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INSIDE

MAY 2002

VOL. 26, NO. 5 (pages 61-72)

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Are you using sterile equipment on your patients? How can you be sure?

2 recent events raise questions about infections

Two bronchoscopy patients die of pneumonia after a scope, which was later recalled, was used on them at The Johns Hopkins Hospital in Baltimore. Johns Hopkins alerted 415 patients that they might have received a life-threatening lung infection from the devices. At press time, fewer than 10 of those patients have tested positive for the pseudomonas bacteria. Hospital officials say the device may be at fault. Pseudomonas bacteria can cause pneumonia in patients already suffering from critical illnesses.

The recall notice was mailed to a loading dock across the street from the department using the bronchoscope, and it took at least a month to reach the physicians. No one knows how many of the recalled scopes are being used every day because many hospitals are unaware of the potential danger for infection from the recalled bronchoscope.

In early March, officials with Melville, NY-based Olympus America, which manufactured the bronchoscope, said that fewer than 40% of the recalled scopes had been sent back to the company for inspection and

EXECUTIVE SUMMARY

Melville, NY-based Olympus America recalled bronchoscopes after determining that a loose port was trapping bacteria. Physicians at The Johns Hopkins Hospital in Baltimore didn't initially receive the notice. Two patients died of pneumonia, and nonsterile bronchoscopes may have caused the deaths. A&A of Alpharetta, GA, has shipped nonsterile medical equipment, which was labeled as sterile, since 1999, according to reports. To avoid problems:

- Monitor disease rates, and investigate any significant increases. Involve infection control or contact your local health department.
- Stay updated on recalls with the notification services offered by ECRI or the Food and Drug Administration.
- Designate one area, such as risk management, infection control, or patient safety, to receive all recall notices. Use stamps or initials to ensure proper distribution.

List of Known A&A Medical OB/GYN & Surgical Devices*

- Curette (flexible and rigid, all sizes)
- Collection set tubing
- Aspiration sets
- Laminaria
- IUD removal instruments
- Mucus samplers
- Biopsy pipettes/endometrial sampling sets
- Uterine sounds
- Pratt dilator set
- Ovum forceps
- Tenaculum forceps
- Needle extenders and guide
- Fetal bladder drain
- Fetal blood sampler
- Harvesting pump and accessories
- Loop/ball electrodes
- Laparoscopy accessories

* This is a partial list; as known at the time of the alert.

Source: Food and Drug Administration's Center for Devices and Radiological Health, Rockville, MD.

repair. The company sent second notices to institutions that did not answer the first notice. Is your facility one of them?

Before the recall was discovered, Johns Hopkins had recognized the rise in infection rates and determined that the bronchoscope was the probable cause. Would your facility recognize such an increase and be able to determine why?

To answer these questions, *Same-Day Surgery* analyzes what happened and offers suggestions from experts in the field. Here's a summary:

On Nov. 30, 2001, Olympus America recalled 15 models of bronchoscopes because a loose port was trapping bacteria in a spot that was not reached during the usual disinfecting process. Although the Johns Hopkins physicians didn't immediately receive the recall notice, they noticed a two- to threefold increase in the number of patients with pseudomonas in December. By early February, they determined the devices were the probable cause. Johns Hopkins officials mailed certified letters in which they asked patients to call their doctors if they experienced symptoms such as fever, coughing, phlegm, or shortness of breath. *(Editor's note: To see the letter, go to www.hopkinsmedicine.org/press/2002/MARCH/patientletter.htm.)* Physicians also called all of their bronchoscopy patients since June 1, 2001, a month before the period when the infection rate increased. They cancelled all elective bronchoscopies for about two weeks, and the defective scopes were removed. Designated telephone lines were set up so that the patients could arrange for free appointments to be evaluated or to obtain more information.

Johns Hopkins physicians say that even though patients may have been exposed to the bacteria during the procedures, not all will become infected. Also, because some of these patients have illnesses such as cystic fibrosis, HIV/AIDS, lung transplants, and cancer, some probably carried the bacteria before they came to the facility for bronchoscopies.

John Hopkins' press releases indicated that they believe the cause of the infection problem may be related to the loose port, says **Wally Pellerite**, assistant to the director of the Food and Drug Administration's (FDA's) Office of Compliance in Rockville, MD. "But there is not direct evidence to establish that, as far as information we have," he says. "There's an ongoing investigation, and more work needs to be done."

Pellerite says he isn't aware of other hospitals that have reported "spikes" in infection rates that may be related to the recalled bronchoscope or any other reason. "I have a lot of people, such as risk managers, contacting me about whether they should be contacting patients who have had infections," he says. "The bottom line is that hospitals need to assess their own problems and make independent determinations."

Shortly after the Olympus America recall was announced, the FDA released an alert saying A&A of Alpharetta, GA, may have shipped unsterilized obstetrics and gynecological medical devices and labeled them as sterile or ethylene oxide processed. Some of the products may not have undergone any sterilization, which raises the threat of infection,

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Recalled Models and Modified Serial Numbers

Recalled models: BF-40, BF-P40, BF-IT40, BF-3C40, BF-XP40, BF-XT40, BF-240, BF-P240, BF-1T240, BF-6C240, BF-160, BF-P160, BF-1T160, BF-3C160, BF-XT160.

Beginning with and including the serial number listed next to each bronchoscope model, all of these scopes with higher serial numbers already have been modified with the corrective action and do not need to be returned: BF-P40, 1132479; BF-1T40, 1121288; BF-3C40, 1110611; BF-XP40, 1100458; BF-XT40, 1120321; BF-40, 1130472; BF-P160, 1100535; BF-XT160, 1100084; BF-160, 1111266; BF-3C160, 1100149; BF-1T160, 1110960; BF-P240, 1141022; BF-1T240, 1130880; BF-240, 1140791; and BF-6C240, 1110201.

Source: Olympus America, Melville, NY.

infertility, and miscarriage. The problem potentially affects products shipped since 1999. **(See list of products, p. 62.)**

Former company employees said that sterile and nonsterile devices had been shipped in the same batches. Agency inspectors who visited the company facilities found evidence that supported those allegations, an FDA official says.

The FDA has urged the company to recall these products. A list of distributors and the products they receive from A&A Medical is being placed on FDA's web site at www.fda.gov/cdrh/recalls/recall31402.html. The firm also does business under the name A&A Medical/Rocket USA and LifeQuest.

If you are using these products, immediately discontinue such use, the FDA advises. For more information, you can contact the FDA Center for Devices and Radiological Health at (800) 638-2041.

To avoid using medical equipment that may be nonsterile or recalled, consider these suggestions:

• **Make sure your infection control processes are in order.** Use infection control teams to monitor rates of diseases in your facilities, suggests **Daniel B. Jernigan**, MD, medical epidemiologist at the Centers for Disease Control and Prevention (CDC) in Atlanta. For hospitals, this team would include a hospital epidemiologist and infection control professionals. Having such a team and monitoring infections may be challenging for freestanding surgery centers, he acknowledges.

"Many may not have the resources or staff to have an involved infection control process," he says. However, all outpatient surgery providers can follow the guidelines outlined in the documents from the Healthcare Infection Control Practices Advisory Committee (HICPAC). These documents are available on the CDC web site (www.cdc.gov) by searching for "HICPAC."

When questions are raised concerning infection related to the use of any device, undertake an investigation, advises **William Schaffner**, MD, the chairman of preventive medicine and chairman of the Infection Control Committee at Vanderbilt University Medical Center in Nashville, TN.

"In my experience, to be quite frank, ambulatory surgery centers and the like do not have the expertise to do these type of investigations," Schaffner says. "They don't have the background, the training, the resources, etc." What's the answer? Contact infection control professionals, or call the local health department, he suggests.

Also, many surgery centers survey surgeons to ask about postoperative infections, so increases may show up in those surveys, sources say.

• **Use recall notification services.** Recall notification services are available through ECRI and the FDA.

Recall notices from manufacturer are not always correct, says **Eric Sacks**, Internet services manager at ECRI, a nonprofit health care technology research organization in Plymouth Meeting, PA. Sacks points to the original recall notice from Olympus America, which didn't specify which models and serial numbers were affected. **(For information on subscribing to the ECRI or FDA recall notification service, see resource box, p. 64.)**

• **Clarify interfacility communication over recalls.** Events such as one at Johns Hopkins where the recall notice went to the wrong area should be a "wake-up call" for surgery providers, experts say.

"Large institutions, my own included, are often decentralized," Schaffner says. "If a recall of this type is received by [staff] within large institutions, they probably shouldn't deal with that just locally, within their own shop. They need to bring it to the attention of the infection control program."

Clearly communicate who within your facility should receive recall notices, Sacks advises. This person could be the risk manager or the patient safety officer, he says.

"The fact that manufacturers send recall notices to the wrong location or nonexistent

SOURCES AND RESOURCES

For more information, contact:
- **David L. Lewis**, PhD, Research Microbiologist, Environmental Protection Agency's National Exposure Research Laboratory, Athens, GA. E-mail: lewisdavel@aol.com.
- **Wally Pellerite**, Assistant to the Director of the Office of Compliance, Food and Drug Administration, 2098 Gaither Road, Rockville, MD 20850. Telephone: (301) 594-4692, ext. 159. Fax: (301) 594-4610. E-mail: wap@cdrh.fda.gov.
- **Eric Sacks**, Internet Services Manager, ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462-1298. Telephone: (610) 825-6000, ext. 5317. Fax: (610) 834-1275. E-mail: esacks@ecri.org.

For more information on A&A, contact:
- **Food and Drug Administration's (FDA) Center for Devices and Radiological Health**, Rockville, MD. Telephone: (800) 638-2041. Additional information also can be found on the FDA's MedWatch web site at www.fda.gov/bbs/topics/NEWS/2002/NEW00799.html.

For additional information on the Olympus America recall, you can access the firm's web site at: www.olympusamerica.com/innards/h_endoscopy.asp?s=11&p=15. Or contact:
- **Laura Storms-Tyler**, Director, Regulatory Affairs and Quality Assurance, Olympus America, Two Corporate Center Drive, Melville, NY 11747-3157. Telephone: (631) 844-5688.

Health Devices Alerts is a database of medical equipment-related problems, hazards, and recalls. The print version of *Health Devices Alerts* includes Action Items, which is published every Friday. Action Items contains reports of ongoing medical device problems, hazards, and recalls that have been verified by ECRI and has specific recommendations for quick follow-up action to prevent harm. A subscription includes *Hazard Bulletins* when there are urgent reports of life-threatening or injury-causing incidents. The cost is $3,045 per year. For ordering information, contact:
- **ECRI**, 5200 Butler Pike, Plymouth Meeting, PA 19462-1298. Telephone: (610) 825-6000, ext. 5547. Fax: (610) 834-1275. E-mail: info@ecri.org.

- FDA medical device postmarket safety notifications can be found at www.fda.gov/cdrh/safety.html. Postmarket safety notifications also can be obtained through e-mail on the day they are released by subscribing to a list server. You may subscribe at list.nih.gov/archives/dev-alert.html.
- ***The FDA Enforcement Report*** is published weekly and contains information on actions such as recalls, medical device notification, and safety alerts. Web: www.fda.gov/opacom/Enforce.html.
- With the FDA's e-mail lists, MedWatch, you can receive immediate notification of safety alerts on drugs, medical devices, and dietary supplements regulated by the FDA. Subscribe at www.fda.gov/medwatch/index.html. To receive immediate e-mail notification of new material on the MedWatch web site, send an e-mail to medwatch@listmanager.fda.gov. Enter subscribe in the subject field. You may leave the body of the message blank. To remove your name from the list, send an e-mail to the above address and enter "unsubscribe" in the subject field.

personnel will persist," Sacks says.

Manufacturers frequently don't know who to send recall notifications to, so they'll send them to a standard list of titles, such as chief executive officer or risk manager, or they'll send them to the department that ordered the device, such as the purchasing department.

You should have procedures to ensure all the appropriate people have been informed, Pellerite advises. The notice can be stamped or initialed, he says.

Jernigan adds, "The take-home message is that institutions should have guidance for staff on which scopes are used for which particular procedure, who is responsible for marking sure repairs are made, and any information sent to facility is centralized to be sure not to miss anything." ■

Video capsule gives views that endoscopy can't

Diagnosis of small bowel lesions enhanced

The crew of the miniaturized submarine, *Proteus*, faced dire threats such as monstrous white blood cells and intruder-eating antibodies as they traveled into Professor Benes' brain to destroy a life-threatening blood clot in the 1966 novel, *Fantastic Voyage.*

While miniaturization that enables physicians to see inside a person's body existed only in the imagination of authors in 1966, it is a reality in 2002. A capsule no larger than a vitamin tablet,

EXECUTIVE SUMMARY

A miniature camera enclosed within a capsule no larger than a vitamin tablet gives gastroenterologists a chance to see parts of the small intestine that traditional endoscopy can't reach. A specialized computer station, a portable data recorder, and the capsule provide a look at the entire small bowel in a diagnostic test that has minimal impact on a patient's day.

- No anesthesia or pain medication is needed.
- The video capsule is easily excreted by the patient one to three days after it's swallowed.
- The test is not a replacement for traditional endoscopy because it doesn't allow biopsy and it can't be directed to look at specific areas.

which contains a camera, light source, battery, and radio transmitter, now enables gastroenterologists to see the entire small intestine and diagnose previously unseen intestinal disorders. Manufactured by Given Imaging in Yoqneam, Israel, the M2A video capsule was approved last year by the Food and Drug Administration (FDA) for marketing in the United States.

"Traditional endoscopy enables us to see 2-3 feet into the small intestine, but that leaves about 15 feet that remains unexplored," says **David R. Cave**, MD, PhD, chief of gastroenterology at St. Elizabeth Medical Center in Brighton, MA. "The video capsule gives us a nonsurgical option to look for the cause of obscure gastrointestinal bleeding when traditional diagnostic tests don't show anything."

Patients come into the same-day surgery facility early in the morning to get "hooked up," take the pill, and leave, says **Kenneth F. Binmoeller**, MD, director of interventional endoscopy services at California Pacific Medical Center in San Francisco. "They can go about their regular day, and they can eat two hours after the video capsule is swallowed," Binmoeller says. Patient preparation is similar to preparation for a regular endoscopy or upper GI exam, with the patient coming in NPO prior to the hookup, he says. The hookup involves wearing a data recorder on a belt and small antenna-like aerials, similar to electrocardiogram leads that are placed on the patient's body to transmit the signals from the video capsule's radio transmitter to the data recorder.

"The video capsule's camera takes two images per second as it travels through the gastrointestinal system, transmits the image to the aerials, which then send the image to the data recorder," Binmoeller explains. When the patient returns later in the afternoon, the aerials are removed and the information from the data recorder is downloaded to a computer. The patient excretes the pill eight to 72 hours after being swallowed, he adds.

While the software can be loaded on any computer, Binmoeller's center maintains a computer that is dedicated to this one purpose. "We want to reduce any risk of picking up viruses or other problems that could distort the data," he explains.

Cost for the computer workstation is $20,000 for hardware, including a data recorder, and software, and each disposable video capsule is $450.[1]

There is no additional staff expense, Binmoeller says. Because patients come into the same-day surgery area early, recovery room nurses handle the hookup since they don't have patients in the area, he says. Patients return late in the day when other staff members are available to unhook the aerials and the data recorder, he adds. Although the hookup is simple and can be done by any staff member, Binmoeller prefers that a nurse handle it in order to answer patient's questions about the procedure and how it works. "The images should be read by a gastroenterologist," he adds.

Credentialing for physicians has not yet been addressed, Cave says. "It is most reasonable to expect a gastroenterologist to prescribe the video capsule and read the results because a gastroenterologist who regularly performs endoscopy is the person most familiar with the anatomy of the small intestine," he adds.

The procedure generally is not reimbursed by

SOURCES

For more information about the clinical aspects of the M2A video capsule, contact:

- **Kenneth F. Binmoeller**, MD, Director of Interventional Endoscopy Service, California Pacific Medical Center, 2340 Clay St., Second Floor, San Francisco, CA 94115. E-mail: kbinmoeller@endovision.com.
- **David R. Cave**, MD, PhD, Chief of Gastroenterology, St. Elizabeth Medical Center, 736 Cambridge St., Brighton, MA 02135. Telephone: (617) 782-5218. E-mail: drcave@pol.net.

For information about ordering equipment and the video capsule, contact:

- **Given Imaging**, Oakbrook Technology Center, 5555 Oakbrook Parkway, No. 355, Norcross, GA 30093. Telephone: (770) 662-0870. Fax: (770) 662-0510. Web: www.givenimaging.com.

managed care, but companies are reviewing the procedure on a case-by-case basis, Binmoeller says. Although the video capsule gives gastroenterologists a look at previously unseen areas without the need for surgery, it will not replace traditional endoscopy, he says. "The capsule travels too fast through the esophagus to give us a good look, and it only gets pictures of small areas of the stomach because of the size and shape of the organ," he says. "We also don't get pictures of the large intestine because the battery doesn't last long enough."

Another disadvantage is that there is no way to control the direction of the capsule, so a physician can't go back, turn the capsule, and look more closely at a certain area, Binmoeller adds.

New technology that does enable the surgeon to "drive" the capsule as it travels through the gastrointestinal tract is in the testing phase, he adds. With the use of a joystick-like device, the surgeon will be able to turn the capsule toward certain areas and in a particular direction, he explains. This will increase the diagnostic capabilities because it will give the surgeon a chance to focus on areas of concern, he adds.

Even with the future capability of "driving" the video capsule, this technology will not give the surgeon the capability to perform any type of biopsy or treatment, Binmoeller points out.

While the video capsule doesn't allow interventional treatment at the time of the study, it does identify the area that needs to be targeted during surgery or follow-up endoscopy, Cave says. "In 60% of my patients who underwent studies with the video capsule, we were able to clearly define the areas of concern," he says.

Overall, Binmoeller and Cave are enthusiastic about the possibilities the video capsule represent.

"If used appropriately," Binmoeller says, "in conjunction with traditional diagnostic methods, it provides a painless, anesthesia-free diagnostic test that can be used for patients with hard-to-diagnose symptoms."

Reference

1. FDA OKs swallowed camera-pill that looks for bowel problems. *MSN Health*, Nov. 14, 2001. Web: content.health.msn.com/content/article/1728.85347. ■

Same-Day Surgery Manager

'You're not the boss of me' — or are you?

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

The title of this column is a lyric in the theme song of the popular TV sitcom titled *Malcolm in the Middle.* Does it bring back memories?

The fact is, it's starting to become a real issue in the operating room. Who really is the boss? Who is in charge? Who is the final decision maker? Some of you know — and others think you know — but in reality, most don't. The answer to all these questions and many more can be found in that little known document that all of us should be required to read and comprehend, but we don't. I did a spot check of 25 staff members over the past month, and 23 had never heard of it. The document is the medical staff bylaws. In it, you will find another section called rules and regulations of the medical staff.

You need to read it. I'm sure most of you will be surprised by its contents. The good news is that every licensed and certified surgical facility has one (required), and the bad news is that 80% probably are outdated. All credentialed surgeons are required to read it, understand it, abide by it, and sign it as a condition of receiving privileges to work in your facility. But do they?

If you tend to be the bossy type, you will love the reading because you can walk around and tell people what to do and have some clout to back you up. Of course, if you are that type, most people probably don't like you to begin with and won't care what you say. But its intention is sound. I've taken some situations that have come up recently to share with you; you decide what is the proper course of action. You might want to consider some of the questions a topic at a staff meeting.

1. It is late in the day, and one of your surgeons calls you and says he has a patient in his office who drove a very long way to see him and he would like to do a simple, quick procedure right now. (Yeah, I know. It's probably not "simple" and certainly not "quick.") What do you do? The patient is going to be severely inconvenienced (or so you are told and have to believe for the sake

of this example) by driving back home and then coming back two days from now to get on the schedule. (Oh, I forgot to mention: It's snowing.) The surgeon tells you if you don't put the patient on, he will take the case down the street to another facility that understands the needs of the patient, or he will change the case to an "urgent" case and do it anyway.

2. A staff member walks into your office and tells you he is being sexually harassed by your favorite surgeon. Where do you go, and whom do you call? Or do you do anything? Should you just document the complaint and send the person back into the room with the surgeon — potentially in harm's way? Do you know what to do?

3. A staff member in anesthesia passes a patient in the holding area who appears to be in "distress." She discovers the patient is a "local only" case and thinks the patient should be medically evaluated before going into the operation room. She locates and discusses the situation with the patient's surgeon, who tells her that the patient is fine. He is doing the patient under local only, he is not using the services of anesthesia, he is doing the procedure anyway, and she should mind her "own business." *("You're not the boss of me now. . . .")* The discussion turns into a shouting match. Who is right? Are you sure?

4. An anesthesiologist on your surgical staff (but not on the staff of anesthesia) does pain management cases. The case is over, and the patient is in the recovery room waiting for a ride home. The "surgeon" (anesthesiologist) used local sedation. Your medical director refuses to stay with the patient and says, "it is the responsibility of the anesthesiologist who did the case" to stay with the patient, not your anesthesia staff. Really? What do you think?

5. A plastic surgery patient shows up 30 minutes before her case (on time) and is told that the cash up front required by the center is $1,800. She becomes indignant and tells your front desk staff that her surgeon (your busiest plastic surgeon) told her that she could pay for the procedure in three payments and that she was not going to pay anything now. Your staff member approaches the surgeon and explains the situation to him. He freaks out and confirms the patient's story and is yelling to get her processed and into the operating room. Sitting down in your office with an ice bag on your head, you are fighting a killer of a headache when your front desk calls you in a panic. What do you do?

I'm sad to say these are all real examples.

In the next issue, I will share how your peers handled these situation — rightly or wrongly — and what happened. I suggest you read your medical staff bylaws in the meantime.

(Editor's note: Earnhart & Associates has free surgery center benchmarks. Visit this web page: www.earnhart.com/benchmarks.htm. Earnhart and 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.) ■

Program reduces need for blood transfusions

Patient safety, cost, preference drive needs

With only 5% of the U.S. population serving as blood donors,[1] it is easy to see that blood is a limited resource. There is no guarantee that donations will increase to keep up with the demand that is required by older patients who undergo complex surgical procedures that result in large volume blood loss.[2] Although great strides have been made to ensure the safety of the blood supply, it is unlikely that the risk of infection from transfusions will be completely eliminated.[3]

The limited supply, as well as concerns about safety, cost, and patient preference, has made the development of a bloodless surgery program an important move for many same-day surgery programs.

"The term 'bloodless' is a misnomer when you are talking about surgery because most surgeries mean the loss of some blood," says **Sherri Ozawa**, RN, director of The New Jersey Institute for the Advancement of Bloodless Medicine and Surgery at Englewood Hospital and Medical Center in Englewood. "A bloodless medicine or surgery program has a focus on minimizing exposure of patients to allogenic blood transfusions." Ozawa's facility became interested in a bloodless surgery program because of the large Jehovah's Witness population served by the hospital and its physicians. The religious tenets of Jehovah's Witness do not allow for blood transfusions or acceptance of any other type of blood product, she says.

"There is no magic formula to reduce the number of transfusions, but we have discovered, out of necessity for our patients who refuse transfusions

EXECUTIVE SUMMARY

A limited blood supply, concerns about the safety of blood transfusions, cost, and patients' religious beliefs are reasons for managers to evaluate a blood management, or transfusion-free, program. The opportunity to avoid blood products during and after surgery may attract patients and keep procedures in same-day surgery.

- Treating anemia three to four weeks prior to surgery with erythropoietics and intravenous iron decreases the need for transfusions.
- Electrosurgical and harmonic scalpels, lasers, and laparoscopic equipment minimize blood loss during surgery.
- Hemodilation, volume expanders, and cell washers reduce the need in cases that do result in blood loss.

of any kind, how to minimize the need for blood," she says. The first step is to boost the effectiveness of the patient's own blood, Ozawa says. "The key is to start weeks ahead of a procedure, and that is usually possible with same-day surgery procedures," she points out.

By administering erythropoietics to promote increased red blood cell production before surgery, a patient can tolerate blood loss without a need for transfusions, Ozawa explains.

At Good Samaritan Regional Medical Center in Phoenix, patients of the Transfusion-Free Medicine and Surgery Program visit the same-day surgery center three to four weeks prior to surgery to be tested for anemia, says **Richard Melseth**, director of the program. "We begin treatment of anemia with erythropoietics, and we often administer intravenous iron," Melseth says. Patients return to the center for follow-up visits as needed to monitor hemoglobin levels prior to the surgery, he adds.

The Good Samaritan and Englewood programs are patient-driven. "Any patient can request a physician who participates in the transfusion-free program," Melseth says. When a patient calls his program, Melseth and his staff refer to a list of physicians that includes internists, family practitioners, and specialists. Once the patient sets up the first appointment with the physician, the patient notifies Melseth's department.

"At that point, we review the procedures, options, and types of medications the physician might prescribe with the patient. We serve as the patient education component of the process," he explains.

At Englewood, patients learn about techniques that will be used to minimize blood loss during surgery and how the operating room team will replace lost blood with other fluids, Ozawa says.

Patients can choose no transfusion in any event or transfusion only in a life-threatening situation, Melseth says. Patients sign the appropriate forms and wear wristbands that indicate no blood or restricted blood use, he explains.

Patients sign release-of-liability forms that indicate their refusal of transfusions at any time during their care, Ozawa says. "Our experience is that patients and their families don't litigate if we've respected their right to refuse transfusions," she says. The hospital has not experienced any increase in claims or any change in their insurance coverage, she adds.

While many same-day surgery programs do not handle procedures with significant blood loss, there are some procedures such as orthopedics and gynecological procedures that carry the risk of unexpected blood loss, Melseth says. "Also, with gynecological procedures, you are working with female patients who are often anemic or borderline anemic," he adds. These patients benefit from preoperative treatment of anemia because then they go into surgery with a greater capability to sustain blood loss without transfusion, Melseth points out.

A bloodless medicine and surgery program can benefit a same-day surgery program because it might keep more procedures in the SDS program, he says. "In our facility, a surgeon will schedule a typical same-day procedure in the inpatient operating room if he or she anticipates a potential need for transfusion," Melseth says. If these patients are evaluated and treated for anemia or other blood-related issues prior to surgery, they can remain same-day surgery patients, he adds.

"Many same-day surgery programs already use techniques to reduce blood loss during surgery," Ozawa points out. "Endoscopic and laparoscopic surgery, electrosurgical and harmonic scalpels, and laser surgical techniques all help create a bloodless field of surgery," she says.

For other cases that present a potential for blood loss, hemodilation, volume expanders, and cell washers can be used, says Ozawa who points out that these are techniques more likely to be used in an inpatient surgery program.

Setting up a transfusion-free program requires time and the support of key medical personnel, Melseth says. Finding physician-champions who are top-rate physicians respected for their skills by other surgeons is important, he suggests.

Educating physicians, staff members, and administrative personnel is a lengthy process,

SOURCES AND RESOURCES

For more information about their experience with bloodless surgery programs, contact:

- **Sherri Ozawa**, RN, Director, The New Jersey Institute for the Advancement of Bloodless Medicine and Surgery, Englewood Hospital and Medical Center, 350 Engle St., Englewood, NJ 07631. Telephone: (888) 766-2566 or (201) 894-3935. Fax: (201) 541-2268. E-mail: sherri.ozawa@ehmc.com.
- **Richard Melseth**, Director, Transfusion-Free Medicine and Surgery Center, Good Samaritan Regional Medical Center, 1111 E. McDowell Road, Phoenix, AZ 85006. Telephone: (877) 815-3114 or (602) 239-6070. E-mail: Richard.melseth@bannerhealth.com.

The following offer information about the development of bloodless medicine and surgery programs:

- **The Society for the Advancement of Blood Management**, 350 Engle St., Englewood, NJ 07631. Telephone: (866) 894-3916 or (201) 894-3916. Fax: (201) 894-0585. Web: www.sabm.org. The web site contains a variety of articles related to blood management, news updates on new techniques and products, and information on educational meetings.
- **The Network for Advancement of Transfusion Alternatives**, Paris. Web: www.nataonline.com. This web site provides links to presentations and articles related to blood management as well as information about new products, educational meetings, and surgical and anesthesia techniques.
- **www.bloodlessprograms.com.** This web site provides a list of hospitals that offer bloodless programs as well as links to bloodless program publications distributed by the web site's sponsor, BloodlessMedia, 1018 E. Magill Ave., Fresno, CA 93710. Telephone: (559) 432-5259.

Ozawa says. "It took us at least one year to develop the program and have the support we needed to get started." Not only did Ozawa point out the patient safety issues related to blood transfusions, she also talked about the cost. "Donated blood and all the costs related to getting it to a patient costs $1,003 to $1,043 per patient," she says.[4] "This doesn't take into account the costs when a patient experiences complications related to the transfusion," she adds.

There are resources to help same-day surgery managers who want to develop a bloodless medicine and surgery program, Melseth says. Professional associations, books, and articles are available to offer tips on rationale and support for the program, and development of the policies and procedures needed, he adds. **(See resource box, at left.)**

Be patient, Melseth suggests. "You have to realize that you are asking physicians to change their behavior, and that takes time," he says. "You are also developing a customer-driven program that requires a lot of education for everyone."

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Changes proposed to HIPAA rules

Less paperwork and hassle predicted

Proposed changes to the Health Insurance Portability and Accountability Act (HIPAA) of 1996 will remove roadblocks to delivering good patient care and operating hospitals efficiently, says **Dick Davidson**, president of the Chicago-based

EXECUTIVE SUMMARY

Changes have been proposed to the Health Insurance Portability and Accountability Act of 1996:

- The proposal removes the consent requirement for treatment, payment, and health care operations.
- The proposal continues to cover oral communication and limits the use of personal health information to the "minimum necessary," but allows treatment-related conversations.
- The proposal eliminates the need for researchers to use multiple consent forms.
- Providers can use model business associate contract provisions. They have an additional year to change contracts.
- The proposal allows a single type of authorization form to obtain a patient's permission for a specific use or disclosure that otherwise would not be permitted.

American Hospital Association. Davidson was author of an editorial in the March 26 *USA Today.*

Under the changes, patients will continue to receive a comprehensive notice of their privacy rights in a 10-plus-page document, Davidson said, and patients will be asked to simply acknowledge that they received this notice. "We believe this approach will accomplish the same goal, and we're not alone," he wrote in the editorial.

The proposal retains patient rights but results in less paperwork, Davidson says.

"The result: better access to care and less paperwork for everyone," he says. "That's a goal patients and providers can all support."

The rule was published in the March 27 *Federal Register*. The American Hospital Association highlights these proposed changes:

• **Notice provisions are strengthened, and consent requirements are removed.** The proposal removes the consent requirement for treatment, payment, and health care operations. It strengthens requirements for providers to notify patients about their privacy rights and practices. Patients would be asked to acknowledge the privacy notice; if they don't acknowledge it, they still can be treated.

• **The "minimum necessary" rule is maintained, but allows treatment-related conversations.** The proposed changes continue to cover oral communication and limit the use of personal health information to the "minimum necessary." However, they make it clear that doctors could discuss a patient's treatment with other professionals involved in their care.

Providers are expected to take reasonable safeguard to protect personal health information. As long as they do that and follow the "minimum necessary" rule, then incidental disclosures, such as another patient hearing a small part of a conversation, would not be penalized. Improper disclosures would still violate the rule.

• **Providers follow state law concerning appropriate parental access to their children's records.** The proposal clarifies that state law governs disclosure to parents. If the state law is silent or unclear, the revisions permit a provider to use discretion to provide or deny a parent access to the records, as long as that decision is consistent with state or other law.

• **Records can't be used for marketing, but appropriate communications are allowed.** The proposal explicitly requires providers to first obtain the individuals specific authorization before sending them marketing materials. The proposal continues to allow doctors and others to communicate freely with patients with health-related information, including disease-management programs.

• **Privacy is ensured, without blocking research.** The proposal eliminates the need for researchers to use multiple consent forms, such as one for informed consent to the research and one or more related to information privacy rights. Researchers can use a single form for both. The proposal doesn't modify the list of patient identifiable information that can be used for research, but officials with the Department of Health and Human Services say they will strongly consider comments before issuing the final rule. Davidson has predicted that the rule will change.

• **Model business associate provisions are used.** The existing rule requires providers to have contracts with their business associates to ensure they will follow the privacy rule's requirements. The proposal includes model business associate contract provisions, which would make it easier and less costly for providers. The changes also would give providers up to an additional year to change existing contracts, which means all contracts don't have to be renegotiated at one time.

• **Authorizations are simplified.** The proposal allows a single type of authorization form to obtain a patient's permission for a specific use or disclosure that otherwise wouldn't be permitted. Patients still need to give permission in advance each time; however, the proposal eliminates the requirement for different types of forms.

Most providers have until April 14, 2003 to comply. Certain small health plans have until April 14, 2004, to comply. ■

Same-Day Surgery® (ISSN 0190-5066) is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodical postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Same-Day Surgery**®, P.O. Box 740059, Atlanta, GA 30374.

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Questions or comments? Call **Joy Daughtery Dickinson** at (229) 377-8044.

Participate in staffing poll for sds managers

Go to www.same-daysurgery.com, the official web site for *Same-Day Surgery,* and vote in our poll: "What is your most challenging staffing problem?" Also, go to the forum to share solutions for morale or work ethic problems.

Also at the web site, you can access previously published issues in the "archives" section.

At the web site, your user name has been preset as your subscriber number on your mailing label. Your password is sds in small letters, then your subscriber number again.

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CE/CME *questions*

After reading this issue, the CE/CME participant will be able to:

- Identify organizations that offer recall notification services. (See *"Are you using sterile equipment on your patients? How can you be sure?"*)
- List a reason that the video capsule will not replace endoscopy. (See *"Video capsule gives views that endoscopy can't."*)
- Identify the document that spell outs the rules and regulations of the medical staff. (See *"'You're not the boss of me' — or are you?")*
- Identify the most important first step for a patient who wants to avoid transfusions. (See *"Program reduces need for blood transfusions."*)

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.

17. Who offers recall notification services?
    A. ECRI and the Food and Drug Administration
    B. Medicare and ECRI
    C. Medicare and the Food and Drug Administration
    D. none of the above

18. Kenneth F. Binmoeller, MD, director of interventional endoscopy services at California Pacific Medical Center, points out that the video capsule that enables gastroenterologists to view areas of the small intestine that cannot be seen with traditional endoscopy will not replace endoscopy for the following reason:
    A. Patients are afraid to swallow the capsule.
    B. Physicians don't like patients leaving the clinic area.
    C. It does not enable biopsy.
    D. The data are hard to interpret.

19. What document spells out the rules and regulations of the medical staff, including who is the final decision maker?
    A. licensing document
    B. medical staff bylaws
    C. Medicare application
    D. none of the above

20. Sherri Ozawa, RN, director of The New Jersey Institute for the Advancement of Bloodless Medicine and Surgery, says the most important first step for a patient who wants to avoid transfusions is to:
    A. schedule the patient early in the morning.
    B. make sure the patient is NPO.
    C. obtain consents from all family members.
    D. treat anemia 3-4 weeks prior to surgery.

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From the Publishers of Same-Day Surgery®

Same-Day Surgery Reports

Supplement to *Same-Day Surgery*

May 2002, BB #513

Introduction

It is estimated that up to 60% of pediatric surgery in the United States is performed on an outpatient basis.[1,2] These include ear, nose, and throat procedures such as bilateral myringotomy and tube insertion (BMT), adenoidectomy, tonsillectomy; genitourinary procedures such as circumcision; ophthalmic procedures such as ptosis and strabismus surgery; and general surgery such as hernia repair and hydrocelectomy.

Children naturally lend themselves to consideration for outpatient surgery due to relatively short procedures and the general health of the patient population. Ideally, optimal techniques would include cost-effective screening methods for preanesthetic evaluation; short-acting premedicants; drugs that provide for rapid induction and emergence, together with minimal to no pain or post-op nausea and vomiting (PONV) in the recovery room; and faster reunion with parents and discharge. Currently, surgery centers are closer than ever to achieving these goals.

Preoperative Evaluation: Current Methods

Many methods are in current practice for the preoperative evaluation of pediatric outpatients. In teaching programs, it is common for resident physicians, physician assistants, or nurse anesthetists who are supervised by an attending anesthesiologist to evaluate all pediatric patients who come in for a traditional "anesthesia appointment."

Other institutions perform preoperative screening of pediatric patients. This can range from simple telephone screening to assessment by physician assistants. The Long Island College Hospital (LICH) is piloting a preanesthetic evaluation program,[3] whereby pediatric patients are screened at the surgeon's office by a registered nurse and her staff for eligibility to bypass a traditional anesthesia appointment (Pediatric Easy-Pass). A "Pediatric Easy-Pass Eligibility Tool," which has been created at LICH, is used to facilitate rapid determination of eligibility. **(See tool, p. 4.)** Children with no known medical history or with mild co-existing disease (ASA I-II) are eligible for bypass. If the patients meet criteria for bypass, they are directed to an open-house meeting where the parents receive a brochure,[4] and the children receive a coloring book[5] as coping devices. The families and patients see a children's video[6] providing general information about pediatric anesthesia, preoperative preparation, and induction techniques, and they examine anesthesia equipment consisting of masks and circuits. As a group, they meet with an attending anesthesiologist, and any questions are answered. On the day of surgery, the attending anesthesiologist performing the case meets the patients and their families and does a focused physical examination and assessment. LICH had a very favorable response thus far to the pilot program.

Cutting-Edge Pediatric Anesthesia for the Outpatient

Author: **Helen V. Lauro, MD**, Clinical Assistant Professor of Anesthesiology, Department of Anesthesiology, State University of New York, Downstate Medical Center, Brooklyn, NY; The Long Island College Hospital, Brooklyn

Peer Reviewer: **Lawrence S. Berman, MD**, Associate Professor of Anesthesiology and Pediatrics, University of Florida School of Medicine, Gainesville

Pediatric NPO Guidelines: An Update

The period of time that a child can safely fast has been reconsidered in the past years. At State University of New York (SUNY), Downstate Medical Center/LICH, the protocol is a four-hour fast from milk and solids for infants younger than 6 months of age; a six-hour fast from milk and solids for children 6-36 months of age; and an eight-hour fast from milk and solids for children older than 36 months of age.

Breast milk is not considered a complete solid. Some institutions also accept a four-hour restriction for breast milk and a six-hour restriction for nonhuman formula[7] for children younger than

6 months of age. Currently, there is no consensus on how to treat infant formula or how to categorize breast milk. Recent studies have shown that clear liquids can be administered safely until two to three hours before the time of surgery without adverse consequences.

Purported benefits include lower incidence of hypovolemia, hypoglycemia, and flexibility in the OR schedule should procedures be moved earlier in the day. Studies by Splinter, et al,[8] found no significant difference in gastric residual volume or pH in children who were allowed to have clear liquids until two to three hours before surgery, compared with controls with standard preoperative fasting.

The Child with a Cold

It often is a contentious point how to manage the child with a cold who presents for elective outpatient surgery. First, it is important to establish criteria for what constitutes an upper respiratory tract infection (URI). Traditional criteria include fever, purulent rhinitis, and productive cough. In an article by Parnis, et al,[9] eight variables were identified as predictors of an adverse event: tracheal intubation; parents reporting their "child has a cold"; snoring; passive smoke; thiopental or halothane induction rather than sevoflurane or propofol; productive cough; lack of anticholinesterase; and nasal congestion.

A scoring system was created that the clinician can use to calculate the probability of the patient having an adverse anesthetic event. Most children with mild URIs can be managed safely without canceling the surgery.

A retrospective study by Schreiner, et al,[10] concludes that parental confirmation of URI is a better predictor of laryngospasm than the use of predetermined criteria. In a recent prospective study by Tait, et al,[11] concerning risk factors for adverse respiratory sequela in 1,076 children ages 1 month to 18 years presenting for elective surgery who had coexisting URIs, the authors concluded that there were no differences in the incidence of laryngospasm and bronchospasm in children with active URIs, recent URIs (within four weeks), and asymptomatic children.

Children with active and recent URIs did have more breath holding, oxygen desaturation episodes (< 90%), and a greater incidence of overall adverse respiratory events than healthy children. Independent risk factors for adverse respiratory events in their study included use of endotracheal tube, history of prematurity, history of reactive airway disease, paternal smoking, surgery involving the airway, presence of copious secretions, and nasal congestion.

Thus, children with active and recent URIs (within four weeks) are at increased risk for adverse respiratory events, particularly if they have a history of reactive airway disease, require surgery involving the airway, have a history of prematurity, are exposed to tobacco smoke, have nasal congestion or copious secretions, or require placement of an endotracheal tube.

Ultimately, the decision to proceed with surgery after providing informed consent as to risks/benefits depends on the individual patient, the type of surgery and anesthetic, and the judgment and experience of the anesthesiologist. If possible, the anesthesiologist should consider alternatives to traditional endotracheal intubation such as mask ventilation or the laryngeal mask airway in children with mild URIs.

What is the Best Sedative Premedicant?

Sedative premedication in children virtually has been revolutionized by oral midazolam, which has a long history of proven safety and efficacy in the pediatric population. Recent studies looking at alternatives such as oral clonidine compared to oral midazolam continue to show the superiority of oral midazolam.[12] Furthermore, administration of oral midazolam has been shown by Brosius, et al,[13] to not result in any significant difference in awakening time, time to postanesthesia care unit (PACU) discharge, awakening concentration of sevoflurane/nitrous oxide, and measurements of the Bispectral Index (BIS, Aspect Medical Systems, Newton, MA).

Sedative Premedication vs. Parental Presence

Another controversial area concerns the effectiveness of sedative premedication vs. parental presence during induction. Many institutions have policies that prohibit parental presence during induction due to concerns about possible disruptive behavior,

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Conflict-of-Interest Disclosure: Rebecca S. Twersky, MD, (board member) reveals that she is on the speaker's bureau and performs research for Stuart/Zeneca Pharmaceuticals, Roche Laboratories, Anaquest, Abbot, Marrion Merrill Dow, and Glaxco Welcome. Helen V. Lauro (author) and Lawrence S. Berman (peer reviewer) disclose that they have no relationships related to this field of study.

parents becoming lightheaded and fainting in the OR, and general discomfort on the part of the staff.

In a recent randomized study by Kain, et al,[14] oral midazolam was found to be more effective than parental presence in an induction room or no intervention in so far as managing preoperative anxiety. Despite this, induction rooms are used successfully at a number of prominent children's hospitals.

In these circumstances, the anesthesiologist should assess the parents' level of anxiety regarding the procedure. If it is high, they probably should not be present on induction, because children in this context usually are more upset if their parent is present than if they are not.[15]

Parents need to be instructed on what events normally happen during the induction process (eyes rolling back, snoring, involuntary movements, agitation, and deep sleep), and they need to be escorted outside when the induction process is complete.

Which is Best — Sevoflurane or Halothane?

A variety of inhalation induction techniques are in practice including the use of scented masks, distraction techniques ("blow up the balloon"), hypnosis techniques (i.e., "a day at the zoo; pilot flying airplane"), or steal inductions. In general, gradual application of the mask is ideal because of a lessened feeling of suffocation, although the concern of pollution in the room always is raised. It is the safest practice to start the intravenous, if it is required, while the child is spontaneously breathing.

A controversial area is the merits of sevoflurane vs. halothane in pediatric anesthesia. Concerns with the use of halothane have included laryngospasm, myocardial dysrhythmias, and halothane hepatitis. Concerns with the use of sevoflurane have revolved primarily around cost issues. These cost concerns are mitigated by the fact that, in most studies, induction of anesthesia with sevoflurane was significantly faster than with halothane.[16] Emergence also is more rapid with sevoflurane compared to halothane, but it may be associated with greater agitation. Additionally, sevoflurane has been shown to be preferable in strabismus surgery because of a decreased incidence of oculocardiac reflex and airway irritability.[17]

Studies on the effects of the breakdown product of sevoflurane, Compound A, in children are limited, but are consistent with safe use[18] so long as sevoflurane is not used with low gas flows (less than 2 liters/minute).

Uncuffed vs. Cuffed Tubes in Children

Another area of continuing controversy revolves around the choice of uncuffed vs. cuffed endotracheal tubes in children. Traditionally, anesthesiologists would use uncuffed tubes for children up to 8-10 years of age, and cuffed tubes were recommended for use only in special circumstances. A recent study by Khine, et al,[19] has suggested no increased incidence of post-intubation stridor or other laryngotracheal sequelae in children intubated with cuffed vs. uncuffed tubes.

Despite this, in a recent survey by Orliaguet, et al,[20] concerning the use of cuffed vs. uncuffed tubes, only 25% of pediatric anesthesiologists use a cuffed tracheal tube routinely for more than 80% of their patients. The most common concern includes fear of airway mucosal injury.

At SUNY, Downstate Medical Center/LICH, most pediatric anesthesiologists selectively choose a cuffed endotracheal tube, one-half size smaller than they would normally use in a pediatric patient, for certain procedures such as tonsillectomy and adenoidectomy, where surgical bleeding is an issue, or for cases of extremely long duration, where a large leak would be an inconvenience. A cuffed tube can be used safely if it is barely inflated at a pressure of 15-20 cm H_2O until the leak disappears.

Intravenous Insertion Techniques

Many anesthesiologists actively encourage children older than 11 to have an intravenous (IV) placed before induction, unless they request an inhalation induction. With that in mind, there are three techniques to diminish the discomfort of IV placement. The use of an emulsion of lidocaine 2.5% and prilocaine 2.5% (EMLA cream, Astra Pharmaceuticals, Westborough, MA) is a well-established method of providing topical anesthesia; however, it has certain disadvantages.

It requires between 45-60 minutes for peak effect, which makes it impractical when the child arrives in the holding area a short time before surgery is to commence. Also, the cream causes vasoconstriction, which makes it more difficult to see the vein when it is time to start the IV. A recent development is the technique of iontophoresis for anesthetizing the skin.

Iontophoresis produces anesthesia by the transdermal delivery of local anesthetic by means of a low-level electric current.[21,22] Our practice at SUNY, Downstate Medical Center/LICH is to inject a small amount of 1% lidocaine subcutaneously with a 25-gauge needle for topical anesthesia in cooperative children.

Routine Use of Muscle Relaxants

The routine use of muscle relaxants in pediatric outpatient anesthesia is controversial and depends on the duration of the case, whether intubation is planned, the status of the patient, and the preference of the anesthesiologist. Traditionally, pancuronium has been the muscle relaxant of choice in pediatrics, secondary to the effect of tachycardia, which is beneficial in this patient population as well as low cost. The potential long duration of action is mitigated by the larger volume of distribution in the pediatric population. Nonetheless, new muscle relaxants have gained popularity.

Rocuronium, a relative of vecuronium, has a rapid onset of action of two to four minutes and a duration of action of 20-45 minutes. At LICH, the majority of anesthesiologists do not administer muscle relaxant to facilitate endotracheal intubation in the majority of pediatric outpatient cases; instead, they prefer to intubate the patient while deeply anesthetized with volatile agent. Rocuronium is popular for surgical cases in which IV access has been achieved ahead of time, except in the neonatal/infant population, with whom pancuronium is preferred.

Pediatric Easy-Pass Eligibility Tool

LAB REQUIREMENTS

Pediatric patients with no known medical history:
No labs unless indicated by history or surgical procedure

Females: Childbearing age: Hb/Hct, Urine HCG
Males: No testing unless indicated by history or surgical procedure

Pediatric patients with coexisting disease:

- Electrolytes - when appropriate
- CXR-significant pulmonary disease, for specific surgical indication
- PT/PTT/PLT - hematologic disease or surgical specific indication
- Drug levels - Example: anti-seizure medications

ASA CLASSIFICATIONS

ASA I: A normal healthy patient

ASA II: A patient with mild systemic disease, such as controlled asthma

ASA III: A patient with multiple diseases that affect activity but is not incapacitating (includes uncontrolled severe asthma, sleep apnea, and cardiac anomalies)

ASA IV and V are not done as elective procedures

INELIGIBLE FOR EASY-PASS

- Asthma
- Bleeding tendencies
- Congenital cardiac defects
- Cystic fibrosis
- Diabetes mellitus
- Down syndrome or any congenital syndromes with anticipated difficult intubation (includes cleft lip/palate)
- Family history of malignant hyperthermia or anesthesia problems
- Former premature < age 3
- History of croup
- Language barrier (not illiteracy)
- Latex allergy
- Loose tooth
- Mentally challenged
- Myotonia congenita or muscular dystrophy
- No working telephone
- Noncompliant with medication
- Requires lab work prior to the day of surgery, other than the minimal labs (CBC, PT/PTT, Urine HCG)
- Saturday elective cases that require labs to be done at LICH
- Seizures (poorly controlled), nonfebrile
- Sickle cell disease
- Sleep apnea
- Substance abuse
- Surgery within 24 hours
- Symptomatic pulmonary disease (Example: severe asthma)
- Younger than (1) month term

Source: The Long Island College Hospital (LICH) Pre-Surgical Evaluation/Anesthesia Consultation Program, Brooklyn, NY.

Maintenance Strategies

Maintenance of general anesthesia traditionally is provided by an inhaled anesthetic, opioid, and muscle relaxant. This method has the advantage of being a balanced technique with rapid awakening and reduced excitability/myocardial depression secondary to effects of volatile agents.

Alternatively, maintenance can be conducted with simply a volatile agent without a muscle relaxant. Clonidine in doses of 2 mcg/kg IV after induction has been shown to reduce the incidence of agitation without resulting in clinically significant bradycardia and hypotension.[23]

Currently, the effect of BIS monitoring in children has been shown in a randomized prospective study to result in less anesthetic use and faster recovery in patients undergoing tonsillectomy and/or adenoidectomy.[24]

Postoperative Pain Strategies

Postoperative pain strategies have focused on methods to provide adequate analgesia without respiratory compromise. Acetaminophen 10-15 mg/kg orally is the most commonly used analgesic for pediatric outpatient surgery. Acetaminophen also can be given prophylactically intraop by rectal suppository, but the dose needs to be higher (25-40 mg/kg) to provide effective analgesia in the PACU.

Narcotic analgesics offer excellent pain relief, albeit with concern for respiratory depression and PONV. Fentanyl up to a dose of 2 mcg/kg, or meperidine in a dose of up to 0.5 mg/kg can be administered by IV. The maximum dose for fentanyl is 5 mcg/kg if the patient is ambulatory, and the maximum dose for meperidine is 2 mg/kg. Recently, studies have shown that nasal fentanyl results in a therapeutic blood level similar to that following IV administration.[25] This is potentially useful in short procedures such as BMT which do not require IV access, and use of narcotics might reduce agitation on emergence.[26]

Newer nonsteroidal anti-inflammatory drugs (NSAIDs) that are specific cyclooxygenase isoenzyme 2 inhibitors (COX-2), without targeting COX-1, are undergoing Phase 3 investigations in pediatric populations.

This will allow selectively blocking pain receptors without the gastrointestinal side effects long associated with other NSAIDs such as ketorolac.

Regional anesthesia, while generally impractical in pediatric outpatients as a sole anesthetic technique, offers excellent results for postoperative pain management, when combined with a light general anesthetic.

One of the most frequent regional techniques in children is the caudal anesthetic, which can be done with bupivacaine, levobupivacaine, or ropivacaine in many varied concentrations from 0.125%-0.25%, with and without epinephrine, depending on the anesthesiologist's preference and clinical experience. The technique usually is performed after an inhalation induction with the child in the lateral position.

Many anesthesiologists at LICH subscribe to the "5-year-old/50 lbs. rule" that if the child is older than 5 years of age or weighs more than 50 lbs., a caudal anesthetic should be discouraged because of concerns for motor blockade.

In that instance, other regional blocks by the surgeon are encouraged depending on the type of surgery (dorsal nerve block of penis for circumcision and ilioinguinal/iliohypogastric for hernias).

Postoperative Nausea/Vomiting

The most frequent side effect of general anesthesia in the pediatric population is PONV. These complications are the most common cause of delayed discharge from the PACU and the most common cause of unanticipated hospitalization following pediatric outpatient surgery.[27]

PONV has an incidence in children ranging from 5% to 80%,[28] depending on factors such as age and gender of child, type of surgery, type of anesthetic, and administration of opioids. Strategies to prevent or mitigate PONV in pediatric outpatients have surged in recent years.

Traditional medications such as droperidol or metoclopramide have been associated with concerns in the pediatric population for sedation, extrapyramidal reactions, headache, and confusion.

Recently, the use of droperidol has been prohibited because of the potential for serious proarrhythmic effects of death (risks of QT prolongation and/or torsades de pointes). Studies by Aouad, et al,[29] have established that IV dexamethasone 0.5 mg/kg is beneficial on PONV and return of oral intake in children undergoing adenotonsillectomy.

The 5-hydroxytryptamine 3-receptor antagonist class of medications (ondansetron, dolasetron) have enjoyed increasing popularity in recent years, particularly in cases such as adenotonsillectomy, with or without dexamethasone. A low dose of ondansetron 75 mcg/kg with or without dexamethasone has been shown to result in a decreased incidence of PONV (< 5%) compared to dexamethasone alone, in children undergoing strabismus surgery.[30]

While some institutions routinely administer ondansetron prophylactically to all pediatric outpatients, concerns are that routine ondansetron may not be cost-effective. Studies by Scuderi, et al,[31] have shown no significant difference between prophylactic and symptomatic ondansetron for outcomes related to levels of satisfaction, time to discharge, and unanticipated admission in adults.

No matter what variations occur in the practice of the institution, the importance of developing an antiemetic protocol to be administered has been shown to result in decreased moderate to severe PONV, and reduction of patients with repeated nausea.[32] The importance of adequate hydration in reducing PONV cannot be overemphasized.

Postanesthesia Care and Discharge Home

Many hospitals transport all pediatric patients with blow-by oxygen, the tanks of which are always full and on stretchers. It is important to be able to assess the status of ventilation during transport; a hand holding the child's chin up can serve as a monitor of breathing by the exhaled breath being felt on the hand. A precordial stethoscope also can be used in the transport process as a monitor of ventilation and circulation; however, this use may be limited in the child with an extremely agitated emergence. Bumpers should be placed on the sides of the stretcher during transport.

Traditionally, children go directly from the recovery room (phase 1 recovery) to a step-down unit (phase 2 recovery), from which they are discharged home. Discharge criteria for the recovery room originally were developed by Aldrete and Kroulik,[33] who assigned a score of 0, 1, or 2 to activity, respiration, circulation, consciousness, and color; a score of 8 being required for discharge.

The Steward post-anesthetic recovery score[34] differs in that color and circulation are eliminated since it is thought that color is hard to interpret in children and that blood pressure has little constant relation to recovery from general anesthesia in children. Some anesthesiologists have used pulse oximetry instead of color in recovery scores.[35]

Discharge from phase 2 recovery step-down depends on having an awake, responsive patient, with minimal pain, and absence of PONV, with no evidence of complications.

The Future: Fast-Tracking

Fast-tracking in pediatrics, while still limited in the pediatric outpatient population, offers intriguing possibilities that children who undergo extremely short procedures such as BMT and hernia repairs can bypass phase 1 recovery and go directly to phase 2 recovery (ambulatory surgery unit step-down).[35] Purported benefits include earlier reunion with family, earlier discharge, and decreased need for antiemetics and analgesics. More studies need to be done in this area.

Summary

Outpatient surgery is advantageous in the pediatric population in terms of decreased cost, minimized hospital stays, earlier reunion with family, and decreased need for analgesics and antiemetics.

A cutting-edge approach in pediatric outpatient anesthesia

can achieve all of the above goals with short-acting premedicants, drugs that provide for rapid induction and emergence, short-acting muscle relaxants, and revolutionary analgesics and antiemetics.

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CE/CME Objectives

After participating in this CE/CME activity, the participant will be able to:

• identify anesthetic techniques to avoid when a 5-year-old child with particular symptoms presents for right inguinal herniorrhaphy;

• list methods of current prophylaxis or treatment of postoperative nausea and vomiting in children;

• identify methods that are currently being used or investigated in postoperative pain management;

• list purported benefits of current NPO guidelines.

CE/CME Questions

To earn CME credit for this issue of *Same-Day Surgery Reports*, please refer to the enclosed Scantron form for directions for taking the test and submitting your answers.

1. A 5-year-old child presents for right inguinal herniorrhaphy. The child has a runny nose of 3-4 days duration, not associated with fever or productive cough. Anesthetic techniques to avoid include:
   A. general anesthesia by mask.
   B. laryngeal mask airway.
   C. regional techniques.
   D. endotracheal intubation.

2. Methods of current prophylaxis or treatment of postoperative nausea and vomiting in children include:
   A. limitation of IV hydration.
   B. ondansetron.
   C. droperidol.
   D. metoprolol.

3. Methods that are currently being used or investigated in postoperative pain management include:
   A. nasal remifentanyl.
   B. intravenous acetaminophen.
   C. COX-2 inhibitors.
   D. COX-2 activators.

4. Current NPO guidelines in the pediatric population encourage administration of clear liquids two to three hours prior to surgery. Purported benefits of this include:
   A. a significant difference in gastric residual volume and pH in children who were allowed to have clear liquids until two to three hours before surgery, compared with controls with standard preoperative fasting.
   B. higher incidence of anesthetic-induced hypotension or hypovolemia.
   C. flexibility in the operative schedule should the procedure occur up to one hour earlier than expected.
   D. higher incidence of hypoglycemia, and increased need for glucose-containing IV solutions.

BIOTERRORISM WATCH
Preparing for and responding to biological, chemical and nuclear disasters

Traumatized health care providers may need stress counseling in horrific aftermath of bioterror attack

A severe test for a mentally tough profession

In a finding that is likely relevant to many other states, a recent tabletop exercise in Columbus, OH, found that the health care system may be better prepared to deal with bioterrorism victims than the traumatized frontline providers who give them care.

The exercise was conducted by the Ohio Senior Interagency Coordinating Group in Columbus.

After running a scenario involving intentional release of pneumonic plague at a rock concert, emergency preparedness officials discovered there was little in place to address the mental health needs of doctors and nurses in the horrific aftermath. In the exercise, an attack with *Yersinia pestis* resulted in 332 fatalities, 720 hospitalizations, and 4,300 people who were examined and released.

"How do you handle all of the nurses and doctors who have seen many, many deaths, who have tried to decrease panic by remaining calm, and who have survived this huge confusion and turmoil?" asks **Kay Ball**, RN, MSA, CNOR, FAAN, a participant in the exercise and perioperative consultant and educator at K & D Medical in Lewis Center, OH. "What about their mental health? That is something that we found that we are weak in. We really have to develop that better."

The hypothetical event began Friday, March 15, when a popular regional band performed at Shawnee State University in Portsmouth, OH. Approximately 2,000 students and community members went to see the band, which is known for its use of smoke and visual enhancements, according to the scenario. **(See tabletop timeline, p. 3.)**

"[The terrorists] aerosolized the agent in a fogging system and that is how it was spread throughout the building." says **Darren Price**, exercise training officer with the state of Ohio Emergency Management Agency in Columbus.

The players take their seats

The exercise had four groups of about nine people, each working at different tables as the events unfolded. The groups were health / medical, law enforcement, fire / emergency medical services, and government. An audience of about 150 people was on hand to observe and evaluate the exercise.

"The whole purpose was to determine our strengths and weaknesses through the disaster that happened," says Ball, who served as facilitator and discussion leader of the health / medical group. "The planning committee will meet and analyze what we learned from this, and then we will bring back everybody who participated."

The scenario was divided into three phases: incubation, response, and recovery. Each phase received about an hour of discussion at the tables, and all players received updated information at the same time. **(See tabletop tips, p. 2.)** The scenario was necessarily arbitrary but designed to

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test the state's resources at many levels, Price notes.

"Anytime, you are dealing with tabletop exercises there are a lot of assumptions and artificialities built in just to make it flow," he says. "We ask [participants] to bring their emergency operations procedures and plans, and to actually react based upon their plan."

While the exercise is still being analyzed, the mental health needs for medical providers became apparent in playing out the scenario. Part of the problem is the historic perception that health care workers must not succumb to the emotional toll of patient care, Ball says.

"Even in surgery today, if we lose a patient on the table, there is nothing really in place to talk about the trauma the practitioners are going through," she says. "We just think that we are these stalwart people and we can't crumble under emotional strains. That was one of the [identified] weaknesses."

In contrast, firefighters and emergency medical service workers had a more thorough stress debriefing process than their hospital-based counterparts.

"Within the hospitals themselves we really don't have the mental and spiritual health that we need," she says.

Moreover, the scenario projected widespread "psychological manifestations" in the affected area, with students withdrawing from school and residents reluctant to return to their homes. Bioterrorism response planners brainstormed about how to fight the problem, including bringing in celebrities and public officials to show it was safe to return to the stricken area.

The scenario included a short delay in determining the etiological agent, with chaos building before plague was confirmed as the infecting pathogen. Even with the new emphasis on bioterror education, that scenario is fairly realistic because so few clinicians have seen infections caused by the potential bioterrorism pathogens.

"The first problem was what kind of a bug was it?" Ball says. "Where do we send the cultures, and how fast can we get them back?

The scenario also had many students leaving on spring break. Given the anticipated exodus of people from the community — particularly into the neighboring states of Kentucky and West Virginia — there was no attempt to set up mass quarantine areas, Price says. Instead the national stockpile of antibiotics was called up and confirmed or suspect cases were treated and isolated.

"We looked at the issue of quarantine and determined it was not really feasible," he says. "You would have these large [quarantine] circles everywhere. We moved more toward isolation [of patients] at that point."

While identifying a weakness in mental health care, the planners found communications were strong between groups, there were no turf battles, and additional resources became available quickly.

"One of the strengths that we found was that we were able to get supplies in and to call in extra people," Ball says. "We were able to pull in lots of people very rapidly. We are learning how to work more with all of the other diverse factions."

Indeed, the exercise was set in a rural area so that resources would be taxed, reaching thresholds that would trigger state response, Price adds.

"We're better prepared today than we were yesterday," he says. ■

Bioterror tips for running a tabletop

Planners of a recent bioterrorism tabletop exercise in Columbus, OH, **(see cover story for more information)** offered the following tips for participants in the exercise:

- The scenario is plausible, and events occur as they are presented.
- There are no hidden agendas or trick questions.
- All players receive information at the same time.
- There is not a "textbook" solution. Varying viewpoints and possible disagreements are anticipated.
- Respond based on your knowledge or current plans and capabilities.
- Current agency or department policies and procedures should not limit discussion and development of key decisions.
- The outcome is neither intended to set precedents or reflect an organization's final position on specific issues.
- Assume cooperation and support from other responders and agencies.
- Speak up! Talk to your colleagues and ask questions. This is your chance to learn how other agencies in your community would respond in an emergency. ■

Dire straits: Plague released at concert

Tabletop scenario from first case to aftermath

Highlights of a recent bioterrorism tabletop exercise run by planners in Ohio **(see cover story for more information)** included the following timeline of events:

Sunday, March 17, 2002, Portsmouth, OH

8:00 a.m.: At the emergency department (ED) of Southern Ohio Medical Center (SOMC), a doctor has just come on duty and sees her first patient, a 22-year-old woman. The patient's sister says the woman has been complaining of chest pain and has a temperature of 102 degrees F. The sister worries that the patient may have caught the "bug" through her position at the Shawnee State University (SSU) dormitory mailroom where she works part time. A rapid flu test shows a negative result.

The physician is suspicious in light of the national anthrax cases five months earlier and orders a sputum and blood culture. Transport assistance is requested for sending the cultures to the Ohio Department of Health (ODH) laboratory for anthrax testing. The woman is admitted. The Portsmouth City Health Department and Scioto County District Board of Health are notified of the situation. In turn, the ODH and Ohio Emergency Management Agency (EMA) duty officer are called.

2:00 p.m.: The 22-year-old woman admitted to SOMC earlier this morning develops severe respiratory complications and dies. A full autopsy is ordered, and the physician awaits the preliminary results of the sputum and blood cultures. As the day progresses, local emergency medical services (EMS) become overwhelmed with patients presenting with flu-like symptoms. People presenting with the most severe symptoms, including high fever and difficulty breathing, are hospitalized; however, with many more sick waiting in the ED, the hospital beds and wards are filling rapidly.

5:00 p.m.: Traffic around SOMC becomes impassible, and several ambulances are severely hindered. Medical facilities request security assistance from local law enforcement agencies.

10:00 p.m.: Six patients admitted during the day with the severe flu-like symptoms also die. New cases continue to arrive at SOMC with an increase in the number of patients reporting each hour.

Monday, March 18

8:00 a.m.: Overnight, a public health emergency was declared in Scioto County. A request was made by Scioto County Health, via the Scioto County EMA and elected officials for state support in the growing crisis.

A Level 2 emergency status is reached in Scioto County. The state assessment room is activated to support the events in Scioto County.

10:00 a.m.: The preliminary tests of clinical specimens taken from the 22-year-old woman who died Sunday are complete. The ODH Lab notifies the local health departments that the specimens have tested negative for *Bacillus anthracis.* The laboratory begins rule-out testing for other pathogens.

3:00 p.m.: Epidemiological evidence points to an event three days earlier as a common activity of the majority of new patients. On Friday, March 15, a popular regional band performed at SSU in Portsmouth. The band is well known for use of visual enhancements. Approximately 2,000 students and community members attended the concert.

4:00 p.m.: Hospital supplies are insufficient to meet demand. Fifteen additional patients have died, and 111 are listed in critical condition. Reports now include similar symptoms among several health care workers and first responders. SOMC hospital beds are full.

5:30 p.m.: ODH Lab staff notifies Scioto County local health officials that the 22-year-old patient's cultures are preliminarily positive for *Yersinia pestis.* Local health officials inform local health care professionals and EMS personnel that, in order to prevent the spread of disease, patients having confirmed pneumonic plague should be isolated until sputum cultures are negative for *Y. pestis* bacilli.

Those suspected of having pneumonic plague should be isolated for 48 hours after antibiotic treatment begins.

Wednesday, March 27

It has been 10 days since the first victims arrived at SOMC and local clinics. There have been no further cases of illness identified in Scioto County in the past seven days.

Waiting for signs of recovery

Resources begin to flow into the area as a result of national public outreach. Visitors, however, avoid the area and the impact of the event on the local economy becomes apparent as local businesses are slow to reopen.

The psychological manifestations associated with this event are widespread. Although school reopens, many students withdraw from classes for the quarter. Local residents, still frightened and shocked, look to local and state officials for guidance as they attempt to return to normalcy. ■

Winds of war: Researchers track airborne anthrax

A strikingly rapid and wide dispersion

Struck by the surprising level of aerosolization after merely opening an envelope, Canadian researchers are now using a spore surrogate to study how airborne anthrax silently spreads within an office building, *Bioterrorism Watch* has learned.

Researchers are using *Bacillus globigii* spores to simulant the movements of *Bacillus anthracis* in a one-story research building at the Defence Research Establishment Suffield (DRES) at the Canadian Forces Base in Suffield, Alberta, says **Kent Harding,** chief scientist at DRES. "We will be looking at movement between actual offices along corridors using the *B. globigii* as a simulant. It is a spore-like material that is a well-accepted simulant used to assess and challenge biological detection apparatus." The DRES is on the cutting edge of bioterrorism research; scientists there were studying the dispersion of anthrax from envelopes prior to Sept. 11 and its aftermath. In response to an anthrax hoax mailing in Canada in February 2001, the DRES conducted a study last year using an 1,800 cubic foot test chamber to represent an office space. "We had a hoax letter in this country that closed down a major federal office building," he says. "We were interested in [determining] had it been a real infectious material in the envelope, what was the extent of the risk? We went to the scientific literature and really didn't find anything."

It was hypothesized that opening an envelope constituted a "passive form of dissemination" that would produce minimum aerosolization of spores unless additional energy was added via panic behavior or strong airflows, the researchers stated.[1]

"Our scenario was in a chamber, which was conducive to studying the movement of materials on air currents." Harding says. "An individual was given a stack of envelopes and told to keep opening them until powder fell out. When that happened, [he or she] stood quietly by the desk and didn't move for 10 minutes. We just looked at the movement of material around the room, just simply as a consequence of opening the envelope and pulling out a piece of standard 8½ by 11 paper folded in three." Almost immediately upon opening the envelope, a significant aerosol concentration was observed in the area of the "desk." It declined slowly over the 10-minute sampling period, but the high-resolution slit sampler plates used to measure the release became densely packed with bacterial colonies. In the study, significant numbers of respirable aerosol particles were released upon opening envelopes containing 0.1 g or 1.0 g of *B. globigii* spores. A potentially deadly dose could be inhaled within seconds of opening an anthrax spore-filled envelope. Also, the aerosol quickly spread throughout the room so that other workers, depending on their exact locations and the directional airflow within the office, would likely inhale doses. There was very heavy contamination on the back and front of clothing worn by the test subject.

"There was a large dose presented to the person opening the envelope, which was not unexpected," Harding says. "But what was surprising was the very rapid and extensive movement around that room simply as consequence of the movement of normal air currents. It distributed around the room very quickly and in fairly high quantity."

The researchers also found that the spores could escape from a sealed envelope, a phenomenon that caught U.S. investigators off-guard during the 2001 attacks. "We did note that in a standard envelope sealed in the usual way — just with licking the glue on the back of — that there are substantial openings on the back of the envelope," he says. "In fact, the 'envelope people' design them that way so you can get a letter opener inside. Spores did escape from those openings, but we never quantified that and never referred to it to anything more than an anecdotal manner."

The Centers for Disease Control and Prevention (CDC) in Atlanta was apparently unaware of the study during the initial stages of the U.S. anthrax attacks. Whether it would have made any difference is impossible to say, though some wonder if it would have resulted in more aggressive treatment of postal workers.[2] Regardless, the CDC decision to administer antibiotics to a broad range of people, not just those in the immediate exposure area, is reinforced by the study, Hawkins says. The Canadian researchers have now fully briefed the CDC about the study and their ongoing research.

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