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INSIDE

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Your facility does *what* procedures? Surgical hospitals expand limits

Increasing numbers of freestandings gain hospital designation

Neurosurgery at a freestanding facility? Yes, and also simple craniotomy, gastric bypass, and colectomy. It's all part of a recent trend toward specialty hospitals, including "surgical hospitals" with no limitations on length of stay. Other specialized facilities include orthopedic facilities, women's hospitals, cancer centers, and cardiac centers.

While surgical hospitals sound like extended recovery care centers, they're actually a new creature that is scratching out a home in a territory between surgery centers and hospitals.

"This industry is growing by leaps and bounds," says **Michael Lipomi**, CEO of Stanislaus Surgical Hospital in Modesto, CA , which converted in 2000 from a freestanding surgery center to a surgical hospital. Lipomi is the president-elect of the Fresno, CA-based American Surgical Hospital Association.

"When we started the association a year and a half ago, we were able to identify 20 [surgical hospitals] that were operating or in some state of development," Lipomi says. "Currently, there are [more than] 40 facilities open and operating and another 50 to 60 in some state of growth or development."

And there's a similar trend: Some traditional acute care hospitals are

EXECUTIVE SUMMARY

A growing number of surgery centers and extended recovery care centers are obtaining designation as a hospital so that they can offer unlimited length of stay.

- Some of the factors include consumerism, reimbursement, and physician interest.
- Surgical hospitals aren't limited to performing procedures on the list of surgeries approved for ambulatory surgery centers.
- Another trend is that some hospitals are converting to all outpatient care.

Be aware of challenges with surgical hospitals

There are some distinct challenges to building and operating a surgical hospital, proponents warn. One of the biggest is the cost, they advise.

And conversions aren't cheap either, administrators warn. Moline, IL-based Trinity Medical Center spent $2 million building an emergency department and $200,000 on other structural changes required for hospitals, such as fire walls, when it converted its Seventh Street outpatient facility to a surgical hospital.

"We needed more space, anyway," says **Bonnie Leinart**, president of Trinity's Illinois campuses. "Additional fireproofing would have disrupted care."

Surgical hospitals also must overcome legal and regulatory hurdles, administrators warn. For example, Trinity had a law passed that allowed fewer than 100 beds and fewer licensing requirements than traditional acute care hospitals.

Once the facility is built, operations can be a challenge, particular if the owners are physicians who may not have the experience, warns **Fred Campobasso**, president/CEO of AMDC Corp., a Chicago-based firm that handles real estate project management, development, finance, and strategic consultation. Potential solutions include outsourcing operations with a management contract; bringing in a operational partner to invest money with physicians and/or the hospital; or hiring someone to run the facility who has experience in outpatient facilities, Campobasso says.

Marketing is another challenge, advises **Michael Lipomi**, CEO of Modesto, CA-based Stanislaus Surgical Hospital, which converted in 2000 from a freestanding surgery center to a surgical hospital. Lipomi is the president-elect of the Fresno-CA, based American Surgical Hospital Association.

"We were a great surgery center, well-known in our community and in the country," Lipomi says. "When we converted to a hospital, we faced the big challenges of communicating to the community and physicians that we are an acute care hospital and we can handle major cases."

Managed care contracts can be a hurdle, he says. "Once you're in a system, trying to renegotiate our contracts, getting them to reimburse us as an acute care hospital and not a surgery center was very difficult," he says.

When converting, Lipomi strongly recommends changing your facility's name. One of the problems his program faced was that "Stanislaus" was retained. "I can tell you we are still having some difficulty with some payers that have a tough time recognizing us," he says.

The biggest challenge, he says, was to retain the surgery center "culture." The surgery center had about 40, mostly longtime, employees who understood the concept of customer-focused care, Lipomi says. When Stanislaus converted, the facility grew to 135 employees.

"It took close to a year to rekindle the culture we had prior to conversion, which was a surgery center mentality — the physician and patient come first," he says. "There's no such thing as 'that's not my job.'" ■

converting to all outpatient care. **(See story, p. 32.)**

Some of the factors causing the growth of surgical hospitals include reimbursement, physician interest, and consumerism, which includes the "branding" of specialty centers of excellence, says **Fred Campobasso**, president/CEO of AMDC Corp., a Chicago-based firm that handles real estate project management, development, finance, and strategic consultation.

"Physicians have an interest in being a little more entrepreneurial and controlling that revenue stream," Campobasso says.

Medicare won't reimburse surgery centers for procedures unless they are on the list of procedures approved for surgery centers.

"It makes it very complex from a reimbursement standpoint if you're not a 'licensed hospital,'" says **Bonnie Leinart**, president of Moline-based Trinity Medical Center's Illinois campuses. Trinity's Seventh Street facility opened in 1997 as an outpatient complex, offering surgery, cancer care, emergency care, extended recovery care, and imaging. The facility recently became licensed as a hospital.

Patients often prefer surgical hospitals because of the atmosphere, proponents say. For example, Trinity's Seventh Street facility was built with a reflecting pond, café, drive-through pharmacy, patio, and views of the exterior landscaping and

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the pond. Some surgical hospitals have amenities including VCRs and professional chefs.

Physicians often are attracted to surgical hospitals because they are user-friendly, proponents say.

"Because we don't have an emergency department [ED], open-heart surgery, or a cath lab, we don't do major neurosurgery, etc.; there's less likelihood of cases being delayed, postponed, or cancelled," Lipomi says. "We cater to the physicians and the patients."

Most surgical hospitals are built from scratch, rather than being converted from freestanding surgery centers, Campobasso says. Many freestanding centers don't have the land available to expand, he explains. However, some facilities are being built as 23-hour centers, with tentative plans to phase into a surgical hospital based on growth and market conditions. Most of the patients stay three days or less, he says.

One of the most important factors that distinguish surgical hospitals from surgery centers is the unlimited length of stay. In outpatient surgery, often there is the potential that the patient will need an overnight facility.

"Once in a while, patients would have excessive pain or nausea, and the doctor wanted them to stay, but we had to transfer them," Leinart says.

The extended recovery care facility faced other regulatory requirements, including no blood transfusions, no patients with infections, and no transfer to extended recovery care beds unless the patients had undergone surgery, as well as staffing limitations and extensive paperwork.

"I wouldn't pursue [building an extended recovery care center] in any state," Leinart advises, who points out that the extended recovery care beds at her facility were a demonstration project. "What we've found, and what I think the state has found, is that this is a concept that really doesn't work. I think we were set to be as safe as a hospital, which is appropriate. You may as well be a hospital."

Costs come down with surgical hospitals

Surgical hospitals realize several advantages over traditional hospitals, proponents say. **(For a discussion of challenges associated with surgical hospitals, see story, p. 30.)** For example, in some states, they aren't required to have an ED and costly support services that typical hospitals have, Campobasso says.

In addition, the facilities are designed for surgical patients who are otherwise healthy, Lipomi says. "For patients, it means that they are not exposed to higher infection rates in general acute care hospitals," he says.

The infection rate at Stanislaus is 0.1%, compared to a 3% rate at hospitals nationwide, Lipomi says. "It's not that the other facilities are bad, but they treat patients we don't normally treat, he says. "We don't have an ED; we don't do trauma; and we don't do chronically ill patients."

In addition, the revenue-enhancement possibilities are significant, Campobasso says. For example, Trinity's campus had 20 extended recovery beds that had an average daily census of four, Leinart says. At the same time, one of the health system's other facilities was at capacity, she says.

"We sought to license as a hospital to have greater flexibility for beds," Leinart says.

Often, hospitals find that surgical hospitals allow a secondary market away from the main campus without the expense of building a traditional hospital, Campobasso says. "If they're expanding orthopedics, for example, and they need capacity in the ORs — if they shift to a specialty hospital concept, it frees up the main ORs for growing some of the service lines of excellence that they're looking to enhance," he says.

The impact of surgical hospitals on other surgical providers is uncertain, but competition is certain to increase.

"I think the consumer will gravitate to more of these 'branded' surgical facilities," Campobasso says. "The belief will be that the quality of care at a specialty outpatient facility will be better than at the hospital itself."

Lipomi is less certain of the impact because surgical hospitals have their own niche, he says. "We

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don't want to be an acute care hospital with open-heart surgery and [EDs] and all of that. We don't do OB," he says. "As such, there's still a critical need for a full-service acute care hospital."

Extended recovery care centers may feel the heat of competition, Campobasso warns. "But I think there's still a place in marketing for the 23-hour same-day surgery concept," he says. "It's by location, and it's very market-specific."

Don't look for traditional surgery center to disintegrate either, Lipomi advises. "I think what's happening is that in smaller communities, with smaller groups of physicians, surgery centers are perfectly appropriate."

For others, consider the surgical hospital model, proponents urge.

"If [facilities want] to have more than same-day services, they're probably best served to go ahead and bite the bullet and be a full-service hospital or specialized hospital, if that option is available in their state," Leinart says

Expect the trend to grow, says **Alan Pierrot**, MD, president of the American Surgical Hospital Association and CEO of Fresno-based FSC Health, which develops, manages, and owns surgical hospitals in joint ventures with physicians.

"I think we will see tremendous proliferation of this model over next decade," Pierrot says. "I think we're on the verge of an explosion of surgical hospital growth." ■

Why would a hospital offer all outpatient care?

While some surgery centers are converting to inpatient status, some hospitals are abandoning that niche and converting to all outpatient care.

In 1999, 12 hospitals in the country were outpatient facilities, according to the Chicago-based American Hospital Association. That number grew to 22 in 2000, according to the association. A look at one facility that took this step provides some of the reasons.

Mercy Community Hospital in Havertown, PA, was a 64-bed medical/surgical hospital with a five-OR surgery center and pain center.

"Recently, the market has been turbulent, particularly in that reimbursement was not keeping pace with costs," says **Martin McElroy**, hospital administrator.

"Also, malpractice has escalated in this area, [and] with the nursing shortage, salaries were going up," McElroy says.

The hospital couldn't survive with 64 inpatient beds when they were surrounded by large established institutions, including one from their own health system within seven miles. Thus, the inpatient hospital services and the emergency department have ceased operation. An imaging center and an outpatient radiology area have been added.

Sixty percent of the full-time employees are being placed elsewhere, and 25% will remain on campus, he says. The remaining 20% have been terminated.

Now, the hospital is adjusting to being an outpatient facility.

"We hope to provide some things that the community is looking for now: state-of-the-art services in a manner that is customer-friendly," McElroy says. "We want to reduce waiting times and focus the specific needs of outpatients."

One of the biggest challenges has been changing the culture to focus more on patients and physicians, he says. "From inpatient to outpatient, the challenge is — what is the level of care you're able to give? Is it customer-friendly to the point at which people feel there's value added to that?"

Expect more hospitals to follow Mercy's lead, McElroy predicts.

"As you look to the future, the things that keep coming up more and more are the ability to serve the patient and physician in a new health care model that has easier access, more timely services being provided, and also the ability to get the turnaround time that patients are demanding," he says. "Those types of things, if we can address them, will help us become successful."

Other hospitals should expect to see similar demands from patients, he predicts.

"Some of those hospitals may lose business, and it also may force them to see changes that we think patients and physicians are demanding," McElroy says. ■

SOURCES

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- **Martin McElroy**, Hospital Administrator, Mercy Community Hospital Center, 2000 Old West Chester Pike, Havertown, PA 19083. Telephone: (610) 853-7001. Fax: (610) 449-0415.

New techniques available for foot, ankle problems

Surgeons need specific training

Advances in surgical technology have affected all areas of same-day surgery, including podiatric surgery. These advances are beneficial to patients, but require more credentialing diligence from the same-day surgery manager and medical director, say experts interviewed by *Same-Day Surgery*.

"Although ankle arthroscopy represents only 3% to 6% of all arthroscopies, it requires specific training within a residency program or a hands-on course," says **John J. Stienstra**, DPM, FACFAS, a podiatric foot and ankle surgeon at the Permanente Medical Group in Union City, CA.

"Ankle arthroscopy is more difficult than arthroscopy of the shoulder or knee because of the size and the geometry of the ankle joint with its three bones," he says.

Although the arthroscopic equipment is basically the same for all arthroscopies, with smaller instruments used for ankles, it does require a surgeon who is experienced in foot and ankle surgery, Stienstra adds.

For this reason, credentialing requirements for surgeons who perform ankle arthroscopy should include specific training in the procedure, not just training in arthroscopy in general, he suggests.

"It is a mistake to assume that the ability to perform shoulder or knee arthroscopy should automatically qualify someone to perform ankle arthroscopy," he adds. **(See "Can your ASC meet the credentialing challenge of new tools, techniques?" *Same-Day Surgery*, June 1999, p. 65. Previously published stories are available on the web site: *www.same-daysurgery.com*.)**

Used to treat ankle damage caused by injury or arthritis, ankle arthroscopy is beneficial to patients and same-day surgery programs because the technique reduces biologic and financial costs by sparing the patient from injuries that might occur during traditional surgery, Stienstra says.

"Small arthroscopic instruments, along with lasers, enable us to cut and tailor tissues, weld things together, vaporize pathologic tissues, and anchor and repair structures within the ankle joint without dissecting blood vessels that are dissected during traditional surgery," he explains.

This procedure means less discomfort and swelling during recovery, Stienstra adds.

Stienstra does not predict an explosive growth in the use of ankle arthroscopy, but describes it as "a slowly expanding envelope." If no surgeon is performing the procedure at a same-day surgery program and there is a qualified surgeon, it does represent an opportunity, he suggests.

Although many same-day surgery procedures often result in shorter recovery times than traditional surgeries, one podiatric surgical technique that requires eight weeks of recovery is actually the better choice for patients suffering from bunions, says **Marybeth Crane,** DPM, FACFAS, a podiatric surgeon in Grapevine, TX. The best bunion surgery, especially for younger patients, is a procedure that realigns the big-toe joint in order to correct a bunion rather than just shaving the bump, she explains.

"Although patients have to stay nonweight bearing on the foot that undergoes the procedure for up to eight weeks, it is a permanent fix unlike the more commonly requested procedure that shaves the bump," she says. In the procedure, the bone is cut and tendons and ligaments are realigned to prevent the hypermobility of the joint that is the primary cause of bunions, Crane says.

Although the simpler removal of the bump means a more immediate return to normal life, the bunion often recurs because the hypermobility of the joint, the cause of the bunion, is still present, she adds.

As with ankle arthroscopy, Crane recommends that credentialing for this procedure require specific training in this procedure since the surgeon must demonstrate an understanding of the internal fixation of the big-toe joint and must be able to graft bone to correct the deformity in some cases, she adds.

EXECUTIVE SUMMARY

Although equipment needs are similar to other same-day surgery procedures, new podiatric techniques offer particular benefits to patients and facilities. Surgeons require special instruction or experience.

- Ankle arthroscopy requires knowledge of the joint and the ability to work within a smaller joint than a knee or shoulder.
- Surgeons should demonstrate knowledge of the internal fixation of the joints in the foot and the ability to perform bone grafts if needed.
- Hands-on courses that focus on the specific podiatric procedure are best for surgeons who didn't gain experience in a residency program.

SOURCES

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- **John J. Stienstra**, DPM, FACFAS, Department of Orthopedics, Permanente Medical Group, 3555 Whipple Road, Union City, CA 94587.

This is a procedure that is being requested by patients on an increasing basis, Crane says. In addition to seeing patients who have recurring bunions, Crane also sees a growing market in young, athletic people.

Another podiatric procedure that has been very popular since 1996 is endoscopic plantar fascial release to treat heel pain, she says. "It is 85% effective in treating heel pain and is preferred by young, athletic people who don't want to undergo the more extensive open heel spur resection," she says.

The procedure lengthens the tendon, which eliminates the pain, Crane adds. As with other newer procedures, she recommends a hands-on course to establish credentials.

"The good news about each new podiatric technique is that they offer younger people a chance to address foot and ankle problems early, well before arthritis or other damage to the joints require major surgery," Crane says. ■

OPPS changes simpler with one coordinator

Employee monitors changes, interprets info

With the multiple changes the outpatient prospective payment system (OPPS) has experienced since its implementation in August 2000, many hospital-based same-day surgery program staff wonder how many items have fallen through the cracks and resulted in claim denials.

Frequent transmittals of changes and ambiguous language have made it difficult for the staff at Asante Health System in Medford, OR, says **Rick Fernandez**, MHA, reimbursement manager for the system.

"Although several people share the function, there is no clear coordination. I am sure that we've missed things that have kept us from implementing timely changes in our system," he says.

For this reason, his health system is evaluating a new job position that will coordinate ambulatory payment classification (APC) activities.

"From January 2001 to October 2001, there were 55 transmittals of changes related to the OPPS," says **Valerie A. Rinkle**, MPA, executive director of Hospital Resource Management, a Medford, OR-based consulting firm that specializes in reimbursement issues. "When you are dealing with this many changes that need to be reviewed and addressed within your own program, it may be necessary to develop a position that is solely responsible for coordinating APC issues."

The job description for APC coordinator should include more than just monitoring changes in the OPPS, Rinkle says.

"An APC coordinator should read transmittals, undertake whatever research is necessary to ensure that the changes are interpreted correctly, develop a work plan to implement changes within the facility, and implement the plan utilizing whatever departments are affected," she says.

The APC coordinator at Nebraska Methodist Hospital in Omaha was put into place about six months before the implementation of OPPS, says **Mary Meysenburg**, RHIA, CCS, service executive of medical records. At the time, the primary responsibility was to coordinate all education and activities needed to be ready for OPPS, she says. Now, the coordinator monitors all change transmittals related to OPPS and monitors the

EXECUTIVE SUMMARY

Frequent changes within the outpatient prospective payment system (OPPS) have kept reimbursement managers of hospital-based same-day surgery program scrambling to keep their internal systems up to date. One solution is to create a position specifically to monitor changes and implement updates.

- A full-time ambulatory payment classification (APC) coordinator is justified most easily by a facility with many ambulatory services that are complex.
- Other options for coordinating changes include subcontracting with a consultant or making APC coordination part of one staff person's job. Whoever handles the coordination should have the authority to work with a variety of departments and people.
- According to some sources, the coordinator does not have to have a coding background or clinical experience.

facility's internal records to identify causes of claim payment delays or rejections, Meysenburg adds. Once a problem is identified, the coordinator is responsible for working with the appropriate people and departments to correct the problem, she says. "Sometimes it's a matter of education, and the coordinator provides that education," she adds.

An APC coordinator is probably a good position to evaluate if your facility has several outpatient services, such as radiation oncology, sleep lab, or ambulatory clinics, in addition to same-day surgery, says Rinkle. If your facility only has same-day surgery and basic outpatient radiology and lab services, it is harder to justify the expense of a dedicated employee, she adds.

Same-day surgery programs in hospitals that don't have multiple ambulatory services do have several options to efficiently handle the changes that must be made, Rinkle suggests. The business office manager, reimbursement manager, chief financial officer, or controller can act as the coordinator as part of his or her job with specific people identified throughout the different departments to handle implementation of changes, she says. The key is to make sure that there is someone who coordinates and follows up on changes that need to be made, Rinkle adds.

"Facilities that are a part of a larger network can get together to fund an APC coordinator position that will monitor changes and implement plans to update systems for all members of a network," she says. "Smaller facilities can subcontract some or all of the responsibility to a consultant who specializes in reimbursement issues."

You can find a subcontractor in several ways, Rinkle says. "Check with professional associations and network with your peers," she suggests. **(See source box, at right.)** "Be sure to check references from other programs using the subcontractor for the same job you want him or her to do," Rinkle adds.

If you do decide to create an APC coordinator position, look for a "hound dog" to fill the slot, Rinkle suggests. "This person needs to be diligent, to be persistent about ensuring follow-through, and to have a good understanding of how departments work together," she says.

A good APC coordinator also needs to have the authority to direct activities that cross departmental lines, she adds.

While an employee who oversees activities related to changes in OPPS, either full time or as part of another job, doesn't need to be a coding expert, he or she should understand the basic principles of coding and be able to talk with coding experts when needed, Rinkle says.

A clinical background is not necessary and, in some cases, may be a potential problem, she says. "Someone with a clinical background might not see missing information in documentation," she points out. "A clinical person might read a chart and understand how the provider got from point A to point C without having to see point B since he or she already knows what happens in between." A nonclinical person will look at the same chart and ask, "What did you do to get to point C?"

While Asante Health System's staff recognize the importance of an APC coordinator, there are several issues that must be evaluated, Fernandez says. "We are taking a close look at cost vs. benefits of having one dedicated position coordinating everything, and we are trying to decide what level of skill we need to hire," he says. "The big question is whether or not to hire an expert in the area or move an existing employee into the position and provide training."

Meysenburg says her facility's administrators did believe that a good knowledge of coding was

SOURCES AND RESOURCE

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- **Valerie A. Rinkle**, MPA, Executive Director, Hospital Resource Management, 30 S. Barneburg, Medford, OR 97504. Telephone: (541) 608-9845. E-mail: vrinkle@hrmlc.com.

For names of consultants who provide help in managing outpatient reimbursement changes, contact:

- **Healthcare Financial Management Association**, Two Westbrook Corporate Center, Suite 700, Westchester, IL 60154-5700. Telephone: (800) 252-4362 or (708) 531-9600. Fax: (708) 531-0032. Web site: www.hfma.org. A printed copy of a resource guide is available only to subscribers of the association's monthly publication ($100 per year), but an on-line version is available at no cost at www.hfma.org/publications/HFM_On-Line_Resource_Guide.htm.

important for this position, so they looked for someone with a coding background. "This person's experience ensures that she can interpret the documentation in relation to the codes used on the claim," she explains.

Although her facility has not performed a formal study to evaluate the benefits of the APC coordinator position, Meysenburg says that by watching the days in accounts receivable and the reports of claim payments delayed or denied, she can tell that the position is worthwhile.

"If we didn't have a knowledgeable person responsible for monitoring OPPS changes and how we code claims, many delayed or denied claims would have had additions or deletions of codes made without anyone checking to see if we were in compliance," she says. "This way, we know that our claims are coded accurately and we are ensuring that we're paid correctly." ■

Mini-facelifts offer quick recovery, attract patients

Benefits are less bruising, swelling, anesthesia

Take Friday off from work to have a facelift and return to work on Monday with a new, fresh look. Sound too good to be true?

It is too good to be true, say experts interviewed by *Same-Day Surgery*.

While having a facelift doesn't have to mean weeks of recovery, the term "weekend facelift" is a misnomer and can lead to unrealistic expectations by patients, says **Daniel Morello**, MD, a White Plains, NY, plastic surgeon and past president of the American Society for Aesthetic Plastic Surgery in New York City.

In addition to the term weekend facelift, mini-lift, and minimal incision facelift are all used interchangeably, Morello says. Physicians and same-day surgery programs that promote such procedures need to be careful about describing the procedure and the results, he cautions.

"Many times, a weekend facelift is really a neck operation that doesn't involve the face or jowls," he says. "It is often little more than minor liposuction."

There are, however, facelifts that address certain segments of the face that require smaller incisions, less recovery time, and less bruising and swelling, says **Robert Singer**, MD, a plastic surgeon in La Jolla, CA.

EXECUTIVE SUMMARY

Mini-facelifts, or segmental facelifts, appeal to patients in their 30s and 40s who have specific, well-defined areas they want to correct. These procedures that address the neck, jowls, and cheeks are growing in popularity.

- Smaller incisions and shorter anesthesia time mean a quicker recovery. Tissue glue reduces bruising.
- Avoid promising two- to three-day complete recovery because every patient's bruising and swelling will differ.
- Evaluate credentialing requirements to ensure surgeon is able to offer a full range of services in case the mini-lift is inappropriate.

"This segmental facelift appeals to many patients who have one or two areas that they would like to improve," Singer says.

These patients are generally in their 30s and 40s and don't want to wait until they are in their late 50s to undergo a major procedure, he explains.

Mini-lifts, or segmental facelifts, might concentrate on cheeks, jowl line, or neck, Singer says. All of these require minimal incisions, less time in the operating room, and less anesthesia, he points out. These characteristics mean less swelling and bruising, and a faster recovery, he adds.

While a two-day complete recovery, which is implied with the term weekend facelift, is unrealistic, new techniques are cutting down on the amount of bruising, Morello says.

"By using tissue glue to close the wound, we eliminate the need for drains, and most patients are wearing no dressing, or only a light dressing, at six days after surgery rather than 12 days after surgery using more traditional methods," he explains. "Of course, the amount of bruising and how long the bruises and swelling last differ from patient to patient."

Although the mini-lifts require less operating time by themselves, many patients will opt for several small procedures at one time so total operating room time may not be reduced drastically, Singer says. "A mini-procedure doesn't mean mini-training," he says. "Although the procedure itself may be less invasive, the same risks associated with any surgery still exist."

For this reason, Singer recommends that same-day surgery managers or medical directors look carefully at the training of any surgeon who

SOURCES

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applies to perform mini-lifts or segmental facelifts.

"Be sure that the surgeon is qualified to perform a variety of cosmetic plastic surgery procedures, not just one or two mini-procedures," he says. Surgeons who only perform mini-procedures may perform them on all patients whether they are good candidates or not, he says.

Candidates for the mini-procedures have specific areas they want to improve, Singer says.

"If a same-day surgery program and its surgeons promise more than the mini-procedure can deliver, the patient will be unhappy with the results," he says. For this reason, a surgeon should be able to judge accurately what results the patient expects and what procedure will best attain those results, Singer says. A surgeon who is not qualified to perform a wide variety of procedures may not be able to provide the best procedure, especially if what is needed is more extensive than a mini-lift, he explains.

Baby boomers' general attitude toward exercise, fitness, and health all point to an increasing demand for segmental facelifts, Singer says. The increasingly competitive job market is another reason people are interested in delaying the signs of aging, he says. "Many people believe a youthful, healthy appearance gives them an advantage," he explains. ■

Same-Day Surgery Manager

How to select the right staff for your program

By **Stephen W. Earnhart**, MS
President and CEO
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Dallas

Depending upon which side of the "profit" curve you are on — i.e., hospital not-for-profit or ambulatory surgery center (ASC) for-profit — will determine how you react to this month's column.

When developing the operating entity for a new ASC, we typically have one or two "steering committee" meetings per month. The steering committee is made up of a representative from each specialty that will be utilized in the new venture. I have been to 11 such meetings in the past 30 days, and it hit me at a meeting last night that the most time is spent on the partnership agreement, the offering memorandum, and staffing. Staffing is a major issue with every new start-up.

Do you want to know what we talked about? Some of it is pretty interesting. First, almost every group of surgeons is concerned about the nursing shortage. They see it in the hospitals they work in, and they are fearful that they will have difficulty recruiting quality staff for their center. Well, there's good news, and there's bad news. We explain that the shortage is real and worsening but that we never have had difficulty recruiting ASC staff due to lack of available nurses. The only exception was nurses who did not wish to work with a certain group of surgeons.

In contrast to what many hospitals are experiencing, we have a waiting list of outstanding nurses who are waiting for an opening.

Why? One reason is the profit-sharing concept. Clearly, that concept is enticing to nurses who typically don't have that option in our line of work. **(For more on profit-sharing, see "Staff incentive plans that make sense," *Same-Day Surgery*, February 2001, p. 21. You can find this story in the archives at *same-daysurgery.com*.)** The lack of being "on-call" and the personal disruptions that it causes is another attraction. And, although cross-training is (should be) mandatory for each department or center, being rotated to a less-desired department rarely occurs. Lack of trauma and OB coverage is a magnet to some, while the rapid pace with generally healthy adults is gratifying to others.

Lest we forget, the ability to work less than full time is a major attraction for mothers of young children who wish to keep their skills sharp by working, and yet not have to disrupt their families

by working a set number of hours per week or month.

While this shifting paradigm attracts staff to ASCs, it does not necessarily meet the needs of invested surgeons in their new business. They are educated that there are three key factors to success in an ASC: cases, staffing, and supply cost. The proper blend of these three ingredients can mean the difference between success and failure (oh, yes, there are many ASC failures) for this new surgery facility. While the concept of "less staff is better than more staff" is often lost on the average department head, in reality, it is true. The key is the right staff and not the number of staff.

So, what do the surgeons look for in their staff? Personality: the ability to smile. You can teach someone to do most anything but smile and have a "can-do" attitude. I can feel the hate mail being written right now, but the reality is that we all want to surround ourselves with people who are fun to be around. One of the very first qualities I look for in my own staff is that smile.

Next, they want dependable people. They want staff who consistently are going to show up on time. Whether you like it or not, arriving at your job on time is a sign of respect for your employer. They want respectful staff.

They talk about skills and those who excel at what they do — and no, experience is not the No. 1 consideration. You may be the "best" orthopedic nurse in the operating room, but if you don't have the others skills they are looking for, they will not want you. Too many times, I see technically superb nurses get passed over for less-experienced but more motivated and enthusiastic applicants. The surgeons will say that they can put up with teaching and training the staff to become technically competent rather than deal with personality issues that jeopardize the success of the center. Passive/aggressive personnel need not apply.

So, after all that, what happens next? The days pretty much are past when there was a significant variance in pay between not-for-profits and for-profits. The pay usually is the same hourly rate for either. The difference and opportunity comes in the ability to share the profits. As staff, we enjoy being chosen to work at the center, but we are not naïve. We expect to be included in the success of the center. When the surgeon receives a distribution, we want one as well. The fact that there are fewer of us on staff means that each one has to pull just a bit harder, and we want and deserve that recognition.

Keep smiling!

(Editor's note: Earnhart & Associates is an ambulatory surgery consulting firm specializing in all aspects of surgery center development and management. Earnhart can be reached at 5905 Tree Shadow Place, Suite 1200, Dallas, TX 75252. E-mail: searnhart@earnhart.com. Web: www.earnhart.com.) ■

Infection control practices change with technology

(Editor's note: In this second part of a two-part series on sacred cows in the OR, we discuss five infection control practices and whether they can be changed safely. In last month's issue, we discussed rituals that exist because "it's always been done that way.")

It is not an easy thing to change operating room practices that have been in place since your "older" nurses were trained, says **Hilda Guevara**, RN, BSN, facility administrator of Central Park Surgery Center in Austin, TX.

"It helps to understand why we have been performing certain rituals and what has changed in the past few years," Guevara says. "Understanding where we've been and why we can change eliminates much of the reluctance a same-day surgery manager might encounter," she adds.

The rituals that are most commonly undergoing evaluation or changes, according to Guevara are:

• **Cover gowns.** In the past, cover gowns were required any time you left the OR, says Guevara. There were two reasons, she says.

"Members of the public would see surgical scrubs and wonder what you might have on them that could contaminate them or the food on the salad bar," she says. Although OR staff members always change into clean scrubs if they should get something on them during surgery, it was a matter of perception, she says. "We also wore cover gowns to keep our scrubs clean when we left the OR," she adds. Now, 75% of OR managers no longer require cover gowns,[1] Guevara says.

"Guidelines have been changed to reflect the myriad infection control studies that show no higher risk to the patient if cover gowns are not used," she explains.

• **Shoe covers.** Although many same-day surgery managers no longer require shoe covers, Guevara points out that this is a policy that can change depending on the situation.

"One reason to wear shoe covers is to protect your shoes during surgery. The other reason is to avoid tracking dirt from the outside into the OR," she explains.

Since many surgery staff members now keep a pair of "OR" shoes and a pair of outside shoes with them, the need for covers isn't as great, she says. If someone doesn't have separate shoes for inside and outside, common sense should determine if covers are needed, she says.

• **Event-related expiration date.** "We used to pull trays of instruments we had sterilized and wrapped after they had been on the shelf for three or six months and send them back to be sterilized again," Guevara says. "Now, we realize that once it's sterile, it stays sterile as long as the packaging isn't damaged."

For this reason, it is common to leave trays on the shelf until needed unless the wrapping is damaged, she says.

• **Hand scrub.** A 10-minute initial surgical hand scrub with three to five minute scrubs between cases is one ritual that is still alive, says Guevara. "Although new scrubs, even some that don't require brushes, do eliminate the need for lengthy scrubs,[2] this is one ritual many OR staff members are reluctant to give up," she says.

At Guevara's facility, staff are given the option of reducing the initial scrub to five minutes with a three-minute scrub between cases.

"Although some of the new surgical handscrub products are more costly, shorter scrub times are not as hard on the skin," she says.

Shorter times help staff avoid various skin conditions such as eczema and rashes that result from constant scrubbing, she adds. **(For more information about alternatives for surgical hand scrubs, see *Same-Day Surgery*, July 2001, p. 73.)**

• **Knife blade changes.** Another ritual that may continue, depending on the surgeon's preference, is the use of two knife blades, Guevara says. "Most surgeons have always used one knife for the initial incision and another for any other dissection," she says.

Some surgeons choose to do so because they believe that making the initial incision dulls the knife`s edge, and they want a sharp blade for the rest of the procedure, she explains. Other surgeons believe the use of two blades is better from an infection control perspective, she adds.

"There are data that show that there is no increased risk with the continued use of the first knife because the microbes on the knife are the patient's own microbes," Guevara says.[3]

The best course of action for this ritual is to let the surgeon decide, she adds.

References

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Programs offer free eye surgery for needy

Across the country, outpatient surgery programs are volunteering their surgeon's time and ORs to provide eye surgery for patients who otherwise could not afford it.

"There are a lot of medically negligent people in the United States who don't have resources to have eye surgery here," says **Thomas Kidwell**, MD, medical director of Eye Surgery Center in Rancho Cordova, CA.

Since 1996, the center has been participating in a national program put on by Mission Cataract USA, a nonprofit foundation offering free cataract surgery one day a year to people of all ages who have no means to pay. This year's effort will be held May 3-4 (free eye screenings) and May 10-11 (free eye surgery). While those dates are the official ones, many programs choose to schedule their free surgery at other times of the year. **(For more information on Mission Cataract USA, see**

EXECUTIVE SUMMARY

Many same-day surgery programs find that offering free eye surgery once a year to needy people is a low-cost way to give something back to the community, boost morale, and receive positive publicity.

- Mission Cataract USA offers an instruction packet and media kit for $250. This year's official effort is scheduled for May 3-4 (free eye screenings) and May 10-11 (free eye surgery), although the dates are optional.
- Some facilities have developed their own programs based on Mission Cataract USA. One program has found that the December holidays are ideal because the patient census is low.

resource box, below right.)

Some centers, such as McGowan Eye Care Center in Framingham, MA, have developed their own free eye-surgery program modeled after Mission Cataract USA. Because the New England center has a low patient census around the December holidays, the McGowan center selected the last Tuesday before Christmas to offer the free surgery all day, explains **Bernard L. McGowan**, MD, director of the center. The procedures, which average about 15, include cataract and glaucoma laser procedures. McGowan's program, which targets people who cannot afford medical insurance, has included patients brought in from other countries by their relatives.

Both centers screen patients.

"We do a screening ahead of time to make sure patients have cataracts and they qualify," Kidwell says. Many patients may not qualify because of other health care problems, such as diabetes, he says. It's important to know what resources are available for patients who don't have medical insurance but don't qualify for the free surgery, Kidwell says. "Explore the resources available in your own community so you have options to give people," he advises. **(See editor's note at the end of the story.)**

Volunteers are at the heart of both programs. With Mission Cataract USA, staff and surgeons are asked to volunteer their time. Vendors donate intraocular lenses (IOLs), and the Eye Surgery Center's optical shop donates glasses.

In McGowan's program, the surgeons volunteer and staff are paid. Vendors donate all of the supplies and medications.

The centers have reaped positive publicity from their efforts. Boston television stations have featured the program several times, McGowan says. "Last year, they put our name on the blank screen with our telephone number, which they left up for 10 seconds," he says. "You can't pay for that kind of advertising."

However, the greatest advantage comes from the feeling of giving something back to the community, McGowan and Kidwell agree.

"There's an incredible number of people working who can't afford health insurance," Kidwell says. Their cataracts may prevent them from working, he says. "By correcting their vision, they may be able to go back to work or better meet requirements of their work," Kidwell says.

The effort is a morale-booster for surgeons and staff, and the December holidays are the perfect time, McGowan says.

"We have such a high percentage of patients who are snowbirds, and there is a lull that occurs," he says. "Most people don't want to be operated [on] around Christmastime. This gives us chance to keep our staff employed, use our facility, do something for the community, and give this treasure — sight."

[Editor's note: Members of the International Associations of Lions Clubs in the United States and Canada work with LensCrafters stores to collect unwanted eyeglasses for recycling. In the United States, the glasses are sent to one of six regional recycling centers where Lions and other groups prepare them for distribution.The first Wednesday in December, LensCrafter stores set aside a morning to provide free eye exams and eyeglasses to needy residents. Also, some Lions Clubs purchase eyeglasses for the needy. For more information, call (630) 571-5466 Ext. 363 or go to www.lionsclubs.org/English/FGiftOS.html.] ■

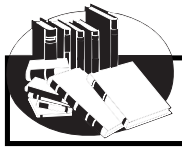
SOURCES AND RESOURCE

For more information on offering free eye surgery, contact:

- **Thomas Kidwell**, MD, Medical Director**,** Eye Surgery Center, 10725 International Drive, Rancho Cordova, CA 95670. Telephone: (916) 631-2000. Fax: (916) 631-2041. E-mail: thomas.kidwell@ncal.kp.org.
- **Bernard L. McGowan**, MD, Director, McGowan Eye Care Center, 297 Union Ave., Framingham, MA 01702. Telephone: (508) 872-4590. Fax: (508) 872-0038. E-mail: blmeyes@mediaone.net**.** Web: www.mcgowaneyecare.com.

There's a $250 registration fee to participate in Mission Cataract USA, which is tax-deductible. The fee covers the instruction packet and media kit, posters, fliers, and camera-ready advertisements. Each registered participant receives week-by-week, step-by-step instructions, including how to get started, how to recruit staff and community volunteers, and how to inform community leaders about the project. The packet also provides financial guidelines and necessary forms in English and Spanish. The media kit provides press releases, public service announcements, and demonstrations of how to get local media to visit your facility. It also contains posters, fliers, and camera-ready ad slicks in English and Spanish. For more information or to register, contact:

- **Mission Cataract USA**, 1233 E. Brandywine Lane, Fresno, CA 93720. Telephone: (800) 343-7265 or (559) 433-1116.



JOURNAL REVIEW

Sugar A, Rapuano CJ, Culbertson WW, et al. **Laser in situ keratomileusis for myopia and astigmatism: Safety and efficacy — A report by the American Academy of Ophthalmology.** *Ophthalmology* 2002; 109:175-187.

Laser in situ keratomileusis (LASIK) surgery is safe and effective for low to moderate myopia and astigmatism, but it is less predictable for moderate to high myopia and astigmatism, according to a new report from the San Francisco-based American Academy of Ophthalmology.

Annoying side effects, including dry eyes, nighttime starbursts, and reduced contrast sensitivity, occur relatively frequently in LASIK procedures, the report said. Many patients have difficulty driving at night after the surgery, the authors said. Complications involving the LASIK flap have been reported to occur in about 4% of primary LASIK cases, according to the report.

LASIK is an excellent procedure for many, but not all patients, the authors concluded. "The best results are obtained by surgeons who pay attention to checking the microkeratome and laser before surgery and maintain excellent surgical technique," the authors said. They emphasized the importance of good postoperative care. "While most patients require very little intervention by the doctor after surgery, when a question or problem does arise, the doctor needs to be available. Failure to promptly address post-surgical complications can have severe consequences."

The report was based on a review of 47 articles published between 1968 and 2000. The review was conducted by the Ophthalmic Technology Assessment Committee 2000-2001 Refractive Surgery Panel.

[For more information on LASIK, including concerns about advertising, see, "Your advertising for LASIK can nullify informed consent," *Same-Day Surgery*, January 2001, p. 1. You can access the story in the archives at *www.samedaysurgery.com*. Your user name is your subscriber number. Your password is sds (in small letters) and your subscriber number again.] ■

Ease of use important for medical event reporting

The report *To Err is Human: Building a Safer Health System*, which was issued in 2000 by the Institute of Medicine in the Washington, DC, indicated a lack of information on medical event reporting within ambulatory health care settings, including same-day surgery programs.[1]

This lack of information implies that the number of ambulatory health care settings that have medical event reporting systems is low, says **Naomi Kuznets**, PhD, director of the Accreditation Association for Ambulatory Health Care's Institute for Quality Improvement (IQI) in Wilmette, IL. A more recent survey by IQI of 539 ambulatory health care facilities that included freestanding surgery centers shows that 33% of participants have reporting systems in place, she adds.

"The Institute of Medicine report included only 1½ pages of information on outpatient care that did not necessarily reflect all ambulatory care," Kuznets says. The lack of information collected in the study implied that the state of medical event reporting within ambulatory care organizations is rudimentary, she adds. After a literature search showed that there is little information regarding medical event reporting within ambulatory care facilities, IQI staff recognized a need to find out what is being done, she explains. The result is the IQI *Medical Event Reporting Special Report.*

Of the 539 respondents to the study designed by IQI, a total of 180 or 33% reported participation in a system that collects information on illnesses or injuries related to medical treatment and/or instances in which illness or injury related to medical treatment is likely to occur, Kuznets says.

Respondents described three types of reporting systems, Kuznets says. Fifty-three percent of respondents participate in voluntary programs in which the medical event reporting system is imposed internally or through a professional association; 43% participate in involuntary programs that are imposed by state, federal, regulatory, or network organizations; and 3% participate in both types of programs, she explains.

Responses show the voluntary programs offer more appropriate information, more feedback, and more opportunity to use the data in a positive, actionable manner, Kuznets says. The problem with mandatory systems imposed by other organizations is the lack of feedback that does not enable the reporting ambulatory organization

a chance to use data to improve quality, she adds.

Attributes of a medical event reporting system that are being used by study respondents include:

- ease of reporting (more than 86%);
- frequent reports (more than 58%);
- actionable feedback (more than 54%);
- information important to the participating program's unique situation (more than 50%).
- reports from several sites (more than 40%);

"Unique information that applies specifically to a participant's specialty makes the medical event reporting system more useful," Kuznets says. For example, a same-day surgery program that specializes in ophthalmology will not want the same information about anesthesia incidents that a multispecialty program that performs a high percentage of laparoscopic procedures will want, she explains.

The types of systems used by study participants ranged from voluntary participation in medical society or professional organization systems, vendor systems, or internal systems to involuntary participation in federal, state, insurer, and surgery center network systems, she says.

When asked how much they would be willing to spend to participate in a reporting system, 102 respondents suggested costs that ranged from $5 to $180,000 per year. The median cost was $200, and the average cost was $2,235, Kuznets says.

While the report spells out the features that are most likely to increase participation in medical event reporting, Kuznets points out that none of the systems in use by the participants measure "near-miss" events. "This is one area in which ambulatory care programs could really increase their opportunities to learn in situations in which they aren't liable for any injuries but could identify potential problems proactively," she says.

[Editor's note: Copies of the IQI Medical Event Reporting Special Report *can be ordered by contacting: The Institute for Quality Improvement, Accreditation Association for Ambulatory Health Care, 3201 Old Glenview Road, Suite 300, Wilmette, IL 60091. Telephone: (847) 853-6060. Fax: (847) 853-9028. Web: www.aaahciqi.org. The cost is $25 plus $5 for shipping.]*

Reference

1. Kohn LT, Corrigan JM, Donaldson MS, eds.; Committee on Quality of Health Care in America, Institute of Medicine. *To Err is Human: Building a Safer Health System.* Washington, DC: National Academy Press; 2000. ■

Fancy charts not needed to ensure positive survey

The best way to present your organization during an accreditation survey is to "take control" within the first 30 minutes by telling the surveyors you want to tell them about a specific aspect of your facility.

"Surveyors have no secret list of what they really want to hear, but they do want you to convince them that you know your patients, you know what they need, and you have looked for ways to improve care," says **Ann Kobs**, president and CEO of Type 1 Solutions, a Cape Coral, FL-based consulting firm.

When you are presenting the quality portion of your story, don't use the quality staff person, Kobs suggests. "One of the basic principles of quality improvement is that everyone participates, especially those closest to the customer," she says.

For this reason, Kobs recommends that a physician or a staff person who is not in nursing but represents a discipline that collaborates in improving care present the quality improvement program.

Don't get caught up in preparation of elaborate charts, storyboards, multimedia presentations, or other presentation paraphernalia, she advises.

"You do need to show that you use statistical tools to analyze data, but other than that, it is best for staff members to just tell their story," she says.

"If all staff members are articulate and telling the same story, that is adequate," she adds.

Also, make sure the focus on quality improvement doesn't stop with the administrative presentation, Kobs recommends.

"As the surveyors go through the organization, it is good to hear that concern about quality doesn't stop in administration," she says. ■

SOURCE

For more information about preparing for accreditation surveys, contact:

- **Ann Kobs**, President and CEO, Type 1 Solutions, 166 S.E. 18th Terrace, Suite A, Cape Coral, FL 33990. Telephone: 87SENTINIL. E-mail: AEJBBK @aol.com.

Legislation delays HIPAA for one year

Newly signed legislation (H.R. 3323) delays implementation of the standards and code sets regulation of the Health Insurance Portability and Accountability Act (HIPAA) for one year until Oct. 16, 2003.

The delay is effective for providers that have filed a compliance plan or can demonstrate compliance by the new deadline.

The Chicago-based American Hospital Association has issued guidance to assist providers in complying with the new law. Go to the organization's web site at www.aha.org/hipaa/resources/electransactextention.asp.

The law does not affect the April 14, 2003, deadline for complying with the medical privacy requirements.

[Editor's note: ***For more information on HIPAA requirements, see "Your facility could be held liable if others misuse your patient records,"* Same-Day Surgery*, March 2001, p. 25. Archives are available on* www.same-daysurgery.com.**

Also, the Federated Ambulatory Surgery Association will hold a HIPAA conference for surgery centers in mid-July 2002 and is developing other HIPAA resources. For more information, contact: FASA, 700 N. Fairfax St., Suite 306, Alexandria, VA 22314. Telephone: (703) 836-8808. Fax: (703) 549-0976. E-mail: fasa@fasa.org. Web: www.fasa.org.] ■

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Editorial Questions
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CE/CME objectives

After reading this issue, the continuing education participant will be able to:

• Identify qualifications for credentialing a surgeon to perform ankle arthroscopy. (See, "*New techniques available for foot, ankle problems.*")

• Identify the one attribute that is essential for the person filling the role of APC coordinator. (See, "*OPPS changes simpler with one coordinator.*")

• Identify the one method used to reduce the amount of bruising experienced by patients undergoing a segmental facelift. (See, "*Mini-facelifts offer quick recovery, attract patients.*")

• Identify the percentage of study participants utilize a medical event reporting system of some type. (See, "*Ease of use important for medical event reporting.*") ■

CE/CME *questions*

Please save your monthly issues with the CE/CME questions in order to take the two semester tests in June and December. A Scantron form will be inserted in those issues, but the questions will not be repeated.

9. According to John J. Stienstra**,** DPM, FACFAS, a podiatric foot and ankle surgeon at the Permanente Medical Group, same-day surgery managers should look for what qualifications when credentialing a surgeon to perform ankle arthroscopy?
   A. experience in arthroscopy in general
   B. training or class specific to arthroscopy of the ankle
   C. podiatric or orthopedic training only
   D. none of the above

10. According to Valerie A. Rinkle, MPA, executive director of Hospital Resource Management, what is one attribute that is essential for the person filling the role of APC coordinator?
   A. clinical background
   B. coding expertise
   C. persistence in following up with others
   D. none of the above

11. What is one method used to reduce the amount of bruising experienced by patients undergoing a segmental facelift, according to Daniel Morello, MD, a plastic surgeon?
   A. tissue glue
   B. less anesthesia
   C. new post-op pain medications
   D. fewer dressings

12. What percentage of study participants utilize a medical event reporting system of some type, according to the Accreditation Association for Ambulatory Health Care's Institute for Quality Improvement's *Medical Event Reporting Special Report*?
   A. 23%
   B. 33%
   C. 68%
   D. 89%

BIOTERRORISM WATCH

Preparing for and responding to biological, chemical and nuclear disasters

Anthrax aftermath: Adverse drug reactions, vaccine controversy undercut CDC extended treatment offer

Some 8,000 people say thanks but no thanks

Despite the lingering possibility of late-onset anthrax infection, more than 8,000 people potentially exposed in the bioterrorism attacks of 2001 have turned down offers of additional antibiotics and immunization with the controversial vaccine, *Bioterrorism Watch* has learned.

Faced with insufficient data to truly assess the risk, the Centers for Disease Control and Prevention (CDC) in Atlanta offered the additional measures but fell short of actually recommending them.

Additional treatment offered as an 'option'

Operating on a thin margin of data about anthrax exposures, incubation periods, and subsequent infections, the CDC concluded it couldn't make a formal recommendation. The additional antibiotics and vaccine were made available as "options" to those exposed.

"The feeling was that this was the best thing we could do for people, and at least, leave it up to them to make a decision," says **Ian Williams**, PhD, medical epidemiologist in the CDC national center for infectious diseases. "We don't know what the answer is, but these are the options. We were really caught between a rock and a hard place on this one."

The 10,000 people potentially were exposed to anthrax in Connecticut, Florida, New Jersey, New York City, and Washington, DC.

They were all originally recommended to take at least 60 days of post-exposure antibiotic prophylaxis, but emerging data suggest that there has been a surprising lack of compliance.

In some preliminary surveys, fewer than half of those exposed were fully adhering to their original 60-day regimen. The CDC now has undertaken a telephone survey of all 10,000 people to identify adverse reactions and other reasons for the lack of adherence. **(See related story, p. 3.)**

The vaccine and additional antibiotic options were brought into play in part because the CDC knew it had large numbers of people who had not completed the original 60-day regimen. But the offer of additional care may have been undermined to some degree by prior adverse antibiotic reactions and fear of an anthrax vaccine that has been mired in controversy for years. Then again, many of those exposed may have felt they were no longer at risk and if their status changed, they would consult a physician.

Anthrax alive at 100 days

Though no known cases of anthrax have developed in any of the individuals who were prescribed the 60-day antibiotic course, the CDC also was aware of some disturbing data in animal studies. Traces of live anthrax spores have been detected in test animals' lungs up to 100 days following exposure, raising the theoretical possibility that the spores remaining still could

This supplement was written by Gary Evans, editor of *Hospital Infection Control*. Telephone: (706) 742-2515. E-mail: gary.evans@ahcpub.com.

cause disease. In that regard, one of the additional options offered to the exposed people was to take antibiotics for another 40 days (bringing total therapy time out to 100 days).

The other option was to take the additional drug regimen and also be vaccinated against anthrax. The latter option included three doses of anthrax vaccine over a four-week period, but antibiotics still had to be taken as the vaccine took effect.

The vaccine was not designed for post-exposure prophylaxis, but the theory is that it may provide additional protection by inducing an immune response to anthrax.

"People were unclear what the upper limit [for the onset of infection] was," Williams says. "That is what really drove both the vaccine and the antibiotic [offer]. We thought that 40 additional days to make 100 days looked sufficient based on our scant data. The vaccine was added because, is 100 days enough? I can't tell you absolutely for sure that it is enough."

Thousands took their chances

Most people were willing to take their chances that late onset anthrax will not occur.

Of the exposed cohort of some 10,000 people, 1,547 elected to receive more antibiotics after their 60-day regimen. Another 192 opted to be immunized with the anthrax vaccine and take additional antibiotics while the series of shots is given. Are the other 8,000-plus people at any real risk?

"Our feeling is that there shouldn't be any late cases of anthrax, based on what we know," Williams says.

"But that very well might be dose-dependent. We can't quantify the dose. If you go back and look at the animal studies that were done, they were actually done with probably lower doses than we have seen in the [U.S. Senate] Hart office building. But based on the data we can draw from animal models, it looks like there shouldn't be late onset cases," he explains.

If such an event occurred, the disease presumably still could be treated — provided the person seeks medical care. Still, making assumptions about anthrax can be tricky.

The CDC has been on a steep learning curve throughout the bioterrorism attack, with officials caught off guard by the ability of anthrax to disperse and spread during mail handling.

In addition, the ability to predict risk of infection in an exposed individual remains elusive, said **Julie Gerberding**, MD, director of the CDC division of healthcare quality improvement.

"We know that the exposure dose probably varies depending on how close you are to the source when it's released and how long you are in the [area] of release," Gerberding reported at a recent CDC meeting on post-exposure prophylaxis for anthrax.

> *"This is not an experiment to help us later. We don't have a control group. All we are doing is using the best science we have, which suggests that this is best way to give protection to people."*

"[But] despite our capacity to think about populations, we cannot accurately identify individual exposure, and we cannot accurately quantify individual risk," she explained.

Faced with that conundrum, the CDC put the same options on the table for all 10,000 people potentially exposed.

"The risk was probably different in different places," Williams says. "If you look at Capitol Hill, the concentration of anthrax released was probably much higher than say, Connecticut, where a letter just went through a post office. But that's group risk. Individual risk is different. [We] can't tell you exactly what your risk is. We'll give you the best available data, but you are going to have to make that decision."

Of the 190 people receiving anthrax vaccine, 80 had some political connection in Washington, DC, and 44 were postal workers in that city. Another 49 people in New Jersey were vaccinated; and the remainder were in New York City (12), Florida (four), and Connecticut (three). Of those who chose additional antibiotics only, 849 were in Washington, DC; 354 in New Jersey; 248 in New York City; 55 in Connecticut; and 41 in Florida.

A mixed message?

The CDC has drawn criticism for its approach, particularly for making a controversial vaccine available but leaving the immunization decision up to patients and their providers.

"It would have been much better if they had come out and said, 'Yes, we think in order to have as much protection as possible against the potential of developing disease, you should receive both

Side effects undermine anthrax drug adherence

More than half dropped drugs by 30 days

Amid the hype and horror of the 2001 anthrax attacks, it seemed a given that the people potentially exposed would be particularly diligent in completing their antibiotic regimens. But as time passed — and side effects continued or worsened for some — compliance fell off dramatically for many of the 10,000 people put on 60-day regimens for ciprofloxacin and doxycycline, according to preliminary data from the Centers for Disease Control and Prevention (CDC).

None of the people who started on antibiotics have developed anthrax, but the CDC wants some answers on the lack of adherence. To that end, the CDC is conducting a telephone survey project that will attempt to reach all 10,000 people for whom post-exposure antibiotic prophylaxis was recommended. The interviews began in late January and are expected to continue through March 2002. The people were potentially exposed to anthrax in Connecticut, Florida, New Jersey, New York City, and Washington, DC.

"We are making sure we get in touch with all of these people to evaluate how they did in terms of taking antibiotics," says **Ian Williams**, PhD, medical epidemiologist in the CDC national center for infectious diseases. "We have data showing adherence definitely wasn't as high as people, prior to this outbreak, would have thought it would be."

The CDC attempted a variety of methods to assess compliance prior to the phone survey, including tracking individuals who did not return to refill their medication. Other methods include giving a sample of those exposed questionnaires that were self-administered, given by a nurse, or by telephone, according to **Nancy Rosenstein**, MD, medical epidemiologist in the CDC national center for infectious diseases.

"In general, adherence has declined over the course of the [first] 30 days to as low as 45%," Rosenstein said at a recent CDC meeting on post-exposure prophylaxis for anthrax.

Some groups were more compliant than others. For example, employees who worked in the American Media Building in Boca Raton, FL, were closer to 70% compliant, she said. But only 45% compliance at 30 days was also found in a "high risk group" of mail handlers in New York City, she added.

"Adherence experts tell me that when we actually count pills, the self-reporting numbers probably overestimate real adherence by as much as 20%," Rosenstein said. "So the real estimates of adherence — taking the antibiotics every day — are obviously substantially lower."

In terms of self-reported adverse events, within two weeks of taking ciprofloxacin, 19% were reporting severe nausea, vomiting, abdominal pain, and diarrhea. At 30-day surveys, many people had switched to doxycycline, but self-reported adverse events increased to 45%.

Again, the predominant symptoms were severe nausea, vomiting, diarrhea, and abdominal pain. About 12% of the people reporting adverse events required additional follow-up with medical chart review and physician interviews, she said.

"I don't want to in any way minimize the impact of these symptoms on people's daily life, but when we actually investigated further, we were unable to identify anybody who actually required hospitalization or an emergency room visit for their adverse events," Rosenstein said.

Thus, based on Food and Drug Administration criteria, no serious adverse events have been linked to taking antibiotics for anthrax exposure. A more complete picture of the adherence problems should emerge from the CDC telephone survey of all recipients. Preliminary surveys have found that 6% to 12% of respondents reported at least missing some of their doses because of the side effects, she said. ■

antibiotic and vaccine,'" says **Phillip Brachman**, MD, a professor in the Rollins School of Public Health at Emory University in Atlanta.

The vaccine has been embroiled in a safety dispute since the military began a mandatory immunization policy several years ago, with some veterans saying it made them sick and others refusing to take it.

"A number of [the exposed people] undoubtedly read about the problems some of the military

folks claimed they had experienced after having the vaccine," Brachman says.

"They associated their problem with the vaccine. Remember, that those people in the military who have made those complaints are a very small number, considering the total number of doses given," he adds. "So there are very few voices creating a lot of concern."

Brachman did what remains the only clinical trail on the safety and efficacy of an anthrax vaccine precursor when he worked for the CDC in the 1950s.

In a study of goat's-wool workers — which was once an occupational risk group for anthrax in the United States — he found the vaccine safe and effective. He reported few side effects to vaccination and an efficacy rate of 92.5%.[1] The vaccine used in the study was a protective-antigen variety similar to the current vaccine. However, the manufacturing process has since changed and a different strain of anthrax is now used.

"There have been a few minor changes, and some people make a lot more out of it then it really should be," he says. "A different strain is being used to prepare the vaccine, but that should make no difference because the organism is not in the vaccine. It is the protein product from the organism."

Dearth of data

An Institute of Medicine committee that convened to look at the current anthrax vaccine cited a dearth of data in concluding: "The published studies have found transient local and systemic effects (primarily erythema, edema, or induration) of the anthrax vaccine.

"There have been no studies of the anthrax vaccine in which the long-term health outcomes have been systematically evaluated with active surveillance. . . . The committee concludes that in the peer-reviewed literature, there is inadequate/insufficient evidence to determine whether an association does or does not exist between anthrax vaccination and long-term adverse health outcomes. . . . To date, published studies have reported no significant adverse effects of the vaccine, but the literature is limited to a few short-term studies,"[2] the committee said.

For its part, the CDC would not have made the vaccine an option for those exposed if it had any doubts about its safety, Williams says.

"It seems to be a very safe, efficacious vaccine," he says. "[The] CDC reviewed the data with the military, which has the most experience with this."

Still, some people may have been confused because the CDC did not roll out the vaccine right after the exposures occurred. Thus, the response was somewhat tepid to a vaccine "add-on" option 60 days after the potential exposure. One problem is that the U.S. military, which controls the dispersal of anthrax vaccine, did not release any stocks in the immediate aftermath of the bioterror attacks, he says.

"One of the lessons we have learned is that if the vaccine had been available when this first started, I think the post-exposure prophylaxis would have been approached much differently," Williams says.

With the military now more amicable on the issue, if a bioterrorist strikes again with anthrax, the vaccine could play an important role from the onset, he emphasizes.

"If this should happen again, the vaccine might be used closer to day zero," Williams says. "After a series of doses over a month or so, most people will develop an antibody response, so it would obviate the need for additional antibiotics. It will be used in more of a true post-exposure fashion."

Those who have been recently vaccinated will be followed over time. Indeed, the CDC is discussing following the whole cohort of 10,000 people. It is an interesting group, having been potentially exposed to anthrax, taken prolonged antibiotic regimens, and in some cases, received a vaccine whose long-term safety is in some question.

Another curious fact — as with other post-exposure regimens for diseases — is that no one will ever know if the additional measures taken by 1,739 of these people actually prevent a late-onset anthrax infection.

"This is not an experiment to help us later," Brachman says. "We don't have a control group. All we are doing is using the best science we have, which suggests that this is best way to give protection to people."

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