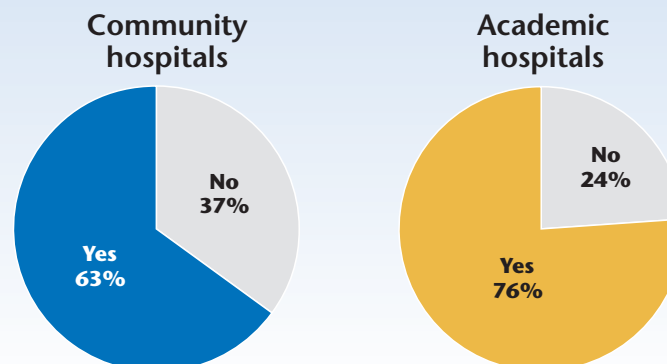
NA = not asked

Others named:

Community hospitals: Urology, bariatric, robotics, ENT, vascular, ophthalmology, plastic surgery, endovascular, head and neck, pediatrics, dental.

Academic hospitals: All services, robotics, urology, ophthalmology, GYN, general surgery, ENT, plastic surgery, bariatric, endovascular, transplant, pediatrics.

Do you routinely have unassigned staff (floats) who cover staff for breaks and lunch?

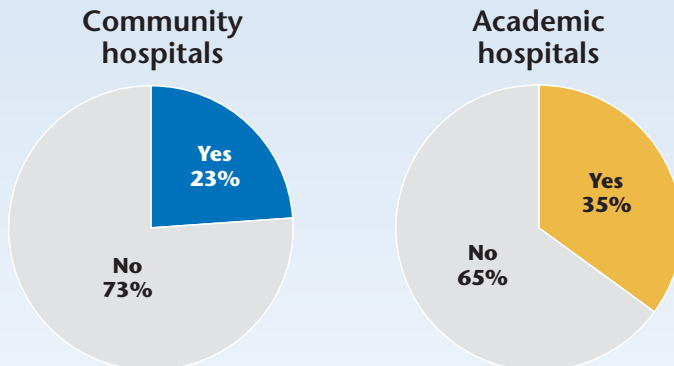


(ACS) as trained individuals who assist the surgeon "by helping to provide exposure, maintain hemostasis, and serve other technical functions."

In all, 67% of community hospitals and 53% of teaching facilities say they use first assistants on a daily basis. Several commented that they use first assistants for all

Human resources

Do you routinely use assistive personnel (eg, nursing assistants, orderlies) to perform certain tasks during surgery (ie, prepping and opening sterile supplies, holding a camera or a limb)?



Assistive personnel are assigned to . . .

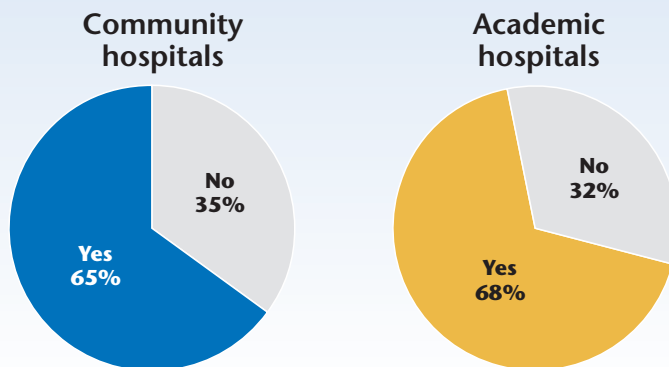
	Community hospitals	Academic hospitals
Prepping	14%	23%
Opening sterile supplies	64%	60%
Holding limb/camera	64%	60%

Other:

Community hospitals: Supporting anesthesia providers, retraction, second scrub.

Academic hospitals: Patient transfer, operating special equipment for total joint procedures, holding heart for CABG.

Are additional nursing personnel routinely assigned to monitor the patient for procedures performed under local anesthesia without sedation or regional anesthesia when monitoring is not provided by anesthesia personnel?



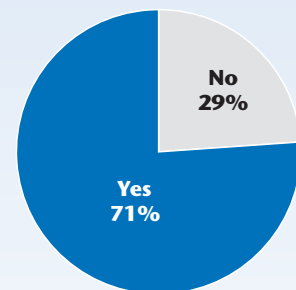
or nearly all procedures (related article, p 12).

For community hospitals, surgical technologists (STs) are the

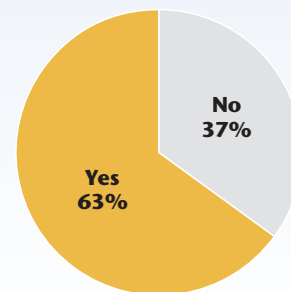
most common type of first assistants, while in teaching hospitals, physician assistants are most frequently used.

Are additional nursing personnel routinely assigned to monitor the patient for moderate sedation/analgesia when monitoring is not provided by the anesthesia provider?

Community hospitals



Academic hospitals



Specialty teams

Also widespread is the use of specialty teams, in which staff are regularly assigned to the same service or surgeon.

The vast majority of respondents—64% of community hospitals and 87% of academic hospitals—have regular teams for at least some of their specialties.

In community hospitals, medium-sized and large departments were the most likely to have specialty teams:

1-4 ORs	10%
5-9 ORs	42%
10+ ORs	43%

Teams were most common for

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Human resources

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orthopedics and cardiac surgery, though a wide variety of other types of surgery were named, including robotic, pediatric, bariatric, urologic, ophthalmologic, and endovascular surgery, to name a few.

"Everyone does all cases, but we have some people who do certain specialties on a regular basis," one person commented. Another said that staff are often assigned to certain surgeons rather than to a specialty.

Though a surgeon and staff satisfier, specialty teams can be difficult to balance with the need to maintain enough personnel with generalist skills who can staff a variety of cases and take call.

Assistive personnel

Assistive personnel, such as nursing assistants and orderlies, sometimes are used to stretch staffing for surgical cases. In all, 23% of community hospitals and 35% of academic facilities say they routinely use assistive personnel for tasks that don't require an RN or an ST. The most common duties are opening sterile supplies and holding a limb or camera, with fewer using them for the surgical prep. Examples of other tasks these assistants perform are providing retraction and holding the heart during coronary artery bypass surgery.

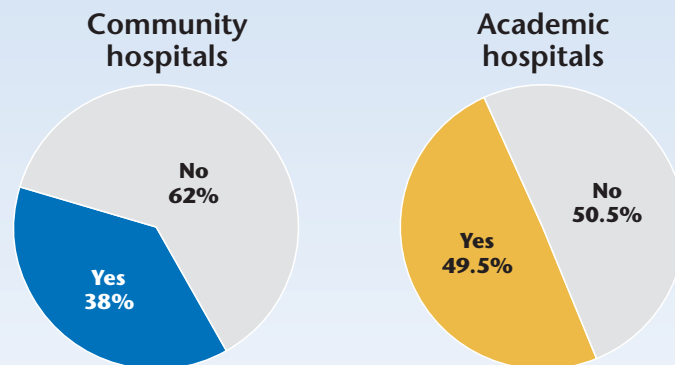
Floating for breaks

To provide scrub and circulating nurses with needed breaks and lunches, the majority of respondents—63% of community hospitals and 76% of teaching hospitals—have staff who are unassigned, or act as floats, to cover staffing needs during these periods.

Monitoring for sedation/analgnesia

For patients receiving sedation/analgnesia, 71% of community hospi-

Are additional personnel (more than 1 scrub and 1 circulator) assigned for robotic-assisted procedures?



Additional personnel assigned to robotic-assisted procedures

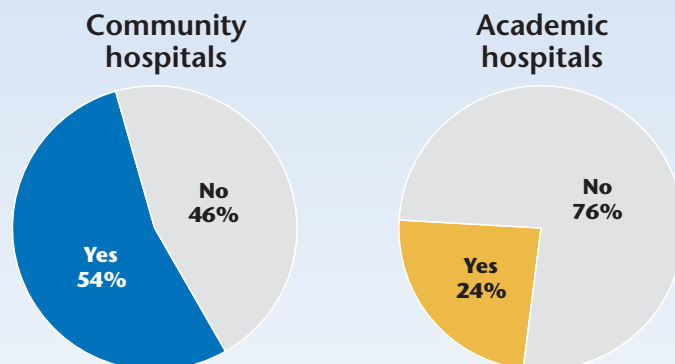
	Community hospitals	Academic hospitals
Additional scrub	43%	31%
Additional circulator	48%	71%
Other	48%	33%

Other:

Community hospitals: RN first assistant, physician assistant, depends on case, for urology only, only during beginning and end of case.

Academic hospitals: For orientation/training purposes only, additional circulator depending on service, second scrub for certain cases, surgical assistant.

Are additional personnel (ie, more than 1 scrub and 1 circulator) assigned for laparoscopic procedures?



Additional personnel assigned to laparoscopic procedures

	Community hospitals	Academic hospitals
Additional scrub	84%	70%
Additional circulator	8%	13%
Other	39%	35%

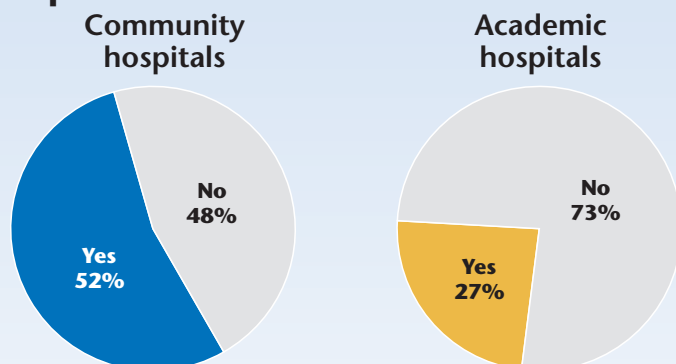
Other:

Community hospitals: First assistant, occasionally a camera holder, RN or scrub tech, additional circulator on complicated cases.

Academic hospitals: Surgical assistant, RNFA, CRNA.

Human resources

Are additional personnel (ie, more than 1 scrub and 1 circulator) assigned for surgery for morbidly obese patients?



Additional personnel assigned

	Community hospitals	Academic hospitals
Additional scrub	82%	46%
Additional circulator	27%	42%
Other	14%	38%

Other:

Community hospitals: Depends on need, extra scrub if staffing permits, based on weight, someone helps circulator with getting case started, second scrub when requested, first assistant, lifting help, third scrub.

Academic hospitals: Technical assistant, mainly for patient transfer, lifting team, RNFA.

tals and 63% of academic hospitals say they assign additional nursing personnel to monitor the patient when monitoring is not provided by an anesthesia provider.

Standards for monitoring during sedation/analgesia were imposed about 10 years ago after nurses reported they were being asked to administer anesthetic drugs and monitor patients, sometimes during long cases. Concerns were raised about patient safety as well as scope of practice. A number of professional associations adopted policies, and the Joint Commission adopted specific standards for sedation in 2000.

The 2010 Joint Commission hospital standards require persons giving moderate or deep sedation and anesthesia to "have credentials to manage and rescue

patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally." In addition, a sufficient number of qualified staff must be present to evaluate the patient, provide the sedation, help with the procedure, and monitor and recover the patient (PC.03.01.01).

AORN recommended practices specify that a perioperative nurse monitoring a patient receiving moderate sedation/analgesia should "have no other responsibilities that would require leaving the patient unattended or would compromise continuous monitoring during the procedure."

For patients receiving local anesthesia or regional anesthesia alone, 65% of community hospitals and 68% of teaching facilities say they assign an additional nurse to monitor patients.

Other cases to which additional personnel are assigned

Community hospitals

- Bone cleaning, procedures requiring
- C-sections, large abdominal cases
- Cardiovascular hybrid cases
- Endovascular aortic grafts
- Head and neck cases (simultaneous procedures)
- Laparoscopic Nissen
- Laser procedures
- Mammoplasties, reduction, bilateral
- Mastectomy with reconstruction
- Organ procurement
- Pain management
- Penile prosthesis
- Plastic cases (some)
- Prostatectomy, radical
- Shoulder arthroscopy
- Shoulder cases, open
- Thoracoscopy, video-assisted
- Thyroidectomy
- Trauma surgery
- Urology and GYN cases (all major)
- Vaginal slings
- Gallbladders (open)
- Urology cases (complex)

Academic hospitals

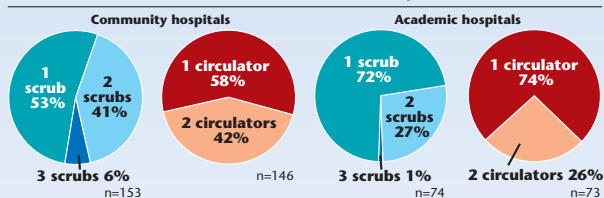
- Breast reconstruction
- Cases with multiple surgeons
- Cases using Cell Saver
- Cerebral aneurysm clipping
- Endoscopic skull base
- Hand cases (fast turnover)
- Head and neck resections (major)
- NICU and PICU patients
- Organ transplants
- Orthopedic cases (complex)
- Pain procedures
- Panniculectomy
- PE tubes
- Plastic free flaps
- Sentinel lymph node procedures
- Trauma

AORN recommends that the RN managing the care of a patient receiving local anesthesia "should monitor and interpret the patient's physiological and psychological responses throughout the procedure" but does not say the nurse must have no other duties.

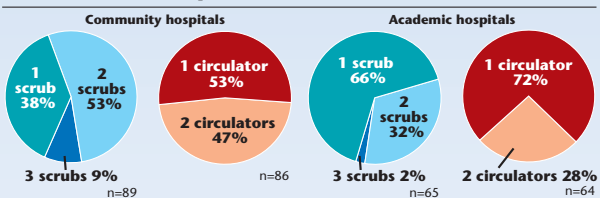
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How many staff are routinely assigned to . . .

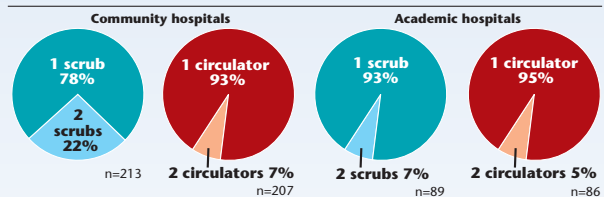
Abdominal aortic aneurysms



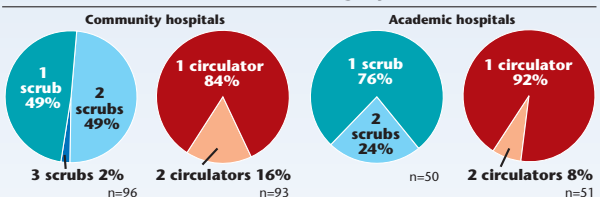
Cardiac procedures (CABG or valve)



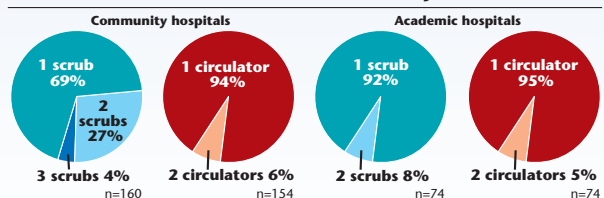
Arthroscopy procedures



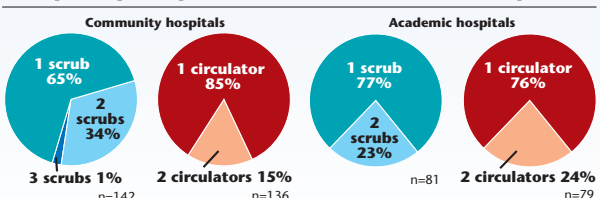
Bariatric surgery



Carotid endarterectomy



Complex spinal procedures (with hardware/implants)



Continued from page 9

Robotic-assisted procedures

For procedures performed with a robot, 38% of community hospitals and 50% of teaching facilities say they assign additional staff. For community hospitals, the type of additional personnel is evenly split between scrubs, circulators, or assistants. For teaching hospitals, additional staff are more likely to be circulators.

The additional staff help in setting up the equipment and starting the case as well as aiding turnover between cases.

At Ohio State University (OSU) Medical Center in Columbus, which was the first hospital to use a da Vinci robot and performs 1,200 robotic-assisted procedures a year, these cases are staffed by 1 scrub person and 1 circulating

RN. The lead ST or the RN service coordinator for robotics is available to assist with case setup, relief, turnover, and other needs.

Laparoscopic surgery

Just over half of community hospitals (54%) but only a quarter of academic centers (24%) in the survey assign additional staff to minimally invasive procedures. By far, the extra person assigned is in the scrub role.

One OR director says her facility assigns a second scrub to any case with a laparoscopic camera. "Our doctors demand it," she notes, saying it is "nearly impossible" to hold the camera still while reaching for instruments.

Others say a single scrub is adequate, or they assign an extra person only occasionally. One wrote that a metal arm is used to hold the camera.

Morbidly obese patients

About half of community hospitals (52%) and 27% of teaching centers provide additional personnel for patients who are morbidly overweight. By far, in community hospitals, these extra staff are scrub persons, while in teaching hospitals, they are split between scrub personnel and circulators.

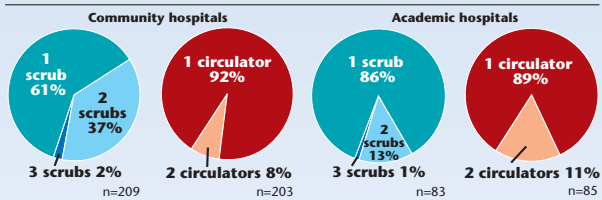
A number of respondents commented that they assign extra personnel depending on the need, physician request, or staff availability. "If needed for exposure and retracting," one wrote. "Someone will help the circulator with getting case started but [is] not assigned," said another. Others assign a first assistant rather than an additional scrub or circulator. ♦

—Pat Patterson

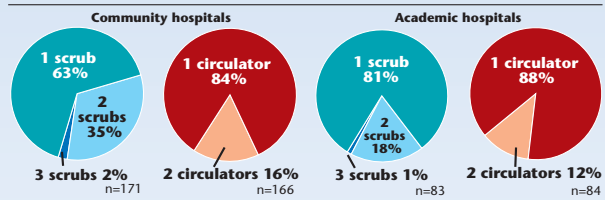
—Kathleen Miller, MSHA, RN, CNOR

How many staff are routinely assigned to . . .

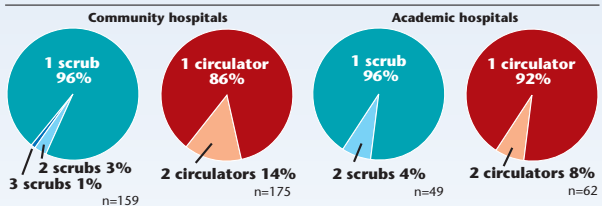
Major abdominal procedures



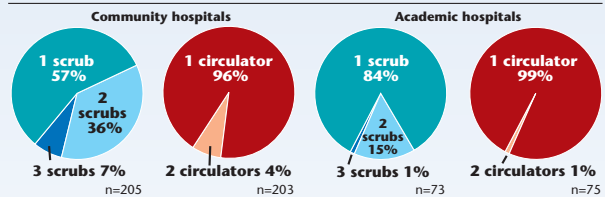
Thoracotomy procedures



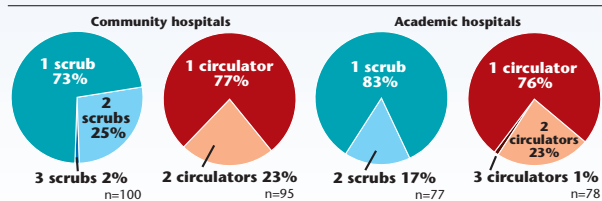
GI endoscopy



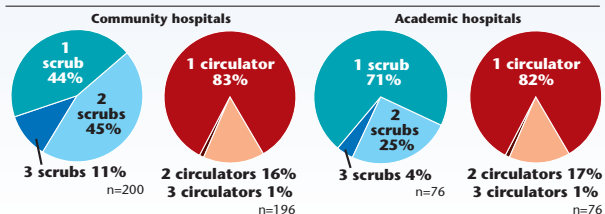
Vaginal hysterectomy



Neurosurgery (eg, tumor, acoustic neuroma, AV malformation)



Total joint replacement (hip or knee procedures)



References

AORN. Recommended practices for managing the patient receiving local anesthesia. *Perioperative Standards and Recommended Practices*. Denver, CO: AORN, 2010.

AORN. Recommended practices for managing the patient receiving moderate sedation/analgesia. *Perioperative Standards and Recommended Practices*. Denver, CO: AORN, 2010.

Joint Commission seeks input on proposed safety goals

The Joint Commission is seeking comments on 2 proposed National Patient Safety Goals—ventilator-associated pneumonia and catheter-associated urinary tract infections. The comment period ends January 27, 2011.

—www.jointcommission.org

Povidone-iodine during surgery lowers surgical infection rate

Intraoperative application of povidone-iodine significantly reduces the surgical site infection (SSI) rate, finds a meta-analysis from France of 24 randomized, controlled studies. The meta-analysis was published in the *British Journal of Surgery*.

The meta-analysis was performed to assess the effect of intraoperative application of povidone-iodine compared with no antiseptic solution (saline or nothing) on SSI rates.

In the analysis, the rate of SSIs was 8% in the povidone-iodine group and 13.4% in the control group.

The reduction in SSI rates was also statistically significant when the analysis was stratified by the method of administering povidone-

iodine (irrigation or spray) as well as the timing and type of surgery.

In all, 24 trials involving 5,004 patients (2,465 with povidone-iodine and 2,539 without) were included in the analysis.

Previous results controversial

Many studies have compared rates with and without intraoperative antiseptic irrigation, but the results have been controversial. The researchers say these results suggest that use of intraoperative povidone-iodine reduces SSI rates. ♦

—Fournel I, Tiv M, Soulias C, et al. *Br J Surg*. November 2010;97:1603-1613. www.bjs.co.uk

Providing first assistants common

Two-thirds of community hospitals and more than half of teaching hospitals responding to the *OR Manager* online survey use hospital-employed first assistants routinely.

The survey found a mix of personnel is assigned to assist, the most common being surgical technologists (STs), RN first assistants (RNFAs), and physician assistants (PAs).

Advanced technology and reduced resident hours are driving the use of assistants. OR directors also say many surgeons expect the hospital to provide an assistant, a factor in building surgeon loyalty.

With rising practice expenses and reimbursement pressure, some surgeons find they can no longer afford to employ their own assistants. Relying on their partners to assist has faded as physicians feel they need to spend more time in their offices seeing patients and generating revenue.

Survey comments reflect that trend. One respondent commented that an assistant is used in "almost all procedures."

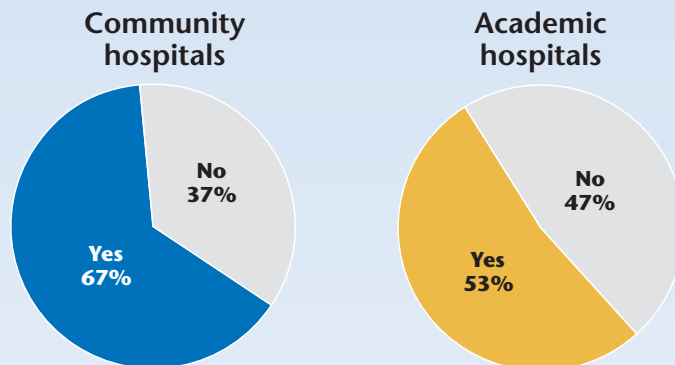
Another said: "Physicians are requiring an RNFA on almost all cases. We often have 4 staff on a procedure, especially lap chole, big abdominal cases, total joints, and ACLs," referring to anterior cruciate ligament repairs.

Said another, "We assign an RNFA for all cases in addition to scrub techs and circulators." Another respondent wrote, "We assign 1 scrub, 1 assistant, and 1 circulator for every case except eyes."

Assistants in teaching hospitals

Traditionally, teaching hospitals have relied on residents, fellows,

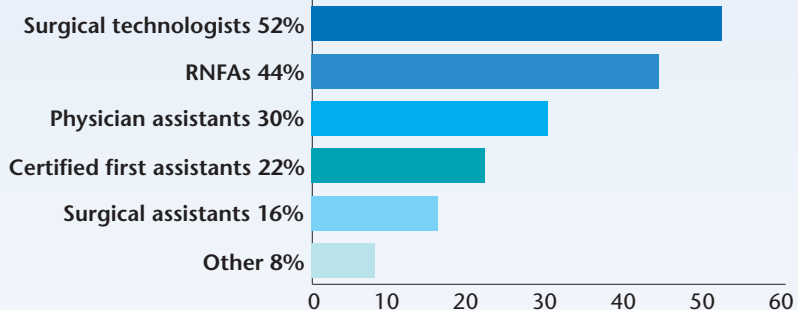
Are any of your hospital-employed staff assigned daily to be a first assistant?*



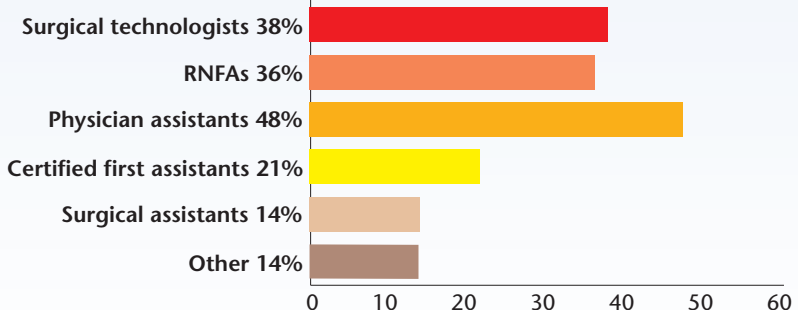
*RNFA, certified first assistant, surgical technologist, surgical assistant, physician assistant, or other.

If yes, what type of first assistants does your OR employ?

Community hospitals



Academic hospitals



Other: RNs, LPNs, nurse practitioners, RNFAs in training.

and medical students to assist in surgery. But more are now using nonphysicians.

"With restricted resident and fellow hours per week, the RNFA

and PA roles have become essential in meeting 24/7, 365 support," says Lynda Petty, BSN, RN, director of perioperative education, policy, and process improvement at

Human resources

Ohio State University Medical Center in Columbus.

Petty, who investigated the role of RNFAs in academic medical centers in the 1990s, says that while certain services, such as open heart and orthopedics, used RNFAs and PAs at that time, their use on other services was rare.

OSU hired its first RNFA in 2006, having had PAs on certain services for some time. RNFAs were first assigned to the open-heart service with PAs. With fellows and residents rotating through the service, Petty says the surgeons find RNFAs and PAs provide consistency and 24-hour coverage.

Who is first assisting?

Qualifications for first assistants aren't standardized, as evidenced by the variety of personnel named by the survey respondents.

The American College of Surgeons (ACS) says nonphysicians who first assist should have additional training and be credentialed "by the appropriate local authority." In addition, when RNs assist, ACS says:

- The size of the OR staff assigned to the case should not be reduced.
- The assistant should not be a substitute for the scrub person.
- Practice privileges for RN assistants should be granted based on the hospital's review and approval of credentials.
- RNs who first assist must not exceed the state's nursing practice act.

Though many ORs expect assistants to be certified, some allow staff RNs, LPNs, and STs to assist with additional training, such as a formal first assistant course.

"It's important to differentiate between an extra pair of hands and an RNFA, a CFA [certified first assis-

First assistants in robotic surgery

In evaluating staffing needs of surgeons who perform robotic surgery, Ohio State University (OSU) Medical Center, determined that a first assistant is required for gynecologic and gynecologic oncology cases for uterine manipulation and to insert instruments in the ports.

Though there are gray areas, Lynda Petty, BSN, RN, director of perioperative education, policy, and process improvement, says OSU decided credentialed first assistants are needed for interventions that involve:

- using instruments and medical devices
- providing exposure, handling and cutting tissue
- providing hemostasis
- manipulating the position of the uterus.

The first assistants include RNFAs, physician assistants, fellows, and surgical residents. These are sources OSU consulted in making its decision.

Resources

American College of Surgeons

Statements on Principles. I. G. Surgical Assistants

www.facs.org/fellows_info/statements/stonprin.html#anchor129977

AORN

- AORN Position Statement on RN First Assistants
 - Core Curriculum for the RN First Assistant
- www.aorn.org

Association of Surgical Technologists

Job descriptions for the surgical technologist and surgical assistant.

www.ast.org

State nursing practice act

tant], or a PA," says Denise Jackson, MSN, RN, APRN, CNS, CRNFA, an advanced practice nurse and certified RN first assistant for a large physicians' practice in west central Texas.

First assistants who are PAs or advance practice RNs are more versatile than an ST, she notes, because they help the surgeon with medical management of patients before and after surgery.

"If you can provide a well-trained first assistant who has developed a level of skill the surgeon trusts, that makes a huge difference for the surgeons," Jackson says.

At BryanLGH Medical Center in Lincoln, Nebraska, STs who assist

have taken a first assisting course or suture class sponsored by the local surgical tech school, says Holly Didier, RN, clinical manager of the ORs. "The surgeon cannot leave the room until the incision is closed if a surgical tech is closing." Surgeons request an ST who can assist and close if they do not have a PA or a private scrub.

Deborah Cooksey, MS, RN, CNOR, director of perioperative services for the 18 ORs at Jackson Hospital and Clinics in Montgomery, Alabama, says that with resident hours reduced and more technology-intensive surgery, "more hands are needed, and first

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assistants are a reasonable way to accomplish this." She also thinks assisting has "a huge benefit" as an advancement opportunity for peri-operative staff.

Jackson Hospital employs 1 certified first assistant and is sponsoring another in training. Cooksey recently received approval for education of a third assistant, who will be assigned to robotic surgery. The orthopedic surgeons employ their own assistants.

Managing first assistants

From a management standpoint, Cooksey advises managers to write the first assistant job description to include other duties they will perform when not in the assisting role.

"It is critical to make them accountable team members," she says. That includes being accountable for functions such as ORs starting on time and room turnover, the same as any other staff member. RNs should also expect to serve as circulators and STs as scrub persons when not assisting.

Wide variation in reimbursement

Reimbursement to physician practices for first assistant services varies widely, says Jackson. In her area, physicians still employ advanced practice nurses and PAs to assist. She is salaried, and the practice bills Medicare and private insurers for her services.

Texas, she notes, has one of the strongest RN first assistant reimbursement laws in the country. (AORN has a report on RNFA scope of practice and reimbursement by state at www.aorn.org)

Medicare reimburses under the physician fee schedule for first assistants who are MDs as well as for certain nonphysicians, such as

Top 10 technology hazards

If your organization is looking for patient safety priorities for 2011, ECRI Institute suggests considering its top 10 technology hazards:

1. **Radiation overdose and other dose errors during radiation therapy.** Radiation misadministration can have devastating consequences.
2. **Alarm hazards.** Most reports have been with physiologic monitoring systems and ventilators.
3. **Cross-contamination from flexible endoscopes.** Contamination from improperly reprocessed scopes has affected large groups of patients.
4. **The high radiation dose of CT scans.** High doses are believed to increase patients' risk of cancer.
5. **IT complications, such as data loss and system incompatibilities.** Though IT convergence has benefits, it also has risks.
6. **Luer misconnections.** Misconnections can allow gases or liquids to be introduced into the wrong lines or administration routes.
7. **Oversedation during use of PCA infusion pumps.** Oversedation

can lead to potentially life-threatening respiratory depression.

8. **Needlesticks and other sharps injuries.** The number of sticks continues to be staggering despite emphasis on safer devices and techniques.
9. **Surgical fires.** Recommendations by the institute and the Anesthesia Patient Safety Foundation advise a fire prevention and management program. A fire safety video is posted at www.apsf.org.
10. **Defibrillator failures in emergency resuscitation attempts.** Measures are needed to help ensure defibrillators are ready for use.

The list reflects ECRI Institute's judgment about risks that should receive priority based on its review of recent recalls, other actions it has examined, review of the literature and medical device reporting databases, and its investigating and consulting on device-related incidents. ♦

The full report with recommendations is available as a free download after registration at www.ecri.org.

nurse practitioners, physician assistants, and clinical nurse specialists.

Jackson says private insurance reimbursement for first assistants in her area varies by the contract. "There are different payments for the exact same code. It's really variable."

The new Institute of Medicine report on the future of nursing, with its emphasis on expanding roles for advanced practice nurses, is generating interest in the first assistant role, she says.

The report, released in October 2010, has a number of recommendations regarding nurses' roles, responsibilities, and education. Among the recommendations is to remove scope of practice barriers

that keep nurses from practicing to the full extent of their training. The barriers are a particular problem for advanced practice RNs, who will be needed to meet the nation's increased demand for health care, the report says. For more on the report, go to www.nap.edu/catalog.php?record_id=12956.

"We see more advanced practice RNs wanting to move into the first assisting role, and more RNFAs wanting to become advanced practice nurses." ♦

Reference

American College of Surgeons.
Statements on Principles. I.G.
Surgical Assistants.

www.facs.org/fellows_info/statements/stonprin.html#anchor129977

A sound process for acquiring tissue

Fourth in a series on managing bone allografts.

A surgeon has requested a new tissue graft not in the current inventory. From the company's literature, it's not easy to tell whether the tissue is similar to others already in stock.

Decisions like these are challenging because tissue grafts come with a host of safety, clinical, and cost issues.

"We are dealing with donated tissue, the same as a unit of donated blood. This is not just a medical supply," notes Victoria Steelman, PhD, RN, CNOR, FAAN, of the School of Nursing, University of Iowa Hospitals and Clinics, Iowa City, an expert on tissue management.

A systematic approach can help ensure that surgeons have the materials they need while also making sure newly acquired tissue is safe and avoids unnecessary duplication and cost.

This article, part of a series that began in the October 2010 issue, suggests steps and criteria for selecting bone allografts. Previous articles have covered the donor screening and recovery process, types of bone allografts and their roles in healing, and tissue processing and regulation.

Critical elements in the selection process include:

- a multidisciplinary team
- physician participation
- criteria for selecting tissue suppliers and evaluating tissue.

(Suggested criteria with ques-

**This is not
just a medical
supply.**

tions to ask suppliers are in the sidebar, p 16.)

Know your tissue supplier

The first step is to select suppliers who adhere to strict standards for donor screening, tissue procurement, processing, and distribution.

"You want to make sure you are dealing with a supplier that is highly ethical," Steelman emphasizes.

The reason became dramatically clear a few years ago when a ring operating in the Northeast procured tissue fraudulently, resulting in 25,000 grafts entering the market without proper donor consent or screening.

A number of patients were harmed, including a Philadelphia woman who developed sepsis after receiving a graft in a hernia repair, a man who tested positive for HIV and hepatitis C after receiving bone implants, and a Colorado woman who needed repeated anterior cruciate ligament repairs after her tendon implant failed, according to *Philadelphia* magazine.

A few years earlier, a 23-year-old Minnesota man died after receiving a contaminated knee graft. Investigators found 14 patients had received tainted grafts from the same tissue bank, the *New England Journal of Medicine* reported.

When the tissue was recalled,

hospitals and surgery centers had to scramble to identify whether grafts from these donors were in their inventory or had been implanted.

The events led to more stringent requirements from the Food and Drug Administration (FDA) and the Joint Commission.

Check registration, accreditation

To know your supplier, at a minimum, make sure the supplier is registered with the FDA, says Steelman. Registration must be checked annually—"it's not a one-time check," she adds. Registered suppliers are posted in the FDA's online database. (See Resources, p 17.)

Accreditation by the American Association of Tissue Banks (AATB) is also strongly recommended. It's important to check specifically what the supplier is accredited for, Steelman advises. "Is the tissue bank accredited just for distribution or is it also accredited for processing and procurement?"

Expect the supplier to provide detailed information about its donor selection criteria, tissue testing, and tissue processing as well as evidence that these processes have been validated.

Also find out if the FDA has taken any actions against the tissue supplier. Notices of recalls are posted on the FDA website. The FDA also issues several types of regulatory action letters against tissue banks, available on its website.

Despite today's stricter standards, one area that still may be difficult to probe is where a supplier obtains its tissue. This information is difficult to get from some

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Questions for tissue suppliers

1. How long have you been in the tissue banking industry?
2. What is the evidence attesting to the quality of your tissue bank?
3. What types of tissues do you process? Please include a brief description of tissues processed.
4. Are you accredited by the American Association of Tissue Banks (AATB)? If so, in what areas are you accredited? Please provide the current certificate.
5. If you do not perform tissue recovery, please list your recovery partners.
6. Where is the donor tissue recovered, domestically or outside the US?
7. How is donor tissue recovered? Under what types of controlled conditions?
8. From how many donors do you recover tissue annually?
9. Please supply your donor selection criteria with respect to criteria that may negatively affect tissue safety and quality.
10. Are consistent medical and social screening and selection criteria applied to all donors?
11. Who makes the final decision on donor tissue acceptance and release? What is this person's background?
12. Do you ever accept a deferred donor or donors previously rejected by one or more other tissue banks?
13. How is tissue processing performed? Is processing performed strictly aseptically, or are terminal sterilization methods used?
14. If terminal sterilization methods are used, what type is used, and what is the level of irradiation?
15. Please supply a description of your processing protocol.
16. What solutions are used in the processing of soft tissue grafts?
17. Do demineralized bone allografts that you provide possess any osteoinductive potential? Please substantiate such claims.
18. Please provide the percentage bone content and residual calcium levels in your demineralized bone products.
19. Do you have a validation process for package sterility?
 - validation tests of the package's sterility
 - use of identifying numbers by which the allograft can be traced to a specific donor as well as the time, place and manner in which the allograft was recovered.
20. Do you have the ability to trace all allograft tissue to the specific donor? Please provide specifics on your tracking methods.
21. What is the shelf life of the package, during which the sterility of its contents is guaranteed?
13. How is tissue processing performed? Is processing

Source: Musculoskeletal Transplant Foundation.

Continued from page 15

suppliers, Steelman notes. If the supplier obtains its tissue from another source, it's important to ask how the supplier ensures the tissue is safe.

Are tissues delivered appropriately?

One weak point in tissue distribution continues to be hand delivery by vendor representatives.

"The hospital or ambulatory surgery center has no way of knowing how the tissue has been stored and if the requirements for storage have been met," Steelman points out, adding, "This practice should be prohibited."

Your facility is accountable for making sure tissue is transported properly. The Joint Commission tissue management standards require facilities to verify that the package integrity is met and transport temperature is controlled for tissues that require a controlled environment (TS.03.01.01). FDA regulations require tissue suppliers to have conducted validation testing on their packaging methods.

Small distributors of medical devices that provide tissue need to be registered with the FDA, just like any other tissue supplier.

The selection process

In acquiring new graft materials, a well-defined process is the best way to address surgeons' requests, ensure tissue is acquired from a safe source, and assess whether the tissue is a clinically efficacious and cost-effective addition to the OR inventory, Steelman advises.

This process is most likely to be successful if a strong medical director heads the tissue bank in your facility. The trend, she says, is to centralize tissue management in the blood bank. "There are good

Managing biologics

reasons for that," she says. The blood bank is accustomed to the FDA tissue regulations, which were patterned after the regulations for blood.

Process steps

The process for considering new tissue materials might include:

- Criteria for tissue suppliers and tissue selection established in advance by a multidisciplinary team with input from surgeons. (Suggested questions to ask suppliers are in the sidebar.)
- A list, or formulary, of tissue materials that will be stocked in the facility, similar to a formulary for pharmaceuticals.
- A standardized process for considering surgeon requests for tissues not in the formulary. This might include a form for the surgeon to complete justifying the need for the tissue.

A surgeon may have a valid reason for requesting a graft that is not on the facility's formulary. But having a defined process with a formulary is a good way to man-

age the inventory and minimize the cost while still providing surgeons with what they need, she says. Then the onus is on the surgeons to support their requests.

Clinical efficacy

Determining the efficacy of a tissue material is not always easy. Published evidence from the peer reviewed literature may be sparse or lacking.

In evaluating a new tissue, it helps to know the graft's intended purpose and how is it classified. Is it osteoconductive, meaning it provides a scaffold for bone formation? Does the graft also need to provide signals to induce bone formation (osteoinductive) or have cells capable of forming bone (osteogenic)? (A chart for classifying grafts was in the November *OR Manager*.)

The American Academy of Orthopaedic Surgeons (AAOS) outlines principles for assessing the clinical burden of proof in its publication, *The Evolving Role of Bone-Graft Substitutes*:

- Consider the healing environment where the graft is needed. Environments have different levels of difficulty for forming new bone. Examples are a metaphyseal defect, a long-bone fracture, or an interbody spinal fusion.
- Seek the highest burden of proof from clinical and preclinical studies to justify the use of an osteoinductive graft material or the choice of one alternative over another.
- Recognize that there is no standardized burden of proof for materials such as demineralized cortical powder or platelet gels with autologous growth factors. These are regulated by the FDA as tissues rather than as medical devices because they involve "minimal manipulation" of tissue.

"As a result," says AAOS, "there is no standardized level of proof of safety and effectiveness required before these products are marketed and are used in patients."

There are no easy answers to managing the complex area of tissue grafts. But having a systematic process with strong multidisciplinary involvement and support is a step in the right direction. ♦

—Pat Patterson

This series is a collaboration between OR Manager and the Musculoskeletal Transplant Foundation.

Tissue regulation resources

American Association of Tissue Banks

www.aatb.org

Food and Drug Administration

Center for Biologics Evaluation and Research (CBER)

Registration of tissue establishments

www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/FindaTissueEstablishment/ucm110270.htm

Information on biologics for health care providers

www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/HealthcareProviders/default.htm

Information on regulatory action

www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/default.htm

Warning letters

www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

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American Academy of Orthopaedic Surgeons. *The Evolving Role of Bone-Graft Substitutes*. Rosemont, IL: AAOS, 2010. Single copies free for download at www.aaos-inc.com/aaos_publications/

Kainer M A, Linden J V, Shaley D N, et al. *Clostridium* infections associated with musculoskeletal-tissue allografts. *N Engl J Med*. 2004;350:2564-2571.

Retained items

Continued from page 1

Role for technology

A role for technology is being recognized in the literature and professional guidelines.

The Mayo Clinic, examining RSIs that occurred in its organization between 2003 and 2006, concluded that manual counting was unreliable as the primary means for avoiding RSIs and that investigating new technologies for achieving reliable counts is warranted (Cima et al, 2008).

AORN's new "Recommended practices for the prevention of retained surgical items" say that adjunct technologies may be considered to supplement manual counts, in addition to improving manual counting methods. The recommendations advocate a multidisciplinary approach to accounting for soft goods, sharps, and instruments plus standardized measures for counting and addressing count discrepancies.

An expert on RSI prevention, surgeon Verna Gibbs, MD, advises caution when considering technology.

"Technology adds another layer to already complex OR systems," she observes. "And technology requires human interface and interaction, which invite new opportunities for error. We also haven't seen how all the new developments will actually work in OR environments."

She says sponges have been retained with the new systems, "because humans operate the technology."

"Technology is not the answer but can assist with a difficult and persistent problem. It is up to hospitals to look at all the solutions that are out there and find what will work best for them."

How do you know the chip won't fall off?

Technology is also expensive. Each technology has sponges that are unique to its system and provide the companies with a continuing source of revenue. Once a hospital buys one company's sponges, it can't easily change to another system, Dr Gibbs points out.

Dr Gibbs, developer of the NoThing Left Behind campaign for RSI prevention (www.nothingleft-behind.org), is professor of clinical surgery at the University of California, San Francisco, and a surgeon at the San Francisco Veterans Affairs Medical Center. She has been testing a refined manual counting method, called Sponge ACCOUNTING, which she says is coming up on a year of experience in 40 hospitals with no retained items reported.

Technology update

Here's an update on the 4 companies that have Food and Drug Administration (FDA) clearance for their counting/detection systems.

The systems perform 3 basic types of functions: count sponges, detect sponges, or count and detect sponges and instruments.

Counting and detecting instruments

As the newest technology, OR-Locate (www.orlocate.com) counts, tracks, and monitors both surgical instruments and sponges in the OR using radiofrequency identification (RFID).

Some retained items beyond reach of technology

Though technology may help prevent some retained items, it wouldn't have prevented 6 of the 8 events recently reported from California. Eight of the state's hospitals were fined \$25,000 to \$75,000 in November 2010 for retained items, including:

- 2 sponges
- a blade for a retractor delivered by a sales rep at the last minute
- part of a Guidant Heartstring proximal seal system
- a guidewire
- a non-radiopaque blue towel used to stanch bleeding in an emergency case
- a malleable retractor
- a drill bit.

Under California law, retained items are one of 28 medical errors hospitals must report because they place patients at risk of death or serious injury. The state can issue fines of \$50,000 for the first event, \$75,000 for the second, and \$100,000 for the third or subsequent errors at the same hospital.

The reports are posted at www.cdph.ca.gov/Pages/NR10-87.aspx

Each instrument and sponge is tagged with an RFID chip, giving the item a unique identity that tells not only where the item is but which item it is. The system confirms that counts are correct or incorrect, and if a sponge or instrument is missing, which one it is.

The RFID chip, the size of a

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The 24th annual

Managing Today's OR Suite

with the
**OR Business
Management
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**Hyatt Regency
Chicago**

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*Cloud Gate, the sculpture by Anish Kapoor,
in Chicago's Millennium Park. Photo by Patrick Pyszka.*



Surgical item counting and detection technologies

	Data matrix label	RFID chip	RFID chip	RF tag
Brand name	SurgiCount Safety Sponge System	ORLocate	ClearCount Smart-Sponge System	RF Assure Detection System
Web site	www.surgicountmedical.com	www.orlocate.com	www.clearcount.com	www.rfsurg.com
Distributor	Cardinal Health		Cardinal Health	Medline Industries
FDA cleared	March 2006	August 2010	June 2007	November 2006
What it does	Counts sponges	Counts/detects instruments/sponges	Counts/detects sponges	Detects sponges
What's new	New model scanning device has improved battery life; brighter, higher resolution screen; and faster processor/imager. Regular software upgrades.	Newest system to enter market is first to count, detect instruments.		New detection mat has radiolucent antennas in a gel pad used to scan entire body at end of case with a touch of a button.
System components	<ul style="list-style-type: none"> • Bar-coded sponges and towels • Touch-screen scanning device • Database application that allows for review, management, and analysis of counting reports 	<ul style="list-style-type: none"> • Sponges and instruments with RFID chips • Touch-screen console for tracking and monitoring sponges and instruments • Antennas detect and count sponges and instruments used during the case • Locator wand to scan for instruments or sponges • Asset management module available 	<ul style="list-style-type: none"> • Sponges and towels with RFID chips • Scanner reads and records unique ID for each sponge and verifies initial count • Scanner bucket counts sponges and matches ID number of sponges to initial count • Wand to scan body before case is closed when counts don't match 	<ul style="list-style-type: none"> • RF tagged sponges and towels • RF detection console • RF detection mat used to scan body at end of case • Wand to scan linen and trash bins and around sterile field to locate a missing sponge • Reporting capabilities
Cost	\$12 per case	\$100,000 per OR, could be reduced to \$70,000, depending on number of ORs	\$10-\$13 per procedure	\$15 per case
No. of installations	>50 hospitals	Pilot expected to start in January 2011	56 hospitals	>100 hospitals

Note: Cost and installation data provided by companies.

Continued from page 18

small hearing aid battery, comes embedded in sterile surgical sponges and can be laser-welded in a ring to existing instruments. A flat surface area of at least 3 mm is needed to attach the chip.

The system also requires trays with detecting antennas for the Mayo stand and back table as well as a kick bucket with antenna, which can read how many and what kind of sponges or instruments are placed on or in them.

Dr Gibbs terms as "revolution-

ary" the company's ability to attach to instruments an RFID chip that can withstand sterilization.

ORLocate's general manager, Donald Mudd, says a common question the company receives is, "How do you know the chip won't fall off in the sterilizer?" He says

5 top reasons counts are likely to fail

An analysis shows the top 5 causes for potential failures involving manual surgical counts are:

- distraction
- multitasking
- not following procedures
- time pressure
- emergency cases.

The findings are from a failure modes and effects analysis (FMEA) on managing sponges, conducted by Victoria Steelman, PhD, RN, CNOR, FAAN. The study has been accepted for publication by the *AORN Journal*.

Education—the number one intervention after a retained item event—won't fix the problem, she says, because none of the failure modes is related to a knowledge deficit.

Other common strategies used after an event, disciplining the employee or reinforcing the policy, work only 14% of the time, she notes.

Counting is not enough to prevent retained sponges 100% of the time, Steelman notes, and ORs need to start evaluating the available technology for assistance.

"I'm not advocating for one technology over the others," she says. "I'm just saying that it's time we start looking at technology to assist us with this. I think all of the technologies are an improvement over counting alone."

the company's laboratory testing shows there have been over a thousand cycles of sterilization of these instruments without failures. "The instrument will have to be replaced before the chip," Mudd says.

Sponges were our biggest problem.

The system costs \$100,000 per OR, which could be reduced to \$70,000, depending on the number of ORs. The company has a mobile lab for retrofitting existing instruments. If a hospital buys 5 OR systems, the company will tag 1,000 instruments at no charge; if 10 systems are purchased, 2,000 instruments will be tagged at no charge. Additional instruments are tagged for a nominal price.

ORLocate expects to pilot its system in January 2011.

Asset management system

ORLocate offers an additional platform for use as an asset management system in sterile processing departments (SPD). Dr Gibbs notes this is a unique attribute of this technology. Because each instrument with a chip has a unique identity, the system can be used to determine which instruments are in which trays and to keep track of instruments needing repair. If an instrument is missing, the system can tell which one. The system can also show how many times an instrument has been used and when it is approaching the end of its life cycle. SPD packing station systems list for \$14,500 each; an administrative station lists at \$13,500.

Computer-assisted sponge counting

The SurgiCount Safety-Sponge System (www.surgicountmedical.com) is the only system that uses a 2-dimensional data matrix label to

count sponges. A computer-assisted scanner records the unique code embedded in each sponge. The size and flexibility of the data matrix code allow it to be embedded even in tiny neuro patties and tonsil sponges, the company says. At the end of a case, the system generates a report of the count.

Sponges are scanned and recorded during initial and final counts. Because each sponge has a unique code, the technology will not allow the same sponge to be counted more than once.

The Mayo Clinic in Rochester, Minnesota, has been using the Safety-Sponge System for the past year with no retained sponges identified.

"We concluded that sponges were our biggest problem, and we wanted to add technology to help with the counting," said Robert Cima, MD, MA, vice chairman, department of surgery and associate professor of surgery at the Mayo Clinic. Speaking at the Managing Today's OR Suite Conference in the fall in Orlando, he reported that the technology has reduced total reportable RSIs by nearly 70%.

Notes Dr Gibbs, "We have seen this system being adopted at large single institutions that have a lot of complexity and turnover of residents and nurses."

RFID chip technology

The SmartSponge System (www.clearcount.com), an RFID-based technology, combines sponge counting and detection. The system reads and records a unique identification (ID) number for each sponge during the initial count and provides a 1-to-1 reconciliation in the final count by matching the ID numbers to sponges. The embedded RFID tags are smaller than a dime.

At the beginning of a case, the

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nurse passes the sponges over a scanner that counts and reads each sponge's ID. The system's LCD screen shows the rolling count.

When surgery is complete, the used sponges are placed in a "smart" bucket that counts each sponge, even if the sponges are stuck together, and the count is displayed on the screen. Because RFID does not require a line of sight between the reader and RFID chips, there is no need to separate sponges or orient the chips in order to scan them, the company says.

"The smart bucket may prove to be a real work saver and safety device for OR nurses, who one day may not have to touch bloody sponges to count them," Dr Gibbs notes.

When initial and final counts don't match, a wand is used to scan the body before the incision is closed to detect if a sponge is present. A light on the wand turns red, and an alarm sounds when the sponge is found. The sponge must be retrieved and added to the bucket to reconcile the final count.

A small 2006 study of an investigational device using this technology by Alex Macario, MD, and colleagues found a detection accuracy of 100% for the wand device.

RF tag technology

RF Surgical Systems, Inc (www.rfsurg.com) has added a new detection mattress system to its sponge detection technology, which uses RF tagged sponges. The company continues to offer a detection wand for locating lost sponges that may be in the trash, linen, or elsewhere in the room.

RF Surgical uses passive low-frequency RF tags, which the company says perform better than RFID chips in fluids and blood,

New detection mattress has antennas.

dense tissue, and through bone and metal without interfering with OR equipment. The RF tags have a yes-no signal to indicate whether an item is present but do not have a means to count items.

The new detection mattress contains an array of 6 radiolucent antennas. The patient lies on the reusable gel mattress, which is covered with a sheet during surgery. At the end of the case, the nurse pushes a button to perform a hands-free scan of the entire body. If an RF-tagged sponge has been left in the patient, an alarm sounds, and a visual display on the console alerts the staff.

"The mattress eliminates human error in the wandering," Victoria M. Steelman, PhD, RN, CNOR, FAAN, told *OR Manager*. Steelman, who is assistant professor in the College of Nursing, University of Iowa Hospital and Clinics, Iowa City, performed a study to find if RF technology could detect sponges through the torso of morbidly obese patients. She found the wand alone had 100% sensitivity if used correctly.

Interim results of a 5-hospital study indicated the RF technology reduced the need for postop x-rays, decreased stress in the OR during closing, and easily identified retained foreign objects. A poster on the study was presented at the American College of Surgeons meeting in Fall 2010 by Christopher Rupp, MD, a surgeon at the University of North Carolina. The study

was partly funded by RF Surgical. ♦
—Judith M. Mathias, MA, RN

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Small outpatient pay updates in 2011

Hospitals and ambulatory surgery centers (ASC) will receive small rate increases for outpatient services under the Medicare Outpatient Prospective Payment System rule for calendar year 2011.

Hospitals face new quality reporting requirements, but none of the new measures is directly related to surgery. ASC quality reporting was postponed once again.

Here are highlights of the rule issued in November 2010 by the Centers for Medicare and Medicaid Services (CMS).

Payment rates

Hospital outpatient payments will rise by 2.35% for inflation. (The actual change in the hospital market basket was 2.6%, but that was reduced by 0.25 percentage point, as required by the health care reform legislation.)

For ASCs, the update is 0.2% after taking into account an inflation increase of 1.5% and a decrease of 1.3 percentage points mandated by the health care reform act.

The ASC Association notes the increase is actually better than the zero CMS had proposed because of adjustments the agency made. But the association protests that the amount is inconsistent with a recommendation for a 0.6% increase by the Medicare Payment Advisory Commission (MedPAC).

Other factors also affect ASC rates in 2011, including changes in procedure relative weight, secondary rescaling, and wage index changes.

This is the first year ASC rates are based entirely on the new ASC payment system, which has been through a 4-year transition. The

new system generally pegs ASC Medicare payments to hospital outpatient rates.

Overall, the government projects 2011 spending of about \$39 billion for hospital outpatient services and \$4 billion for ASCs.

ASC procedures added

The rule adds 6 procedures to the list Medicare will pay for when performed in an ASC. These include transcatheter occlusion or embolization (CPT 37204), uterine fibroid embolization (37210), and iliac artery stent placement (37221, 37223). Also added are 50593 (ablation of renal tumors) and 52649 (prostate laser enucleation).

Hospital quality reporting

For hospitals, CMS added to the list of outpatient quality measures that will need to be reported in future years for a full outpatient payment update. None pertains directly to surgery.

- 4 measures are added for the 2012 payment determination, bringing the total list to 11. One measure is for health information technology, and 3 are for imaging.
- 8 measures are added for payment determination in 2013, for a total of 23 measures. Of these, 1 pertains to electronic health records, and 6 apply to the emergency department.

CMS plans to require reporting of all 23 measures for a full payment update in 2014.

The 2 surgery-related measures continue to be:

- OP-6: Timing of antibiotic prophylaxis
- OP-7: Antibiotic selection for surgical patients.

Under the rule, CMS will validate quality data from 800 ran-

domly selected hospitals, auditing 12 cases each per quarter. The hospitals will have to score at least 75% in the audits to receive their full outpatient pay update in 2012. Audits will not affect payments in 2011.

ASC quality reporting postponed

Quality reporting for ASCs was again postponed for 2011. CMS has had the authority since 2008 to implement a quality reporting system for ASCs and to reduce payments to facilities that do not report their data. But so far, CMS has decided not to exercise this authority, the ASC Association notes.

Health reform

As part of the health care reform legislation, known as the Affordable Care Act, under the outpatient rule, Medicare patients can now have an initial physical exam and preventive services without a deductible or copay. Examples are blood pressure screening, screening mammograms, cholesterol screening, and screening for colorectal cancer.

CMS decided not to finalize an outpatient payment adjustment for cancer hospitals in 2011. The Affordable Care Act required CMS to conduct a cost study of outpatient costs in certain cancer hospitals and make a payment adjustment if cancer hospitals were found more costly. ♦

The rule is posted at www.cms.gov/HospitalOutpatientPPS/HORD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1240960&intNumPerPage=10



Ambulatory Surgery Centers

Best ASC supply chain practices

Medical-surgical supplies are essential to the delivery of health care. That is why even small hospitals usually have a staff member who is in charge of ordering, buying, stocking, and distributing the thousands of supplies and who knows how to manage vendors and negotiate contracts. Larger hospitals have high-level executives who manage trained professionals running multi-million-dollar supply chain operations.

Few ambulatory surgery centers (ASCs) have such a luxury. Yet they still need supplies, and both business and clinical success depend on being able to procure the right products for the right price. Those materials management duties usually fall to nurses and office managers.

The ASC advantage

Knowing a few basic principles can help them perform those duties more easily and efficiently. Overflowing a room at the Ambulatory Surgery Center (ASC) Association conference in the spring,

“
**Begin
with a
strategy.**
”

ASC managers demonstrated their interest in adding best practices in materials management to their range of knowledge.

There to help was Michael Neely, president of the consulting firm Perimeter Solutions Group in Atlanta. Neely, who spent 20 years as a hospital materials manager before becoming a consultant, founded Perimeter 5 years ago.

When it comes to dealing with vendors, he says, “ASCs don’t have the same leverage as hospitals in controlling expenses because of their lower purchasing volume.” At the same time, those owned by physician investors have an advantage, he says, when selecting high-priced devices subject to

physician preference. Physicians who have a financial stake in the surgery center are more likely to consider standardizing their choices to save money.

Finding best practices

“Implementing best practices will pay dividends and go a long way toward creating a professionally managed materials department in any ASC,” Neely says.

Best practice, according to Neely, means having a strategy for managing materials and costs. Elements of that strategy include working with vendors, clinicians, and financial managers to establish supply budgets and procurement policies. Too often, Neely says, the focus is on reducing prices paid for products. A better practice is to look at the cost per case for each procedure and establish a process to stay within limits. Measure all cost variables for a case: products, time, and labor.

“Utilize performance measures and metrics,” he says, “because improving performance is dependent

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upon measuring progress.”

Items to measure may include linen use in pounds per patient, personal care items provided on admission, and medical supplies used in procedures. He advises tracking:

- the number of expired products on hand at the end of each quarter
- fill rates, which reflect how well vendors comply with purchase orders
- inventory accuracy determined by comparison of products on hand with established par levels.

When surgical teams improve budget discipline, he adds, ASC managers should reward them and share news of their achievements with the rest of the staff.

Value analysis means informed decisions

Before selecting a new product, most hospital materials managers rely on the value analysis process. At too many ASCs, Neely says, the decision to introduce a new product includes little review of the proposed product, or of products already in use.

“The best practice is to implement value analysis,” he says.

Hospital value analysis can be rigorous. Often a committee shares the work, with representatives from purchasing, clinical departments, and perhaps specialties such as infection control, radiology, or facilities management where such product knowledge is helpful. Ideally, the value analysis committee also includes employees who actually use the products. For the most expensive devices and equip-

Focus beyond best price.

ment, a financial manager or reimbursement expert might step in to describe the implications of choosing a particular product.

The process starts with a determination of need. Whether a physician wants to try a new type of instrument or the contract for house-keeping supplies is about to expire, there is an expectation that the organization needs to buy something.

Value analysis is the weighing of alternatives. Which products are clinically appropriate, or effective in the opinion of the user department? Of the acceptable products, which is the least expensive?

Expense is not limited to price. It also includes the expected useful life of the product, maintenance costs, and expenses related to implementation, such as staff training or allocation of additional space. The best choice will be the product that provides the most additional value (such as improved clinical outcomes) at the lowest expense.

Benefits of standardizing

A common result of the value analysis process is that the committee will identify the best product but find that the facility already uses a variety of similar items, often because of physician preferences. Convincing the group to standardize brings a host of bene-

fits, such as the lower prices that come with higher purchasing volume; the efficiencies from having fewer product codes to order and inventory; and having a product that is familiar to all users.

According to Neely, the elements of effective value analysis are:

- a formal process
- an interdisciplinary team
- a review of expenditures
- defining the need
- application to all products and services
- elimination of unnecessary costs
- a result that maintains or improves quality.

Making the deal

The materials manager or the ASC staff member filling that role has the job of negotiating a contract for the selected product. Even if the facility’s group purchasing organization has the vendor and product on contract, the materials manager may be able to obtain a better price by pointing out that the ASC has decided to use the vendor’s product exclusively.

To make the value analysis committee’s decision stick and to maintain negotiating leverage with the vendor, the ASC must have a consistent purchasing policy for the entire organization.

According to Neely, it is common for purchasing decisions to be left up to individual departments. A better practice, he says, is for materials management to be covered under the administrative policies, which apply to all departments.

Among those policies should be the use of purchase orders. Strict guidelines should cover who may order products at various spending

levels, how to ensure contract compliance, and how to obtain exemptions in special cases.

Vendors should be part of the system, not adversaries, most materials managers agree. There is a long tradition, however, of vendors seeking to maximize sales and profits by cultivating separate relationships with physicians and using them to override purchasing policies. Materials managers need to be aware of this and be prepared to treat vendor reps fairly but as equals.

For example, many companies have their own standard contracts containing their terms and conditions and expect customers to sign and accept them. There is no reason the ASC should not develop its own terms and conditions, incorporate them in a policy, and present them to the vendor.

"You gain leverage by presenting your terms first and establishing control from the start," he explains. It helps to use a team approach, with both supply and clinical people at the negotiating table, to make it clear that the entire facility is united in its approach to purchasing.

Managing orders and inventory

How often and how much to order vary by product. For each product, determine the annual usage, the cost of issuing a purchase order, the price of the item, and the annual cost of holding it in inventory. In general, higher cost items should turn over more frequently, while lower cost items can be ordered less frequently in larger quantities. However, products with expiration dates need to be ordered



Use performance metrics.



with those life cycles in mind to avoid having to dispose of expired items or, worse, to need an item for a procedure and find it has expired. Rather than comprehensive annual inventories, he recommends shorter cycles and regular reports based on item counts as well as dollar values.

"It's not about keeping inventory as low as you can," Neely notes. "It's about finding the right level, one that optimizes turnover."

Custom packs are susceptible to becoming obsolete as preferences change. "Routinely review packs for usage, alternatives, and cost," he says. There may be a standard kit that provides the same items at a lower cost.

At most ASCs, space is limited, and supplies tend to be kept in multiple locations. Try to find a central storage location, Neely advises. That makes inventory control easier and makes the supplies accessible to all. It also frees space in procedure rooms.

Outdated equipment and supplies that are no longer needed may also be taking up precious space. Consider selling or donating them, he says. "One facility's junk is someone else's treasure."

A well-organized materials management system will save money, often a substantial amount

soon after implementation. Volume discounts will increase; case costs will decrease; there will be fewer expensive off-contract orders and emergency orders.

The materials manager should document these results and produce written reports for top management, Neely says. "It's too easy to forget or undervalue these accomplishments."

It is especially important to track savings, he adds. Once physicians and owners see the numbers that prove the value of the effort, the credibility of the materials manager will increase.

"Documentation validates the effort, and is a powerful demonstration of ROI," he notes.

It is also important to check regularly with "customers" who use the supplies. Procedure volumes and types may change, making former par levels inadequate.

"Many unhappy customers don't complain," Neely says.

The next step: Automation

During the past several decades, the hospital supply chain industry has developed increasingly sophisticated computer systems designed to track inventory, issue purchase orders, record usage, and receive and pay vendor invoices. Unless an ASC is affiliated with a hospital and can tap into the hospital's materials management information system (MMIS), it will probably find such complete automation unaffordable.

One company, SourceMedical in Birmingham, Alabama, has developed inventory control software designed to serve the ASC market specifically. About 2,400 ASCs have

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*Chloraprep solution brochure: "Surgical site infections: the economic impact"

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become its customers, installing components of its Vision software package.

"Most ASCs use inventory control systems for case costing," says Patrick Doyle, vice president of sales at SourceMedical. But they don't have materials management systems to track par levels."

Those who do automate, he says, generally try to adapt systems designed for physician practices. "They get the bills out, but they don't do anything else," he notes.

The SourceMedical systems monitor usage with "perpetual inventory" based on preference cards. When the level drops below par, the system automatically generates a purchase order. SourceMedical systems interface with those of all major distributors, Doyle adds.

What they lack and what ASCs do not need, Doyle says, are huge, complex financial and distribution elements. "You don't need a hospital system because you don't have a central supply department. You don't have departmental levels. That doesn't translate to a surgery center."

With a price tag of about \$30,000, the latest Vision update contains components for scheduling, billing, case costing, and inventory control. It may also be rented for about \$1,000 per month.

"If you use all the functions, it becomes part of the workflow," Doyle says. While it is easier for newly built ASCs to open with the full package operating, existing centers can expect implementation to take 8 to 12 weeks because of their limited staffing.

Reports help to educate physicians.

"If you had a full-time person it would take a week," he says. Much of the implementation time is devoted to building libraries and transferring data to the facility's server.

Efficiency means savings

Surgery Center at Pelham in Greer, South Carolina, was one of the first ASCs to install SourceMedical's Vision products, when it opened in 2004. The software monitors charges during procedures and tracks supply costs at the item level. Pelham is jointly owned by 33 surgeons and Spartanburg (South Carolina) Regional Hospital.

According to administrator Bill Hazen, RN, one of the most useful features is the case cost report that each physician receives, allowing them to compare notes on supply use. "It helps us to educate physicians," he says. Hazen also finds the cost reports useful in dealing with suppliers. By showing them the ASC's profit margin for a given procedure, he can convince them to keep prices in line. Even employees, who participate in profit sharing, have become aware of costs and supply prices. "It's teaching employees," Hazen says. "My surgery techs know what every product costs."

At Specialty Surgical Center

(SSC) in Sparta, New Jersey, patient satisfaction has increased to 97% since adoption of Vision in 2009. Returns of patient surveys and online registration increased to 85% from 20%, according to administrator Bonnie Brady, RN.

SSC also uses the supply chain component of Vision.

"I spend 95% of my day working with the Vision Resource Management system," says materials manager Lisa Martin. "It is a very efficient system for managing the inventory of a small ASC that is not a small inventory at all."

The system initiates purchase orders, and when products are delivered, it automatically updates inventory records.

Martin says the system is especially useful for documenting implant use. It is used to maintain an implant log, listing manufacturer, lot number, and expiration date of each item used. In case of a recall, the log would be used to show whether the recall would affect any listed products and to identify the affected patients.

Martin also uses the system to produce an accurate daily inventory report, for the entire center or for specific areas, a function she says is invaluable in inventory management.

"Vision has the capability of producing count sheets for each shelf of each room," she notes, "so the staff needs only to count items and enter data to have a same-day evaluation of the value of the resources on hand." ♦

—Paula DeJohn



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At a Glance

SCIP infection measures not linked to better outcomes

Better adherence to infection-related SCIP measures is not significantly associated with better patient outcomes, with 1 exception, a study finds.

The study of 200 hospitals participating in the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) and SCIP calculated correlations between compliance with 4 SCIP process measures and 4 risk-adjusted outcomes. The 4 SCIP measures were antibiotic administration within 1 hr before incision, appropriate antibiotic prophylaxis, antibiotic discontinuation within 24 hours postop, and appropriate hair removal.

Of 16 correlations, 15 showed no significant associations with outcomes. The exception was appropriate antibiotic prophylaxis, which was correlated with fewer surgical site infections ($p = 0.004$). The authors concluded that different quality measures might be needed for surgical site infections.

—Ingraham AM, Cohen ME, Bilimoria KY, et al. *J Am Coll Surg.* 2010;211:705-714.

FDA panel recommends Lap-Band in less obese patients

An FDA panel voted 8-2 on December 3 to recommend expanding use of Allergan's Lap-Band to patients who are less than severely obese.

If the FDA agrees with the recommendation and grants approval, Lap-Band use will be expanded to patients with a BMI of at least 35, or a BMI of at least 30 with one or more obesity-related conditions, such as diabetes or high blood pressure. The Lap-Band is currently approved for patients with a BMI of at least 40, or at least 35 with 1 or more obesity-related conditions.

The vote could pave the way to double the number of eligible patients and make other types of weight-loss surgery available to the less obese, the *New York Times* reports.

—www.allergan.com/index.htm

Joint Commission survey shows Universal Protocol support

An online survey with more than 2,100 respondents shows widespread support for the 2010

revisions to the Universal Protocol, the Joint Commission reports.

In all, 88% of respondents agreed or strongly agreed that their organizations were able to fully implement the revised protocol. Revisions included simplified and clarified requirements for preprocedure verification, site marking, the time-out, and documentation.

—www.jointcommission.org

A brush-up on statistics for OR management teams

A review of statistics for anesthesiologists and OR directors has been made available by a leading researcher in OR management, Franklin Dexter, MD, PhD, and his colleagues.

Knowledge of basic statistics is necessary to make optimal decisions using science, they note. Decisions not based on statistical methods are vulnerable to psychological bias, studies have shown. Research has also shown this knowledge isn't picked up on the job but must be studied.

All of the materials are publicly available. A review is posted on his website. ♦

—www.franklindexter.net/education.htm