OR managers and directors are key players in supply purchasing

OR managers and directors are key players in their organizations when it comes to the purchasing of surgical supplies and equipment. They are closely involved in buying decisions, either as the primary decision maker or as a member of a committee.

More than any other leader or group, they head up efforts to manage the cost and utilization of high-dollar physician preference items like joint prostheses and laparoscopic instruments. They say their role in purchasing is growing.

These are highlights of results on purchasing power from the 2006 annual OR Manager Salary/Career Survey. Questions on supply management were expanded this year. For more, turn to p 9.

Survey results on salaries, benefits, and other issues were in the October issue. Results on staffing, including the OR skill mix, were in the September issue. This month’s issue focuses on managing the supply chain:

P 10: How ORs track, manage their supply costs
P 18: Vendor policies
P 19: Value analysis teams.

FDA shares data on events related to the reuse of single-use devices

The analysis found no deaths related to commercially reprocessed SUDs. The 1 report of a death was associated with a tracheostomy tube intended for reuse in the same patient. The FDA found 46 other reports of injury and 18 reports of malfunctions clearly associated with SUDs, but reprocessing was only one of several possible causes, the FDA notes (chart).

Apparently, the FDA ran a computer search for the AP reporter, but neither

Continued on page 14

Conference issue
Managing Today’s OR Suite
Nov 8 to 10, 2006
Orlando, Fla
Please see the ad for MEGADYNE in the OR Manager print version.
Five Commandments of Counts
A health system reinvigorates its counting practices with input from human factors experts. Learn how they did it.

Moving to intraop documentation?
Read tips for involving the staff and making a smooth transition.

Sometimes reporting requires a bit of sleuthing. It may not be a who-done-it question, but a question of whether published information is true.

When Editor Pat Patterson read an AP story that reported that the FDA had received 13 reports of patient deaths from reuse of single use items (SUDs), she was surprised. She questioned the figures. The article said there were 421 other trouble reports, including 130 involving serious patient harm.

“It struck me as odd,” she recalls, “since we were not seeing reports of deaths elsewhere. That number of deaths and incidents would have drawn attention.” Since the pros and cons of reuse of SUDs are of high interest to the OR, Patterson decided that it was something that was worth looking into.

She talked with Mark Bruley, vice president for accident and forensic investigation at ECRI, which investigates problems with medical devices. He told her that ECRI was not receiving reports of deaths due to reuse of SUDs. He agreed the information was suspect.

Patterson then talked to the AP business reporter, Linda A. Johnson. She told Patterson that the Food and Drug Administration (FDA) had provided the data she used in her article. She gave Patterson the name of the FDA person who had supplied the information.

Patterson contacted the same press person at the FDA and asked for a detailed analysis. This was in August. It wasn’t until Sept 12 she finally got the information she requested. That data is detailed. This was in August. It wasn’t until Sept 12 she finally got the information she requested. That data is reported in this issue.

A push for state legislation
In this detailed analysis of 434 reports from the FDA MedWatch database from Oct 22, 2003 to July 21, 2006, no deaths were reported that were related to commercially processed SUDs. Although there were reports of injury and device malfunctions, reprocessing was only one of several possible causes, according to the FDA.

Earlier in August, the AP ran a correction saying the original report had been based on “erroneous information” from the FDA.

But articles such as the AP article and an earlier one in the Washington Post Dec 11, 2005, stir consumer alarm.

Advocacy groups are pressuring for legislative action. In New Jersey, a new Patient Safety Act will require hospitals to fill out a separate form pertaining to reused SUDs when reporting adverse events. Consumer groups in that state are pushing for stronger legislation.

PatientGUARD (Patient Groups United Against Reprocessing Dangers), a coalition of 22 patient advocacy groups allied with a state trade group representing pharmaceutical companies and medical device makers, wants the legislature to require hospitals to obtain written consent from patients before a reprocessed SUD is used during treatment.

Although we strongly support patient decision making, it is difficult to imagine that most patients, as they face surgery, would be able to quickly grasp the pros and cons of the reuse of a single-use instrument and weigh the merits of giving written consent for its use.

The advocacy groups would also have someone go to the surgeon and ask him or her if use of the reprocessed SUD is okay. And then there is the detailed record-keeping.

These roadblocks would kill much of the reprocessing of SUDs and the attendant cost savings for hospitals.

Patterson has put together information you can use to evaluate your OR’s use of reprocessed SUDs or simply to make your own mind on this controversial issue. The article presents all sides of the issue, including the question of whether you should charge patients less for a reprocessed SUD.

Good reporting involves questioning information and pursuing sources for the correct information.

Patterson’s sleuthing has paid off.

—Elinor S. Schrader
Please see the ad for
STERIS CORPORATION
in the OR Manager print version.
Wrong surgery more common than thought

Wrong-side, wrong-site, wrong-procedure, and wrong-patient errors may be more than twice as common as generally accepted or reported in the literature—and there’s little evidence that current prevention methods are enough, according to a study in the September Archives of Surgery.

The authors estimate the annual incidence of wrong surgery in the US at 1,300 to 2,700 out of more than 75 million surgical procedures. This is more than 5 to 10 times greater than the error rate accepted by industry’s quality-defect standard Six Sigma, the authors note.

They base their estimates on data from 4 sources: the National Practitioner Data Bank, Florida’s mandatory reporting system, the American Society of Anesthesiologists’ Closed Claims database, and an anonymous website reporting tool hosted by the authors (www.wrong-side.org).

Contributing factors

The health care system isn’t set up to prevent these errors, say the researchers from the University of Chicago and the University of Miami. Among factors they identified that lead to wrong surgery:

- procedure factors
  - similar or same procedures back to back in the same room
- human factors
  - breakdowns in communication and teamwork
  - fatigue
  - inexperience
- patient factors
  - similarity of patient names
  - patient ignorance or confusion about the procedure
  - patient not consulted before sedation or block is administered
- failure of existing safety checks, such as not cross-checking for consistency in the consent form, patient chart, or OR scheduling form
- wrong side of patient prepped and draped

Prevention inadequate

These events are totally preventable, the researchers say, but prevention depends on the clinician’s ability and willingness to use prevention mechanisms:

- Despite extensive promotion by the American Academy of Orthopaedic Surgeons (AAOS) of a site-marking policy since 1997, only 70% of orthopedic hand surgeons are aware of the policy, and only 45% of those have changed their habits as a result of the policy.
- Patients’ involvement in marking their own operative site is low.
- Errors are still occurring despite use of the universal protocol for prevention of wrong surgery from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

The time-out required by JCAHO is “a step in the right direction” but fails to address the complexity of these incidents, the authors say. “The time-out policy falls short in addressing health care challenges such as unavailable equipment, varying roles, and unavailability of team members.”

A call for reporting

“We don’t know enough about these errors,” the lead author, Samuel C. Seiden, MD, told OR Manager.

He compared the problem to errors in transfusion medicine, noting there are about 2,000 studies on safety measures for preventing transfusion errors.

In contrast, there are only about 10 reports on wrong surgery.

“We don’t have nearly the understanding we need,” he said.

He and his coauthor, Paul Barach, MD, MPH, call for reporting of all errors—those that result in harm as well as near misses—to develop a culture like those that improved safety in transfusion medicine, aviation, and nuclear power.

Such a change will require an environment that allows providers to feel safe reporting without retribution, stigma, and shame, they say.●


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Please see the ad for CARDINAL HEALTH in the OR Manager print version.
‘Visionary leader’ brings people together

Peggy Doyle is a leader who brings people together, regardless of their discipline or role. For 27 years, she has served as director of the OR and perioperative services at Brigham & Women’s Hospital in Boston, one of the nation’s leading medical centers.

Doyle has assisted Brigham through more than 2 decades of growth, including the combination of 4 OR suites after the merger of 3 hospitals, expansion from 4 to 39 operating rooms, the evolution of outpatient surgery and same-day admissions, and the adoption of technology to improve the efficiency and quality of care.

She’s kept ties to nursing while forging close working relationships with surgeons, anesthesiologists, and support staff.

Doyle will be honored as OR Manager of the Year Nov 8 to 10 at the Managing Today’s OR Suite Conference in Orlando, Fla.

As OR Manager of the Year, Doyle receives an expense-paid trip to the Managing Today’s OR Suite conference, including airfare, hotel, meals, and registration. She also receives a scholarship from Kimberly-Clark Health Care to attend the Georgetown University Healthcare Leadership Institute in Washington, DC, in the summer of 2007.

“Peggy’s hallmark is her visionary approach and uncanny ability to see beyond the activities of the nursing department,” wrote OR assistant nurse managers Barbara DiTullio, RN, BSN, MA, and Kathleen Leavitt, RN, BSN, in one of the 20 letters sent in support of Doyle’s nomination.

“Peggy is the type of nursing leader who is needed in every OR throughout the country,” wrote Brigham’s chief of surgery, Michael J. Zinner, MD, saying she is part of the reason Brigham is able “to recruit some of the very best nurses throughout the city and state.”

Brigham’s chief medical officer, Anthony J. Whitemore, MD, cited Doyle’s ability to be an “extraordinary leader” in “a complex OR environment perpetually constrained by insufficient capacity and lack of funds.”

He said Doyle has navigated her staff steadily through crises, including the serious flooding of 4 or 5 ORs, power outages that disabled central processing, and unanticipated overloads of trauma cases.

“Her ability to deliver so reliably in the face of adversity testifies to the devotion of her nursing staff and their willingness to push beyond,” his letter said.

An early nursing mentor

Doyle first experienced OR nursing when it was part of every student nurse’s rotation.

“I enjoyed it, so I stayed,” she says. Early on, she identified a nurse leader she wanted to emulate, Martha Krutt, at what was then Boston City Hospital.

“She was a great leader who could have managed any organization,” Doyle says. “She was a strong, independent nurse at a time when nurses were often humble. She also had a great relationship with the physicians and their peers in nursing.”

Doyle was recruited for her first management position at the age of 25.

Realizing the need for more education, she went on to earn her baccalaureate and master’s degrees in nursing.

Advocate for technology

As the technology of surgery has advanced, Doyle has participated in its evolution. In the 1980s, she envisioned the need for airport-type monitors that would show the status of all of Brigham’s ORs. She and a team of nurses created the specs for what would become OR Display, software developed by Brigham’s IT staff that has been in use for 10 years.

OR Display “has been instrumental in helping the OR staff perform 30,000 annual procedures with 85% utilization at an average hospital census of 91%,” says Hugh L. Flanagan, MD, medical director of the OR suite and postanesthesia care unit.

Doyle also helped guide development of OR facilities to house the world’s first intraoperative MRI scanner, installed in 1994. She is now involved in planning a suite to house a high-tech OR, PET/CT scanner, and high-field MRI scanner.

Collaborating with others

But it is Doyle’s ability to lead and collaborate with others, including staff, physicians, administrators, patients, and families that was mentioned most in her nominations.

 Asked what quality she thinks has helped her most as a leader, Doyle says she believes it is this ability to develop good relations with others.

“You need to have the ability to talk with others about any issue but do so in a respectful way,” she says.

It’s not always easy, she says candidly. “Communication and dialogue are things we work on every day of our lives. The question is, ‘How do we disagree but come to consensus on common ground?’”

Recently, acknowledging that she herself felt challenged by some communication issues, Doyle arranged for 100 nurses, physicians, and support staff to participate in a 3-day seminar to teach the skills of Crucial Conversations, provided by VitalSmarts (www.vitalsmarts.com).

“We work a lot on team building here,” she adds. “We have a strong leadership group in perioperative services. They are supportive of one another and have developed good relationships.”

Staying at the top

Brigham & Women’s is one of only 3 hospitals nationwide named to Solucient’s list of the Top 100 Hospitals 10 or more times. How does Brigham’s perioperative services department continue to function at the level needed to help the institution stay at that high level of performance? Doyle cites a cohesive nursing leadership group and a strong relationship with surgical and anesthesia colleagues.

“We all have respect for each other’s disciplines,” she says. “It really is a team.”
Please see the ad for
MEDLINE INDUSTRIES
in the OR Manager print version.
OR directors have purchasing clout

OR managers and directors have clout when it comes to the purchasing of surgical supplies and equipment.

All respondents to the OR Manager Salary/Career Survey say they influence selection and purchase of capital equipment, and almost all (99%) influence decisions on surgical supplies.

They continue to gain decision-making power—83% said their involvement in purchasing decisions has increased in the past year.

More than one-third (35%) say they are the primary decision maker for selection and purchasing. This is most likely in small ORs with 1 to 5 rooms, where more than half (56%) take the lead role.

The largest group—44%—serves as members of a decision-making committee or team. The team approach is most common in teaching hospitals (58%) and large ORs with 10+ rooms (53%).

These are the results from the 2006 OR Manager Salary/Career survey, which was mailed in May to a random sample of 1,200 OR Manager subscribers with 266 returned for a rate of 22%. Other survey results were published in the October and September OR Manager.

Who leads on physician-preference items?

Surgical services directors carry weight in managing the cost of physician preference items such as orthopedic implants, endomechanical devices, and sutures.

Two-thirds (66%) say the director takes the lead in managing the cost and utilization of these expensive items. The director is much more likely than any other individual or group to be the leader in this area.

For about 1 in 5 (19%), a value analysis or standardization committee has the lead role. This is most prevalent in teaching hospitals (24%) and in ORs with 6 to 9 rooms (23%) and 10 or more rooms (27%).

Hospital administrators or chiefs of specialties were much less likely to take the lead in this area.

Moving ahead on standardization

ORs have been aggressive in standardizing supplies. More than 80% have standardized their sutures and custom packs. Almost two-thirds (64%) have standardized their endomechanical products, such as laparoscopic instruments and staplers.

And almost half (45%) have managed the tough task of standardizing orthopedic implants, which are heavily influenced by physician choice.

ORs were about equally successful with standardization, regardless of the type of hospital or number of ORs.

How do you monitor supply costs?

Overwhelmingly, survey respondents use cost per case as their performance indicator for managing the cost of surgical supplies, with 72% choosing that as their measure. There was little difference

What is your involvement in purchasing decisions changed in the past year?

Yes, increased 83%

Yes, decreased 17%

What is your involvement in purchasing decisions?

Member of committee 44%

Advisory capacity 21%

Primary decision maker 35%

Who leads in managing cost and utilization of surgeons’ preference items?

OR/surgical services director 66%

Materials management director 21%

Committee 19%

OR business manager 11%

Hospital administration 10%

Chiefs of specialties 6%

Which surgical supplies are standardized?

Sutures 83%

Custom packs 83%

Endomechanical devices 64%

Orthopedic implants 45%

Biologicals (eg, bone) 33%

Pacemakers 27%

Neurosurgical devices 21%

Cardiac devices 18%

Other items standardized include cameras, specialty video equipment, and endoscopes.

What do you use as a cost performance indicator for surgical supplies?

Cost per case 72%

Cost per minute 22%

DRG 10%

Other 6%

by type of facility or size of OR.

The next most common measure is cost per minute, used by 22%
How ORs track, manage supply costs

Before an OR team can control its costs, it needs to know what they are. This year’s OR Manager Salary / Career Survey asked managers what they use as a cost indicator for surgical supplies (related article, p 9).

In interviews, 4 OR business managers discussed indicators they use and how they employ them in making decisions and controlling costs.

**University of Wisconsin, Madison**

**30 ORs (22 inpatient, 8 outpatient)**

22,000 procedures a year

Supply cost indicators used at this academic medical center include:

- supply expense per case
- supply expense per OR minute
- implant cost per case
- implant cost per OR minute.

The first 2 indicators, kept on a spreadsheet, are calculated by dividing the supply expenses from the OR’s monthly operating statement by the number of cases and OR minutes for that month. The result is an average supply expense per case and minute.

“We monitor that to watch for trends,” says Katherine Hurtgen, MBA, OR business operations manager.

**Scorecard monitors trends**

A new automated scorecard gives managers a user-friendly tool for monitoring financial health and other indicators (illustration, p 13). Indicators are coded green for on target, yellow for out of range, and red for “Stop, we have to find out what’s going on.” Red requires a report to senior administrators.

“It’s a simple tool to look at,” says Hurtgen. “We’ve been tracking these measures all along on spreadsheets. Now we can just pop into the system and see how we’re doing.” The management team sets the goal and variance range for the indicators. On expense per case, for example, the indicator turns red if the figure is more than 10% outside the average for a given month. The scorecard software is from ActiveStrategy (www.activestrategy.com).

Implant expense per case is calculated by marrying data from the purchasing system with case records from the OR information system.

If there’s a spike in supply costs for a given month, Hurtgen digs deeper. She might review implant usage to see if that is driving costs. Recently, the culprit has been ventricular-assist devices (VADs), which cost about $73,000 each and serve as a bridge to heart transplant.

Cost analysis is becoming more robust with the recent installation of a PeopleSoft purchasing system, interfaced with the OR system, GE Centricity Perioperative.

“This can give us the price per unit for all items listed on the preference card for a case,” Hurtgen says. “I can get cost-per-unit at the end of a case pretty easily.”

The biggest glitch has been the difference in the unit of measure of supplies ordered and used.

“When we first went live, I was looking at the data and saw a $1,200 stapler—it was really a box of 6,” she says. “It’s caused them to focus on what we’re spending and project their needs. This has been working very well for the past 2 years.”

**St Joseph Hospital, Orange, Calif**

**27 ORs (14 main OR, 13 outpatient)**

25,000 procedures a year

Two indicators managers rely on most:

- supply cost per OR minute
- average implant cost per case.

“My goal is to keep the supply dollars per unit of service the same. If we do more minutes than budgeted, we will obviously spend more, but if the dollar amount per unit of service is roughly the same, it’s justifiable,” says Terrence Wooten, OR business manager.

Supply cost per minute is also a target for the staff incentive program. Staff can earn a bonus for, among other things, lowering supply cost per minute by 2%. (See September 2005 OR Manager.)

Wooten also tracks the cost per case of high-cost implants, looking for trends. For example, if the hospital has negotiated a contract for better pricing, he expects to see a decrease.

He monitors the budget using monthly variance reports, though these aren’t available from the finance department for about 3 weeks after the end of the month. For quicker feedback, Wooten gets a report from the materials coordinators on that month’s purchase orders.

“We try to track those week-to-week so there are no surprises,” he says. “Depending on where we are for the month for purchases that aren’t patient related, we might say, ‘Do we need this now? Or can we get it later?’”

The cost data is also used in making decisions about new products.

“When surgeons want new items, we look at the cost of the procedure with and without the item. We also look at the reimbursement, net revenue, and what the gross margin would be if the supply is added,” he says.

‘Checkbook’ controls instrument spending

A “checkbook” approach helps keep instrument spending in line at St Joseph Hospital in Orange, Calif.

Each OR service line manager has a monthly instrument budget (the yearly budget for the service divided by 12), which he or she uses like a checking account.

“They have the choice of spending it all in 1 month or banking it and spending it later. We track it month-to-month,” explains Terrence Wooten, OR business manager.

“It’s caused them to focus on what they are spending and project their needs. This has been working very well for the past 2 years.”
**Highline Medical Center, Burien, Wash**

**9 ORs**

**5,400 procedures a year**

At this community hospital in suburban Seattle, the major productivity measure is the OR minute. Supply cost indicators are:

- total expenses/case
- supply expense/case
- supply cost/OR minute.

Krista Christensen, MBA, CPC, business manager for surgical services, compiles a financial summary each month using those indicators, getting most of her information from the budget report. The summary is shared with the director of surgical services, chief nursing officer, and controller.

Every month, a budget variance meeting is held, which departments that are over budget must attend.

“For us, it is usually the supplies that are off,” particularly expensive items like total joints, Christensen says. In June, for instance, the total joint volume doubled in one month, which threw the expense per OR minute off.

Christensen keeps track of areas she knows will affect the budget so she can provide a rationale.

“I look at any new services we didn’t budget for, whether we’ve had a spike in our volume, and whether the value of the inventory on the shelf has increased,” she says. For example, late last year, the hospital introduced cryosurgery of the prostate, which carries a large supply expense. The cost wasn’t included in the 2006 budget, which was already completed.

“If we are over budget, I can work back and say, ‘These are the things that contributed to it,’” she says. “We brought in a new service, and they tend to forget there is going to be a budget impact.”

**Shands Hospital at the University of Florida, Gainesville**

**26 ORs**

**16,000 procedures a year**

Like many others, Shands uses supply cost per case as an indicator.

“We see it rise every year. It’s almost entirely due to technology,” says Fred Buxbaum, OR business manager.

Some of the biggest challenges are high-cost implants such as InFuse (bone morphogenic protein used in spinal surgery), vagus nerve stimulators, and cochlear implants.

But it’s about more than costs—a variety of factors affect whether a procedure is profitable, Buxbaum stresses.

At Shands, an Implant Committee was formed last year to look at the broader issues of managing these expensive items. Members include a representative from administration, who chairs the meetings and reports directly to a vice president, and personnel from the OR, information services (IS), purchasing, and reimbursement.

In addition to costs, the committee examines:

- Who are the payers? What is the profitability for each of the major payers for an implant procedure?
- Is there a difference in inpatient and outpatient reimbursement? “For certain types of implants, we are better off having the procedure done on an outpatient basis if appropriate and being paid under the APCs,” Buxbaum says, referring to the ambulatory patient classifications Medicare uses for hospital outpatient payments.
- Is the chargemaster set up correctly for these procedures?
- Is the procedure being coded and billed correctly?
- Is it a pricing issue? The hospital may need to negotiate better prices for some products.

“By gathering the data and having the right people at the table, you’re able to formulate a plan that results in improved profitability for your hospital,” Buxbaum says. ✨
Please see the ad for
GETINGE
in the OR Manager print version.
# Surgical Services Scorecard

<table>
<thead>
<tr>
<th>Objective</th>
<th>Actual</th>
<th>Goal</th>
<th>Variance</th>
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<tbody>
<tr>
<td><strong>1. Patient satisfaction</strong></td>
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<tr>
<td>1.1 Improve patient satisfaction with surgical services</td>
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<td>OR/RR staff concerns for privacy</td>
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<td>Info family/visitors received</td>
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<td>Explanation of OR procedures</td>
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<tr>
<td>Rating of surgery experience</td>
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<td><strong>2. Employee growth and management</strong></td>
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<td>2.1 Maximize recruitment and retention of qualified staff</td>
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<tr>
<td>Vacancy rate: RN (Surgical Services)</td>
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<td>Turnover rate: RN (Surgical Services)</td>
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<td><strong>3. Clinical effectiveness, quality, and safety</strong></td>
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<tr>
<td>3.1 Improve quality of clinical care</td>
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<tr>
<td>Time-out compliance documentation</td>
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<tr>
<td>Antibiotics infused: CABG, hip, knee</td>
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<td>Antibiotics infused: Hysterectomy</td>
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<td><strong>4. Financial health</strong></td>
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<td>4.1 Deliver care in a fiscally responsible manner</td>
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<td>Case volume (Surgical Services)</td>
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<td>Revenue (Surgical Services)</td>
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<td>Expense per case: Inpatient</td>
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<td>Gross margin ratio (Surgical Services)</td>
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<td><strong>5. Market position</strong></td>
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<td>5.1 Increase patient volume for selected service lines</td>
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<td>Pediatric volume (age categories)</td>
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<td>Anesthesia offsite volume (pediatrics)</td>
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<td>Robotic cases</td>
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<td><strong>6. Operational efficiency</strong></td>
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<tr>
<td>6.1 Increase operational efficiency</td>
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<td>On-time starts</td>
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Note: The color coding for the indicators is hypothetical.
Source: Surgical Services, University of Wisconsin. Reprinted with permission.
the reporter nor the FDA reviewed the individual reports to see if they were relevant to reprocessing of SUDs. Reports in the FDA’s MedWatch database are often difficult to interpret. The FDA’s form for submitting a report asks, among other things: “Is this a single-use device that was reprocessed and reused on a patient?” People often check the box in error, the FDA says. Each report must be examined to see if a reprocessed SUD actually was involved. Even then, the cause of an event often cannot be identified.

The database is part of a debate about whether FDA oversight of reprocessing is adequate. Third-party reprocessing companies say the process is safe and well regulated. But original device manufacturers, which stand to lose business if their products are reused, say their devices aren’t designed to be reprocessed and doing so is a risk to patients. They are calling for Congress and state legislatures to take action.

The US House Committee on Government Reform held a hearing on reuse Sept 26. The chair, Rep Tom Davis (R-Va), says the panel plans to look into whether the FDA reporting system is adequate and whether the FDA’s new requirement to label reprocessed SUDs, which took effect Aug 1, will aid reporting. The panel also has asked the Government Accountability Office (GAO) to update its June 2000 report, looking at the safety of SUD reprocessing, FDA oversight, and how SUDs compare with new devices. A date for release has not been announced.

Safety or economics?

Much of the battle over reuse of SUDs is economics rather than safety, some observers say.

Reprocessed SUDs cost about half what new devices cost. Third-party reprocessing has grown into a $100 million a year industry.

Exactly how many hospitals use reprocessed SUDs is unknown. The Association of Medical Device Reprocessors (AMDR) says its members, Ascent Healthcare Solutions (formed by the merger of Alliance and Vanguard) and SterilMed, do 95% of the nation’s SUD reprocessing and have 3,000 accounts, but some may be part of the same organization.

**FDA analysis of reports related to reuse of single-use devices**

Analysis of 434 reports submitted to the FDA from Oct 22, 2003, to July 21, 2006, in which the reporting form was checked “yes” in response to the question, “Is this a single-use device that was reprocessed and reused on a patient?”

**Deaths**

- Of 14 separate deaths:
  - 5 associated with multi-use items (not single-use device)
  - 5 associated with implantable device (not SUD)
  - 3 associated with SUDs that were not reprocessed
  - 1 associated with SUD (tracheostomy tube) intended to be cleaned and sterilized for continued use in same patient.

**Infections**

- There were 12 reports of infection (including 1 duplicate). Of the 11 remaining reports, it appears only 1 involved a reprocessed SUD—a trocar. The report noted infection at the port site and the need for additional surgery to retrieve pieces of the broken trocar.
  - The other reports were associated with reusable devices, implantable devices, or initial use of SUDs (including an electrosurgical electrode associated with both an infection and burn to the liver/gallbladder).

**Injury and malfunctions without injury**

- There were 46 additional reports of injury and 18 other reports of malfunctions without injury clearly associated with SUDs for which reprocessing was one of several possible causative factors:
  - The 46 reports of injury also included reports of:
    - 40 additional procedures to retrieve a broken device
    - 1 bleeding requiring a transfusion
    - 1 skin burn
    - 1 cut finger
    - 1 open-heart surgery with valve replacement
    - 1 prolongation of surgery
    - 1 bone graft.
  - 18 malfunction reports included the following problems:
    - 10 device did not work as intended and was replaced
    - 3 device broke with no mention of intervention
    - 1 normal battery depletion
    - 1 insulation peeled off
    - 1 bent operating tip
    - 1 loose rubber seal
    - 1 broken dialyzer that had to be replaced.

**Remaining reports**

- 340 remaining reports do not fall into the previous categories:
  - 300 implantable, multiuse/reusable, or SUDs that were not reprocessed
  - 35 report mislabeling, device mislabeling, out-of-box failures, or events determined to be clearly not device related
  - 5 FDA doing further followup to determine whether reprocessing actually occurred.

*Source: Food and Drug Administration, Sept 12, 2006.*
The battle is being fought on a legal and legislative front.

In 2005, Johnson & Johnson and its Ethicon Endo-Surgery unit sued Ascent’s predecessors over trademark infringement.

“Ethicon believes we should remove their mark in device reprocessing and put our own on. We contend that to remove the trademark is contrary to federal law, so this needs to be resolved in litigation or a negotiated settlement,” says Don Selvey, Ascent’s vice president for regulatory affairs and quality assurance.

Ethicon Endo-Surgery acknowledged the suit but would not comment further.

**Battle in the states**

Device manufacturers have taken the battle to the states. Bills to regulate reprocessing have been introduced in Utah, Massachusetts, Rhode Island, and Virginia, and are expected to be introduced in Ohio and New Jersey, according to AMDR. The bills address liability and informed consent for patients if SUDs are reused.

Utah is the only state to have passed a law that requires reprocessors of critical SUDs to assume the liability related both to the original manufacturing and reprocessing of the device.

“That means should a reprocessed device fail, it’s the reprocessor’s fault, even if it is an original manufacturer’s defect. We oppose that, but that’s what we see the original manufacturers pushing,” says Dan Vukelich of AMDR.

Original manufacturers counter that customers sometimes return failed devices saying they are defective when they were actually damaged by reprocessing.

New Jersey, as part of its state Patient Safety Act, will require hospitals to fill out a separate form on SUDs when they submit a report on an adverse event at their facility.

A newly formed New Jersey coalition named PatientGUARD has been advocating legislation. The coalition is joined by the HealthCare Institute of New Jersey, a trade association of major pharmaceutical and medical device companies.

**The manufacturer’s view**

Smith & Nephew opposes reuse of SUDs for several reasons, says Nigel Wilkinson, vice president for regulatory affairs and quality:

- Its single-use devices aren’t designed for reprocessing, and doing so “could pose a risk to patient safety.” The company is particularly concerned about reuse of its arthroscopic shaver blades.
- The company says its own and independent testing of its blades reprocessed by third parties has found contamination, compromised package seals, and damaged cutting edges.
- A survey the company sponsored in 2002 found 82% of nurses and 71% of physicians said they would be uncomfortable if a reprocessed SUD was used on them or their family member.

Wilkinson referred to a study at Loma Linda University that tested 7 new and 16 reprocessed shaver blades and found the reprocessed ones had residual protein and DNA and damage, while no damage or contaminants were found on the new blades. The report, presented as a poster at a 2003 arthroscopy conference, does not describe who reprocessed the blades or how the reprocessing was done. The study was partly funded by an unrestricted educational grant from Smith & Nephew.

In 2003 reports for investors, the company said its sales growth had been affected by reuse of its arthroscopy blade, and it had launched an education campaign on risks of the practice.

**Informed consent for patients?**

One focus of state legislation is whether patients should be informed if a critical type of reprocessed SUD will be used in their care.

Backers of the Massachusetts bill think informed consent is necessary because “there is still some debate about whether [new and reprocessed SUDs] devices are equivalent,” says Laura Allen of the Massachusetts Medical Device Industry Council. She referred to the Loma Linda study on shaver blades and concerns about the adequacy of FDA oversight. “We think there is still room to discuss whether reprocessed devices are essentially the same as devices coming out of the package new,” she says.

A risk management expert does not agree there is a need to inform patients that a reprocessed SUD will be used in their care. Malcolm S. “Duffy” Parsons, president of RiskOne Consulting Group, Columbus, Ohio, has followed the reprocessing issue for a number of years.

“Are patients told every time we reprocess a surgical instrument or any other device that is reusable even though there is some risk of infection? No,” says Parsons. “The patient assumes the hospital has a process for inactivating microorganisms.”

The same principle applies to reuse of SUDs, he says. The patient assumes the hospital has a process for making decisions about which products it will use, and clinicians have an opportunity to participate in that decision. In so doing, the hospital considers whether a product is manufactured according to good manufacturing practices and, if applicable, is reprocessed according to the appropriate standards. If that is the case, no additional consent is needed, he says.

Parsons says he questions the motives behind the informed consent legislation.

“If a patient has the opportunity to say whether a new or reprocessed device should be used in their care, they will opt for the new one every time. If so, the motive seems to be for patients not to tolerate reuse. Then you have to ask, ‘Is the motive also financial?’”

**What about charging?**

If facilities pay less for reprocessed SUDs, should they charge patients less than for a new device?

“There are many factors that are built into a hospital charge,” says Rick Gundling, vice president of the Healthcare Financial Management Association.

Continued on page 17
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Materials management

**Tips for a smooth start on reusing single-use devices**

A few years ago, if you asked Michael Frisina whether his OR would reuse single-use devices (SUDs) he would have said, “No way.”

Frisina admits he’s a convert.

Starting in October 2005, his facility signed a contract with a third-party reprocessor to begin reusing a long list of reprocessed items. The facility projected savings of $88,000 in the first year but achieved more than 50% of that by the end of the first 4 months.

“We have not had a single physician complaint about any of the reprocessed items since we started,” says Frisina, who is administrative director for surgical services for the 12 ORs in the Tuomey Healthcare System, Sumter, SC.

“Do your homework” is his advice to OR managers who are considering the reuse of SUDs. Several steps were crucial to getting the project off to a smooth start.

- **Involve the physicians early.** “We got the physicians involved at the beginning and let them know what we were planning,” he says. “We didn’t want to do all of the work up front only to have them say, ‘No, we’re not going to accept these products.’”

- **Have the product standardization committee research third-party reprocessing companies.** Be sure to include surgeons on the committee. See which reprocessing vendors are covered by your group purchasing contract. Examine the list of devices from each company that have received Food and Drug Administration 510(k) clearance. Companies that market reprocessed SUDs must meet the FDA’s regulations, which include 510(k) clearance. To inform yourself about the requirements, go to the FDA’s reuse home page at www.fda.gov/cdrh/reuse.

- **Once you’ve narrowed the list of companies, invite them in for presentations.** Insist that they answer your questions. Plan to visit their plants if possible. Have your risk manager and legal counsel examine their liability insurance coverage.

- **Give surgeons an opportunity for feedback.** At Tuomey, the team organized a blind trial for the surgeons before making its decision to use reprocessed devices. They told the surgeons that during the trial they would be using reprocessed items, but they would not know which instruments were involved. The trial was conducted for about 2 weeks for 40 to 60 cases and used various types of devices in several specialties.

“We said to the surgeons, ‘If you have problems in any of your cases, let us know,’” he says. There were no complaints about the reprocessed items.

- **Prepare the staff.** “The staff had a lot of concerns initially,” Frisina says. “They knew of hospitals that did it on their own and didn’t do it well. We assured them we weren’t doing it just to save money. But we were considering it because the savings were high enough that, if we could do it safely without sacrificing quality, we had to consider it for the overall health of the organization.”

- **Make it seamless to the staff.** Make it easy for the staff to segregate items for reprocessing. Tuomey has posters to inform the staff which SUDs can be reprocessed. The vendor provides plastic bins placed in each OR, the postanesthesia care unit, and other locations. When full, the bins are removed by the environmental services staff and delivered to a designated area near the loading dock. The bins are then transported in a soiled-materials truck to the materials management department, where the vendor prepares them for shipping to its plant. Frisina says the hospital does not pay shipping charges. Frisina says a big concern he had initially was how recalls would be handled. If an original manufacturer issued a recall for SUDs that were being reprocessed, how would the hospital be able to identify them?

In that case, he says the third-party reprocessor would come to the hospital and remove all items identical to the recalled item, both new and reused. It would replace them at no charge, the same as an original manufacturer would do.

**Reuse of single-use devices**

Continued from page 15

“There are all kinds of things to consider besides the direct cost of a particular supply item.” Among these are overhead (including the costs of bad debt and charity care), labor costs, the volume and frequency of the service, and payer policies.

Two readers of OR Manager described their approaches to charging. The OR director at a community hospital says nurses and physicians raised this issue when the hospital embarked on reuse. The director said the hospital would not charge patients less for reused SUDs because the hospital for the most part is not paid according to its charges, and patients don’t pay for all of the costs of a procedure. The second facility, an academic medical center, tracks its use of reprocessed SUDs and uses a weighted average of the cost of new and reused devices in its charges.

**Resources**

Food and Drug Administration, Center for Devices and Radiological Health. Reuse web site. www.fda.gov/cdrh/reuse

**Physician errors linked to missed diagnoses**

Basic errors by physicians, including ordering tests too late or not at all and failing to follow up on patients, played a role in nearly 60% of malpractice cases in which patients were harmed by missed or delayed diagnoses, researchers found in an analysis of 307 malpractice claims. A large majority of cases involved cancer diagnoses—mainly breast and colorectal.

The most common breakdowns were failure to order appropriate tests (55%), create a proper follow-up plan (45%), or obtain an adequate history or physical exam (42%) and incorrect interpretation of tests (37%). Suggested improvements include use of electronic records, better algorithms, and nurse practitioners to ensure follow-ups occur.

Materials management

OR vendor policies stress credentialing

Sales representatives use a number of tactics to sell supplies and equipment to ORs. Most behave professionally and are good resources on how to use products.

Vendor representatives are sometimes invited into the OR when a surgeon wants technical information on a new product. But unapproved and unannounced reps in ORs can lead to patient safety and liability issues, as well as bills for items the vendor says were requested, but the hospital never approved for purchase.

Two organizations described their policies for credentialing vendor representatives, which require evidence that reps are familiar with policies on OR practice and purchasing.

The American College of Surgeons and Association of periOperative Registered Nurses (AORN) have guidelines to aid in developing policies on health care industry representatives in the OR.

“From a time and a place for vendor support in the OR, but it needs to be under hospital control,” says Sunder R. Nambiar, RN, MPH, CNOR, executive director for perioperative services at Loma Linda University Medical Center in Loma Linda, Calif. Loma Linda has developed a policy that includes having the rep sign off on a web-based orientation packet that explains the organization’s policy. (The packet can be viewed at www.llu.edu/llumc/perioperative/ pdfs/periop-vendor.pdf?PHPSESSID =#searc.)

Two-stage credentialing process

Kettering Medical Center in Kettering, Ohio, began developing its policy in 2004 with systemwide meetings of the purchasing departments, which were reporting increasing incidents of unapproved instruments and equipment being brought into ORs, says Tricia Osborn, MBA, business office manager for surgical services. Her office supports 37 ORs in the 4-facility system, 21 of which are at the medical center.

The new policy, implemented in January 2005, involves a 2-stage process.

The first stage must be completed by any vendor rep who wishes to enter any area of the hospital, Osborn says. Vendors must present to the purchasing department:

- evidence of a negative TB test as well as a vaccination record
- credentials to sell for a particular company
- certification that they have received training from the company in aseptic technique
- knowledge of the basic vendor policy. Approved representatives receive a “vendor credentialing card” that is valid until the rep’s next TB test is due, or no longer than a year. A vendor must have the card whenever present in Kettering facilities.

Credentialing for the OR

To enter an OR requires a second stage of credentialing. Among additional criteria are the documentation on company letterhead or some other acceptable form that the rep has been trained in the use of the company’s instruments.

Credentials are withdrawn when a rep changes companies, says Osborn. At that point, the vendor repeats the credentialing process.

Any new representative who wishes to enter an OR must review and sign the Kettering OR policy, which states, among other things, that the person will not participate in patient care in any way, even by adjusting or manipulating a device. The policy also states that any product not approved for purchase will not be paid for, regardless of whether a surgeon uses it.

Vendor reps must make an appointment at least 24 hours ahead of the scheduled surgery to have access to an OR.

Appointment required

Once the appointment is made, a note is placed on the case record that the rep will be present. Reps sign in and out with the control desk or nurse specialist for the OR they are visiting. They may not enter the surgeons’ lounge or use hospital phones or computers.

“When a vendor arrives, they are referred to the control desk, which checks to make sure their credentialing card is valid and that they have reviewed and signed the OR policy,” Osborn says. “If it is their first time, they are referred to the specialist nurse, who generally hands them off to the circulating nurse in the OR.”

T here is a mention on Kettering’s patient surgical consent form that a health care industry rep may be in the OR. Patients may object, but Osborn says she is not aware of any patient doing so.

Sign-off on packet

At Loma Linda, the process is similar but has some different elements. Nambiar’s department worked with purchasing staff, OR managers, and service line specialists to draft a policy and the orientation packet.

The credentialing process starts when a vendor rep asks to be in an OR or a surgeon calls and asks that the vendor be allowed access. The rep is told that he or she must present a TB test and vaccination record and documentation of training in aseptic technique.

Then the vendor must download and read the orientation packet, which includes policies on purchase of unapproved items and an absolute policy that the vendor is not allowed to touch the patient or any caregiver at any time in the OR.

The last page of the packet must be downloaded, printed, and signed before a rep is allowed to check in at Loma Linda, Nambiar says.

The rep checks in with the purchasing-buyer assistant at each site, he says. The rep is issued a tag that must be prominently displayed on the rep’s scrubs, so everyone in the OR knows the person is not a member of the clinical staff, he adds.

Identifying vendors has been an issue at Kettering. Osborn acknowledges, especially when surgeons allow reps to enter without making an appointment or checking in.

Continued on page 21
A growing number of hospitals are using value analysis teams (VATs) to help control costs, improve standardization, and assess quality of new products and equipment. In 1999, Swedish Medical Center, Seattle, began using the VAT approach, which has been used in industry for decades, along with a vendor registration process to control access to surgery departments.

“We are trying to make decisions about what’s going to happen rather than what’s happened already,” says Allen Caudle, MBA, the system’s vice president of supply chain management.

Swedish’s 58 ORs located at 3 hospital campuses perform 39,000 annual surgical procedures. Overall, the 4-hospital system spends $170 million each year on supplies and equipment.

A VAT is a 10- to 12-member group that includes physicians, nurses, administrators, and other experts who have knowledge about products, supplies, equipment, services, financial analysis, and materials management. VATs evaluate and make decisions before purchasing new products and equipment.

Swedish Medical Center’s 5 VATs cover surgery, pharmacy, medical-surgical, administrative services, and specialized services (neurological, vascular, cardiac, and interventional radiology).

“It has been extremely successful for surgery,” says Kate Rogers, RN, MSN, CNOR, administrative director of perioperative services. “We have been able to streamline the approach so requests are promptly addressed.”

**Strict policy on payment**

In addition to the VATs, Swedish has a strict rule that prohibits paying for products without prior authorization and a purchase order.

“The expectation of vendors is that a purchase order is the ticket to payment,” Rogers says.

“Basically, if you don’t have a purchase order, the product should not arrive in the OR. If it does slip through, the invoice will not be paid. It is not perfect, but it helps nurses focus on the patient, rather than monitoring vendor products.”

Rogers says the VAT process and vendor registration save nurses time and improve OR efficiency.

“‘In the past, vendors would go directly to doctors’ offices and demonstrate the latest device,’’ she says. “‘The path of least resistance was to tell the vendor when the surgery was scheduled and just to bring the item in.’”

When the rep showed up in the OR right before the scheduled surgery, nurses would have to decide what to do. This typically meant checking with the surgeon, and if the surgeon confirmed the need for the item, the nurse would open it for use.

“The item was not on any charge sheet or item file. We had no way to charge for it, but the surgeon wanted to use it,” Rogers says.

Once the item was in the OR, the vendor would send an invoice for the item.

“We had no way of even knowing if it even was used,’’ she says. “This no longer happens because the process is tight. Vendors are confronted and told bringing items into the OR is not appropriate.”

**A 100% score**

Swedish requires vendors to register to gain access to the ORs and patient care units. After studying the protocol rules, vendors must score 100% on a 10-question test to be registered.

“The first question is, ‘Do you understand you need a PO to get paid?’” Caudle says. “This way, they can’t say they didn’t know.”

The one exception is for emergencies.

“If there is a patient-specific emergency, vendors know they must call the VAT leader with the issue,” Caudle says. A decision generally can be made within 24 hours.

Once an emergency request is filed, “clinical resource managers (RNs) talk with the doctor to find out why the product is necessary,” he says. “Seventy-five percent of the time the doctor says we can use the existing product. But sometimes we have to use the new product.”

For patient-specific items, the VAT can turn around a request in 3 to 4 days, Rogers says. For example, if a surgeon wants a specific implant, the surgeon contacts the clinical resource manager, provides justification, and the item is provided, Rogers says.

These items are tracked to avoid multiple one-time uses.

To gain entrance to the OR, a registered rep must check in for a daily pass with a valid reason for a visit. When they check in, vendors receive a badge for the day with their picture on it. “After 24 hours, lines go through the badge to show it has expired,” Caudle says.

**How the VAT process works**

Each VAT, which meets monthly to review requests, requires a 3-step process for physicians and staff to submit and gain approval for requests.

- A physician or staff member identifies a product or service he or she believes is necessary. The physician fills out a short Clinical Justification Form that explains why the product or service is necessary.
- Once the physician initiates a product request, the vendor fills out a 10-page Product/Service Evaluation Worksheet. The document includes the description of the product, why it is different than other products, and information on regulatory approvals, utilization forecasts, financial impact, and the clinical impact, such as whether the product contains latex.
- The supply chain management staff fill out a document for the VAT called the Device/Product/Service Summary Report.

“We meet every month with an agenda of 10 to 20 items,” Caudle says. “The surgical VAT has been up since day one—it is where the money is.”

For a new product to be used in Swedish’s ORs, physicians and vendors must demonstrate its quality, value, and ability to contain costs, Caudle says.

**Continued on page 21**
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Materials management

Continued from page 18

“We’re meeting with our managers to see if we can establish an abbreviated version of our in-house training for vendors. On hepatitis B, we’re reviewing that to see if it is a requirement or a recommendation. Requiring that would mean a lot of extra work.” Loma Linda also does not require a hepatitis B vaccination from vendors, Nambiar says, “because the vendors never touch the patient.”

Nambiar says the online orientation packet seems to be working well at Loma Linda, allowing vendors to review policies on their own time, while protecting the hospital when they register and sign the document page saying they accept the rules.

At Kettering, Osborn says, the policy has been in effect for less than 2 years, and compliance has been uneven.

“As with any policy, it’s only as good as the enforcement,” she says. “We’ve had pockets of success. Some specialties, like orthopedics and neuro, are not as observant as others—but we keep trying.”

—Kate McGraw

Kate McGraw is a freelance writer in Santa Fe, NM.

Resources


Medicare to weigh spinal fusion evidence

Medicare has called a meeting on Nov 30 to address the question, “Does spinal fusion improve outcomes for Medicare patients?”

The Medicare Coverage Advisory Committee (MCAC), a panel of 12 to 15 physicians, will listen to presentations, take comments, and discuss the evidence.

The purpose of the meeting is to have a “public discussion” about the evidence for spinal surgery, said Medicare official Steve Phurrough, MD, in an interview with Orthopedics This Week. He stressed that the panel will look at the evidence only and not make a decision about coverage.

Coverage decisions for spinal fusion are currently made by Medicare’s local carriers.

Two sources of evidence the panel is likely to consider are the outcomes research by Richard Deyo, MD, and colleagues of the University of Washington, Seattle, and the Spine Patient Outcomes Research Trial (SPORT) at the Dartmouth Medical School, Hanover, NH.

Information about the MCAC meeting and how to register are at www.cms.hhs.gov/mcd/viewmcac.asp?where=inde x&mid=37.

Continued from page 19

Each VAT, including surgery, also has a product resource committee that reviews items or services of $5,000 or less and makes recommendations to the VAT.

During the first 3 years, Caudle says the VAT worked fairly well, although some physicians continued to bypass the process. “Physicians didn’t believe they had to go through the VATs,” Caudle says. “They just (told vendors) they wanted something, and it appeared.”

After the hospital mounted an education program through medical staff committees and vendors, compliance improved and became part of the hospital culture.

“Now, we have nearly zero rogue buying,” Caudle says. “The surgeons and vendors know if (a product) doesn’t get approval from the VAT, it won’t be paid for.”

“Surgeons reluctantly went along with it in the beginning and now have grown accustomed to the VAT process,” Rogers adds.

Standardization efforts aided

The VAT process has drastically reduced the number of products at the hospital.

“We have more standardization, but how much depends on the type of products,” Caudle says.

For example, Swedish reduced the number of vendors for hernia mesh to 1 from 5.

“We try to get to 1 or 2 products, except for the strong physician-preference items,” he says.

Because Swedish performs about 1,000 total hips and 1,000 total knee procedures annually, each of these types of prostheses has 2 vendors. But with more than 1,000 annual spine procedures, he says surgeons want 4 vendors for spinal implants.

“We moved to an aggressive capitaled program (for spine implants) and have saved about $800,000 this year,” he says.

Last year, Swedish also formed a technology assessment team to evaluate cutting-edge technologies and avoid simply reacting to what clinicians want.

“We started slow and are just getting up to speed,” he says. “We are trying to incorporate this process into the capital budgeting process.”

The technology assessment team reviews each product and submits recommendations to the appropriate VAT.

“We want to find out the total cost of the technology. What are the installation and operating costs? What is it replacing? What are the clinical outcomes?” he says. “We want to stay ahead of the curve.”

—Jay Greene

Jay Greene is a freelance writer in St Paul, Minn.
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FDA approves second lumbar artificial disc

Synthes Spine’s ProDisc in August became the second lumbar artificial disc to receive Food and Drug Administration (FDA) approval. The first was Charité by DePuy Spine, approved in 2004.

The ProDisc should be better accepted. Data show it is easier to implant, with less of a learning curve than Charité. And outcomes look strong compared to traditional spinal fusion.

Both OR time and blood loss are significantly less with ProDisc than traditional fusion. Outcomes for pain and return to work were also favorable, according to new data presented by the clinical researchers led by Rick Delamarter, MD, at the North American Spine Society meeting in September in Seattle (chart).

They say theirs is the first randomized investigational study to show statistically superior outcomes for an artificial disc compared with fusion.

“I think because of this, ProDisc will be better accepted with a better chance of reimbursement from CMS,” says Robin Young, editor and publisher of Orthopedics This Week, referring to the Centers for Medicare and Medicaid Services.

Julie Blatnik, RN, BSN, CNOR, director of the spine care program for St Paul, Minn-based HealthEast Care System, who is familiar with the training for both Charité and ProDisc, says it appears that the ProDisc technique is easier, and it uses about one-third as many instruments as the Charité.

Charité, meanwhile, has met bumps in the road. Surgeons have been slow to adopt it, and many insurers do not cover it. Some 5,000 Charité disc replacements have been performed, compared to about 200,000 spinal fusions performed each year.

FDA to follow outcomes

The FDA will follow outcomes of the ProDisc closely. Synthes must conduct a 5-year study to assess the long-term safety and effectiveness of the disc in the 286 patients who participated in the preapproval clinical trials. The company also must evaluate overall success, complete an annual analysis, and report any major adverse events, such as implant breakage, subsidence, or expulsion from the disc space. The FDA say results of the study and analyses will be reflected in supplementary labeling for the disc. The conditions are similar to those for the Charité disc.

Disc design

The ProDisc was designed by a French spine surgeon, Thierry Marnay, MD, and has had more than 15 years of clinical follow-up in Europe. The disc consists of 3 parts (photo):

- a metal (cobalt-chrome alloy) endplate that is anchored to the bottom surface of the vertebral body
- a second endplate that is anchored to the top surface of the vertebral body
- a plastic (ultra-high molecular weight polyethylene) inlay that fits between the 2 endplates.

The artificial disc replaces the damaged disc. The endplates and inlay help restore the natural distance between the vertebrae. The top endplate slides over the domed part of the inlay, allowing movement at the implant level and alleviating pain associated with movement.

Indications

The FDA’s approval letter to Switzerland-based Synthes states the ProDisc is indicated for use in patients who:

- are skeletally mature
- have no more than Grade 1 spondylolisthesis at the involved level
- have degenerative disc disease at 1 level in the lumbar spine (L3-S1)
- have pain caused by a degenerated disc confirmed by the patient’s history and radiographic tests, such as MRI
- have had no relief from pain after at least 6 months of conservative treatment.

Surgeon training

Like the Charité, the ProDisc is... 

(Continued on page 25)
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implanted anteriorly through an incision in the abdomen. A general surgeon exposes the spine, and a spine surgeon removes the damaged disc to create a space between the 2 vertebrae to implant the artificial disc. The procedure generally takes about 1 to 2 hours.

Initially, only 120 to 150 surgeons will be invited to the training for the ProDisc, including those who participated in the clinical trials. But Synthes plans to start training for other surgeons to learn the procedure, according to one of the investigators, Jack Zigler, MD.

There will be 2 structured courses that include didactic instruction, case reviews, skills labs, cadaver spine insertion, and individual surgical demonstration. Individual proctoring will also be available.

HealthEast, an early adopter of the Charité disc, expects to perform its first ProDisc procedures in December or January. Two surgeons will be attending some of the first ProDisc training courses, Blatnik says. Both have been using the Charité disc. One says he has been pleased with its results in his carefully selected patients, though he was skeptical at first, she says.

HealthEast surgeons have performed about 15 Charité procedures, with 3 being multilevel. The system has 17 orthopedic and neuro surgeons.

Reimbursement

Because of HealthEast’s work with its surgeons and insurers, Blatnik says that its Charité cases have been reimbursed at a level that is at least as good as its fusion cases in terms of the percentage of charges that are reimbursed. The list price of the Charité is $11,500. The price for the ProDisc is expected to be $9,989 with no discounts. (Synthes has not made its price public.) Blatnik says Synthes has said that initially it will deliver the disc individually for cases so it can monitor patient selection and make sure only surgeons who have had the training will be performing the case. Synthes did not respond to OR Manager’s request for comment.

Blatnik says she is gradually seeing more acceptance of the artificial disc by insurers, but the region’s Blue Cross & Blue Shield plan has not approved reimbursement for it. The Blue Cross & Blue Shield Association’s Technology Evaluation Center issued an assessment in 2005 that found the artificial disc did not meet its criteria. Blues’ plans in each area make their own coverage decisions.

Medicare covers the procedure under DRG 499 and 500 (back and neck procedures except spinal fusion), with a payment of between $4,700 and $7,200, much less than the cost of the Charité device alone. After initially saying it would cover the procedure, Medicare reversed its position in May 2006, allowing coverage for the Charité disc for patients under 60 at the discretion of local Medicare medical directors; coverage is excluded for patients 60 and over.

Blatnik notes that HealthEast surgeons are very careful in their patient selection, making sure the patient is an appropriate candidate and that the procedure will be covered by insurance.

What’s next?

FDA approval of the first artificial cervical disc, likely the Prestige from Medtronic Sofamor Danek, is expected early in 2007.

“The cervical disc will be received enthusiastically and should have a higher rate of acceptance than the lumbar disc,” Young says. It’s also less expensive.

—Judith M. Mathias, RN, MA
—Pat Patterson

References

An H, Phillips F M.


Please see the ad for
MOBILE INSTRUMENTS SERV & REP
in the OR Manager print version.
John Poisson is on a mission. The executive vice president of Physicians Endoscopy, LLC, is spreading the word that ambulatory surgery centers (ASCs) can be profitable and share their profits with the community by providing charity care or preventive health education.

“Well-run surgery centers are usually quite profitable, and with that success comes a responsibility to give back to the local community,” Poisson says.

Physicians Endoscopy, headquartered in Doylestown, Pa, partners with 13 ASCs and has another 5 in development. Many of the centers have a community support initiative to provide free care to poor patients or health education and screening to encourage colorectal cancer awareness.

At the Endoscopy Center of Western New York near Buffalo, the partners set aside 4.2% of profits for charitable care in the first year of operation. In the second year, GI surgeons approached 2 primary care physician practices that serve indigent populations to request that they send patients to the surgery center. The surgeons and staff provide preoperative and postoperative evaluations as well as the procedure at no charge, Poisson says.

“The primary care doctors were taken aback at first,” Poisson says. “They said, ‘No specialist has ever approached us to provide free care.’ The surgeons get such positive feedback from the primary care providers that they are motivated to keep doing it.”

At another center in Reading, Pa, the GI surgeons elected not to provide free care at the ASC because many of them staff the local hospital’s free GI clinic. Instead, the Berks Center for Digestive Health focuses on community education. Staff work at health fairs and speak on colon cancer awareness at Elks Club or Rotary meetings or on the local cable station.

One year, the center rented the Colossal Colon, a 40-foot long, 4-foot tall model of the human colon that hundreds of people in the community crawled or walked through. “Coco,” as it is nicknamed, shows what the colon looks like when it is affected by colorectal cancer, Crohn’s disease, diverticulosis, ulcerative colitis, hemorrhoids, and cancerous and noncancerous polyps.

“Besides being the right thing to do, charitable care and health education is terrific PR for the center in the community,” Poisson says.

**State CON mandates**

Physicians Endoscopy centers are located in states in which there are no charity or indigent care mandates. But in some states, providing charity or indigent care is not optional; it is required by the ASC’s certificate of need (CON). There are 37 CON states. Of those, approximately 25 regulate ASCs but not all require charity care, says Dean Montgomery, director of the American Health Planning Association.

Montgomery says to date there is no organized effort to quantify the states’ requirements for charity care, but he says it typically ranges between 2% to 4% of a center’s adjusted gross revenue. He believes surgery centers can and should provide more indigent or charity care.

“Outpatient surgery centers are extraordinarily profitable, so a 3% contribution is not a significant impact compared to the amount hospitals must give to the community,” Montgomery says.

The Federated Ambulatory Surgery Association (FASA) conducted a survey in 2006 that showed 83% of its members provide charity care or hardship payment write-offs. Of the ASCs that provide charity care, 60% provide it at the patient’s or surgeon’s request.

The survey also showed the majority of ASCs—60%—do not account for charity care in their financial statements, which makes quantifying how much...
Please see the ad for
RES-Q
in the OR Manager print version.
**Tax advantages of charity care**

ASCs in Georgia can write off the total billed amount (minus Medicare and Medicaid adjustments) as indigent care. The CON-regulated Surgery Center, LLC, Columbus, Ga, meets its indigent/charity care requirements and achieves significant tax savings.

### Open treatment distal radius fracture

<table>
<thead>
<tr>
<th>2CPT code</th>
<th>Billed amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>25620: Open reduction with external fixation</td>
<td>$2,808</td>
</tr>
<tr>
<td>76000: C-arm</td>
<td>$4,368</td>
</tr>
<tr>
<td>L8699 : Implant</td>
<td>$5,222</td>
</tr>
<tr>
<td><strong>Total charges</strong></td>
<td><strong>$12,400</strong></td>
</tr>
<tr>
<td><strong>Approx ASC costs</strong></td>
<td><strong>$2,580</strong></td>
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<tr>
<td><strong>Total write off</strong></td>
<td><strong>$12,400</strong></td>
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</tbody>
</table>

### Cataract surgery

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<thead>
<tr>
<th>2CPT code</th>
<th>Billed amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>66984 Cataract removal</td>
<td>$3,200</td>
</tr>
<tr>
<td><strong>Total charges</strong></td>
<td><strong>$3,200</strong></td>
</tr>
<tr>
<td><strong>Approx ASC costs</strong></td>
<td><strong>$600</strong></td>
</tr>
<tr>
<td><strong>Total write off</strong></td>
<td><strong>$3,200</strong></td>
</tr>
</tbody>
</table>

*Source: The Surgery Center, LLC, Columbus, Ga.*

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charity care the industry provides challenging, says Kathy Bryant, FASA executive director.

“We think ASCs are providing a lot of charity care, but many ASCs don’t keep the information on their books,” Bryant says.

She adds that for-profit ASCs contribute to the community through income, property, and sales taxes from which not-for-profit hospitals are exempt.

**Georgia requires 3%**

In Georgia, a CON state, the state requires 3% of an ASC’s adjusted gross revenue (total charges adjusted for losses from bad debt, Medicaid, and Medicare) be provided as charity or indigent care or be paid directly to Georgia’s Indigent Care Trust Fund.

“We’d rather the centers provide the care in their local community than write us a check,” says Matt Jarrard, health planning data manager for the Georgia Department of Community Health.

Of Georgia’s 52 ASCs regulated by certificates of need, 33 hold indigent and charity care commitments. Many single-specialty and all office-based ambulatory surgery facilities do not have charity or indigent care requirements, Jarrard says.

Georgia follows federal poverty level guidelines for indigent care. Indigent care is discounted 100%. To be eligible, the 2006 guidelines state that patients must be at or below the 125% poverty guideline, or their annual income is at or below $24,000 for a family of 4. (See http.aspe.hhs.gov/poverty for current guidelines.)

At The Surgery Center LLC in Columbus, Ga, charity care is provided on a sliding scale of income, based on the federal government’s poverty level guidelines, says Jennifer Winters, business office manager. The maximum discount is 75%, with patients paying 25% of charges.

**Less costly to provide care**

Winters says that during the first 3 years her multispecialty center operated, it waited for the state’s bill, then wrote a check for the required 3% adjusted gross charges. But when the surgeons realized the advantages of providing direct care over a monetary contribution, the center began seeking patient referrals.

“Physicians were hard to get on board at first. They preferred to pay the fine,” Winters says. “But once they realized it would cost us less to provide the care based on adjusted gross charges over writing a check out of our revenues, they came on board.”

ASCs realize tax advantages when providing charity care. The charity/indigent care amount reported to the state is deductible. “Therefore you are reporting less net income on your income statement,” Winters says.

**Educating MD offices**

After the board at The Surgery Center agreed to provide direct care to patients in need, staff began notifying schedulers at family practice offices and clinics to refer their lower-income patients.

Qualifying patients must complete a 4-page application that documents their income level. “Most of our lower-income patients are used to applying for assistance,” Winters says. “Most of them come with the required documentation in hand.”

Patients are pleased with the service provided in the ambulatory surgery setting. Winters says, “They are accustomed to waiting all day at a hospital for their continued..."
Please see the ad for
MEDTRONIC
in the OR Manager print version.
surgery. They’re surprised they can be in and out of the center so quickly, and they always remark on the compassionate care.”

**Enforcing compliance**

Despite the state regulations, Montgomery of the American Health Planning Association believes CON indigent/charity requirements are not strictly enforced across the states.

Jarrard of Georgia’s Department of Community Health says Georgia’s facilities are audited only when applying for a CON, but the department is working to review each regulated ASC’s annual commitment more proactively.

Winters says many of her ASC colleagues in the state just wait for a bill to come to pay the fine. “Some people just ride the line and hope the state won’t ever ask for the money. That’s a gamble we’d rather not take,” she says.

“**Right thing to do**”

The “we do it because we have to” approach is the one Poisson hopes to change.

“I believe we need to add a new focus to ambulatory surgery care,” he says. “Since the beginning, ASCs have concentrated on profitability and quality; now let’s add giving back to the community that supports us.”

Poisson recommends that a center begin considering charitable care contributions after it is up and running for about 1 year. “The topic ought to be on the board agenda at the time you’re ready to make your first distribution to investors,” he says. “It may get voted down the first time, but keep bringing it up until the board sees the merits.”

—Leslie Flowers

Leslie Flowers is a freelance writer in Indianapolis.

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**‘Secret patient’ checks out ASC’s cleanliness, courtesy, and privacy**

Retail stores employ secret shoppers to provide undercover intelligence on customer service. National Surgical Care, which develops, acquires, and operates ambulatory surgery facilities throughout the US, adopted this covert consumer technique to monitor patient satisfaction with the attitude and environment of its 23 ambulatory surgery centers.

Every month, an employee is chosen to surreptitiously walk through the center for one day with the eyes of a patient or family member. At the end of the day, the secret patient completes an assessment form (see p 33) and writes additional observations. The findings are discussed at the next medical quality improvement committee or staff meeting, says Dawn McLane-Kinzie, RN, MSA, CASC, CNOR, vice president of National Surgical Care.

“Staff really enjoys doing it, and we learn so much from the process,” says McLane-Kinzie, who created the customer service audit.

She says every employee gets the opportunity to be a secret patient. On breaks and when they won’t be noticed, the secret patient walks through the lobby and waiting area, admitting, preoperative area, OR, and postanesthesia care unit. Often, the secret patient will ask other patients and family members about their experience. Even business office staff will dress in scrubs to observe the OR under the guise of needing to talk with the materials manager.

“We try to keep the person a secret so staff does not know they are being observed,” McLane-Kinzie says. Some measures the secret patient assesses are facility cleanliness and temperature; staff courtesy; and whether beverages, privacy, and emotional support are provided.

What has National Surgical Care learned from the secret patient observations?

“We learned we could do a better job with patient privacy—keeping curtains pulled and voices low, making sure names aren’t visible on charts to other patients, and doing away with clutter,” McLane-Kinzie says.

“Another area we’ve improved on is minimizing unnecessary personal chatter, like conversations about a date someone had the night before or what they’re having for dinner, especially when patients haven’t eaten.

“We learned the overall noise level was too high and disconcerting to patients. They’re thinking, ‘Why is my nurse talking about this when I’m about to have surgery?’”

McLane-Kinzie says the secret patient assessments have improved customer service, especially because feedback comes from peers.

“It’s so much more valuable when a fellow nurse says, ‘It really is annoying to hear personal conversations when you’re the patient,’ than it is for me as an administrator to tell staff to talk more quietly or keep charts out of public view,” she comments.

—Leslie Flowers

**Building new ORs?**

Please see the ad for
SANDEL MEDICAL INDUSTRIES
in the OR Manager print version.
# ‘Secret patient’ facility assessment

Please check the appropriate column for each area.

<table>
<thead>
<tr>
<th>Lobby/waiting area</th>
<th>1= Poor</th>
<th>2= Fair</th>
<th>3= Average</th>
<th>4= Good</th>
<th>5= Excellent</th>
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<tbody>
<tr>
<td>Cleanliness of area</td>
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<tr>
<td>Atmosphere</td>
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<td>Heat/cool settings comfortable</td>
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<td>Nourishment/beverage available</td>
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<td>Accommodations/handicap</td>
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<td>Admitting</td>
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<td>Greeted/acknowledged upon arrival</td>
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<td>Prompt service for registration</td>
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<td>Confidentiality</td>
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<td>Individual attention given</td>
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<tr>
<td>Courtesy</td>
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<tr>
<td>Preoperative</td>
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<tr>
<td>Privacy provided</td>
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<tr>
<td>Procedure explained, questions answered</td>
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<td>Reassurance of quality patient care</td>
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<td>Emotional support for patient and family members</td>
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<td>Operating room</td>
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<tr>
<td>Greeted by staff and informed of chain of events</td>
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<tr>
<td>Comfort provided with pillows, warm blankets</td>
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<td>Tranquil induction</td>
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<td>Positive reassurance: &quot;Will see you when you wake up&quot;</td>
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<td>Postanesthesia care unit</td>
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<tr>
<td>Privacy provided</td>
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<tr>
<td>Minimal noise level</td>
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<td>Comfort/appropriately medicated</td>
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<td>Reorientation</td>
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<td>Organized transfer to Phase II</td>
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<td>Phase II recovery</td>
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<tr>
<td>Nourishment offered at appropriate times</td>
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<tr>
<td>Thorough discharge instructions given</td>
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<tr>
<td>Assistance provided for preparation for travel home; ie, emesis basins, appropriate dressings</td>
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<tr>
<td>Recovery time-frame as patient expected</td>
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</table>

Source: Dawn McLane-Kinzie, RN, MSA, CASC, CNOR, National Surgical Care. A printable version is in the OR Manager Toolbox at www.ormanager.com.
Improving OR efficiencies

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Christy Dempsey, RN, MBA, CNOR, Vice President, Perioperative and Emergency Services, St John’s Regional Health Center, Springfield, Mo

Dec 6, 2006
Block Utilization 360: Maximizing Utilization and Profitability in the OR
Mary Diamond, RN, MBA, Director, Surgical Services, Sharp Metropolitan Medical Campus, San Diego

Jan 10, 2007
Process Improvement in the OR: Practical Applications of Six Sigma Tools
Tina Foster, RN, MBA, Black Belt, Six Sigma, Vice President, Capacity Management Consulting, McKesson

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Please see the ad for INTEGRATED MEDICAL SYSTEMS in the OR Manager print version.
Ruling makes some charge RNs ineligible for unions

The National Labor Relations Board (NLRB) ruled Oct 3 that certain full-time hospital charge nurses are management and thus ineligible to join unions. In the case involving Oakwood Healthcare, Dearborn, Mich, and the United Auto Workers, the board voted 3-2 that permanent charge nurses exercised supervisory authority by assigning employees to care for specific patients. The board did not include temporary or rotating charge nurses as management.

The decision, which labor leaders see as creating a new standard for union membership, could have significant implications for union efforts to organize nurses. Unions said they will fight the ruling.

—www.nlrb.gov/nlrb/press/releases/

Alcohol-based hand rub dispensers OK in exit corridors

It’s official—the Centers for Medicare & Medicaid Services (CMS) issued a final rule in the Sept 22 Federal Register that permits alcohol-based hand rub dispensers in all appropriate areas of health care facilities including exit corridors.

The rule specifically allows ambulatory surgery centers to install dispensers in exit corridors under the same conditions as other health care facilities. But the rule notes the requirement for 6-ft wide corridors may be difficult for ASCs to comply with.

In the final rule, CMS concludes that any fire safety concerns posed by the alcohol are outweighed by strong evidence that alcohol-based hand rubs are effective for hand hygiene and infection control.

—www.gpoaccess.gov/fr/index.html

Bariatric surgery patients do better in centers of excellence

Hospital readmission rates from bariatric procedures were nearly cut in half by 12 surgeons in North Carolina designated as centers of excellence for bariatric surgery by the state’s Blue Cross and Blue Shield plan. Among the findings:

• Readmission and complication rates decreased from 7.6% to 4.7% in 1 year.
• The proportion of bariatric procedures performed by centers of excellence increased from 55% to 61%.
• Readmissions declined at facilities that were not centers of excellence but remained 75% higher than centers of excellence rates.

Blue Cross and Blue Shield of North Carolina says this is among the first national peer review data showing clinical advantages of a centers of excellence program. The plan was among the first to launch a program in 2004.


Jehovah’s Witness program reduces use of blood products

A transfusion-free program for Jehovah’s Witness patients having liver transplants also reduced overall use of blood products for non-Jehovah’s Witnesses, according to a study in the September Archives of Surgery. Liver transplantation is typically associated with a large loss, resulting in multiple transfusions and related complications, such as transmission of blood-borne viral infections.

Researchers from UCLA Hospital compared non-Jehovah’s Witness patients who had liver transplants before the transfusion-free program was initiated (group 1) and afterward (group 2). The mean number of intraoperative packed red blood cells and fresh frozen plasma used in group 2 was significantly lower than in group 1.


Surgeons operate in zero gravity

In a world first, French surgeons on Sept 27 performed an operation on a human in weightless conditions—hoping it will be a step toward surgery in space. Using an Airbus 300 modified to simulate conditions in space, surgeons and anesthesiologists in harnesses removed a cyst from the arm of a 46-year-old volunteer strapped to the operating table. For the 8-minute operation, surgeons worked in 22-second intervals. Instruments were held in place by magnets, and the cyst floated away from the patient after excision, tied to a string. The operation is part of a European project to develop earth-guided surgical space robots that could perform emergency surgery aboard the International Space Station.

—www.washingtonpost.com

At a Glance