Surviving the demands of an OR design and construction project

For some OR managers and directors, designing and building a new surgical suite is a once-in-a-lifetime project. For others, it’s almost a way of life as their facilities continue to expand and upgrade for new technology.

Joining a project team means donning a new hat in addition to the many managers already wear. They have to learn the language of architects and engineers, keep track of the timeline, stay on top of technology trends, and involve physicians and staff. If the OR is being renovated, they also have to juggle the OR schedule, address surgeons’ concerns, and protect patients from infection and disruption.

This issue has articles to help OR teams who are embarking on a design and construction project.

Orthopedic companies may face a headwind on implant pricing

Orthopedic companies could be facing a headwind in their ability to keep raising implant prices. Hospitals may finally get a break. For years, hospitals have faced rising costs and written the checks, while companies cultivated surgeons, who chose implants without necessarily paying attention to their cost.

Now a Wall Street analyst is warning investors that orthopedic companies face challenges as the prices hospitals are paying become more transparent. The wide variation in prices hospitals pay for implants is “unsustainable,” analyst Bruce M. Nuddell said in June, based on his survey of 100 facilities.

Meanwhile, orthopedic companies face a new round of subpoenas from the US Department of Justice. Five manufacturers said in June they had received subpoenas as part of a federal antitrust investigation.

The investment community seems to be waking up to economic challenges hospitals have faced for a long time. Implant prices have been climbing by an average of 8% to 10% annually, according to Orthopedic Network News, eating up a larger percentage of hospitals’ Medicare reimbursement for joint replacements.
Please see the ad for MEGADYNE in the OR Manager print version.
A knee prosthesis just for women—is it a clinical advance or a marketing gimmick? The gender-specific knee is the latest innovation from the orthopedic industry, known for upping the ante with new and more costly products that may or may not have a clinical benefit.

At least 2 orthopedic companies have new knees they say better imitate the natural shape and movement of a woman’s joint.

Soon to come, no doubt—TV and magazine ads aimed at women, who have 60% of the 400,000 knee replacements performed annually.

Zimmer Holdings claims to be the first, with its Gender Solutions High-Flex Knee, cleared by the Food and Drug Administration in May. Zimmer says the design is based on “scientifically documented shape differences between women’s and men’s knees” derived from sophisticated 3D CT scanning and modeling.

Stryker Corp, a competitor, says its Triathlon Knee “was designed with women in mind” and is better able “to fit the female anatomy while still accommodating the male population.”

A good marketing target

Demographics are clearly part of the strategy.

A Harris survey commissioned by DePuy Orthopaedics shows women with osteoarthritis are more likely than men to say their pain is severe but are less likely to see an orthopedic surgeon. Industry would like to see that change.

DePuy enlisted Broadway star Angela Lansbury as its spokesperson.

“A lot of women think chronic pain is part of getting old,” Lansbury says in a DePuy press release. But she says after her own knee replacement, “I can dance again.”

Women are a good marketing target. They make many of the health decisions for their families. They also live longer than men. As the population ages, more women and men will be candidates for joint replacement. And the Baby Boomers have a reputation for wanting only the best—an implant prosthesis that not only will keep them mobile but keep them active.

Surgeons differ in their opinions on the new knee.

One of Zimmer’s developers, Richard E. Booth, MD, chief of orthopedics at Pennsylvania Hospital, Philadelphia, says, “Knee implants have been functioning very well for men and women. But we want to meet women’s unique needs by making knee replacements that feel, fit, and function even better.” Zimmer claims to have a sheaf of studies that show the benefits.

Other surgeons say the concept isn’t new, noting other companies also have smaller knee implants. Commercializing it for women is the new twist.

“Everybody likes to feel something has been made custom for them,” one surgeon observed. “Some of it is realistic, but a lot of it is marketing.”

For surgical services value analysis committees, the women-only knee presents the now familiar task of sorting out where clinical benefit ends and marketing begins.

Some developments may help make these deliberations easier:

- The orthopedic companies are on the radar screen of the US Department of Justice. Five companies received subpoenas in June as part of a continuing investigation into the industry’s practices.
- There’s new awareness that price transparency initiatives could expose the wide differences in what hospitals pay for orthopedic implants. OR leaders may be surprised to learn that, at least according to one stock analyst’s survey of 100 hospitals, standardizing on implant vendors makes no difference in prices hospitals pay (article, p 1).
- At last, it looks like the tide of rising prices could be turning more in favor of hospitals.
Please see the ad for
SKYTRON INC
in the OR Manager print version.
In his survey, Nuddell, with Sanford Bernstein & Co, found striking price variations. The average paid for a primary hip implant was $4,937. But there was a big disparity. Highlights:

- Volume made little difference in pricing. Even among hospitals with similar volumes, there was “enormous variation” in the average implant price, ranging from under $2,000 to $9,000.
- Even for high-volume hospitals, there was a 2-fold variation ($4,000 to $9,000).
- The variation was not explained by differences in the mix of implant types used (eg, all-cemented, hybrid, and cementless models). On average, high-tech implants made up 30% of a hospital’s mix.
- There was no relationship between the payer mix and the average implant price; in other words, hospitals with a higher percentage of Medicare patients didn’t pay less. On average, 63% of primary hip implants are paid by Medicare or under Medicare rules.
- Standardizing on implant vendors hasn’t helped bring prices down. Hospitals who buy most of their implants from a single vendor don’t receive lower prices, Nuddell found.

Some hospitals that pay high prices don’t seem to be aware of it. Of 37 hospitals in the survey that pay more than 10% above the mean for hip implants, 27 thought they were getting the same prices as their peers. Findings were similar for knees.

Nuddell predicts that once hospitals become aware of this “true pricing environment,” they’ll become more aggressive on controlling costs.

He also thinks companies will have a harder time getting higher prices for newer products, such as knee implants targeted specifically at women (see Editorial) and products for minimally invasive surgery.

He didn’t discuss the fact that many hospitals already belong to benchmarking services for implant pricing and probably have a good idea of what others pay.

New round of subpoenas

Regarding the Department of Justice subpoenas, the companies that received them—Biomet, DePuy, Stryker Corp, Zimmer Holdings, and Smith & Nephew—said they were cooperating with the probe, which stems from possible criminal violations in the manufacturing and sale of orthopedic implants. The subpoenas requested documents starting from January 2001.

Little is known about the probe because the government doesn’t comment on such investigations.

Biomet’s CEO, Daniel Hann, told analysts the subpoena the company received was “very broad” and related to “pricing and bidding” but could not provide additional information.

In 2005, orthopedic companies received subpoenas from the US Attorney’s office in Newark, NJ, related to consulting arrangements with surgeons. At that time, observers thought the investigation would cause more distance between the companies and surgeons, which could be an advantage for hospitals.

Ongoing investigation

Regarding the new subpoenas, an analyst for Lehman Brothers, Bob Hopkins, said that the fact that the Justice Department’s Antitrust Division is in Washington, DC, and national in scope “strongly suggests the original investigation has been escalated.

“There is a possibility this is a completely separate investigation, but it is likely the two are related,” he wrote in a June 26, 2006 report. “Either way, the involvement of the Antitrust Division and the wording of the subpoena suggest a serious investigation that may be ongoing for some time.”

Hopkins added that he thinks changes in the market are coming, which “should ensure that the balance of power will continue to shift incrementally towards the hospitals.”

The investigations along with more awareness of pricing may give hospitals more clout in contract negotiations, which have been weighted heavily in favor of the orthopedic companies and their strong relationships with surgeons.
Please see the ad for
KARL STORZ ENDOSCOPY-AMERICA
in the OR Manager print version.
Experienced OR managers share expertise

New OR managers face the challenge of learning new skills as they move into management positions. At the Managing Today’s OR Suite Conference, Nov 8 to 10, in Orlando, Fla, new managers will have an opportunity to attend sessions by veteran managers who will share their know-how, experience, and information (sidebar).

We asked several of the speakers about the most challenging issue they faced as new perioperative managers.

**Human resources**

As a new manager, Heather Carelock recalls quickly discovering that associates, employees, and physicians worked with baggage. “My greatest challenge was how to help and counsel persons who were in dire straits that affected them both personally and professionally.”

DeNene Cofield had a similar challenge. She found dealing with difficult and chronically negative people was her most difficult issue. “I learned to sit down with them and explain expectations instead of just hoping. They will never change. It requires action and structured coaching.”

**Finances**

When Judy Dahle first became a manager, she found the most challenging financial issues were understanding the terminology, learning how to read the budget sheets, and finding out whom to talk to get answers. “Also important,” she said, “was understanding the hospital culture and financial system.”

**Project management**

Now a veteran of many projects, Mary Diamond recalls that as a new manager, “there were so many things to do. It was difficult to keep a project on track, to work on getting things done, and to check with people. Whatever the project, it takes you away from what you are doing, and it takes careful planning.”

**Information technology**

With a nursing rather than an IT background, Bob Baxter says he has more of a clinical approach to information systems than just IT.

The most critical challenges for new managers depend, he believes, on the current status of the OR. Is it moving from paper to electronic records? Is it switching from one system to another? If the OR is moving to having a computer in each OR, where should the computer be? “We placed the computers on mobile carts so the circulating nurse can see the screen and the surgical field,” he says.

Baxter also is concerned about the accuracy of data. He finds he needs to integrate the charge sheet and OR record to ensure that charges for all of the supplies have been included for a specific procedure.

**Special track offered for new managers**

A special track at the Managing Today’s OR Suite conference, Nov 8 to 10, in Orlando, Fla, hones skills new OR managers need.

**Preconference Seminar**

S-3: Human Resource Issues for New Managers

Two experienced OR directors and a vice president of human resources will discuss the partnership between clinical managers and the human resource department.

**Speakers:** Heather Carelock, RN, MHA, CNOR, director, surgical services, Mary Washington Hospital, Fredericksburg, Va; Katie Chamblee, vice president, human resources, Seton Health Corporation of North Alabama, Inc; and DeNene G. Cofield, RN, BSN, CNOR, administrative director, surgical services, Medical Center East, Birmingham, Ala, a member of St Vincent’s Health System.

**Breakout Sessions**

A-3: Budgeting Basics for New Managers

An introduction to financial terminology and techniques for forecasting the capital budget. How to justify capital equipment acquisition, determine return on investment, and do a break-even analysis will be covered.

**Speaker:** Judy Dahle, RN, MS, director, Benchmarks, OR Manager, Inc, Santa Fe, NM.

B-3: Materials Management for the New OR Manager

Strategies for managing supply expense and understanding cost drivers will be discussed. The value analysis process and the contract negotiating techniques will be explained.

**Speaker:** Amy Bethel, RN, MPA, CNA, executive director, surgical services, Iowa Health Des Moines.

C-3: Project Management: A Goal Without a Plan Is Not a Goal

What are the manager’s role and responsibilities? Why projects fail, and why they succeed will be covered.

**Speakers:** A husband-and-wife team, Larry Diamond, MBA, MHA, FACHE, PMP, CPHIMS, president, Diamond Consultants, Inc; and Mary Diamond, RN, MBA, CNOR, director, surgical services, Sharp Metropolitan Medical Campus, San Diego.

D-3: What a New Manager Needs to Know about OR Information Technology

What questions do you need to ask about your software system? The speaker will offer suggestions for working with your IT department to get the most out of your system.

**Speaker:** Bob Baxter, RN, CNOR, charge analyst, surgical services, Overlake Hospital Medical Center, Bellevue, Wash.

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Thirty days into a new 21-OR suite, leaders at Memorial Sloan-Kettering Cancer Center in New York City had already identified winning features they think will help improve patient and staff safety.

Though Memorial Sloan-Kettering performs only cancer care and has a longer-than-average case length at 4.5 hours, many of the lessons learned during the 5-year project apply to any hospital planning new ORs, says Aileen Killen, RN, PhD, CNOR, director of nursing for surgical services.

During planning for the suite, Killen and her colleague, David P. Jacques, MD, FACS, formerly vice chairman of the Department of Surgery, applied principles learned during a patient safety fellowship offered by the Health Forum. They will update their experience in the new suite in a breakout session at the Managing Today’s OR Suite Conference Nov 8 to 10 in Orlando.

These are some early winners.

Nurses’ work station
At a work station that swings out from the wall, circulating nurses can keep patients in view while entering documentation. They can also watch the surgery on a video monitor and control equipment with a touch screen.

“Preserving the line of sight is a huge winner,” says Dr Jacques. But it requires sacrificing space, “which is why most designers will reject it. It’s a lot easier to tuck the computer against the wall and have the nurse facing away from the patient.” Because the desk swings out, careful planning was needed to supply the work station with the necessary conduits for power and IT services.

‘Wall of knowledge’
A “wall of knowledge” assembles information so the whole surgical team can see it, including physiologic data, names of the OR team, and key patient information such as allergies. The “wall” has 3 elements:

- a 42-inch flat-panel display that integrates live data for nursing, surgery, and anesthesiology (related article)
- a video display of the surgical field, whether the surgery is open or laparoscopic
- PACS (picture archiving communications system) to display digital imaging.

“The quickest and most obvious improvement is that we can display the names of everyone on the team as well as the live documentation,” says Killen. Names can be posted at the beginning of the case as well as when relief staff take over.

Studies have shown that knowing names of team members improves the safety climate and increases the likelihood that team members will speak up if they see problems.

Continued on page 10
An innovative 42-inch screen display that integrates live nursing, surgical and anesthesiology data is part of the “wall of knowledge” in the new ORs at Memorial Sloan-Kettering Cancer Center, New York City, the first hospital to purchase the OR-Dashboard from LiveData (www.livedata.com).

Massachusetts General Hospital’s OR of the Future in Boston has been testing OR-Dashboard. The LiveData system can help ORs improve efficiency and patient safety, says Warren Sandberg, MD, PhD, an anesthesiologist and principal investigator at Mass General.

“It allows the staff to focus their cognitive capacity more fully on their patients,” he says.

Visible from any location in the OR, the display shows live readings from equipment and physiological monitors. It also shows data from the patient’s record, including allergies, blood pressure, and medications.

“We needed to find some way to share information,” says Aileen Killen, RN, PhD, director of perioperative services at Memorial Sloan-Kettering.

“We want situational awareness. Before, if we wanted to know the blood pressure, we had to ask. Now we can see it on the screen.”

OR-Dashboard was designed as a platform to display information from a variety of hospital information systems in an easy-to-read format, says Jeffrey Robbins, CEO of LiveData, Cambridge, Mass. Funding for the project comes partly from the US Army.

As nurses document the progress of the case, the screen changes to show what is happening with the patient, Dr Sandberg says.

“The system does not require any user to interact with it,” Dr Sandberg says. “Any functionality is triggered by systems that are integrated with it.”

Information is presented on the screen in a series of panel displays. For example, if a patient is allergic to latex or has a sensitivity to Betadine, everyone in the room will be able see it on the screen, says Marie Egan, RN, MS, project manager of the OR of the Future at Mass General.

“Nurses seem to like it. If everyone in the room is wearing an RFID (radio frequency identification) tag, staff can look up at the screen and know who is in the room,” Egan says. “Simply knowing their names facilitates the working relationship, especially if a situation in the OR becomes urgent.”

The display aids handoffs because a staff member coming in to relieve someone else can be immediately brought up to date without having to ask.

Improved handoffs are essential for Memorial Sloan-Kettering’s longer operations that can last up to 8 hours.

“We perform many longer cases involving multiple teams,” Killen says. “Shared information is the key to effective handoffs, as required by the JCAHO patient safety goals.”

LiveData can also synchronize OR data with other visual data—videos, radiology, and pathology images—and information for the entire operation can be replayed, says Jeffery Scott, LiveData’s vice president of marketing. Staff also can view the OR screen anywhere, using a personal computer equipped with a web browser.

“LiveData makes it possible for everyone in the OR to be on the same page: to instantly view, understand, and act upon continuously changing information,” Scott says. “It can help the OR team reduce errors and near misses due to oversight, failure to recognize an issue, or miscommunication.”

—Jay Greene

Jay Greene is a freelance writer in Thompson, Conn.
A quieter environment

An unintended but welcome consequence of greater use of information technology is a quieter work environment. There are fewer distractions, such as phone calls and pages, which have been shown to be a patient safety risk. “People who visit from outside pick up on the quiet instantly,” says Dr Jacques.

Aids to communication include:

• An audiovisual (AV) system in each OR connected to the nurses’ control station enables nurses to monitor the status of every case.
• An AV hookup enables surgeons to communicate with pathologists “without squawking across the room at a speaker phone,” Dr Jacques notes.
• Phones at nurses’ and anesthesiologists’ work stations eliminate the need to walk across the room to use a common phone.
• A tracking system with airport-style screens enables the staff to see the status of patients and events. The system is part of the enterprisewide scheduling system, Epic. Each area, including surgery, can customize the tracking system to its needs.
• A Vocera system (www.vocera.com), which uses small wireless communication badges, is being installed housewide. Anesthesiologists will be the first to use Vocera in the OR so they can be located quickly. “With a 72,000 sq-ft space, we decided that was an important safety feature,” Killen says.

Consistency in OR design

A guiding principle was to design the ORs to be 95% the same and 5% specialty specific, including the layout, configuration of the boom, and major equipment. A researcher who visited Memorial Sloan-Kettering observed that there were more near misses when staff worked in unfamiliar rooms.

The ORs are organized into 5 pods to keep specialties together. “Teamwork makes a difference in patient outcomes,” Killen notes. The nursing staff works primarily in 1 or 2 specialties. (There is little call because few procedures are done on nights or weekends.)

Better ergonomics

All ORs are equipped with 2 ceiling-mounted booms. One boom is for minimally invasive surgery equipment (all of the rooms are MIS capable). The second boom carries other equipment and services such as the electrosurgical unit, light sources, and warming blankets. Because the rooms are large—17 ORs are 600 sq ft, and 4 ORs are 800 sq ft—it is a long way from the OR table to the wall. Having equipment on booms keeps cords off the floor, avoiding a trip hazard. Booms also enable video screens and equipment to be positioned comfortably and save the staff from having to push heavy equipment carts.

Infection control

A pass-through between each OR and the central core allows instruments and supplies to be retrieved without the nurse leaving the room. (Each of the ORs’ 5 pods has a central core.) “This is both for patient safety and infection control,” says Killen.

A recent study of complex cases found nurses left the room an average of 7.5 times per hour of incision time during long cases, “significantly disrupting the case flow,” note the authors led by Caprice Christian, MD, MPH, of Brigham and Women’s Hospital, Boston.

Early adopter of technology

Killen and Dr Jacques will also talk about pitfalls of being an adopter of new technology and how they resolved them. For example, the nurses’ phone, which plugs into a USB port on the computer, conflicts with the keyboard—when someone dials the phone, the numbers show up on the nurse’s screen.

Reference


A photo feature on Memorial Sloan-Kettering’s new ORs is at www.ormanager.com.
Getting organized for a building project

You are assigned to shepherd a multimillion-dollar project to redesign your OR. How do you start? What do you need to begin?

Dozens of OR managers and directors annually embark on such projects, many taking on leadership positions for the first time. The task can be overwhelming, and mistakes are often made that could be avoided through better planning, experts say.

“I have just been given the responsibility for our OR project. It would be nice if I had a guide to lead me through it,” says Jim Jurrens, RN, director of the surgery support center at 150-bed Alaska Native Medical Center, Anchorage. The hospital, which performs 10,000 annual surgical procedures in 8 ORs, provides care for the state’s 229 tribes.

Since March, Jurrens has been working with senior management to define the scope of the project. Tentative plans include adding 6 ORs and remodeling and expanding 2 endoscopy suites, day surgery, and postanesthesia care areas. Once a budget is approved, Jurrens says he will form a project team to develop detailed plans.

“We are at max capacity,” he says. “All the ORs are blocked for scheduling. We utilize our ORs 90% of the time. We have no room to move.”

A planning tool

One suggestion for managers like Jurrens who are beginning an OR construction project is to create a customized Project Evaluation and Review Technique (PERT) chart, says Daniel R. Beney, PE, associate medical planner and engineer with Harley Ellis Devereaux, a Southfield, Mich-based architectural firm. A PERT chart is a critical path planning tool originally used by the military to plan large construction projects.

“A PERT chart is a network diagram that represents project activities, milestones, the critical path, and projected timeline,” says Beney, who spoke at the 2006 OR Business Management Conference May 10 to 12 in Austin, Tex.

“Activities are color coded to indicate which project team member has primary responsibility for an activity,” Beney says. “The PERT chart helps the project team determine what they need to do during each phase of the project, who has primary responsibility for completion of an activity, and the overall time it will take to complete a project.” (See illustration, p 12.)

When to form project team

In the early planning stages, Beney says some hospitals start by assigning a 10- to 15-member project team. He recommends the team appoint a project leader. The multidisciplinary team should include clinical, technical, and support staff.

“The project team will insure that features that may have a significant impact on OR efficiency and turnover time are not overlooked,” Beney says.

Other hospitals, like Alaska Native Medical Center, begin the process by involving senior management in developing the initial scope of the project. After the budget is approved, the project team is formed.

“It usually isn’t a complete team in the beginning,” Beney says. “Most of the time they haven’t talked enough about the scope of the project and what they want to accomplish.” In these cases, he adds, there usually are delays because critical decisions haven’t been made.

Once the scope of the project is determined, OR managers and project teams can develop PERT charts to help visualize steps necessary to complete the project, Beney says. The PERT tool can be used before contracting with architects and construction contractors, although contracting with experts in the beginning can be beneficial, he adds.

“If they haven’t been involved in a construction project before, getting (professionals) involved may be a good idea,” Beney says. “If they do have a good idea of what they want to do, maybe they can wait on the architect.”

Drawing up the PERT chart

Once the project team is assembled and the scope of the project is defined, Beney says OR managers can create their own PERT chart by listing activities that must be completed to reach an event or project milestone. The PERT chart should be reviewed and refined by the entire project team including the architect and construction manager, he says.

For example, the chart can list the following events: A (project starts), B (project team created), C (types of ORs decided), and D (recommendations developed by team). These events occur before the architect develops schematic designs (events E and F).

“In many projects, activities from a previous event or milestone overlap into current activities,” Beney says. “If there is too much overlap, there is a good chance there will be a delay in the project.”

In the sample PERT chart, critical path activities are shown as the center spine with all activities having an assigned completion time, Beney explains. Parallel activities are shown as branches parallel to the center spine. The overall project time is the sum of all of the critical path activity times. The primary responsibilities of the project team members are defined by the color code key shown below the PERT chart.

—Jay Greene

Jay Greene is a freelance writer in Thompson, Conn.
OR design & construction

Example project
Renovation of 4 ORs and new 22-cubicle PACU

Source: Harley Ellis Devereaux, Southfield, Mich.

Events (milestones)
A. Start of project
B. Project team created
C. Determine types of ORs (specialty vs general)
D. Investigation and recommendations from in-house project team
E. Start of schematic design phase
F. Schematic design sign-off and final equipment list provided
G. Design development sign-off
H. Vendor starts site-specific drawings for major equipment
I. Site-specific drawings completed
J. Completion of contract documents
K. Sign-off of construction documents
L. Bids received from subcontractors
M. Subcontractors selected
N. Construction starts
O. Construction complete
P. All fixed equipment installed
Q. Approval of authority having jurisdiction
R. Building occupancy

Activities for an OR design and construction project
1. Create in-house project team
2. Internal meetings to determine scope of project
3. Determine types of operating rooms (specialty vs general)
4. Investigation, review, and recommendations from in-house project team
5. Contract services of an experienced medical equipment planner
6. Contract services of an experienced health care architect
7. Contract services of an experienced health care construction manager
8. Conduct site visits of existing health care facilities
9. Equipment assessment (new, existing, technology upgrades)
10. Field investigation of facility’s existing conditions and limitations
11. Construction cost estimate based on current scope
12. Conceptual schematic design plans and owner review
13. Develop final equipment list and technical specifications
14. Facility systems investigation and review
15. Construction phasing and infection control issues
16. Create design development plans and elevations
17. Further engineering development and investigation
18. Operating room ceiling plan coordination
19. Design development owner review meetings
20. Design development construction estimate
21. Develop site-specific drawings for major equipment
22. Coordinate site-specific vendor requirements with project team
23. Above-ceiling facility systems and medical equipment coordination
24. Completion of all plans, elevations, and specifications
25. Final facility systems review and documentation
26. Owner review of architectural and engineering construction documents
27. Develop construction estimate for construction documents
28. Review and approval of construction documents by authority having jurisdiction
29. Send out construction documents for bids from subcontractors
30. Review bids from subcontractors
31. Not used
32. Review contract documents with selected subcontractors
33. Construction
34. Review of shop drawings and respond to request for information
35. Fixed equipment installation
36. Assist vendors during installation
37. Final review and approval from authority having jurisdiction
38. Move coordination of mobile equipment and furniture
39. Equipment in-service and system training
What’s new in AIA facilities guidelines

Aligning design requirements between inpatient ORs and ambulatory surgery centers is one of the changes in the 2006 Guidelines for Design and Construction of Health Care Facilities from the Facilities Guidelines Institute and the American Institute of Architects, Washington, DC.

“We expanded the guidelines to provide the same kind of environmental design features for outpatient surgical facilities as we have for inpatient facilities,” says Joseph Sprague, chair of AIA’s Health Guidelines Revision Committee. “The committee believes outpatients should be cared for and treated no differently than inpatients in terms of safety.”

Private rooms now required

In a major change, the guidelines shift to single-patient, private rooms as a minimum standard for new hospital construction. In new construction, there shall be a maximum of 1 bed per room unless the functional program demonstrates the need for a 2-bed arrangement, which must be approved by the licensing authority.

When facilities are renovated, and present room capacity is more than 1 patient, new capacity shall be no more than the present capacity, with a maximum of 4 patients.

The rationale is that private rooms are quieter, reduce risk of infection, and provide greater privacy, Sprague says.

Highlights of the guidelines that affect surgery:

OR minimum size unchanged

The committee decided not to increase the minimum square footage requirement of 400 sq ft for new general inpatient ORs. The guidelines continue to recommend that rooms for cardiovascular, orthopedic, neurological, and other specialized procedures be at least 600 sq ft.

“We did not increase any of the OR sizes,” says Sprague. “There was a lot of debate, but you need two-thirds of the committee to agree, and that wasn’t possible.”

The committee was reluctant to increase the minimum because not every hospital can afford larger ORs. For renovations, hospitals may seek approval from local authorities for a minimum of 360 sq ft, the guidelines say. Most hospitals build new ORs between 550 sq ft and 650 sq ft, he says.

PACU size clarified

Another change clarified the size of postanesthesia care units (PACUs) to a minimum of 80 sq ft, excluding circulation space, says Kurt Rockstroh, chair of the subcommittee on hospital chapters.

“Some people may consider it an increase, but it is more a clarification of the 80 sq ft previously defined,” Rockstroh says. “People had argued that clearance at the foot of the bed—the circulation corridor—could be counted as part of the 80 sq ft. You can’t count the circulation corridor now.”

Sprague says increases in equipment, infrastructure, and staff in PACUs convinced the committee to clarify the language essentially to require more space.

Phase 2 recovery rooms

For single-bed, phase 2 recovery rooms, the new guidelines now require minimum 100-sq-ft rooms, Rockstroh says. “Before we had language that required 80 sq ft for cubicle curtain rooms. We needed to clarify this for single-bed rooms.”

Minor outpatient rooms

A change for ambulatory surgery centers is to increase the Class A minor surgery rooms to 150 sq ft from 120 sq ft. “Types of procedures and the amount of equipment are increasing in ASCs, and we needed to increase the minimum size,” Rockstroh says.

OR storage space

The committee decided to leave the minimum requirements for OR storage space. The 2001 guidelines specified minimum requirements of not less than 150 sq ft, or 50 sq ft per OR, for storage space.

“You never have enough storage space,” Sprague says. “We debated it. It is true the amount of equipment in the OR has increased dramatically, but it is very costly square footage.” The committee did not receive any proposals to increase storage space, he noted.

Infection control enhancements

The guidelines emphasize infection control in design of new ORs.

“We added several provisions and clarifications to improve infection control,” Sprague says. Some measures include:

- Walls, ceilings, and floors must be sealed. For example, the 2006 guidelines have a new definition of monolithic ceilings, Rockstroh says. “Some hospitals use lay-in ceilings, but we found maintenance is substandard.” Lay-in ceilings essentially are acoustical tile ceilings with metal tracks. Monolithic ceilings have to be free of cracks and fissures, and all openings (for lights and booms) have to be gasketed.
- For HVAC (heating, ventilating, and air conditioning) systems, new language says air flow must have a “face velocity of 25 to 35 ft/min,” Rockstroh says, to improve air circulation.
- OR rooms are now permitted to have air returns high on the wall and near the floors, giving engineers flexibility in design.
- ORs are required to maintain minimum air circulation except for maintenance and other shutdowns in HVAC systems. “You can’t do surgery when systems are shut down,” Rockstroh says. “This clarification says that in times when the OR is not in use, you must maintain systems at a minimum operating level.”

The Guidelines for Design and Construction of Health Care Facilities can be ordered from the American Institute of Architects at www.aia.org/aah. Or call 202/626-7541 or 800/AILA-3837, and select option 4. E-mail bookstore@aia.org. Tentative price is $110.
M aintaining air and water quality during a surgery department construction project is a big challenge. OR managers have special responsibilities to reduce the chances that patients will develop an infection during their stay.

How many surgical site infections are due to facility construction is not known. “I have never seen a study that estimates the number of deaths from surgical infections as a result of construction projects,” says Larry Lee, a certified industrial hygienist with Pacific Industrial Hygiene, a Kirkland, Wash-based company that consults with hospitals on infection control. But no one would argue about the importance of maintaining a healthy environment during construction.

**Developing an ICRA**

Once a decision is made to initiate a construction project, hospitals should conduct an Infection Control Risk Assessment (ICRA).

An ICRA is a determination of the potential risk of transmitting biological agents in the facility. Based on the ICRA, the facility owner develops specific recommendations for mitigating infection risks during construction. The owner also should monitor the effectiveness of the risk-mitigation plans as the project progresses.

The Centers for Disease Control and Prevention (CDC) recommends an ICRA in its 2003 Guidelines for Environmental Infection Control in Health-Care Facilities. An ICRA also is part of the Guidelines for Design and Construction of Health Care Facilities published by the American Institute of Architects (AIA)(sidebar). The Joint Commission on Accreditation of Healthcare Organizations and more than 40 states reference the AIA guidelines for licensure or accreditation of health care facilities. A new edition of the AIA guidelines was scheduled to be issued in July 2006 (ww.aia.org). The ICRA section is in Chapter I.5.

**OR manager’s responsibilities**

Judene Bartley, MS, MPH, CIC, an epidemiologist and vice president of Epidemiology Consulting Services, Beverly Hills, Mich, who helped develop and promote inclusion of an ICRA in the AIA guidelines, says OR managers have 2 major infection control responsibilities as part of the construction team:

- Participate in the ICRA.

“OR managers first need to understand the regulations for their state,” Bartley says. “They also should provide input to the team about the importance of maintaining a clean and moisture-free environment.”

Bartley notes there are a few changes in the 2006 AIA guidelines that pertain to infection control. One expected addition is a closer assessment of finishes and surfaces and the role they play in infection control as well as the overall efficiency of cleaning and prevention of fungal problems.

“Walls in procedure rooms must be smooth and seamless,” she says. “Managers should consider moisture-resistant materials when selecting furniture and equipment. These are issues you have to address when conducting an ICRA.”

**Working with the contractor**

In monitoring OR construction projects, Jayne Byrd, RN, MSN, director of surgical services at Rex Hospital, Raleigh, NC, says her biggest challenge is to make sure contractors understand how to work safely in a hospital setting. Rex Hospital is involved in an OR construction project to replace the inpatient surgery area by building a new OR suite and remodeling the old one.

An ICRA is a multidisciplinary process that focuses on reducing risk from infection throughout facility planning, design, and construction (including renovation) activities. A multidisciplinary team considers:

- the environment
- infectious agents
- human factors
- the impact of the proposed project.

The team includes, at a minimum, experts in infectious disease, infection control, patient care, epidemiology, facility design, engineering, construction, and safety, as circumstances dictate.

**Infection Control Risk Assessment**

“Part of our job is to make sure contractors and construction workers understand the rules we have developed under the contract,” Byrd says. “We offer education and remediation on an ad hoc basis to the foreman and employees.”

By implementing an ICRA, construction managers and their subcontractors have a tool to determine what levels of infection control are needed throughout the new or existing facility, says Lee.

“A lot of my clients are learning about ICRA as they begin projects,” Lee says. “A big advantage of conducting an ICRA is to use the plan to negotiate obligations for infection control with contractors.”

Lee says the construction contract can require compliance with the ICRA. “You can build the construction schedule around the ICRA. You can also write in penalties if a contractor does not follow the rules,” he says.

**Blowing the whistle**

“If we spot something wrong, we blow the whistle, and they stop,” Byrd says. “But you have to be creative in how you do it because you don’t want to blow your schedule.”
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For example, Byrd says jack hammering outside OR walls disturbs surgical cases. “As the foundation work begins, and parking lots get removed, there is significant structural vibration,” Byrd says. “Our existing ORs are aligned against this outside wall. We make decisions daily regarding which rooms are best suited for which cases, but not all of our rooms are of a reasonable size for every specialty. Neurosurgery, for example, cannot function in a small room, and many of these cases are microscope dependent. Clearly, vibration and noise are non-negotiable aggravations.”

When necessary, she calls the construction foreman and asks that jack hammering stop for a time. “It has worked well due to the mutual respect of the OR team and the construction team,” she says. “However, it is a huge issue for surgeons. All we can do is work with them and remind them that if we ‘blow the whistle’ every day, we will never meet our schedule.”

Byrd also works closely with infection control professionals during an OR project. “They have a higher level of participation and make sure the rules are enforced,” she says.

While the Life Safety Code is primarily the responsibility of infection control directors and facility managers, “OR managers need to understand these issues and be prepared to educate construction staff about safe egress in and out of the OR area,” Bartley says.

“The most critical thing for OR directors are the barriers,” she notes. “The company may say it understands that patients are at risk. But how do they put those walls up without creating dust, and how do they do that without creating Life Safety issues?”

OR managers need not be experts in barriers, she says. “What they should look for is solid barriers (not plastic, though plastic can be used temporarily to protect areas while solid barriers are installed), a tight enough seal, and proof that the barrier is functioning properly,” she says. There needs to be some type of monitor or test to see that air is flowing into the work site and from the work site out into the corridor.

OR managers should also make sure barriers are installed during nonsurgical times, and cleanup is done carefully to ensure the OR area is not affected, she adds.


Registering complaints
OR managers should know the procedure for filing complaints or getting information during construction.

Typically, managers should report problems directly to hospital safety officers. “But if you see an immediate problem, you need to take corrective action,” Bartley says.

Byrd says she is most concerned about construction workers walking through restricted OR areas.

“We need to ask the construction supervisor directly if the workers understand hospital infection control rules,” she says. “Sometimes patients go through construction areas. We need to make sure workers understand patient confidentiality rules.”

Depending on the pace of the project, Byrd recommends daily walk-throughs of the construction area. One of the first things she notices is whether the air is flowing toward the construction area—the so-called negative air pressure requirement—as it should be.

“We look for obvious infectious materials, plastic barriers that are compromised, walls or duct systems that have gaps or rips, dust mats that are properly placed, and make sure there are no leaks in the water supply or heating and AC systems,” she says.

Dust and water control
Dust control is one of the biggest problems for ORs, Lee says. For example, making sure dust mats are properly placed at the construction entrance is important, she says. Tacky mats or walk-off mats, which have an adhesive surface, are commonly placed directly outside construction areas to trap dust on workers’ feet and equipment wheels. Sometimes a dampened dust mat (rubber-backed carpet) is used instead. “But it is extremely important to HEPA-vacuum the carpet when soiled and dry the carpet at the end of the day to prevent microbial growth,” Lee says. Though it may seem obvious, workers need to be trained to step on the mats because they don’t want to leave dirty footprints, he says.

Demolition of walls and ceilings can aerosolize settled mold spores, he says. Inhaling spores produced by mold species such as Aspergillus fumigatus or Aspergillus flavus can cause life-threatening infections in persons with compromised or debilitated immune systems.

“Surgical patients are especially at risk from exposure to fungus,” Lee says.

Other construction dusts can also affect indoor air quality. For example, glass fiber from fiberglass pipe insulation and ceiling tile are irritants that can cause skin rashes; gypsum and cement dusts are irritants; and exposure to welding fumes, paint aerosols, and smoke can annoy patients and employees. In addition, delivery of construction equipment and supplies from outdoors can introduce unfiltered air containing pollen, mold spores, and other outdoor particulate matter into the building.

Air and water sampling
Regular air and water sampling is important, but cost is an issue in how often it is done. “Few hospitals do environmental sampling before construction projects for cost reasons,” Byrd says. “Sampling during construction is a very good idea.”

Lee comments, “My chief concern is that not enough hospitals do fungal air sampling to test for dust generation. The CDC doesn’t recommend it, but I believe it should be in the overall infection control program.”

There are several ways to monitor and sample air quality. “You can test for bacteria or total particulates,” Bartley notes. “Some people recommend total particulate sampling. The trouble is, we don’t have standards for hospitals. We have to develop relative standards.”

One way to test is called “rank order-
What can we learn from AbTox case?

Two former executives of the defunct sterilizer company AbTox were convicted in April 2006 for selling a sterilizer that hadn’t been cleared by the Food and Drug Administration (FDA).

Eighteen patients lost sight in one eye after the sterilizer was used to reprocess cataract surgery instruments. The sterilizing agent reacted with brass joints in the instruments, creating a toxic residue that damaged patients’ eyes, the FDA reports.

The executives, Ross Caputo and Robert Riley, headed AbTox when the company received FDA permission to market a small gas plasma sterilizer only for use in sterilizing flat stainless steel surgical instruments without lumens or hinges. Instead, the defendants marketed a larger, unauthorized version and promoted its use for an array of nonstainless steel instruments.

According to the FDA, 168 of the unauthorized sterilizers were sold to hospitals nationwide during the 1990s at a cost of over $18 million. Several hospitals reported to AbTox that their sterilizer was suspected of causing patient injuries, but the company failed to notify the FDA as required, the agency reports.

The FDA investigated. Caputo and Riley eventually were convicted of fraud, selling an adulterated (unapproved) or misbranded (mislabeled) medical device, and conspiracy to defraud the FDA.

A ‘gatekeeper’ for device safety

This is a rare occurrence. But what lessons can we learn to help ensure new devices and equipment we bring into our facilities are safe for patients?

The initial “gatekeeper” for device safety is the FDA. The FDA has regulations companies must meet to market health care products or equipment in the US.

Too often, we assume products and equipment we buy have been reviewed by the FDA. When we bring these items into our organizations, we assume responsibility for them. Though the vast majority of companies comply with FDA requirements, a few may not, as evidenced by the AbTox case.

Managers need to understand the FDA’s process. They also need to make sure their organization has a sound process for evaluating new devices and equipment.

FDA review

Under FDA regulations, medical devices are classified as Class I, II, and III, which determines the extent of regulation required. The FDA grants 2 types of approval to market devices in the US:

- A premarket submission, known as a 510(k), in which the company must provide evidence to show the device is safe and effective because it is “substantially equivalent” to a device already on the market.
- A premarket approval (PMA) is required for Class III devices, high-risk devices, and devices that aren’t “substantially equivalent” to those already on the market. The PMA process is more involved and requires clinical data to back claims.

The PMA process is termed “FDA approval” while the 510(k) process is termed “FDA clearance.” (Most Class I and some Class II devices are exempt from this process because they don’t entail significant risk to patients.)

The FDA has a web site where you can verify that a product or equipment has been cleared or approved: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/cfPMN.cfm.

Companies must also comply with other FDA regulations, including registering, labeling, quality systems requirements, and medical device reporting.

Managers need to make sure that a product’s FDA status is verified before the product is purchased. Don’t assume anything. Ask, “Did anyone request a copy of the 510(k)?” If the company

FDA web sites

Check these web sites for information on medical devices:

**Center for Devices and Radiological Health (CDRH)**

[www.fda.gov/cdrh](http://www.fda.gov/cdrh)

Responsible for ensuring the safety and effectiveness of medical devices as well as radiation safety. Medical device premarket review takes place under CDRH.

**Office of Device Evaluation**

[www.fda.gov/cdrh/ode/germlab.html](http://www.fda.gov/cdrh/ode/germlab.html)

Lists FDA-cleared sterilants and high-level disinfectants.

**Recalls and safety alerts**

[www.fda.gov](http://www.fda.gov)

Go to FDA home page and look for the link. This page has FDA Warning Letters that are sent to manufacturers and facilities when the FDA finds significant deviations from its regulations.

**MedWatch**

[www.accessdata.fda.gov/scripts/medwatch/](http://www.accessdata.fda.gov/scripts/medwatch/)

Voluntary reporting for serious adverse events, product use errors, and quality problems related to FDA-regulated medical devices, drugs, and other products.

**FDA e-mail bulletins**

[www.fda.gov/emaillist.html](http://www.fda.gov/emaillist.html)

Sign up for any of the FDA’s 20 e-mail lists.

resists, be wary. Companies misrepresenting products should be reported to the FDA’s MedWatch program at https://www.accessdata.fda.gov/scripts/medwatch.

Do your homework

Though it’s important to try new technologies, we must be prudent. Diligence is especially necessary when dealing with a company you aren’t familiar with or new technology. In some cases, individuals we knew from a previous company go to work for the new
Please see the ad for SPECTRUM SURGICAL INSTRUMENTS in the OR Manager print version.
AbTox case
Continued from page 17

company, and we go along with their recommendations based on our previous relationship. A good philosophy is: “These individuals do not work for my facility; I do.” Protect your patients, yourself, and your facility first.

Facilities affected by AbTox’s uncleared sterilizer probably believed in the product and did not see reason to doubt that the product worked. But a little homework could have resulted in a different outcome.

Evaluating new products

These steps are recommended for evaluating new products or technology:

1. Thoroughly investigate the product by requesting and reviewing the detailed technical data and product literature. Highlight questions and refer them to the company for complete answers. Discuss the technology with the sterile processing manager, who should assist with obtaining all necessary information for reprocessing the device or equipment.

2. Insist on receiving information in writing. For example, if the sales representative states, “It’s OK to flash sterilize the device in an emergency,” make sure you have flash sterilization instructions in writing from the device manufacturer, including the cycle time, temperature, minimum exposure time, and drying time needed, if any. (Some devices such as power equipment require a short dry cycle when flash sterilized.) If the device is reusable, insist that the manufacturer provide complete, validated instructions for cleaning and reprocessing. This is an FDA requirement. (See March 2006 OR Manager, p 31.)

3. Have the company’s information reviewed by the risk manager and infection control committee. Depending on the device, approval may be needed from the facility’s institutional review board (IRB).

4. Request that your materials management department check with one of the services that reviews health care technology. These include MD Buyline (www.mdbuyline.com) and ECRI (www.ecri.org). These organizations, which require a membership to receive reports, provide valuable information for decision making.

5. Review the FDA’s web pages for clearances, warning letters, etc (sidebar, p 17). You can sign up with the FDA to receive e-mails on recalls, alerts, and other product information.

6. Contact other facilities using the same product or equipment to see what their investigation and experience have been.

The majority of companies and sales representatives we deal with are professional and dependable. We could not manage our departments without them. But the bottom line is “buyer beware”—we are ultimately responsible for the goods and products we bring into our facilities.

—Nancy Chobin, RN, AAS, ASCP, CSPDM
Corporate Consultant/Educator
Saint Barnabas Health Care System
West Orange, NJ

Conference dates

OR Business meeting to be in Savannah

The 2007 OR Business Management conference will be at the Hyatt Regency, Savannah, Ga, May 9 to 11.

With historic southern charm, Savannah dates back to 1733 when it was founded by James Edward Oglethorpe and a band of English settlers. The Hyatt is located on the Savannah River in the heart of the historic district, with restaurants and shopping nearby. The historic district is dotted by colorful old houses and 21 tree-filled squares that were a key part of Oglethorpe’s plan for the city. In May, the gardens and flowering trees will be at their best.

The OR Business Management conference focuses on the business aspects of managing the OR. It attracts business managers, materials managers, OR directors, and others who are involved in the financial management of the OR.

Managing Today’s OR Suite


The conference will be at a new hotel, Gaylord National on the Potomac, Washington, DC, October 29 to 31, 2008.

Caesars Palace, Las Vegas, will be the site for the conference Oct 7 to 9, 2009.

Preventing infection
Continued from page 16

ing.” Electronic particle counters can easily measure air quality outside of the facility for total particle counts where contamination is the highest. Then air is measured inside the OR as a comparison.

“Measure where you know you have the highest filtration, compare the percent drop in particle counts related to the filtration level, and you can determine if the air system is functioning well,” Bartley says.

Contractors should be required to build air-flow gauges into the barriers to make sure the air is going toward the construction site, she says. “It is costly sometimes, depending on the size of the project, but the risk is great when things go wrong.”

Lee agrees. “You try to isolate construction areas by doing things like placing the construction area under negative air pressure,” he says. “Each construction enclosure is placed under negative pressure using HEPA-filtered negative-air machines to prevent dusts and vapors from moving outside the construction areas.”

Control water to prevent mold growth

Control of water is another infection control issue. Water can leak from broken pipes, unattended hoses, or sprinklers. If areas are not promptly cleaned and dried, mold can grow on materials such as gypsum wallboard, ceiling tile, or spray-applied fire-proofing, Lee says.

During demolition of older walls, hidden mold is often discovered. Mold abatement and cleaning are conducted both as an infection control and an indoor air quality measure.

“There are so many places in construction where water can cause problems,” he says. One construction project he worked on had a major water leak when a new heating system freeze plug burst.

“We had 7,000 gallons of water flood an area, and we needed to take immediate steps to dry things out. Others (contractors) might try to hide the fact because it might impact their schedule. You need to keep an eye on accidents like this,” he says.

—Jay Greene

Jay Greene is a freelance writer in Thompson, Conn.

An ICRA Checklist is available at www.ordesignandconstruction.com.
Please see the ad for GANDER in the OR Manager print version.
Who’s guarding safety of human tissue?

The tissue industry is learning how to be more regulated.

A lawyer formerly on the staff of the FDA who worked on the agency’s good tissue practices regulation thinks that, despite this incident, oversight has improved.

“When we definitely getting there. The industry is safer, better regulated, and better able to regulate itself than ever before,” says Areta Kupchyk, JD, who now represents tissue banks and related clients at the law firm, Reed Smith, Washington, DC.

Major incidents

The BTS scandal is the second major incident the industry has seen in 5 years. In that time, there have been about 5 million tissue transplants, Rigney estimates.

In 2001, a healthy 23-year-old man, Brian Lykins, died in Minnesota after receiving a knee graft that turned out to be contaminated with the bacterium Clostridium sordellii.

The graft came from CryoLife, which used a processing method not validated for spore-forming organisms, according to the New England Journal of Medicine. In all, 14 patients were identified with allograft-associated clostridium infections from tissue processed by CryoLife.

“When CryoLife happened, the FDA was becoming more savvy about fungal and bacterial infections as well as the traditional communicable diseases like HIV and hepatitis,” says Kupchyk, who also served as the FDA’s attorney on the CryoLife case.

“The whole industry was shaken by that incident. I think everyone, including the FDA and CryoLife, learned from it.”

She says the industry is still learning how to be more regulated. “I see the industry working hard at trying to understand what is expected of them and trying to do the right thing,” she says.

Still, Kupchyk expects there will be more events with contaminated tissue.

Continued on page 23
Please see the ad for
STERIS CORPORATION
in the OR Manager print version.
What is AATB accreditation?

The American Association of Tissue Banks (AATB) accredits tissue banks that engage in any 1 or more of 5 processes:
- retrieval
- storage
- donor eligibility screening
- processing
- distribution.

Accreditation process

New accreditation typically takes 9 months and includes:
- application
- review of standard operating procedures (SOPs) by independent reviewers (most former FDA officials)
- self-audit by the tissue bank
- inspection by independent contractors
- blind review of application documents by the AATB Accreditation Committee.

Accreditation must be renewed every 3 years.

Continued from page 21

“though hopefully with less severity,” she says.

The tissue industry is profitable, tempting newcomers, and some are unscrupulous. Technically, tissue cannot be bought or sold, but firms can charge fees, and there is no regulation over the fees they can charge.

On the plus side, Kupchyk says “the industry is now hypersensitive” to improper behavior. “There is more of an incentive for tissue processors to deal only with banks that are registered, AATB accredited, and inspected.

“That won’t stop fraud. But the more oversight you have, the less likely someone will get away with it—the more cops on the road, the fewer speeders.”

Advice for facilities, physicians

The best advice for physicians and nurses, says Rigney, “is to see that the tissue banks you deal with are accredited by AATB.” All 5 tissue banks that received tissue from BTS are AATB accredited. They were LifeCell, Los Mountain Tissue Bank, Blood and Tissue Center of Central Texas, Tutogen Medical, and Regeneration Technologies, Inc. BTS itself was not accredited.

Rigney says the BTS discrepancies were discovered because the tissue banks followed AATB standards, which involve testing of tissue and review of records.

Another step physicians and health care facilities can take is to insist that the tissue banks they use obtain tissue only from sources that are also accredited. AATB standards don’t require tissue banks to use accredited sources, but they do require banks to audit their sources at least every 2 years to see that they are in compliance with the standards.

BTS was registered with the FDA as well as New York State and had been inspected. But that didn’t detect the forged documents.

Risk to patients from the BTS tissue appears small. “The biggest processors all have systems to inactivate viruses and bacteria,” Rigney says.

At least a dozen people claim they have contracted diseases from contaminated BTS tissue, according to press reports. Several dozen have filed lawsuits, seeking class action status for hundreds of other patients. But the Centers for Disease Control and Prevention (CDC) has not confirmed any cases of disease transmission from BTS tissue, Rigney says.

Could more be done to inactivate microorganisms in tissue?

The overwhelming majority of tissue distributed is bone, which is irradiated, he says. Bone accounts for 75% to 80% of the approximately 1 million grafts distributed annually.

“The majority of bone is irradiated at a dose far exceeding what is needed to destroy microorganisms,” he says. “We also have standards that rule out using grafts with certain types of bacteria.” Irradiation cannot be used in all tissue types because it can affect the integrity of the tissue.

How many banks are accredited?

What percentage of tissue banks are accredited isn’t clear.

About 2,300 banks are registered with the FDA, but not all are actually tissue banks or need to be registered, Rigney says. “We think the overwhelming majority of tissue supplied for transplant in the US is coming from tissue banks accredited by AATB,” he says. There are 92 accredited banks, and he estimates about 150 are operating.

The overall record for tissue transplants is good, he points out. The only reports of TB and hepatitis B transmission through tissue grafts occurred more than 50 years ago. The only reported transmissions of HIV through tissue grafts were 15 to 20 years ago.

Transmission of hepatitis C from 1 donor to 8 patients was reported in 2003. The donor was negative for hepatitis antibodies at the time of death. Of the 44 allografts transplanted from the donor, all of the transmissions were in organs or soft tissues; none were found in patients who received skin or irradiated bone (MMWR 52[13]:273-276).

AATB now requires use of more accurate nucleic acid testing (NAT) for detecting HIV and HCV in cadaveric tissue. The test narrows the window from when a person contracts the virus to when the test can detect it.

“The industry is still learning how to be compliant,” Kupchyk says. “Even if we don’t see out-and-out fraud, we still will see people making mistakes.

“But as the years go by, we will see a better and stronger tissue supply.”

The CDC has frequently asked questions about tissue transplants, including testing for BTS tissue recipients, at www.cdc.gov/nicidod/dhqp/tissueTransplantsFAQ.html

References


WEB extra

Sample tools for tissue tracking and a daily tissue count are in the OR Manager Toolbox at www.ormanager.com. The tools were developed by Denise Giachetta-Ryan, RN, CNOR, MPA, associate professor and director of the Surgical Technology Program, Kingsborough Community College, Brooklyn, NY.
Please see the ad for MCKESSON in the OR Manager print version.
Working from home, an anestesiologist at Duke University Medical Center (with the proper authorization) pulls up the next day’s surgical schedule. On the schedule, she clicks a patient’s ID number to view the preoperative assessment. She can also access a past anesthesia record.

The next day, a nurse reviews the patient’s preop checklist. As she checks off each item, an icon turns from red to green on big screens located throughout the surgical department. All preop icons must be green before the patient goes to the OR. For a high-risk patient, like one with latex allergy, an alert flashes on the big screens.

At the OR control desk, big screens show the status of patients in all of Duke’s 45 ORs.

Nurses in the postanesthesia care unit (PACU) are also monitoring the cases on big screens. Later, a nurse consults the screens to find a patient a bed.

Forty-eight hours later, as the physician sees the patient for a postop assessment, he enters his notes in his handheld computer, and the data goes into the patient database. They’re all using ORView, an integrated perioperative information system developed at Duke using web-based tools. The system, which recently won an international award, weaves together real-time data from 15 to 20 different systems, yet looks and works like a single system.

The original idea was to make information available through the web so anesthesiologists could look up cases and the OR schedule at home, says the system’s inventor, Iain Sanderson, MD, an anesthesiologist and associate chief information officer at Duke.

“What it became is an integrated system,” he says.

Intraoperative nursing documentation is not part of the system yet but will soon be, he says.

Duke developed ORView after trying an integrated perioperative system from a commercial vendor but finding it didn’t work as expected.

“This approach allows us to continue with the best-of-breed systems but still tie it together,” says Dr Sanderson, who is considering developing a business plan for the system. He says vendors such as IBM have shown interest.

In June, ORView won for Duke ComputerWorld’s 21st Century Achievement Award for Medicine (www.cwhonors.org). The international award recognizes those who have used information technology to benefit society.

How feasible?

How feasible is such a system for a smaller hospital?

Though Duke is large, ORView was developed by a 5-person team, says Asif Ahmad, a Duke vice president and the chief information officer.

He estimates the cost of maintaining ORView will be $250,000 a year, “pocket change, compared to the cost of an EMR [electronic medical record] system.”

Ahmad finds it surprising that perioperative information systems don’t get more attention from CIOs, considering that surgery accounts for 25% to 50% of a hospital’s revenue and is one of the places where patients are most vulnerable. “Hopefully, this award will raise awareness of the need and what can be done,” he says.

A nurse checks the status of OR cases on big screens at Duke University Medical Center. Photo by Jon Gardiner. Courtesy of Duke University.
Where are the bottlenecks in your operations? Are patients waiting in preop? Are they overflowing in recovery? Why are patient satisfaction scores low? Are patients uncomfortable about privacy? Answers to these problems may lie in the physical layout of your ambulatory surgery center (ASC).

“The design and flow of patients through an ASC can make or break your efficiency, and efficiency is one of the main ways we distinguish ourselves from hospitals,” says Rebecca Craig, RN, BA, CNOR, CASC, administrator of the Harmony Surgery Center, Fort Collins, Colo.

Focusing on the design and layout of a center to solve problems is simple, but not easy.

“Ambulatory surgery centers are as complex as anything you can design and build,” says Robert Owens, principal of Boulder Associates, Inc, an architecture and interior design firm in Boulder, Colo (www.boulderassociates.com).

Issues factoring into the complexity include:

- **State building regulations.** Rules vary, but many states base their regulations on the American Institute of Architects (AIA) Guidelines for Design and Construction of Health Care Facilities. Updated guidelines were expected to be published in July, see p 13 (www.aia.org).
- **Technological advances.** “Every few years the guidelines are rewritten because of changes in perioperative technology and techniques,” says Wayne Carr, director of design and construction for HealthSouth Corp, which owns and operates more than 200 ASCs. “It’s a fine balance between satisfying building requirements and designing a center that flows correctly and accommodates technology.”
- **Privacy law.** The Health Insurance Portability and Accountability Act (HIPAA) requires measures to protect patient privacy, which affect the design of areas where confidential patient information is discussed.
- **Speed.** ASCs tout their efficiency and short turnover times, which means patient flow must be almost flawless. Facilities also need convenient support systems, such as supply rooms and nourishment centers. “Unlike a hospital, which has separate departments for central sterile supply and storage, an ASC needs its functions located close together and to flow from one to the other easily,” Owens says.

**Expand or build?**

When centers have maximized their space and volume or must renovate substantially to meet updated codes and regulations, it’s usually time to build a new facility, Carr says. This is especially true for centers more than 15 years old. An exception is a center in a great location with ample parking and name awareness.

Carr argues that it usually costs the same or less to build a new facility as to renovate an old one. “In a 15-year-old facility, the ORs are too small, the mechanical equipment is wearing out, and interior finishes need to be replaced,” he says.

**The basic envelope**

Carr has developed a prototype for building new HealthSouth ASCs. He interviewed nurse administrators and staff and applied their ideas in drafting the plans, which are amended to meet each state’s regulations. Physicians at 3 HealthSouth facilities reviewed the plans and supported the nurses’ recommendations.

The nurses’ recommendations include where power doors are needed for transporting gurneys, where to place light
switches and power outlets, how doors should swing into a room, locating nourishment centers in the recovery room to reduce travel time, and placing ice machines at a level that nurses do not need to bend to reach.

“Getting nurse input made the difference between building centers that are OK and ones they really love,” Carr says.

A well-designed ASC
The HealthSouth prototype is proprietary, but Carr shares his recommendations for the basic envelope of a well-designed ASC:

• Ideally, an ASC should be in a square-shaped building, with the interior constructed to create a circular process flow. Long, narrow buildings require more walking.
• Location on the ground floor is preferred but not absolutely necessary. A ground-floor location makes it easier to admit and discharge patients and receive bulk supplies.
• The building must be located in an area zoned for medical use.
• The building should have a large and consistent column grid, with columns equally separated by a minimum 30 ft. Carr explains the relevance of 30-ft column space by adding together the minimum 18-ft clear width in the typical OR, the minimum 8-ft clear width in the sterile corridor (required by various codes for corridors where gurneys and patient beds will be moved), and wall thickness. These dimensions equal approximately 29 ft. “ORs will just get larger in the future,” Carr says.
• The minimum ceiling height in an OR should be 10 ft. Above the ceiling and below the building structure should be at least 2 ft, 6 in (preferably 3 ft) for ductwork, sprinkler and medical gas piping, light fixtures, and support framing.
• If the site is in a leased building, the entire building must have sprinklers installed according to the National Fire Protection Association, or the surgery center will have to add them, “an expensive undertaking,” Carr says.

At 500 sq ft, this OR provides ample space for flexibility among specialties. Frosted windows let in light yet provide patient privacy. Photos courtesy of Boulder Associates.

Color and daylight set the tone for this ASC waiting room.

• The locations of fixed building elements, such as stairs, elevators, mechanical rooms, public toilets, and mechanical chases, should be considered when deciding on a site. Before leasing or buying a space, ensure their locations do not limit the facility design or hinder growth.
• Design with the knowledge that technology will change, and the center must adapt to it. Provide stub outs for later electrical and medical gas additions. "If you set yourself up for maximum flexibility, you can come back later and make changes to accommo-
Effective ASC designs

Architects and veteran ASC administrators offered these recommendations for effective facilities:

First impressions

• Parking lot. The ASC experience begins before the patient and family step into the facility. Parking should be ample, close to the building, and free or heavily discounted.

• Entrance. Visible signage is paramount. Some centers that share building space with other offices have color-coded pathways that lead patients to the center’s entrance.

• Registration. Side panels that enclose the registration area assist with privacy. Many centers preregister patients so they only need to let the receptionist know they have arrived. Information systems allow for faster registration, fewer registration personnel, and less waiting time.

“When you have less waiting time, you can have a smaller front desk and waiting area. This space can be moved into the perioperative process,” says Scott Latimer, president of the American Institute of Architects’ (AIA) Academy of Architecture for Health and vice president and national director of Kurt Salmon Associates health facility consulting group (www.kurtsalmon.com).

Waiting room

Design is becoming more like a boutique to differentiate ASCs from hospitals, says T. Scott Rawlings, an architect for RTKL in Washington, DC, (www.rtkl.com) and member of AIA’s Academy of Architecture for Health. “As hospitals enhance their décor, ASCs have had to go to the next level and offer a more salon-like setting.”

Refreshment centers for family and friends must be separate from the patient waiting room. “The last thing you want is someone who can’t eat or drink to smell coffee,” says Donna Quinn, RN, MBA, CPAN, CAPA, director of the Orthopaedic Surgery Center, Concord, NH.

To avoid alarming families of other patients, never discharge surgical patients through the waiting area.

Operating rooms

ORs are getting bigger to accommodate more equipment. The AIA guidelines call for a minimum of 400 sq ft per OR, but Robert Owens, of Boulder Associates, Inc, an architecture and interior design firm in Boulder, Colo, says he would not design an OR with less than 440 sq ft. “Really, 500 sq ft is optimal,” he says. Architects say physicians are split on their preference for having equipment placed on towers or booms suspended from the ceiling. The booms allow for faster room turnover by keeping equipment off the floor. The towers are less expensive and portable. One solution—provide both. Some centers provide towers and build the infrastructure into the ceiling to add booms later, Carr says.

Preoperative and postoperative areas

These core areas are grouped because the flow among them is critical to an ASC’s efficiency.

Medicare guidelines state that an ASC must have a separate recovery room and waiting area. See Medicare Guidance to Surveyors, 416.44(a)(2). To share staff and support services such as beverage centers and storage rooms, recent ASC designs connect the preop and postop areas with a nurse’s station or divide them with a glass wall. Phase I PACU continues to stand alone to satisfy the 1-to-1 nurse ratio and to separate conscious patients from those just rousing from anesthesia.

A trend is to build sections within a combined preop and postop area. For example, one 20-bay room has 5 sections of 4 bays equipped for either preop or postop functions.

“The key is flexibility,” says Rebecca Craig, RN, BA, CNOR, CASC, administrator of Harmony Ambulatory Surgery Center, Fort Collins, Colo. “I like any space that can be used for more than one function.”

Creating privacy in the preop and postop areas is a challenge, especially when nurses must care for more than one patient. Strategies include 3 walls and a sliding glass door or a curtain for each bay. Some centers put half walls between patients.

A minority of centers have enclosed rooms where patients and family start preoperatively, returning to the same room postoperatively. Sinks and lockers for belongings are provided. Though architects say this design can be space inefficient and unwieldy for gurney transport, one ASC administrator says private rooms please patients, families, and physicians.

The Indianapolis Surgery Center has had private patient rooms for preop and postop since it opened in 1992, says the executive director, Shannon Arrendale, RN, MBA. The surgery center performs 11,000 procedures annually and is expanding from 32,000 sq ft to 41,000 sq ft this year. When the expansion is complete, the center will have 41 preop and postop patient rooms as well as 16 rooms with their own bathrooms for 23-hour stays.

“It is easier for staff to access patients with only a curtain, but our nurses have gotten used to the enclosed rooms,” Arrendale says. “I believe this level of privacy is more of what patients will demand in the future.”

Architects say preop bays are getting larger to accommodate the growing number of procedures that can be performed in them, such as pain management and orthopedic blocks.

In PACUs, Quinn recommends placing a sink between each bed and equipping all bays with computer workstations.

Storage space

“There’s never enough storage space for nurses,” Carr quips. He suggests making the equipment holding and supply rooms large enough to ensure corridors and unused ORs do not become storage rooms.
date the new technology,” Carr says.

• Don’t plan too far ahead. Most centers must drastically remodel or build new facilities every 15 years, Carr says. “I’ve been in a number of surgery centers that are 15 years old and still function reasonably well, but I haven’t been in one that old that is state of the art,” he says. “Once a building is constructed, many things are literally ‘set in concrete.’ Significant changes will take place in medical technology and equipment, types of procedures, building codes, and AIA guidelines in that time period that will impact design.

“The best approach is to find a site that is flexible and adaptable to change.”

• Do not oversize power sources, such as emergency generators and electrical service. Centers also usually need to replace the HVAC equipment and vacuum pump after 15 to 20 years.

• Plan to update interior finishes every 10 to 15 years. “Most of the time an older facility that hasn’t been refreshed simply looks tired and can’t compete with the new center across town,” Carr says.

Right sizing
The most important aspect of designing an ASC is right-sizing it, Owens says. “Predicting volume and case mix is the key to building an ASC that is the right size,” he says. “If you build a bigger surgery center than you need, you pay for that every month, regardless of whether you have the cases to support it. You can’t reduce the size of a building like you can reduce the number of FTEs when your volume or case mix changes.”

In the design phase, centers can plan to expand later. But Owens cautions that adding ORs requires adding a proportional amount of preop and recovery bays, as well as storage, waiting room chairs, staff lockers, and business office space. “If you have the capital, add this support space when you build, then add the ORs when your volume supports them.”

Sustainable design
Green or sustainable building is a...
growing trend in health care. Applying evidence-based design concepts, more architects are incorporating natural light, nontoxic building materials, and color theory to create a healthier working environment.

“It’s been proven that a healthy, sustainable office environment increases productivity and decreases sick time,” says T. Scott Rawlings, an architect for RTKL in Washington, DC. For more information on sustainable building, visit the web site of the US Green Building Council (www.usgbc.org).

Working with an architect and general contractor

It’s essential to hire an architect with extensive experience in ASCs to build a new or remodel an existing center, administrators advise.

“Your architect needs to be reputable, well-organized, and able to communicate well with you and the contractors,” Quinn says. “You’re going to be in this relationship for a while. Choose someone you trust.”

Craig says she has seen fellow ASC administrators make the mistake of choosing an architect who specializes in hospitals. “You need someone who has the efficient ASC process flow in mind,” Craig says. If remodeling or expanding, determine in advance if contractors will work during office hours or on nights and weekends when the center is closed.

“You have to weigh the extra price of the off hours with the noise and possible service interruption during the day,” Quinn says.

—Leslie Flowers

Leslie Flowers is a freelance writer in Indianapolis.

The glass panels in this reception area provide patient privacy and direct sound away from the waiting area. They also allow light to continue through the room.

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OR Benchmarks

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**Disruptive behavior common in ORs, study finds**

Disruptive behavior happens often in hospital ORs and can have a negative effect on patient outcomes, according to a survey by VHA Inc. Among findings:

- 94% of respondents said disruptive behavior contributes to adverse events and compromises patient safety and quality.
- Respondents linked disruptive behavior to adverse events (67%), medical errors (67%), compromises in patient safety (58%), impaired quality (68%), and patient mortality (28%).
- 46% were aware of an adverse event that potentially could have occurred from disruptive behavior.
- 19% said they knew of an adverse event that occurred as a direct result of disruptive behavior.

The report includes recommendations for preventing disruptive behavior.


**Surgery without sharps effective**

Selected general surgery procedures can be performed entirely without sharps, eliminating the risk of injuries to surgical personnel, report researchers from Johns Hopkins University.

Sharpless techniques, including a skin adhesive, electrocautery, tissue stapler, and minimally invasive instrumentation, were evaluated during 358 procedures. Conventional scalpels and suture needles were readily available and used when necessary.

In all, 87% of the procedures were completed without sharps, including open laparotomies, laparoscopic surgery, and soft tissue procedures. Sharps were needed in 12 cases.


**Hospitals using internal pools, education to improve staffing**

Hospitals are cutting back on use of temporary nurses to save money and expanding use of internal staffing agencies or float pools to address short-term staffing needs, according to a survey released June 26 by the Center for Studying Health System Change.

The 2005 survey of 32 hospitals in 12 US markets also found hospitals are trying to retain nurses by offering across-the-board wage increases and flexible schedules. Long-term strategies include expansion of hospital-based education programs and extended orientation programs. To assist nursing schools, who face an aging faculty, some hospitals are subsidizing faculty salaries, lending their own nurses as instructors, and helping to recruit faculty.


**Flexible schedules, safe workplace help retain veteran nurses**

Hospitals seeking to retain and recruit veteran nurses should offer flexible work hours, ergonomic safety, increased benefits, expanded professional roles, and better designed equipment and buildings, according to a report entitled “Wisdom at Work: The Importance of the Older and Experienced Nurse in the Workplace,” funded by the Robert Wood Johnson Foundation.

The report is one of the few ever to ask older nurses what would keep them working until retirement, the foundation says.

“The seasoned nurses we interviewed believe we must very quickly transform the work environment so that older nurses are welcomed, accommodated, appreciated, and used wisely,” says the lead author, Barbara J. Hatcher, RN, PhD, MPH.

The report reviewed the literature, polled experts, and surveyed 377 nurses at 7-hospital Presbyterian Healthcare Services in Albuquerque, NM.

—www.rwjf.org