The number of reloads for endoscopic devices was the major driver of supply costs in a new benchmarking report on laparoscopic gastric bypass surgery.

Supply costs varied widely, from $1,918 to $8,509, for the 8 facilities participating. The study was conducted by OR Benchmarks, a service of OR Manager, Inc.

The study compared costs for the Roux-en-Y laparoscopic gastric bypass for 33 cases. Roux-en-Y is the most common and successful type of malabsorptive surgery for obesity, according to the National Institutes of Health.

The surgery involves constructing a 15-mm stomach pouch (about the size of a small plastic medicine cup) and bypassing a segment of the intestines by constructing a Y-shaped limb of small bowel. Patients lose weight because the procedure restricts the amount of food they can eat and nutrients they can absorb.

About 56% of weight-loss surgery is performed laparoscopically, according to the American Society for Bariatric Surgery. Laparoscopic gastric bypass has advantages over the open approach, including fewer wound infections, abdominal wall complications, and shorter hospital stays. Weight loss is similar for open and closed surgery. Lapa-roscopic obesity surgery, which

Continued on page 7

A business executive turned on the light for transplant surgeon Darrell Campbell, MD. When Alcoa chairman Paul O’Neill discussed safety in his aluminum conglomerate, Dr Campbell became inspired.

O’Neill, former U S Treasury Secretary, reported that when Alcoa made employee safety its number one priority, recruitment and retention increased, as did profits.

“Safety became my mantra,” Dr Campbell said. “I believed all good things for the hospital would flow from the principle of patient safety.”

Two years into the process, the University of Michigan (U-M) Health System in Ann Arbor has earned top scores by the Michigan Health & Safety Coalition, which awarded U-M its highest ranking in all categories.

“What may not be the safest in the country yet, but that’s our goal,” Dr Campbell says.

Campbell leads U-M’s patient safety crusade. He splits his time as chief of clinical affairs in charge of safety and quality and as a transplant surgeon.

His patient safety team has infused the hospital culture with its mission, creating an atmosphere of open communication.

Cultural of transparency

“We want a culture of transparency—we’re not perfect and we make mistakes—and blamelessness—we will

Continued on page 14
Please see the ad for INTEGRATED MEDICAL SYSTEMS in the OR Manager print version.
CNO or COO?
Readers weigh in on the best reporting structure for perioperative directors.

Coping with staffing
Is your OR suffering from schedule gaps—surgeons want to operate early and late in the day? What strategies can help?

Tips on tissue
What are the appropriate ways to handle tissues for transplant?

Who’s in charge? Should the director of perioperative services report to the chief operating officer (COO) or the chief nursing officer (CNO)?

This question generated spirited discussion at the OR Business Management Conference in May in Albuquerque (article, page 12.)

A panel advocated having the perioperative director report to the COO.

“It’s the dollars,” said the panel, which included a nursing director of perioperative services, two physician directors, and a hospital administrator.

The ORs generate about 50% of the hospital’s profit margin and use a large share of its resources.

It’s best for the OR to report to the COO “so we get the support we need to market and manage our resources,” argued Gloria Hunt, the nurse on the panel.

If the OR reports to nursing, the director has to spend time educating the CNO about the OR’s needs, the panel argued.

“You don’t have time for that. If you report directly to the COO, it could solve a lot of problems,” Hunt said.

Most report to nursing
But that’s not the usual situation.

For more than a decade, the OR Manager career/salary survey has found the vast majority—about 70%—of OR directors report to nursing.

There are good arguments for reporting to nursing.

The CNO may be more likely to understand the OR’s staffing and education needs than the COO.

Perioperative directors see an urgent need to have clinical educators who can help build and maintain the competence of the nursing staff. Will a COO understand the need for this position or mainly look at the cost?

Education is a patient safety issue. With the nursing shortage, ORs are hiring more inexperienced RNs who need months of orientation. ORs also contend with a constant barrage of new technology—patients can be harmed if the staff and physicians aren’t educated in using new equipment correctly. And new high-tech services may require more staff.

Perioperative directors also feel a strong professional allegiance to nursing. Nurses have fought for years to maintain a role for the professional nurse in the operating room. The CNO may be more likely to see the importance of this issue. Some administrators and physicians may not appreciate the difference between the professional and technical roles in surgery or understand why it’s necessary to keep an RN circulator on every case.

The CNO also may be more likely to support OR nurses’ involvement in shared governance models that provide an avenue for nurses to participate in decisions about their professional and work lives. This type of participative decision making has proven to be a major factor in a hospital’s ability to attract and retain nurses.

Is dual reporting ideal?
A dual reporting relationship might seem ideal—report to the COO for the budget and physician issues and to the CNO for nursing and professional issues.

But that’s not as easy as it sounds. Not all the issues can be neatly divided between one or the other—what if there’s a conflict between the budget and staffing needs? How do you decide who’s really in charge? Who wins out?

With a dual reporting structure, a director is likely to end up educating two bosses instead of just one.

Whatever the reporting structure, as in most matters involving the OR, the successful director has to be a skilled diplomat who’s capable of managing upward with the boss—as well as laterally to the physicians and as a leader and coach with the staff.

—Pat Patterson
4

Please see the ad for
OLYMPUS ENDOSCOPY
in the OR Manager print version.
**Fish! feeds hunger for meaning at work**

Steve Lundin, PhD, or Dr Tuna as he is called by his clients, doesn’t remember how he got his nickname, but it fits this former college football player turned executive, professor, and now inspirational speaker.

Lundin is a big guy—235 lb to be exact—and is co-author of *Fish! A Remarkable Way to Boost Morale and Achieve Results*, based on the guys who sell fish at the Pike Place Fish Market in Seattle.

*Fish!* has sold more than 1 million copies, and the *Fish!* film is the best-selling business video in the world.

Lundin will speak about the Fish! philosophy at the Managing Today’s OR Suite conference October 6 to 8 in Chicago. He is featured at the Friday luncheon sponsored by Advanced Sterilization Products.

“Fish! is an international movement because it speaks to a growing hunger that people are feeling today,” Lundin says. “People are increasingly seeking meaning in their lives and want to be authentic at work, even if they aren’t at their dream job.”

Lundin’s colleague and co-author John Christensen came upon the fish market because he had a day to kill in Seattle.

As John approached Pike Place Market he heard a commotion and was attracted by the laughter. What he found was a fish market with incredible energy, excitement, and playfulness as the fishmongers went about their tasks in a remarkably vital way. At that moment, Christensen saw the potential for a film, and Lundin began thinking of a book.

**Serving the human spirit**

“One of the most common observations I’ve made in my many years in business is that many people treat their work life as if it doesn’t count,” Lundin says. “They pass through their work life and fail to realize that half of their breaths are taken in the workplace. I believe that if work isn’t serving your human spirit, it is too big a price to pay,” says Lundin, who has been an administrator for the Veterans Affairs health system, a think tank executive, national sales manager, business school dean, and business owner.

“It’s not about work and life—it’s all life. And the choices we make are what honor our life.”

The power of choice underlies the four principles of Fish!:

- **Choose Your Attitude**
- **Play**
- **Make Their Day**—a small act of kindness or unforgettable engagement can turn even routine encounters into special memories.
- **Be There**—the glue in our humanity is in being fully present for one another.

Lundin has a special affinity for nurses because his mother was a head nurse and his youngest daughter is studying to be a nurse practitioner. He has inspired staff at the Mayo Clinic, St Jude Children’s Research Hospital, and Baltimore Sinai Hospital, among others.

“The best feedback I’ve gotten from nurses is that Fish! reminds them why they got into nursing in the first place. It inspires them to be fully human at work.”

For more information about Lundin or Fish!, visit Charthouse Learning at www.charthouse.com.

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Leslie Flowers is a freelance writer in Indianapolis.
Please see the ad for
MEDLINE INDUSTRIES, INC.
in the OR Manager print version.
Weight-loss surgery

Laparoscopic gastric bypass
8 facilities submitting 33 cases

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Source: OR Benchmarks. www.orbenchmarks.com

Continued from page 1

may be associated with more complications than other types of minimally invasive surgery, has a steep learning curve. It takes 120 cases before a surgeon’s complication rate begins to decline, according to Perugini et al.

An experienced surgeon can routinely perform a laparoscopic gastric bypass in less than 1 1/2 hours. The average hospital stay is 1.6 to 3.6 days, according to the literature.

Supply costs
The facility with the lowest total supply costs in this benchmarking study used a custom bariatric kit and 2 to 10 additional reloads. In contrast, the facility with the highest costs paid list price for its laparoscopic supplies and used a higher-than-average number of reloads—16 to 19 (chart, p 9).

All participants used a combination of reusable and disposable trocars and other instruments. An ultrasonic scalpel was used in all cases at a median cost of $340 per case. The percentage of facilities using disposable instruments was:
- trocars 88%
- scissors 38%
- graspers 100%
- Verres needles 63%

Specialized trays
Two facilities used specialized bariatric surgery trays, with a wide range in costs:
- Facility A: $2,613 per kit
- Facility B: $865 per kit.

Facility A performed 2 of its study cases without the kit, which wasn’t available, pulling individual supplies, which cost $1,490 more than the kit.

Facility B, which had the lowest total supply costs, is Medical Center East in Birmingham, Ala. The hospital’s surgical services director, DeNene Cofield, RN, BSN, CNOR, says items included in the kit must be used “100% of the time for 100% of the patients. We don’t do any convenience packaging for our kits.”

Medical Center East’s surgeons use DVT prophylaxis with low molecular-weight heparin only in selected cases and are meticulous in drying the gastric staple line and oversewing the line manually if bleeding persists. They use reinforcing material only in these selected cases.

Leading predictors of DVT are the length of the procedure and patient immobility.

“One of the strategies should be to minimize the length of case—anything you can do to minimize the length of surgery is going to pay for itself,” Cofield says.

Patients have their Foley catheters removed 1.6 to 3.6 days, according to the literature.

One strategy should be to minimize the length of case.

Continued on page 9
Please see the ad for LAWSON SOFTWARE in the OR Manager print version.
continued from page 7

In Cofield’s opinion, typically 3 to 4 stapler fires should be needed to complete the gastric division. The number of stapler reloads is governed by surgeons’ technique and preferences. In Cofield’s opinion, typically 3 to 4 stapler fires should be needed to complete the gastric division. “More than this may indicate a technique issue,” she says.

At Medical Center East, the average number of staple reloads is 10:

1. Reload for transecting the jejunal common enterostomy.
2. Reloads to close the jejunal enterostomy.
3. Reloads for the gastric transection.
4. Reload for the gastrojejunalostomy.

Cofield also recommends making sure the stapler vendor provides support to help keep the surgeons and staff properly trained in the firing of staplers. Her facility evaluates every stapler incident as a user error, knowledge deficit, or product failure, and every stapler misfire is treated as an incident reportable to the vendor. When there is a stapler incident, Cofield says the hospital has negotiated for a one-for-one stapler replacement “so we share some of the risk with the vendor.” Though most misfires are user errors, she believes the replacement policy provides an incentive to vendors to make sure staff and surgeons are trained.

### References


The benchmarking study for bariatric surgery is still open. For information about participating, visit www.orbenchmarks.com or phone 800/442-9918.

### New York guidelines for bariatric surgery

New consensus guidelines in New York State were developed by 9 health plans and 12 bariatric surgeons. The guidelines were developed after the health plans’ medical directors observed that the field was growing rapidly with “considerable variation in operative techniques, surgeon skill, and institutional commitment.”

#### Patient selection

The guidelines’ absolute criteria for patient selection are:

- a body mass index (BMI) of 40 or greater
- a BMI of 35 or greater with a life-threatening or disabling comorbid condition

Among 10 other considerations are long-standing obesity and reasonable attempts to lose weight in a structured and documented program.

#### Surgeon requirements

Among requirements for surgeons are:

- completing a fellowship or preceptorship in bariatric surgery that includes patient education, support groups, operative techniques, and postop follow-up, with at least 25 bariatric procedures performed during the training
- performing a minimum of 25 bariatric surgical cases a year
- recognizing that 100 cases are needed to master basic procedures and technology
- obtaining 25 CME credits in bariatric surgery every 2 years
- using a multidisciplinary approach and having an infrastructure in place to provide lifelong follow-up to bariatric patients.

#### Facility requirements

Facility requirements include, among others:

- a specially equipped OR for bariatric surgery with tables and equipment for the morbidly obese and super obese
- hospital beds, air-pressure mattresses, commodes, stretchers, wheelchairs, and gowns to accommodate bariatric patients.

The consensus guidelines and a primer on bariatric surgery are at www.nyhpa.org
Expect to see more scrutiny of bariatric surgery

After rapid growth, obesity surgery is facing questions about costs and complications. Are too many hospitals doing bariatric surgery without enough patient follow-up? Are some surgeons performing procedures before they have enough experience?

A New Mexico newspaper reported in April on three lawsuits against the University of New Mexico Medical Center in Albuquerque because of weight-loss surgery. One involved a 500-pound former football player who died after surgery at age 25. In another case, a 51-year-old nurse with rheumatoid arthritis died after surgery to help her lose some of her 429 pounds.

The May 4 New York Times tells about Linda Culpepper, who sought care at Vanderbilt after weight-loss surgery left her with life-threatening malnutrition. Her hair was falling out, her skin was flaking, and her muscles were so wasted she could hardly walk. A lung specialist later said Culpepper should not have been cleared for surgery because of the state of her lungs. She said the small hospital in Georgia where she had her operation did not offer a support group, and she had only one meeting with specialists before her procedure.

Among other issues:
- growing skepticism by insurers
- the high cost of the surgery and related care, which runs from $20,000 to $50,000
- whether patients can keep the weight off long term.

More than 140,000 obesity procedures are expected to be performed this year, up from about 30,000 in 1998.

Pullback by payers

UnitedHealthcare, the nation’s largest health insurer, has stopped paying for weight-loss operations, as has Humana, according to the March 29 Los Angeles Times. Blue Cross and Blue Shield of Florida said it will stop in January. Without insurance, few patients could afford the cost.

A spokeswoman for America’s Health Insurance Plans, a trade group, said companies are concerned about the high costs of surgery and the fact that some hospitals and doctors are performing it without the proper qualifications and equipment.

In response, advocates of obesity surgery are lobbying state legislatures to pass bills mandating coverage for weight-loss surgery.

Demand for data

Though surgery has proven to be the most effective therapy for morbid obesity, there’s a call for more evidence on the risks and long-term weight control. Patients who don’t get the proper follow-up may learn to out-eat the surgery, negating its benefits.

On the plus side, there is strong evidence that surgery can cure diabetes. A 5-year follow-up study of 1,160 patients who had laparoscopic gastric bypass found 83% of the 190 patients with Type 2 diabetes had their disease resolved.

There are also benefits for improving sleep apnea, hypertension, and joint problems.

But the complication rate is also high. The National Institutes of Health reports that after obesity surgery:
- 10% to 20% of patients require further operations to correct complications, the most common being abdominal hernia, which laparoscopic surgery has helped to resolve.
- Nearly 30% of patients develop nutritional deficiencies such as anemia, osteoporosis, and metabolic bone disease. These usually can be avoided if vitamin and mineral intakes are high enough after surgery.

In a review of 3,464 cases by Podnos et al, the most common perioperative complications for laparoscopic gastric bypass were wound infection, anastomotic leaks, and GI tract hemorrhage. (See chart, p 11.)

The learning curve for surgeons was 75 to 120 cases.

What’s the learning curve?

A big determiner of patient outcomes—surgeon experience.

According to a report of 188 cases by Perugini et al, the learning curve was 120 cases, and the complication rate did not go down until the surgeon had performed that many cases. The finding was somewhat higher than the 100-case learning curve found by Schauer et al and the 75 cases found by Oliak et al.

Volume also makes a difference. Surgeons who performed fewer than

Are you monitoring outcomes?

Every bariatric surgery program should have a database for monitoring outcomes, advises the administrator of the surgical weight-loss program at Medical Center East, Birmingham, Ala. The hospital expects to perform 1,000 weight-loss surgeries this year.

“This will help you understand who your maximum-risk patient is,” says DeNene Cofield, RN, BSN, CNOR, Medical Center East’s director of surgical services. Medical Center East monitors:
- reoperations within 30 days
- hospital readmissions within 30 days
- mortality
- complications (leakage, hernias, and strictures).

Each of these is sorted by open or laparoscopic cases, and these in turn are subdivided by:
- age
- sex
- body mass index (BMI).

Commercial databases for monitoring bariatric surgery outcomes are available but so far are designed for surgeons. One example is the Minnesota Bariatric Database from Exempla Medical, LLC, Eden Prairie, Minn (www.exemplomedical.com; 612-702-5817). A database that includes hospital data is under development.
Centers of Excellence in bariatric surgery

Bariatric surgeons are rolling out a Center of Excellence program, which is scheduled to start taking applications in July. Criteria are expected to include a target for annual procedure volume, a comprehensive program for patient selection and follow-up, and reporting of outcomes data. The program will be voluntary and have two steps:
- provisional approval after reviewers document that resources are in place to conduct a bariatric program
- full approval based on outcomes data verified in a site visit.

Reviews will be conducted by a panel of bariatric surgeons.

Surgeon leaders say they believe a program designed by bariatric surgeons is needed. Though some insurance companies have centers of excellence programs, surgeons say the companies do not share the basis for their selections and do not share outcomes data.

The Center of Excellence program is sponsored by the American Society for Bariatric Surgery and will be administered by an independent entity, the Surgical Review Corporation. Information is at www.asbs.org.

10 bariatric procedures a year had twice the risk of adverse outcomes as high-volume surgeons—28% versus 14%, in a study of 4,685 patients from Pennsylvania’s discharge database.

The death rate was also much higher—5% for surgeons doing 10 or fewer cases versus 0.3% for high-volume surgeons. Overall, the mortality rate was 0.6% and rate of adverse outcomes was 17%.

Most dangerous of all is the low-volume surgeon (10 to 50 weight-loss operations a year) operating in a low-volume hospital—a situation with a 55% risk of adverse outcomes.

A better handle on outcomes

With the growing skepticism, expect more focus on outcomes.

The University of Pittsburgh has received a $6 million grant from NIH to lead a 6-center study on long-term effects of bariatric surgery. The study will look at quality of life; morbidity and mortality; and the effect of surgery on cardiovascular disease, congestive heart failure, and diabetes.

Expert guidelines

New guidelines on obesity surgery are coming from professional societies and public health agencies.

The Association of periOperative Registered Nurses (AORN) published a comprehensive bariatric surgery guideline in May, outlining clinical aspects as well as program planning.

Over the next few months, expert panels are expected to weigh in.

In Massachusetts, the state appointed an expert panel to study the safety of weight-loss surgery after several patients died. A report was expected in late May.

Louisiana is enrolling 40 state employees in a study to see if weight-loss surgery keeps insurance costs down over the long run by preventing other health problems.

References


Complications after gastric bypass

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Power is held by the people who believe they have control. The most powerful people in your OR may not be who you think they are—it might be the preoperative staff who control the flow of patients or the transporters who control when patients arrive in the unit.

“We can have as much power as we want. Political acumen can be learned,” said William F. Moskal, EdD, in his keynote at the OR Business Management Conference May 12 to 14 in Albuquerque, NM. The conference attracted 280 OR directors, OR business managers, and others concerned with the financial management of surgery for 3 all-day seminars and 18 breakout sessions on operational and materials management as well as OR design and construction.

Moskal, of IRI Consultants to Management, Detroit, taught practical tools for diagnosing the political landscape, using external networks, and building internal allies.

**Five keys to effective periop services**

With ORs driving 50% of the typical hospital’s margin, the department’s effectiveness should be a high priority for the entire organization. A multidisciplinary panel led a lively discussion of Five Characteristics of a Successful Perioperative Services Department. The five attributes include:

1. **Clear business focus**
   With surgery centers and surgical hospitals gnawing away at the business, hospitals need to analyze what distinguishes them from the competition—it might be inpatient care, cardiovascular services, or bariatric surgery.
   “You don’t just want to increase numbers. You’re better off selecting a couple of things to focus on,” said Jeffry Peters, president and CEO of Surgical Directions, a Chicago-based consulting firm.
   To help prioritize, he suggested asking the finance department for a report on the services that contribute the most to the bottom line. Consider those with the best clinical outcomes.

2. **Surgeon satisfaction**
   Concentrate on what will bring surgeons to your facility and make them want to stay, advised William Mazzei, MD, anesthesiologist and medical director of perioperative services at the University of California, San Diego.
   The top five service attributes for surgeons:
   - on-time starts for surgical cases
   - rapid room turnover
   - anesthesia availability
   - quality anesthesia providers
   - equipment.
   “There’s a very high correlation between surgeons recommending a hospital and on-time starts,” he said. “That is something I would focus on.”

3. **Strong, collaborative leadership structure**
   The most effective structure, the panel advised, is a team of a perioperative nursing director and a medical director of perioperative services.
   “I think the medical director has become the new trend. I think the support and help we can get makes our job easier,” particularly on physician issues, said Gloria Hunt, RN, MBA, CNOR, a...
Who should the medical director be? Typically, it’s an anesthesiologist who is an informal leader—the name that pops up when people ask whom to go to with issues. It is a person who is clinically respected, has strong interpersonal skills, and is a team player.

The medical director might be in an administrative role 1 to 5 days a week and should be paid a stipend by the hospital, Dr Mazzei said.

“The most critical aspect is not glamorous—it is being a foreman,” he said. The role involves:

• starting the day by reviewing the schedule and making necessary changes
• monitoring operations throughout the day with the nursing leadership
• planning for the next day’s schedule.

4. Streamlined organization

The panel advocated having the perioperative nursing director report to the chief operating officer (COO). Reporting to the COO is important, Peters said, so the OR gets the resources and support it needs.

Audience views were mixed. In a show of hands, most reported to nursing. The 2003 OR Manager career/salary survey found the vast majority (73%) of OR directors reported to nursing rather than hospital administration.

Acknowledging the advantages of reporting to the COO, some in the audience said they also needed support from nursing for clinical issues and education.

“The COO typically makes the decisions, so you are better off reporting directly to the COO and establishing that relationship,” Peters advised. Hunt suggested that in some cases there is dual reporting to the COO and the chief nursing officer.

5. Information technology

The panel strongly recommended that ORs have a full-time system administrator for OR information systems.

“The person needs to be highly skilled in knowing how the OR systems interface with other systems. There isn’t any hospital that doesn’t have 5 or 6 systems you need to be interfaced with,” said Hunt. Daily attention is also needed to maintain the chargemaster, item file for OR supplies, and surgeon preference cards—all crucial to the OR’s financial success.

About a third of the audience indicated they had such a position.

Because of the complexity of OR systems, it’s best if the system administrator reports to the OR leadership rather than the IT department, Hunt commented. “But there might be a dotted line to IT.”

Amusing look at the road ahead

Closing the conference, Dr Mazzei took the audience on an amusing tour of the road ahead for surgical services.

In the future, he suggested, a nurse will be able to download all of the pertinent information from a patient’s prior electronic medical record to create the history and physical.

The patient may have an electronic tattoo to mark the surgical site—which could be scanned to alert the anesthesiologist the patient has arrived and to confirm the site for Joint Commission requirements. A palm-sized probe waved over the pericardium will transmit data to the cardiologist for a consult.

And in this high-tech future, the perioperative nursing director and medical director will meet over a relaxed, 4-star lunch using an electronic device to review and update the next day’s OR schedule.

The audience joined in a lively discussion of five characteristics of successful perioperative services.

2005 OR business conference in Tampa, Fla

The 2005 OR Business Management Conference will be May 2 to 4 at the Tampa Marriott Waterside Hotel and Marina, Tampa, Fla. The 3-day conference will have optional all-day seminars on Monday with 2 days of general sessions and breakouts on Tuesday and Wednesday.

The addition of optional all-day seminars in 2004 was popular, with three fourths of attendees electing that option.

“With this conference, we are able to go to smaller cities, and we think you will like Tampa,” said Ellie Schrader, president of OR Manager, Inc, which sponsors the conference.

In addition to excellent conference space, the Tampa Marriott Waterside offers an Olympic-sized pool, health club, spa, and marina. The hotel is within walking distance of the Florida Aquarium, the Ice Palace Arena, and the Channelside entertainment center, with shops, restaurants, a movie theater, and IMAX.

Tampa is easily accessible by major and discount airlines. The Marriott Waterside is 10 minutes from the airport.

For those able to stay a few days, the Tampa area offers nearby beaches on the Gulf of Mexico, golf, and other recreational activities.
not engage in finger pointing,” says Dr Campbell.

The hospital has a Speak Up with Patient Safety Concerns Policy, which states that employees cannot be criticized or have job prospects influenced negatively because they brought up a safety issue.

This openness extends to patients and families. U-M has a full-disclosure policy that empowers staff to admit patient safety errors.

“Without any lawyers, we bring the family in, apologize, tell them we wish we could undo what we have done, and show that we will try to make sure it never happens again,” explains Dr Campbell. “We usually still get sued, but a lot of emotion is taken out of the case because we admitted we were wrong.”

**Patient safety rounds**

Dr Campbell and patient safety coordinator Maureen Thompson, RN, MSN, get to the root of errors by going on unannounced patient safety rounds throughout the hospital. They are joined by a pharmacist who is the pharmacy’s medication safety representative, a nursing administrator, a risk manager, and a patient advocate who is the wife of a former patient whose care was compromised by a medical error.

“She provides a viewpoint from a family member that none of us can offer,” says Thompson.

About 10 to 15 staff members, mostly nurses on a particular unit, gather in a conference room and candidly answer questions such as, “What’s happened lately that’s scared you? What’s the last thing that went wrong?”

“These kinds of questions bring out the practical issues that the people who are doing the work face every day,” Dr Campbell says.

Employees are promised confidentiality if requested, but no one has, Thompson says.

At a recent safety round on the postop surgical floor, a nurse expressed her frustration that patients were coming up from the postanesthesia care unit (PACU) with their pain not under control. Postop nurses had to leave their other duties to tend to these patients, some of whom were in extreme pain.

“We immediately got together the key people—an anesthesiologist, PACU nurses, residents, and other faculty—to make sure they re-emphasized that pain scores needed to be under 5 before sending a patient to postop,” Dr Campbell says.

**Rapid feedback**

Fast responses to staff safety concerns have been key to buy-in and cultural change, Dr Campbell says.

“We immediately address any issue we can with staff and administration,” Dr Campbell says. Thompson e-mails affected staff, especially those who raised the concern, with the action taken to bring about change.

“It’s created trust. With this rapid feedback, employees think, ‘Hey, these people mean business. I’ll tell them patient safety concerns every time,’” reports Dr Campbell.

U-M’s Office of Clinical Affairs also provides a physician on call 24 hours a day to assist staff with safety concerns at the bedside.

“If anyone calls and says ‘I’m worried. I need you to come see this patient,’ Dr Campbell puts down his pen and goes directly to the unit or intervenes immediately,” Thompson says.

U-M encourages employees to go up the chain of command with concerns, but if they aren’t satisfied and still feel a patient’s care is compromised, they are free to contact the on-call physician.

Thompson distributes a bimonthly electronic newsletter to keep safety in everyone’s consciousness.

“The safety movement here at University Hospital is very promising, very exciting, in the sense that staff knows this is important and we’re going to pursue it,” says Denise O’Brien, RN, MSN, CAPA, APRN, BC, clinical nurse specialist in the U-M PACU.

**Perioperative safety**

In the perioperative units, patient safety rounds and staff legwork have resulted in several process and equipment changes:

**Wrong-site surgery**

OR staff takes extensive measures to prevent wrong-site surgery. U-M surgeons usually mark the surgery site in the preoperative holding area, especially for digits, lymph nodes, and breast biopsies. A nurse may mark the site, however, if the surgeon has filled out a specific form in the preop clinic. The form then follows the patient into the OR.

The informed consent document contains seven points:
1. Description of the diagnoses
2. Recommended procedure
3. Potential side effects of procedure
4. Alternatives to procedure, eg, chemotherapy, radiation
5. Diagrams that point to surgical site
6. Possibility of blood transfusion and description of potential complications
7. Consent for tissue donation to U-M cancer research.

To ensure the patient understands the consent form and process, U-M follows the recommendation of the National Quality Forum: Ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion.

“The informed consent process can be really difficult for patients,” Thompson says. “The patients are under a lot of stress. We like them to take it home, go over it with other family members, call us with questions, then sign it.”

**Double-checks for correct site**

U-M builds 4 redundancies into the surgical site-marking process to ensure a patient’s correct surgical site:
- The attending surgeon and the
Measuring safety progress

These are some of the tools the University of Michigan’s Patient Safety Committee uses to track safety improvements.

Safety Attitude Questionnaire
www.uth.tmc.edu/schools/med/imed/patient_safety

University of Texas Center of Excellence for Patient Safety Research and Practice has developed survey tools for measuring staff and physician attitudes about the safety and teamwork culture.

Agency for Healthcare Research and Quality
www.ahrq.gov

AHRQ, the research arm of the U.S. Department of Health and Human Services, specializes in research in quality improvement and patient safety, among other areas. The agency has provided grants to study evidenced-based ICU safety interventions at 80 Michigan hospitals.

National Surgical Quality Improvement Project
www.nsqip.org

An effort led by Veterans Affairs Medical Centers to measure and improve the quality of surgical care. NSQIP includes 128 Veterans Affairs Medical Centers and 10 beta sites in the private sector.

National Quality Forum Safe Practices in Hospital Care
www.qualityforum.org

A private, not-for-profit membership organization that endorses strategies for health care quality measurement and reporting. Stakeholders endorsed 30 safe practices for reducing the risk of patient harm.

In addition, U-M has switched to

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California judge upholds nurse staffing ratios

A California Superior Court judge upheld the state’s new nurse staffing requirements in a May 26 ruling. The judge ruled against the California Healthcare Association (CHA), which challenged the state Department of Health Services’ interpretation that the new regulations require hospitals to reassign patients to a substitute nurse when the primary nurse is on a break, transporting a patient, or temporarily unavailable. The judge upheld the state’s requirement that hospitals maintain specific nurse-to-patient ratios at all times.

—www.ahanews.com

General surgery workload faces dramatic increase

General surgeons will be much busier in the coming years, predict researchers from the University of California, Los Angeles, and West Los Angeles Veterans Administration.

The number of people older than 65 years is projected to increase by more than 50% by 2020, while the number of younger individuals increases by only 13%.

By linking 3 data sources, the researchers predicted general surgeons’ workload will increase by 32%. Increases in 5 categories, breast/soft tissue, gastrointestinal, hepatobiliary, hernia, and other abdominal, range from 20% to 40%, with the largest growth in GI surgery.

If the number of general surgeons increases by 100 each year, the workload per surgeon is projected to increase 29% by 2020. If the total number of general surgeons increases by 200 each year, the workload per surgeon is projected to increase 26%.


Skyrocketing malpractice premiums hamper access to care

The Medical Group Management Association (MGMA) finds physician group practices continue to struggle with excessive medical liability premiums, and premium increases are hampering practices’ ability to provide care to patients.

An MGMA survey found:
• an average premium increase of 37% between 2003 and 2004, on top of a 40% increase the previous year
• 16% of practices have physicians who plan to retire, relocate, or restrict their services in the next 3 years
• nearly 24% of practices no longer treat certain high-risk patients as a result of premium increases, causing patients to travel to other facilities for certain procedures.

General surgical practices were seeing increases of 49%, neurosurgeons 39%, orthopedic surgeons 34%, and anesthesiology practices 31%.

The U.S. Senate is scheduled to consider liability reform legislation targeting specialties that are especially hard hit by premium hikes.

—www.mgma.com

Continued from page 15

chlorhexidine as an antiseptic for inserting IV lines.

Surgeon resistance

One obstacle to the patient safety mission has been surgeon resistance to what may seem like extra measures, such as repeating back phone orders or marking incision sites preoperatively. This is when Dr Campbell wears both his surgeon and chief-of-staff hats.

“Modifying physician behavior can be tough,” Thompson says. “But Dr Campbell is on a first-name basis with all of the surgeons. He’s here in the middle of the night operating like the rest of them. He’s able to get them to be open to doing things differently.”

Adds Dr Campbell, “I’ve had quite a few heart-to-hearts about this issue with my colleagues.”

Other safety measures

Other measures throughout U-M Health System resulting from the patient safety quest:
• Sedation nurses carry their own packs when they attend to a patient.

Previously, sedation nurses traveled to where the patient was, took medications out of that area’s stock, and administered them. U-M determined this was a safety hazard because of the medication’s availability to the general staff who could misuse it.
• Additional monitors were installed in procedure rooms so nurses standing behind a patient’s head during an upper GI procedure can see the patient and the monitors at the same time.
• To prevent medication errors, standard doses of intravenous pain medicines were changed so numbers such as 0.1 and 1.0 could not be transposed. For instance, concentrations are 0.1 or 0.5 to prevent a decimal mixup.

A robotic system is used in the pharmacy to avoid human errors, and similarly named medications are placed on separate pharmacy shelves. Physicians are asked to avoid sloppy penmanship or abbreviations in prescribing.

Thompson adds that step by step the changes have added up to a safer hospital. “Some of these changes may seem minute, but each one is like a dot in a Serat painting,” she says. “It can be a slow, iterative process, but I’m confident we’re moving our institution toward safer patient care.”

—Leslie Flowers

Leslie Flowers is a freelance writer in Indianapolis.
What new Stark rules mean for ORs

Y our hospital wants to extend a courtesy discount to physicians for surgery. The CEO wants to pay surgeons to be on a value analysis committee. A surgeon wants to buy a laser and lease it back to the hospital.

Are these arrangements permitted under physician self-referral rules?

New rules for the Stark law spell out what the government considers appropriate. These Phase II regulations, effective July 24, carry out the Stark II law, effective in 1995. The Phase I rules were issued in 2001.

Some highlights of the complex rule were provided by Michelle Marsh, an attorney with Walter Lansden Dortch & Davis in Nashville, Tenn.

Why are the regs important?

“These rules clarify and tone down what could be a very broad prohibition on financial relationships under the Stark statute,” Marsh says.

The purpose of the Stark law is to discourage physicians from having financial relationships with hospitals and other entities to which they make referrals, with the aim of preventing abuse of taxpayer-funded programs such as Medicare and Medicaid.

In passing the law, the government also realized it needed to provide certain exceptions for arrangements that don’t pose a significant risk of abuse. Those exceptions are spelled out in the regulations.

Who is covered?

The Stark statute covers 11 designated health services, including inpatient and outpatient hospital services. The statute does not cover freestanding ambulatory surgery centers (ASCs) that are not a department of a hospital, providing the center only provides services paid for under the Medicare ASC fee schedule.

Can hospitals pay physicians for being involved in cost management projects?

The regs make it clear a hospital can contract with physicians for legitimate administrative services, Marsh notes. The regs also set up a “safe harbor” for determining “fair market value” for physician payment for these services. Fair market value is considered either:

- an average rate paid to emergency department physicians in the area
- an average hourly rate under 4 of 6 widely published physician compensation surveys. (The surveys are listed in the rules.)

The Stark II rules don’t address gain-sharing arrangements, however. In gainsharing, a hospital might agree to split savings from a cost-reduction effort with physicians.

There has been some movement on gainsharing on other fronts. Several years ago, the Health and Human Services Office of Inspector General (OIG) took a strong stand against gainsharing. Since then, HHS has developed some pilot programs, but these are caught up in litigation. So at the moment, gainsharing is up in the air.

Per-click payments for equipment

The Stark rules allow a hospital to pay a physician a per-use rate for a piece of equipment that the physician owns and leases to the hospital.

The per-click rate must be set at fair market value, and the lease must meet other requirements spelled out in the regs. Generally, the lease has to be in writing signed by both parties, specify the equipment covered, cover equipment that doesn’t exceed what is necessary for the hospital’s business purposes—that is, isn’t just a way to funnel money to a doctor who is a referral source—and cover equipment used exclusively by the hospital leasing the equipment.

Hospitals can feel pretty comfortable that they are paying fair market value if the per-click rate is comparable to what they would pay any other vendor for use of that equipment, says Marsh.

But it’s very important not to vary the fee according to the volume of referrals—in other words, you couldn’t pay a higher per-click rate to a high-volume surgeon than a low-volume surgeon.

Courtesy discounts to physicians

A new provision—the regs allow giving free or discounted health care to physicians, physician family members, or physicians’ office staff. The professional courtesy discount must:

- be offered to all physicians on the medical staff or in the community or service area without regard to the value or volume of their referrals—not only to high-volume admitters
- apply to services routinely offered
- be set forth in a written policy approved by the governing board in advance
- not be offered to a beneficiary of a federal health program, such as Medicare, unless there is a financial need
- include informing the patient’s insurer in writing if the copay or deductible is reduced.

Courtesy discounts must not violate the Antikickback Statute or any other federal or state law or regulation for billing or claims submission. (The Antikickback Statute is another federal law that prohibits inducements or rewards for physician referrals.) It’s wise to have documentation to show the hospital is offering courtesy discounts broadly—not just because it wants one or a few physicians to bring more business.

Linking information systems

Also new—the regs allow hospitals to provide physicians with information technology (IT) services or items to encourage them to use electronic health records. Requirements are that the IT services:

- must be offered on a community-wide basis, not just to top admitters
- not violate the Antikickback Statute or any other federal or state law or regulation on billing and claims submission.

“The key is to have this be truly communitywide to defend against any charge that it was intended as a remuneration for referrals,” says Marsh. The Phase II Stark rules (42 CFR Parts 411 and 424) were in the March 26 Federal Register at www.gpoaccess.gov/fr/index.html.
Rewards and recognition for CS techs

When managers talk about improving performance of the central sterile (CS) processing department, the question always comes up—how can you improve pay and recognition for the CS staff?

CS technicians are among the lowest paid in the facility, yet they are faced with increasingly complex instrumentation. Surgeons and OR staff depend heavily on CS, yet the department lacks visibility, and the staff is often overlooked.

In interviews with OR Manager, two CS directors shared their approaches to reward and recognition. They are Richard Schule, BS, CST, CRCST, CHMMC, FEL, manager of the Surgical Processing Department (SPD) at the Cleveland Clinic in Ohio, and Susan Nielsen, RN, MSA, CNOR, administrative director of the Central Processing Department (CPD) for William Beaumont Hospital, Royal Oak, MI. The Cleveland Clinic, with 59 ORs, has a surgical volume of 37,000 procedures a year. William Beaumont’s main OR, with 36 ORs, has a volume of about 38,000 cases annually.

Q How have you improved visibility of the CS department in your organization?

Schule: As the manager or supervisor of your department, you have to get involved with your customers—you have to get out and listen. We have a customer survey we send every 6 months to perioperative staff nurses and surgical technologists. We use that as a sounding board. The survey results are graphed, and this information is shared at team meetings with the services and SPD staff responsible for those specialty instruments. Trends are identified, successes celebrated, and attention given to non-comformities.

In addition, we assign technicians responsibility for a primary and secondary service. This provides our customers with key contacts on each shift as well as creates ownership and helps to increase pride in work.

Nielsen: I am on a soapbox constantly about CPD. A year or so ago, I did a “road show” for each of the 5 OR cores, each of which has 1 or 2 services. I took a CS supervisor and a couple of staff members to their in-services and gave an overview of what we do and what they can do to help us. It gave the OR staff a chance to meet the voices on the other end of the intercom, and it gave them the message that we want to meet their needs.

Q What have you done to improve relations between the OR and CS?

Schule: We try to build a team approach. On each shift for each of the services, 2 SPD technicians are responsible for that service. Technology has taken such a leap that it is difficult to train everyone on every piece of equipment. It is advantageous to have specialized technicians, especially for services like spine, orthopedics, and MIS (minimally invasive surgery). That doesn’t mean the technicians will not rotate assignments, but it is a point of contact for the OR. In each OR a list is posted of the contacts in the SPD department. So if the OR staff picks up the phone any time of day, they know who they can ask for.

We have shared governance in the hospital. I established an operations committee made up of CS staff. They make a lot of the decisions and do planning for things like CPD Week. We have instituted an Employee of the Month, who must meet criteria for attendance, productivity, teamwork, and attitude.

We have a newsletter called The Pipeline. We featured one of our supervisors, who has been here 25 years and met his wife here. We have put up a display in our Employee Service Center with some of the staff who have become certified.

Another thing we do—if one of our staff or someone in their family is having surgery here, because we have an instrument tracking system, we know who did every instrument set for that case and who pulled the case cart. The person who had surgery writes a thank you note to post in the department. Then the staff knows they all contributed to making that person’s surgery successful.

Of course, we also send people to the OR for observation during their orientation.

It’s not just one thing—you use every single resource and idea you can identify.

Q Rewards and recognition for CS techs

Nielsen: We conducted a performance improvement project, with the support of the administration, that has helped raise the level of service our CPD provides to the OR (related article p 20).
The Cleveland Clinic is very large. Are specialized techs feasible for smaller organizations?

Schule: Prior to coming here, after I got out of the Navy, I worked at a hospital that had 22 ORs. I did the same thing there—I had specific people who were a point of contact. In my opinion, when you have technicians who take ownership of a specific service, you are able to provide a higher quality of service.

You always want to provide an opportunity to increase the knowledge of the technicians and give them some degree of empowerment or ownership. They are very much a part of the quality care team, even though they do not give direct patient care.

Nielsen: We have teams that specialize in orthopedics, retinal surgery, and neuro. We contract with a company for reprocessing of our laparoscopic equipment.

Have you found a way to address pay levels for CS techs?

Schule: This continues to be a struggle for us and for others in the profession. There have been successes at individual facilities, but not at the local or state level. CS and SPD professionals need to realize that administrators are not going to increase their salaries solely based on volume and throughput. And administrators need to realize they no longer can hire folks off the street.

This profession has become as technical as surgical technologists, radiation technologists, or respiratory therapists. We must work together and provide a better rationale for why the CS and SPD professional should have similar earning potential to their counterparts.

Our vision is to develop a clinical ladder in SPD. Our goals for this year are to revise job descriptions and become ISO 9001:2000 certified. I am unaware of any other CS or SPD that is certified on its own quality merits. This is a big commitment on the part of the staff that will raise their knowledge level, and it will be an expression of our customers’ commitment to quality through an internationally recognized standard.

Nielsen: One of the first things I was able to do was to upgrade the techs’ classification by one level. We are now the highest paid CPD in the Detroit metro area. That helps.

Are you upgrading qualifications and encouraging certification for CS techs?

Schule: Out of our 63 technical positions, 44 are certified, or 70%. This is accomplished in several ways—some people require classroom-style learning, some take correspondence courses, and some challenge the certification exam based on their qualifications. It doesn’t matter what vehicle they use as long as they go after it.

We are moving toward making certification a part of the job requirements. I believe everybody should have a base of knowledge when they come to us, which reduces the cost of teaching them the basics. Certification doesn’t necessarily mean more money at this point, but we are trying to work it into the job description.

We also explain to them that what they are learning here will help them get jobs elsewhere—some of our technicians would qualify as supervisors or lead technicians for other hospitals.

We have a waiting list of people wanting to join our department’s team. Some lack technical expertise, and we have suggested they go to the local community college and take a class. It makes them more marketable when they come to me with their applications, and it shows they have a commitment to the profession.

Nielsen: We have raised the qualifications. Before, it was a high school education. Now you either have to have some experience with instruments or to have taken a CPD course. Courses are offered in our area community colleges. I think CS is going to go the way of surgical technology, where they started training them in-house, then provided courses, and now in some areas, it is a 2-year associate degree.

We have also concentrated on getting people certified. When I came, there was one certified; now there are 15 out of our 97 FTEs.

Is there financial help for people who want to be certified?

Schule: There are scholarships available—and they don’t get enough applications. Some vendors also award points for dollars spent toward their products. Those points can be used to purchase correspondence courses. The points can also be used as incentives for “employee of the quarter” awards or other recognition programs for your department, at no cost to the institution.

For scholarships, check web sites of the American Society for Healthcare Central Service Professionals (www.ashscp.org) and the International Association of Healthcare Central Service Materiel Management (www.iahcsmm.com).

What is the turnover rate for your CS personnel?

Schule: Five years ago, we were averaging approximately 15% to 20% turnover each year. The last few years we have settled down to about 2% to 5% a year. That does not include disciplinary departures.

Nielsen: In January 2002, we were down 10 positions. We were able to fill those positions and keep most of those employees, and the turnover rate for 2002 and 2003 was between 6% and 7%.

Richard Schule will present a seminar entitled the Quality-Driven Central Processing Department at the Managing Today’s OR Suite conference Oct 6 to 8 in Chicago.

A conference brochure is at www.ormanager.com

Have an idea?

Do you have a topic you’d like to see covered in OR Manager? Have you completed a project you think would be of help to others? We’d be glad to consider your suggestions.

Please e-mail Editor Pat Patterson at ppatterson@ormanager.com
Getting to the bottom of case cart errors

A growing surgical volume and too few instrument sets, particularly in orthopedics, was bringing a rising tide of calls from the OR to the central processing department (CPD).

The CPD already knew it had quality issues with its case carts. With the backing of the administration, a performance improvement (PI) team at William Beaumont Hospital in Royal Oak, Mich, identified problems and solutions that have helped mend relations between the OR and CPD. Beaumont’s CPD supports the 36-room main OR, which performs about 38,000 cases a year, or 120 to 150 cases a day.

Susan Nielsen, RN, MSA, CNOR, administrative manager for central services (CS), described the PI project and the difference it made. Nielsen, who wrote her master’s thesis on CS, reports to the OR director.

Step 1: Get administrative support

Nielsen emphasizes that before launching a PI project, “you really need the backing of the administration and your leadership. If you don’t have that, you don’t have the availability of resources.”

The PI project was sanctioned by the administration, which provided a management engineer to assist the team. The engineer was helpful in analyzing data and developing reports.

Step 2: Organize a team

The team included, in addition to Nielsen, a CPD staff member from each shift, the CPD supervisor, an OR nurse, a data technician, and the management engineer.

“We made sure we included a person from the OR,” she says. “We wanted to accomplish what our customers wanted, not just what we saw as the goal.”

The project began with one service, orthopedics, because it accounted for 30% of the instrument volume.

“We figured that if we could get ortho under control, it would be easy to do the other services,” she says.

Before starting the project, the team went for PI training, which the administration provided.

Step 3: Gather data

To prepare for data gathering, the team brainstormed about what they thought the errors might be—wrong or incorrect case carts, case carts missing, instrument sets missing, instruments missing from the sets, and disposable items missing. The team guessed the main problem was that case carts were missing instrument sets because there was not enough inventory. But rather than assuming that, they collected data.

“We designed a simple form the staff in the OR could use to let us know what was wrong with the case carts,” Nielsen says.

The form had check boxes the OR staff would use to indicate what was missing. The form was stapled to the case cart pick list for every orthopedic case. In all, 877 forms were returned over a 3-month period. The forms were collected by an OR nurse and given to a data technician to compile.

Step 4: Analyze data

Analyzing the data from the forms, the team was surprised to find the No. 1 problem was not missing instruments but disposable supplies. Disposables accounted for 33% of case cart errors, followed by missing instruments at 25%.

With this finding, “we changed our whole focus,” Nielsen says, deciding to concentrate first on the disposable issue.

Step 5: Analyze the process

Before planning and testing improvements, the team reviewed how case carts were currently assembled. The team did a flowchart of the assembly process plus a fishbone diagram to assess the reasons why disposables on a case cart might be incorrect.

“We found there were variations in how carts were pulled with new people and people who had been here a long time,” Nielsen notes. Among reasons they identified for errors were:

• items in the incorrect bin
• bins incorrectly marked
• incorrect pick lists, for example, with items that should have been deleted that weren’t
• different names for the same item
• no formal right procedure for picking items.

Step 6: Identify and test quick fixes

The team identified and tested easy-to-implement improvements to the process:

• Checked to make sure terms used on the pick list matched labels on the bins. Terms constantly change as new products are brought in.

“We had new people who were trying to pull something that no longer existed in our storeroom,” Nielsen says. Now when a product changes, the materials coordinator automatically changes the bin label and alerts someone to change the pick list.

• Developed a feedback form for CS technicians. If a tech is pulling a case and discovers an item is labeled incorrectly, the tech fills out a form to give to the materials coordinator, who makes the labeling change.

• Introduced an audit process. In the morning or afternoon, one of the coordinators does a case cart audit.

“We put little red dots on random pick lists on the case carts,” Nielsen explains. The coordinator takes each cart that has a list with a red dot and reviews the contents in detail. If something is incorrect, she fills out a feedback form, then goes over the form with the employee who picked the cart.

“She will explain what was wrong and try to find out why. For example, was the item in the wrong bin? Then we try to rectify the process,” Nielsen says.

• Instituted a grid for the case cart staging area. With the large volume of case carts pulled for the next day’s surgery—60 or 70—the CPD needed a system to make it easy to find which case cart is for which OR and which case. (For space reasons, the CPD can only send case carts for the next day’s

Continued on page 22
Please see the ad for SURGICAL INFORMATION SYSTEMS in the OR Manager print version.
Central processing

Continued from page 20

first and second cases to the OR the night before. The rest must be kept in CPD.)

A grid is outlined on the floor with yellow construction tape and has a square for each cart. There is a white board with a corresponding grid where the staff writes the OR number and surgery time in each square.

“When you need to find a cart or add something to a cart, it is easy to go to the board and find exactly where it is,” Nielsen says.

As the process was improved, the team continued to survey the OR staff. Eventually, the rate of incorrect disposables went down to the point that instruments came to the top of the problem list.

Fixes for instruments

Improving the process for missing instruments was more challenging. With a growing volume, the hospital does not have enough instrument sets to supply all case carts for the next day’s cases. To address this problem, the team went through the same PI process.

Among the fixes:

• A “missing list” for instrument sets for the next day’s case carts. If a tech can’t fill a cart completely because a set isn’t ready, the tech files a “missing list.” Copies are given to techs processing instruments so they know the priorities. Unfortunately, because the list is so long, not even all of the priority sets get done, Nielsen says.

• A tagging system for instrument sets. CPD coordinators, who always know what instrument sets are needed, tag sets that will be needed again later that day before they are taken to the decontamination area. The sets are tagged with big red binder clips, which can be purchased in office supply stores. “The tags are easily seen in decontam, and the techs pick those sets to put through first,” Nielsen says. The clip stays on the tray throughout the process.

• Documenting missing instruments. Control charts are used to track the number of instrument sets missing from cases each day. “If the number of missing sets stays between the upper and lower control limits, we know we are able to meet the demand. If the number exceeds the upper limit, we look at that day to see why,” Nielsen says.

• Reassignment of staff. Technicians are moved around the department to accommodate the workload. For example, in the morning, some staff may be moved from decontamination to the processing area to take care of the priority sets. Also, more cases are pulled later in the day because if they are pulled in the early afternoon, not all of the instruments may be back from the OR, reprocessed, and on the shelf.

The next part of the project will be to decrease the number of errors in each instrument set.

Sample forms from Beaumont’s PI project are in the OR Manager Tool Box at www.ormanager.com

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Managing Today’s OR Suite

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The brochure for the conference is available at www.ormanager.com or by calling 800/442-9918.
Another HIPAA deadline is looming—April 21, 2005, is the date for compliance with the Security Rule. By then, your ambulatory surgery center (ASC) must have plans in place to protect patients’ electronic protected health information (ePHI), as required by the Health Insurance Portability and Accountability Act.

A key difference from the more familiar Privacy Rule—the Security Rule applies only to electronic information. The Privacy Rule, already in effect, applies to all information, electronic, written, and oral. There is some overlap, so you may already be doing some of what the Security Rule requires.

Don’t put off your compliance effort, cautions Robert Tennant, senior policy advisor in health informatics for the Medical Group Management Association (MGMA). “Just like the privacy rule, it gets tougher if you leave it to the last minute. Read some of the materials that are available free and get up to speed,” he suggests. Then see if some areas require more effort than others. You may decide to bring in someone to assist with the more technical matters.

“If you wait, you are going to be scrambling.”

Focus on business processes

Instead of focusing just on what you need to do to comply with the rule, focus on security to protect your own business processes, Tennant suggests. For example, one rule requirement is a risk analysis of threats to your electronic information. Ask yourself, what could happen to your business if there were a breach in electronic security? What if your billing system crashed, and you lost a month of receipts? Do you have backups of patient records in case your system goes down? “Basically, this is what a risk analysis is—walking through your facility and looking at the potential problems,” he says. These are areas you most likely will want to address anyway.

Some good news—the rule provides flexibility for small organizations like ASCs.

\[
\text{It gets tougher if you wait until the last minute.}
\]

HIPAA Security Rule

Basic requirements

The security rule requires organizations to safeguard the integrity, confidentiality, and availability of patients’ ePHI during its:

- receipt
- creation
- storage
- transmission.

Safeguards

Safeguards are required in three areas:

- administrative
- physical
- technical.

Key concepts

The rule has:

- required elements: Must be implemented
- addressable elements: Flexibility is allowed, but if elements are not implemented, facilities must document why.

What is not covered

The Security Rule does not cover:

- paper-to-paper fax
- phone calls
- video conferencing
- voice mail messages.

What is covered

- computer-generated faxes
- fax-back services.

The rule has both:

- Required elements, which must be implemented
- Addressable elements, which are required but allow flexibility. If these are not implemented, the facility needs to document why.

“The government says you can consider things like the size, complexity, and capability of your technical infrastructure, as well as the cost of implementing some of these measures,” Tennant says. You also can consider the probability.
Please see the ad for 3M HEALTHCARE in the OR Manager print version.
of a risk. There might be a small risk of a hacker getting into your system but a greater risk of a system failure for some other reason. You can rate the risks as high, medium, or low to set priorities.

Penalties under the Security Rule are not as onerous as for the Privacy Rule. Civil penalties are $100 per violation, up to $25,000 per year for each requirement violated. In contrast, Privacy Rule penalties can go much higher, up to $250,000 and/or 10 years in prison.

Because ASC managers typically aren’t computer experts, there may be a temptation to lean heavily on software vendors for compliance. But compliance is the ASC’s responsibility.

“If your vendor gives you a written statement that says, ‘We are HIPAA compliant,’ it is your responsibility to be sure they are doing what they need to do,” advises Barbara Harmer, RN, MHA, president of MedAssist Consultants, Celebration, Fla, who speaks frequently on HIPAA.

**Do a gap analysis**

A number of policies and procedures are required. ASCs should do a “gap analysis” by comparing existing policies and procedures with the rule’s requirements and develop new policies as needed. After the policies and procedures are finalized, employees and other workers need to be trained on the requirements. Training is required not only for employees but also for others who work in the facility such as contracted anesthesia providers, temporary personnel, and volunteers.

The rule has requirements for safeguards in three areas:

- **Administrative safeguards**
  - Have you done a risk analysis and developed a risk management plan for ePHI? This is a key requirement of the rule.
  - Have you assigned responsibility to a security officer? This might be your administrator or business manager.
  - Do you have a workforce security plan? For example, do you have ways to ensure only appropriate employees have access to patient records? Do you have a plan for terminated employees, such as changing their passwords and retrieving their keys?
  - Do you have sanctions for members of your workforce who fail to comply with security policies and procedures?
  - Do you have a way of auditing use of confidential information?
  - Have you done or are you planning to do security awareness and training for your staff?
  - Do you have a procedure for handling security breaches?
  - Do you have contingency plans for backing up and recovering your data and managing data in an emergency?
  - Do you have business associate agreements with third parties who handle your ePHI? If you already have privacy agreements, these may have to be updated for security.

- **Physical safeguards**
  - Do you have a way of locking rooms where computers are located and electronic records are stored?
  - Do you have a contingency plan for recovering data in case of a disaster or emergency?

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**Generic timeline for complying with HIPAA Security Rule**

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<thead>
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<th>2004</th>
<th>2005</th>
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<tr>
<td>Apr</td>
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<td>_______</td>
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<tr>
<td>Designate security officer</td>
<td>Conduct gap analysis</td>
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**Continued from page 24**
New joint statement on propofol

In response to requests, the American Association of Nurses Anesthetists (AANA) and the American Society of Anesthesiologists (ASA) issued a brief joint statement in April about propofol administration. They said they issued the statement because of “patient safety issues” related to use of propofol sedation by “unqualified individuals.”

Controversy in endoscopy

Propofol has raised controversy, particularly in GI endoscopy, because some endoscopists are using it as an alternative to the traditional drug regimens. In some cases, propofol is being given by RNs who do not have anesthesia training. Advocates say studies show this approach can be safe and cost-effective.

AANA and ASA say agents such as propofol require special attention because sedation is a continuum, and it is not always possible to know how an individual patient will respond. There is potential for “rapid, profound changes in the depth of sedation/analgesia” as well as a lack of antagonists.

The statement advises that propofol sedation be given only by persons trained in general anesthesia who are not also involved in the surgical or diagnostic procedure. Noting that this position is in accord with the propofol package insert, the statement says “failure to follow these recommendations could put patients at increased risk of significant injury or death.” Other agents are of similar concern, such as thiopental, methohexital, or etomidate.

The statement is not intended to apply when propofol is given to intubated, ventilated patients in critical care settings.

Studies on propofol

On the other side are 2 reports from researchers in Switzerland that show propofol can be given safely by nonanesthetists who are familiar with the drug’s use and pharmacological properties and who conduct careful monitoring. A review article by Chen and Rex cites “multiple studies” documenting safe administration of propofol by nonanesthetists but notes the practice is controversial and in need of further study.

Examining how use of propofol affects efficiency, Wurz and Bernstein analyzed 1,056 charts to evaluate differences between drug regimens. They found time savings of 5.3 minutes per case, which they decided was not enough to warrant changing their use of traditional medications.

The AANA/ASA statement is at www.asahq.org. Look under News.

References


Implementing the HIPAA Security Rule (Special Publication 800-66) at www.csrc.nist.gov. Look under Publications and scroll down to Drafts. The guide has examples for small and large organizations.

HIPAA Toolbox from the Medical Group Management Association at www.mgma.com. Look under Store and search for HIPAA Toolbox. Price is $140 for MGMA members and $219 for nonmembers.

Vendor template for meeting HIPAA security requirements. A checklist on what to ask vendors from the North Carolina Healthcare Information and Communications Alliance. Free at www.nchica.org/HIPAAResources/Samples.

The final Security Rule was published in the February 20, 2003, Federal Register and is at www.cms.hhs.gov/hipaa/hipaa2/regulations/security.
Some liposuctions exceed guidelines

Although most outpatient liposuction procedures in a new benchmarking study stayed within guidelines for the amount of fat and fluid removed, more than 1 in 10 exceeded the guidelines.

In 12% of cases, more than 5 L of fat and fluid was extracted, the limit set by the American Society of Plastic Surgeons (ASPS) for outpatient liposuctions.

The volume of fat and fluid ranged widely—from less than a medicine cupful to more than 13 L—the equivalent of more than six 2 L bottles of soda.

There also was a wide range in procedure times, from 51 minutes to 262 minutes (more than 4 hours).

“Liposuction can be very different procedures, depending on the amount of aspirate you are talking about,” says Naomi Kuznets, PhD, managing director of the Accreditation Association for Ambulatory Healthcare (AAAHC) Institute for Quality Improvement, which conducted the study. A total of 19 facilities participated, submitting 349 cases. The study included only procedures performed under sedation, regional anesthesia, or general anesthesia. An earlier study covered tumescent liposuction, which uses only local anesthesia.

Patients by and large were happy with liposuction—94% responding to a survey 6 months later were positive about their decision, and 89% were satisfied overall.

Complication rate 3%

The median amount of fat and fluid removed was 2.5 L, less than the 4.5 L to 5 L maximum recommended by professional societies. ASPS recommends any case that will remove more than 5 L be performed in the inpatient setting. The American Academy of Dermatology (AAD) recommends no more than 4.5 L be removed, regardless of the setting.

The average dosage of lidocaine given, 26 mg/kg, was well below the AAD-recommended limit of 55 mg/kg and the more conservative ASPS limit of 35 mg/kg. The range given was 0 to 66 mg/kg.

Complications were reported for 11 of the 349 cases (3%), comparable to the rate reported in the literature.

The most common complications were hematoma or seroma (6), followed by postoperative nausea and vomiting (3), and arrhythmias (2). No patients were hospitalized.

There were no deaths nor other serious events that have been previously reported, such as equipment failure, hypoxia, necrotizing fasciitis, nerve damage, pulmonary embolism, or respiratory arrest.

Patient safety concerns

One reason for conducting the study was patient safety concerns. Liposuction generated headlines in the late 1990s after a series of patient deaths. Many of these were associated with tumescent liposuction, in which mega-doses of highly diluted lidocaine with epinephrine are injected. In some cases, multiple procedures, such as an abdominoplasty and facelift, were done in one session.

Since 1998, plastic surgeons have taken a more conservative approach and are less likely to infuse large amounts of wetting solution, remove mega-amounts of aspirate, and perform multiple procedures in the same session.

In addition, several states, including New York, New Jersey, and Florida have set guidelines, and accreditation of office surgery facilities has expanded. The American Society of Plastic Surgeons has issued guidelines (see p 29).

Nevertheless, though serious complications in this study were absent, it’s apparent some providers are still exceeding the guidelines.

Of the 19 facilities participating, 4 were freestanding ambulatory surgery centers, 14 were office-based facilities, and 1 was a hospital outpatient unit.

Liposuction is the most common cosmetic surgery, with more than 380,000 performed in 2003—up 117% from 1997, according to the American Society for Aesthetic Plastic Surgery (www.surgery.org).
New practice advisory on liposuction

Though some members of the public may see liposuction simply as a cosmetic procedure, “it is real surgery with real risks,” notes the American Society of Plastic Surgeons, which, along with other societies, has published a practice advisory on liposuction.

“Over the years, advances in liposuction have allowed for ever-increasing amounts of fat to be removed,” noted Robert Iverson, MD, chair of the society’s Committee on Patient Safety.

The advisory covers techniques, anesthesia, patient selection, liposuction volume, multiple procedures, postoperative care, facility selection, surgeon training and qualifications, and facility accreditation.

Highlights

A few of the recommendations:

• Plastic surgeons should use the American Society of Anesthesiologists Guidelines for Sedation and Analgesia (www.asahq.org/publications and services/standards).

• The liposuction patient must be assessed using the same standards used for anyone undergoing surgery, including a complete preoperative history and physical.

• Large-volume liposuction (> 5,000 mL of total aspirate) should be performed in a hospital or a facility that is accredited or licensed. Postoperative vital signs and urinary output should be monitored overnight in an appropriate facility by qualified and competent staff.

• Large-volume liposuction combined with other procedures should be avoided.

• Physicians performing liposuction must be trained as surgeons. Surgeons performing procedures outside their specialty must obtain additional education and experience.

• Plastic surgery, including liposuction, should be performed in a surgical facility that is accredited, Medicare certified, or licensed by the state.

A task force was formed in 2000 to develop the advisory after several highly publicized patient deaths involving plastic surgery. ❖

Reference

Democrats’ effort to change overtime rule blocked

House Republicans blocked an attempt by Democrats to force an election-year vote on the Bush administration’s new overtime pay rules, the Associated Press reported May 13. The Democrats’ measure would have required the new regulations to keep eligibility for all workers who currently receive overtime pay.

The rules, issued April 23 and effective in August, in general guarantee overtime for workers earning up to $23,660 a year and protect or expand eligibility for those earning up to $100,000.

Nursing unions argued that the new regs don’t do enough to protect overtime pay of the 75% of RNs who are paid hourly. Under the regs, nurses can be considered exempt from overtime as learned professionals. But the Department of Labor said current practices for hourly pay are unlikely to change because of market forces such as the nursing shortage.

More hospitals covered by bloodborne pathogens rule

Though most hospitals already are covered by federal or state bloodborne pathogens rules, some government facilities have not been covered. To address that gap, Congress recently authorized expanding the rule to non-federal, government-owned hospitals in 26 states that previously had neither their own bloodborne pathogens standards nor an obligation to meet the federal rule.

The 26 states are Alabama, Arkansas, Colorado, Delaware, Florida, Georgia, Idaho, Illinois, Kansas, Louisiana, Maine, Massachusetts, Michigan, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Texas, West Virginia, Wisconsin, the District of Columbia, and Guam.

A hospital found in violation of the rule could be fined.

—www.cms.hhs.gov/providers/hpps/frnotices.asp

—Pat Patterson

Correction

In the June issue, the article on the new overtime rules should have said that employees earning $23,660 or less are guaranteed overtime pay, up from $8,060 in the current rules. Those earning between $23,660 and $100,000 may be eligible, depending on the nature of their job duties. The ceiling for overtime pay eligibility is $100,000 a year.

What bariatric equipment do ORs need?

What equipment should you buy if you’re setting up a bariatric surgery program? How much should you plan to spend? An equipment list, including costs, and a list of vendors is in the OR Manager Toolbox at www.ormanager.com

The equipment list is courtesy of Medical Center East, Birmingham, Ala.

Call for abstracts for 2005 meetings

Share your successes with your colleagues. Proposals are requested for OR Manager’s conferences:

Managing Today’s OR Suite
Oct 19 to 21, 2005, San Diego

OR Business Management Conference
May 2 to 4, 2005, Tampa, Fla

Send proposals of about 500 words describing the session you wish to present. Sessions are approximately 1 1/2 hours long.

Managing Today’s OR Suite focuses on practical topics related to management of surgical services, such as achieving greater efficiency, management of information, leading and developing staff, and keeping costs under control. The OR Business Management Conference emphasizes financial management, materials management, OR technology/equipment management, and OR design and construction.

The deadline for proposals and suggestions is Nov 1.

Fax or e-mail proposals to Billie Fernsebner, RN, MSN, education specialist, OR Manager, Inc, at 303/442-5960 or bfernsebner@ormanager.com. If you have questions, please call 303/442-1661.
Please see the ad for SKYTRON INC in the OR Manager print version.
Cidex OPA contraindicated for urological instruments in bladder cancer patients

Cidex OPA should not be used for reprocessing urological instruments that will be used in bladder cancer patients, the product’s manufacturer, Advanced Sterilization Products (ASP), says.

There have been 24 cases reported worldwide of anaphylaxis-like reactions in patients with a history of bladder cancer who had cystoscopies with instruments reprocessed in Cidex OPA. Most had repeated cystoscopies. Of these, 17 cases were in the U.S., 6 in Japan, and 1 in the United Kingdom. The U.S. cases were in 5 facilities. Most were not hospitals. All involved manual reprocessing.

“We believe a lot of the problem is that these facilities are not using optimal reprocessing techniques. They are not cleaning as well as they should, and they certainly are not rinsing these devices in the manner recommended on the label,” says Martin Favero, MD, PhD, ASP’s director of scientific and clinical affairs. ASP sent letters notifying customers and others in the urologic community.

—www.cidex.com

Free toolkit on JCAHO’s surgical safety protocol

The Association of periOperative Registered Nurses (AORN) sent a toolkit to hospitals in May to help them comply with the Joint Commission on Accreditation of Healthcare Organization’s new surgical safety protocol. July 1 was the deadline for implementing JCAHO’s Universal Protocol, which aims to eliminate wrong-site surgery. Endorsed by the American Hospital Association and its American Society of Healthcare Risk Management, among others, the kit has a CD-ROM, pocket guide, sample correct-site surgery policy, patient brochure, frequently asked questions, and other materials. Visit www.aorn.org or call AORN at 303/755-6304.

Manhattan hospital fined $20,000 for surgical breaches

The New York state health department fined the Manhattan Eye, Ear and Throat Hospital $20,000 in May for serious breakdowns in care after 2 patient deaths from complications related to cosmetic surgery. The state found 10 violations including failure to conduct basic preoperative assessments, monitor vital signs, ensure monitoring devices were operating at full capacity (alarms not audible), and take prompt and effective action when patients’ conditions changed.

The state required the hospital to address deficiencies, including retaining a consultant to review the anesthesia department, train the surgical staff in CPR, and set up an ongoing quality monitoring program.

—www.health.state.ny.us/nysdoh

Laparoscopic-assisted colectomy acceptable alternative to open surgery

A trial with more than 800 patients from 48 institutions found recurrent-cancer rates at 3 years were similar in patients who had laparoscopic versus open procedures for colon cancer. Overall survival at 3 years was also similar.

Recovery was faster in the laparoscopic surgery group (5 versus 6 days), and laparoscopic patients had briefer use of parenteral narcotics and oral analgesics. Rates of intraoperative complications, 30-day postoperative complications, readmission, and reoperation were also similar in the 2 groups.


Expanded rule for tissue screening

Tissue processors will have to meet more requirements for donor screening under a new rule from the Food and Drug Administration (FDA) issued May 25. The rule is the second of three regulations to improve oversight of the tissue processing industry.

The rule covers not only musculoskeletal tissues, eyes, and skin but also reproductive tissues (semen, ova, and embryos), stem cells from cord blood and cells from circulating blood sources, and tissues used in cellular therapies.

Tissue processors will have to screen for more infectious agents, including transmissible spongiform encephalopathies, such as Creutzfeldt-Jakob disease. The rule gives the FDA flexibility to respond to new disease threats, such as West Nile virus and possible bioterror agents, without more rulemaking. The rule takes effect May 25, 2005.

—www.fda.gov