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***The OR Management Series***

# **Patient Safety in the OR**

5th Edition

**A compilation of articles from *OR Manager***

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# Foreword

**T**his update of the 2011 *Patient Safety in the OR* reflects an ever-greater emphasis on processes and standards aimed at improving outcomes. We've included 15 articles from 2012 and 25 from 2013, along with 5 articles published thus far in 2014.

Every issue of *OR Manager* includes articles related to patient safety because almost everything done in the perioperative environment is related to patient safety. We have kept readers apprised of the latest regulatory and compliance standards, recalls, safe sterilization practices, protocols for avoiding surgical site infections and readmissions, preoperative and postoperative best practices, and advances in surgical techniques, to name just some of the topics we cover.

Earlier this year we reported on the South Carolina Safe Care Commitment project as one example of an organization striving to meet the high reliability standards put forth by the Joint Commission in late 2013. The authors of that report ("High Reliability Health Care: Getting There from Here") advocate a robust process

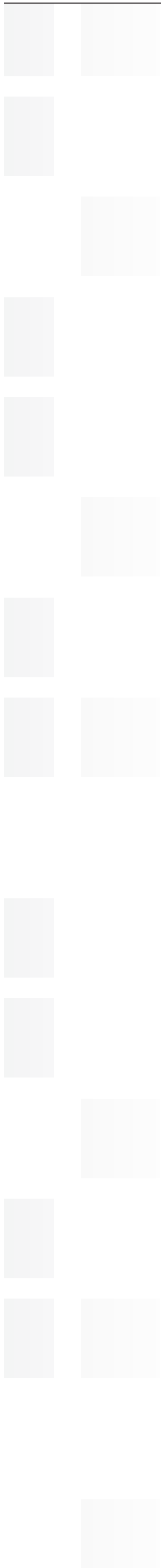
improvement approach after safety failures, and they note that organizations using this approach have seen impressive reductions in surgical site infections and ineffective handoffs.

Implementation of the Affordable Care Act is shifting the emphasis to greater collaboration and coordination among healthcare providers. Those themes are also explored in our patient safety articles, along with new approaches to age-old problems common in many ORs.

This latest edition of *Patient Safety in the OR* offers timely, relevant articles that can serve as a reference for OR administrators, perioperative directors, and their staffs as they strive to make their facilities and processes safer for their patients.



Elizabeth Wood  
Editor, *OR Manager*



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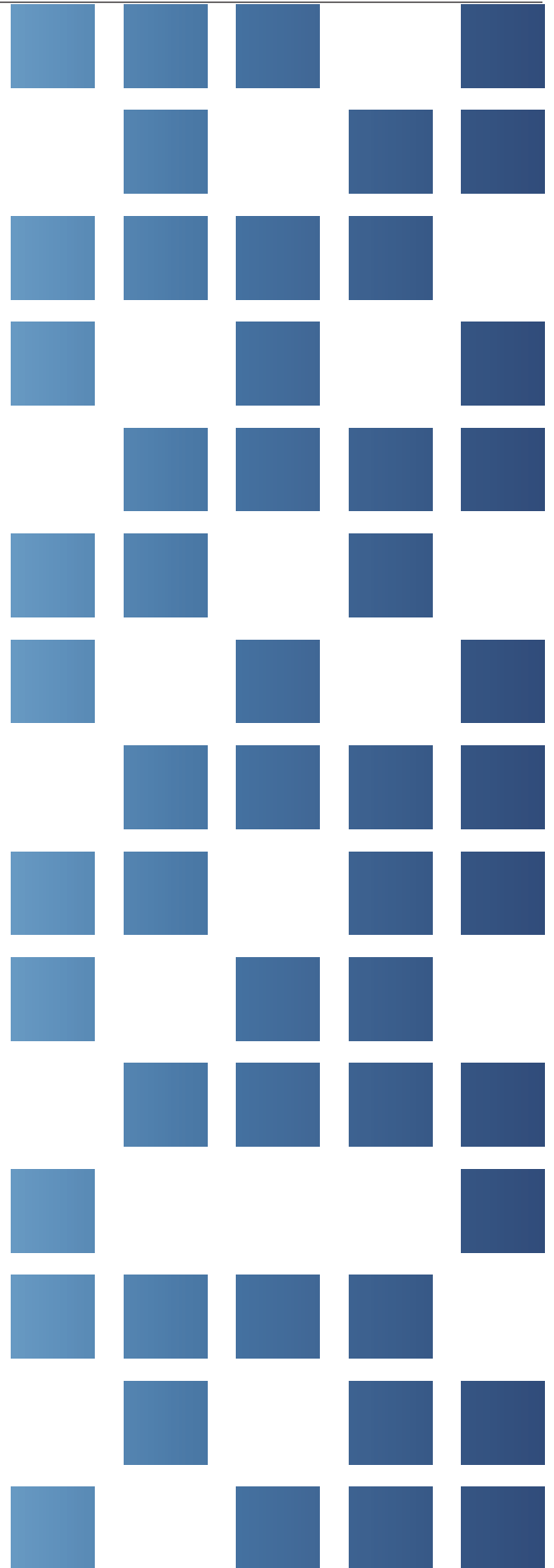
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# I. General



# A safer, faster way for postoperative x-rays

**W**ith patient safety as its primary goal, the University of Michigan Health System has created a new process using bar-coded sponges and electronic radiology orders to ensure no items are unintentionally left in a patient during surgery. Electronic orders provide for a standardized process that not only is safer but also saves 15 to 20 minutes in OR time.

“Having a surgical item left in the patient is something that should never happen,” says Ella Kazerooni, MD, MS, professor of radiology and associate chief of radiology.

“Unfortunately, in complex and emergency cases, in particular, or in larger patients, items are more likely to be left behind, and we want to do everything we can to prevent that.”

## Collaboration is key

Though recognizing there was technology that could assist in preventing a retained item, “we also recognized that technology alone isn’t the answer,” says Shawn Murphy, MS, BSN, RN, CNOR, director of nursing OR/PACU and associate hospital administrator. Also important, she says, were collaborative relationships, team building, standard work processes, education, and comprehensive policies.

The U-M Health System, with 27 ORs, uses bar-coded sponges (SurgiCount Safety-Sponge System, Irvine, California), which are scanned before the sponges are added to the sterile field and when they come off. The sponges have radiopaque tags that allow them to be seen on an x-ray.

“The bar-coded sponge system can alert the surgical team to a sponge that is not accounted for, but an x-ray is still needed to determine if that sponge remains in the patient,” says Murphy.

## Automating radiology orders

“Our top challenge in radiology was to speed up the process of taking an x-ray and communicating results to the surgical team,” says Dr Kazerooni.

Steps in the automated ordering process include:

- When the OR team finds a sponge, instrument, or needle is missing, the circulating nurse enters an order for an x-ray in the hospital’s computerized order entry system.
- The order shows up immediately in the electronic work queue in the radiology department. The circulating nurse no longer has to fill out a requisition, call radiology, or have someone deliver the order to radiology.

- The radiology technologist assigned to the OR is paged and goes to the OR as soon as possible.
- All x-ray images are digital and are sent immediately to the PACS [picture archiving and communication system], where they can be viewed.
- After the x-ray is read, the radiologist calls directly into the OR and talks with the surgeon on speaker phone rather than writing the result on paper that is faxed or hand carried to the OR.

## Standardized order

A benefit of the automated system is a standardized x-ray order that requests specific information: the type of surgery, what item is being looked for, and the phone number of the OR.

“The electronic order accomplished several things,” says Dr Kazerooni. “It gets the request to radiology quickly, it relays the correct information so the radiologist knows specifically what to look for, and it gives a specific number to call with the x-ray findings.”

The previous paper order only requested an intraoperative x-ray to rule out a foreign body. Radiologists often didn’t know what foreign body they were looking for or exactly where, says Dr Kazerooni.

She estimates the electronic order process saves 15 to 20 minutes of OR time, which reduces the time a patient is under anesthesia, helps reduce delays, and decreases OR time charges.

## Saving OR time

A previous obstacle to x-rays before electronic orders were introduced was that surgeons thought the process took too long and weren’t willing to wait for x-ray results before closing the incision or moving the patient from the OR.

“We had to prove we could turn this around quickly so we could add value to their work flow and patient care.

“We did that, and now they don’t have to wait long to get the information they need while the patient is still in the OR,” says Dr Kazerooni. ❖

—Judith M. Mathias, MA, RN

*Access a video about the U-M process to prevent retained surgical items.*

<http://www.uofmhealth.org/news/retained-surgical-items-0206>

*This article originally appeared in OR Manager, July 2012;28:21.*



# A steep price to pay: Fatigue compromises staff and patient safety

It's not uncommon for nurses to work 3 12-hour shifts at 1 hospital and then work another 3 at a different hospital, yet anyone who works 12 hours is putting their patients in jeopardy, Sheryl A. Michelson, MS, RN-BC, said at the AORN Congress in March 2013.

"This is not what nurses want to hear, but we need to think about this. We didn't go into nursing to hurt people," Michelson said during a compelling presentation on worker fatigue.

"When we allow people to work 6 12-hour shifts in a row, we are pretty much signing their death certificate or maybe someone else's in the community who gets hit by the person driving home," Michelson told a packed audience.

Having known 2 nurses who died from falling asleep at the wheel after working long shifts, Michelson is highly attuned to the dangers of auto accidents. "One was a very dear friend of mine. She left 3 young children, and it had a huge impact on me," she said.

As the manager of perioperative education at Stanford University Hospital in Stanford, California, Michelson is on call every fourth or fifth weekend, working from 3 pm Friday until Monday morning as the administrative manager. Over time, she has noticed an increase in complaints about staff behavior among people working long shifts, such as lack of teamwork, yet she also found more staff were requesting more hours.

Michelson, a member of Stanford's needlestick injury committee, sought to learn the association between injury incidence and length of shift. Through an extensive literature search, she learned some startling facts about the effects of fatigue: \$18 billion per year is lost in productivity and accidents (among nurses and other shift workers such as fire fighters and the police), and there are at least 1,500 fatalities, 100,000 auto crashes, and 76,000 injuries annually.

It's important to know that fatigue constitutes overwhelming tiredness and impaired cognitive and physical function, she said. Nurses will admit to feeling exhausted, but they don't know when they are dangerous. Often, it's not until a major error occurs that people realize how much fatigue affects their performance. In one study, among 22,000 RNs who rotated shifts, 35.5% admitted to falling asleep while caring for patients.

At Stanford, an academic institution with more than 600 beds that treats mainly adult patients,

## Does your OR department use 12-hour shifts?

Yes	49%
No	51%

## What are 12-hour shifts used for?

Weekdays only	38%
Weekends and holidays only	4%
A combination of the above	58%

"we don't force people to do 24-, 48-, or 72-hour call shifts, but many places do that," she said. Some people take long hours voluntarily, and others are being mandated to do so because of how their hospital schedule is run. "They don't feel that they have the ability to say 'this is not safe,'" Michelson said.

## Fallout from fatigue

Safety risks increase after working 8 hours, so working 10- or 12-hour shifts significantly increases the risk that nurses will harm themselves or their patients, according to Michelson.

"Sleep duration is linked to metabolism and appetite regulation. Glucose tolerance is altered by short-term sleep restriction, so even being sleep-deprived just 1 or 2 days a week raises the risk of being overweight or prediabetic," Michelson said, adding that at least one-third of the attendees in the room were likely diabetic.

Other risks associated with sleep deprivation include a higher likelihood of injury, preterm birth, and rate of accidents. In a small study of 45 ICU nurses working 12-hour shifts, she said, all but 2 staff members surveyed admitted to having had an auto accident in the previous 12 months.

In a study of 47,000 nurses, 54% admitted to being impaired in some way from fatigue during a 28-day period. Inadequate rest is also linked to moodiness, cognitive problems, reduced job performance and motivation, depression, worse hand-eye coordination, and decreased memory.

## Research defines dangers of shift work sleep disorder

The combination of 12-hour shifts and call can be lethal. That may be 1 reason why more than half (51%) of surgical services directors don't use 12-hour shifts, according to the 2013 OR Manager Salary/Career Survey. For those who do use 12-hour shifts, most respondents use them for weekdays, weekends, and holidays (58%); but slightly more than a third (38%) use them only for weekdays, and just 4% use them only for weekends and holidays.

Even if you don't have 12-hour shifts in your OR, you may have part-time employees who are working these shifts elsewhere, and taking call can easily disrupt normal sleep cycles. OR leaders must be aware of the potential problem of sleep disturbances, including shift work sleep disorder (SWSD). Employees with SWSD have a difficult time staying awake when working the night shift even if they had sufficient sleep before the shift. They may also have difficulty getting to sleep during the daytime, sleep too much during the day, or have difficulty waking up to go to work at night.

### SWSD dangers

Jeanne Geiger-Brown, PhD, RN, FAA, associate professor and assistant dean for research at the University of Maryland School of Nursing, says her sleep research has identified 4 primary areas of neurocognitive changes with SWSD: performance deficits such as not performing a task as well as when rested; impaired information processing such as decline in short-term memory and reduced ability to learn; cognitive flexibility, which results in faulty risk assessments and less ability to recognize better alternatives; and impaired mood, including anxiety, depression, and decreased communication skills.

These deficits not only can lead to patient harm but may cause the employee personal physical harm (through accidental needlesticks or falling asleep at the wheel of a car) and may adversely affect interpersonal relationships.

Unfortunately, people may not be aware of the danger. "Research has shown that with repeated days of not getting enough sleep each night, vigilant performance gets worse and worse, but a sleep-deprived person doesn't have a parallel increase in sleepiness, so they can have a false impression that they aren't as impaired as they actually are," Geiger-Brown says.

People at risk for SWSD include women, older individuals, and those working in health care. "Most nurses are women, have an average age of 46, and are working in health care, so it's not surprising they're at risk for SWSD," says Kathryn Lee, PhD, RN, FAAN, CBSM, professor and associate dean for research at the University of California at San Francisco School of Nursing. An experienced sleep researcher, Lee adds that other risk factors include an anxious personality and lack of internal locus of control.

Although it relies on subjective responses, the Epworth Sleepiness Scale can be helpful in identifying how much the disrupted sleep is affecting the shift worker.

### SWSD solutions

It's vital to help employees find relief from SWSD. Although correlation doesn't imply causation, it's worth noting the night shift has been associated with an increased risk of breast cancer, vascular disease, metabolic syndrome, irregular menstrual cycles, lower birth weight infants, and diabetes. The most common complaints are gastrointestinal symptoms such as irritable bowel syndrome and abdominal pain.

Managing SWSD includes better sleep hygiene (see main article). In some cases, treatment with modafinil or armodafinil may be necessary.

To learn more about SWSD in staff (and in patients), access "Shiftwork Sleep Disorder: The Role of the Nurse, Understanding SWSD for You and Your Patients" at <http://www.americannursetoday.com/Article.aspx?id=10218&fid=9534>. Access a tool kit about sleep disorders at <http://eo2.commpartners.com/users/swsd/>.

—Cynthia Saver, MS, RN

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## Strategies to catch some z's

Sleeping in a darkened, cool room, napping and exercising in a timely manner, and using caffeine appropriately are some ways nurses can get better sleep. And studies support the benefits of working shorter shifts, even though this is not a popular option, she said.

Among the changes Michelson suggested are to avoid scheduling people for more than 2 or 3 consecutive night shifts and allow 10 to 12 hours of recovery time between shifts. The airline industry has altered pilots' schedules to increase safety, she noted, and the health care industry should do likewise.

In 2011, following a deadly plane crash, the Federal Aviation Administration instituted new rules about the number of consecutive hours pilots are allowed to fly, including a 30-hour period each week when they must not work. The airlines require annual training on topics such as nutrition, exercise, and sleep disorders, she added.

The average RN gets 25.7 minutes of break during a shift, and nurses who work longer shifts tend to get shorter breaks than those who work shorter shifts. Studies have shown that short naps lasting less than 45 minutes are effective at restoring energy and alertness, she said—so it's important to take a break and sleep for a short period, if possible.

Caffeine (at least 200 mg) can be helpful if it's consumed 15-30 minutes before starting a shift or during the period between 3 am and 5 am when people tend to get very sleepy.

To the dismay of many in the audience, she advised using it only at work and never at home because drinking caffeine routinely will diminish its effectiveness.

Likewise, she noted that exercise helps people sleep better, but it must be carefully timed; it's better to exercise after a shift than before going to work.

## What's next?

When asked whether she thought the Joint Commission would mandate changes to shifts, Michelson said the Commission has mandated that institutions begin taking some responsibility and look at how they are attempting to mitigate worker fatigue. "Hospitals will be hard-pressed to justify letting people work 24-hour shifts," she said.

As these changes evolve, nurses will have to take call on days when they're not working because they won't be allowed to take call after their regular shifts, and it may be necessary to hire additional full-time employees. But Michelson stressed that nurses can be proactive and try to adjust their schedules before anything is mandated. ❖

—Elizabeth Wood

*This article originally appeared in OR Manager, September 2013;29:11-13.*

# Blood management: Reducing blood use reduces risks and lowers costs

It's common for physicians to order 2 units of blood. But with growing awareness of the hazards of transfusions, hospitals are adopting stricter measures to manage their blood supplies, including developing guidelines for transfusions and making sure physicians are compliant.

Over the past 5 years, research has shown that transfusions during surgery carry risks of higher mortality, surgical site infections, and other complications.

A federal panel on use of blood products found too many patients are receiving blood transfusions they don't need, putting them at risk, wasting limited blood resources, and raising costs.

The Health and Human Services Advisory Committee on Blood Safety and Availability issued findings and recommendations in June 2011 (sidebar).

One finding was that blood management programs have shown a significant reduction in blood use without patient harm.

Also in June, the Joint Commission issued its final Patient Blood Management Performance Measures, which provide metrics hospitals can use to gauge how they are meeting blood management goals (sidebar).

## Accelerating interest

"What really accelerated the interest in blood management was evidence coming out of the critical care literature, including the 2009 clinical practice guideline on transfusions from the Society of Critical Care Medicine and Eastern Association for the Surgery of Trauma," Joseph Thomas, BSN, RN, told *OR Manager*.

This was the first formal practice guideline to recommend single-unit transfusions rather than 2 units for nonhemorrhaging patients, says Thomas, vice president of program services for the Strategic Healthcare Group, LLC, a blood management consulting firm ([www.bloodmanagement.com](http://www.bloodmanagement.com)).

## An antiquated trigger

The first prospective randomized controlled clinical study on blood transfusions, Transfusion Requirements in Critical Care (TRICC), was not published until 1999. The study compared outcomes in patients transfused with red cells when hemoglobin concentrations dropped below 7 g/dL (restrictive group) and those transfused when hemoglobin concentrations dropped below 10 g/dL (liberal group).

The restrictive group had lower overall 30-day mortality (18.7% vs 23.3%) and lower in-hospital mortality (22.2% vs 28.1%).

"The TRICC study showed that a hemoglobin trigger of 7 was not only as effective but superior to a trigger of 10," says Thomas, adding that "the hemoglobin trigger of 10 is antiquated and not based on any evidence." It dates to 1942 when a prominent anesthesiologist from the Mayo Clinic promoted the idea that patients would have a better recovery if their hemoglobin levels were maintained above 10 g/dL.

The TRICC study is still viewed as the one having the greatest impact on transfusion practice, says Thomas. Prior to this study, practitioners based transfusion decisions on retrospective studies that found patients had adverse effects due to anemia.

## Federal panel findings

Recognizing the role of transfusion practices in quality and costs, the HHS Advisory Committee on Blood Safety and Availability in June 2011 found:

- blood transfusions carry significant risks that may outweigh their benefits and add unnecessary costs
- wide variability in use of transfusions indicates both excessive and inappropriate use of blood transfusions in the US
- medical advances and an aging population are expected to raise transfusion demands that could exceed supplies in 1 to 2 decades
- improvements in the quality and safety of blood have lagged behind improvements in rational use of blood
- additional data on blood use and clinical outcomes are needed to manage transfusions effectively and support evidence-based practices
- hospital blood management programs have demonstrated significant reduction in blood use without increase in patient harm.

[www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/recommendations\\_201106.pdf](http://www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/recommendations_201106.pdf)

## Joint Commission measures

New Patient Blood Management Performance Measures:

- PBM-01 Transfusion consent
- PBM-02 RBC Transfusion indication
- PBM-03 Plasma transfusion indication
- PBM-04 Platelet transfusion indication
- PBM-05 Blood administration documentation
- PBM-06 Preoperative anemia screening
- PBM-07 Preoperative blood type testing and antibody screening.

[www.jointcommission.org/patient\\_blood\\_management\\_performance\\_measures\\_project/](http://www.jointcommission.org/patient_blood_management_performance_measures_project/)

“Everyone had just assumed that if anemia has some risk, they should prevent an adverse event from potentially happening by giving blood to correct the anemia. No one ever asked whether patient outcomes improved when they were transfused,” he says.

Over the past 5 years, the number of studies has grown (sidebar).

A study, published online December 14, 2011, in *The New England Journal of Medicine*, provides new evidence that a more restrictive transfusion threshold is appropriate, including in elderly patients with cardiovascular risks. The study also helps confirm that the findings of the TRICC trial apply to patients outside the ICU.

In the trial, rates of death or inability to walk without human assistance at 60-day follow-up were similar in patients randomized to a liberal transfusion threshold (hemoglobin 10 g/dL) and to a more restrictive transfusion strategy (hemoglobin <8 g/dL or symptoms of anemia). Differences were not significant in rates of in-hospital acute myocardial infarction, unstable angina, or death. Rates of other complications also were similar.

### Cost a factor

Besides patient safety and quality, cost is another driving factor for managing blood transfusions. Blood is expensive, easily ranging from \$1 million to \$10 million per year for acquisition alone, notes Thomas.

“Blood is a limited resource. It is a waste of blood and dollars to continue ordering and transfusing 2 units of blood when 1 will do,” Nicole Brocato, MSN, MBA, RN, told *OR Manager*. She is executive director of quality improvement and clinical research at John Muir Health.

Brocato explains that it costs \$200 to \$300 to acquire a unit of blood and \$650 to administer it. John Muir Health, a 2-hospital health system in Concord and Walnut Creek, California, had an escalating blood budget of \$6 million a year.

### Blood management program

Over 3 years from 2007 to 2009, John Muir saved more than \$2.9 million by implementing a blood management program that focused on:

- a new hospital policy of physicians ordering 1 unit of blood at a time instead of 2 units
- lowering the transfusion trigger of hemoglobin



An eye-catching poster reminds clinicians to get on board with single-unit blood transfusions.

## Evidence on transfusions

Evidence is causing concern about blood transfusion.

### Key reports

- In a 2009 study analyzing 125,000 patients in the National Surgical Quality Improvement Program (NSQIP) database, intraoperative transfusion of 1 to 2 units of packed red blood cells was associated with increased 30-day mortality, surgical site infections, pneumonia, and sepsis in general surgery patients. Decreasing blood transfusions decreased patient morbidity.

There was a statistically significant difference in infection rates with just 1 unit of blood. It was worse when 2 units were given, after correcting for patient variables.

—Bernard A C, Davenport D L, Chang P K, et al. *J Am Coll Surg.* 2009;208:931-937.

- The first prospective randomized controlled study of transfusion in cardiac surgery was published in 2010. The Transfusion Requirements after Cardiac Surgery (TRACS) study found patients treated under stricter guidelines for use of red blood cell transfusions in cardiac surgery had similar rates of morbidity and mortality as patients who received more transfusions.

—Hajjar L A, Vincent J L, Galas F R, et al. *JAMA.* 2010;304:1559-1567.

- Another study tracked more than 100,000 Medicare patients who had coronary artery bypass graft surgery. A wide variation was found in blood transfusions without a large difference in the rate of deaths, suggesting many transfusions may be unnecessary.

—Bennett-Guerrero E, Zhao Y, O'Brien S M, et al. *JAMA.* 2010;304:1568-1575.

concentrations of 10 g/dL to 7 g/dL. Presently, the physicians are using a trigger of between 8 g/dL and 7 g/dL.

More than \$900,000 was saved the first year, more than \$1 million was saved the second year, and the savings have been sustained.

The savings don't include the reductions in labor, supplies, testing, or adverse events but simply the amount paid to the local blood provider, says Thomas, who worked with John Muir on the project.

John Muir started its blood management program for its cardiac surgery service in 2007 after exceeding the Society of Thoracic Surgeons blood transfusion benchmark.

The program is now systemwide. The cost savings have been a secondary but welcomed outcome.

Thomas says his firm consistently achieves 20% to 40% reductions in blood use in hospitals they work with.

### Changing habits

Many physicians have become more comfortable in the hemoglobin 8 g/dL range, but most have not reached the 7 g/dL range except for critical care physicians, says Thomas, noting that 8 g/dL is still an improvement. The bigger challenge has been convincing physicians to order 1 unit of blood instead of 2.

"It's not because of a lack of information. It's just such an engrained habit," says Thomas.

At John Muir, the change began by having round-table discussions with the physicians and showing them the data. He emphasized that every unit of blood increases a patient's complica-

tion rates, and each unit is a different liquid tissue transplant that should be treated with respect.

Autologous blood collected a week or two before surgery is not completely safe either, he says. Any biological substance stored in a refrigerator changes its properties. Every day blood is stored there is a buildup of cytokines, plasma-free hemoglobin, potassium, and cellular debris, which promotes inflammation. Red cells stored over time become sticky and inflexible and less able to perfuse the capillaries.

Thomas says he also points out to physicians that the 2 units of blood they automatically order and give are not just 1 large unit split in half; each unit is completely different. He advises them that they can as easily give 1 unit and reassess the patient before giving a second.

"It's not about avoiding transfusion; it's about minimizing exposure to a potentially harmful substance," he says.

As part of raising awareness, Thomas uses creative reminders, such as screen savers that say, "Why give 2 when 1 will do?" and posters showing animals entering Noah's Ark 2-by-2. At the end of the line is a single unit of blood saying, "Two-by-two was good for Noah, but not for blood transfusions. Get on board with single-unit transfusions; don't flood your patient."

### Transfusion committee

Integral to John Muir's success was the formation of a transfusion committee. The committee appointed a transfusion safety officer, identified a physician champion, and developed an education plan and new transfusion order form.

Three core people are needed to make a blood management program work, Brocato notes:

# John Muir Transfusion Order Form



1ORD

**Check one:**    Routine       **STAT**, specify product if not all products needed **STAT** \_\_\_\_\_  
 **OR** \_\_\_\_\_ (surgery date)    **Minimal effective dose of all blood components should be used**

Use Normal Saline 500 ml for priming IV tubing for transfusions	
<b>Premeditations :</b> <input type="checkbox"/> Acetaminophen (Tylenol) 650 mg PO x 1 dose <input type="checkbox"/> Diphenhydramine (Benadryl) <input type="checkbox"/> 25 mg <input type="checkbox"/> 50 mg PO or <input type="checkbox"/> IV x 1 dose	
<b># units</b>	<b>Please check off at least one indication for each type of blood component order</b>
<input type="checkbox"/>	<p><b>Packed Red Cells</b>, transfuse over _____ hours or 2-3 hours per unit.                  (Cannot exceed 4 hr from time of blood bank release)  <input type="checkbox"/> Irradiated; specify justification _____</p> <p><b>SINGLE UNIT transfusions are often effective.</b>   <input type="checkbox"/> Recheck Hct/Hgb after one unit of packed red cells  <b>One unit of packed red cells in an adult will increase Hct by 3%, Hgb by 1g/dL.</b>  <b>Most recent hemoglobin</b> _____ g/dL or <b>hematocrit</b> _____ %    Date _____</p> <p><b>Indication:</b>    <input type="checkbox"/> Rapid blood loss: ongoing blood loss or potential for life-threatening blood loss  <input type="checkbox"/> Hematocrit <math>\leq</math> 21% or Hemoglobin <math>\leq</math> 7 g/dL  <input type="checkbox"/> Patient normovolemic but demonstrates evidence of impaired O<sub>2</sub> carrying capacity as indicated by:  <input type="checkbox"/> Tachycardia, hypotension, shock not corrected by adequate volume replacement alone                  Other (please specify) _____</p>
<input type="checkbox"/>	<p><b>Platelet Pheresis</b> transfuse over _____ min or 30 min per unit  <input type="checkbox"/> Irradiated; specify justification _____</p> <p><b>Most recent platelet count</b> _____ /cc<sup>3</sup>    Date _____</p> <p><b>Indication:</b>    <input type="checkbox"/> Platelet dysfunction due to (specify) _____  <input type="checkbox"/> Platelet count <math>\leq</math> 10,000/ cc<sup>3</sup> prophylactically in a patient with failure of platelet production  <input type="checkbox"/> Platelet count <math>\leq</math> 20,000/ cc<sup>3</sup> and signs of hemorrhagic diathesis (petechiae, mucosal bleeding)  <input type="checkbox"/> Platelet count <math>\leq</math> 50,000/ cc<sup>3</sup> in a patient with (indicate):  <input type="checkbox"/> Active hemorrhage    <input type="checkbox"/> Invasive procedure (recent, in-progress, planned)  <input type="checkbox"/> Platelet count <math>\leq</math> 100,000/ cc<sup>3</sup> in a patient with (indicate):  <input type="checkbox"/> cardiac surgery post-pump with evidence of platelet dysfunction  <input type="checkbox"/> surgery of, or potential for bleed, brain/eye/orbit</p> <p>Other (please specify): _____  <b>A single dose of platelets (adult: one pheresis) will increase platelet count by 25,000 - 35,000/ cc<sup>3</sup>.</b></p>
<input type="checkbox"/>	<p><b>Plasma</b>, to transfuse over _____ min or 30 min per unit  <b>Most recent INR</b> _____    Date: _____</p> <p><b>Indication:</b>  <input type="checkbox"/> Acute reversal of Warfarin    <input type="checkbox"/> Thrombotic Thrombocytopenia Purpura/Hemolytic Uremic Syndrome  <input type="checkbox"/> INR <math>\geq</math> 2, with anticipated invasive/surgical procedure and/or potential for/presence of significant hemorrhage  <input type="checkbox"/> If INR <math>&lt;</math> 2, please specify justification: _____</p> <p><b>Two units of FFP or thawed plasma (dose of 10 - 15 mL/ kg) is usually adequate to correct a coagulopathy</b></p>
<input type="checkbox"/>	<p><b>Pre-pooled cryoprecipitate (Cryo5)</b>, to transfuse at over _____ min or 30 min per unit  <b>Indication:</b>   <input type="checkbox"/> Fibrinogen <math>\leq</math> 100 mg/dL   <input type="checkbox"/> Fibrinogen <math>\leq</math> 150 mg/dL w/ active hemorrhage   <input type="checkbox"/> Dysfibrinogenemia  <b>One bag per 50 kg is usually adequate when cryoprecipitate is required</b></p>
<b>Special product requests (specify justification):</b> _____	

Date	Time	Physician's signature & ID#	Printed name	Contact #
Blood band # _____			(When applicable)	

Transfusion Service # Walnut Creek 35371, Concord 22177



Patient Identification \_\_\_\_\_

- an executive director with links to senior administration
- a transfusion safety officer with links to nursing and ancillary staff
- a medical director (physician champion) with links to medical staff.

At John Muir, Brocato is the program's executive director. The safety officer is an RN who performs monthly audits of criteria for transfusion and nursing documentation, works closely with nursing, blood bank staff, and the medical director and reports to the executive director.

The medical director is a respected trauma surgeon who is recognized as a conservative blood product user. He is willing to accept controversy and engage the medical staff in a paradigm shift, Brocato says.

### Success factors

She advises that a successful transfusion committee must be multidisciplinary, multispecialty, and action-oriented. Steps she recommends:

- Gather baseline data on how much blood the hospital is using. The blood bank will have total volumes by product type.
- Find out what the organization's hemoglobin triggers are for transfusion compared to the evidence. Then look at the quality department's compliance data for how often the triggers are met. A trigger may be 10 g/dL, but physicians may transfuse at 12 g/dL.
- Establish new triggers using data from the literature and physician input.
- Develop a transfusion order form with the new triggers and educate the users (chart).

### Communicating the message

John Muir's transfusion committee had the transfusion order form approved by the medical executive committee, and the medical director presented the form at all medical staff department meetings. The committee also wrote newsletter articles about the form, presented in-service programs, and sent a letter with the order form to all the physician offices.

Use of the transfusion order form is mandatory for John Muir physicians. They can order only 1 unit of blood at a time.

Physicians must recheck the patient's hematocrit and hemoglobin after the first unit and before a second unit can be ordered. If the physician orders 2 units, only 1 is delivered.

The form is used for all elective transfusions. Anesthesiologists are not required to use the order form during surgery if blood is needed. Use of the form is not required in emergencies, such as the care of trauma patients.

The blood bank must be engaged in this process, advises Brocato. "They have to be willing to take the heat when they refuse to fill an order for 2 units."

As of July 1, 2011, the blood bank no longer completes any blood orders that are not on the order form. Previously, it filled handwritten orders and sent a reminder to use the form, but that is no longer done.

Some of the steps take time, Brocato notes. The physicians were given a year and a half to become used to the order form. Because of that, she has not heard complaints since the July 1 transition.

Blood management is a win-win, says Brocato. "It is the poster child for saving money and improving outcomes and patient safety." ❖

—Judith M. Mathias, MA, RN

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# Capnography: New standard of care for sedation?

**C**apnography—is it the standard of care for patients having moderate sedation? Should capnographic monitoring be added for procedures performed under moderate sedation in areas like the preop holding area, GI endoscopy unit, and cath lab?

The issue is generating discussion following an update in the American Society of Anesthesiologists (ASA) Standards for Basic Anesthetic Monitoring, which took effect July 1, 2011. The standards call for continuous monitoring of exhaled CO<sub>2</sub> (ie, capnography) for moderate sedation (sidebar).

The update is a change from the 2005 standard, which said that during regional anesthesia and monitored anesthesia care, the adequacy of ventilation shall be evaluated by continual observation of clinical signs and/or monitoring for exhaled carbon dioxide.

The changes stand to have far-reaching effects.

Managers in endoscopy units, cath labs, radiology departments, emergency departments, and other treatment areas outside the OR are considering how to incorporate the changes into policies and procedures, staff training, nursing documentation, and budgeting for equipment and supplies.

## Quality, safety the goals

“Our ultimate goal in updating the standards was to ensure quality patient care and patient safety,” Donald E. Martin, MD, a member of the ASA committee that wrote the update, told OR Manager.

“Historically, the use of pulse oximetry made a tremendous difference in patient safety, and the use of capnography in intubated patients made a tremendous difference. Now that level of safety is being extended to a large number of patients who are having more invasive procedures done with monitored anesthesia care,” says Dr Martin, professor of anesthesiology, Penn State University College of Medicine, Hershey, Pennsylvania.

Also, ASA closed claims analyses are finding that respiratory depression has become more common as more procedures that were once performed under general anesthesia in the OR began to be performed in other locations on older and sicker patients under deep and moderate sedation.

“The trend has been to increase monitoring, and it’s surely paid dividends,” he says.

## Standards for Basic Anesthetic Monitoring

Effective July 1, 2011, these standards from the American Society of Anesthesiologists apply to all general anesthetics, regional anesthetics, and monitored anesthesia care.

### Standard II

During all anesthetics, the patient’s oxygenation, ventilation, circulation, and temperature shall be continually evaluated.

### Ventilation 3.1 Objective:

To ensure adequate ventilation of the patient during all anesthetics.

### 3.2 Methods:

3.2.4 During moderate or deep sedation, the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.

[www.asahq.org/For-Healthcare-Professionals/~media/For%20Members/documents/Standards%20Guidelines%20Stmts/Basic%20Anesthetic%20Monitoring%202011.ashx](http://www.asahq.org/For-Healthcare-Professionals/~media/For%20Members/documents/Standards%20Guidelines%20Stmts/Basic%20Anesthetic%20Monitoring%202011.ashx)

New technology, including better, less expensive equipment, has made increased monitoring more practical.

### Technology, costs

Capnography monitors use infrared spectroscopy (a beam of infra-red light passed across the gas sample onto a sensor) to measure the expired concentration of CO<sub>2</sub>, a measure of effective ventilation. The end-tidal CO<sub>2</sub> level and respiratory rate are displayed on the monitor numerically as well as graphically by a time-based waveform called a capnogram.

For a patient under moderate sedation, an accessory hose attached to the oxygen can-

## **Studies: Capnography use during moderate sedation**

### **Study in children**

In a study analyzing 163 children having GI endoscopy procedures with moderate sedation, capnography improved the standard of care by allowing early detection of respiratory compromise.

*Lightdale J R, Goldmann D A, Feldman H A, et al. Pediatrics. 2006;117:e1170-1178.*

### **Meta-analyses**

A meta-analysis concluded that during procedural analgesia and anesthesia, respiratory depression was 28 times more likely to be detected when patients were monitored by capnography rather than by traditional methods (pulse oximetry, visual inspection).

*Waugh J, Khodneva Y, Epps C. Anesth Analg. 2008;106(4 Suppl):S27.*

A meta-analysis of clinical studies concluded that during procedural sedation and analgesia, cases of respiratory depression were 17.6 times more likely to be detected

in cases monitored by capnography than in cases not monitored by capnography.

*Waugh J B, Epps C A, Khodneva Y A. J Clin Anesth. 2011;23:189-196.*

### **Early warning sign**

In 247 patients having elective endoscopic retrograde cholangiopancreatography and endoscopic ultrasonography under moderate sedation, researchers found capnographic monitoring acts as an early warning system, reducing the frequency of hypoxemia, severe hypoxemia, and apnea.

*Qadeer M A, Vargo J J, Dumot J A, et al. Gastroenterology. 2009;136:1568-1576.*

### **Randomized trial**

In a randomized controlled trial of 132 patients receiving propofol sedation in the emergency department, adding capnography to standard monitoring (pulse oximetry, cardiac function, and blood pressure) resulted in a decrease in hypoxia and identified all hypoxic events before onset.

*Deitch K, Miner J, Chudnofsky C R, et al. Emerg Med. 2010;55:258-264.*

nula captures the expired CO<sub>2</sub>. During general anesthesia, expired CO<sub>2</sub> is captured in tubing attached near the end of the endotracheal tube or mask.

Monitors are available for \$3,000 to \$5,000. Depending on the type of monitor, single-use CO<sub>2</sub>-measuring oxygen cannulas cost from \$2.50 to \$12, compared to about 40 cents for a regular nasal cannula.

### **Evidence for capnography**

Studies support use of capnography compared with pulse oximetry for earlier and more reliable warning of respiratory depression, says Lisa Heard, BSN, RN, CPN, CGRN, nurse manager for endoscopy services at North Shore Medical Center, Salem, Massachusetts, and a past president of the Society of Gastroenterology Nurses and Associates (SGNA) (sidebar).

Key papers showing the effectiveness of capnography in moderate sedation are by Jennifer Lightdale, MD, and colleagues at Children's Hospital Boston and John Vargo, MD, and associates at the Cleveland Clinic. Before taking her current position, Heard spent 17 years at Children's Hospital, where she was involved in Dr Lightdale's studies.

"The results convinced us to use capnography on all of our pediatric patients receiving sedation," says Heard. "We found we could decrease poor outcomes because we were alerted by the capnogram to intervene quicker when patients had disordered breathing."

Heard says this experience prompted her to initiate its use in North Shore's 7 endoscopy rooms.

When the new ASA standard was issued, Heard enlisted the chief of anesthesia, who was already a proponent, as a champion. Another champion, the chief of medicine, is helping to expand capnography to areas that use patient-controlled analgesia (PCA) as well as to the emergency department and gastroenterology.

"Our main challenges are financial," says Heard, referring to the cost of implementing the standard. She also notes that a bad patient outcome that capnography could have prevented would also be expensive.

### **Not a 'magic pill'**

"Capnography is not a magic pill," says Heard. "You can't say that because you use capnography, you are going to save lives. What it does is to tell you when a patient's ventilation changes before any other monitoring device."

For example, if a patient's oxygen saturation drops to 95, 92, and 88, a pulse oximeter alerts the nurse to intervene by repositioning the airway. In contrast, the capnometer alerts the nurse of a problem with the patient's ventilation before the oxygen saturation starts dropping, allowing the nurse to intervene and prevent a drop in oxygen saturation.

### **Capnography adds information.**

"We're not saying, don't use pulse oximetry and just use capnography. We're saying that used together they result in safer patient care," Heard says.

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## VA weighs capnography

The Department of Veterans Affairs (VA) is considering the new ASA standard as it revises its moderate sedation directive, “but we are not sure which way they will go,” says Cindy Taylor, MSA, BSN, RN, CGRN, nurse manager for GI endoscopy/bronchoscopy at Hunter Holmes McGuire VA Medical Center, Richmond, Virginia. The VA system presently does not require capnography for moderate sedation, and Taylor questions whether the VA will update the directive because of the lack of outcomes data and the cost of new equipment.

“Outcomes data is the first thing the VA may look at,” says Taylor, “and right now outcomes data is not there to substantiate the cost of the capnography.”

But Dr Martin notes that a randomized controlled trial is unlikely to be conducted. He says the type of injury from hypoventilation and oversedation described in the ASA closed claims data is rare, making it hard for researchers to conduct a study with enough patients to show a difference in outcomes.

“If facilities are looking for an outcomes study with hundreds of thousands of patients that separates out the benefits from capnography in addition to pulse oximetry in moderate sedation patients, it is true they won’t find one,” he says.

He adds that anesthesiologists would hesitate to participate in a randomized trial comparing patients with monitoring to those without monitoring because of the potential risk to unmonitored patients, making it unlikely such a study will be done.

## GI endoscopy guideline

The American Society for Gastrointestinal Endoscopy (ASGE) in its 2008 guideline on Sedation and Anesthesia in GI Endoscopy states: “Extended monitoring techniques may provide sensitive measures of a patient’s ventilatory function (capnography) and level of sedation (BIS index monitoring); however, there is insufficient evidence in the literature to support the routine use of extended monitoring devices during moderate sedation.”

Taylor says practitioners may interpret this to mean that monitoring ventilation with a pulse oximeter and signs and symptoms is sufficient.

## Ahead of the curve

Phoebe Putney Memorial Hospital in Albany, Georgia, began implementing capnographic monitoring for moderate/deep sedation and for patients with postoperative PCA pumps over a year ago. Many new monitors were purchased.

“The ASA standard will begin pushing other institutions to add capnography for moderate sedation patients and others,” says Carol Wright, BSN, RN, CNOR, director of the OR, SCP, anesthesia, and perfusion. “We were ahead of the curve.”

Capnographic monitoring is now standard for every patient at Phoebe Putney who receives procedural sedation no matter where that occurs.

Wright says she and her colleagues struggled with how to implement capnography in the preoperative holding area, where regional anesthetic blocks are performed and lines inserted, because they also administer medications for anxiety. To make it easier for the preop nurses, the decision was made that any patient having any procedure in the preoperative holding area would be monitored.

The biggest pushback was from surgeons and proceduralists, who believed it was the anesthesia provider’s responsibility to assess a patient’s airway, not theirs. Wright says they learned it was their responsibility when no anesthesiologist was present, and this was the new standard of care.

Capnography is invaluable in areas that don’t have anesthesia coverage, Wright says. “We see capnography as imperative for patient safety. It alerts us to reduced ventilation before we have a larger problem on our hands.”

## CMS requirement coming?

Jennifer Haines, BSN, business manager for surgical services at Chester County Hospital and Health System in West Chester, Pennsylvania, calls the new ASA standard a “good idea that adds an additional level of safety for patients.” She is in the process of acquiring new monitors for the endoscopy unit and cath lab.

“This is a big deal for all of us. We are going to have to do a lot of education and buy a lot of new expensive equipment. We are figuring out what we need to be ready because we expect CMS to require capnography for moderate sedation in the next year or so,” she says, referring to the Centers for Medicare and Medicaid Services.

John R. Rosing, MHA, FACHE, who consults with hospitals on Joint Commission and CMS matters, says the Joint Commission told him in September 2011 that it is studying the capnography issue.

“I can’t predict what CMS or the Joint Commission is going to do about the ASA standard,” he says. “The best we can say right now is that we don’t know what CMS is thinking because its interpretive guidelines regard moderate sedation as analgesia, not anesthesia. The Joint Commission, on the other hand, regards moderate sedation to be along the continuum of anesthesia and thus may be leaning to require [capnography].” Rosing is vice president and principal, Patton Healthcare Consulting.

Haines says she believes many institutions will wait for CMS to adopt a standard before getting on board. She says many are interpreting a phrase in the ASA standard that says, “unless precluded or invalidated by the nature of the patient, procedure, or equipment,” to mean, “If you don’t have the equipment, you don’t have to do it.” In other words, they see the standard as a recommendation and not a requirement.

## Educating clinicians

When capnography use is expanded, clinicians have to be trained to interpret the capnogram

wave forms and the kinds of waves that indicate apnea or hypoxia.

Nurses must document the patient's capnographic readings on the procedural record. In addition to writing a single number from the capnometer, Heard recommends adding an end-tidal CO<sub>2</sub> column on the patient flow sheet to allow the nurse to indicate a normal waveform. If there is an abnormality in the capnogram, the nurse should describe it in the patient note with the intervention performed (eg, repositioned airway, suctioned oropharynx) and the result.

"That is the best way to show not only that the nurse was monitoring the capnogram but that when a change was recognized, it was documented," she says. ❖

—Judith M. Mathias, MA, RN

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# Early action advisable to prepare for new alarm safety standards

**W**alk into any patient care unit—whether preoperative, intraoperative, or postoperative—and you will hear numerous alarm signals. Some are signaling a medical necessity, but many are false alarm noises that do not require action.

Health care workers can hear several hundred alarm signals per patient per day, which may cause alarm fatigue. Overwhelmed or desensitized by the constant barrage, care givers may take unsafe actions, such as turning down the devices, shutting them off, or ignoring them.

Patient safety advocates have warned of alarm fatigue for years, and it's a growing concern as hospitals invest in more complex devices with a growing number of features and sensors.

In June, the Joint Commission approved a new National Patient Safety Goal on clinical alarm safety (NPSG.06.01.01). The effective date is January 2014.

The goal consists of 4 elements of performance to be phased in over 2 years—2 start in 2014 (Phase I), and 2 start in 2015 (Phase II).

The Joint Commission says it plans to publish the Phase I and II requirements at the same time to provide the field with complete information about the ultimate requirements of NPSG.06.01.01.

Phase II requirements may be enhanced before they are implemented in 2015. These changes could arise from hospitals' experience with Phase I requirements as well as newly emerging evidence about best practices. If any changes to the Phase II requirements are made, accredited hospitals will be notified.

The new goal will appear in the 2013 Update 2 to the Comprehensive Accreditation Manual for hospital and critical access hospital programs.

## Phase I begins in 2014

The first 2 elements of performance (EP) require the following:

EP 1. As of July 1, 2014, hospital leaders establish alarm safety as an organizational priority.

EP 2. During 2014, hospitals identify the most important alarms to manage based on the following:

- input from medical staff and clinical departments
- risk to patients if the alarm is not answered or malfunctions
- whether alarms are needed or unnecessarily contribute to alarm noise and fatigue

- potential for harm based on incident history
- review of best practices and guidelines.

## Form a multidisciplinary committee

Before July 1, hospitals will want to form a multidisciplinary committee to review the literature and decide which alarm signals or alarm systems are most important to manage, says John R. Rosing, MHA, FACHE, vice president and principal, Patton Healthcare Consulting, Milwaukee, Wisconsin.

It is important that hospitals do this early, so the prioritization of alarms is established before July 1, says Rosing. The committee should keep detailed minutes of its meetings, including a directive from leadership stating that alarm safety is an organizational priority. This documentation will be needed to demonstrate compliance when the Joint Commission does its survey, he says.

"I believe the committee should be organizational and not departmental," advises Mary Logan, JD, CAE, president of the Association for the Advancement of Medical Instrumentation (AAMI). "If you try to approach the alarm problem as an OR issue, a PACU [postanesthesia care unit] issue, an ICU [intensive care unit] issue, or something else, the problem isn't going to be solved," says Logan. The committee needs to involve nursing leadership, quality and patient safety leadership, physician leadership, clinical engineering, and information technology, she says.

"A senior administrator, such as a chief nursing officer or a chief medical officer, has to lead this effort," says Robert Maliff, MBA, director, applied solutions group, at ECRI Institute. "You need someone who is really going to believe in this and push this and secure the resources, or things will fall through the cracks," he says.

Every member of this multidisciplinary team has a distinct role, says Maliff. For example, physicians are vital because they are ultimately responsible for patient care, and they can help establish alarm parameters. Nurses are crucial because they are ultimately responsible for responding to all alarms. Clinical engineering staff are important because they will be responsible for changing the alarm defaults. Both AAMI and ECRI Institute are engaged in activities to promote safe alarm system management and support the National Patient Safety Goal (see box).

## Resources for alarm management

### Association for the Advancement of Medical Instrumentation (AAMI)

The AAMI website contains useful information on safely managing alarm systems with links to activities the AAMI Healthcare Technology Safety Institute is engaged in to promote safe alarm system management, including:

- survey of hospital practices in setting alarm parameters, followed by a study of alarm parameters
- library of literature on best practices on alarm system management
- webinars on safe alarm management
- summary of the Clinical Alarms Summit hosted by AAMI in 2011.

<http://www.aami.org/htsi/alarms/>

### ECRI Institute

ECRI Institute offers information such as articles, policies, and webinars on safely managing alarm systems on its website. The website also includes:

- Health Devices Top 10 Health Technology Hazards, which lists alarm hazards as the number 1 issue for 2012 and 2013

- Health Devices Achievement Award winners, which includes the Johns Hopkins Hospital Comprehensive Alarm Management Initiative
- Pennsylvania Patient Safety Authority alarms resources. ([https://www.ecri.org/Forms/Pages/Alarm\\_Safety\\_Resource.aspx](https://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx))

### Joint Commission

The Joint Commission published a Sentinel Event Alert on medical device alarm safety in April 2013. The alert contains suggestions for assessing and managing risks associated with alarms and complements the expectations of the new safety goal.

([http://www.jointcommission.org/sea\\_issue\\_50/](http://www.jointcommission.org/sea_issue_50/))

Other Joint Commission resources include:

- 2 Take 5 podcasts ([http://www.jointcommission.org/podcast.aspx?CategoryId=13&F\\_All=y](http://www.jointcommission.org/podcast.aspx?CategoryId=13&F_All=y))
- replay of an alarm safety webinar held in May. ([http://www.jointcommission.org/alarm\\_safety\\_webinar/](http://www.jointcommission.org/alarm_safety_webinar/))

## Tailor strategies

According to the Joint Commission, it is important for each hospital and each department to understand its own situation and to develop a systematic, coordinated approach to alarm management. Standardization contributes to safe alarm management, but solutions may have to be customized for specific clinical units and patients.

Each care unit has a unique set of circumstances dictating how alarm signals are heard and responded to, says Rikin Shah, senior associate, applied solutions group, ECRI Institute. Thus, alarm response strategies should be tailored to each unit.

The architectural layout and the alarm coverage model play a huge role, says Shah. For example, most PACUs are open spaces with direct lines of communication between nurses and patients, so most alarm signals are both heard and seen across the unit. In ICUs, where patients are secluded in small private settings, a more robust plan for communication and alarm response is needed.

Alarm fatigue is not quite the same issue in the OR that it is in the ICU, says Rosing. In the OR, it is understood what alarm signals mean for a patient, and they are responded to quickly. But, Rosing says, OR leadership will still want to participate in committee discussions and decisions about alarms.

Rosing anticipates that surveyors will go into the OR and ask, "Have you been part of the discussion on alarm management and fatigue?" OR managers will want to be able to say "yes we have," says Rosing, and they may want to continue with "we have decided to leave our alarm settings as they are." That would reflect a deliberate decision made by OR leaders as opposed to not having been at the table at all, he says.

## Prioritize alarms

The approved version of the safety goal is easier to comply with than the draft would have been, says Rosing. The annual inventory of alarms has been deleted, and the phasing of the safety goal into 2014 and 2015 rather than January 1, 2014, allows more time for implementation.

Even though the annual inventory has been deleted, he says, it will likely be necessary to create a master inventory list of all alarms or alarm systems so the committee will have something to work from as it prioritizes the alarms that are the most important.

It also may be useful to categorize this list by service, such as alarms serving the OR, PACU, ICU, medical-surgical units, telemetry units, and the emergency department.

"When identifying the highest priority alarms," notes Logan, "you have to ask, 'What are the ac-

## **Top 10 Actions You Can Take Now: 10 things you can do now to improve alarm conditions in your health care organization**

- Gain cross-disciplinary leadership support.
- Establish a cross-functional team with clinical leadership to address alarm fatigue across all environments of care.
- Re-establish priorities: Process should drive technology adoption rather than allowing technology to drive the process.
- Develop a continuous improvement process for constantly optimizing alarm system policies and configurations.
- Conduct clinical testing and analyze alarm data to implement optimized alarm limits and delays (both alarm condition and alarm signal generation delays) and to reduce clinically nonactionable alarm conditions.

- Test acoustics on clinical floors: Environmental noise impacts patient and staff well-being and patient safety.
- Implement an alarm system configuration policy based on clinical evidence.
- Change single-use sensors more frequently to reduce nuisance alarm conditions (except in pediatric units).
- Mandate alarm system management training for all clinical operators.
- Share experiences with AAMI, the FDA, TJC, ECRI Institute, and others with problem reporting systems so everyone can benefit from your efforts in a cross-disciplinary way.

*This list was originally published in Clinical Alarms: 2011 Summit, a report from the Association for the Advancement of Medical Instrumentation, [www.aami.org](http://www.aami.org). Reprinted with permission. Any other distribution of AAMI-copyrighted material requires written permission from AAMI.*

tionable alarm signals and why? What are the non-actionable alarm signals and why? How can you assess who needs to hear them and why?"

For example, says Logan, nurses and anesthesiologists have very specific requirements for the alarm signals needed in the OR, which are different from the alarm signals nurses need in the PACU, surgical ICU, or cardiac ICU. "This is why everyone has to work together," she says.

In 2011, AAMI and the Food and Drug Administration co-convened a Clinical Alarms Summit. It brought together clinicians, regulators, alarm system experts, industry, and others to discuss and set priorities for alarm management issues. The Joint Commission, ECRI Institute, and American College of Clinical Engineering also participated in the summit, which brought much greater national attention to the problems with alarm management and identified priorities for action.

A list of "Top 10 Actions You Can Take Now" to improve alarm conditions in health care organizations was developed from audience discussion at the summit (see box).

### **Phase II begins in 2015**

In the last 2 elements of performance, the following steps are required as of January 1, 2016:

EP 3. Hospitals will establish policies and procedures for managing the alarms identified in EP 2.

At a minimum, these policies and procedures will address:

- clinically appropriate settings for alarm signals
- when alarm signals can be disabled

- when alarm parameters can be changed
- who in the organization has the authority to set alarm parameters, change alarm parameters, and set alarm parameters to "off"
- monitoring and responding to alarm signals
- checking individual alarm signals for accurate settings, proper operation, and detectability.

EP 4. Hospitals will educate staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible.

### **Manage alarms**

Two of the key issues to be addressed by policies and procedures for alarm management are clinically appropriate settings for alarm signals and unnecessary alarm signals.

"To have clinically actionable alarm signals, which means eliminating nuisance alarm noise, you first need to look at what is happening in the context of your unit," says Shah.

For example, how are system alarm sounds such as leads-off alarm signals being handled? Too many leads-off alarm signals could be a result of inadequate skin preps and lack of electrode replacement. Most hospitals probably already have a skin prep policy for leads and electrode replacement, and they could eliminate many of these system nuisance alarm sounds if they were following their policies, Shah says. He noted that ECRI Institute was part of an alarms management review at Johns Hopkins Hospital in Baltimore in which proper skin preps and

electrode replacement eliminated close to half of the alarms on an acute care unit. AAMI's "Top 10 Actions" list also includes changing leads.

Another policy that might already be in place is standardization of default volume settings on monitoring equipment or in central stations, says Shah.

"One of the things we recommend is attacking the 'low-hanging fruit' first," says Maliff. "Start with the care areas with a lot of alarms and a lot of monitored patients. It is a tall task to tackle every single unit with physiologic monitors," he says.

Health care delivery organizations need to set a timeline for what they are going to get done by when, says Logan. Hospitals that think they can wait until the 4th quarter of 2015 to implement new alarm policies "are going to be in big

trouble," she says. "This is something that takes planning and takes time." ❖

—Judith M. Mathias, MA, RN

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# Fast action, team coordination critical when surgical fires occur

**N**ew information on surgical fires sheds light on risk factors, patterns of injury, and why OR teams need to plan for their occurrence.

A May 2013 study led by Karen B. Domino, MD, MPH, is the first to assess closed malpractice cases of surgical fires. Dr Domino, professor of anesthesiology and pain medicine and adjunct professor of neurological surgery at the University of Washington, Seattle, and colleagues analyzed 103 OR fire claims in the American Society of Anesthesiologists (ASA) Closed Claims Database from 1985 to 2009.

Most claims involved patients who had monitored anesthesia care (MAC) with open oxygen delivery for upper chest, neck, and head procedures. Electrosurgical instruments were responsible for fires in 90% of claims.

Recognition of the fire triad (oxidizer, fuel, and ignition source), particularly the role of supplemental oxygen by an open delivery system during use of electrosurgical instruments, is key to prevent OR fires, says Dr Domino. Prevention is important because fires occur so quickly in the presence of oxygen, she says.

A December 2012 report from the Pennsylvania Patient Safety Authority analyzed 70 reports of OR fires submitted to its database from July 1, 2004, to June 30, 2011.

The fires occurred on the surgical field or in the patient's airway.

Of 65 reports with information about the ignition source, an electrosurgical unit was the source in 58%, a fiberoptic light cord in 38%, and a laser in 3%.

The role of oxygen was highlighted in 7 reports, with 2 specific mentions of nasal cannulas, 1 "leak" in the oxygen tubing, 1 oxygen mask over a tracheostomy stoma, and 1 using an electrosurgical instrument to incise a trachea during a tracheostomy.

The data shows a slight downward trend in the number of fires—ranging from 1 per 157,545 procedures from 2007 to 2008 to 1 per 309,305 procedures from 2010 to 2011—but there is still a need for vigilance, says Mark Bruley, CCE, vice president, accident and forensic investigation at ECRI Institute, coauthor of the report.

## Role of MAC, oxygen

In her study, Dr Domino found that malpractice claims related to electrosurgical-ignited fires during MAC increased from 6% of such claims between 1985 and 1989 to almost one-third of claims related to MAC between 2000 and 2009.

"We are seeing more fires in MAC cases in recent years because we are doing more MAC cases," she explained. MAC has become a lot more popular, especially in the ambulatory setting, because patients have less nausea and vomiting and are less sedated; thus, they can be discharged more quickly.

## About best practices

"Joint Recommendation for Healthcare Industry Representative Credentialing Best Practices" outlines best practices for 3 levels of representatives.

- Level I reps don't have access to patient care areas.
- Level II reps have access to patient care areas but not to sterile or restricted areas.
- Level III reps have access to patient care, sterile, and restricted areas such as the OR.

Requirements are tailored to the level of access.

Elements of the best practices document include credentialing requirements (eg, proof of liability insurance, immunization, proof of criminal background check, training requirements), what should not be required (eg, electrical safety training), and enforcement.

Training requirements specific to the OR (sterile and aseptic techniques), which are required only for Level III reps, should be based on guidelines from AORN and the American College of Surgeons.

Source: *Joint Recommendation for Healthcare Industry Representative Credentialing Best Practices*. Available for download at <http://www.hcirbestpractice.org>.

## Managing vendor access

In addition to computer systems, here are other actions you can take to regulate vendor access:

- Require vendors to wear a different color of scrubs.
- Lock up scrubs and make vendors show their badge to obtain them.
- Give vendors a special colored badge to wear that is timed and dated.
- Require vendors to call and schedule an appointment. “Reps who drop in are interrupting patient care,” says Coleen Norberg, purchasing manager for Ellis Medicine. According to a survey by L.E.K., 75% of hospitals require vendors to make an appointment.
- Get surgeons on board. Norberg says showing the requirements to the surgeons and explaining that it’s a patient safety issue has helped improve cooperation. “Once we gained the surgeons’ support, they helped to convert the most difficult vendors.”
- Get staff on board. Educating staff about the requirements and emphasizing the need for patient safety helps improve staff buy in, Norberg says. “Those in the OR department need to be the eyes and ears for credentialing compliance success,” she adds.

“Vendor credentialing has to be a cultural approach, just like safety and infection control,” says Bruce Mairose, MHA, BBA, vice chair of operations for supply chain management at the Mayo Clinic. “Employees in the organization need to be watching, and if there is a problem, they need to let the supply chain management department know so we can handle it in collaboration with the clinical department.”

A contributing factor is that many MAC patients are given propofol, which can result in more respiratory depression more quickly, so anesthesia providers put oxygen on these patients—whether they need it or not—just out of fear they might desaturate, she says.

Anesthesia personnel also give more oxygen now than in the past, says Dr Domino, because of pulse oximetry. “They are more cognizant of the oxygen saturation, and they give more oxygen,” she says.

According to the ASA Task Force on Operating Room Fires and the Anesthesia Patient Safety Foundation, the most important practice for managing fire risk is to determine if supplemental oxygen is needed during the procedure. This is especially important when oxygen is administered via a nasal cannula or face mask, which would saturate the surgical field with high oxygen concentrations.

To reduce risk, keep oxygen concentrations at less than 30% because there is less combustion at this level, says Dr Domino.

Risk can be reduced further by using open draping techniques to prevent accumulation of oxygen under the drapes.

When there is a risk of fire and the patient requires oxygen, anesthesia personnel should consider a general anesthetic with an endotracheal tube or laryngeal mask, rather than expose the patient to a heightened risk, Dr Domino says.

Other recommendations include not using regular monopolar electro-surgical instruments, if possible, in high-risk situations. If used, the power settings should be as low as possible, consistent with clinical needs, says Bruley. Instead, consider using bipolar electro-surgical instruments, if they will meet the needs of the procedure, he says.

## Coordinated approach

The Pennsylvania Patient Safety Authority says a coordinated approach to surgical fire prevention and response by the surgical team is important to eliminate fire hazards and to minimize the time needed to extinguish the fire.

Three elements are necessary for a fire: a heat source, oxygen, and fuel:

- The surgeon is usually in control of the heat source (eg, electro-surgical unit) and can remove it from the field.
- Anesthesia personnel are usually in control of the oxygen source and can turn it off.
- The circulating nurse and scrub technician can help ensure that alcohol-containing skin-prep solutions are meticulously applied; the skin is dry before applying surgical towels and drapes; moist sponges, towels, and aqueous solutions are available; and exposed ends of fiberoptic light cords are kept off the field.

The end of the fiberoptic light cord is as dangerous as a lit cigar on the surgical field, with temperatures reaching 670° F, Bruley notes.

If a fire occurs, the surgeon and other team members can remove burning materials and extinguish the fire with water or saline, their hands, or a wet sponge or towel. Ideally, a wet sponge or towel is always available for an emergency.

Anesthesia personnel should minimize the availability of oxygen. Burning materials that have been removed can then be extinguished by other team members, if needed, with water, saline, or—in extreme cases—with a fire extinguisher.

Of the 70 OR fire reports the Pennsylvania Patient Safety Authority analyzed, 23 named ways in which fires were extinguished.

These included:

- removing a surgical drape and dousing it with saline
- moving a surgical sponge to a basin of saline
- removing, disconnecting, or turning off the light cord when it was the ignition source
- dousing the fire with saline or water
- extinguishing the fire with towels (1 noted the towels were wet)
- putting out a bone cement fire with the hand
- extinguishing a fire caused by the electrosurgical unit entering the trachea with use of the surgeon's hand, dousing the site with saline, and discontinuing supplemental oxygen.

### Risk assessment

The Pennsylvania Patient Safety Authority recommends a simple fire risk assessment score, such as the one Christiana Care Health System, Wilmington, Delaware, developed to identify procedures likely to pose an increased risk for surgical fires. A score showing the following 3 elements are present indicates high risk:

- surgery above the xiphoid
- open oxygen source
- available ignition source (eg, electrocautery, unit, laser, fiberoptic light cord).

A score of 3 indicates high risk; 2 indicates low risk, with potential for conversion to high risk; 1 indicates low risk.

The score can be included in the World Health Organization's Surgical Safety Checklist preoperative briefing or the Universal Protocol time-out.

OR teams need to have a standardized plan and discussion, notes Dr Domino. "You can have fire risk on your checklist, but if the team doesn't communicate that the surgeon will announce to the anesthesiologist when he is going to use the electrocautery, the anesthesiologist won't know and will leave the oxygen running," she says.

Continuing education and communication along with fire prevention protocols are key to reducing OR fires. ❖

—Judith M. Mathias, MA, RN

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# FDA issues Unique Device Identification final rule

The Food and Drug Administration (FDA) on September 24 published the final rule for its Unique Device Identification (UDI) system to provide a consistent way to identify medical devices throughout their distribution and use.

“A UDI system for medical devices is an important step towards increasing patient safety, modernizing postmarket surveillance, and facilitating medical device innovation,” says Jay Crowley, the FDA’s senior advisor for patient safety, center for devices and radiological health.

Once implemented, the UDI system is expected to have many benefits for the healthcare system and the device industry, says Crowley, including:

- improved visibility as devices move through the distribution chain up to the point of patient use
- enhanced ability to quickly and efficiently identify marketed devices during recalls and other safety actions
- enhanced ability to accurately identify devices and adverse event reports
- strengthened support for electronic health records through a standard way to document device use.

## UDI core elements

The UDI system has 2 core elements:

- A unique number assigned by the device manufacturer, called a unique device identifier, which includes information such as lot or batch number, serial number, expiration date, and manufacturing date. A distinct identification code will be used for human cells, tissues, or cellular- and tissue-based products regulated as devices.
- A publicly searchable database administered by the FDA, called the Global Unique Device Identification Database (GUDID), that will catalogue device information for every device required to bear a UDI. No identifying patient information will be stored in this database.

Crowley says he expects the FDA, medical device industry, healthcare systems, clinicians, patients, and others will use the GUDID to obtain important descriptive and use information and to find similar devices in cases of recalls or shortages.

“The GUDID will be used as a foundation for improving the quality of device public health reporting and medical device recalls,” he says.

“The new UDI rule will—over time—impact all medical devices used in the hospital,” says James P. Keller, Jr, vice president, health technology evaluation and safety, ECRI Institute. “Some of the first to be affected are key parts of a surgery department’s operations (ie, implants). It’s important for OR managers to first become familiar with the gist of the rule and work with materials management and clinical engineering professionals to consider how medical devices with new UDI labeling will be recorded in their inventory management and purchasing systems.”

## Phased-in implementation

Implementation of the UDI system will take place over 7 years, focusing first on high-risk devices and extending to most other devices. Some low-risk devices are completely exempt from the rule.

In general, the rule requires:

- 1 year after publication of the final rule—labels and packages of Class III devices and devices licensed under the Public Health Service Act must bear a UDI. A 1-year extension may be requested; submission must be no later than June 23, 2014.
- 2 years—labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI, and the UDI must be permanently marked on the device if it is intended to be used more than once and reprocessed before each use. Data for these devices must be submitted to the GUDID database.
- 3 years—Class III devices with a UDI on the label and package must be permanently marked if intended to be used more than once and reprocessed before each use. Labels and packages of Class II devices must bear a UDI, and data for these devices must be submitted to the GUDID database.
- 5 years—Class II devices requiring a UDI on the label or package must be permanently marked if intended to be used more than once and reprocessed before each use. Labels and packages of Class I devices and devices that have not been classified must bear a UDI, and these devices must be submitted to the GUDID database.

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- 7 years—Class I and unclassified devices with a UDI on the label and package must bear a permanent UDI marking if intended to be used more than once and reprocessed before each use.

The UDI system, which builds on current device industry standards and processes, reflects substantial input from the clinical community and the medical device industry, says Crowley. By building on systems already in place, the FDA strives to reduce the burden on the medical device industry. ❖

—Judith M. Mathias, MA, RN

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[http://www.fda.gov/Medical Devices/DeviceRegulation andGuidance/UniqueDevice Identification/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm)

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*This article originally appeared in OR Manager, November 2013;29:5, 26.*

# Joint Commission targets fatigue from clinicians' extended hours

In a new alert, the Joint Commission adds its voice to calls to curb fatigue from extended work days and work hours. The alert highlights evidence linking fatigue to adverse events and outlines actions organizations can take to mitigate fatigue, especially among nurses and physicians.

The commission says the alert is purely educational, and there will be no change in the survey process.

Despite the evidence of risks posed by fatigue, health care has been slow to adopt changes, particularly for nursing, the commission says.

Numerous studies have linked nurse fatigue to patient safety, the alert notes. The first, a groundbreaking 2004 study, showed nurses working shifts of 12.5 hours or longer are 3 times more likely to make an error. Other studies have linked long shifts to the risk of errors, close calls, and decreased vigilance, as well as higher rates of nurse injuries.

"An overwhelming number of studies keeps saying the same thing—once you pass a certain point, the risk of mistakes increases significantly," according to Ann Rogers, PhD, RN, FAAN, a sleep medicine expert at Emory University, quoted in the alert.

Residents' duty hours have also been a focus of studies, and standards have been set by the Accreditation Council for Graduate Medical Education.

## Steps to address fatigue

The commission suggests 8 steps to help address effects of fatigue from extended work hours. Here is a summary:

- Assess your organization's fatigue-related risks, including assessment of off-shift hours, consecutive shifts, and other staffing practices.
- Assess handoff processes because they are a high-risk time, especially for fatigued staff.
- Invite staff input into scheduling to minimize potential for fatigue.
- Create and adopt a fatigue management plan that includes scientific strategies to fight fatigue, such as actively conversing with others, engaging in physical activity, using caffeine judiciously, and taking short naps.
- Educate the staff about sleep hygiene and fatigue's effects on patient safety. Sleep hygiene

includes getting enough sleep and practicing good sleep habits.

- Provide opportunities for staff to express concerns about fatigue, supporting their concerns and taking action.
- Encourage teamwork to support staff who work extended hours to protect patients from harm, such as second checks for critical tasks or complex patients.
- Consider fatigue as a potential contributing factor when reviewing all adverse events.
- For organizations with a policy for sleep breaks, assess the environment provided for sleep breaks.

## 12-hour shifts in the OR

Perioperative managers and directors gave extended shifts mixed reviews in a survey by *OR Manager* (September 2010 issue).

In all, two-thirds of participants used 12-hour shifts for nursing staff. Of those, the largest group said 25% or less of their staff worked these longer hours.

The top 3 reasons for 12-hour shifts in the OR were:

- matching operating schedules of some surgeons or specialties
- covering off-shifts
- aiding recruitment and retention.

Many said the extended shifts are popular with nurses, and doing away with them would be unpopular in a specialty where recruitment and retention are an issue.

AORN has a guidance statement on safe call practices plus a position statement suggesting that periop RNs not be required to work in direct patient care for more than 12 consecutive hours in a 24-hour period and not more than 60 hours in a 7-day period, consistent with an Institute of Medicine report. Exceptions, such as disasters, should be outlined in organizational policy. ❖

The Sentinel Event Alert, issued December 14, 2011, is available at [www.jointcommission.org](http://www.jointcommission.org).

*This article originally appeared in OR Manager, February 2012;28:1, 5.*

# Malignant hyperthermia: A crisis response plan

**M**alignant hyperthermia (MH) is a genetic skeletal muscle disorder that is incited by anesthesia drugs including succinylcholine and inhaled anesthetic agents (Gurunluoglu et al, 2009; Hopkins, 2011; Kim et al, 2011). The disorder is particularly dangerous because it rapidly develops into a hypermetabolic state resulting in hyperpyrexia, tachycardia, and intense and unrelenting muscle contraction as well as alterations in electrolyte and acid-base balance (Kim et al, 2011).

Though the incidence is reported to have increased from 2000 to 2005 from 10.2 episodes per 1 million hospital discharges to 13.3, the mortality rate has steadily declined to approximately 11.7% as greater understanding of the pathophysiology and treatment of the disorder has developed (Rosero et al, 2009).

Clinician and patient preparation are key in developing a plan of care for any patient having a general anesthetic. Personal and family histories should be obtained to delineate which patients have a greater risk for an MH crisis, such as those who

have a myopathy (Wappler, 2010). Gender and geographic factors have also been found to contribute to increased mortality rates in persons already having an MH diagnosis (Rosero et al, 2009).

Preparation also involves having emergency equipment and medications readily available as well as developing an action plan to address an MH crisis.

## Crisis management

An MH crisis develops rapidly and taxes resources quickly. Managing an MH crisis requires an approach involving multiple personnel and multiple tasks promptly initiated and deliberately executed.

Crisis resource management is a methodology focusing on task delegation during stressful situations such as an MH crisis. Deeply rooted in the aviation industry, crisis resource management has become essential in health care because it promotes development of team dynamics and cooperation (Rudy et al, 2007). Similarly, crew resource management inspires a group of personnel to function cooperatively as a team with an ultimate goal of safety (McConaughy, 2008).

## MHAUS Treatment Recommendations for Malignant Hyperthermia

**CALL the MH 24-hour Hotline (for emergencies only)**

**United States: 1+800-644-9737**

**Outside the US: 00+1+303-389-1647**

**START Emergency Therapy for MH Acute Phase Treatment**

1. **Get help. Get Dantrolene. Notify surgeon.**
2. **Dantrolene Sodium for Injection 2.5 mg/kg rapidly IV through large-bore IV, if possible.**
3. **Bicarbonate for metabolic acidosis.**
4. **Cool the patient.**
5. **Dysrhythmias: Usually respond to treatment of acidosis and hyperkalemia.**
6. **Hyperkalemia.**
7. **Follow: ETCO<sub>2</sub>, electrolytes, blood gases, CK, serum myoglobin, core temperature, urine output and color, and coagulation studies.**

*Source: Malignant Hyperthermia Association of the United States. Emergency Therapy for Malignant Hyperthermia. Copyright 2011 MHAUS.org. All rights reserved. Reproduced with permission. Available at [www.mhaus.org/healthcare-professionals](http://www.mhaus.org/healthcare-professionals)*

## Malignant Hyperthermia Task Distribution Worksheet

Each set of tasks is printed on a different-colored card. The cards are held together with a ring and can be easily separated for use.

### Circulator/OR staff

- Overhead announcement of MH emergency & summon MH cart to room.
- Call MHAUS (1-800-644-9737). Hand phone to anesthesia team.
- Help reconstitute Dantrolene.
- Insert Foley catheter and obtain urine specimen as needed.
- Obtain supplies for cold lavage of open cavities.

### Anesthesia technician

- Bring MH cart to room.
- Bring i-STAT and appropriate lab containers to room.
- Bring bags of ice to room.
- Bring additional drugs to room.
- Prime a bag of sterile water using warming device & label "DO NOT CONNECT TO PATIENT."

### Surgeon

- Stop operating ASAP.
- Cold lavage of open cavities.

### Anesthesia team

- Instruct circulator to call an overhead announcement of MH emergency and ask for MH cart.
- Turn off all triggering anesthetics.
- Hyperventilate at 10 L/minute with 100% O<sub>2</sub> via bag valve mask.
- Assign tasks and delegate as required.
- Calculate Dantrolene dose (2.5 mg/kg. Note: each bottle contains 20 mg) & repeat as needed.
- Cease warming devices.
- Draw lab work (whole blood profile, CK, coagulation studies, electrolytes).
- Place NG & initiate cold lavage.
- Treat metabolic acidosis (1-2 mEq/kg sodium bicarbonate) if lab values unknown.
- Treat urine output <0.5 mL/kg/hr with hydration & diuretics.
- Monitor urine output (treat dark/cola-colored urine with bicarbonate, hydration, & diuretics).
- Continue to follow MHAUS treatment protocol.

### Additional anesthesia/ancillary staff.

- 3 to 4 people mix 2.5 mg/kg of Dantrolene (utilize 60 mL sterile water per 20 mg bottle).
- Insert A-line & large-bore IVs/central line as needed.
- Maintain charting of events & interventions.

MHAUS = Malignant Hyperthermia Association of the United States. [www.mhaus.org](http://www.mhaus.org)

Source: Geisinger Medical Center. Reprinted with permission.

Crew resource management practices often center on team training and building to prepare for crisis situations (France et al, 2008).

Teamwork and task sharing are important to master before a crisis because most health care providers are specialists and have limited understanding of their colleagues' responsibilities (Sundar et al, 2007).

Responding to an MH crisis demands multiple activities to be executed concurrently, which can have a severe impact on a limited staff.

Therefore, all members of the operating team must understand team member responsibilities and roles and actively participate in managing this event.

### Treatment guidelines

Specific treatment guidelines are essential in the management of an MH crisis. The Malignant Hyperthermia Association of the United States (MHAUS) provides treatment guidelines, which are generally accepted in anesthesia practice (sidebar).



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## **A task distribution worksheet**

Treating the patient in an MH crisis is complicated and potentially manpower-consuming. Cognitive aids that outline the necessary steps can be helpful (Harrison et al, 2006). Principles of crisis resource management, crew resource management, and task distribution assignments can also be applied.

Previous authors have developed task distribution assignments using a model employing strictly nursing personnel (Hommertzheim, 2006).

Ziewacz et al described crisis checklists outlining steps for operating room emergencies, including MH. The current literature has not, however, outlined a model that delineates specific tasks for particular personnel.

This article describes a task distribution worksheet that highlights and fully utilizes the skills and cooperation of each member of the operating team, including anesthesiology, the operating surgeon, nursing personnel, and ancillary staff such as surgical technologists and perfusionists.

The MH task distribution worksheet is intended to ensure that the roles necessary to treat a patient having an MH crisis are fulfilled. The worksheet assigns roles for:

- the circulating nurse/OR staff
- anesthesia technician
- anesthesia team
- surgeon
- ancillary personnel.

## **Color-coded sections**

The task worksheets are printed on half-sheets of laminated paper joined with a ring, allowing each party to take a color-coded section that pertains to his or her individual responsibilities during the MH event (sidebar, p 20).

Though the MH task distribution worksheet was created using the staff mix of our current facility, it should be viewed as a dynamic model that can be tailored to any surgical venue or staffing model.

## **Task distribution roles**

The roles of OR personnel are distributed as follows:

### **Circulating nurse**

The circulating nurse/OR staff member must initiate the call for help and declare an MH crisis with an overhead page alerting the OR suite that an MH event is occurring. The overhead page must include a request for the MH cart and solicit additional staff for assistance. The circulating nurse also calls the MHAUS hotline to allow the anesthesia team to concentrate on treatment tasks. In addition, the circulating nurse is responsible for assisting with Dantrolene reconstitution, obtaining supplies needed for cold lavage, and placing a Foley catheter if required.

## **Anesthesia technician**

The anesthesia technician functions as a supply and delivery agent. The anesthesia technician is responsible for bringing supplies to the room, specifically, the MH cart, i-STAT machine with appropriate items for lab work, bags of ice, extra rescue medications from pharmacy, and sterile water with tubing for the reconstitution of the Dantrolene. The anesthesia technician also primes the sterile water line through a fluid warming device to speed reconstitution of the Dantrolene.

## **Surgeon**

The surgeon's primary responsibility is to cease operating as soon as possible and administer cold lavage to open cavities.

## **Anesthesia team**

The anesthesia team, consisting of the certified registered nurse anesthetist (CRNA) and anesthesiologist, is ultimately responsible for task distribution and providing additional assignments to ancillary personnel as needed. The anesthesia team must:

- instruct the circulator to place an overhead announcement declaring the MH emergency and requesting the MH cart be brought to the operating room
- cease all trigger agents and hyperventilate the patient with 100% oxygen via a bag valve mask separate from the anesthesia machine.
- calculate, reconstitute, and deliver an appropriate dose of Dantrolene.

Initial doses of Dantrolene of 2.5 mg/kg up to 8-10 mg/kg (24-hour limit of 30 mg/kg) repeated serially as necessary is accepted as the definitive treatment (Guranluoglu et al, 2009). The initial dose in an average adult requires the reconstitution of 9 vials of Dantrolene, which consumes the greatest manpower.

Warming devices are discontinued, and lab-work is obtained. A nasogastric tube is also placed by the anesthesia team to allow for cold saline lavage. Acidosis is treated, and hydration is maintained with further treatment administered as indicated by the MHAUS recommendations.

## **Additional and ancillary staff**

These staff should be assigned to mix Dantrolene; insert invasive monitors as indicated, such as an arterial line or additional intravenous lines; and assist with charting.

## **Introducing the worksheet**

The MH task distribution worksheet was formally introduced at a joint staff meeting consisting of members of the anesthesiology service, OR nursing personnel, surgical technologists, and ancillary staff. A slide presentation covered the basic pathophysiology of MH and treatment modalities.

The MH task distribution worksheet was presented with time for questions and answers

about the implementation of the worksheet during the actual emergency. Hands-on scenarios in the ORs allowed staff members to interact and collaborate as they worked through simulated MH scenarios.

Since that time, new employees are introduced to the MH task distribution worksheet in small group training and orientation sessions. The training program has extended beyond the main OR to other areas where anesthesia care is provided, including gastroenterology, endoscopy, and the outpatient surgery center.

Because MH is rare, the tool has not been formally used during a real-life MH crisis event. A pilot study quantifying the perceived benefits of this tool in practice is under development.

MH is an extremely dangerous medical condition requiring prompt intervention. Ziewacz et al imply that interventions should be instituted within 3 to 7 minutes of the onset of the MH crisis to improve the outcome. The task distribution worksheet is a guide to promote efficient and rapid intervention during an MH crisis, ensuring that each team member rapidly completes essential tasks in an organized manner. ❖

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*A photo of Geisinger's color-coded task cards and an Excel spreadsheet are in the OR Manager Toolbox at [www.ormanager.com](http://www.ormanager.com)*

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# Raising the bar for safety in the handling of surgical specimens

Is this specimen fresh or frozen? Is it routine, or does it require a lung protocol? Does it go to the frozen section lab or the microbiology department?

Proper labeling and handling of surgical specimens are critical to reduce the risk of misdiagnosis and the need for repeat surgery.

Decreasing specimen-handling defects is one goal of the Michigan Health and Hospital Association (MHA) Keystone: Surgery collaborative, which aims to reduce surgical complications and mortality by 5%.

The collaborative has made a difference: The defect rate declined by more than 50% from 3.18% to 0.46% from 2010 to 2011. Keystone: Surgery members from 3 hospital systems described their efforts to improve specimen handling.

## Ensuring a specimen chain of custody

Sparrow Hospital in Lansing, Michigan, had begun improving specimen safety before joining Keystone: Surgery in 2010. Using failure mode and effects analysis (FMEA), a team had identified what needed to be fixed or improved.

“Becoming part of Keystone has enhanced our process even further,” says Lynn Raynor, MSN, RN, CNOR, clinical nurse specialist, surgical services at Sparrow.

One improvement is a process to ensure the chain of custody for a specimen:

- The chain begins when the surgeon hands a specimen to the surgical technologist (ST) and tells the ST what the specimen is and what process is needed in the lab.
- The ST hands off the specimen to the circulating nurse, repeating what the surgeon said.
- The nurse labels the specimen container and places the specimen in the container.
- The nurse completes the tissue requisition and initials it. The requisition is also initialed by the transporter and the lab person who accepts the specimen.
- During the debriefing at the end of the case, the circulating nurse announces all specimens obtained; if no specimens were obtained, that is also announced.
- A copy of the lab requisition is filed by date in a binder at the OR front desk, in a step suggested by an OR secretary. This helps ensure

that all specimens intended to be delivered to the lab actually were delivered.

The OR secretary makes sure the transporter brings a copy of each requisition back from the lab. The lab requisition was revised to include an extra copy for the binder.

“This has been helpful on a couple of occasions to clarify questions,” notes Raynor.

## Tracking specimen data

The Sparrow OR in collaboration with the lab tracks specimen data so the number and types of errors can be identified using a tool developed by Keystone: Surgery.

“If we see any trends, we can hone in on what’s happening and correct it,” says Raynor.

Early in the collaborative, Raynor says the OR saw process errors decline to zero over a 6-month period because of improvements identified through the tracking information.

“We have learned we have to keep our finger on the pulse” to spot and correct any errors, she says. It’s also necessary to reinforce the new process with the staff and physicians. A safety board in the OR reports a running count of days without specimen errors and communicates any safety information and lessons learned from errors.

## Learning from defects

A learning-from-defects tool has been instrumental in preventing errors, says Mary Pride, BSN, RN, department manager. The tool is part of the Comprehensive Unit-Based Safety Program (CUSP) and is provided by Keystone.

The tool guides caregivers and leaders through a defect analysis to identify what contributed to the defect and how to prevent it from recurring.

This tool helped identify a potential source of errors by the OR assistant who transports specimens to the lab. He noted that he often was distracted by a phone call to pick up a frozen section that must be delivered to the lab immediately while he was reconciling routine specimens in the specimen room to take to the lab.

The solution was to declare a “no-distraction zone” when the OR assistant is reconciling specimens, says Pride. Before entering the specimen room, the assistant gives up his phone to focus on ensuring consistency between the specimen requisitions and the tissue log. He then takes those specimens to the lab and does not pick up

## SURGICAL SPECIMEN SUBMISSION

ROUTINE PROTOCOL	FROZEN SECTION	LYMPHOMA WORK-UP	LUNG PROTOCOL	MICROBIOLOGY SPECIMEN
<b>ROUTINE</b>	<b>FROZEN</b>	<b>LYMPHOMA</b>	<b>LUNG</b>	<b>MICRO</b>
No Fix	No Fix	No Fix	No Fix	No Fix
NO FIXATIVE ↓ deliver to FROZEN SECTION LAB	NO FIXATIVE ↓ deliver to FROZEN SECTION LAB	NO FIXATIVE ↓ deliver to FROZEN SECTION LAB	NO FIXATIVE ↓ deliver to FROZEN SECTION LAB	NO FIXATIVE ↓ deliver to MICROBIOLOGY DEPARTMENT
Mon-Fri, 8am-5pm: leave at frozen section window Off-hours and weekends: leave in frozen section refrigerator	notify Pathology before Monday-Friday, 8am-5pm – CALL 161279 Off-hours and weekends – PAGE On-call staff: 3300 (Resident) or 2281 (Pathologist)			for assistance Mon-Fri, 8am-5pm: CALL 16..... Off-hours and weekends: PAGE On-call staff at 3300 (Resident) or 2281 (Pathologist)
	<div style="border: 1px solid black; background-color: #FFD700; padding: 5px; width: fit-content; margin: 0 auto;">No Fix</div>	Generic label for additional requests		

**The specimens are labeled with a color-coded sticker for time-sensitive or special-handling specimen streams**

*A color-coded specimen submission form created by the Henry Ford Health System.*

his phone until he returns to the OR. Another OR assistant covers the phone while he is gone.

“The learning-from-defects tool has been super-helpful,” says Pride.

She notes that in discussing a defect, “we make sure everyone understands that it’s absolutely nonpunitive and is for our learning to prevent further errors.”

### Standardizing processes

At the Henry Ford Health System in Detroit, Michigan, the OR, pathology, and laboratory medicine have worked together to standardize processes, notes Rita D’Angelo, MS, CQE, SSBB, manager, Quality Systems Division, Pathology and Laboratory Medicine.

D’Angelo is managing 2 teams of nurses, pathologist assistants, and quality specialists with the goal to create one standard approach to collect, label, and deliver specimens to the lab.

Henry Ford had begun looking at specimen defects long before it joined Keystone: Surgery and realized the pathology lab received a considerable amount of inaccurate or incomplete information from other departments, says D’Angelo.

“We realized we didn’t have a clearly defined standard of work or training on either side. We had defective processes,” she says. In starting to working with Keystone: Surgery, “We already

had a good idea of what was missing and what was needed.”

### Videos aid communication

In their work, the Henry Ford teams learned surgeons and nurses did not necessarily communicate complete information about specimens. The surgeon identified the specimen as it was taken from the patient, but the nurse didn’t always hear the surgeon or know how to spell the name of the specimen.

To illustrate the correct process, D’Angelo filmed a training video for the nurses on how to collect and label the specimens.

“The nurses were thrilled with it, but they suggested the surgeons also needed to see it,” she says.

She made a second video in which a surgeon spoke to the surgeons about what was required in handing off a specimen to make sure the circulating nurse knew the correct information.

The surgeons pointed out that after they call out the specimen, they move on to another part of the procedure and may not have time to make sure the nurse heard the specimen information correctly. The nurses noted that they and the surgeons did not use the same nomenclature for specimens, leading to the realization that the pathology department had not provided a list of specimen types for reference.

“Training the surgeons and getting them involved were milestones, but we’re realizing other things we still have to do,” says D’Angelo.

### Developing standard work

To develop standard work, 3 teams of nurses and pathology personnel are observing processes in both departments. The teams will then develop a standardized process to handle specimens in the OR and hand them off to the lab. At that point, they will include the surgeons. All will vote on the process to adopt. The physician steering committee will roll out the process to the rest of the clinicians and staff.

The standardized process will be included in the OR’s new Epic software, which will automate the requisition and submit it to the lab electronically. When the lab receives the specimen, the requisition will be waiting.

Meanwhile, the IT department is creating a site using Microsoft’s Sharepoint software. Circulating nurses will document their frozen sections, and the information will be viewed in the frozen section room so lab personnel know what specimens are coming out of each OR.

As part of standard work, the OR has introduced a color-coded labeling system to denote the tissue type and test (illustration, p 10). When the lab receives the specimen, it knows what test is needed and where the specimen needs to go. Each OR has a poster of the color-coding system.

Standardizing the process requires time and effort, D’Angelo notes, but it has lowered the specimen defect rate to about 2 a week from about 40 a month before the Keystone project began.

### Steps to guide handoffs

Marquette General Hospital in Michigan’s Upper Peninsula has revised its specimen handoff communication protocol based on its involvement with Keystone, says Patricia Wills, BSN, RN, CNOR, director of clinical education for perioperative services.

Although there had been a policy on handoff communication for specimens, it wasn’t necessarily followed, Wills notes.

She and team members educated the staff about the process and developed these steps:

- The surgeon calls out the name of the specimen; the ST repeats the name to the circulating nurse; the nurse repeats back the specimen name and receives verification from the surgeon.
- Music is to be turned down and conversation held to a minimum during specimen collection.

- If circulating nurses are gathering multiple specimens for frozen sections, they must call the OR desk to send help, which could be a floating RN, an ST, a manager, or an educator.

### Communicating with pathologists

As the pathologists have begun requiring new tissue-handling processes for certain specimens, communication and education with the pathologists are “doubly important,” says Wills.

An example is requiring certain specimens, such as lung tissue, to be transferred in a sterile manner, which had not been done before.

The head of the pathology department gave an in-service session for the OR staff about the new processes. The OR had to determine which sterile containers to use to transfer specimens because some of the lung tissue samples were large.

At the beginning, bone jars intended for large bone flaps were used, but the \$10 cost was prohibitive. Instead, the staff decided to use a sterile basin covered with a sterile adhesive drape.

Another staff idea was color-coded specimen requisitions. Bright yellow requisitions are now used for specimens that require special handling, such as frozen sections and breast specimens sent fresh that need to be processed within an hour. The requisition for routine specimens is white.

Included on the special-handling requisition are:

- reason for evaluation
- OR number
- name of circulating nurse
- name of surgeon who requested special handling
- time placed on dumbwaiter lift to the lab
- test requested.

The goal is to decrease requisition errors to 0 to 1 per month, a goal that is being met in most months. ❖

—Judith M. Mathias, MA, RN

More on Keystone: Surgery is at [www.mhakeystonecenter.org/surgery\\_overview.htm](http://www.mhakeystonecenter.org/surgery_overview.htm).

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# Safety, cost savings, simplicity back broader use of bloodless surgery

**M**ore than 120 centers throughout the US have bloodless surgery programs to serve patients who refuse blood transfusions for religious and other reasons. The practice, which began more than 50 years ago, has evolved through research on blood conservation and new techniques to minimize the need for transfusions.

The Joint Commission is taking a serious look at reducing transfusions, which could spur the growth of blood management and bloodless surgery programs across the country, says Mark Zawadsky, MD, medical director of the Bloodless Medicine and Surgery program at Georgetown University Hospital in Washington, DC.

Blood management has also attracted the attention of the AABB (formerly the American Association of Blood Banks) and the Department of Health and Human Services (HHS).

## Many transfusions unnecessary, costly

The HHS Advisory Committee on Blood Safety and Availability issued findings and recommendations in June 2011.

Among the findings was that too many patients are receiving blood transfusions that they don't need, putting them at risk, wasting limited blood resources, and raising costs.

More than 15 million units of whole blood and red blood cells are transfused annually in the US according to HHS, and as many as 30% of transfusions may be unnecessary.

In 2011, the Implementation Guide for The Joint Commission Patient Blood Management Performance Measures was developed to target indications and screening for blood transfusions ([http://www.jointcommission.org/patient\\_blood\\_management\\_performance\\_measures\\_project/](http://www.jointcommission.org/patient_blood_management_performance_measures_project/)).

Though use of the measures is not an accreditation requirement, participants at a national summit on overuse of blood transfusions, held in 2012 by the American Medical Association and the Joint Commission, called for implementation of the measures at the local and national levels.

## 'Build it and they will come'

Several hospitals have been pioneers in bloodless surgery.

Three years ago, Georgetown University Hospital responded to the needs of the Jehovah's Witness community, which lacked a bloodless center in the DC area.

The Witness community provided organizational support for the program as it was being established, which includes a medical director, nurse coordinator, secretary, and an administrative coordinator.

"We put together hospital protocols and policies to help streamline the process, so when patients who want to avoid blood transfusions come to us, we can immediately tell them the procedures we offer," says Dr Zawadsky.

More than 200 patients a year undergo bloodless surgery at Georgetown, and about 10% come from outside the Witness community. In the past year, Dr Zawadsky, an orthopedic surgeon, performed some 25 hip and knee replacements in patients in the bloodless program.

"A lot of what we are doing is simply basic good medicine, and it doesn't have to be just for patients who are bloodless surgery patients. All patients can benefit from these techniques," he says.

When starting a program, Dr Zawadsky recommends involving the anesthesia department. Anesthesiologists evaluate patients preoperatively, manage them during surgery, and follow up with them in the postanesthesia care unit (PACU). He believes that if you have an anesthesia champion to push the benefits of giving less blood, surgeons may be encouraged to operate this way.

## Major strategies

Bloodless surgery at Georgetown and other hospitals consists of 3 strategies (sidebar):

- Preoperative anemia management—administering IV iron or Procrit (epoetin alfa, a synthetic form of the protein human erythropoietin that stimulates bone marrow to make more red blood cells) and discontinuing antiplatelet medications and supplements.
- Intraoperative techniques to minimize loss of red blood cells—normovolemic hemodilution and cell salvage.
- Postoperative conservation of patients' blood and anemia management—restriction of blood draws for lab tests and administration of IV iron or Procrit if necessary.

"The strategies we use to prepare patients for bloodless surgery are low-tech and common sense," says Patricia Ford, MD, an oncologist/hematologist and medical director of the Center for Bloodless Medicine and Surgery at Pennsylvania Hospital, Philadelphia.

## Evidence on transfusions

Mounting evidence supports concerns about blood transfusions.

- Data on more than 48,000 surgical patients at Johns Hopkins found frequent transfusions were given to patients who didn't need them. Transfusions varied 3- to 4-fold among surgeons (Frank S M, Savage W J, Rothschild J A, et al. *Anesthesiology*. 2012;117:99-106).
- In an analysis of nearly 941,500 surgical procedures in the American College of Surgeons National Surgical Quality Improvement Program database, patients who received 1 unit of blood intraoperatively had higher rates of mortality and more serious morbidity. These rates increased further with transfusions of more than 1 unit (Ferraris V A, Davenport D L, Saha S P, et al. *Arch Surg*. 2012;147:49-55).
- A comparison of Jehovah's Witness patients who refused blood transfusions with non-Witness patients who underwent cardiac surgery at the Cleveland Clinic between 1983 and 2011 showed that Witness patients had significantly lower rates of myocardial infarction, additional operations for bleeding, and prolonged ventilation, along with shorter intensive care and hospital stays (Pattakos G, Koch C G, Brizzio M O, et al. *JAMA Intern Med* 2012;172:1154-1160).
- Examining hospital variability in the use of blood transfusions in patients undergoing major noncardiac surgery at academic medical centers between 2006 and 2010, researchers observed dramatic hospital variability. Because of potential complications associated with transfusions, reducing this variability may result in improved surgical outcomes, the authors say (Qian F, Osler T, Eaton M P, et al. *Ann Surg*. 2013;257:266-268).

Every year, Dr Ford guides some 700 patients through procedures from heart surgery to hysterectomies without transfusions.

About 95% of Dr Ford's patients decline a transfusion based on religious convictions, but an additional 5% decline for other reasons, such as fear of bloodborne infections.

### Blood management cost-effective

"Blood is expensive—costing about \$1,100 to acquire and administer 1 unit," says Sherri Ozawa, RN, clinical director of the Institute for Patient Blood Management at Englewood Hospital and Medical Center in Englewood, New Jersey.

"If a hospital's blood budget is \$5 million a year, and they decrease it by 10% to 20%, that is a significant savings," she says.

Research by Ozawa and colleagues (Shander et al, 2010), found annual expenditures for blood and transfusion-related activities for surgical patients ranged from \$1.62 million to \$6.03 million per hospital.

Englewood Hospital started its bloodless surgery program in 1994, and 2 years later, blood use had dropped by 40%.

### Transfusion poses risks

Evidence is growing that blood transfusions are associated with increased postoperative morbidity and mortality (sidebar).

According to the most recent National Blood Collection and Utilization Survey, funded by HHS and conducted by the AABB, the annual number of adverse effects from transfusions that required any diagnostic or therapeutic intervention was 60,110, or 1 in 394 transfusions.

In 2012, the health alliance Premier found that use of blood products beyond a level deemed medically necessary can increase complication rates and length of hospitalization. Premier rec-

ommends industry-wide standardization of blood utilization practices.

Ozawa notes that, conceptually, blood is "really a liquid organ transplant that's treated as a medicine used to manage anemia. It is the only transplant that can be administered by nurses."

### Autologous blood not used

Preoperative autologous blood donation is not used for patients in bloodless surgery programs.

"All it does is make the patient anemic," says Dr Ford.

Many patients mistakenly believe that their own blood is 100% safe because it's theirs, she says. However, human error can make any transfusion risky. The lab can confuse the blood samples, the blood bank can issue the wrong unit of blood, or the nurse or physician can administer the blood to the wrong patient. The blood bank may not label the blood correctly, store it correctly, or return it to the correct patient.

A new Johns Hopkins study on shelf life (Frank et al, 2013) found that red blood cells stored longer than 3 weeks begin to lose their capacity to deliver oxygen to tissue, and these changes are not readily reversible after transfusion.

"When blood is stored for a prolonged period of time, the red cells deteriorate," says Dr Ford. "They lose enzymes, and don't carry oxygen as well as they should. They also become deformed and don't travel through small blood vessels as well as they should."

### Transfusion restrictions

In March 2012, the AABB released a clinical practice guideline on red blood cell transfusion that focused on a restrictive transfusion strategy and the use of patient symptoms as well as hemoglobin concentration to trigger transfusions (<http://annals.org/article.aspx?articleid=1103943>).

A hemoglobin transfusion trigger of 10 g/dL had been the standard since the 1940s.

The first study to challenge this standard, the Transfusion Requirements in Critical Care (TRICC) trial, was performed in 1999 by Hebert et al. The study compared outcomes in intensive care patients transfused when hemoglobin concentrations dropped below 7 g/dL (restrictive group) and those transfused when hemoglobin concentrations were below 10 g/dL (liberal group). The restrictive group had lower overall 30-day mortality and lower in-hospital mortality rates.

A 2011 study by Carson et al confirmed these findings and showed the results also apply to elderly surgical patients with cardiovascular risks. More than 2,000 hip fracture patients with a cardiac history were transfused at either a hemoglobin of 10 g/dL or <8 g/dL. Results showed no difference between the 2 groups in morbidity, mortality, or rehabilitation milestones, but wound infection rates were almost twice as high for the more liberal strategy of 10 g/dL.

### Are triggers necessary?

"A patient's hemoglobin can go very low, and the body can still support adequate tissue oxygenation, and the patient can survive without a transfusion," says Dr Ford.

Pennsylvania Hospital statistics from 2007 showed that in patients with hemoglobins of 4 g/dL, no deaths were directly related to withholding blood products. Even at hemoglobins of 2 g/dL and 3 g/dL, survival rates were 50% and 70%, respectively, says Dr Ford.

The hospital saw the number of transfusions immediately lowered by 10% when it modified its guideline from 8 g/dL to 7 g/dL about 2 years ago and began requiring the physician ordering the transfusion to cite a reason if the hemoglobin was above 7 g/dL. An additional modification to order 1 unit of blood at a time and reassess the patient before ordering a second unit also helped lower the number of transfusions.

Georgetown's trigger for transfusion is a hemoglobin of 7.5 g/dL, and staff now order and transfuse 1 unit of blood, then check the hemoglobin before ordering a second unit.

Englewood Hospital's policy does not have a hemoglobin level trigger for transfusion, but most physicians use 7 g/dL, says Ozawa.

"We believe the decision to transfuse needs to be a physiological decision, not a numbers-based decision. There are patients who do fine with a hemoglobin of 5 g/dL and others who have problems at 11 g/dL."

### Simple strategies

Strategies for bloodless surgery patients are simple to implement, can decrease unnecessary blood transfusions, and can save on health care costs for all patients, says Dr Ford.

These include:

- Correct anemia preoperatively.
- Eliminate unnecessary blood tests.

- Don't transfuse based solely on a number; use clinical assessment as to whether a unit of blood is necessary.
- Don't automatically order 2 units of blood; give 1 unit and reassess the patient before ordering a second.

Applying these principles across the spectrum of surgical care could dramatically reduce all patients' exposure to donor blood. ❖

—Judith M. Mathias, MA, RN

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# Solid OR governance is the foundation for safety

*Ten Elements of Safer Surgery. First in a series.*

**W**hat's the essential ingredient for an OR to run safely and effectively? Many would sum it up with one word—leadership, followed closely by collaboration.

An OR led by a strong team from surgery, nursing, and anesthesia backed by the hospital's top management places a hospital in a stronger position to meet financial and quality goals.

This is the first article in a series on safer surgery, which will cover the components needed to strengthen performance in perioperative services on advancing the quality of care and services. The series is based on the SaferSurgery initiative of Advocate Health Care, a Chicago-based health system with 10 hospitals (sidebar).

## Leadership and safety

Without a solid governance structure, it's hard for a perioperative department to resolve flawed processes that can affect patients.

"I've participated in many root-cause analyses over the years," comments Gary Stroud, MSN, RN, chief clinical officer for Prezio Health. "If you don't have a solid structure, it's only a matter of time before you're going to repeat that root-cause analysis" because core issues tend not to be addressed in a systematic, sustainable way. He was operations officer for the surgical services clinical program at Intermountain Healthcare based in Salt Lake City.

There's emerging evidence that leadership is key to successful adoption of practices like a surgical safety checklist.

A qualitative analysis of 5 hospitals by the Harvard School of Public Health published in 2011 found effective implementation hinged on leadership persuasion and a coordinated effort to explain the rationale and provide education. Further research is underway.

Experts offer the following factors as keys for a strong governance structure.

## Align strategic direction

Because surgery is a core service of most hospitals as well as a revenue and cost center, the strategic goals of the organization and perioperative services need to be aligned.

The surgical services structure at Intermountain incorporates all levels of leadership up to and including the board level.

"The best method I have witnessed [for governance] is to have medical and operational staff participation with board guidance and support," Stroud says of his experience there. As heads of the system's surgical services clinical program, he and the medical director of perioperative services led goal setting and planning initiatives, worked with individual hospitals on those initiatives, and sat on committees that included board members.

For Advocate Health Care, OR governance is central to the SaferSurgery initiative. The initiative is aligned with the system's goals to provide superior patient outcomes and become the best system nationally.

## Build a solid structure

Several experts advocate this model for perioperative governance:

- A Surgery Committee is responsible for setting policies and is accountable for seeing the policies are carried out.
- A smaller "executive committee" reports to the Surgery Committee, carries out the policies, and manages daily operations.

Members of the Surgery Committee should include representatives of the senior hospital administration as well as medical staff and nursing leaders. Depending on the size of the facility, the executive committee typically consists of the perioperative nursing director, an anesthesiologist, and a surgeon. Many ORs also have a medical director for the OR, typically a paid position, who works in tandem with the surgical services director. (Characteristics of good governance are in the sidebar.)

## Select members carefully

Physician membership needs to go beyond titles, Stroud advises. "You need individuals in medical staff leadership roles who come to meetings and who share passion about moving forward with evidence-based practices."

Advocate Lutheran General (ALG) Hospital in Park Ridge, Illinois, which helps to lead Advocate's SaferSurgery effort, has a 9-member Surgical Services Executive Committee (SSEC) and a daily operations team.

SSEC members include the vice president for medical management (chief medical officer), the

## Ten components for safer surgery

The components of Advocate Health Care's SaferSurgery initiative:

1. Perioperative governing body
2. Single path for surgical scheduling
3. Preanesthesia testing (PAT) with standardized protocols/hospitalists
4. Document management system for scheduling and PAT
5. Excellence in sterile processing
6. Crew resource management
7. Implementation of WHO Surgical Safety Checklist
8. Daily huddle
9. Error reporting
10. Just culture.

chief operating officer, the chair of anesthesia, the chair of surgery, the executive service line leader for surgery (nursing leader), the OR business manager, the medical director of the main OR, and the chairs of orthopedic and OB-GYN surgery.

The SSEC oversees the block schedule and budget, monitors operational and quality metrics, enforces policy, and sets the agenda for performance improvement.

### Designate a daily management team

ALG's daily management team consists of Cindy Mahal-van Brenk, MS, RN, CNOR, the executive service line leader; David Young, MD, an anesthesiologist and medical director of preanesthesia testing; and John White, MD, the chair of surgery. Dr Young is also a consultant with Surgical Directions.

Leadership has helped to propel Advocate Health's performance in the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP). Advocate has achieved superior results on morbidity and mortality, urinary tract infection, and surgical site infection. The system's performance on quality metrics has also earned favorable reimbursement rates from Blue Cross.

### Keep motivations in mind

In establishing a governance structure and selecting committee members, Stroud notes, "You need to have an eye toward what motivates everyone who has a seat at the table."

Some members will participate because they believe deeply in the organization's mission and others because they benefit personally or professionally.

## Perioperative governance: Key characteristics

The surgical enterprise is led by a perioperative governing body that functions like a board of directors.

### Functions

The governing body:

- manages department resources including:
  - OR and postanesthesia care unit utilization
  - OR scheduling
  - block time qualifications and allocation
  - block time utilization by surgeon and/or group.
- monitors and manages key performance indicators with:
  - defined data elements
  - clear definitions
  - consistent methodology.

### Qualifications

Governing body members are those who:

- put self-interest second to the organization's interest
- understand the organization's financial situation
- are politically astute
- are effective negotiators
- are active listeners
- act as champions
- accept accountability.

*Compiled from information provided by Deloitte Healthcare Consulting, Sullivan Healthcare Consulting, and Surgical Directions.*

### Establish responsibility and accountability

Responsibilities and accountability for the Surgery Committee and operations team need to be clearly outlined. That extends to policies that govern clinical quality as well as operational issues.

The block schedule is an example. No matter how well designed initially, a block schedule "will never be sustained if you don't have a governance structure that says, 'These are the rules. If you don't follow them, there will be consequences. If you do follow them, we will do everything in our power to make your life as easy as possible,'" says Randy Heiser, MA, of Sullivan Healthcare Consulting.

He adds that in his experience, "98% of surgeons are happy with that model. They want to

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know the expectations. They want an OR that respects their time.”

Active management is also critical for safety.

“When front-line OR staff believe in the governance structure and are supported for doing the right thing for patients, that is when potential incidents turn into near misses,” Heiser says. “But when nurses believe the only result from speaking up will be to be chastised by physicians, they will let things go and hope someone else catches problems.

“On the other hand, if the governance structure backs them, they become strong advocates for patients.”

### **Build in accountability**

At ALG, the SSEC sets direction, monitors progress, and allocates resources for clinical quality improvement initiatives.

Mahal-van Brenk reports to the committee regularly on clinical quality measures as well as on good catches and any sentinel events.

“This information is all shared with them,” she says. If there are outliers in the metrics, members ask, “Where is our gap? How can we hardwire this process?”

### **Data for decision making**

ALG’s perioperative leadership team monitors a variety of reports and dashboards to track how the department is meeting the system’s metrics for health outcomes, finances, patient satisfaction, and staff and physician satisfaction.

Transparency is essential for the committee to be effective, she notes. “You have to bring the issues to the table. I can say anything in that group, and they can say anything to me. We challenge each other continuously to be better and to do what’s best for the OR.” ❖

—Pat Patterson

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# Stryker's Neptune recall raises stakes for compliance

**S**trict requirements needed to comply with a recall for the Neptune brand of roving suction devices are raising questions and concern for ORs whose facilities continue to use the devices.

The recall of the Neptune Waste Management System from Stryker, used to collect and dispose of fluid waste, was initiated in June 2012 after the company received reports of serious tissue damage, including 1 death. Hospitals unable to find a suitable alternative to using the Neptune 1 Silver and Neptune 2 Ultra were required to file a certificate of medical necessity (CMN) if they chose to keep using the affected products.

Since then, further action has been taken by the Food and Drug Administration (FDA) and Stryker. Facilities that continue to use the Neptune 1 Silver and the Neptune 2 Ultra had to file an update to their CMN by March 25.

Under the CMN, these facilities must meet detailed requirements, including a 9-point presurgery checklist, or risk having the CMN revoked.

Though Neptune Gold and Bronze users do not need to use the presurgery checklist, they must agree to conduct training, ensure personnel are informed about the incidents, and make sure their devices have warning labels.

During its investigation, the FDA also advised Stryker that the Neptune 1 Silver and Neptune 2 Ultra lacked the necessary regulatory clearance.

## Adverse events

The requirements come after the reports of injuries and death involving incorrect application of the Neptune's high-flow suction.

Incidents recorded in the FDA's adverse events database show high-flow suction was connected to chest tubes in at least 2 cases and to a Jackson Pratt drain in 1 case (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>).

In one report cited by the FDA, a patient died after the Neptune was connected to the chest tube during a pneumonectomy, and the suction pulled the heart muscle from its left position in the chest, causing a tear in the aorta.

## Worry about the consequences

OR managers and directors at the facilities that continue to use the Neptune 1 Silver and Neptune

2 Ultra worry about the consequences of meeting the CMN requirements.

One concern is that the Neptune checklist will divert the surgical team's attention from the Joint Commission's Universal Protocol for preventing wrong-site surgery, raising the risk of an error.

Another worry is that reverting to conventional methods for fluid waste disposal could subject OR personnel to the risk of bloodborne pathogen exposure. The Neptune system's rovers collect large amounts of surgical fluids and flush them away through a docking station without exposure to the staff.

## Initial recall

In response to the reports, Stryker in June 2012 recalled the instructions for use (IFU) of the Neptune waste management system.

The IFU did not specifically warn against connecting the high-flow Neptune suction to a passive drainage tube. Stryker revised the IFU and in October 2012 instructed customers to educate users on the revisions and apply warning labels to all Neptune devices, cautioning that the suction is dangerous if not used properly.

## Requirements raised

Stryker issued stricter requirements on February 20 after further incidents occurred in facilities that continued to use the Neptune models under the CMN. FDA audits found a number weren't complying with the initial requirements. Among the new requirements are:

- Train all users (ie, surgeons, residents, anesthesiologists, nurses, technicians, health profession students) and make them aware of the risks associated with the device.
- Keep a master list of all personnel who have been trained on the use of the device.
- Inform all users that additional adverse events have been reported.
- Ensure that warning labels are present on each device.
- Implement a 9-point pre-use checklist, which the circulating nurse must complete before every procedure. Stryker will audit these records to ensure use of the checklist. Failure to complete the checklist form is grounds for revoking the CMN.

- Identify a training facilitator for each facility to ensure implementation of the checklist, and partner with Stryker for additional training.
- Complete a business reply form acknowledging these actions have been taken.

In a March 27 update, the FDA acknowledged facilities' concerns about the requirements but simply referred users to the Stryker Neptune website for information to carry them out (<http://neptunecustomer.com/>).

### Safety issues

Though the deaths and injuries that have occurred are tragic, the numbers are low considering the number of Neptune units in hospitals and the years they have been used, notes Chris Lavanchy, engineering director of the Health Devices Group at ECRI Institute, who says he has discussed the recall with both Stryker and the FDA. The nonprofit institute began tracking the recall last year and has issued alerts and special reports for its subscribers.

"These machines have been used since early 2000, and we're just hearing about a few of these incidents in the last 3 years," he says.

### How did this happen?

The Silver model, which is associated with several of the events, seems to have a relatively narrow range of vacuum levels (254-483 mmHg), biasing suction toward the high side that could be injurious when applied to tissue, Lavanchy notes.

"Whether that characteristic of the Silver actually was responsible for these incidents, we can't say, but it has been something people have speculated about," he says.

The range for the Gold units is broader (50-530 mmHg), and the vacuum level can be turned down so the suction is not as powerful.

The Ultra model, a newer version of the Gold, has the option of displaying the vacuum level in different units of measure—millimeters of mercury (mmHg), inches of mercury (inHg), and kilopascals (kPa).

In the US, mmHg is commonly used, and inHg is used rarely; kPa, seldom used in the US, is more common in Europe.

A problem could arise, Lavanchy notes, when the Ultra is inadvertently set on a unit of measure other than mmHg, which could cause users to think they are applying a lower level of vacuum than they actually are. For example, 250 mmHg would be 10 inHg and 33 kPa. Again, it's not known whether this contributed directly to the incidents.

Regardless of the type of suction applied, he says, "It is the responsibility of the person using the suction to verify the level of the suction and whether that is safe for the tissue you're applying it to."

### Concern about alternatives

Reverting to conventional wall suction means collecting waste in suction canisters, Lavanchy

notes. Rather than having fluids always contained by the rovers, the staff must either apply solidifiers so the canisters can be disposed of as regulated medical waste or dump the canisters manually, potentially exposing them to blood-borne pathogens. This potential for exposure and compliance with Occupational Health and Safety Administration regulations are the reasons many facilities adopted enclosed waste management systems such as the Neptune in the first place.

A major question is whether the risk to patients of using a Neptune system is greater than the risk to staff from emptying canisters of blood and body fluids, he says.

In looking at alternatives, hospitals have questioned whether they should replace their Neptunes with another enclosed waste management system, which might end up having the same requirements down the road.

The FDA has told ECRI Institute that it is not actively looking at other companies at this time, but that doesn't mean it won't in the future, Lavanchy says.

### Regulatory clearance

The original FDA clearance was for the Stryker Neptune Gold, he notes. After receiving the adverse event reports and looking into the matter, the FDA determined that because the Silver and Ultra models had somewhat different features than the Gold, they were not equivalent and thus required separate 510(k) clearance. Whether to apply for a new 510(k) when a device is modified can be a judgment call for the company, Lavanchy notes. The company must determine whether the new model entails safety or efficacy issues that warrant a new 510(k) application.

### Regulatory status

The Neptune-1 Gold and Bronze devices continue to be legally marketed, and there is no change in their status, although the Gold is no longer being actively marketed, Stryker stated. Regarding the other models:

- Neptune 1 Silver: The company has decided not to submit a 510(k) and will withdraw this model from the market. All support for that device will stop by March 1, 2014.
- Neptune 2 Ultra: Stryker has submitted a 510(k) but does not know when or if the device will be cleared. The FDA has requested additional information. Stryker says it is working to respond to the requests.

Stryker and the FDA recommend that users of the Neptune 1 Silver and Neptune 2 Ultra transition to a legally marketed device as soon as possible. ♦

—Judith M. Mathias, MA, RN

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# Trauma center's mortality rate drops dramatically with use of new protocols

**T**rauma events occur every 5 minutes in the United States, and 30% of trauma patients die within 120 minutes of the event because of major organ injuries that lead to heavy blood loss.

Better outcomes are achieved when care is initiated within 60 minutes, a time frame commonly referred to as the "golden hour."

Because of the rapidly evolving healthcare environment, trauma centers are continually challenged to improve the care delivery process for critically injured patients. In 2009, Houston's Memorial Hermann-Texas Medical Center cam-

pus identified an opportunity to improve care and developed a more systematic delivery approach for managing trauma patients.

"The main objective was to create a dedicated trauma OR team and eliminate the need for the circulator to leave the OR," explains Darlene Murdock, BSN, BA, RN, CNOR, Clinical Nurse IV.

After instituting the dedicated OR and trauma team—among many other protocols led by the affiliated physician team and the dedicated nursing staff—Memorial Hermann-Texas Medical Center, one of the nation's busiest Level I trauma centers, improved its mortality rate for trauma patients by 62%.

"We feel confident that the dedicated OR and trauma teams played a large role in providing more efficient quality care," adds Murdock.

## Trauma room designated

"Prior to our initiative, we did not have a dedicated trauma OR and staff," says Murdock.

There are 39 ORs, she notes. Because trauma happens without notice, the circulating nurse was at times leaving the room to obtain the necessary equipment for the trauma case. To ensure the highest level of care was provided, the leadership team instituted a change.

In 2009, the OR director and trauma chief designated the largest of the 39 ORs

## RN TRAUMA ROOM CHECKLIST

WIPE DOWN ROOM (INCLUDING PHONES, COMPUTERS, & ALL EQUIPEMENT)	
<b>EQUIPEMENT</b>	<b>CRASH CARTS</b>
BED – BASE TOWARDS ANESTHESIA, REMOVABLE HEADPIECE ATTACHED AT THE FOOT, TRAUMA SHEETS, ARM BOARDS, ROLLER, ELECTROSURGRERY ELECTRODE PAD CONNECTED, UNDERBODY FORCED AIR WARMING BLANKET CONNECTED TO MACHINE AT THE FOOT OF THE BED	UNPLUG TO TEST DEFIBRILLATOR, AND PLUG IT BACK IN AFTER TESTING. CHECK EXPIRATION DATES ON SUPPLIES ON TOP AS WELL AS SUPPLIES INSIDE AS INDICATED BY THE CARD ON TOP
ELECTRIC SUCTION/SMOKE EVACUATION SYSTEM / WALL SUCTION	TRAUMA ROOM (SHOULD HAVE STERILE EXTERNAL DEFIBRILLATOR PADS)
ELECTROSURGRERY UNIT (BIPOLAR ADAPTER)	OR 8 (ROBERTSON CORE)
ARGON GAS BEAM COAGULATOR	PEDI 5/6 (ROBERTSON CORE)
FLUID WARMER	PEDI 3/4 (HALLWAY)
HEADLIGHTS (BOXES AND CROWNS X2)	HALLWAY BY OR 10
COMPRESSION STOCKINGS DEVICE	OR 38/39 X2 (HERMANN CORE)
UPPER / LOWER BODY FORCED AIR WARMING SYSTEM MACHINES	OR 30 (HERMANN CORE)
IRRIGATING BIPOLAR W/ PEDAL	OR 23 (HERMANN CORE; SHOULD HAVE EXTERNAL DEFIBRILLATOR PADS)
CRANIOTOMY DRILL (HOSE, FOOT PEDAL, FILTER)	MALIGNANT HYPOTHERMIA CARTS (OR 8 ROBERTSON CORE; HALLWAY NEAR OR 27)
NITROGEN HOSE CONNECTED TO WALL	
TOURNIQUET (BOTH HOSES ATTACHED)	
<b>GENERAL PREP STAND</b>	
BETADINE PREP	ADEQUATE PAPERWORK (I.E BLOOD REQUEST FORMS, COUNT SHEETS, ANES.)
CHLORHEXIDINE PREP	FORCED AIR WARMING BLANKET
COMPRESSION STOCKINGS	CLIPPERS W/ CLIPPER HEAD
MARKING PEN	INDWELLING URINARY CATHETER KIT
<b>NEURO PREPSTAND</b>	
CLIPPER W/ BOTH TYPES OF CLIPPER HEADS	HORSE SHOE HEADREST AND SKULL PINS W/ BACITRACIN OINTMENT
4X4'S (X2)	TAPE
CHORAHEXIDINE PREP	ALCOHOL
<b>NOTES:</b>	
<b>PLEASE MAKE SURE ROOM SUPPLIES ARE ADEQUATELY STOCKED</b>	
CHECKED BY: 7:00 - _____ 19:00 - _____	
DATE: _____	

Checklists and surveys reprinted with permission from Memorial Hermann-Texas Medical Center.

## SURGICAL TECH TRAUMA ROOM CHECKLIST

WIPE DOWN ROOM (INCLUDING TABLES, LIGHTS, AND ALL EQUIPEMENT)	
<b>INSTRUMENTS (MAKE SURE ALL SETS ARE COMPLETE)</b>	<b>NEURO TRAUMA SUPPLIES</b>
TRAUMA LAP SET	ADULT CRANIOTOMY PACK
LAP B SET	ABSORBABLE GELATIN COMPRESSED SPONGE
SELF RETAINING RETRACTOR & BLADES	ABSORBABLE HEMOSTATIC AGENT
	NEURO DOCTOR'S BINS (RESTOCK)
TRAUMA CHEST/RIB SET	CRANIOTOMY HEADREST
STERNAL SAW	<b>SUPPLY CARTS (RESTOCK)</b>
CV SPECIALS	BEDSIDE CART
INTESTINAL SET	TRAUMA CART / NEURO CART
LONG INSTRUMENTS SET	COMPUTERIZED ROLLING STAPLER CART- PLEASE PLUG IN
TRAUMA MAYO TRAY	TRAUMA COMPUTERIZED ROLLING SUPPLY CART X2 --PLEASE PLUG IN
TRAUMA TOWEL CLIPS	
CRANIOTOMY SET	
CRANIOTOMY DRILL	
CRANIAL PLATING SYSTEM	
<b>GENERAL TRAUMA SUPPLIES</b>	
GENERAL TRAUMA PACK	
0, 2-0, 3-0, 4-0 SILK TIES; 2-0, 3-0 SILK SH; 2-0, 3-0 SILK SH POP OFFS; 2-0, 3-0 VICRYL SH	
SKIN STAPLER	<b>NOTES:</b>
GREEN TOWELS X3	
BLUE DISPOSABLE TOWELS	
WHITE DISPOSABLE TOWELS	
3 PACK OF GOWNS	
GREEN SHEETS	
PAPER GOWNS X2	
STERILE MAYO TRAY	
LAP CHOLE DRAPE	
LONG ELECTROCAUTERY TIP	
FLUID WARMER DRAPE	

**PLEASE MAKE SURE ROOM AND SUPPLY CARTS ARE ADEQUATELY STOCKED.**

CHECKED BY: 7:00 - \_\_\_\_\_ 19:00 - \_\_\_\_\_

DATE: \_\_\_\_\_

"We made check-off sheets for both circulators and surgical technicians to ensure nothing was missed," explains Murdock. "This redundant system has served as a tremendous help," she says.

The circulators are accountable for the room setup and must confirm room readiness by turning in completed check-off sheets to the charge nurse at 7 am and 7 pm.

"Because of the check-off sheets, supplies and equipment are always in the same place now, so when a surgeon asks for something, you know right where to get it," says Naomi Brown, BSN, RN, OR surgical nurse III.

### Trauma team initiated

Designating a team of RNs and surgical technicians just for the trauma room

for trauma, and after a thorough overview of the process and best practice, the following changes were made:

- The room was reorganized and stocked with trauma surgery equipment and supplies.
- A check-off sheet and protocols were put in place to ensure all equipment and supplies were present.
- Supply cabinets were labeled for ease of retrieving supplies.
- Computerized rolling trauma supply carts were streamlined to ensure efficiency and complete charge capture.
- Instrument sets were streamlined, and additional instruments were ordered.
- Supplies were added to the trauma pack to eliminate time spent on opening individual packages.

### Check-off sheet implemented

In 2010 the check-off sheet was updated and made more user-friendly, and a second check-off sheet was created—now there is 1 for the circulator and 1 for the surgical technician, each with different supplies and equipment to check.

has been key to increasing patient safety, efficiency, and surgeon satisfaction, says Laura Keller, BSN, RN, OR clinical manager for the night shift.

"If you are always in the same room, you know where things are, you know where things belong, and you know how the room is set up," notes Keller. Familiarity with the team members also adds to the trauma surgeons' comfort level. "When things get tense in the room and the patient is crashing, they don't have to worry. They know we know what we need to do," says Keller.

Keller has 4 RNs and 5 surgical technicians who rotate through the 12-hour night shift. There are 10 trauma surgeons. To create the team, Keller says she asked the people she knew could handle the stress of being in the trauma room.

"No one told me no," says Keller, "but they didn't want to do it every night. That is why we rotate them."

### Surveys show satisfaction

Surveys were developed to see how the circulators and trauma surgeons perceived the efficiency and preparedness of the trauma room and team. The surveys were developed by Murdock in August 2012 to measure the success of the initiative. On a monthly basis Murdock and Brown

## Surgeon Survey

The Night Shift periOperative Performance Improvement Committee is seeking your input to better prepare our trauma rooms. Your response to this survey is greatly appreciated.

Date: \_\_\_\_\_ OR# \_\_\_\_\_

Did the circulator have to leave the room for equipment or supplies? Yes or No

If yes what item(s) did the circulator have to go and retrieve? \_\_\_\_\_

Overall rate the room preparedness for the nursing staff for this trauma you just completed.  
(1 to 5 with 5 being fully prepared)      \_\_\_5\_\_\_4\_\_\_3\_\_\_2\_\_\_1

Comments \_\_\_\_\_

## Circulator Survey

The Night Shift periOperative Performance Improvement Committee is seeking your input to better prepare our trauma rooms. Your response to this survey is greatly appreciated.

Date: \_\_\_\_\_ OR# \_\_\_\_\_ Case Cart # \_\_\_\_\_ Patient's ASA \_\_\_\_\_

Check one: \_\_\_General\_\_\_ \_\_\_Neuro\_\_\_ \_\_\_Ortho\_\_\_ \_\_\_Poly-trauma\_\_\_ \_\_\_Pedi\_\_\_

Did you have to leave the room for equip or supplies? Yes or No

If yes what item did you have to go and retrieve? \_\_\_\_\_

Overall rate the room preparedness for the trauma you just completed.  
(1 to 5 with 5 being fully prepared)      \_\_\_5\_\_\_4\_\_\_3\_\_\_2\_\_\_1

Comments \_\_\_\_\_

evaluated the results and shared the results with everyone on the trauma team. This process continues today; the feedback on how the team operates ultimately impacts patient care, which is the department's highest priority.

After each case the surgeons complete a survey to tell the team how the case went and how well they thought the team worked, says Murdock. "The surgeons want to fill out this survey; they ask for it at the end of each case," she says.

The circulators also fill out the survey, commenting on the room setup and noting whether they had to leave the room for anything. Survey results indicate a significant decrease in the number of times the circulator has to leave the room for equipment and supplies.

"Our survey has really helped us to determine where we are and where we need to go," says Murdock.

Judging by a 4-month average of results from 108 completed surveys, a majority of circulators and trauma surgeons are satisfied with the trauma room setup. The average score was 4.6 on a scale of 1 to 5.

To ensure the hospital continues to move toward providing the highest level of quality care, Murdock says the team is in the process of implementing AORN's recommended practice for the trauma room temperature to remain at 85°F until the patient becomes normothermic, to help improve outcomes. ❖

—Judith M. Mathias, MA, RN

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# II. Handoffs, Briefings, Checklists, Time-outs



# A cure for the distracted time-out before surgery

**D**oes this ever happen in your OR? The circulating nurse calls for the time-out. But the team doesn't seem to be focusing. Music is playing, an assistant is draping the C-arm, and team members are talking about the football game. The circulating nurse tries again and gives up.

A cognitive psychologist from the University of Minnesota says she often saw distracted teams in OR observations at 8 hospitals in the state.

The psychologist, Kathleen Harder, PhD, used the findings to develop the Safe Surgery Process to prevent wrong surgery. She is presenting the findings and rationale in workshops as part of the Minnesota Time-Out Campaign. The campaign, sponsored by the Minnesota Hospital Association and Minnesota Department of Public Health, is part of a 3-year effort to end these adverse events.

Many time-outs were "completely dysfunctional. They just ticked off a list. People weren't listening," says Harder, who is director of the Center for Design in Health at the University of Minnesota. The observations at 5 hospitals were funded by the Minnesota Department of Health; the University of Minnesota Medical Center (UMMC), Fairview, in Minneapolis funded observations at its 3 facilities.

## Progress in prevention

The project may be starting to bear fruit. The number of days between wrong-site events rose from an average of 11 days before the time-out campaign to about 30 days in the first 6 months afterward. Overall, wrong-site procedures in Minnesota fell by 23% to 24 in 2011.

"If this trend continues, it will mark significant progress towards eliminating this nearly always preventable event," the health department said in its January 2012 report. More facilities reported they are using the Minnesota Time-Out both in and outside the OR.

Root causes for wrong-site procedures in 2011 included:

- source documents that did not indicate laterality
- difficulty identifying the correct vertebra for spinal procedures because of unusual anatomy or multiple degenerated vertebrae
- lack of a policy for site marking or a time-out when administering regional blocks.

## Engaging the team

The campaign's first phase was to reinforce the 5-step Minnesota Time-Out for every patient, every procedure, every time.

Harder says she developed the time-out steps to engage all team members cognitively. Each member has a specific role intended to engage him or her in verifying the correct patient, procedure, and site. The time-out steps are based on an analysis of the reported errors as well as on human and cognitive factors that come into play during surgery, such as distractions, interruptions, and confirmation bias; that is, the tendency to see only information that confirms what we already think is true. The culture of the OR also plays a role, including a perceived hierarchy that inhibits team members from speaking up if they have a concern.

Harder says sharing the research findings and rationale from cognitive psychology has helped in discussing the purpose and merits of preoperative verification with skeptical surgeons.

Carol Hamlin, MSN, RN, director of departmental performance for perioperative services at UMMC, Fairview, says she has heard from staff firsthand that "the rationale makes a world of difference in willingness to practice the process as designed."

These are the key verification steps with the rationale.

## 'Sources of truth'

In the prep area, before marking the site, the surgeon verifies the correct site by consulting the "sources of truth"—the consent form, surgeon's orders, and imaging if applicable. If able, the patient is asked to state the procedure and site. If there is a discrepancy with any of these information sources, the discrepancy is resolved before the surgeon marks the site.

*Rationale:* Marking the surgical site from memory can lead to errors. "Given the fallibility of human memory, relying on memory is not a good idea," Harder says. Though surgeons "may think their memory is stellar, there's a lot of evidence it's not."

## Transport to the OR

Before moving the patient to the OR, the person doing the transport double checks that the site is marked correctly, comparing it with the consent form.

### Step 1

The surgeon calls for the time-out just before the incision after the patient is prepped and draped.

“If the surgeon starts the time-out, it shows it is really important, and we are going to do this as a team,” says Kathleen Harder, PhD.

“Also, the surgeon knows when he or she is ready to begin the procedure.” When the surgeon calls for the time-out, the team ceases activity.

### Step 2

The circulating nurse reads directly from the consent form that was verified during the preop process, stating the patient, procedure, site, and laterality. The nurse does not rely on memory.

### Step 3

The anesthesia provider reads the patient’s name from the anesthesia record; states a shorthand version of the procedure, and states the antibiotic, dose, and time from administration. (This is the only part of the time-out not focused on the correct patient, procedure, and site.)

### Step 4

The scrub person states a shorthand version of the case he or she has set up for and visualizes the site marking, stating, for example, “I see the site mark on the right knee.” Giving the scrub person a specific role helps to level the hierarchy.

### Step 5

The surgeon finishes the time-out from memory, by stating: “This is Mrs Smith, and she is having a right knee arthroplasty.” The reason the surgeon concludes the time-out is to listen to what everyone else has said. At this point, reciting the patient and procedure from memory verifies that the surgeon is cognitively engaged with the correct procedure.

*Rationale:* “We found that sometimes the patient was not marked in the preop area and made it all the way to the OR, but nobody said anything,” Harder says. “That told me the process was not engrained.”

### Introduce the patient

When the patient arrives in the OR, the transporting person introduces the patient, saying, “This is Sally Smith. She is here for a right hip replacement.”

The transporter confirms the patient’s identity with the circulating nurse and anesthesia provider. They check the patient’s ID band (medical record number and date of birth) with the consent form and anesthesia record.

*Rationale:* This step ensures that the correct patient has arrived in the correct OR and that the documents actually belong to that patient. “Sometimes, patients can end up in the wrong OR, or the wrong documents arrive in the OR, and it’s not caught,” Harder notes.

An added benefit of the introduction: The patient feels more comfortable.

“I’ve gone into places where this is fully implemented, and there is such a difference. The patient is made to feel at home,” she says.

### Prep the marked location

The site that is marked is the site to be prepped. When the surgeon marks the site in the preopera-

tive area, the mark must remain visible after prepping and draping.

If the site can’t be marked, as with teeth or ureteral stents, the mark is placed on an anatomical diagram that accompanies the patient to the OR and is referenced during prepping and time-out.

*Rationale:* “We found in observations that the mark was not always near the site. [Sometimes] it was more of a laterality marking, for example, on the left arm for a left breast procedure,” Harder says. That can lead to errors.

### Streamline the time-out

The briefing and time-out are separate processes. The time-out is held as the final check right before the incision. The briefing takes place earlier. The two were separated because the time-out was “flooded with information,” Harder notes. “The final safety check was not getting the due diligence it deserved.”

Conducting the briefing earlier also helps the case flow. “It’s a little late to discover just before the procedure that the necessary equipment isn’t in the OR or that an implant can’t be located.”

*Rationale:* The time-out is held right before the incision to “address memory confounds that can occur if the time-out is done before the surgeon scrubs,” Harder says.

In some cases she observed, the surgeon would do the time-out and then go out to scrub.

The surgeon might then chat with a colleague about another case.

“That can confound the information in the surgeon’s head,” she notes. “The surgeon can walk into the OR and do the wrong procedure. That has happened more than a few times.”

### **A role for each person**

In the time-out’s 5 steps, each person has a specific role, with the aim of engaging each team member cognitively and avoiding multitasking (sidebar).

The ability to multitask “is a myth in complex systems,” says Harder.

Performing the steps in this order has caught more than one prospective error, she says. “In Colorado, where Banner Health has implemented the Safe Surgery Process, it caught an error in the first week it was used.”

### **When to do the briefing?**

At UMMC, Fairview, “we had a lot of discussion about when to do the briefing,” Harder says. “We decided it could be done at any time from the case setup to just before the patient positioning.”

The point of the briefing is to ensure that the team has the “correct mental model,” she notes. Team members also introduce themselves if they don’t know each other. Research demonstrates that if teams do that, members are more likely to speak up if there is a concern.

The key to timing the briefing is that all 4 disciplines—surgeon, circulating nurse, anesthesia provider, and surgical technologist (ST)—must be present to share the same information.

Harder says some surgeons have asked why they can’t do a roving briefing; that is, talk separately with the circulating nurse, anesthesia provider, and ST.

The reason: All parties may not hear the same relevant information.

She once saw an anesthesia provider get upset with a surgeon because the surgeon had shared information only with the circulating nurse that was also relevant to anesthesia. That led to a problem in the patient’s care.

The briefing should not be confused with the case planning that comes earlier. The briefing is not the time to order equipment, for example.

“The preplanning needs to start when the patient is scheduled for surgery. The briefing is the last-minute verification of the plan,” says Hamlin.

The Minnesota campaign has a collection of tools to help with implementation at [www.mn-hospitals.org/index/timeout](http://www.mn-hospitals.org/index/timeout). ♦

—Pat Patterson

Watch a 5-minute video with the model time-out at [www.mha-apps.com/media/to.html](http://www.mha-apps.com/media/to.html)

*This article originally appeared in OR Manager, June 2012;28:12-14.*

# Adopting a ‘no interruption zone’ for patient safety

The time-out is called, but conversations are going on, and the staff is still assembling equipment. No one seems to be listening. Then during the case, the anesthesiologist has trouble hearing over the loud music and chatter. The circulating nurse needs confirmation on a specimen but can't get the surgeon's attention.

Distractions and interruptions happen in the OR as often as every 3 minutes, studies show. Do these distractions contribute to errors?

Researchers recently conducted a controlled study to find out. In a lab, 18 surgical residents performed laparoscopic cholecystectomies on a simulator. Each resident performed procedures both with and without distractions and interruptions. Distractions and interruptions were introduced randomly without residents being aware of the study's purpose. In results:

- 8 of 18 (44%) of the participants made major errors when there were distractions and interruptions
- only 1 of 18 (6%) did so when there were none.

## No-distraction strategies

Some ORs are taking steps to tame distractions during critical periods of cases. One strategy is the “sterile cockpit” or the “no distraction zone” (NIZ), a term more applicable to health care.

Aviation adopted the sterile cockpit years ago after an analysis of 78 accidents showed 72% were linked to distractions.

“On average, in aviation, there are 7 warning signs before an accident,” but distractions can keep a crew from recognizing them, says Steve Harden, an airline captain with LifeWings, who has consulted with hospitals on patient safety for 12 years.

The Federal Aviation Administration now has a rule saying that during critical phases of the flight, such as takeoff and landing, no conversations or paperwork not directly related to the flight operation are allowed. Pilots are suspended for violations.

## An NIZ for the OR

As in aviation, an NIZ in the OR is a quiet time during critical phases of a procedure triggered by a word such as “Delta.”

For example, an NIZ can be declared during the 3 phases of the World Health Organization (WHO) Surgical Safety Checklist: sign-in (brief-

## Tips: No interruption zone (NIZ)

- Agree on a term for declaring an NIZ, such as “Delta.”
- Customize the surgical safety checklist to include Delta.
- Have the surgeon reinforce the use of Delta during the briefing.
- Conduct interdisciplinary teamwork training on use of the NIZ.

ing), time-out, and sign-out (debriefing). The trigger word can also be used anytime during a procedure when a team member sees something amiss or requires quiet.

During an NIZ, the team:

- stops all conversation
- stops all unnecessary activity
- turns down any music
- addresses the situation in an engaged way.

“The bottom line is that the NIZ helps you build a wall between your team and distraction-induced errors,” Harden says.

## NIZ: The prerequisites

An NIZ can't be used in isolation, Harden stresses. To be effective, it must be part of a culture of patient safety and teamwork.

A safety culture accepts that because all procedures are performed by humans, errors will occur, no matter what tools or countermeasures are used. A safety culture is characterized by professional support, mutual respect, cross-checks, and the willingness of all team members to speak up if something seems amiss.

The record on speaking up isn't strong.

Based on results of safety climate surveys analyzed by the Agency for Healthcare Research and Quality in 2011, “we know that if any hierarchy is present in the interaction, over 50% of staff will not speak up,” says Harden.

Teamwork training, such as education in crew resource management (CRM) or TeamSTEPPS, an evidence-based teamwork system, helps to lay the groundwork.

In the training, interdisciplinary groups of physicians, nurses, and other personnel learn principles of patient safety, communication, assertiveness, and other methods that create more cohesive units.

"A collegial, interactive team catches and neutralizes mistakes, holds one another accountable, and backs each other up," Harden notes.

At Nebraska Medical Center, for example, before teamwork training, 69% of OR personnel say they would speak up, he says. That rose to 93% afterward.

### **Design in the buy-in**

Safety strategies like the NIZ and surgical safety checklists are most likely to be accepted and used consistently if they are designed or modified by front-line clinicians who will actually use them. The WHO checklist is intended to be modified to fit each organization's needs.

"The key principle is that the people who use a checklist are the ones who design it," Harden says.

"A mistake I see a lot of places make in the way they design or revise their checklists is to have it done by administrators in surgical services."

It's more successful if the checklist is modified by a multidisciplinary work group of nurses, techs, and physicians.

For physicians who sit on the work group, he adds, "You have to be crystal clear that they are representing their peers." The physicians agree that they will convey to their peers how the checklist is to be used.

### **Introducing the NIZ**

Nearly all procedural areas in the 6-hospital Memorial Health System, based in Hollywood, Florida, have adopted the NIZ, triggered by the word "Delta."

"When someone says 'Delta,' it means, 'I have a problem. Stop,'" says Jenny Kadis, MS, RN, CPAN, the system's director of clinical effectiveness.

A safety statement about using Delta is part of the surgical safety checklist.

During the briefing at the beginning of a case, the surgeon reminds the team about Delta by saying something like: "Speak up for safety. Look for red flags. Use Delta any time."

If the surgeon forgets, anyone else on the team can remind the surgeon to make the safety statement.

Delta is also called anytime during a case when a team member spots a problem. Some examples:

- A surgical technologist called a Delta when a piece of equipment wasn't working.
- An anesthesiologist called a Delta when there was a lot of music and chatter, and he needed to hear.
- A labor and delivery nurse called a Delta when a lap sponge was missing while she was counting on a c-section.

First, she said, "A sponge is missing." No one listened. She repeated the statement.

Again, no one stopped. "Then she said, 'Delta,' and they all stopped closing and looked up," Kadis recalls. The sponge was found with the placenta in the specimen bucket.

### **The right word**

It took a surprising amount of time to identify the right word for triggering the NIZ. Delta was suggested because of its tie to aviation.

There was considerable discussion about what Delta might mean in different clinical areas. Eventually, consensus developed. Now Kadis says Delta is recognized throughout the Memorial system.

### **Laying the groundwork**

Memorial began building the foundation for a safety culture in 2007 when it introduced CRM.

"That's the key to success, the willingness to fund training," Kadis says. "We brought it in with full support of the executive team." Even in the wake of the nation's economic downturn, Memorial continues to fund a CRM director position.

CRM training is mandatory for all personnel in procedural areas, including physicians, and the requirement is included in the medical staff bylaws. Aides, transporters, and unit secretaries also participate in training.

Physicians must train within 6 months of joining the organization. One cardiologist had his procedural credentials suspended until he completed the training class.

The chief medical officer is a driving force. During the rollout of the CRM training, he and Kadis targeted key physicians, visiting their offices, making phone calls, and following up to enlist champions.

### **Assertiveness for staff**

Having the staff feel comfortable with speaking up is essential for safety, Kadis notes. Memorial's staff receive training in assertiveness.

She's developed real-life scenarios so they can practice. Examples:

- A surgeon preparing to list 15 specimens at the end of a case says, "Listen, because I'm only going to say this once." How do you respond?
- A Delta is declared. A vendor who is in the OR is on the phone and won't get off. How do you handle the situation? (At Memorial, any person present in the OR is considered a team member and is expected to adhere to policies.)

### **Showing the value**

Physicians need to see there is something for them in participating, Kadis adds, saying, "We've worked hard to show value."

One way to show value is to record concerns that arise during debriefings at the end of cases and to act on them.

Circulating nurses fill out a debriefing form. The concerns are categorized, recorded in an Excel spreadsheet, and sent to the OR director, who assigns personnel to address them.

"That person is responsible for giving an update to the physician within 72 hours. They don't have to be solved by then," she notes.

### **Resolutions are recorded and quantified.**

Managers report regularly at the Department of Surgery meeting, saying, for example: "In the past 6 months, we've made 1,100 updates to preference cards. We've examined the lights in Room 10, and they're going to be replaced. We've had the vendor provide additional staff training on the video system."

They also share success stories: "During a briefing, we found out a baby was allergic to a medication, and only the circulating nurse knew."

Turnover time has improved because staff is more prepared for cases.

Business has also improved. After the OR director was able to document 50 delays caused by insufficient instrument sets for lap choles, the administration approved the purchase of additional sets, enabling more cases to be performed.

Kadis says she can't overemphasize the need for team training.

"People think CRM is just about building a time-out process," she says. "But it's not only the time-out; it's speaking up; it's working as a team; it's talking openly."

"There's so much more than just building the tools. Tools are great. But if you just read a poster, and you're not talking to each other, you might as well not bother." ❖

—Pat Patterson

*A copy of Memorial Health System's surgical safety checklist with the safety statement is in the OR Manager Toolbox at [www.ormanager.com](http://www.ormanager.com).*

*Steve Harden can be reached at [sharden@safepatients.com](mailto:sharden@safepatients.com). A recording of his OR Manager webinar, *Eliminating Distraction-Induced Errors, with further tips*, can be purchased at [www.ormanager.com](http://www.ormanager.com).*

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# Has your checklist effort stalled? Some advice on how to restart it

*Fifth in a series on ten elements of safer surgery.*

**T**his marks the fifth year since the worldwide roll-out of the World Health Organization (WHO) Surgical Safety Checklist. In some hospitals, the checklist has taken root and become a way of life. In others, acceptance is slower. For others, after an initial burst of enthusiasm, the checklist has become just a series of tick boxes.

What's the difference between a checklist effort that is alive and one that lags?

For this article, experts, including the Safe Surgery 2015 team led by surgical checklist pioneer Atul Gawande, MD, offer 12 key factors for ensuring that the checklist fulfills its true purpose—serving as a tool to aid team communication and minimize risks to patients.

The first question: Was the checklist implemented effectively to begin with?

A study of 5 hospitals in Washington State indicates the effort can falter without strong leadership by senior clinicians and extensive education. Conley et al found effective implementation depended on leaders explaining the rationale for the checklist persuasively and showing how to use it, along with extensive education, including demonstrating best practices; pilot testing; providing coaching and feedback; and anticipating the need for long-term training, observation, encouragement, and quality control. When leaders didn't provide this groundwork, and clinicians didn't understand the checklist's rationale or weren't adequately prepared to use it, they became frustrated and disinterested, and use of the checklist fell off, even though the hospital mandated its use.

## **Safe Surgery 2015**

To foster checklist adoption, the Harvard School of Public Health in Boston, home of Dr Gawande's initiative Safe Surgery 2015, has partnered with the South Carolina Hospital Association (SCHA) to have all hospitals in the state adopt the checklist for routine use in their ORs by the end of 2013. The effort recently expanded to North Carolina and Virginia.

Based on the evidence, Safe Surgery 2015 estimates successful implementation and proper use of the checklist could save more than 500 lives per year in South Carolina.

The Harvard team offers webinars, conference calls, and other resources to help ORs introduce

the checklist meaningfully and monitor its impact. Free resources are at [www.safesurgery2015.org](http://www.safesurgery2015.org).

Here's advice to help ensure the checklist continues to be a living document in your ORs.

## **A process, not a checklist**

Keep in mind that safe surgery is a process, not just a checklist, advises Kathleen Harder, PhD, a cognitive psychologist and human factors expert at the University of Minnesota.

"The focus is on the process—a checklist alone will not prevent an error if the process is not done well."

Harder assisted the Minnesota Hospital Association and the Minnesota Department of Health in developing the state's Safe Surgery Process and has conducted workshops throughout the state. The process includes a 5-step time-out based on human factors research and observations in hospital ORs (sidebar).

## **Identify the critical elements**

Modify the checklist to meet the needs of your organization and individual specialties, and involve the teams that will use the checklist. Teams will be more likely to use the checklist if it's relevant to their needs.

"Ask what your critical issues are, and make sure those are on your checklist," advises David Young, MD, director of presurgical testing at Advocate Lutheran General (ALG) Hospital in Park Ridge, Illinois, where the checklist is part of the Safer Surgery process.

## **Approach physicians one-on-one**

Approaching physicians individually, though time-consuming, is an effective way to get buy-in, Bill Berry, MD, MPH, MPA, program director for Safe Surgery 2015, noted in a recent webinar.

In working with hospitals, he has found that 10% to 20% of physicians immediately see the checklist as helpful and will actively participate.

"This is generally where you find your champions," he said.

Of the remaining physicians, about half are passively compliant and won't fight the checklist. "This is the group I think you can influence with a one-on-one conversation." And those who are resistant or even hostile might also be persuaded not to actively oppose the checklist if a champion explains it to them.

Safe Surgery 2015 offers these tips for one-on-one conversations:



## Minnesota time-out

### Step 1

The surgeon calls for the time-out just before the incision after the patient is prepped and draped.

"If the surgeon starts the time-out, it shows it is really important, and we are going to do this as a team," says Kathleen Harder, PhD.

"Also, the surgeon knows when he or she is ready to begin the procedure."

When the surgeon calls for the time-out, the team ceases activity.

### Step 2

The circulating nurse reads directly from the consent form that was verified during the preop process, stating the patient, procedure, site, and laterality. The nurse does not rely on memory.

### Step 3

The anesthesia provider:

- reads the patient's name from the anesthesia record
- states a shorthand version of the procedure
- states the antibiotic, dose, and time from

administration. (This is the only part of the time-out not focused on the correct patient, procedure, and site.)

### Step 4

The scrub person:

- states a shorthand version of the case he or she has set up for
- visualizes the site marking, stating, for example, "I see the site mark on the right knee."

Giving the scrub person a specific role helps to level the hierarchy.

### Step 5

The surgeon finishes the time-out from memory, by stating: "This is Mrs Smith, and she is having a right knee arthroplasty."

The reason the surgeon concludes the time-out is to listen to what everyone else has said. At this point, reciting the patient and procedure from memory verifies that the surgeon is cognitively engaged with the correct procedure.

- Don't try to "fix" a physician with the checklist. The goal is to open their minds, engage them, and get them to try the checklist.
- Have a respected peer talk with them one-on-one.
- If you believe a physician isn't going to use the checklist, don't try to force it.
- Ask the physician not to obstruct others in using the checklist.

(Resources for how to conduct a one-on-one conversation are at [www.safesurgery2015.org](http://www.safesurgery2015.org).)

Peer pressure can make a difference.

One ambulatory surgery center posted a photo of each physician who agreed to try the checklist, notes Lizzie Edmondson, senior project manager for Safe Surgery 2015.

When one hold-out asked why his photo wasn't posted, he was told, "Those are the people who are checklist champions." He agreed to try the checklist so his photo could be displayed.

### Give each team member a role

"We have speaking parts for the surgeon, anesthesiologist, and nurse," says Jennifer Misajet, MHA, RN, CNOR, regional director of perioperative services for Kaiser Permanente's Northern California region based in Oakland.

"If you have a speaking part, you are more engaged because you have something to contribute to the activity."

The Kaiser region has embedded the checklist as part of its Highly Reliable Surgical Teams (HRST) initiative, which involves all of the region's medical centers.

Advocate Lutheran General uses a challenge-and-response approach for the OR portion of the checklist.

"You want to require an answer to each part," explains Cindy Mahal-van Brenk, MS, RN, CNOR, executive service line director for surgery.

Here's an excerpt:

*Circulator to anesthesia provider:* "Would you please state the patient's name?"

*Anesthesia provider:* "David Smith."

*Circulator:* "Please tell me which antibiotic you gave."

*Anesthesia provider:* "I gave 1 g Ancef at 15:30."

*Circulator:* "Is the patient on a beta-blocker?"

*Anesthesia provider:* "No beta-blocker is indicated."

*Circulator to the surgeon:* "Dr Jones, please state the procedure you will be performing."

*Surgeon:* "I am performing a left hemi-arthroplasty."

*Circulator:* "Is the site marked?"

*Surgeon:* "The site is marked."

### Add teamwork training

Team training provides a foundation for communication, the checklist's fundamental purpose. Studies show combining team training with the checklist improves outcomes.

In a pilot study led by Bliss et al, use of a checklist plus structured team training produced a statistically significant difference in 30-day morbidity. The report is in the December 2012 Journal of the American College of Surgeons.

In a study of 74 facilities in the Veterans Health Administration published in 2010, Neily and colleagues found an 18% reduction in mortality when team training and the checklist were combined.

## Safer Surgery series

This series of articles covers Ten Elements for Safer Surgery developed by Advocate Health Care, a 10-hospital system in the Chicago area.

Previous articles in the series focused on:

- OR governance: January 2013
- Safer surgical scheduling: February 2013
- Presurgical assessment: March 2013
- Excellence in sterile processing: April 2013.

### Stay vigilant

Never stop observing how teams use the checklist, the Harvard team advises.

"You can never turn your attention away. You have to continue to talk about it and continue to keep people excited about doing it," Edmondson suggests. Regularly observe teams using the checklist and offer coaching as needed, she advises. During the observations, ask surgical teams for feedback about the checklist effort and what could be improved. (Safe Surgery 2015 offers an observation tool on its website.)

In Kaiser Northern California, perioperative nurse managers audit regularly.

"If you don't do audits and see teams using the checklist, you will get drift," Misajet says.

Managers use a rounding tool to guide audits and offer coaching on the spot if needed. If they see themes that need to be addressed, they bring the issue to the facility's HRST group for discussion.

### Harness the debriefing

Hospitals that are able to sustain the checklist do the sign-out (debriefing) phase of the checklist really well, Edmondson says.

During the debriefing, in addition to confirming counts and specimens, the team reviews any concerns about the patient as well as what could have gone better.

These hospitals have a process for tracking the concerns, fixing them, and giving feedback to the clinicians who raised the concerns.

Fixing problems gives OR teams an incentive to continue with the checklist and debriefings because their lives get easier as a result.

During one debriefing, Misajet notes, a surgeon raised concern about the state of the laparoscopic surgery light cords.

The manager enlisted the sterile processing department, which checked the cords in all of the sets and repaired and replaced cords as needed.

The surgeon, skeptical that the problem had been fixed, was invited to view and test cords from about a half-dozen sets and saw they all worked.

"He realized the value of the debriefing," Misajet notes.

Nurse managers are piloting new software from Bowwave (Great Falls, Virginia) that is in-

stalled on their iPads and customized for tracking debriefing issues (sidebar).

### Take your safety pulse

A safety culture survey provides a way to measure nurses' and physicians' responses to patient safety initiatives like the checklist over time, according to Safe Surgery 2015. It's a way of taking the safety culture's pulse.

The Joint Commission requires hospitals to use valid and reliable tools for measuring the culture of safety (LD.03.02.01, EP 1). One example is the AHRQ Hospital Survey on Patient Safety Culture from the Agency for Healthcare Research and Quality ([www.ahrq.gov/legacy/qual/patient-safetyculture/hospindex.htm](http://www.ahrq.gov/legacy/qual/patient-safetyculture/hospindex.htm)).

### Make it safe to speak up

The checklist won't be effective in protecting patients if nursing staff are reluctant to speak up when something seems amiss. ALG weaves these skills into its team training, in which 91% of perioperative nurses and physicians have participated.

To learn whether nurses feel safe about speaking up, Mahal-van Brenk plans to survey the staff, asking them to rate on a scale of 1 to 5 how comfortable they feel bringing concerns to the attention of individual physicians. She plans to share the results privately with individual physicians.

It's critical for nurses to be comfortable, she says, because "the last thing [physicians] want is not to get information about a concern."

### Keep senior leaders involved

Senior leaders not only must lend initial support for the checklist but also must stay in touch with the OR on how the effort is progressing.

"We encourage implementation teams to give higher-level leadership updates on their progress," Edmondson says. "We also encourage senior leaders to go to the OR suite and talk to people who are using the checklist."

Safe Surgery 2015 offers an observation tool senior leaders can use.

### Share stories

Capturing stories about "good catches" by the checklist that prevented harm to patients is an effective way to gain support. Record some of these stories and post them where staff and physicians can see them, the Harvard team suggests.

"Keeping track of these stories is one of the best ways to measure the impact of the care you give in your hospital every day," says Dr Berry.

He estimates from reviewing the literature that using the checklist makes a difference for about 1 patient in 1,000.

"That is not a large number, but it is a life," he says. That means that for 1 in every 1,000 patients who comes through your doors, the checklist would make a difference between them going home unharmed or not leaving the hospital at all.

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## Always seek to do better

What key feature distinguishes hospitals that have embraced the checklist from those that have not? When the checklist is embedded, “the first thing they tell us is, ‘We could do better,’” says Edmondson. “They never feel they have completed the project.”

For them, the desire to improve is a continuing quest. ❖

—Pat Patterson

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*This article originally appeared in OR Manager, May 2013;29:1,12-15.*

# Implementing a daily huddle protects patients, avoids delays

*Sixth in a series on ten elements of safer surgery.*

**C**ould you and your team find 30 minutes a day to prepare for the next day's surgical schedule? The effort can be worthwhile.

A Chicago-area hospital has found that a half-hour daily huddle not only heads off delays and cancellations but also spots clinical and patient safety issues so they don't become obstacles the next day. The huddle team has caught near misses, including surgical side and site discrepancies. They also have identified patients with unresolved clinical problems; made sure loaner sets and implants are on hand; and saved time and aggravation.

"A lot of people have daily huddles. We've taken the huddle and expanded it," says David Young, director of preanesthesia testing at Advocate Lutheran General (ALG) Hospital in Park Ridge, Illinois.

Every day at 2 pm, the huddle team meets in front of a smart board showing the upcoming cases, which average about 75 a day. ALG performs about 12,000 procedures a year in its main OR and 6,000 in its ambulatory surgery unit.

Attending the huddle in addition to representatives from scheduling and nursing are personnel from presurgical testing, the preoperative unit, sterile processing, materials management, anesthesia, and ambulatory surgery as well as the surgical navigator who is the liaison with patients' families.

The huddle also serves as the first step in the patient identification process.

"We are actually saying the patient's name and double checking the procedure ordered," notes Cindy Mahal-van Brenk, MS, RN, CNOR, executive service line director for surgery.

## **Community of accountability**

A chief advantage of the huddle is that it raises the level of accountability, Dr Young observes. "Before, everyone worked in silos." Now, in the huddle, each member must acknowledge that preparations for surgery have been addressed.

"If you're the sterile processing person, and you say all of the trays are here, everyone knows you've stated that," he says.

Similarly, if the anesthesia representative says a patient has been cleared, and it turns out later that a problem wasn't taken up with the primary care physician, "they own that," he adds.

These are ALG's key elements for successful huddles.

## **Same time, same place**

The huddle is held every day at the same time and place.

"You have to set the time aside, start on time, and be efficient," Dr Young says. Huddles usually take 30 minutes but can take 45 minutes if the patient list is complex.

Attendance is expected and documented. The employed staff nearly always attend; attendance by the nonemployed personnel is at 50% to 75%, Mahal-van Brenk estimates.

## **Follow a set agenda**

Having a standard agenda moves the meeting along. ALG's agenda starts by recapping the current day's problems. Then the bulk of the time is spent reviewing the schedule for the next day.

"We review the entire schedule case by case. It was slow at first, but it has gotten much faster," Dr Young says.

"We are looking for any problems that might occur the next day. Is there enough time allotted to the cases? Is a surgeon scheduled at more than one site? Are there pending lab results?" Decisions are made about adjusting the schedule.

Among other issues discussed: Were loaner sets delivered? Are new implants being brought in? Will the company rep be on hand? Are there patients with complex allergies or antibiotic needs?

They also review issues that surfaced during the preanesthesia process.

"Prior to this, nurses didn't have a forum to express concern about a patient they thought was high risk," Dr Young observes. "Now they are able to bring this up and share it with the entire team."

In one example, the huddle resolved an issue with a patient who was scheduled for a total hip revision. Normally, 2 units of blood would be ordered. But no blood had been ordered, and the case was scheduled for 1 1/2 hours.

Dr Young, who led the huddle that day, thought that didn't make sense.

"We got the surgeon on the phone. It really was a cup change, not a total revision," he says. "So the time was appropriate and so was not having additional blood. We saved ourselves aggravation."

## ***Safer Surgery series***

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- Excellence in sterile processing: April 2013
- Checklists: May 2013.

At times, the issue is as simple as a language barrier. The presurgical department then arranges for a translator to be present when the patient arrives, providing a source of comfort for both the patient and family.

### **Keep leaders involved**

Having a physician champion is essential, as it is for other patient safety initiatives. Mahal-van Brenk stays involved as well.

“For the first 3 months, you need a consistent leadership presence, so people know this is serious,” she says. She still attends periodically to reinforce that message.

### **Teach presentation skills**

Nurses have learned to hone their style for their huddle presentations, which for some is a new skill, like presenting on rounds. “It takes a while to learn the key elements,” says Dr Young.

Nurses know they will be expected to know something about each patient, which he thinks has helped them to organize their time better.

The huddle program at ALG has helped to resolve not only scheduling issues but also a broader range of concerns that affect safety and efficiency.

“The problem was how to coalesce all of the information that is floating around in everyone’s head and put it together to minimize the risk of delays and cancellations,” Dr Young says. “The huddle has helped us achieve that.” ❖

—Pat Patterson

*Dr Young is also a consultant with Surgical Directions. [www.surgicaldirections.com](http://www.surgicaldirections.com).*

*This article originally appeared in OR Manager, June 2013;29:12-13.*

# Lack of surgical checklist compliance suggests need to improve implementation

**S**urgical checklist compliance among 4 Canadian hospitals was around 60% in a large, retrospective study of acute care operations performed in 2010 and 2011.

Although Alberta Health Services in Calgary, Alberta, Canada, had mandated checklist use starting in 2009, limitations such as instructional misuse, lack of perceived benefit, and lack of procedural understanding had led to misuse or non-use of the checklist, according to Michael Laffin, MD, with the University of Alberta, Edmonton, Alberta, Canada.

Dr Laffin and his colleagues studied data from 4 hospitals in the Calgary region to assess checklist use and identify predictors of noncompliance. The database included information on regional demographics, American Society of Anesthesiologists (ASA) class, surgical factors, admission type, outcomes, briefings, time-outs, and debriefings.

Their multivariable logistic regression analysis showed that, of the more than 132,000 cases performed, compliance rates for the briefing, time-out, and debriefing were 62%, 63%, and 62%, respectively. Dr Laffin reported their results at the 2013 American College of Surgeons Annual Clinical Congress.

Factors associated with noncompliance included:

- patient age less than 40 years
- lack of general anesthetic (ie, local or regional anesthetic use) and conscious sedation performed in the OR
- urgent or emergent operations
- procedure duration of less than 30 minutes
- patient ASA class greater than or equal to 3
- presence of an anesthetic trainee or added absence of a surgical trainee.

Checklists were less likely to be completed during “the 2 extremes of operative risk,” ie, emergent or high-risk procedures as well as shorter, lower risk procedures, and compliance varied widely among facilities, he said.

“There’s a growing body of literature that shows although institutions are adopting the checklists, surgical teams are not,” said discussant Harry Papaconstantinou, MD, FACS, a colorectal surgeon at Scott & White Healthcare in Temple, Texas. Sixty percent compliance may sound low, he noted, but the original paper on surgical checklists had a 57% compliance rate.

Dr Papaconstantinou raised several questions:

- Does compliance improve outcomes, and if so, is there a plateau?
- Were clinical outcomes assessed?
- Was there a difference in the type of procedures? For example, orthopedic surgery usually has a higher incidence of wrong-site surgery.
- Are we asking our nurses to document too much?

Because of the large sample size and use of the database, Dr Laffin said, his team did not look at specific outcomes. However, he noted that the literature supports use of the checklist; it is doing what it’s supposed to do.

He also said they did not find specific differences between teams performing different types of surgery.

“Documentation burden on nurses is huge in Canada, but I think documentation of all the operative materials is something that’s important from a research perspective, from an administrative perspective, and from a patient care perspective,” Dr Laffin said. “It needs to be a priority.”

E. Patchen Dellinger, MD, FACS, chief of general surgery at the University of Washington in Seattle, noted that studies have shown that fewer complications occur when checklists are completed. He also referred to an *Annals of Surgery* study showing that administrative databases indicated 100% completion of the checklist, but direct observation found it was much less than that.

“As much as making sure you’re doing the right operation on the right place, it’s the engendering of teamwork and discussion and communication in the operating room that makes the checklist really work,” Dr Dellinger said.

To help improve compliance in the future, Dr Laffin suggested, researchers may look at nursing notes to better understand what influences noncompliance. They may also interview OR team members to identify perceptions and beliefs around checklist use and barriers to its implementation. ❖

—Elizabeth Wood

*This article originally appeared in OR Manager, February 2014;30:21.*

# OR debriefings put the safety checklist 'on steroids'

**S**ee it, say it, fix it. That saying by a former FedEx pilot set the stage for a major quality improvement effort in surgical services at a South Carolina medical center.

A key QI tool is debriefings performed at the end of every case.

These quick exchanges help to bring defects to the surface and get them addressed quickly.

Debriefings highlight a variety of defects from patient safety risks to minor annoyances. Payoffs from fixing them are safer care with fewer delays, with better surgeon and staff satisfaction and labor productivity.

The debriefings data has put the OR's surgical safety checklist "on steroids," says Michael Rose, MD, anesthesiologist and vice president of surgical services at McLeod Health based in Florence, South Carolina. McLeod is one of the original designers of Premier's QUEST High Performing Hospitals program, a voluntary inpatient QI project sponsored by the 2,500-member health care alliance.

McLeod Regional Hospital, the system's 450-bed flagship, has a surgical volume of about 19,000 cases a year.

## QI from the top

QI at McLeod is led from the top. Senior executives gather each morning to review quality metrics on a whiteboard. Were there any codes in the past 24 hours? How are patient experience scores? What new best practices are being introduced?

Since joining the Premier program 3 years ago, McLeod's mortality index improved from 1.02 to 0.799 for 2011, compared to 0.6 to 0.7 for peer hospitals, with 19 fewer deaths than ex-

pected. The 30-day all-cause readmission rate, 6.2%, is below the 8.0% QUEST average.

McLeod's core measures for 2011 averaged:

- 97.51% for on-time antibiotic administration
- 97.31% for antibiotic selection.

McLeod is also a low-cost provider for its market, having reduced its case-mix adjusted cost per discharge by 22% for the baseline through 2010, notes Donna Isgett, MSN, RN, senior vice president of corporate quality and safety.

## Resolve to 'fix it'

To lay the foundation for QI in surgical services, McLeod brought in FedEx pilot Michael Farnsworth, a commanding presence and expert in crew resource management, now deceased.

One of his key points was, "See it, say it, fix it—with an emphasis on fix it," Dr Rose recalls.

The idea is, "If you are going to ask people to identify risks and defects, you need to create a time in each operation for people to be heard." Then you need to fix it.

OR leaders seized on the World Health Organization Surgical Safety Checklist as a tool not only to make care safer but also to improve operational performance.

A group from surgical services, including medical staff, anesthesia providers, nurses, and technicians, decided they needed to create an opportunity for any team member to tell management what it needed to focus on.

Management "committed to them we were going to come back and do it," says Dr Rose.

The group decided that the WHO checklist, including the debriefing, would be completed for every case. The checklist, launched in 2008, identifies safety measures to check during 3 phases of the operation:

- before anesthesia induction (brief)
- before the skin incision (time-out)
- before the patient leaves the OR (debrief).

Studies have found use of the checklist significantly reduces surgical morbidity and mortality.

Though many ORs have embraced checklists, debriefings have been slower to catch on than the briefing and time-out. In the 2011 OR Manager Salary/Career Survey, only 37% of respondents were using debriefings, whereas 55% of respondents had implemented briefings.

## The debriefing

In the debriefing, called the "Sign-out" in the WHO checklist, the nurse verbally confirms with the team:

- the name of the procedure recorded
- that the counts are correct
- specimen labeling
- any equipment concerns.

Then the surgeon, anesthesia professional, and nurse review key concerns for the patient's recovery and management.

# Lessons Learned & Opportunities

## BRIEF TEAM & MANAGERS

*What Happened? What are the details of the event? Who, What, When, Where, How? Why did it happen?*

## LEARN, TEACH, ACT...

*Action Items, Assigned To, F/U Date, Logged*

## FOR SURGICAL BRIEF LIMIT 140 CHARACTERS

*Key learning from today that we all should know tomorrow*



### Debriefings a focus

At McLeod, the debriefings have become a focus. Some 2,000 debriefings have been analyzed and the data used to set priorities for improvement.

Debriefings “allow us to see where there are risks, vulnerabilities, and system defects,” says Dr Rose.

As fixes were made, surgeon satisfaction rose because they saw their cases being completed with fewer delays.

“We have learned that this kind of communication dramatically alters the day for surgeons,” he says.

The OR’s labor productivity is also up. Labor has been reduced by 3 to 4 minutes per case on average as delays have decreased, says April Howell, RN, CNOR, assistant director of surgical services.

“If you have 4 to 6 people in a case, and there is a 15-minute delay, that is a lot of time. The connection between the debriefing information and operational effectiveness has been very direct.”

### How debriefings are conducted

The debriefing is performed at the end of each case as the surgeon closes the incision. The circulating nurse asks the team for information such as:

- where the patient is going from the OR
- the patient’s specific needs
- blood loss
- review of specimens and labeling.

The nurse then asks if there were any issues that could have made the case go better and then completes a paper debriefing form (illustration). In lieu of detailed comments, the nurse might simply write, “See me,” or “Call me about this.”

Howell collects the forms and compiles the information daily in an Excel spreadsheet, which is sent to the management team and a few others.

“We know within 24 hours if there has been a problem with a case,” she says. If necessary, she can go back to the staff member in the room and ask about the situation.

Examples are a wrong patient sticker on a chart, a wrong consent filled out, or a supply not available. An attempt is made to address each defect.

### ‘People are listening’

The benefit of tracking and fixing defects, she says, is that the surgeons and staff realize “people are listening.”

Since data collection on debriefings began in November 2010, the percent of cases with defects has declined from 17.5% to about 8%.

“What I hear from staff is that we’re identifying problems and fixing them so they’re not repeating as much,” Howell says.

Compiling the debriefings takes about 1 hour a day, she estimates.

“It’s a little time-consuming. But we’ve seen a huge return on investment both in patient safety and staff and surgeon satisfaction.”



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## Learning from a fall

From one debriefing, the management team learned what went wrong in a case where a patient fell from an OR table. Fortunately, the patient was not significantly injured.

A team member had raised concern about the patient's positioning, but others had brushed off the concern.

Instead of being hushed up, the incident was shared and discussed with the staff.

"We took a look at all of our positioning, brought in educators, and got different tools for our staff," Howell says.

They also discussed the need for each team member to have a voice and to listen to others.

## Catching a near miss

A wrong-site surgery averted got the attention of a surgeon who had not fully bought in to briefings and debriefings. A laterality discrepancy was caught during the briefing.

From then on, says Howell, he had buy-in.

Other near misses identified have been patients with allergies and patients who are Jehovah's Witnesses and won't accept blood transfusions.

Events where harm actually reached the patient or got close "have fallen dramatically," Dr Rose says.

In a complex system like an OR, "it's not necessarily possible to get defect rates to zero," he says. "But the team's capability through collaboration can substantially mitigate the actual harm that results when something has gone awry. We think we're seeing that in our data."

## Staff voice support

McLeod's staff voiced their support for briefings and debriefings in a 2011 safety culture survey.

One staff member responded: "I strongly believe the checklist encourages conversation among members of the staff. It helps the team discuss every aspect of the patient's condition and focus on the critical abnormal points.

"The surgical arena can be both a stressful and demanding area to work [in], but with effectively implementing the checklist, the process has slowed enough for us to focus on the important point, the patient."

The survey was conducted by the Harvard School of Public Health and the South Carolina Hospital Association.

## Safety and quality structure

McLeod has reached out to learn about performance improvement, Dr Rose notes.

Every employee and a number of physicians have received PI training, working with a team led by Atul Gawande, MD, and his group from Harvard as part of the South Carolina Hospital Association's Safe Surgery 2015 initiative ([www.safesurgery.org](http://www.safesurgery.org)). The initiative's goal is for the WHO checklist to be used in every OR in the state by the end of 2013.

McLeod's managers and a group of physicians were also part of a distance learning group led by Marshall Ganz, PhD, of Harvard, an expert on community organizing and organizational behavior.

"We learned a lot about the theory and method of interacting with people," says Dr Rose.

One lesson was the benefit of interacting peer to peer when introducing a change such as the checklist, particularly for the physicians.

"Our strongest physician users are now using the peer-to-peer connection to take the idea to each of their peers," he says, adding, "It's painstaking work over a long time."

## Sustainability

To sustain the effort, the management team audits briefings, time-outs, and debriefings, giving immediate feedback to the teams.

Support comes from the top, Dr Rose observes, with senior execs and board members regularly coming to the OR.

The chairman of the board, a realtor, visits the OR, dresses in scrubs, and talks with team members.

Isgett says McLeod's participation in the Premier QUEST project creates "constant movement" to improve. Hospitals pledge to be transparent in sharing data and best practices.

In turn, she says, "We feed that back into other QUEST hospitals. That is the secret to the work—flowing it through." ❖

—Pat Patterson

*For more about the WHO Surgical Safety Checklist, visit [www.who.int/patientsafety/safesurgery/en/index.html](http://www.who.int/patientsafety/safesurgery/en/index.html)*

*This article originally appeared in OR Manager, November 2012;28:20-22.*

# Preoperative practices overhauled after surgical checklist failure

Use of the World Health Organization's surgical safety checklist has reduced surgical complications and mortality, but a narrow escape after a checklist failure at an Italian hospital suggests that more vigilant efforts are needed to avoid errors.

In August 2012, an 81-year-old patient with vascular dementia was brought to the OR at G. Fracastoro Hospital, San Bonifacio (Verona), Italy, for left carotid artery surgery, as indicated on the sign-in sheet when his surgery was scheduled.

In the preoperative area, the anesthetist obtained the patient's consent, confirmed the surgical site, and asked a colleague to perform an ultrasound-guided cervical plexus block of the left carotid artery because he was not skilled in this technique. The surgeon was absent from the preoperative area while the anesthesia was being given.

During the time-out prior to surgery, however, the surgeon realized that surgery should be performed on the right carotid artery, not the left. The patient was given general anesthesia, and the procedure was performed on the right carotid artery. Afterward, the patient was admitted to the ICU for postoperative monitoring for 24 hours.

## How errors creep in

The incident is an example of the "Swiss cheese" model of failure, in which slices of cheese represent barriers against organizational failure and the holes in the cheese slices indicate weaknesses in individual parts of the system. The system as a whole fails when the holes in each slice momentarily align, allowing an error to creep into the defenses designed to protect against failure.

In the carotid case, the holes were as follows:

- The side was listed incorrectly on the initial scheduling sheet.
- The nurse on the patient unit indicated the wrong side (perpetuating the error from the scheduled list instead of double-checking with the surgeon, as should be done in unclear or ambiguous cases).
- The front page of the medical record stated "right occlusion, left stenosis," which was unclear.
- Two anesthetists were involved in the procedure.
- The patient's dementia prevented him from recognizing the error.

- The surgeon was not present when the plexus anesthesia was induced.
- The right side was indicated in the electronic memo of the operation created by the surgeon during the patient's first visit but was not printed in the medical record.
- There was a lack of communication among all surgical team members and the patient.

## Role of checklists

Checklists are used in the surgical units and ORs of many hospitals in Italy, although the country in general has been slower to adopt their use than have US hospitals. In 2009, the Italian National Health Service published OR Safety Recommendations that included a surgical checklist, but that checklist was used largely on an experimental basis. In 2012, checklists were put into place in the surgical departments of all Italian hospitals. Nonetheless, the carotid case demonstrates that even with the use of checklists, there's still a danger of wrong-site surgery.

The carotid case was the first time that the checklist had failed in that particular OR, but it clearly demonstrates poor communication and lack of nontechnical skills among the OR team. These skills are well developed in civil and military aviation environments but are less common in health care organizations. All surgeons, anesthetists, and nurses should have strong situational awareness, decision making, communication, leadership, and teamwork skills.

In conjunction with nontechnical skills, checklists are designed to promote interdisciplinary communication and to provide a framework for the many perioperative steps involved in patient care. To augment these skills at G. Fracastoro Hospital, interdisciplinary teams composed of surgeons, anesthetists, and nurses participated in a project at the hospital led by civil aviation pilots who had had crew resource management training.

As part of this project, an OR checklist prototype tailored to different specialties (general, pediatric, obstetric and gynecological, vascular, urologic, and orthopedic surgery) was developed to improve communication and to better manage potentially critical situations, decision making, and situational awareness.

Each specialty checklist was used in different simulated scenarios, followed by debriefings with

the entire team. Communication has improved with the use of these checklists, and the OR manager continues to monitor their use to avoid communication breakdowns.

As a result of the carotid incident, a clinical audit was conducted with input from all members of the surgical team. A new procedure for filling out the surgical checklist was produced and approved.

As part of this, the patient's mental status is assessed on the basis of medical history and, if necessary, consultation with a neurologist. The sign-in process was rewritten and now involves the entire surgical team whenever any aspect of a case is unclear, and the electronic memo is now included in the official documentation for every surgical patient. ❖

— *P Sette, MD, is OR manager at G. Fracastoro Hospital in San Bonifacio (Verona), Italy.*

— *R M Dorizzi, MD, is with Corelab, Laboratorio Unico di AvR, in Pievesestina di Cesena, Italy.*

— *A M Azzini, MD, is with the Department of Pathology, Infectious Diseases Unit, at Azienda Universitaria Ospedaliera Integrata, Verona, Italy.*

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# Team participation and planning produce quality handoffs

**A**fter a poor handoff from the OR to the postanesthesia care unit (PACU) was identified as the culprit behind a serious adverse event, Nancy Robinson, DNP, MSN, RN, LHRM, CCM, made it her mission to avoid a recurrence.

"I'm passionate about safe patient hand-offs," says Robinson. "I didn't want this to happen to another patient."

Robinson, who is director of education at Health Central Hospital, Ocoee, Florida, part of the Orlando Health System, tackled the project of improving handoffs as her doctorate in nursing capstone project, working closely with Marcia Olieman, MBA, RN, director of surgical services. The result was a tool that has boosted OR and PACU nurse satisfaction and is still being used 2 years later.

In 2006, the Joint Commission launched a National Patient Safety Goal for implementing standardized handoffs, and in 2013, the Commission's Center for Transforming Healthcare released *Improving Transitions of Care: Handoff Communications*. The tool is based on the acronym SHARE: Standardize critical content, Hardwire within your system, Allow opportunity to ask questions, Reinforce quality and measurement, and Educate and coach.

Many hospitals are using these principles when they address how to conduct a handoff, which seems to be a simple task. But like a young person in whom a surgeon unexpectedly finds cancer, appearances can be deceiving. Handoffs aren't simple. An effective handoff requires commitment, coordination, and yes, a bit of passion.

## The value of handoffs

OR leaders, clinicians, and other administrators intuitively know that accurate handoffs help prevent errors that can harm patients. But handoffs can also improve outcomes. A study of 1,507 neonates, infants, children, and adults published in the *Joint Commission Journal on Quality and Patient Safety* found that using a structured handoff when transferring patients from the cardiovascular OR to the cardiac ICU significantly reduced the number of unplanned extubations and the amount of time patients were on the ventilator.

"The handoff protocol definitely contributed to those results," says Mark Twite, MD, BCH, MB, an anesthesiologist at The Heart Institute of Children's Hospital Colorado in Aurora and 1 of

the study's authors. Having an awareness and a structure to the handoff "shows we think it's a really important part of patient care," he says. For example, when the anesthesiologist tells the nurse and the respiratory therapist where the endotracheal tube is taped, both clinicians will know to speak up if they note even a small difference in placement.

Dr Twite attributes the reduction in ventilator time to setting expectations. "That helps the ICU team decide on who to fast-track for extubation, and the anesthesiologist, surgeon, and nurse are all on board with the plan. Everyone is hearing the same message."

## Assemble the right team

Like professional coaches, OR leaders must strive to build the best team possible to attain success. "It's hard to get everyone to come to the table," Olieman acknowledges.

At Health Central Hospital, a community hospital that has 8 ORs and performs nearly 5,000 procedures a year, she and Robinson surmounted that challenge by drafting champions from each area affected by handoffs to be on the team. The chief of anesthesia and a certified registered nurse assistant known for his strong patient advocacy, along with representatives from the PACU and the OR, comprised the team. These leaders were able to help "bring reluctant ones into the fold," says Olieman. The interdisciplinary team also managed to break down silos, getting staff from various departments to talk more about issues beyond handoffs.

Ina Cherepaha-Kantorovich, MN, RN (EC), advanced practice clinical educator for the preadmission, PACU, endoscopy, and cystoscopy units at Toronto General Hospital in Ontario, Canada, suggests asking for volunteers to fill staff spots on the team. The working group for handoffs facilitated by Cherepaha-Kantorovich and Maria Masella, MN, RN, educator in the OR, included 4 staff nurses from the OR and 4 from PACU.

"You also have to have organized meetings and follow-up during implementation so the process doesn't fall apart," she adds. "Include staff all the way." Cherepaha-Kantorovich and Amanda Zakrzewski, a PACU staff nurse, spearheaded the process.

Think outside the box; a nonclinical person can be a great facilitator, says Mary Grzybowski, BSN, RN, administrative clinical advisor for PACU at

Beth Israel Deaconess Medical Center (BIDMC) in Boston. A staff member from the business transformational office who is embedded in the perioperative area helped the 10-member multidisciplinary BIDMC team establish an effective handoff procedure.

“We are focused on clinical, so we don’t always see how to attack a problem from a bigger picture,” Grzybinski says. The business staff member “helped us see the business end and keep us focused.”

### Analyze the process

Many OR leaders use Lean tools to analyze the handoff process. A value stream analysis showed the team at Health Central Hospital deficiencies in the current process, Robinson says. The team at BIDMC also performed a value stream analysis and identified several categories of changes that could be made.

“The value stream map helped us know how everyone perceived handoffs so we were on the same page,” Grzybinski says. Team members learned what others needed from them.

“PACU nurses sometimes only got part of a patient’s information because the provider didn’t realize that the whole picture made a difference in the case,” she says. “Then we did an impact difficulty analysis grid that helped us analyze the difficulty of fixing each problem and the impact fixing that problem would have on improvement in handoffs. Communication had the highest difficulty and the highest impact, so we decided to tackle that.”

The team created an affinity diagram that examined 4 areas: communication before transport,

post-transport communication, disposition of the patient, and communication interoperatively to the unit that will receive the patient after surgery (sidebar). Strategies were identified to address each area.

Robinson says a factor that’s easily missed in an analysis is whether people are focused on the handoff or on the task. When observing handoffs from the OR to the PACU, she was struck by the fact that participants were doing many tasks while trying to receive important patient information.

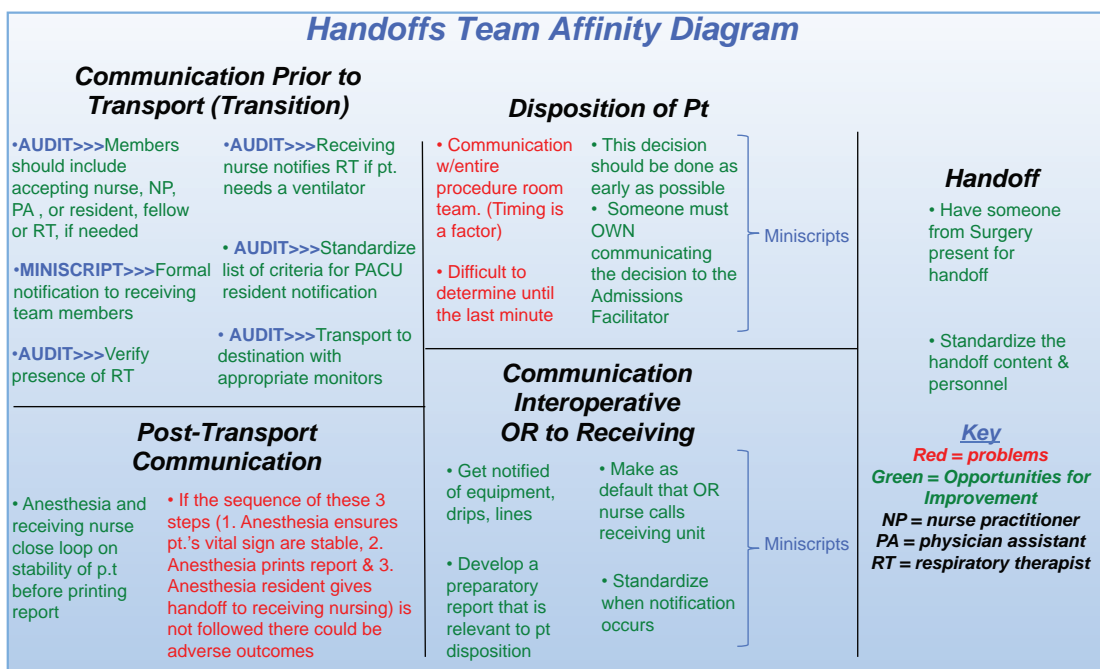
“When you are performing tasks and receiving information simultaneously, you don’t retain what you are being told,” she says. That led to the creation of a “no fly” zone—report is not given until basic tasks, such as connecting the patient to the monitor and oxygen, are completed, so the PACU nurse can give the other clinicians his or her full attention.

Another vital part of the analysis is examining attitudes. “The biggest challenge for making the change wasn’t the surgeons, it was the OR nurses,” Cherepaha-Kantorovich says.

In fact, OR nurses didn’t like the initial tool, saying it didn’t reflect what they did. A survey revealed OR nurses felt “devalued” because the PACU staff weren’t paying attention to what the OR nurses were saying. The PACU nurses revamped their approach, and the process was revised so that it better reflected contributions from the OR nurses.

### Put the process in place

Protocols, especially those incorporating checklists, are a frequent—and effective—solu-



The affinity diagram shows communication problems and opportunities in each of 4 key handoff areas. Clinicians can use miniscripts to ensure they provide needed information.

Source: Beth Israel Deaconess Medical Center, Boston. Used with permission.

## Handoff Communication Guidelines PERIOPERATIVE PEARLS

P	<b>Patient name:</b> _____ <b>Age:</b> _____ <b>Allergies:</b> _____ <b>Procedure performed</b> _____ <b>Primary language spoken:</b> <input type="checkbox"/> English <input type="checkbox"/> other: _____ <b>Past medical history:</b> <input type="checkbox"/> Diabetes <input type="checkbox"/> HTN <input type="checkbox"/> COPD <input type="checkbox"/> Asthma <input type="checkbox"/> OSA <input type="checkbox"/> Renal Disease <input type="checkbox"/> Seizures <input type="checkbox"/> Cardiac <input type="checkbox"/> CAD <input type="checkbox"/> PVD <input type="checkbox"/> CVA <input type="checkbox"/> Liver Disease <input type="checkbox"/> ETOH <input type="checkbox"/> Smoking (ppd _____) <input type="checkbox"/> Arthritis <input type="checkbox"/> MRSA <input type="checkbox"/> VRE <input type="checkbox"/> TB <input type="checkbox"/> C Diff <input type="checkbox"/> Deaf <input type="checkbox"/> HOH <input type="checkbox"/> Blind <b>Position during surgery:</b> <input type="checkbox"/> supine <input type="checkbox"/> prone <input type="checkbox"/> lithotomy (type of stirrups: <input type="checkbox"/> candy cane <input type="checkbox"/> allen) <input type="checkbox"/> jack knife <input type="checkbox"/> Other _____ <b>Precautions:</b> <input type="checkbox"/> falls <input type="checkbox"/> Seizure <input type="checkbox"/> Aspiration <input type="checkbox"/> Decubitus <input type="checkbox"/> Isolation: <input type="checkbox"/> Contact <input type="checkbox"/> Droplet <b>Personal Items:</b> <input type="checkbox"/> Dentures <input type="checkbox"/> Glasses <input type="checkbox"/> Hearing Aids <input type="checkbox"/> Prosthesis : ( _____ ) <b>Pain management:</b> <input type="checkbox"/> PCA pump <input type="checkbox"/> Epidural <input type="checkbox"/> On-Q pump <input type="checkbox"/> Other: _____
E	<b>Extremities:</b> <input type="checkbox"/> Ted hose <input type="checkbox"/> SCD's <input type="checkbox"/> Pulses <b>Adverse events intraoperative:</b> _____ <b>Equipment needs:</b> <input type="checkbox"/> CPM <input type="checkbox"/> Ventilator <input type="checkbox"/> Wound Vac <input type="checkbox"/> NGT <input type="checkbox"/> Cell saver <b>Elimination:</b> <input type="checkbox"/> Foley <input type="checkbox"/> Suprapubic tube <input type="checkbox"/> I&O <input type="checkbox"/> Straight cath
A	<b>Assessment:</b> <input type="checkbox"/> Skin <input type="checkbox"/> Incision <input type="checkbox"/> Packing <input type="checkbox"/> Musculoskeletal <input type="checkbox"/> Neuro <b>Drains:</b> <input type="checkbox"/> JP <input type="checkbox"/> Hemovac: location _____ <input type="checkbox"/> Penrose <input type="checkbox"/> Blake tube <input type="checkbox"/> Chest tubes: <input type="checkbox"/> Rt <input type="checkbox"/> Lt <input type="checkbox"/> Urology stents: <input type="checkbox"/> Rt <input type="checkbox"/> Lt <input type="checkbox"/> G tube <b>Dressings:</b> Location _____ Number ____ Drainage: <input type="checkbox"/> Yes: Type _____ <input type="checkbox"/> No <b>Antibiotic:</b> <input type="checkbox"/> Yes: Time last dose _____ <input type="checkbox"/> No <b>Vital Signs:</b> Temp: _____ HR _____ BP _____ RR _____
R	<b>Relationships:</b> Family location: _____ Contact phone #: _____ <b>Radiology:</b> <input type="checkbox"/> CXR <input type="checkbox"/> Other
L	<b>Labs due:</b> <input type="checkbox"/> H&H <input type="checkbox"/> BMP <input type="checkbox"/> CBC <input type="checkbox"/> PT/PTT <input type="checkbox"/> T&C <input type="checkbox"/> Accucheck <input type="checkbox"/> Blood sugar <input type="checkbox"/> ABG <input type="checkbox"/> Critical values: _____ <b>Lines:</b> <input type="checkbox"/> Central <input type="checkbox"/> Arterial <input type="checkbox"/> Peripheral: location: _____ <input type="checkbox"/> Swan-Ganz <input type="checkbox"/> CVP <input type="checkbox"/> PICC line <input type="checkbox"/> Port: location: _____ <b>Blood products:</b> _____
S	<b>Special devices:</b> <input type="checkbox"/> Pacemaker <input type="checkbox"/> AICD <input type="checkbox"/> Insulin pump <input type="checkbox"/> Other _____ <b>Special needs:</b> <input type="checkbox"/> DVT protocol <input type="checkbox"/> Specialty bed: _____ <b>Spiritual needs:</b> _____ <b>Special communication needs:</b> <input type="checkbox"/> Sign language interpreter <input type="checkbox"/> Interpreter <b>Surgical Unit:</b> <input type="checkbox"/> SCU <input type="checkbox"/> OSU <input type="checkbox"/> CVICU <input type="checkbox"/> PCU <input type="checkbox"/> IMCU <input type="checkbox"/> MSU <input type="checkbox"/> TMU

*This worksheet, which facilitates handoffs, is not part of the medical record. Source: Health Central Hospital, Ocoee, Florida. Used with permission.*

tion to handoff challenges. For instance, a 2013 study in Pediatric Anesthesia found that a checklist dramatically improved the quality and reliability of the handoff.

Olieman recommends allowing protocols to develop organically. “We kept the flow of information during the handoff loose at first so that it could be developed, and then we standardized so it included what each person needed to know,” Olieman says.

Ultimately, the team developed a paper tool (sidebar). Olieman says the paper format is key to the tool’s success: “When a nurse gets a patient, she needs to know information really fast without flipping through a dozen computer screens.” The tool, which isn’t part of the permanent patient record, provides that.

“Although some people might think it’s double documenting (because some of the information on the tool has to be entered into the computer), it’s not,” Olieman notes. “It’s not hard and it’s not complicated. It’s like a worksheet.”

The tool has expanded so that it starts in the preoperative area and travels with the patient through the OR, the PACU, and onto the nursing unit.

“It’s color coded, so each unit has ownership for their section,” says Robinson, who adds, “It’s not just a piece of paper; it’s a process by how we can make the patient’s trajectory through the system safe and meet regulatory agency requirements.”

BIDMC’s guidelines “spell out what happens from step to step, whether the patient is going to

## Sample narrative script

This is an example of the narrative scripts used at Beth Israel Deaconess Medical Center, Boston, to remind providers what information to provide. Among the other scripts are 1 for the anesthesia provider to the RN circulator and 1 for the anesthesia provider to the RN receiving the patient after surgery.

### *Narrative script: RN circulator to receiving unit*

**Sender** (RN Circulator) Hi, We are finished in room \_\_\_\_, Dr \_\_\_\_\_ patient \_\_\_\_\_, who had a \_\_\_\_\_ procedure. He/she will need the following:

- Ventilator or specific respiratory set up (eg, t-piece)
- Drips and patients weight
- Invasive monitoring set up
- Precaution status
- Epidural

**Receiver** (Receiving RN) Thank you OR I need clarification of the following...

**Sender** (RN Circulator) Can we have a slot/room?

**Receiver** (Receiving RN) Thanks for the information. You can go into slot/room \_\_\_\_\_ OR we will call you back with a slot/room.

*Source: Beth Israel Deaconess Medical Center, Boston. Used with permission.*

the PACU or the ICU," says Grzybinski, adding that scripts help everyone remember what needs to be included (sidebar). "Otherwise, people tend to tell what they think is important, which might not be what's important to the other person," she says, citing situations in which the anesthesiologist fails to mention the patient doesn't speak English or can't hear at all without his hearing aids.

"We try to broaden the horizons of all providers," Grzybinski says. "It's not just what one provider needs; it's what we all need to take excellent care of the patient." Laminated cards of the scripts are available.

The structured handoff used at Children's Hospital Colorado outlines the order of report. After the patient is on the ICU monitor and the vital signs have been checked, the OR nurse and ICU nurse both verify the patient's identification. The cardiac surgeon or fellow gives report, followed by the anesthesiologist or anesthesia fellow and the OR nurse.

Dr Twite says the team in the cardiovascular ICU then does a "wrap up, going through the plan for the patient—hemodynamic goals, where we are going with extubation, the plan for sedation—and at the end they cover any questions or concerns. Then the ICU assumes official care of the patient."

Whatever the process, Cherepaha-Kantorovich emphasizes that consistency is vital even if that means standing firm. "If a surgeon or OR nurse didn't come, the PACU nurse didn't accept the patient," she says. "You need the consistency so that people understand it is serious; it's important for the patient's safety." She and the OR nurse educator made sure they were available to staff to facilitate implementation, and now the process is standard practice.

## The time factor

Rapid throughput is essential for a successful OR, so staff and leaders worry about the time spent on handoffs. Fortunately, this fear is often unfounded. "There was some reluctance [among] OR nurses to participate," says Robinson. "They were eager to get back to the OR to start the next case." By eliminating the inefficiencies discovered through the value stream analysis, however, nurses easily found the time they needed.

"Taking time up front can save time later on," Cherepaha-Kantorovich adds. The handoff takes about 5 minutes and replaces the multiple calls PACU staff used to have to make to the OR to obtain missing information.

And, of course, time isn't standing still in the OR while the nurse is in the PACU or ICU. "While we are doing the handoff, our team is doing the room turnover," says Dr Twite. He says the entire team agrees that any delay "is a small price to pay for accurate handover of patient information. An accurate handover is part of excellent patient care and excellent outcomes."

## Follow up

To ensure the handoff process meets the team's needs, it's helpful to survey clinicians at key intervals. Robinson used a Likert scale to assess satisfaction among OR and PACU nurses before and after implementation. After implementation, satisfaction increased in both areas, with a particularly dramatic increase among OR nurses. "[The handoff process] helped them put aside the task part of the job and remind them why they became perioperative nurses," Olieman says in accounting for the increase.

Cherepaha-Kantorovich surveyed staff before and after implementation and 1 year later. "The final evaluation was very positive," she says, add-

ing that the new process has now been in place for 18 months. Most surgeons and PACU, OR, and anesthesia staff believed the handoff tool had improved communication and helped to convey accurate patient information to the PACU staff.

### **A commitment to patient safety**

“Anytime there is a change, it’s hard,” Robinson says. “But this [handoff tool] has become hardwired into the process.” Olieman says the tool is part of orientation and that the perioperative nursing council has taken ownership of it. Perhaps the most exciting payoff for the team at Health Central Hospital was that in 2012 they received an award from the Florida Hospital Association.

So what advice does Olieman have for other OR nurse leaders planning to work on handoffs? “Don’t be afraid to take on the big, scary project. It was overwhelming, but we did it.” ❖

—Cynthia Saver, MS, RN

*Cynthia Saver, a freelance writer, is president, CLS Development, Inc, Columbia, Maryland.*

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# Team training, checklist equal better outcomes in pilot

**T**eam members simply introducing themselves to one another at the start of a case made a difference in the rate of infectious events in a pilot study. The rate was 1.9% when the introductions were documented and 21.1% when they were not. (The infectious event rate included surgical site infections, urinary tract infections, and pneumonia.)

Overall, in the study at Saint Francis Hospital and Medical Center, Hartford, Connecticut, team training plus use of a surgical safety checklist reduced adverse events from 24% in control patients to 16% in cases with team training only and to 8% in cases with checklists plus team training.

The authors say this is the first study to examine how team training can help teams using a checklist with validation through the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database.

A report of the study, which used the AORN Comprehensive Surgical Checklist, is in the *Journal of the American College of Surgeons*.

## Study groups

Data on patients from the NSQIP database was used as controls and compared with:

- a group of 246 procedures performed by teams who had communications training
- a group of 73 procedures performed by teams who had communications training and used a checklist. Both physicians and staff received the training.

Complications included surgical site infections (SSIs), venous thrombosis, pulmonary embolus, and urinary tract infections.

The pilot study stemmed from a fellowship project by Scott Ellner, DO, MPH, FACS, a general trauma surgeon and vice chairman of surgery at Saint Francis and a fellow with the American Hospital Association and the National Patient Safety Foundation.

After IRB approval was granted, the group held a kickoff in September 2010 to explain the project to those involved, including perioperative nurses, surgeons, anesthesiologists, certified registered nurse anesthetists (CRNAs), surgical technologists, and nursing assistants, notes Cynthia Ross-Richardson, MS, BSN, RN, CNOR, the NSQIP coordinator at Saint Francis.

At the meeting, the group completed a safety attitudes questionnaire (SAQ) to determine the

baseline patient safety culture in the OR. The SAQ is a validated survey developed at the University of Texas.

## Team training

The SAQ responses were used in forming the communication team-training sessions. The study team analyzed the SAQ answers, and Nancy Krafcik-Rousseau, PhD, a communication specialist at Saint Francis, used them to form the communication team training sessions.

These 3 hour-long sessions included topics such as differences between introverts and extroverts, effective dialogue among OR personnel, and how to use a checklist. Sessions were offered on all shifts, including weekends.

## Introducing the checklist

The checklist was introduced in didactic sessions “because we wanted to build upon the importance of each specific measurement and part of that checklist,” says Ross-Richardson. Staff also brought up their concerns.

Dr Ellner was a key to checklist implementation, she says, because the staff considered him a role model.

“You have to have a champion working on the front lines every day. He is passionate about dealing with conflict and making sure the patient is safe. Without him, I don’t think the project would have been as successful,” she says.

The check-in phase of the AORN checklist is initiated in the preoperative area. The remaining 3 phases are completed in the OR. The checklist, on a laminated card, starts with the time-out, which is initiated and led by the anesthesia provider.

## Study observers

During the study cases, trained observers assessed whether the checklist was used, tracked the number of times the circulating nurse exited during the case, and documented any safety-compromising events.

Three medical students, including Lindsay Bliss, MD, who had a strong interest in quality and safety, were trained to be observers.

“Dr Bliss was passionate about the project and went well above and beyond what we were expecting,” notes Ross-Richardson.

“An observer would bring the checklist to the nurse in the preoperative area and follow

the patient and checklist throughout the preop, intraop, and postoperative periods to sign-off in the PACU.

“We had a lot of commitment from them,” she adds. “One case lasted 9 hours, and the observer was there for all of it.”

### **Safety events**

Events were grouped according to the nature of the deficiency, such as communication, equipment availability or malfunction, disruptive behavior, patient flow and process, and sterility.

Observations were tallied and analyzed, and the data was matched with the NSQIP data.

Though 150 cases with checklist use were necessary to maximize the likelihood of statistical significance, the sample size was 73 because of limited availability of trained observers.

Still, the numbers collected did demonstrate some statistical significance, says Laura Sanzari, BSN, RN, APACHE outcomes coordinator for Saint Francis.

### **Checklist and outcomes**

Three components of the checklist were linked to significant changes in morbidity, though other events also showed a decrease. There were more deep SSIs when:

- confirmation of patient identity was lacking
- there was a failure to address the procedure and procedure site during the check-in section of the checklist.

Also, cases where it was not documented that the team members had introduced themselves to one another were more likely to have infectious events than those where the introduction was documented (21.1% vs 1.9%).

The fewer times the circulating nurse exited, the lower the morbidity rate. Exits varied from 0 to 25 per case.

### **What accounts for the results?**

Sanzari says she thinks the findings relate to the plan of care and disseminating the plan to the team prior to the procedure. The plan of care was part of team training.

“Having the plan of care, which includes the procedure, name, site, supplies, and equipment, affects the number of times the circulating nurse leaves the room,” she says. “Traffic in and out of a room causes air disturbances, which could lead to surgical site infections.”

Why would introductions make a difference?

One theory, she says, is that introductions instill a sense of accountability and help to ensure that everyone’s voice can be heard.

Using a checklist also had an effect on OR time. Without a checklist, cases lasted an average of 155 minutes; with a checklist, that dropped to 145 minutes.

“It all relates to discerning the plan of care—knowing ahead of time what’s needed, checking the equipment, and making sure it works,” Sanzari reiterates.

### **Team training is key**

“Conducting this study has opened the door for others to realize there are ways to improve patient care in a simple, not very costly way,” says Ross-Richardson. The tools are available, and most are free—the key is team training.

If a hospital has instructors who can provide team training, it can design a program using the SAQ. The SAQ provides a baseline measure of clinicians’ concerns. Team training can address those concerns, starting an OR on the path to safer surgery.

Saint Francis is continuing the team training when new issues arise and when new staff come on board.

The researchers say they will use the data to support universal adoption of the checklist at their medical center. They also plan to pursue a multicenter study to increase the statistical power of their research. ❖

—Judith M. Mathias, MA, RN

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# III. High Reliability



# Rounding tool off to a good start in improving patient satisfaction

A mobile, web-based rounding tool is allowing the perioperative leadership team at Vail Valley Medical Center (VVMC) in Vail, Colorado, to collect, analyze, and report on information gathered from surgeons, staff, and patients to improve quality of care and move toward high reliability.

Software designed by MyRounding Solutions in Littleton, Colorado, was customized to VVMC and downloaded into an iPad ([www.myrounding.com](http://www.myrounding.com)). Icons and simple navigation menus make rounding, data gathering, and tracking of trends simple.

“MyRounding is so great because it is so portable, and the software is very easy to use and navigate through, whether you are computer literate or not,” notes Mary Jo Steiert, BSN, RN, CNOR, director of perioperative services at VVMC.

VVMC is a community hospital with 4 rooms in its main OR, 4 rooms in its adjoining surgery center, and 4 rooms in its surgery center in Edwards, Colorado, which is 4 miles from Vail. VVMC also includes the Steadman Clinic, a world-renowned orthopedic clinic, and the Steadman Philippon Research Institute, where 9 orthopedic fellows a year develop their surgical skills.

Though perioperative services just began using the VVMC-specific MyRounding in November 2013, the hospital has been working with Safer Healthcare (<http://www.saferhealthcare.com/>)

since the beginning of 2012 as a test site for developing the tool for use in their high reliability training.

Safer Healthcare (Littleton, Colorado) is a training, consulting, and healthcare products firm that focuses on establishing a patient safety culture through creating high reliability healthcare organizations. “Rounding to influence” is 1 element of an evidence-based bundle of leadership methods used in highly reliable organizations.

Structured and consistent rounding also has been found to increase patient satisfaction and improve HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) scores. MyRounding uses HCAHPS best practices and patient-centered scripts.

Everyone on the VVMC perioperative leadership team has their own iPad with the MyRounding software, including Steiert, the perioperative educator, perioperative nurse liaisons, specialty team leaders, and charge nurses in the OR, preoperative area, and postanesthesia care unit.

## Leadership rounding questions

For her leadership rounding, Steiert has a set of questions in the iPad for the surgeons and a set for the staff, with icons for each (sidebar above).

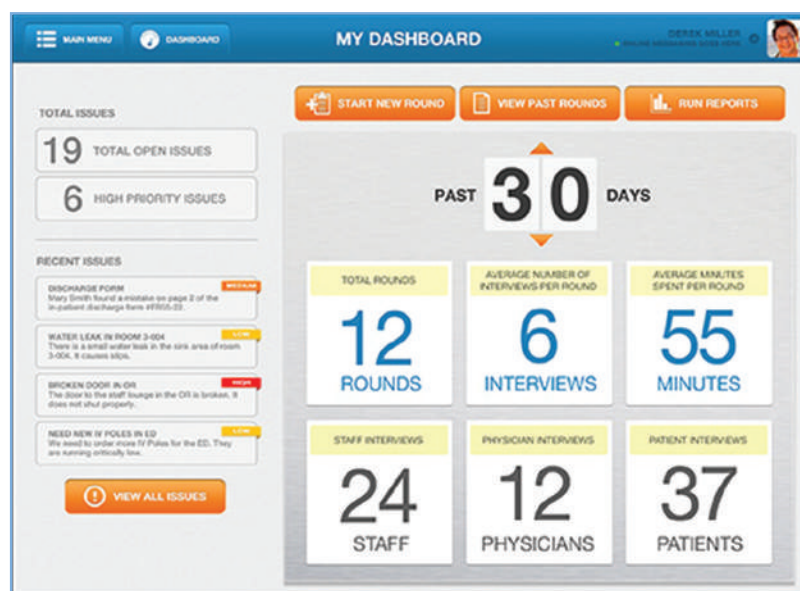
“We created a series of questions for surgeons and staff, asking them about their perceptions of what we can do to improve their work environment and the quality of patient care,” says Steiert. “I touch the staff

icon and the questions appear.” (See sidebar.)

## Questions for staff

- On a scale of 1 to 5 overall [1 is low, 5 is high], how are things working in this department?
- Is there anything you can think of specifically that is working well in this unit or department?
- Is there anything you can think of that is not working well in this unit or department?

“I can record their voices when they give me their answers, or I can put the data into the



Source: MyRounding Solutions, Littleton, Colorado.

iPad as we are talking,” says Steiert. “I also can take photographs, so if I am on a unit and I see something that my staff doesn’t like, I can take a picture of it, and that can be stored data as my justification for my rationale to make a change.” (See sidebar.)

### Questions for surgeons

For the surgeons’ questions, Steiert touches the surgeon icon and a script and questions appear, and then she records the surgeons’ answers.

The script begins with: “Dr X, would you mind spending a moment with me to talk about patient safety and quality improvement in the OR? We are trying to be proactive and address any concerns and capture any ideas that you may have that can help us improve our patient care.”

- On a scale of 1 to 5, how would you rate the quality of nursing in the OR?
- Are there any concerns or ideas that you would like to share about patient safety here in our OR? Yes or No.
- Are there any quality improvement projects that you think would be beneficial to our department? Yes or No.
- On a scale of 1 to 5, how satisfied are you overall here in our department?
- Is there anything I can do personally to help you make your practice in our OR more effective? Yes or No.
- Is there anyone who you would like to recognize for going above and beyond the norm?

At the end of the interview, Steiert presses a button to save and start a new interview.

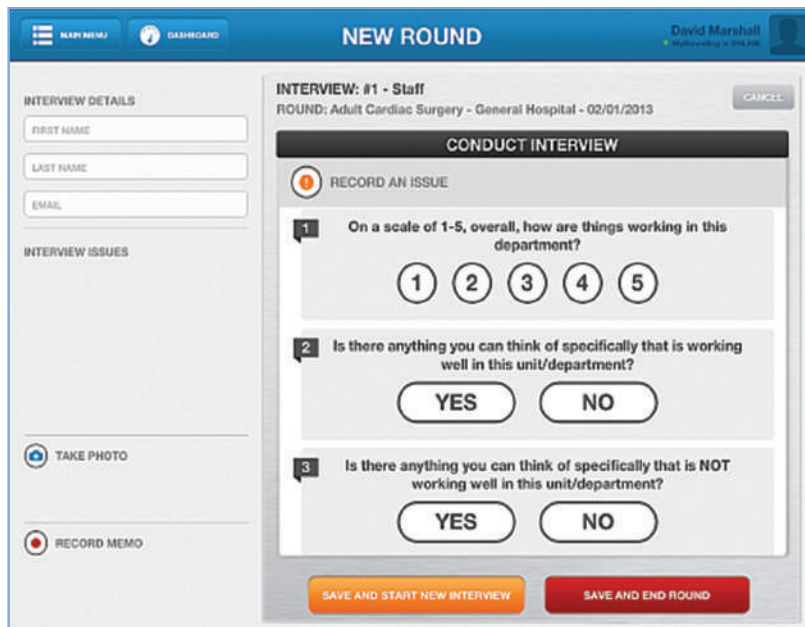
“It works quickly,” says Steiert. “About 5 minutes of their time is all I need.”

### Nurse liaison rounding questions

After a nursing liaison position was added in November 2013, a series of questions were created for the nurse liaisons to ask patients and their families. Two nurses share the position.

### Questions for patients

- Do you understand your plan of care and what to expect from admission to discharge? Yes or No.
- Is there any additional information that you would like, or do you have any questions? Yes or No.



Source: MyRounding Solutions, Littleton, Colorado.

- Do you feel that all members of your care team understand and agree on your plan of care? Yes or No.
- Do you feel like you had a voice in your plan of care with all members of your care team? Yes or No.
- Do you feel like we have kept your family members up to date and informed about the progress in your procedure today? Yes or No.
- Is there anything we could have done better to help you or your family? Yes or No.
- Do you have any last questions or concerns?

### Questions for the family

Questions the nurse liaison asks family members begins with a script: “I just want to check in with you to see how you are doing and give you an update.”

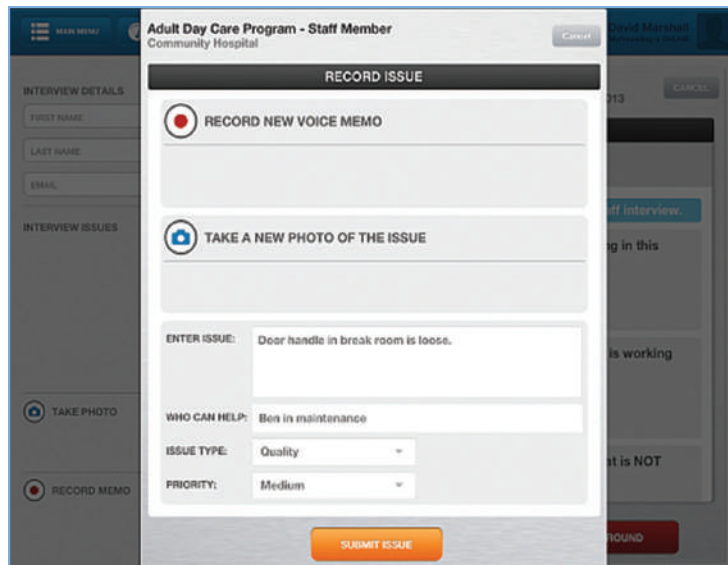
The nurse then tells them about the current status of the patient and asks the following questions:

- Is there anything I can do to make you more comfortable while you are waiting? Yes or No.
- Is there any additional information you need, or are there any questions I can answer for you? Yes or No.
- Are you able to follow the progress of your family member using our patient board? Yes or No.
- Would you like me to continue to check in with you to monitor the situation? Yes or No.

“I like the last question, especially,” notes Steiert. “Knowing the nurse will be there if they have questions is comforting to them.”

### Trending the issues

With the stored information, the MyRounding software identifies trends and issues and compiles statistics on the data.



Source: MyRounding Solutions, Littleton, Colorado.

“The tool helps us close the loop on issues because it trends the issues, which helps us resolve them,” says Steiert.

For example, 1 of the top trends identified was that staff and surgeons were focused on getting first-case patients into the OR on time. A corresponding trend was that patients were delayed going into the OR because their H&Ps weren’t on the chart.

An A3 Lean methodology was used to determine why the H&Ps weren’t on the chart and what needed to be done to have them on the chart in a more timely fashion.

“We worked with the surgeons’ offices, PAs, fellows, and IT to discover the obstacles and how to overcome them,” notes Steiert.

As a result, Steiert says, they figured out the latest possible time to stop looking for an H&P, call the surgeon, and get the patient into the room on time. “One thing nurses don’t like to do is call the surgeon, especially for the first case of the day, saying ‘we can’t find your H&P,’” she says.

Steiert says they worked backward to accomplish this, asking: “If we want the patient in the room by 7:29 am, what needs to happen before that time?”

It helped create a whole process for standardizing work, she says. For example, they are trying to standardize all the work the night nurses need to do to have things ready for the day shift for the first case of the day and what the evening shift needs to do to help the night shift. “It has sparked more work than we have time to do, but it is fun and people are getting energized,” says Steiert.

Another example: A hand surgeon from the Steadman Clinic was doing a case during the Thanksgiving holiday when the ski slopes opened, and many people were coming in with injuries. There was a particular elevator missing from 1 of his hand sets.

When Steiert did her rounding the following Monday, she asked him how things went over the weekend because she knew he had been on call. When she asked him if he was satisfied with the care his patients received or if there was something they

could have done to make it better, he answered: “Yes, we could only find 1 Kleinert-Kuts elevator for this special procedure.” He said the procedure was designed by these 2 surgeons and it goes better when their elevators are used.

Steiert went to the surgical processing department and asked how many Kleinert-Kuts elevators they had and if they were included in the hand sets or if they were put up separately in peel packs.

She found they were down to 1 elevator, and it was in a peel pack. She ordered 5 additional elevators so 1 could be in every hand set.

She followed up with the hand surgeon the next day, telling him she had ordered 5 more that would be in all of the hand sets the following week.

### Effectiveness of tool

Steiert says in the next 3 months they should have a lot more data and will be able compare surgeon, staff, and patient satisfaction before and after they began rounding with the tool.

Perioperative leadership surveyed staff and surgeons before they started rounding about their level of satisfaction with the way things were going in the department. In a few months, they will do a post-survey to see if there is a difference.

Already, Steiert says, comments from surgeons, the executive team, and staff indicate they have noticed an improvement in patient care and customer service. Instrumentation and equipment is ready sooner, and patient satisfaction scores have improved across the organization. ❖

—Judith M. Mathias, MA, RN

### Resources

Centers for Medicare & Medicaid Services.

HCAHPS: Patients’ perspectives of care survey.

<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS.html>

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# South Carolina models high reliability standards through pilot program

The South Carolina Hospital Association (SCHA) and the Joint Commission Center for Transforming Healthcare have teamed up to make the state's healthcare highly reliable.

In a joint project titled "South Carolina Safe Care Commitment," 21 hospitals in South Carolina are learning about high reliability practices (chart).

High reliability is defined as consistent performance at high levels of safety over long periods of time. Highly reliable healthcare is care that is dependably excellent, every time, for every patient.

The multiyear project, launched in February 2013, was built on a combination of the work South Carolina was doing with a collaborative model to improve the quality and safety of patient care and the platform of work the Joint Commission had done around the 3 key components of highly reliable organizations, says Rick Foster, MD, senior vice president for quality and patient safety at SCHA.

The 3 components are:

- full leadership commitment and participation in driving a system to high reliability
- an organization-wide culture of safety
- system-wide application of robust process improvement (Lean, Six Sigma, Change Management) (figure).

"We have been very encouraged by the number of hospitals that responded initially," Dr Foster says. "The 8 systems represent about 40% of patient discharges in the state, so it represents a pretty good percentage of our inpatient work."

## Leadership commitment

"Striving for high reliability is not just another project—it is a long-term commitment to fundamental and social change in our hospitals and health systems," says Dr Foster. "We were very intentional about including the term 'commitment' in the name."

Hospital CEOs cannot commit to the program and then turn it over to someone else in the organization to lead the effort. "We told them they need to turn it over to themselves and stay actively involved," he says.

Participating hospitals sign a 3-year commitment promising that their CEOs and leadership teams will be actively involved. Those leaders are expected to:

- complete the Joint Commission's High Reliability Self-assessment Tool
- perform a safety culture survey assessment
- use a common process to identify events of harm and close calls that will help facilitate the development of a standardized high reliability measure.

The image shows a graphic for the South Carolina Safe Care Commitment project. At the top, it features the logos for the Joint Commission Center for Transforming Healthcare and the South Carolina Hospital Association (SCHA). The central text reads "South Carolina Safe Care Commitment". Below this, a central blue circle contains the "Safe Care" logo with the tagline "creating highly reliable healthcare - every patient, every time!". Surrounding this central circle are logos for eight participating hospital systems:

- ANMED HEALTH**: AnMed Health Medical Center, AnMed Health Rehabilitation Hospital, AnMed Health Women's and Children's Hospital
- MUSC Health**: MUSC Children's Hospital, MUSC Medical Center
- GEORGETOWN HOSPITAL SYSTEM**: Georgetown Memorial Hospital, Waccamaw Community Hospital
- PALMETTO HEALTH**: Palmetto Health Baptist, Palmetto Health Children's Hospital, Palmetto Health Heart Hospital, Palmetto Health Richland
- GREENVILLE HEALTH SYSTEM**: Greenville Memorial Hospital, Greer Memorial Hospital, Hillcrest Memorial Hospital, North Greenville Hospital, Patewood Memorial Hospital
- ROPER ST FRANCIS HEALTHCARE**: Bon Secours St. Francis Hospital, Roper Hospital, RSF Mount Pleasant Hospital
- Ralph H. Johnson VA Medical Center**
- BAPTIST EASLEY HOSPITAL**: caring is our calling, Baptist Easley Hospital

Printed with permission from the South Carolina Safe Care Commitment project.

## Key components of a highly reliable organization



*Printed with permission from the South Carolina Safe Care Commitment project.*

Ultimately, participating facilities will receive comparative information from peer organizations on these key high reliability metrics.

### Self-assessment tool

Each hospital has a leadership team led by its CEO that participates in up to 3 in-person meetings each year with SCHA and the Center for Transforming Healthcare, along with a series of webinars and coaching calls.

During the first meeting, the teams were provided information on high reliability in general, and then they heard from hospitals that were already successfully applying practices to achieve consistent excellence in patient care.

Each hospital completed the High Reliability Self-assessment Tool developed by the Joint Commission and received a report back from the Joint Commission team. Hospitals used the report to move forward with their individual high reliability plans.

The South Carolina Safe Care Commitment is part of a beta testing group for the tool, says Dr Foster.

### Standardized safety reports

At the meetings, the SCHA and Joint Commission teams also looked at each hospital's existing culture of safety surveys. All but 2 organizations in the state were using surveys from the Agency for Healthcare Research and Quality (AHRQ).

Dr Foster says they are looking at a standard system for safety culture reporting and will begin using Healthcare Performance Improvement's Safety Event Classification system as a uniform reporting system to allow hospitals to track near misses. This system is already being used by many hospitals that are moving toward high reliability, he says.

Healthcare systems differ from high reliability industries like commercial aviation, amusement

parks, and nuclear power in that they tend to focus on reviewing and taking action only when harm actually occurs, whereas the other organizations also look at their near misses, says Dr Foster.

"We hope to have a system that helps hospitals better track events that might lead to harm, which has been an area that has been difficult to measure," he says.

By the second year, Dr Foster says, hospitals should have better baseline statistics on their rates of harm and near misses.

### Safe Surgery program

One of the preexisting initiatives SCHA is involved in that Dr Foster says provided the foundation for their move toward high reliability is the Safe Surgery program. As part of this program, carried out in partnership with Atul Gawande, MD, and his team at Harvard's department

of health policy and management, Boston, all South Carolina hospitals committed to putting the World Health Organization's Surgical Safety Checklist into routine use in their ORs by the end of 2013.

"When you look at the level of leadership engagement, the culture, the environment where staff work, and the opportunity to reduce invasive harm and near misses in the OR, there is no other area from a hospital standpoint where I think the principles of high reliability apply more," says Dr Foster.

SCHA has been working with every acute care hospital in the state as well as a number of ambulatory surgery centers to implement the checklist and change the way surgical teams communicate. They have been tracking process and outcomes measures, and they hope to complete a formal report by the first quarter of 2014, he says.

Dr Foster noted that 1 hospital is using the debriefing part of the checklist to track near misses. "It was the first time a surgical team reported that they hadn't had a wrong-site or wrong-patient surgery in 2 years, but they had 4 situations in the past week that could have led to an error. The checklist totally changed the way they look at errors," says Dr Foster.

Thanks to the Safe Surgery program, SCHA has built a strong network of physician champions across the state that includes anesthesiologists and surgeons who are some of the individuals responsible for looking at how to spread high reliability across the organization.

### Lessons learned

Beyond the 21 hospitals initially participating in the initiative, the South Carolina Safe Care Commitment is designed to improve safety and quality in healthcare organizations across the state.



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The initial cohort of hospitals has been willing to share and learn from one another, and they will help spread this model to the newer cohorts.

The idea of having multiple overlapping cohorts is that the first group of hospitals becomes mentors and coaches for the next group, says Dr Foster.

Hospital participation and progress in moving toward high reliability will be recognized annually at the first meeting each year. ❖

—Judith M. Mathias, MA, RN

## References

<http://www.safesurgery2015.org/about-us.html>

<http://www.scha.org/south-carolina-safe-care-commitment>

<http://www.scsafecare.org>

*This article originally appeared in OR Manager, January 2014;30:1, 12-13.*

# Targeted Solutions Tool helps banish communication barriers during surgery

**P**rocess and communication concerns led OR management at the University of Florida Health Shands Hospital, Gainesville, to implement a Surgical Safety Process using the Joint Commission Center for Transforming Healthcare's Targeted Solutions Tool (TST) for Wrong Site Surgery.

"When we reviewed our patient safety reports, what came to the surface loud and clear was that we could be communicating better," Diane Skorupski, MS, RN, CNOR, NE-BC, told OR Manager.

"The reports showed us there were opportunities for improvement in our process, and we chose the TST to help identify those opportunities," says Skorupski, associate vice president for perioperative services at Shands.

Even though the TST is labeled Wrong Site Surgery, notes Skorupski, "it's more than that—it's really a Robust Process Improvement method to reduce process errors across the system, including scheduling, preoperative, intraoperative, and post-procedure."

## Identify problems

To identify process problems, leadership and staff trained on the TST performed 100 audits in each area—scheduling, preoperative, and intraoperative. The audits took about 3 weeks to complete.

Sifting through the information gleaned by the audits was "exciting," says Skorupski. "The TST easily identified where we were hitting the mark and where we needed to address process issues."

Like the patient safety reports, the TST found communication to be a problem.

Skorupski, the chairman of surgery, and the medical director—who is an anesthesiologist—presented the findings of the TST, opportunities for improvement, and the new Surgical Safety Process during a multidisciplinary grand rounds. The safety process includes a briefing, time-out, and debriefing. No surgery was scheduled during this time, and 800 people attended, including nurses, surgical technologists, surgeons, residents, and anesthesia providers.

The attendees were told they would be coached on how to do the briefing, time-out, and debriefing, and their practice would be audited.

Currently the auditors document their findings on paper, but soon they will do the audits on an iPad and download the findings onto a Pareto chart.

## Use team approach

Before implementation of the Surgical Safety Process, the circulating nurse and the anesthesiologist performed a time-out when the patient was brought into the OR. This consisted of patient identification and anything pertinent to the patient's anesthesia.

A second time-out was done when the surgeon arrived. A third time-out was performed after the patient was anesthetized and before the incision was made.

Now a briefing is done in the OR before induction with all parties present.

"What we clearly identified was that we wanted more of a team approach, and we wanted everyone to come together—the surgical technologist, surgeon, RN, and anesthesiologist—and have a discussion about the plan of care with the patient before induction," says Skorupski.

The briefing is started by the surgeon or anesthesiologist, who asks, "Is everyone ready for our briefing?" Team members introduce themselves and discuss the points in the briefing. The patient also participates in the discussion.

"We have found that patients love being involved in the process, especially the introductions," notes Skorupski.

At first, some team members objected to introducing themselves to each other because they work together all the time. But the chairman of surgery pointed out that they were not introducing themselves to each other but to the patient.

"Once they started thinking of it that way, there was no longer a problem," she says.

During their postoperative rounds, the surgeons say, patients tell them how wonderful it was to be introduced to the people who would be taking care of them while they were under anesthesia.

## Customize briefing to the patient

Skorupski says they tried very hard to keep the number of discussion points to a minimum and told team members to customize the briefing to each patient. For example, a pediatric hernia patient would not be on beta blockers, so that type of discussion would not be necessary. "This was a new thought to them because most were used to a checklist where they had to go through each bullet," she says.

## Surgical Safety Process – UF&Shands

<b>BRIEFING (In OR)</b> Pre-induction/procedure Stop called by attending anesthesiologist and attending surgeon/proceduralist before induction and before prep.	<b>TIME-OUT</b> Pre-incision Stop called by surgeon/proceduralist before surgical incision/procedure start.	<b>DEBRIEFING</b> Pre--emergence Stop called by circulating nurse/assigned team member upon surgeon's notification that wound closure is beginning or procedure is nearing completion. Notify Attending Anesthesiologist of anticipated debriefing.
<ul style="list-style-type: none"> <li>~ INTRODUCTION OF TEAM MEMBERS</li> <li>~ CORRECT PATIENT                             <ul style="list-style-type: none"> <li>~ ID x 2</li> <li>~ Electronic ID</li> </ul> </li> <li>~ CONSENT/PROCEDURE</li> <li>~ SITE MARKING</li> <li>~ ALLERGIES</li> <li>~ ANTIBIOTICS</li> <li>~ MEDICATION VERIFICATION                             <ul style="list-style-type: none"> <li>~ Current meds</li> <li>~ Anticoagulants?</li> </ul> </li> <li>~ BLOOD                             <ul style="list-style-type: none"> <li>~ H&amp;H available?</li> <li>~ ABO verification?</li> <li>~ Units available?</li> </ul> </li> <li>~ POSITIONING</li> <li>~ SCIP MEASURES                             <ul style="list-style-type: none"> <li>~ Beta Blocker</li> <li>~ DVT Prophylaxis</li> <li>~ Antibiotic</li> <li>~ Normothermia</li> </ul> </li> <li>~ CASE SPECIFIC                             <ul style="list-style-type: none"> <li>~ Implants available?</li> <li>~ Equipment</li> </ul> </li> <li>~ IMAGING DISPLAYED/CORRECT</li> <li>~ POSTOP DESTINATION?</li> <li>~ ANY SPECIAL CONCERNS                             <ul style="list-style-type: none"> <li>~ Patient Specific</li> </ul> </li> <li>~ ARE WE READY TO BEGIN?</li> </ul>	<ul style="list-style-type: none"> <li>~ CORRECT PATIENT</li> <li>~ SITE MARKED &amp; VISIBLE</li> <li>~ CONSENT/PROCEDURE</li> <li>~ ANTIBIOTICS</li> <li>~ BLOOD AVAILABLE?</li> <li>~ ANY CONCERNS?                             <ul style="list-style-type: none"> <li>~ Vital Signs</li> <li>~ Anesthesia</li> </ul> </li> <li>~ ARE WE READY TO GO?</li> </ul> <div style="text-align: center; margin-top: 20px;">  </div>	<ul style="list-style-type: none"> <li>~ ATTENDING SURGEON INITIATES</li> <li>~ CAVITY/WOUND CHECK</li> <li>~ STATUS OF FIRST COUNT</li> <li>~ SPECIMENS</li> <li>~ BLOOD RETURNED</li> <li>~ FAMILY CONTACT?</li> <li>~ ANY EQUIPMENT ISSUES?</li> <li>~ ANY CHANGE IN DISPOSITION?</li> <li>~ REPORT CALLED?</li> <li>~ ANY CONCERNS?</li> </ul>
<p><b>A "Pause" is required for change in physician performing the procedure, change in patient position or prior to starting another surgical or invasive procedure (i.e. completing procedure on index finger, starting procedure on thumb)</b></p>		

*Reprinted with permission from the University of Florida Health Shands Hospital, Gainesville.*

Specialty teams known as colleges (see OR Manager, July 2013, pp 1, 6-9) were consulted about which discussion points they wanted in the briefing, and a staff-driven committee decided which points to include. "Now, if a situation comes up, the first thing people say is, 'Let's add it to the briefing points,' so we have to be careful we don't keep adding to the list to the point that it becomes unwieldy," says Skorupski.

After team members introduce themselves, they check the patient's identification (ID). The surgeon confirms the patient's name and ID number on the wristband, and the anesthesiologist checks the name and ID number on the computer to make sure the correct patient record is pulled

up. The circulating nurse reads the patient's name, ID number, and procedure from the consent form.

"All 3 are involved in the identification of the patient at the start," notes Skorupski.

Once the patient identification process is completed and the team is assured of the correct patient and procedure, the surgeon scans the briefing discussion points, which are posted on a 3- by 5-foot laminated poster in each OR, and discusses any pertinent information with the other team members (sidebar).

In a typical discussion, the surgeon might ask if there are any unusual medications the patient might be taking or other special concerns to discuss. The anesthesiologist might

say, "We are concerned about the potential of a difficult airway and will be taking the following special precautions."

The surgical technologist might ask if there needs to be antibiotics in the irrigating fluid on the sterile field.

The circulating nurse might show the surgeon an implant to make sure it is the correct one.

After the team discusses all the relevant points, the surgeon asks, "Are we ready to begin?" This question is important, Skorupski says, because it invites team members to acknowledge whether they are ready.

If the surgeon instead said, "Let's get started," the discussion would be cut off, she says.

### **Shorten the time-out**

After the briefing, the patient is anesthetized, prepped, and draped. Before the knife is passed, the surgeon or resident initiates the time-out.

"The time-out is crisp," says Skorupski, "because we covered all of our bases in the briefing."

The surgeon asks if everyone can see the site marking and if the antibiotic is in. The anesthesiologist says the patient has been induced, vital signs are stable, and the antibiotic is in.

Then the surgeon asks, "Are we ready to go?" All team members verbally respond to the question.

### **Check on any concerns**

"The debriefing is supposed to start as the wound closure is beginning or near completion, but we are still struggling with the best time to start the debriefing," notes Skorupski. Sometimes the surgeon leaves and the resident closes. "We are trying to define a point in time that will trigger the debriefing," she says.

A month ago, Skorupski says, they decided to put stop signs on the doors of each OR to remind surgeons to debrief. The sign asks, "Did you debrief?"

The circulating nurse calls a stop as the wound closure begins and says, "It's time to debrief."

The circulator reviews the discussion points, saying, for example, "All specimens are off the field and labeled, and pathology slips are made out."

If unused blood is going with the patient to the ICU, that is acknowledged.

The surgeon might say the Potts scissors seemed dull and need to be sharpened.

The surgeon contacts the family, and the circulating nurse calls the report to the postanesthesia care unit or ICU.

To end the debriefing, the surgeon or circulating nurse asks, "Are there any concerns?"

When the OR goes live on Epic in May 2014, Skorupski says she wants to make the debriefing electronic so there is an automatic feed to other

departments. This way, for example, the sterile processing department will be notified if scissors need to be sharpened.

If a scheduling problem with the case surfaces during the debriefing, that information will go right to the scheduler, so there will be real-time feedback.

The debriefing is a way to empower the staff, and Skorupski hopes they will come to appreciate what an important part of the process it is.

### **Pause for change**

A pause is required for a change in the surgeon performing the procedure, change in patient position, or before a second procedure on the same patient is started.

During the pause, for example, the circulating nurse will read from the consent if it is a second procedure and say, "Yes, that is the procedure we are doing."

### **Promote communication**

To promote communication, the RNs are participating in simulation training.

"We want them to speak up—to say 'No, we can't start this case' or 'No, we can't go any further until blood has been drawn,'" says Skorupski.

"The training is going over well," she adds.

Skorupski says she is seeing an improvement in communication when she rounds.

The surgeons tell her it is good to get everyone together at the beginning of the case and have a conversation.

The circulating nurses and surgical technologists say they are more prepared for the procedure because they learn at the beginning of the case the supplies that might be needed even if they are not listed on the preference card.

"What I am seeing is more of an esprit de corps in the OR since kicking off the Surgical Safety Process last May," says Skorupski. "There is more [a spirit] of 'Yes, we are all on the same page,' and we are all taking care of our patient and recognizing our patient as an important person who we have to communicate with." ❖

—Judith M. Mathias, MA, RN

### **Reference**

Joint Commission Center for Transforming Health-care Targeted Solutions Tool for Wrong Site Surgery. [http://www.centerfortransforminghealthcare.org/tst\\_wss.aspx](http://www.centerfortransforminghealthcare.org/tst_wss.aspx)

*This article originally appeared in OR Manager, January 2014;30:14-16.*

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# IV. Preventing Infections



# Are you on target for meeting SSI, SCIP metrics?

**O**R leaders will want to check that their surgical site infection (SSI) rates are in line with 5-year goals in the updated National Action Plan for reducing health care-associated infection (HAI) from the Department of Health and Human Services (HHS).

By and large, hospitals are on target to meet SSI goals by the end of 2013, HHS reports. But they can't let up.

Two of the action plan's 9 goals directly relate to surgery:

- 25% reduction in SSIs
- 95% adherence to SCIP measures, referring to the Surgical Care Improvement Program.

HHS plans to keep the focus on infection prevention with a new tool for use in state validation surveys, based on the one already used for ambulatory surgery centers (ASCs).

The action plan was posted for comment on April 19, 2012, with comments accepted through June 25, 2012.

Phase 1, rolled out in 2009, focused on hospitals. Phase 2 extends to ASCs and dialysis clinics, with Phase 3 planned for long-term care.

## Progress on SSIs

SSIs decreased by 10% for 2010 from the 2006-2008 baseline period, HHS notes, and during 2010, 8% fewer SSIs were reported than predicted.

The biggest improvement over the past 2 years was for coronary artery bypass graft (CABG). Smaller reductions were seen for 2 of the other procedures evaluated, knee arthroplasty and colon surgery.

"We are moving in the right a direction, and that is definitely good news," says Linda Greene, MPS, RN, CIC, director of infection prevention and control for Rochester General Health System in Rochester, New York.

Central line infections fell by 33%, and invasive methicillin-resistant *Staphylococcus aureus* (MRSA) infections were down by 18%.

The same could not be said for *Clostridium difficile* infections, which are at historic highs—75% now begin outside the hospital in settings such as nursing homes and outpatient clinics.

The data is from the Centers for Disease Control and Prevention (CDC) surveillance system, the National Healthcare Safety Network (NHSN).

Over 5,000 facilities are enrolled in NHSN. Hospitals are required to participate if they are

part of Medicare's inpatient quality reporting program in order to report data on central line-associated bloodstream infections.

## Surveyor tool for hospitals

The state survey infection control tool is intended to improve the quality and consistency of surveys, HHS says.

The hospital tool was piloted in several states in 2011, expanding to all states in 2012. Starting in federal FY 2013, the tool will be used in all state surveys of hospitals, according to Centers for Medicare and Medicaid Services (CMS) plans.

CMS says it is also providing surveyors with more training and requiring accreditors like the Joint Commission to make infection control a priority.

Hospitals were cited for infection control deficiencies in 1.7% to 2.3% of regular state surveys between 2007 and 2010, HHS reports.

## Focus for perioperative leaders

Greene suggests that perioperative managers and directors review their infection prevention program to be sure it is in line with the HHS action plan:

- Review the pilot state surveyor infection control tool to see what areas surveyors will be looking at.

"Although the tool is currently being piloted, it addresses important structure, process, and outcome measures that are part of a robust infection prevention plan," Greene says. This includes OR-specific issues such as disinfection, sterilization, and cleaning.

- Know how your organization is doing on its SSI metrics:

—surgical infection ratios (SIR)

—SCIP compliance.

(Hospitals that have a low denominator may not be able to calculate an SIR for a single quarter.)

- Check your SIR data for colon surgery and abdominal hysterectomy for the first quarter of 2012, if available.

Hospitals were required to begin reporting their SSI data for these 2 procedures to CMS on January 1, 2012, to qualify for a full Medicare payment update in 2014.

Your hospital's SSI rates for these procedures eventually will be reported to the public on Medicare's Hospital Compare website.

## National standardized infection ratios (SIRs) for surgical site infections\*

	95% CI for SIR		
	SIR	Lower	Upper
Hip arthroplasty	0.971	0.914	1.030
Knee arthroplasty	0.892	0.840	0.947
Coronary artery bypass graft	0.820	0.766	0.876
Cardiac surgery	0.835	0.692	1.000
Peripheral vascular bypass surgery	0.935	0.718	1.196
Abdominal aortic aneurysm repair	0.648	0.255	1.363
Colon surgery	0.909	0.853	0.968
Rectal surgery	1.285	0.854	1.857
Abdominal hysterectomy	1.065	0.964	1.174
Vaginal hysterectomy	1.243	1.006	1.520

Source: Centers for Disease Control and Prevention. \*Data from all NHSN facilities during 2010, using only SSIs that were classified as deep incisional or organ/space and detected on admission or readmission.

### Get to know your SIR

Become familiar with SIR, the metric the CDC and CMS now use to report SSIs and other HAIs, Greene recommends.

Note whether your SIRs are better or worse than average.

"You don't want to be blind-sided by this," she advises.

The SIR compares a facility's actual number of SSIs with the US experience, adjusted for risk factors:

- A SIR significantly higher than 1.0 indicates more infections were observed than predicted.
- A SIR significantly less than 1.0 indicates fewer SSIs than predicted were observed.

### SCIP progress

According to the latest available data from 2009, hospitals were exceeding 95% compliance for 3 of 5 SCIP-Infection metrics:

- SCIP Inf 1: On-time antibiotic administration

- SCIP Inf 2: Antibiotics consistent with recommendations
  - SCIP Inf 6: Appropriate hair removal.
- But 2 metrics had not yet reached the 95% goal:
- SCIP Inf 3: Antibiotics discontinued within 24 hours after surgery
  - SCIP Inf 4: Glucose control for cardiac surgery patients.
- The 2010 data was not yet available.

The pilot CMS infection control survey tool is available at <http://www.aimediaserver6.com/ORManager/HHS%20Hospital%20Infection%20Control%20Surveyor%20Tool%20050112.pdf>

The National Action Plan is available at [www.hhs.gov/ash/initiatives/hai/actionplan/index.html](http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html)

*This article originally appeared in OR Manager, June 2012;28:22-23.*

# Curbing OR traffic: Finding ways to minimize the flow of personnel

**A** traffic cop? Stop signs? Flashing lights? Is there a way to curb the number of people passing in and out of ORs during cases? The number during a lengthy major surgery can reach a dozen or more, with door openings every minute or two.

Door openings affect the OR's ventilation system. The more people, the more bacteria. In a new study led by Andersson, et al, from Sweden, the OR traffic rate was linked to high bacterial counts close to the surgical wound (sidebar).

Door openings also add to distractions and interruptions, possibly affecting team performance and surgical outcomes, Healey and colleagues observe in a 2006 study.

There is no recommended limit to the number of personnel in a surgical case. The Centers for Disease Control and Prevention and AORN advise that the number be minimized.

## Why door openings?

In the Swedish study, 32% of door openings were considered unnecessary. Of these:

- 55% had no discernible reason
- 27% were for social visits
- 18% were for logistical planning for other operations.

Among major reasons were:

- supply issues: 26%
- staff breaks: 20%.

Only 7% were related to the need for expert consultation.

OR personnel apparently think all of the in-and-out is necessary. Even when teams knew they were being observed, the number of door openings and closings didn't change, in a study led by Shital Parikh, MD, from Cincinnati Children's Hospital Medical Center. (See sidebar on research.)

Blaming individuals isn't the answer, say the Swedish authors. They suggest organizational changes, such as raising the knowledge level and improving logistics and preoperative planning.

Some ORs have introduced changes that have reduced traffic.

## Curbing traffic

Facilities in Kaiser Permanente's Southern California region have taken steps to limit traffic as part of the Highly Reliable Surgical Teams program. The program emphasizes a team-based

culture and standardized protocols (OR Manager, February 2010, pp 16-18).

Staff are cautioned that excessive in-and-out traffic during surgery is a distraction that can contribute to infection and errors, says Marie Paulson, BSN, MS, RN, CNOR, the region's director of perioperative services. She acknowledges "it's a fine balance, to provide training and have the appropriate staff in the room."

Circulating nurses are encouraged to coordinate activity during cases.

"If the circulator identifies too many are present, she needs to take accountability for patient care and ask them to leave," Paulson says. Circulators are also encouraged to ensure personnel, such as vendor representatives, are in the room only for the time needed.

Staff are instructed not to use ORs as shortcuts to the sterile core and are asked not to stick their heads in a room just to say hello.

## Staff relief

Though staff breaks are necessary, the exchange of personnel contributes to traffic and raises the risk of losing critical information during a handoff. Some organizations have re-examined how they manage breaks. Managers considering changes should consult with their HR departments and review their state's labor laws.

As part of Highly Reliable Surgical Teams, Kaiser has identified critical events during surgery when safety can be compromised:

- the time-out to verify information about the patient and case
- site mark verification before the incision after prepping and draping
- surgical counts, whether for relief or the final count
- critical events during the case deemed by the physician, such as aortic cross-clamping, inserting a carotid stent, or inserting a joint prosthesis.

Though staff relief is managed by each facility, the general recommendation is for OR staff not to accept breaks routinely during these critical times, Paulson says.

## Planning for relief

In the Kaiser facilities, it is suggested that before each case, the OR team discuss relief with the physicians during the time-out.



## OR traffic: Research highlights

### Door openings and bacterial counts

OR traffic, including a high rate of door openings, was linked to high bacterial counts close to the surgical wound, in a Swedish study of orthopedic trauma cases.

In only 7% of the cases were door openings related to expert consultation. The leading reasons were:

- supply issues: 28%
- staff breaks: 20%.

More than one-fourth (27%) involved social visits or no detectable reason.

—Andersson A E, Bergh I, Karlsson J, et al.  
*Am J Infect Cont.* 2012. Online ahead of print.

### Door openings and distraction

Door openings averaged 33 per case in a study of 50 general surgery operations in a single OR in the UK. The researchers observed an average of 1 interruption per minute, with a possible impact on team performance and surgical outcomes.

—Healey A N, Sevdalis N, Vincent C A.  
*Ergonomics.* 2006;49:589-604.

### Cardiac OR traffic

Researchers in the UK studying 46 cardiac cases in 2 ORs found:

- an average of 92.9 door openings per case
- a rate of 19.2 door openings per hour in 2 cardiac ORs.

The OR door open for an average of 6.4 minutes (10.7%) of each hour of operating time.

The authors note a “possible trend” toward increased SSIs with increased levels of OR traffic.

—Young R S, O’Regan D J.  
*Interact Cardiovasc Thorac Surg.* 2010;10:526-529.

### Foot traffic in OR

An observational study recorded 19 to 50 traffic events per hour for 28 cases in all specialties. The preincision period represented 30% to 50% of all events, with information requests accounting for the majority.

—Lynch R J, Englesbe M J, Sturm L, et al.  
*Am J Med Qual.* 2009;24:45-52.

### Monitoring does not curb traffic

Monitoring alone may not be sufficient to limit OR traffic.

A study observing traffic in pediatric orthopedic ORs found no difference in traffic when OR personnel were notified they were being observed and when they were not.

The average number of door swings per hour was about 40. Door swings could reach 200 in a long case, such as spine surgery, which can last 5 hours.

—Parikh S N, Grice S S, Schnell B M, et al.  
*J Pediatr Orthop.* 2010;30:617-623.

For example, for a 3-hour case starting at 9 am, there typically would be a break and perhaps a meal. During the time-out, the circulating nurse would say to the surgeon and anesthesia provider, “Is there a time, other than the critical times, when you would want me to wait to take a break? Otherwise, I will let you know when it is time. If it is not an appropriate time, please let me know.”

The nurse is not asking permission, Paulson explains, but rather alerting the team when break time arrives.

When relieved, the nurse says, “Dr Jones, I’m going to be relieved. I am giving Sally a report.”

Physicians have been receptive to this practice, she says. As part of the team-based culture, team members introduce themselves at the start of a case and introduce their relief person, which aids communication.

Kaiser is unionized. Paulson says the staff and labor partners “were receptive and supported the highly reliable aspects of patient care, so this has not been a problem. We still provide breaks and meals and comply with all state and federal regulations.”

The focus is always on “what is in the patient’s best interest,” she notes. “Patients deserve the best team who knows their needs and has the best understanding of what is going on.”

### Limiting morning breaks

Ogden Regional Medical Center in Ogden, Utah, decided to limit morning breaks for its 7 ORs after much discussion with the staff.

The staff were OK with the change once they understood the reasons—safety for the patient because of better infection control and fewer communication lapses, says Lori Gordon, RN, director of surgical services. “We realized breaks are disruptive,” Gordon says. “People were trying to hurry, and sometimes information wasn’t passed on.” Plus, changing scrub persons increased the chance for a break in technique.

Staff who don’t have a break in the morning may take a longer lunch or leave early. Gordon also tries to provide inexpensive treats that the staff appreciates, such as free soft drinks in the lounge.

### **'Do not enter'**

Staff generally are not relieved during cases such as total joint replacement and major spine surgery at Holland Hospital in Holland, Michigan. During these cases, a "do not enter" sign is placed on the door.

Total joint cases generally last 1 1/2 to 2 hours, and major spine cases can run 4 to 6 hours.

Both staff and anesthesia providers are asked to abide by the limit, notes Kathy Shaneberger, MS, RN, CNOR, director of surgical services.

### **Enlisting technology**

Display screens and wireless communication badges are ways technology is helping to reduce traffic.

Cincinnati Children's uses a computerized system to track patient status, Dr Parikh notes. Nurses can click a tab in the hospital's Epic software to record the patient's status. The status is displayed on monitors at the OR's front desk.

"We can look at the board and know where the patient is. That has eliminated a lot of traffic for information purposes," says Dr Parikh, a pediatric orthopedic surgeon.

Ogden Regional Medical Center and Holland Hospital employ Vocera, a wireless communication system that uses push-button badges and smartphones ([www.vocera.com](http://www.vocera.com)).

"With Vocera, the staff does not have to leave the OR to communicate. It's like a phone but quicker," says Gordon.

Circulating nurses can easily call the anesthesia provider when a room is ready, for example. Or the nurse can call sterile processing to request an instrument.

Gordon wears a Vocera badge herself to help in managing the schedule. "The staff will call me if something has changed," she says.

For additional traffic control, OR assistants' role has been expanded to include responsibility for providing equipment for cases.

### **Additional ideas**

Other steps organizations have taken to limit traffic:

#### **Surgeon request form**

When scheduling a case, surgeons at Cincinnati Children's fill out a Surgeon Request Form. The form, faxed to the OR's scheduling desk at posting, records the surgeon's estimate of incision-to-close time and any special needs for the surgery. (The form is in the OR Manager Toolbox at [www.ormanager.com](http://www.ormanager.com).)

"This helps us to communicate preoperatively what we will need during surgery," says Dr Parikh.

Preference cards are kept up to date so cases can be set up accurately, minimizing the need to leave the OR.

#### **Designated OR coordinator**

A designated OR coordinator for orthopedics works with the surgeons and vendors at Cincinnati Children's to ensure the proper instrument

sets and implants are ordered for cases in advance, which also helps in preparing for cases and avoiding unnecessary traffic.

### **Starting longer cases early**

As much as possible, at Cincinnati Children's, major cases such as spine surgery and joint reconstruction are started early in the day so they can be finished before the shift change at 3 pm, Dr Parikh notes. A shift change with its change in personnel means more traffic, a greater risk of information loss, and disruption of OR flow.

### **Limiting numbers of personnel**

Though there are often good reasons for vendors, students, and trainees to be present during surgery, facilities are taking steps to minimize the numbers.

Cincinnati Children's limits students to 1 to 2 at a time per case. Observers must be approved by the residency coordinator to make sure others are not scheduled for the same case, Dr Parikh notes.

Like many facilities, Ogden Regional requires vendor reps to be credentialed and to check in when they arrive.

Vendors are asked to limit personnel in the facility to one per company at a time, Gordon says. They are asked to limit time in the OR to what is pertinent to the case.

A focus on patients' safety coupled with communication technology and systems changes that enable better case preparation are tactics that have aided these organizations in keeping traffic down, which reduces air turbulence and creates a calmer environment for the entire surgical team. ♦

—Pat Patterson

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# Joint project targets prevention for colorectal surgical infections

Seven hospitals working with the Joint Commission and the American College of Surgeons (ACS) on a 2-year project to reduce colorectal surgical site infections (SSIs) have saved more than \$3.7 million by avoiding an estimated 135 SSIs, the commission announced in November 2012.

The commission is pilot testing the approach used in the project with the aim of rolling out targeted solutions for all accredited hospitals in 2013.

Joint Commission President Mark Chassin, MD, FACP, said colorectal surgery was chosen as a focus because it's a common major surgery with a significant rate of complications, particularly SSIs. Also, complication rates vary widely, suggesting there is room to improve.

Through the project, led by the Joint Commission's Center for Transforming Healthcare, the participating hospitals:

- reduced their rate of superficial incisional colorectal SSIs by 45% and reduced colorectal SSIs overall by 32%.
- decreased the average stay for patients with any type of colorectal SSI from 15 days to 13 days, compared to an average 8-day stay for patients with no SSIs.

## Data-driven process

Participating hospitals followed a data-driven process using surgical outcomes data from the ACS National Surgical Quality Improvement Project (NSQIP) to pinpoint specific risk factors for their patients and to develop targeted interventions to reduce their colorectal SSI rates.

Dr Chassin emphasized the importance of each hospital identifying the risk factors of its own patient population and developing interventions targeted to those risk factors.

"There is no one-size-fits-all way to prevent SSIs," he said. "We have learned that you have to use sophisticated tools like rapid process improvement, including Lean Six Sigma and change management, to find out exactly how poor outcomes occur."

Two hospitals represented on a Joint Commission press call achieved a sustained reduction of at least 50% in their colorectal SSI rates. Cedars-Sinai Medical Center in Los Angeles saw its colorectal SSI rate fall from 15.5% to 5.5% during the 2 1/2 year project and decline to less than 5% since July 2012. The Mayo Clinic, Rochester, Minnesota, reduced its rate from 9.8% to 4%.

## Targeted solutions

The participants identified 34 variables that increased SSI risk including patient characteristics, surgical procedure, antibiotic administration, peri-operative processes, and measurement challenges.

Among targeted solutions for reducing superficial incisional SSIs were:

- standardizing preop instructions for skin cleansing
- establishing specific criteria for wound management.

Solutions for reducing all types of colorectal SSIs were:

- warming patients to maintain temperature throughout the surgical episode
- weight-based antibiotic dosing.

There were 2 interventions all 7 hospitals agreed on:

- standardizing patient instructions on use of preop skin cleansing with wipes containing chlorhexidine gluconate (CHG)
- changing to clean gloves, gowns, supplies, and instruments for the skin closure.

## 'No magic bullet'

At Cedars-Sinai, the surgeon champion, Shirin Towfigh, MD, FACS, worked with a multidisciplinary team of surgeons, nurses, performance improvement specialists, and others to analyze risk factors of the hospital's surgical population and develop interventions. In all, 46 surgeons were involved.

"We knew there was no magic bullet to prevent all SSI," she says. She met with each surgeon, including the 10 colorectal surgeons, to see what was feasible to change in their practices to improve quality.

"We tried to make it as simple and easy as possible and not to impinge on the independence of the surgeon's practice," she says.

The major interventions are summarized on a one-page sheet (illustration).

Dr Towfigh says 2 factors were key in achieving the SSI reductions:

- having a surgeon champion rather than an administrator as the project leader
- making sure the interventions were evidence-based.

Interventions were planned so as not to interfere with efficiency.

## Surgical Site Infection Bundle: Reducing Risk in Colorectal Surgery Patients

### Preoperative Elements

#### 1. CHG SHOWER\*

During the last pre-surgery visit, instruct your patients to shower with a special antiseptic soap that contains Chlorhexidine.

### Intraoperative Elements

#### 1. ANTIBIOTICS\*

Use Cefotetan 1g alone for all Procedures.

- If >80kg, use 2g.
- If allergic, use Levofloxacin/Metronidazole 500mg/500mg.

If patient is already receiving IV antibiotics (Cefotetan, Zosyn or Flagyl) for treatment, give a pre-incision dose if the last dose was administered more than 1hr prior.

#### 2. ANTIBIOTIC REDOSING\*

Re-dose antibiotics if the case is prolonged beyond 4hrs (examples includes Cefotetan, Zosyn, and Flagyl)

#### 3. CHG SKIN PREP\*

**ALWAYS USE:** Chloraprep  
**EXCEPT:** Betadine

- Permanent Stoma
- Open wound (optional)



### Intraoperative Elements

#### 4. WOUND PROTECTOR\*

Wound Protectors are clinically proven to decrease the risk of wound infection and maintain moisture at the incision site.

#### 5. OBSERVE HAND HYGIENE\*

- Gel in prior to entry to OR room
- Wash your hands with soap and water after degowning and degloving.

#### 6. SKIN CLOSURE PROTOCOL\*

1. Surgeon announces "Time to Close."
2. Surgeon confirms Wound Classification (clean-contaminated, contaminated, or dirty)
3. Scrub Nurse removes all dirty instruments, including:
  - Forceps, Needle holder
  - Suction tip
  - Bovie cautery pen
  - Light handles
4. Sterile gloves and gown change by all team members
5. Clean closure instruments are brought to field
6. Saline irrigation of wound after fascia is closed
7. Dressing application of occlusive dry dressing (e.g., island dressing, gauze with tape or Tegaderm).

### Postoperative Elements

#### 1. WOUND DRESSING/CARE

- Daily post-operative CHG bathing and discharge patient with CHG\*
- Maintain dry occlusive dressing; change dressing as needed.
- Dressing removal within 48 hours after surgery\*
- Consider wound probing or wicks if dirty or contaminated wound
- Culture** wounds if concern for infection

### Preoperative Optional Element

#### 1. BOWEL PREP (OPTIONAL)

Use of bowel prep may vary by surgeon.

On day prior to surgery:

Mechanical Prep +/- Oral Antibiotic Prep

Choice of antibiotics:  
(First antibiotic dose to be taken AFTER completing mechanical prep, and second 4hrs later)

Neomycin Sulfate 1g, two doses in the evening

AND EITHER  
Erythromycin Base 1g, two doses in the evening

OR  
Metronidazole 1g, two doses the evening before OR the morning of surgery

\*Required bundle elements

Updated 03/02/12

Source, Cedars-Sinai Medical Center, reprinted with permission.

For example, for the skin closure, the OR staff arranged to change to clean supplies and instruments as seamlessly as possible by having the items available in the room. Rather than having a separate closure tray, closing instruments and supplies are set aside at the beginning of the case.

In another change, Cedars-Sinai converted from povidone-iodine to alcohol-chlorhexidine gluconate (CHG) for surgical skin antisepsis, first for colorectal cases and then for other specialties and procedures. However, patients with colostomy stomas that are not being reversed are still prepped with povidone-iodine.

Surgeons were informed the change would be made, and then povidone-iodine for surgical site antisepsis was simply removed from the supply stock, Dr Towfigh says. When nurses expressed concern about pushback from some surgeons, Dr Towfigh told them to refer the surgeons to her, and she would review the evidence with them.

At the Mayo Clinic, Rochester, Minnesota, interventions once adopted are embedded in patient care "so they are part of our system whenever possible," said Jenna Lovely, PharmD, surgical pharmacotherapy manager.

An example is patients' body mass index (BMI), which emerged as an SSI risk factor in the Mayo data set. An electronic trigger now automatically identifies patients with a BMI over 30.

"We have moved from this being a QI project to being the way we work," Lovely said. ❖

—Pat Patterson

For more about the colorectal SSI prevention project go to [www.centerfortransforminghealthcare.org/projects/detail.aspx?Project=4](http://www.centerfortransforminghealthcare.org/projects/detail.aspx?Project=4)

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# Have you taken steps to avoid the abuse of IUSS?

I have heard the following statement from OR personnel: “We use rigid sterilization containers and run a 270-275°F (132-135°C) prevacuum steam sterilization process in our OR. So we no longer use IUSS.”

## Is that an IUSS cycle?

IUSS, or immediate-use steam sterilization, was formerly known as flash sterilization.

This article discusses the what, when, and how of IUSS along with risks, the Joint Commission perspective, and how to minimize use of IUSS.

## What is IUSS?

The Multi-society Immediate-Use Steam Sterilization statement issued in 2011 broadly defines “immediate use” as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field. The sterilized item is:

- used during the procedure for which it was sterilized
- used in a manner that minimizes its exposure to air and other environmental contaminants
- not stored for future use
- not held from one case to another.

The standard, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ST79) from the Association for the Advancement of Medical Instrumentation (AAMI), in section 2.61 defines IUSS as a “process designed for the cleaning, steam sterilization, and delivery of patient care items for immediate use.” AAMI ST79 also states, “Since drying time is not usually part of a pre-programmed cycle for immediate-use, the items processed are assumed to be wet at the conclusion of the cycle.”

## IUSS cycles

An IUSS cycle can be either a gravity or dynamic-air removal (eg, prevacuum or steam-flush pressure-pulse) cycle run at 270-275°F (132-135°C) for the time recommended by the device manufacturer’s written instructions for use (IFU). This includes extended cycles if required. What makes IUSS different from terminal sterilization is that there is no dry time. That is why items must be used immediately.

AAMI and AORN recommend using rigid containers intended for IUSS cycles to protect instruments during aseptic transfer to the sterile field. Processing unwrapped items is not recommended, because they are wet and could become contaminated during the transfer process.

So the answer to the question, “Is processing instruments in a rigid sterilization container at 270-275°F (132-135°C) in a prevacuum steam sterilization process considered IUSS?,” is yes, if there is no dry time, and the items are wet at the end of the cycle.

## When to use IUSS

AORN states IUSS “should be used only when there is insufficient time to process by the preferred wrapped or containerized method intended for terminal sterilization.” IUSS “should not be used as a substitute for sufficient instrument inventory.”

AORN, AAMI, and the Centers for Disease Control and Prevention agree that IUSS should not be used to sterilize implants.

## How to use IUSS

Here are the steps to keep in mind:

- Medical devices processed by IUSS should be cleaned, packaged, and sterilized according to the manufacturer’s IFU.
- Cleaning should be performed in an area that has the equipment (eg, sinks and mechanical and/or ultrasonic washers), cleaning agents, tools (eg, brushes), and water quality needed to follow the medical device manufacturer’s IFU.
- If the OR processing area does not have the appropriate setup, devices should be sent to the sterile processing department (SPD) for cleaning, packaging, and sterilization.
- Packaging material should be that recommended by the device manufacturer’s IFU and should provide protection for aseptic presentation. Unwrapped trays are not recommended.
- The sterilization cycle, exposure time, temperature, and drying times (if recommended) should be followed. It is no longer acceptable to run a 3- or 10-minute 270-275°F (132-135°C) gravity cycle for IUSS unless those cycles are recommended by the device manufacturer’s IFU.

## Why is immediate use sterilization being used?

More than 80% of the time in a study at one large hospital, immediate-use steam sterilization (IUSS) was used for reasons other than its recommended purpose—intraoperative contamination, such as when an instrument is dropped. The most common reasons documented were:

- operating room turnover
- receipt of an unsterile instrument
- intraoperative contamination
- contamination from breaches in packaging
- a one-of-a-kind instrument.

—Zuckerman S, Parikh R, Moore D C, et al. *Am J Infect Cont.* 2012;40:866-871.

- The same sterilization cycle and parameters used in SPD need to be used in the OR. This may require the use of an extended cycle, eg, 270-275°F (132-135°C) gravity cycle for 30 minutes, or a 270-275°F (132-135°C) dynamic-air removal cycle for 10 minutes.
- The sterilization cycle should be documented with physical monitors and chemical and biologic indicators (BIs) and the results documented along with the name of the patient.

AORN states that because these devices are hot and wet, care should be taken to transport the devices to the point of use “in a manner that minimizes the risk of contamination of the item and injury to personnel.”

### Take care to document

A recent study by Zuckerman et al, conducted in Vanderbilt University Hospital’s main OR, identified potential lapses in practice related to IUSS, including incomplete documentation of:

- use of chemical and BIs (ie, used in each load)
- peak temperature
- cycle time
- description of specific instruments sterilized.

The authors encourage “institutions to strictly assess the rationale for IUSS and documentation of core IUSS components. Only through sound documentation can practices be monitored and quality improved.”

### Joint Commission perspective

John Rosing discussed observations about IUSS from Joint Commission surveys in the October 2012 OR Manager. He noted: “Joint Commission surveyors won’t cite an organization for sterilizing instruments for immediate use. Rather, they will check that data is being collected on instances when immediate-use sterilization is used and then check to see if action is being taken

based on the data. If surveyors don’t find that, they may cite the organization under the performance improvement standards.”

Data to collect routinely and to aggregate monthly, Rosing advises, includes:

- the number of IUSS episodes attributed to lack of instruments
- the evaluation completed by OR leadership and submitted to the infection control committee for its evaluation.

The committee should present its data on the number of IUSS episodes that were due to a lack of instruments to the hospital’s finance department to justify the need to buy more instruments.

### Traceable to the patient

At the 2011 meeting of the International Association of Healthcare Central Service Materiel Management (IAHCSSM), a Joint Commission surveyor said that the Joint Commission is also interested to see that any devices, including implants, processed by IUSS be traceable to the patients on which they are used or implanted.

AAMI ST79 Section 10.3 states: “IUSS of implantable devices is not recommended; however, if it is unavoidable, full traceability to the patient should be maintained.” Traceability is important because of the serious consequences of infections related to implants.

### Releasing implants

AAMI ST79 also states that “releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.” AAMI ST79 has 2 forms in Annex L that can be used to track documentation of premature release of implants. One is an Implantable Devices Load Record, and the other is an Exception Form for Premature Release of Implantable Device/Tray that includes documenting why premature release of the implant was needed and what could have prevented this premature release.

Joint Commission surveyors will check these forms to see how many implants are released before the BI is available. They will expect to see a Department of Surgery policy that includes multidisciplinary input to address who can authorize early release of implants. The Joint Commission suggests this be a surgeon.

### How to minimize IUSS

Be sure you and your superiors are aware of the Joint Commission’s National Patient Safety Goal 07.05.01, in particular EP 4, which states: “As part of the effort to reduce surgical site infections, conduct periodic risk assessments for surgical site infections in a time frame determined by the hospital.” This could be interpreted to apply to IUSS. Conduct a risk assessment to determine why the facility is using IUSS and determine how to eliminate all reasons except for intraoperative contamination.

The data collected, as suggested above, will assist in this risk assessment.

### Policy on loaners

As a result of the risk assessment, your facility may determine that the policy and procedure for loaner instruments needs to be updated and/or enforced.

Communication is key. When loaner sets are used, the correct instrumentation needs to arrive at least 2 business days before the scheduled case to facilitate proper cleaning, sterilization, and quarantine of implants until the BI results are negative. The IAHCMM position paper and sample policy are invaluable tools to use in this process.

Management teams from the OR, sterile processing, infection prevention, and risk management need to work together to develop policies and procedures to ensure IUSS is not performed for convenience. Abuse of IUSS has the potential to increase risk for development of SSI. ♦

—Martha Young, MS, CSPDT

*President, Martha L. Young, LLC, providing SAVVY Sterilization Solutions for Healthcare-Woodbury, Minnesota*

*Martha Young is an independent consultant with long experience in medical device sterilization and disinfection.*

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# Hospitals share data to prevent colorectal SSIs

**W**hy does our hospital have a higher rate of venous thromboembolism (VTE) than others in our state? How are others preventing surgical site infections (SSIs) after colorectal surgery? What's behind our urinary tract infection (UTI) rate?

Hospitals in Tennessee are openly discussing issues like these through the Tennessee Surgical Quality Collaborative (TSQC), a 21-member state-level group focused on improving surgical outcomes.

## Hospitals can reduce complications

Reducing surgical complications is a high priority as organizations seek to improve care and lower costs. Complications not only cause pain and suffering but increasingly are tied to reimbursement from Medicare and private payers.

The Tennessee project is showing that hospitals can reduce complication rates by sharing data, comparing results, and exchanging ideas on improving care.

TSQC is a partnership of the Tennessee Hospital Association (THA) and the state chapter of the American College of Surgeons (ACS), with funding from the Blue Cross Blue Shield of Tennessee Health Foundation. All participants are enrolled in the ACS National Surgical Quality Improvement Program (ACS NSQIP).

Similar collaboratives are underway in 9 states and at least 7 health systems, according to ACS, with Tennessee and Florida having the largest.

The Tennessee collaborative began in 2007. A report of results from 2009 through 2010 when there were 10 participants showed significant improvements in 5 of 21 types of complications for general and vascular surgery:

- acute renal failure
- graft/prosthesis/flap failure
- ventilator time >48 hours
- superficial SSI
- wound disruption.

Three outcomes got worse: deep vein thrombosis, pneumonia, and UTI. The report was published in the *Journal of the American College of Surgeons*.

Net costs avoided were estimated at \$2.2 million per 10,000 cases. TSQC estimates overall savings of \$8 million for that period based on annual volumes.

Though the reasons why the 5 measures improved so dramatically was not readily apparent, one reason might be willingness to share data and compare notes candidly, says Joseph B. Cofer, MD, FACS, head of TSQC and professor of surgery at the University of Tennessee College of Medicine, Chattanooga.

A more recent report, as yet unpublished, shows improvement has been sustained for 4 of 5 outcomes in the initial study.

"This has been a gradual process over 5 years," he told OR Manager. "I think we're going to see sustained improvement."

Surgeons are willing to participate because the collaborative uses NSQIP, which is scientifically validated, says Dr Cofer, noting that "when you show surgeons the data, they try to get better."

Developed by surgeons, NSQIP focuses on 30-day outcomes and uses data from patients' charts, not claims. The data is risk adjusted, case-mix adjusted, and audited.

The collaborative's funding supports about half of a hospital's \$120,000 annual cost for joining NSQIP. That includes membership plus a full-time surgical clinical reviewer (SCR), a requirement. The reviewer collects data on 40 surgical cases in an 8-day cycle and enters it in the NSQIP data base. Each hospital must also appoint an engaged surgeon champion.

## Digging into data

The TSQC hospitals meet quarterly and share data in a blinded fashion. Though initial meetings were tentative, Dr Cofer says trust has developed.

"The members dig into the data and openly share with each other where the opportunities are," adds Chris Clarke, BSN, RN, THA's senior vice president of clinical services, who manages the project.

A participant might say, for example, "Our infection rate was high last year. What do you think we should be doing?"

Or a report might show Hospitals B and G have the lowest UTI rates. They volunteer to discuss their prevention efforts.

## A colorectal SSI bundle

TSQC hospitals have agreed to trial a bundle of interventions for preventing SSIs from colorectal surgery that goes beyond measures in the



## Making a difference in care using NSQIP data

Hospitals that participate in the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) get validated, risk-adjusted data on 30-day outcomes for surgical patients.

But how do you involve front-line staff so the data can make a difference in patient care?

At Baptist Memorial Hospital-Memphis, NSQIP data is shared with surgeons and nurses who are engaged in continuously improving care. The hospital is a member of the Tennessee Surgical Quality Collaborative (TSQC) (related article).

An example is the collaborative's colon bundle for preventing surgical site infections (SSIs). At Baptist Memorial, the bundle's interventions are posted above the scrub sinks where surgeons and staff can review it.

Here are steps the hospital is taking to implement the bundle's 4 interventions.

### Maintaining normothermia

*Goal: Maintain temperature for colon surgery patients to be at least 36°C during the procedure.*

All patients are prewarmed prior to surgery regardless of temperature using a warming gown (Bair Paws). Forced-air warming devices (Bair Hugger) are used during surgery.

"There is a real focus on normothermia for long procedures and for patients who present with comorbidities," says Daryl Miller, BS, RN, director of surgical services.

"If nurses see a patient's temperature is dropping, they can turn up the Bair Hugger,"

adds Kay Loyd, BSN, RN, CEN, performance improvement specialist. Some surgeons also use warmed IV fluids.

### Supplemental oxygen

*Goal: Administer high-flow oxygen (FiO<sub>2</sub> at 80%) for the first 6 hours postoperatively.*

Before this intervention was added to the postop orders, Loyd requested a review by pulmonologists at the request of risk management. Four pulmonologists reviewed it and saw no problem, she says. Anesthesia providers let the surgeons know if a patient is not a good candidate.

### Prophylactic antibiotics

*Goal: Select the appropriate antibiotic.*

For the colon bundle, as with the SCIP measure, antibiotics are to be given consistently with current guidelines for colorectal surgery. (SCIP is the Surgical Care Improvement Project.)

### Postoperative glucose

*Goal: Maintain patients' blood glucose level <200 mg/dL on the day of surgery (postop day zero).*

Patients' blood glucose is checked in the preoperative area and again in the postanesthesia care unit.

"The nurses know the goal is less than 200," Loyd says. "If patients are diabetic, they are often checked intraoperatively as well."

### Making a difference

An example of how the data is applied is renal failure. Reviewing the results, a multidisciplinary group noticed renal failure outcomes were somewhat elevated. The pharmacist on the

committee thought one reason might be the use of nonsteroidal anti-inflammatory agents for postop pain control. Certain of these agents carry a "black box" warning from the Food and Drug Administration.

The physicians were alerted and have become more conscious of NSAID use.

Within 6 months, the incidence of renal failure returned to an acceptable range.

"That was a great example of how a multidisciplinary team works," she says.

### Sharing with surgeons

Baptist Memorial's surgeon champion, Stephen Behrman, MD, FACS, has asked that the NSQIP 30-day outcomes by surgeon be posted in the physicians' lounge with names blinded. Surgeons can identify their own results by their ID numbers and compare them with peers.

"Dr Behrman can sit down with a surgeon if there's a problem to see what can be done to improve their outcomes," Loyd says.

She thinks the surgeons' response to NSQIP has been more positive than it is to SCIP. She notes that more patients are audited, and the data is more specific.

"SCIP looks at patients only through postop day 2 or 3," she says. "NSQIP looks at outcomes at up to 30 days postop. So we are getting a realistic view of how our patients do long term."

—Pat Patterson

Surgical Care Improvement Project (SCIP). The interventions are based on information NSQIP provided on SSI prevention.

"We looked at all of the promising practices, not just those that have Level 1 evidence," Clarke says. "These are things we identified as enhanced opportunities beyond the standard SSI reduction strategies that would be worth trialing."

The surgeon champions were asked to trial the bundle with their own patients and then to spread it among peers. The SCRs will track compliance.

The bundle includes:

- redosing the antibiotic for surgery lasting more than 3 1/2 hours
- adjusting the antibiotic dose for morbidly obese patients
- tracking patients' blood glucose levels on the day of surgery regardless of whether they are diabetic
- monitoring patients' temperatures continuously and keeping them warm throughout the case
- administering supplemental oxygen for 6 hours postoperatively.

"Our data in Tennessee suggests there is a correlation between high blood glucose and SSIs for colorectal surgery," Clarke notes.

On normothermia, TSQC goes beyond documenting that a warming device was applied to include monitoring patients' temperatures throughout the case. The reason is that a patient's temperature can vary before, during, and after surgery, notes Cheri Cole-Jenkins, RNC, MPH, manager of the quality department at 300-bed Parkwest Medical Center in Knoxville, Tennessee, a TSQC participant.

"We're challenging ourselves to see that the [warming device] is doing what it is intended to do, which is to maintain temperature," she says.

For the surgical skin prep, most TSQC members already use an alcohol-chlorhexidine gluconate solution, which studies have found is associated with a lower SSI rate than povidone-iodine.

### **Making a difference for VTEs**

Cole-Jenkins says data from TSQC has helped her hospital to highlight areas where it has strong results and other areas where there are challenges.

"We found we were a low outlier—a good thing—for pneumonia, particularly given that our population is fairly high in smoking," says Cole-Jenkins. She attributes the result to the hospitalist program, an aggressive pulmonary group, and strong respiratory therapists.

With VTE, however, they found challenges. "Having the hard evidence [from TSQC] enabled us to recognize we were out of line with the rest

of the participants. We were doing something significantly different," she says.

A team led by the surgeon champion, who is chair of the endovascular team, narrowed the problem to peripherally inserted central catheter (PICC) lines.

The VTE rate decreased after 2 steps were taken:

- changing from using 3-lumen to 2-lumen PICC lines, unless there is a specific need
- providing the nursing staff with further education on site selection for PICC lines.

"It is highly motivating when you have data, can apply it, and realize it makes things better for patients," Cole-Jenkins says.

"This is data, but it's also people's lives. The impact of having an SSI is possibly life-altering. Whatever we can do to keep that from happening is what we need to be doing."

### **Sharing with surgeons**

Some organizations share individual NSQIP data with the surgeons.

Dr Cofer provides individual outcomes data with faculty surgeons twice a year, showing them how they compare with the group with identities blinded.

After reviewing their reports, surgeons may come to him seeking more information. For example, they might want to know why their mortality rate was higher than their peers' for the same procedure. The SCR can print a report that provides the details.

"We now have data that we didn't have 5 or 6 years ago, and it's data we can believe in," Dr Cofer says. ♦

—Pat Patterson

*More about ACS NSQIP is at [www.acsnsqip.org](http://www.acsnsqip.org).*

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# New AORN recommendations focus on infection prevention, patient safety

**A**ORN leaders' efforts over the past few years have led to evidence-rated recommendations for some of the 2013 Perioperative Standards and Recommended Practices (RPs), representing "landmark progress in the evolution of recommended practices," according to Ramona Conner, MSN, RN, CNOR, manager of the standards and recommended practices. Conner introduced speakers who gave updates on the RPs for prevention of transmissible infections, sterile technique, and sharps safety at the AORN Congress in March 2013 in San Diego.

Here are highlights of the session. For complete language, see the 2013 Perioperative Standards and Recommended Practices.

## Sterile technique

AORN's Recommended Practices for Sterile Technique have replaced the RP for Maintaining a Sterile Field and now include the RP for Selection and Use of Surgical Gowns and Drapes.



*The first drape is placed with the cuff at the halfway point. The second drape is placed from the opposite side and completely covers the cuff of the first drape.*

*Illustration by Colleen Ladny and Kurt Jones.*

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A change in the recommendation about sterile fields generated audible surprise during the presentation by lead author Sharon A. Van Wicklin, MSN, RN, CRNFA, CPSN, PLNC, CNOR, a perioperative nurse specialist with AORN.

AORN has had a long-standing recommendation that, once created, the sterile field should not be left unattended until the procedure has been completed, and this has not changed. The new recommendation is that if there is an unanticipated delay or during periods of increased activity, such as when the patient is being brought into the room, the sterile field that will not be immediately used may be covered with a sterile drape (illustration).

This recommendation shows how evidence can change practice; recent research demonstrates that covering the sterile table "may actually help to preserve the sterility of the field and to prevent environmental and microbial contamination," Van Wicklin said. For example, a study of 41 total joint replacements showed that covering the instruments during periods of increased activity shortened overall exposure time and led to a 28-fold reduction of instrument contamination.

Sterile fields should be covered in a manner that does not allow the portion of the cover that falls below the sterile field to come above the sterile field.

AORN also recommends that organizations work with their infection prevention personnel to develop a standardized procedure for covering the sterile field.

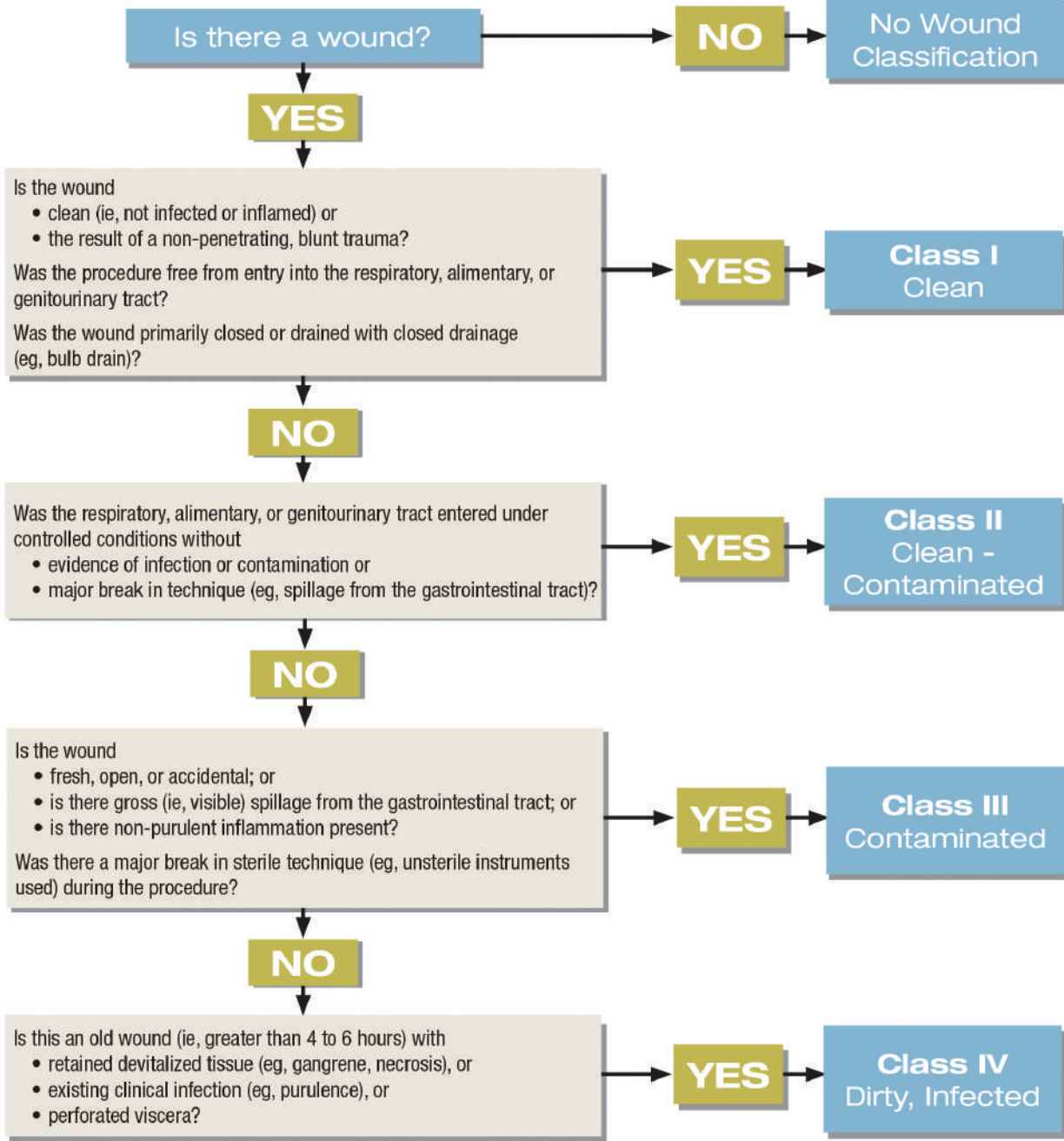
According to Van Wicklin, covered sterile fields should be monitored, and policies about monitoring, uncovering the field, and the length of time the sterile field is covered should be determined by each individual facility, ideally with the help of an infection preventionist.

## Gloves

One new recommendation is to use a closed assisted gloving method; the open assisted gloving method should be used only when closed assisted gloving is not possible or practical, according to Van Wicklin. This is not a change but rather a clarification based on the evidence.

The double-gloving recommendation, also a part of the RP for prevention of transmissible infections and the RP for sharps safety, was added

## Surgical Wound Classification Decision Tree



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NOTE: These are the original source documents for development of the CDC surgical wound classification system.

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to the sterile technique RP because of its importance as a means to prevent surgical site infection (SSI), she noted. The recommendation is to double glove during procedures when there is potential for exposure to blood, body fluids, or other potentially infectious materials.

“There may be rare occasions when double-gloving is not absolutely necessary, but the amount and quality of the evidence that supports the recommendation for double-gloving is very clear,” she said, citing support from the Centers for Disease Control and Prevention (CDC), the American College of Surgeons, and the American Academy of Orthopaedic Surgeons (AAOS). In addition, a meta-analysis of 5 trials found that significantly more perforations were detected when a perforation indicator system (ie, wearing a colored pair of surgical gloves underneath a standard pair of surgical gloves) was used than when it was not (77% vs 21%, respectively).

The RP includes specific times for changing gloves:

- after each patient procedure
- after touching the surgical helmet system, ie, hoods and visors (new)
- after adjusting the eyepieces on an operating microscope (new)
- after direct contact with methyl methacrylate
- when gloves begin to swell on the hands
- when a perforation is suspected or actually occurs
- every 90-150 minutes (new).

Several studies have shown a positive correlation between the rate of glove perforation and the length of time that they're worn. AAOS recommends changing outer gloves at least every 2 hours. Recognizing that gloves cannot be changed at a precise time during a procedure, AORN recommends a span of time during which gloves should be changed (ie, every 90 to 150 minutes). But the published literature does not provide an answer on whether to change 1 or both gloves, Van Wicklin pointed out.

### Other sterile practices

- Based on studies showing high levels of contamination of the C-arm drape, another new recommendation is to consider the upper portion of the C-arm drape contaminated.
- A recommendation is added to use the isolation technique during bowel resection and resection of metastatic tumors. This can be accomplished with a single or dual setup, and instructions are included in the RP.
- Minimizing the number of personnel in the OR is not a new recommendation but is emphasized in this RP, Van Wicklin said. Studies have documented the relationship between increased numbers of personnel and higher levels of particulates in the environment.

### Sharps safety

The Recommended Practice for Sharps Safety, previously a guidance statement with suggested strategies for preventing injuries, is now a new RP expected to be released to e-subscribers in June 2013 and will be published in the 2014 Perioperative Standards and Recommended Practices book, according to lead author Mary Ogg, MSN, RN, CNOR, a perioperative specialist at AORN.

There have been 132 documented cases of patient to health care worker transmission of HBV, HIV, and HCV, she noted. The RPs are based on regulations from the Occupational Safety and Health Administration.

This RP recommends the following:

- Safety-engineered devices (eg, safety scalpels, needleless IV connectors).
- Blunt suture needles unless contraindicated. A review by the Cochrane Collaboration (highest level of evidence) found that blunt suture needles reduced glove perforations by 50% and lowered disease transmission. These have been rated as acceptable in 5 of 6 studies.
- Alternative wound closure devices.
- A neutral zone or hands-free technique for passing sharps, blades, and needles.
- Double-gloving.
- A glove perforation indicator system.

### Transmissible infections

Perioperative actions to prevent transmission of health care-associated infections (HAIs) are included as part of a new section of the Prevention of Transmissible Infections RP, according to Lisa Spruce, DNP, RN, ACNS, ACNP, ANP, CNOR, director of evidence-based perioperative practice for AORN and lead author of this RP.

There are 500,000 surgical site infections per year; SSIs make up 1.7 million of all HAIs, based on statistics compiled by the CDC. SSIs are the second most common type of HAI after urinary tract infections. Actions to prevent SSIs include:

- maintain a clean environment and surgical attire
- use skin antisepsis
- use good hand hygiene
- minimize OR traffic
- verify adequate sterilization.

The research on the merits of decolonization of the patient is conflicting, especially on *Staphylococcus aureus* in the nasal pharynx, Spruce said. Physicians may or may not elect to do this, so it's important to keep an eye on developments.

The CDC recently issued an alert on carbapenem-resistant Enterobacteriaceae. A tool kit available at [www.cdc.gov/hai/organisms/cre/cre-toolkit/index.html](http://www.cdc.gov/hai/organisms/cre/cre-toolkit/index.html) provides guidelines for preventing this HAI.

A new recommendation involving prevention of central line-associated bloodstream infections (CLABSIs) is included because clinicians put in lines in the OR, Spruce said. They should use the same technique used to insert these lines at the bedside. The CDC recommends use of a maximal sterile barrier (ie, hair cover, mask, sterile gown, gloves, full-body drape).

She encouraged clinicians to follow CDC guidelines for prevention of catheter-associated urinary tract infections (CAUTIs). Use catheters only as indicated, not just for convenience; document the date and time of insertion; and remove them as soon as possible after surgery, preferably within 24 hours. She emphasized that perioperative RNs should be educated and demonstrate competency on catheter insertion.

A new feature is a useful surgical wound classification decision tree that was reviewed by the CDC (chart). Also new is a quick reference table for care and transportation of patients who are on contact, airborne, or droplet precautions.

Accrediting (eg, Joint Commission) and regulatory agencies (eg, the Centers for Medicare and Medicaid Services) require all facilities to have an infection control plan, so “this should be a very easy RP for you to implement,” Spruce said. ❖

—Elizabeth Wood

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# 'Operation Zero' targets surgical site infections

**A** surgical site infection (SSI) prevention "bundle" is helping OR teams at Maine Medical Center (MMC) in Portland to further a strategic goal of preventing SSIs. Known as Operation Zero, or "Op-Z," the initiative is led by the chief of surgery, Brad Cushing, MD, with inspiration from a family whose healthy 85-year-old father died from an SSI after a total hip replacement at MMC.

Op-Z includes, in addition to the SSI bundle, notification of the entire perioperative team when a patient they cared for develops an SSI.

The SSI bundle, known as the Op-Z Checklist, is posted on the wall in each OR (sidebar). Before each case, the OR team verifies that it has reviewed the Op-Z checklist. The bundle constitutes one item on the presurgical checklist.

The Op-Z prompt encourages everyone in the OR to look around and make sure their colleagues are complying with the bundle's elements, such as covering all hair and wearing long-sleeved warm-up jackets, says Karen Dumond, MSN, RN, CNOR, nursing director for the OR.

The bundle is not part of the time-out, she notes. Instead, surgeons are simply encouraged to say, "The team has reviewed the Op-Z Checklist," prompting the team to pause and check for compliance.

## Developing the bundle

The bundle was developed by groups of perioperative team members who suggested items they thought should be included. There were groups for the preoperative, intraoperative, and postoperative periods as well as for the ambulatory surgery unit and postanesthesia care. There also were groups for colon and vascular surgery.

Each group reviewed the literature, came up with 3 priorities, and sent those to the Surgical Services SSI Reduction Steering Committee. The committee reviewed the items and selected the initial bundle.

Reaching consensus took a lot of give and take.

"Everyone wanted to see the evidence," Dumond says. There may not be published studies specifically related to practices such as wearing

long sleeves or not bringing items such as briefcases into the OR, though these are based on infection prevention principles.

(AORN's Recommended Practices for surgical attire advise wearing a long-sleeved jacket that is snapped closed. The rationale is that the sleeves help to contain skin squames shed from bare arms, and a closed jacket prevents the edges of the jacket from contaminating the skin prep area or sterile field. AORN also recommends not bringing items such as backpacks and briefcases into the OR because they are made of porous material that can harbor dust and pathogens.)

## Op-Z Checklist

**The bundle for preventing surgical site infections at Maine Medical Center:**

- **All hair covered in OR, including facial hair.**
- **Attire appropriate. All staff to wear hospital-provided, clean/laundered apparel in the OR. Hospital-provided cover jackets will be worn in the presence of open sterile supplies. Exception is scrubbed personnel. Rings, bracelets, and watches are either removed or contained.**
- **No unnecessary items are brought into the OR. That includes briefcases or any other items not needed for the case.**
- **The sterility of all operative materials ensured.**
- **Appropriate skin prep used in proper fashion.**
- **Measures to ensure normothermia are in place, if appropriate.**
- **Blood sugar control plan instituted, if appropriate.**
- **Redosing antibiotic schedule determined and timer set, if needed.**



*A lighted marquee at the OR entrance reminds everyone of the focus on preventing surgical site infections.*

### **Establishing a standard**

At MMC, the steering committee took the position that it needed to establish a standard that everyone would follow consistently.

“That makes people think about what they’re doing and about other areas we need to look at,” says Dumond.

Hair covering was an issue.

“The goal is that the head covering has to be clean and cover all hair,” she says.

Skull caps weren’t eliminated, however, because some surgeons who wear headlights said the bouffant caps caused the light to slide around. Skull caps can be worn only by individuals whose hair is shaved close to the back of the head.

Compliance with jackets was difficult in the summer, Dumond notes, “but people seem to be doing it. It’s easier now that we are going into winter.”

### **Kicking off Op-Z**

The Op-Z Checklist was rolled out in August 2011 with an all-hands meeting for surgeons, nurses, and anesthesia providers held in the hospital’s auditorium. This was not a routine meeting. As the audience entered, scrolling on the screen was a list of all of the SSIs at MMC, listing the procedures but not patient names.

“Almost every specialty was involved. It was very powerful,” says Dumond.

The family of the 85-year-old patient, George H. Ellis, PhD, was present. The patient’s son-in-law, Stephen Hudspeth, JD, gave a moving presentation, emphasizing that behind every patient with an SSI is a family.

“I’m told you do 1,800 hip and knee replacements annually,” he told the audience. “I’m told that in the past 6 months, there have been zero infectious outcomes,” even though the usual infection rate nationally for a hip replacement is 1.5%.

“That is 27 families over a year’s time who have you to thank for their continued ability to enjoy a loved one with them.” He asked the audience to imagine those 27 families assembled there and, behind them, hundreds more who represented their families and communities.

After Ellis’s death 5 years ago, the family set up a fund at MMC specifically for the purpose of infection prevention, and the family checks in regularly for progress reports.

Hudspeth congratulated the OR teams assembled for their work every day in preventing infections. Because of their work, he said, “These are families who don’t have to go through what we went through.”

Many in the audience had tears in their eyes.

### **Reinforcing practices**

A bit of levity helped to reinforce infection prevention practices at the meeting.

After a review of SSI statistics, the audience watched 2 humorous videos to help get the point across about the SSI bundle. The committee had checked in advance with the patient’s family to make sure they wouldn’t see the humor as disrespectful, Dumond notes.

One video illustrated the correct application of the surgical prep solutions. Using an inflatable doll, the surgeon applied the prep and set the timer for 3 minutes to let it dry. He then took the scalpel, made the “incision,” and the doll deflated.

In the second skit, a mock orthopedic case, the team showed how to review the Op-Z line on the preop checklist. As they looked around, they realized that the anesthesia provider had to put a jacket on. The surgical technologist had a lock of hair showing, and someone clipped it off in humor. They then started the “case” using a kitchen knife and power tools brought from home.

The skits went over very well, Dumond says.

### **Teams notified of SSIs**

Though surgeons have always been notified of SSIs, as part of Op-Z, the entire team that was in the OR during that case is now notified, including the surgeon, anesthesia provider, nurse, and ST, as well as the admitting unit and postanesthesia care staff.



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"It is not meant to be punitive but to raise awareness," Dumond says. "It helps to get people out of thinking, 'That doesn't happen to me.'"

### Checking on compliance

To ensure adherence with the SSI bundle, teams of anesthesia providers, surgeons, and staff will be conducting observations, as they did to ensure compliance with the time-out.

"We have more work to do," Dumond says, noting there is progress, such as more hair being covered. Baskets have been hung on the wall outside the ORs to hold belongings like briefcases.

She credits Dr Cushing for his leadership in building the momentum behind Op-Z. "He is very innovative. He really puts thought and work into this," she says. "He asks, 'How can we do this so it will have an impact?'"

When Dr Cushing first proposed to the nurses having the SSI bundle as another line on the

surgical checklist, the reaction at first was, "not one more thing," recalls Dumond, admitting she agreed. Then the nurses began thinking about how they could make it work.

Changing culture is hard, she comments.

"The staff may wonder, 'Is this just the flavor of the month? If I wait, will it go away?' To make it a culture change, you have to get the message across that this is not going away." ❖

—Pat Patterson

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# Preventing SSIs: Keys to solutions lie with your front-line clinicians

**H**ow will a surgical site infection (SSI) develop in the next patient who has colorectal surgery? What can we do to prevent it?

These 2 questions helped a team at Johns Hopkins Hospital in Baltimore to identify 6 interventions that achieved a 33% reduction in SSIs after colon operations.

The key was a patient safety program that empowers front-line providers to develop solutions for preventing harm to patients. The surgical comprehensive unit-based safety program (CUSP), developed at Johns Hopkins, got its start in 2 surgical ICUs in 2001. Results showed the program improved the safety culture and was linked with reduced lengths of stay, fewer medication errors, and possibly lower nursing turnover.

Johns Hopkins and others have adopted CUSP to aid in reducing central line-associated bloodstream infections, ventilator-associated pneumonia, and mortality.

In a nationwide project, CUSP reduced bloodstream infections in ICUs by 40%, saving more than 500 lives, the Agency for Healthcare Research and Quality (AHRQ) reports.

## Applying CUSP to SSIs

Based on these experiences, Elizabeth C. Wick, MD, FACS, a colorectal surgeon and assistant professor of surgery at Johns Hopkins, and her colleagues decided to apply CUSP to colorectal SSIs.

"We came up with a surgical CUSP after an American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) pilot we were participating in showed we had a colorectal wound infection rate of 30%," Dr Wick told OR Manager.

"The CUSP program is unique," she adds, "because it focuses on the front-line providers who take care of patients day to day in the OR. It gives them the power to identify and fix defects."

A report on the project appeared in the *Journal of the American College of Surgeons*.

AHRQ has funded a new national Surgical Unit-Based Safety Program, or SUSP, using the same approach. Hospitals can join for free (sidebar).

## Launching the project

For the colorectal surgery project, a CUSP leadership team was formed that included "provider champions" from surgery, nursing, and anesthesia; a team coach who facilitated meetings

## 5-step plan to lower colorectal SSIs

The 5-step surgical CUSP plan:

- Educate team members on the science of safety, which includes an introductory talk addressing safety at a local level.
- Have team members complete a 2-question survey asking:
  - How will an SSI develop in the next patient?
  - What can we do to prevent an SSI?
- Have a senior hospital executive partner with surgical services to improve communication and educate leadership. The executive attends CUSP meetings and makes resources available to address safety concerns and assist with system-wide barriers.
- Teach team members to use a structured learning-from-defects tool.
- Have team members use tools, including checklists, to improve teamwork and communication. Teams review unit-level SSI data monthly and develop initiatives to improve teamwork, enhance communication, and address identified hazards.

and managed improvement projects; and a hospital executive who was committed to the project. "None of us had any experience with CUSP except for the anesthesia representative, who had experience in the ICU," says Dr Wick.

The leadership team met monthly. Also joining the team, which eventually totaled 36 members, were nurses, certified registered nurse anesthetists (CRNAs), surgical technologists (STs), and anesthesiologists. The leadership team then designed a 5-step plan to educate the team on the science of safety, complete the 2-question survey, and teach tools for improving teamwork and communication (sidebar).

## Front-line clinicians key

The CUSP leadership team convened all front-line providers, including STs, nurses, surgical residents, anesthesiologists, CRNAs, and surgeons.

## Six interventions to prevent colorectal SSI

The interventions introduced by the CUSP team:

- standardization of skin preparation
- administration of preoperative chlorhexidine showers
- selective elimination of mechanical bowel preparation
- warming of patients in the preanesthesia area
- adoption of enhanced sterile techniques for bowel and skin portions of a case
- addressing lapses in prophylactic antibiotics.

They were given an introductory lecture on the science of safety covering these points:

- Safety is part of the work system.
- There are principles for designing safe processes (eg, learning from mistakes, standardizing work, and developing checks).
- Interdisciplinary teams make wiser decisions because they have diverse and independent input.

After the lecture, the participants were asked to answer 2 questions anonymously:

- How will an SSI develop in the next patient?
- What can we do to prevent an SSI?

The survey yielded 95 concerns. Reviewing those concerns, the team identified 6 interventions to prevent SSIs (sidebar).

### A surprising concern

“The most surprising concern was that all patients were not getting the appropriate antibiotics,” says Dr Wick. “I think addressing the prophylactic antibiotic problem was one of the key things we did.”

At Johns Hopkins, colorectal surgery patients who are allergic to penicillin receive clindamycin and gentamicin for surgical prophylaxis.

The team learned that anesthesiologists and surgeons had safety concerns about the large 5 mg/kg dose of gentamicin recommended by the infection preventionists. Because of those concerns, they were either holding the gentamicin and just giving patients clindamycin or giving 2.5 mg/kg of gentamicin.

“We would have never known that if we hadn’t tapped into the concerns of front-line providers,” says Dr Wick.

At the request of the CUSP team, practitioners from the epidemiology and infection control service addressed the concerns and educated the providers.

That raised compliance with appropriate gentamicin dosing from 33% to 92%.

### Standardizing the skin prep

Perioperative nurses told the CUSP leadership team they thought both the prep solution and technique should be standardized.

The technique varied and was performed by both nurses and surgical residents.

Prep solutions with either a chlorhexidine gluconate (CHG) or povidone-iodine solution were used, and there was confusion about which solution to use if the patient had an ostomy. Because CHG is contraindicated for mucous membranes, povidone-iodine was used on patients with ostomies.

Recent studies have found CHG to be superior to povidone-iodine for preventing SSIs. A large multicenter prospective randomized trial by Darouiche et al found patients whose skin was prepped with a CHG-alcohol product had a significantly lower overall SSI rate than those prepped with povidone-iodine—9.5% vs 16.1%. Two meta-analyses published in 2010 by Lee et al and Noorani et al, found lower SSI rates when a CHG prep was used.

### Consensus protocol for prep

Based on the nurses’ feedback and a literature review, the CUSP team developed a consensus protocol, which stated that nurses instead of residents would perform all of the preps in the colorectal surgery ORs, and CHG would be used for all patients, including those with ostomies.

“Now we use CHG all the way up to the stoma and use povidone-iodine on the stoma,” says Tracie Cometa, BSN, RN, a nurse clinician II who was on the CUSP team.

Cometa invited a representative from CareFusion, the vendor for ChlorPrep (2% CHG/70% isopropyl alcohol), to provide in-service education for all staff who worked in colorectal surgery.

There was concern that having the nurses perform the prep would slow down cases. The residents had performed the preps because they knew the specific area attending surgeons wanted prepped and could perform the prep before attending surgeons arrived.

“We all agreed to try having the nurses apply a CHG prep for 2 months,” says Dr Wick. “Because we rapidly saw improvement in our surgical site infection rate after starting CUSP, that helped the surgeons get on board.”

“We are looking at spreading the practice to the rest of general surgery,” adds Cometa.

### Instituting CHG washcloths

In addition to standardizing the skin prep, the CUSP team introduced the use of washcloths impregnated with CHG.

“We used the CHG cloths because of the success in other services with high infection rates,” notes Dr Wick.

As a new routine practice, all patients were given CHG washcloths and instructed to shower or bathe with them on the evening before surgery.

"I'm not sure they made a difference because most of the bacteria are from the colon, but they helped to ensure the patients got a really good bath the night before surgery," she says.

### Eliminating routine

The CUSP team decided to eliminate the routine preoperative use of the mechanical bowel prep after discussing literature that suggests the bowel prep may be associated with increased SSI rates.

One possible reason is that patients may be dehydrated from the bowel prep and require more fluids in the OR, which might put them at a higher risk for infection, says Dr Wick.

The mechanical bowel prep question is still confusing, however, she says. After a year of omitting this practice, the CUSP team reintroduced the mechanical bowel prep, this time with oral antibiotics, based on new guidelines expected soon from the Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, and the Surgical Infection Society.

### Overcoming barriers

Partnering with a senior executive was a key strategy in overcoming some tough barriers, notes Dr Wick. The executive's role is to attend the CUSP meetings, make resources available, and assist with overcoming barriers.

There was also a problem getting anesthesia CUSP team members assigned to colorectal cases, particularly CRNAs.

With the senior executive, the CUSP leadership team met with the OR leadership, and slowly there was improvement in having CUSP team members assigned to the ORs where colorectal surgery is performed. Now the initials CR (for colorectal) are put next to CUSP team members' names so they can be assigned to the colorectal ORs, notes Cometa.

SSI rates started improving once a team of providers aware of the problem was assigned to the colorectal patients.

"Even before we had a lot of interventions implemented, we started to see an improvement in SSI rates," says Dr Wick. "It was the teamwork that really started making the difference." ♦

—Judith M. Mathias, MA, RN

*More on the Surgical Unit-Based Safety Program (SUSP) is at [www.hopkinsmedicine.org/quality\\_safety\\_research\\_group/our\\_projects/action\\_II/SUSP/](http://www.hopkinsmedicine.org/quality_safety_research_group/our_projects/action_II/SUSP/)*

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## New national project aims to lower SSIs

A national project has helped lower central line-associated bloodstream infections in the ICU by 40%. Could it do the same for surgical site infections (SSI)?

The new effort funded by the Agency for Healthcare Research and Quality (AHRQ), now signing up hospitals, enlists front-line clinicians to uncover solutions for preventing SSIs in their own organizations.

"Initially, we will focus on colorectal surgery because that has a high complication rate," says Sean Berenholtz, MD, MHS, of the new Surgical Unit-based Safety Program (SUSP).

"What we hope to do in this project is to give providers tools to better understand where their defects are."

SUSP goes beyond process measures to track outcomes by partnering for data collection with the American College of Surgeons National Surgical Quality Improvement Project (NSQIP) and the Centers for Disease Control and Prevention's National Healthcare Safety Network.

Participation in SUSP is free. But hospitals need to commit resources, including executive partnership and time for a surgeon, anesthesia provider, and nurse to implement the interventions and monitor progress.

SUSP is based at the Johns Hopkins Armstrong Institute for Patient Safety and Quality. Learn more at [www.hopkinsmedicine.org/quality\\_safety\\_research\\_group/our\\_projects/action\\_II/SUSP/](http://www.hopkinsmedicine.org/quality_safety_research_group/our_projects/action_II/SUSP/).

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# Safer surgery: Six steps that aim for excellence in sterile processing

*Fourth in a series on ten elements of safer surgery.*

It's axiomatic that sterile processing is critical to safe and effective surgical care. The sterile processing department (SPD) is like an "engine room" for the OR, where the staff produce the sterile instruments and other equipment needed for surgical cases.

An OR with a volume of 75 cases a day can require upwards of 50,000 individual instruments, many with complex and intricate parts. Any flaw in cleaning and reprocessing is a potential threat to patients. It's a demanding job, and one that is often unsung.

Surgical departments striving for safer care include sterile processing as colleagues and allies.

OR Manager interviewed 4 SPD leaders about their efforts to build bridges with their surgical colleagues, embrace continuous improvement, and focus on customer service. These are their suggestions for achieving excellence in sterile processing.

## **One: 'Heart of patient care'**

These SPD managers make sure their staffs know the essential role they play in patient care.

Rudy Gonzales, MSN, RN, CNOR, CRCST, CHL, has led his department at the Louisiana State University Health Science Center in New Orleans in recovering from the complete destruction of the SPD at the former Charity and University Hospitals after Hurricane Katrina. He's participating in the building of a new replacement University Medical Center to open in 2015.

Gonzales says he tells his staff: "The doctors can cure disease, the nurses can care for the pa-

tients, but if they don't have the right equipment, they can't do their jobs effectively. We never want to have something we've done to affect the patient."

Sue Klacik, BS, CRCST, FCS, who manages central sterile (CS) services at St Elizabeth Hospital, a 350-bed Level 1 trauma center in Youngstown, Ohio, conveys the same message: "My staff know they are every bit as important as the team in surgery."

She makes sure the staff are empowered. "If at 2 am, they see something that doesn't look right for a case the next day, they contact surgery to see if there's a problem and discuss a way to resolve the issue."

Valuing the staff carries through to compensation. These leaders make sure their staff's pay is competitive with that of other area hospitals.

## **Two: Stay in touch with the OR's needs**

Visibility and customer service are leading strategies these leaders employ to make sure they're meeting the OR's needs.

## **Keep communication open**

"I've learned over the years that if you don't want to hear from the OR, they will lose trust in you because you are not addressing the issues," says Mark Duro, CRCST, FCS, manager of the Central Sterile Processing Department at New England Baptist Hospital in Boston, a leading orthopedic center performing 25 to 30 joint replacements a day.

When there is an issue in the OR, depending on how serious it is, Duro goes directly to the room. Less critical issues are reported on a communication sheet that records the date, time, personnel involved, the issue, suggestions for possible solutions, and a signature. Duro reviews the sheets once a week and addresses the issues.

## **Participate in daily huddles**

Every day at 1:30 pm, Klacik or a CS coordinator joins a huddle in the OR to review the next day's schedule and determine needs. At 3 pm, she huddles with the CS staff.

"We talk about what's happening tomorrow," she says. "We discuss which trays to watch for. If loaner trays aren't in, we start calling the vendor."

## **Safer Surgery series**

This series of articles covers Ten Elements for Safer Surgery developed by Advocate Health Care, a 10-hospital system in the Chicago area.

Previous articles in the series focused on:

- OR governance: January 2013
- Safer surgical scheduling: February 2013
- Presurgical assessment: March 2013.

## Ten components for safer surgery

The components of Advocate Health Care's Safer Surgery initiative:

1. Perioperative governing body
2. Single path for surgical scheduling
3. Preanesthesia testing (PAT) with standardized protocols/hospitalists
4. Document management system for scheduling and PAT
5. Excellence in sterile processing
6. Crew resource management
7. Implementation of a critical safeguards checklist
8. Daily huddle
9. Error reporting
10. Just culture

Source: Advocate Health.

If necessary, she adjusts staffing to meet the requirements of the next day's surgical schedule.

### Round in the OR

Klacik and CS coordinators round in the surgery department throughout the day. "If surgery has a question or comment, they can stop and tell us," she says. "They know we are accessible, and we can nip problems in the bud."

### Attend OR staff meetings

Duro attends OR staff meetings to share information. At one point, the OR was reporting holes in sterilization wrappers. An OR staff member asked, "Why not use containers?" Duro had a chance to explain that many instrument sets have not been validated by the device manufacturer for the use of sterilization containers.

"We have to follow the manufacturer's instructions for use (IFU) for everything—not just the equipment but also the packaging material," he told them, noting that failure to follow the IFU can incur liability.

### Three: Educate, educate

Education of CS techs is the backbone of a safe, efficient sterile processing program, Klacik emphasizes.

"I can't stress how important education is in this job," she says. With today's demands, "techs need to be technically trained and to have critical-thinking skills."

Klacik, an approved CRCST instructor, also serves as the educator for the department. "We teach the standards and recommended practices, along with the rationale behind them," she says.

She also provides in-service education on all new equipment, including the IFU.

At St Elizabeth, certification of CS techs is a condition of employment. Klacik teaches the classes herself. The hospital purchases the books, and education is conducted on work time.

### Four: Provide the right working conditions

Klacik ensures the SPD staff have the proper equipment and work environment to do their jobs well.

"At our work stations, we have the correct conditions—the right lighting, equipment like magnifying glasses, quality monitors, and other tools," she says.

IFUs are available on PCs throughout the department, which provide access to onesourced-ocs.com, an online database of manufacturers' instructions.

At New England Baptist, sterile processing is almost completely automated. In planning the department, which opened 3 years ago, Duro and his team scoured the US and Europe for the latest in technology.

### Five: Support the staff and hold them accountable

Accountability goes hand in hand with education.

"If someone has made an error, we bring it to their attention so the error doesn't occur again," Klacik says. "They know what they do affects patient care, and they are meticulous."

Gonzales, who now has a master's, relies on the bedrock values he learned in the Army: "Make sure your staff have what they need to do the job, make sure they're trained, and make sure their pay is correct. Then most things will work out."

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**Six: Foster continuous improvement**

At Virginia Mason Medical Center in Seattle, which has pioneered Lean management in health care, the director of sterile processing, Sam Luker, MBA, CRCST, and his team have a constant focus on eliminating waste and mistake-proofing sterile processing. Every day begins with a daily “newspaper” reporting on defects that reached the OR the previous day.

Encouraged by a Japanese sensei, the department recently began working on a process to create just-in-time instrument sets built to order for surgeons performing the next day’s cases. ❖

—Pat Patterson

*This article originally appeared in OR Manager, April 2013;29:1, 6-7.*



# Scope storage: Don't get hung up on a number

**H**ow long can a flexible endoscope be stored before it needs to be reprocessed for use in a patient? Guidelines differ, raising questions about the appropriate storage or "hang time."

Evidence is limited. What's the best course? How do accreditation surveyors assess this?

Though infections from GI endoscopes are rare, estimated at about 1 in 1.8 million procedures, contaminated scopes are linked to more health care-associated infection outbreaks than any other medical device, according to the Centers for Disease Control and Prevention.

All of the published incidents of pathogen transmission in GI endoscopy are linked to the failure to follow cleaning and sterilization/disinfection guidelines or defective equipment, notes the 2011 Multisociety Guideline on Reprocessing Flexible GI Endoscopes.

## Improper cleaning and reprocessing

In discussing hang time, don't miss the real reason infections are spread—improper scope cleaning and reprocessing.

The most critical aspect of preventing transmissions is to be sure the whole process is followed correctly, stresses Kathryn Snyder, BSN, MM, RN, CGRN, endoscopy/bronchoscopy/motility manager at the University of Virginia (UVA), Charlottesville.

She offers a few reminders:

- Is your staff up to date on the latest society guidelines and manufacturers' instructions for endoscopy equipment?
- Are all reprocessing steps followed all of the time?
- Does the organization provide the resources to ensure processes are performed correctly?
- Do endoscopy technicians receive annual training and competency validation?
- Is documentation complete and consistent for endoscope reprocessing throughout your organization?

## Guidelines on hang time

Two major guidelines differ in their recommendations on storage for flexible scopes based on the same 3 studies (sidebar):

- AORN advises reprocessing scopes before use if unused for more than 5 days.
- The Multisociety Guideline from the American

Society for Gastrointestinal Endoscopy and Society for Healthcare Epidemiology of America says the issue is unresolved and data is insufficient, adding that reuse within 10 to 14 days of high-level disinfection appears safe.

The Society of Gastroenterology Nurses and Associates (SGNA) standards, revised in 2012, refer to the Multisociety Guideline, saying the issue "warrants further data and research."

## Making an informed choice

In considering hang time, managers need to review the evidence and make an informed decision appropriate to their organization, advises Cindy Taylor, RN, BSN, MSA, RN, CGRN, nurse manager of GI endoscopy/ bronchoscopy at Hunter Holmes McGuire VA Medical Center, Richmond, Virginia.

"I don't think there is a right or wrong answer, as long as there is a rationale to back up the deci-

### ***Training: The missing piece in endoscope reprocessing***

Training is often the missing piece in endoscope reprocessing, notes Kathryn Snyder, BSN, MM, RN, CGRN.

At her institution, the University of Virginia, Charlottesville, endoscopy techs are oriented for 6 weeks, not only on scope reprocessing but also on assisting the care team before, during, and after the procedure. The techs are retrained annually and must demonstrate competency to an expert.

Recently, endoscopy nurses also began receiving annual training and competency validation on scope reprocessing and handling.

"We found nurses weren't accustomed to trouble shooting scopes and assisting the MDs if the scope got clogged and so forth," she says. "It was an eye opener for some of our newer nurses who had never reprocessed a scope before."

Nurses also are better able to respond to patients' questions about reprocessing that they may have read about on the internet.

## **Studies: Endoscope storage**

### **Contamination after storage**

An Australian study that sampled 200 endoscopes before the first case of the day found the overall contamination rate was 15.5%, with a pathogenic contamination rate of 0.5%. The mean time between the last case on one day and reprocessing before the first case on the next day was 37.6 hours (median 18.8 hours).

The most frequently identified organism was coagulase-negative *Staphylococcus*, an environmental nonpathogenic organism.

—Osborne S, Reynolds S, George N, et al. *Endoscopy*. 2007;39:825-830.

### **Testing reprocessed scopes**

A study tested 3 types of GI scopes (upper endoscopes, duodenoscopes, and colonoscopes) that had been reprocessed and stored in dust-proof cabinets. Samples were obtained daily for 5 days from the scopes' surfaces, piston valve openings, and accessory channels. They then were brushed and flushed after 5 days.

All scopes were bacteria free immediately after high level disinfection. In all, 4 of the 135 daily assays were positive, all for skin bacteria cultured from the endoscope surface. All flush-through samples were sterile.

—Rejchrt S, Cermak P, Pavlatova L, et al. *Gastrointest Endosc*. 2004;60:76-78.

### **Three-phase study**

A 3-phase study evaluated 4 endoscopic retrograde cholangiopancreatography (ERCP) scopes and 3 colonoscopes.

- Phase 1: Scopes were assayed after high-level disinfection and daily for 2 weeks.
- Phase 2: This procedure was repeated to confirm the results.
- Phase 3: Endoscopes were assayed after high-level disinfection and again after 7-day storage.

In phase 1, 6 of 70 assays were positive, all in the first 5 days. No cultures were positive in phase 2. In phase 3, 1 scope had a positive culture but only for *Staphylococcus epidermidis*, a low-virulence skin organism.

The authors conclude that reprocessing is unnecessary after at least 7 days of disuse and possibly up to 2 weeks.

—Vergis A S, Thomson D, Pieroni P, et al. *Endoscopy*. 2007;39:737-739.

sion that is supported by the literature, the standard of care, and society guidelines," she says.

"Be sure your policy is attainable," she adds. "Better to not have a policy than to have one and not follow it."

Some issues to keep in mind:

- GI endoscopes must be properly cleaned and at a minimum subjected to high-level disinfection (HLD).
- Consult with your physicians and infection prevention experts on the proper process for endoscopes used in immunosuppressed patients or in sterile regions such as the biliary tree, pancreas, or peritoneal space.
- If endoscopes are turned over frequently, storage time may not be an issue.
- Keep in mind that in the studies of storage time, the types of organisms cultured from endoscopes after storage were primarily nonpathogenic skin bacteria.

### **The VA's policy**

The Veterans Health Administration currently follows a directive to reprocess unused scopes

after 12 days of hang time, Taylor notes.

The hang time is documented:

- using a printout from the reprocessing machine
- keeping the printout in a plastic sleeve attached to the scope by a beaded chain
- scanning reprocessing information into each patient's medical record, including the HLD parameters, date reprocessed, person who reprocessed the scope, and the reprocessing machine number.

Immediately prior to the scope's use, the plastic sleeve is removed, and the reprocessing information is verified by a nurse or technician.

"This has become part of our time-out before the procedure," says Taylor.

### **Practice at UVA**

UVA is considering adopting a 2-week storage time for flexible scopes, says Snyder. Storage time will be tracked by:

- using a standardized form to document the data and time endoscopes were reprocessed and kept on file for 3 years

- tagging each scope with the date and time it was reprocessed
- removing the tag just prior to the scope's insertion in the next patient.

"The idea is that you never use a scope without taking the tag off," she says. "And you take the tag off immediately before insertion, not when you are setting up the scope." That is in case a physician decides to use a different scope at the last minute.

### When surveyors visit

A surgeon surveyor from the Joint Commission asked about hang time in a 2010 visit to Taylor's facility. "He just wanted to know if we had a policy," she says.

At UVA, surveyors did not ask about hang time during recent inspections by the Joint Commission and Centers for Medicare and Medicaid Services (CMS). But that experience doesn't necessarily apply to others, Snyder cautions. Surveys vary by state and surveyor. ♦

—Pat Patterson

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# Spore test for liquid chemical sterilant processing system

A spore test strip is now available for the Steris System 1E Liquid Chemical Sterilant Processing System. The Steris Verify Spore Test Strip for S40 was cleared by the Food and Drug Administration (FDA) in June 2012.

What is the role of this new spore test strip? How is this test method different from using biological indicators (BIs) and chemical indicators (CIs)?

The FDA, the Association for the Advancement of Medical Instrumentation (AAMI), and the Steris Corporation provide information that can help in using these test methods appropriately.

## The role of liquid chemical sterilization

Liquid chemical sterilization differs from other common sterilization methods that use heat or gas/vapor/plasma, the FDA notes on its website. The FDA recommends that use of liquid chemical sterilants be limited to reprocessing only critical devices that are heat sensitive and incompatible with other sterilization methods.

Though the survival kinetics for microorganisms for thermal sterilization methods, such as steam and dry heat, have been extensively studied and characterized, the FDA says the kinetics of sterilization using liquid chemical sterilants are less well understood.

The FDA's guidance on liquid chemical sterilants/high-level disinfectants refers to literature suggesting that sterilization processes based on liquid chemical sterilants "in general may not convey the same sterility assurance level (SAL) as sterilization achieved using thermal or physical methods."

Other points by the FDA about sterilization with liquid chemical sterilants:

- Liquids cannot adequately penetrate barriers such as biofilms, tissue, and blood to attain organism kill as thermal sterilization processes can.
- The viscosity of some liquid chemical sterilants "impedes access to narrow lumens and matted surfaces of devices."
- Devices cannot be wrapped or adequately contained during processing "to maintain sterility following processing and during storage."
- Devices require rinsing "with water that typically is not sterile."

These are reasons why the FDA cleared the System 1E as a processor and not as a sterilizer. This means a liquid chemical sterilant process

should not be your first choice for items that come in contact with compromised tissue.

## Monitoring liquid chemical sterilization

It's important to know that the Verify Spore Test Strip for liquid chemical sterilization is not the same as a BI used for steam sterilization.

In its regulatory documents for the spore test strip, the FDA notes that BIs are not appropriate for monitoring liquid chemical sterilization. The FDA has not cleared any BIs for that purpose because, the agency notes, the literature suggests that "sterilization with a liquid chemical sterilant may not convey the same sterility assurance as other sterilization methods."

The standard for a terminal sterilization process is an SAL of  $10^{-6}$ , which means there is less than or equal to a 1 in 1 million chance that a single viable microorganism is present on a sterilized item. That is what a BI is intended to measure.

An SAL of  $10^{-6}$  is appropriate for items intended to come in contact with compromised tissue (that is, tissue that has lost the integrity of the natural body barriers), according to the AAMI steam sterilization guideline (ANSI/AAMI ST79).

The Verify Spore Test Strip contains a known number of bacterial spores (at least  $5 \log_{10}$  or  $10^5$  per strip) of known resistance (*Geobacillus stearothermophilus*) to a liquid chemical sterilant used in a defined processing system. The Verify Spore Test Strip does not demonstrate that conditions were adequate to achieve an SAL of  $10^{-6}$ , but it does tell the user that the sporicidal activity of the S40 sterilant dilution was able to kill at least  $5 \log_{10}$  or  $10^5$  spores.

## Using spore test strips

Use of the Verify Spore Test Strip is optional as a means to test the sporicidal activity of the sterilant used in the System 1E, as noted in the Steris instructions for use (IFU).

If the spore test strip was needed for monitoring the System 1E, it would have to have been cleared by the FDA at the same time as the System 1E processor and chemical indicator (CI) were cleared. This is a requirement for steam and low temperature sterilization processes new to the market.

In an e-mail communication, Steris stated, "Steris recommends that the Verify Spore Test Strip be used daily in the first processing cycle of

the day." This means the strip is placed into the processor along with the items to be processed.

The Steris IFU state to incubate the spore test strip at "55-60°C (131-140°F) for at least 24 hours." If the spore test strip shows growth, the IFU say to "follow department procedures for liquid chemical sterilant process failures."

### Using chemical indicators

The purpose of the CI is to measure the level of active ingredient in the liquid chemical sterilant. A CI must be available for a liquid chemical sterilant to be cleared for market.

Several CIs from different manufacturers are available to monitor the System 1E.

The Steris IFU for the Verify CI recommend use of the CI "during each processing cycle to detect the presence of the active ingredient, peracetic acid, in the use dilution of S40 Sterilant Concentrate." A note states that the Verify CI for the System 1E should be used in each load tested with a spore test strip.

The IFU describe what the CI's "pass" level means and how to tell if the processed items may be used or not.

### Physical monitors and documentation

The computer-controlled System 1E, according to the company's information, "continually monitors the cycle, including the full time, exposure time, temperature range of the exposure time, and the conductivity of the use dilution."

AAMI's chemical sterilization and high-level disinfection standard (ANSI/AAMI ST58) has recommendations for the documentation of chemical sterilant cycles. In highlights:

- Printouts should be checked at the beginning of the cycle to verify that the cycle identification number has been recorded and that the printer is functioning properly.
- At the end of the cycle before items are removed from the processing equipment, the operator should examine and interpret the printout to verify that cycle parameters were met and should initial the printout.
- Printouts should be maintained, as should a record of repairs and preventive maintenance.

Cycle documentation should include: identification of the processing unit, specific contents of the load, patient name, procedure, physician, exposure time, temperature, date and time of cycle, chemical concentration at exposure phase, name or initials of operator, results of CI or spore strip testing, and reports of inconclusive or nonresponsive CIs.

ANSI/AAMI ST58 recommends maintaining full traceability to the patient. This includes recording the load identifier on the patient chart or recording the patient name or other identifier on the load record.

For facilities that wanted a spore test when the System 1E entered the market, your wish has come true. But remember to run a CI in each load and document the results according to the recommendations in ANSI/AAMI ST58. ❖

—Martha Young, MS, CSPDT

*President, Martha L. Young, LLC, providing SAVVY Sterilization Solutions for Healthcare Woodbury, Minnesota*  
*Martha Young is an independent consultant with long experience in medical device sterilization and disinfection.*

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# Taking control of implant processing practices

**A**re you following recommended practices when processing implants? Both the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of Perioperative Nurses (AORN) state that a load containing an implant should be quarantined until the results of the biological indicator (BI) testing are available. The rationale is to reduce the risk of surgical site infection (SSI).

The Joint Commission's National Patient Safety Goal NPSG.07.05.01 states that hospitals should "implement evidence-based practices for preventing surgical site infections." The goal's EP 3 says:

Implement policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Centers for Disease Control and Prevention and/or professional organization guidelines).

Thus, if you are releasing implants before BI results are available, you are not adhering to guidelines and thus not implementing an evidence-based practice that prevents SSIs.

## How should I monitor implant loads?

Routine release of implant loads should be an active decision based on the evaluation of all available data. AAMI recommends in its ST79 steam sterilization standard that an experienced and knowledgeable person should make that decision at the end of the steam sterilization cycle after evaluating the results of each monitoring tool. AAMI recommends using these monitoring tools:

### Physical monitors

These are the recorders, displays, digital printouts, and gauges on steam sterilizers that read the time, temperature, and pressure of the cycle.

If the sterilizer has a recording chart, it should be checked each morning to ensure chart paper is inserted and the pen is functioning. The date and sterilizer number should be marked on the chart before each cycle is started.

For printouts, verify that the cycle identification number has been recorded and that the paper is functioning. At the end of the cycle, verify by reading and recording your initials that the cycle parameters are correct for the load contents.

### External chemical indicator (CI)

A Class 1 CI should be used on the outside of each package, unless the internal chemical indicator is visible, to distinguish between processed and unprocessed items. The indicator should be examined at the end of the cycle, before it is dispensed, and before it is used in the operating room.

### Internal CIs

A Class 3, 4, 5, or 6 CI (use only in the specific cycles for which they are labeled) should be used as an internal chemical indicator inside each package, tray, or containment device (reusable rigid sterilization container system, instrument case, cassette, or organizing tray) to determine that the sterilant penetrated the packaging and contacted the implant being processed.

Place the CIs in the areas least accessible to the sterilant. The CI should be retrieved and read in the OR before the item is placed in the sterile field. If the CI response indicates an ineffective sterilization process, the package in question should be sent back to the sterile processing department (SPD) for reprocessing.

### Biological indicator

A BI process challenge pack (BI PCD) containing a Class 5 integrating CI should be used in each load that contains an implant. The implant should be quarantined until the BI testing is available. AAMI states: "Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule."

In documented medical exceptions, the implant could be released based on the results of a Class 5 CI (not a Class 6 CI).

### Documenting exceptions

AAMI provides an example of an implant log and an exception form to use for documentation in Annex L of the ST79 standard. The form includes the patient's name, surgeon's name, time of procedure, reason for premature release of implant, and what could have prevented this premature release.

The Joint Commission uses the AAMI ST79 standard during surveys and expects to see that ST79 Section 10.6.3 and Annex L are being used.

It is important to have a surgeon authorize the early release of implants before the BI re-

## ***New guidance on loaner sets***

As a help for managing loaner sets, the International Association of Healthcare Central Service Materiel Management (IAHCSMM) has a new Position Paper on the Management of Loaner Instrumentation.

The paper recommends that loaner instrumentation be received in the facility's decontamination area at least:

- 2 working days (48 hours) before a scheduled case for existing sets
- 3 working days (74 hours) for new sets.

If loaner sets aren't received in time, the OR may end up using immediate-use steam sterilization (IUSS) (previously called flash sterilization)—a practice strongly discouraged for implants.

IUSS should not be performed on implants, except in a documented emergency when no other option is available, according to the recent multi-society position paper on IUSS from AAMI, AORN, and other organizations.

AORN states in its recommended practices for sterilization that, in an emergency, when flash sterilization of an implant is unavoidable, a rapid-action BI with a Class 5 chemical integrating indicator should be run with the load. The implant should be quarantined on the back table and not released until the rapid-action BI provides a negative result.

This statement is intended to discourage use of IUSS. If IUSS is used, the manufacturer's written IFUs for cleaning, packaging, loading, and sterilization parameters should be followed.

sults are available. This documentation should be used to determine patterns of events that cause an emergency release of implants so that situation can be corrected.

OR personnel have told me that if the liability is shifted to the surgeon, the practice of releasing implants early or using immediate-use steam sterilization is dramatically reduced.

### **If the BI is positive**

If the BI is positive or the Class 5 CI indicates an ineffective sterilization process, the implant should not be used.

If the cycle parameters, the external or internal chemical indicator results are not correct, or the BI is positive, do not use the load. Inform the appropriate supervisor so appropriate follow-up measures can be initiated.

Appropriate follow-up measures for monitoring products that indicate a sterilization process failure are described in the AAMI steam sterilization standard under Section 10.7.5 (Actions to take when biological indicators, chemical indicators, or physical monitors indicate a failure). All monitoring information should be fully traceable to the patient.

### **Why are improperly processed implants a risk?**

Implants released before the BI result is known may have microorganisms on them that could cause an SSI, which may not be evident for up to a year after surgery.

During implant surgery, removal and manipulation of the tissue immediately adjacent to the implant create an area where microorganisms could multiply. In addition, surgery interrupts the blood supply, which prevents antibiotics from contacting the microorganisms.

Removal of the implant (ie, joint, vascular graft, or intraocular lens) may be necessary to stop the infection, and this could cripple or kill the patient. That's why it's critical to take every step possible to ensure implants are properly sterilized and BI results are negative before the implant is used on a patient.

### **Why aren't implants quarantined?**

There are many reasons why implants may be released prematurely. These are a few:

- Loaner instruments may not arrive in sufficient time to process the devices properly and quarantine implants. That can be the result of a loaner policy that is not successful at meeting the AAMI standard and the facility's needs.
- Poor scheduling by the hospital or vendor, insufficient vendor inventory, or emergencies are other reasons. Possibly, the manufacturer's written instructions (IFU) did not arrive with the sets, and obtaining those delayed the processing.
- Lack of inventory, whether loaner, consignment, or owned implants/instruments, may not be sufficient to meet the surgery schedule. Instruments that arrive broken or dirty can also delay processing.
- OR block schedules may require use of one-of-a-kind instruments in specialty trays or loaner/consignment trays for back-to-back cases.
- Resources may be lacking, such as personnel, appropriate equipment, cleaning agents, tools recommended in the IFUs, and space in SPD.

A new position paper on loaner sets can help in developing your own policy (sidebar).

## How do I change practice?

How can you stop the practice of releasing implants for use before the BI results are known or using immediate-use steam sterilization? Be sure you and your superiors are aware of the Joint Commission NPSG.07.05.01, in particular, EP 4, which states: "As part of the effort to reduce surgical site infections, conduct periodic risk assessments for surgical site infections in a time frame determined by the hospital."

This could be interpreted to apply to the release of implants. If you continue to release implants before the BI results are known or process implants by immediate-use steam sterilization, you need to do a risk assessment to determine how to eliminate these practices.

Management teams from the operating room, SPD, infection prevention, and risk management departments need to work together to develop policies and procedures to ensure all implants are not released until the BI results are available, and implants are never processed by immediate-use steam sterilization.

Meeting the AAMI and AORN recommendations is a step closer to eliminating SSIs and improving patient outcomes. ❖

—Martha Young, MS, CSPDT

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*Martha Young is an independent consultant with long experience in medical device sterilization and disinfection.*

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# Unprocessed tray incident prompts investigation, leads to process improvements

The circulating nurse was cleaning up after surgery in an ambulatory surgery center (ASC) when she noticed the internal chemical indicator (a Class 5 integrating indicator) had not reached its appropriate endpoint response, which is a pass. That meant an unprocessed instrument tray had been used on the patient. Her discovery set off an investigation to determine why this occurred.

Could this happen in your facility? This article discusses the events that led to the use of the unprocessed tray and describes the process improvements implemented to reduce the chance for such an event in the future.

## Patient notification

After the unprocessed tray was discovered, the surgeon promptly informed the patient in a manner that conveyed full disclosure, compassion, and accountability. The surgeon also prescribed antibiotics to decrease the risk of postoperative infection and closely monitored the patient for signs and symptoms of infection.

Although the risk of transmission of bloodborne pathogens was assessed as low, the facility followed its procedure for management of patient exposure to blood and body fluids. The patient underwent postexposure testing for bloodborne pathogens for 6 months after the surgical procedure, as recommended by the Centers for Disease Control and Prevention.

## Root cause analysis

A team of the ASC's stakeholders was called together to determine how an unprocessed instrument tray was used for a procedure and how to prevent this from happening again. The team consisted of the surgeon, OR staff who were in the room during the case, and nursing and physician leaders from the departments of surgery, sterile processing, infection prevention, and patient safety.

By the time the team met, ASC staff and leaders had conducted a preliminary investigation and made some discoveries about why the instrument tray was not processed. A few days prior to the incident, a sterilizer needing repair had been taken out of service, creating a backup of trays to be loaded into the remaining sterilizer, which was operating correctly. The physical space in the sterilizing area was small and imme-

diately adjacent to the sterile storage area. The unsterilized instrument tray was inadvertently placed in the sterile storage area.

## First event

The first event that led to use of the unprocessed instrument tray was that the tray was placed in the sterile storage area and released for use. Personnel did not read the external chemical indicator on the tray before it was released. Though a barcode scanning system was used in the department, the system did not have the capability to identify whether a package had not been processed.

## Process improvements to consider

- Update or write a policy and procedures that state actions to take when a sterilizer is removed from service so all personnel know where to place trays/packages to be sterilized once the sterilizer is placed back into use.
- Review the storage areas in the sterile processing area to determine if more space can be created for storage of unsterile items. A human factors approach would be to avoid having the sterile and unsterile storage areas next to each other to prevent medical devices from being stored in the wrong area.
- Upgrade the instrument-tracking system or purchase a new workflow management information system with the capability of scanning packages before and after the sterilization process, including when they are released for use, to determine if they were processed. The results of the physical monitors and chemical and biological indicators could also be accessed at this time. Such a system could alert you if the wrong sterilization cycle was used, if the physical monitoring results were not correct, or if a biological indicator was not run with an implant. This is just a short list of features of newer information systems.
- Train OR/sterile processing personnel to read and identify the acceptable endpoint results of the external chemical indicator to ensure the packages have been through the process before they are released for use. Verify and document competency.
- Ensure that an experienced, knowledgeable person makes decisions about load release based on the evaluation of all available data (physical monitors, chemical and biological indicators) for particular loads.

## Second event

The second event that led to the use of the unprocessed tray was failure of the OR staff to read external and internal chemical indicators. Contributing factors to this event included:

- A new employee with previous OR experience was setting up the case. The handoff process for nurse preceptors did not provide clear communication about specific skills for which the new employee was expected to demonstrate competence, including chemical indicator reading.
- The day the chemical indicator was not read was a heavy case-load day, and there was pressure to turn over rooms as quickly as possible.
- During setup of the case, nurses reported frequent interruptions by anesthesia providers and other staff.

## Process improvements to consider

- Use the AORN Comprehensive Surgical Checklist, which includes recommendations from the World Health Organization and the Joint Commission's Universal Protocol and National Patient Safety Goals. This is a single, comprehensive, multidisciplinary checklist to use for preprocedure check-in, sign-in, time-out, and sign-out for every surgery to reduce surgical complications and mortality. During the time-out, the scrub person and circulating nurse should check the box, "Sterilization indicators have been confirmed."
- Train OR personnel to read and identify the acceptable endpoint results of the external chemical indicator and internal chemical indicator to ensure the trays/packages have been through the sterilization process, and the sterilant reached the inside of the tray/packages before they are introduced to a sterile field. Verify and document competency. The preceptor also needs to check the chemical indicator results before placing the set on a sterile field. A second check by another staff member would add another safety factor.
- Follow the AORN recommended practice for sterile technique, which states, "Perioperative team members should inspect the sterilization chemical indicator in the sterile package to verify the appropriate color change for the sterilization process selected." This is done before the package is placed on the sterile field.
- If your facility uses rigid sterilization container systems, open the container on a separate clean, flat, and dry surface to inspect the integrity of the packaging (eg, security locks, latch filters, valves, and tamper-evident devices to ensure they are intact). Check the endpoint results of the external indicator before opening the container and the internal indicator before placing the tray on the sterile field. Place the tray on the sterile field only if the integrity of the container is not compromised and the chemical indicators have reached their acceptable endpoint.

- Minimize interruptions during the room setup, and establish a feasible time frame for turnover to reduce the chance for mistakes that could affect patient safety.

## Risk assessment

Doing a root cause analysis after an event helps to identify possible sources for the event and action plans to prevent future occurrences.

Facilities should also perform a proactive risk assessment. This process includes identifying the likelihood that such an event could occur, the consequences if an event does occur, assessment of how to prepare the facility to manage the event, implementation of actions to take to ensure an event does not occur, and communication of the changes being implemented to prevent an event.

Consider performing a risk assessment of the sterilization process (eg, decontamination, preparation and packaging, sterilization, quality control, sterile storage, and product distribution) to identify events that could lead to failure. Eliminating risk points helps improve patient safety. ❖

—Martha Young, MS, CSPDT

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*Martha Young is an independent consultant with long experience in medical device sterilization and disinfection.*

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# V. Preoperative Screening



# Preoperative screening program reveals missed diagnoses and reduces mortality

Cancelled surgical procedures at Carilion Roanoke Memorial Hospital (CRMH) in Roanoke, Virginia, are considered a success rather than a failure.

"That's because we cancel procedures for cause," says Sandy Fogel, MD, FACS.

Before 2010, many patients at CRMH were having surgery with undiagnosed, untreated medical problems, and postoperative 30-day mortality was too high.

After a preoperative screening clinic was set up, however, postoperative 30-day mortality was cut almost in half at CRMH, a 763-bed hospital with 31 ORs.

These days, a patient who is found to have an abnormal ECG during preoperative screening, for example, may need a stress test and an angiogram, so the surgery is cancelled.

"That's a potential cardiac complication or death we have avoided," says Dr Fogel, a general surgeon and the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) champion at CRMH.

## Quality report prompted change

Implementation of the preoperative screening clinic was spurred by CRMH's first ACS-NSQIP report after becoming a member in 2007.

"Our first report showed that surgical mortality was significantly higher than expected and significantly higher than the national average," says Dr Fogel.

He put together a working group to review patient charts and find the cause of the high mortality rate. This group consisted of both physicians and nurses who reviewed charts and brought their different perspectives to the project.

"The single finding that made us think we were operating on patients with undiagnosed diseases was that admitting nurses were reporting that patients were short of breath at rest and there were no diagnoses in the chart to explain why," he says.

Looking further, the group found that 42% of hyperglycemic patients were not diagnosed as diabetic. They also found patients with angina who had no diagnosis of coronary artery disease and hypertensive patients who had no diagnosis and were not on any medications.

## Preoperative screening lacking

Because southwest Virginia has a relative shortage of primary care physicians and because primary care physicians in Virginia aren't reimbursed for preoperative screening, it became habit over the years for surgeons to do their own screening, notes Dr Fogel. "As we discovered in our chart reviews, many of the patients were not adequately screened preoperatively," he says.

The NSQIP findings prompted Dr Fogel and other surgeons to first seek help from the primary care physicians. But it would have been overly burdensome and time-consuming to do complete preoperative screening of all surgical patients.

The surgeons then considered other preoperative screening models:

- A preoperative screening service run by hired primary care physicians. This idea was rejected because the hospital wouldn't be reimbursed for the preoperative assessments and therefore didn't want to pay additional salaries to physicians hired for that purpose. In addition, the patients' primary care physicians would be cut out of the loop with another primary care physician taking care of their patients.
- All histories and physicals done by nurse practitioners. This model was deemed too expensive, and the surgeons decided it would take too long to find and hire the 10 or more nurse practitioners they needed.
- An anesthesiologist-run clinic. Anesthesiologists were also in demand for clinical duties and could not be spared.

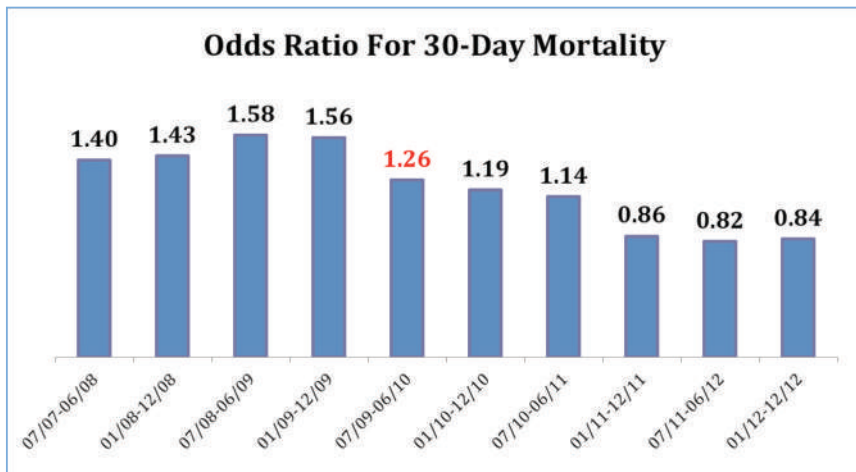
Finally, the surgeons decided on a preoperative screening clinic run by RNs.

To help them develop a screening tool, the surgeons asked primary care, internal medicine, cardiology, pulmonary, and infectious disease practitioners what specific questions they usually ask their patients to pick up on a disease.

The final list of questions was made into a computer-based checklist for the preoperative screening nurses to use, and it was incorporated into the hospital's electronic medical record.

## RNs screen all patients

The preoperative screening clinic was opened adjacent to the hospital in 2010. Every patient scheduled for surgery is required to undergo a preoperative assessment by a nurse.



Source: Carilion Roanoke Memorial Hospital.

There are 15 nurses in the preoperative clinic who work from 7 am to 8 pm in staggered shifts to accommodate the patients' schedules. They assess 100 surgical patients per day, including endoscopy patients.

Spending approximately 1 hour with each patient, the nurses discover an enormous number of undiagnosed problems, says Dr Fogel.

Some of the screening is done by telephone. For example, a 20-year-old man scheduled for an inguinal hernia repair would not have to be screened at the clinic unless the nurses found problems during the telephone assessment.

If a problem is identified in the clinic, the patient's primary care physician is contacted. Because the primary care physicians are now seeing the patients for a particular problem such as uncontrolled diabetes, an abnormal ECG, or uncontrolled hypertension—not just for preoperative screening—their time is better spent, notes Dr Fogel.

If the primary care physician prefers to have a patient assessed by a specialist such as a cardiologist, the preoperative screening nurses make all of the arrangements for the patient.

Dr Fogel notes that when they were setting up the clinic, they persuaded each specialty service to keep open slots each day for these urgent preoperative visits. "We have been pretty successful in getting that accomplished," he says. To help with this, patients now come to the clinic 1 to 2 weeks before surgery instead of 2 to 3 days ahead. "If we pick up abnormalities, there is either time to correct them or time to postpone their surgery," he says.

### Mortality cut almost in half

"After implementation of the new preoperative screening clinic, overall 30-day surgical mortality decreased from 3.5% to 1.9%, which is clinically

and statistically significant," Agathoklis Konstantinidis, MD, told OR Manager. Dr Konstantinidis, a general surgery resident at CRMH, compiled the preoperative screening data for a presentation at the ACS-NSQIP National Conference in July.

Between July 2007 and December 2009—before the preoperative screening clinic was started—the odds ratios

for 30-day mortality in all cases were 1.40, 1.43, 1.58, and 1.56 in successive ACS NSQIP 6-month reporting periods (chart).

Beginning with the first report after implementation of the preoperative screening program in 2010, there was a progressively decreasing odds ratio for 30-day mortality in successive reporting periods: 1.26, 1.19, 1.14, and 0.86. In the last report in 2012, the odds ratio dropped to 0.84, says Dr Konstantinidis.

Of more than 20,000 patients who were screened in 2012, 5,866 patients had some previously unidentified risk factor:

- 3,691 had undiagnosed obstructive sleep apnea
- 2,361 had an abnormal preoperative ECG
- 437 had undiagnosed diabetes
- 192 had undiagnosed hypertension
- 67 had undiagnosed shortness of breath

Other risk factors also were found, and some patients had more than 1 undiagnosed problem.

In 2012, as a result of the screening, surgery for 218 patients was cancelled and 147 were referred to cardiology specialists for further evaluation. In the past, operations were performed without knowledge of patients' risk factors, Dr Konstantinidis notes.

The last time Joint Commission surveyors visited the hospital, Dr Fogel says, they were shown the results of the preoperative screening process, and the Joint Commission asked CRMH to put it on their website as a best practice.

"We are very proud of that," he says. ♦

—Judith M. Mathias, MA, RN

*This article originally appeared in OR Manager, December 2013;29:12-13.*

# Safer surgery: The preoperative testing process

*Ten elements of safer surgery. The third in a series, this article focuses on presurgical evaluation.*

**M**aking sure patients have the appropriate preoperative preparation, including testing, is necessary not only for patients' safe care but also for a smooth process on the day of surgery.

Advocate Health Care, a Chicago area system, has standardized preop testing requirements and the patient history form for 9 of its hospitals to help streamline the process. The preadmission testing (PAT) is one of 10 components of Advocate's Safer Surgery program (sidebar).

The project was led by David Young, MD, director of preanesthesia testing, and Cindy Mahalvan Brenk, MS, RN, CNOR, executive service line director for surgery at Advocate Lutheran General (ALG) Hospital in Park Ridge, Illinois. Dr Young is also a consultant with Surgical Directions.

ALG performs about 12,000 procedures a year in its main OR and 6,000 in its ambulatory surgery unit.

In developing its preoperative program, ALG strived to achieve what Dr Young terms "the ideal PAT state":

- Patients are preregistered by phone within 24 hours of surgery scheduling. As soon as patients are preregistered, they are triaged for PAT.
- Patient charts are completed 3 days prior to surgery as a goal.
- The patient history tool is standardized in the patient record.
- Lab and ECG testing is conducted on site in a location convenient for patients.
- Testing is determined according to standardized guidelines based on the patient's condition and complexity of surgery.
- Guidelines are established for lab and ECG results that will be considered abnormal.

Here's a look at each step in the process.

## Registration and triage

As soon as the hospital receives a surgical scheduling request, the patient is preregistered by phone, and the procedure is given an encounter number, allowing the nurses to document in the record.

When scheduling, surgeons' offices must fax a standard form with certain required information, such as the patient's diagnosis, the procedure, and any comorbidities. (See February 2013 OR Manager. The form is available in the OR Manager Toolbox at [www.ormanager.com](http://www.ormanager.com).)

The registration department contacts the patient to set up a phone screening or in-person appointment. The decision for phone screening or an appointment is primarily the surgeon's choice. Patients who are admitted and do not have a primary care physician on staff are assigned a hospitalist, who will see them in PAT.

## PAT guidelines

ALG prefers that surgeons and primary care physicians delegate preop testing and evaluation to its PAT department. Many physicians do so because it streamlines their process and helps ensure that a case won't be canceled because the patient wasn't evaluated according to the appropriate guidelines.

"A primary care physician doesn't want to lose surgeon referrals by not having patients properly prepared for surgery," Mahalvan Brenk notes.

## Preop appointments

About 20% of ALG's patients are seen in person before the day of surgery. The PAT unit is located on the first floor with valet parking available, and testing is performed at that location.

The PAT department has 2 sections. The preop evaluation unit where patients are seen is staffed by experienced RNs and hospitalists. Charts are assembled and preop phone calls are made in a separate office. The unit is staffed by 7 RNs.

## Meeting the 3-day goal

Meeting the goal of having patients' charts prepared 3 days ahead of surgery requires coordination. Documents are managed electronically using fax-filing software to avoid having to manage paper forms.

"When a patient's information comes in, it goes into the patient's chart—an electronic file folder—by day of the week they are having surgery," Mahalvan Brenk explains.

Nurses review lab results and other information as it comes in, referring to guidelines for abnormal test results.

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If a finding is abnormal, it is immediately sent to the primary care physician or to one of the hospitalists as the first line of triage.

If information is missing 3 days before surgery, nurses contact the office. Mahal-van Brenk instructs them to communicate directly with the physician or the physician assistant rather than leave a phone message. Text messaging can be helpful.

### **Daily huddle**

Missing information is also addressed in the daily huddle held to review the next day's cases. The huddle, attended by representatives from anesthesia, nursing, PAT, and sterile processing, reviews the schedule, chart completeness, and other preparations needed to make sure surgery proceeds safely and smoothly.

"If a chart is incomplete, we usually make a call [to the surgeon] to say it can't be the first case," she notes.

If an office has a pattern of incomplete charts, Mahal-van Brenk follows up herself, contacting the office and meeting with the staff if necessary. She also takes time to meet with new office staff.

"We meet one on one to get them on board and explain the process," she says. "That builds relationships, and they have a resource to ask questions. That one-on-one time is key."

### **Achieving consensus**

Because the Advocate hospitals have worked together on multiple projects, a process was established for developing consensus on preop testing and evaluation guidelines.

The guidelines were developed by a team of nurses and anesthesia providers who examined current standards and best practices, Mahal-van Brenk says.

Having a project manager is essential when conducting a project across multiple facilities, Dr Young stresses, adding that this role can't be performed by a person who already has another clinical or management position. "Someone has to own the process who doesn't also have a full-time position in their own facility."

### **Communicating with MD offices**

To make sure all of the physician offices were familiar with Advocate's preop guidelines and the expectations, Mahal-van Brenk and Dr Young met with them directly.

In the meetings, "We let them know what we were doing, why we were doing it, and explained the hospitalist model.

"The hospitalists help them postoperatively," she points out, "because they follow their patients in the hospital, managing their diabetes, resuming blood pressure medication, and so forth." ♦

—Pat Patterson

*Previous articles in the series focused on OR governance (January 2013) and safer surgical scheduling (February 2013).*

*This article originally appeared in OR Manager, March 2013;29:18-19.*

# Why are there so many unneeded preop tests?

**W**hat preoperative tests does your facility require for a healthy 40-year-old having a knee arthroscopy? What about a healthy 82-year-old having an elective procedure? Do these patients need testing at all?

A good deal of testing is performed without clinical indications, studies have found.

Researchers at the University of Texas Medical Branch (UTMB), Galveston, are learning more about what drives overuse.

In 2 reports in the past year, they documented unnecessary testing in patients having elective hernia surgery and patients having noncardiac surgery who had cardiac stress testing.

They're also finding wide geographic variations, similar to those seen for elective surgery. They've learned testing is more prevalent in areas with higher rates of malpractice suits.

The findings are leading to discussions about the need for standardized national guidelines, Taylor Riall, MD, PhD, associate professor in the Department of Surgery at UTMB, told *OR Manager*. She also holds the John Sealy Distinguished Chair in Clinical Research.

## Studies document overtesting

In the study of elective hernia repair, 64% of 47,000 ambulatory surgery patients had preop laboratory testing. More than half of those with no documented comorbidities had testing. Yet test results didn't make a difference in whether surgery went forward. In a subgroup tested on the day of surgery, 62% had at least one abnormal result, but hernia repair was performed anyway. Nor did the abnormal results predict postop complications these patients would develop.

In the second study of 75,000 Medicare patients having noncardiac surgery, 4% had a cardiac stress test though they had no indications for that test. Unnecessary testing rates varied geographically from 2.7% in the Pacific West to 4.7% in the Midwest.

This unneeded testing could be a significant cost to Medicare, which reimburses from \$92 to \$341 for a stress test, depending on the type, the authors commented.

## Overtesting in the elderly

Overuse of testing is even more prevalent in healthy older patients, Dr Riall's group has learned. An analysis of Medicare data showed 75% of those aged 81 to 90 having elective surgery

had preop testing without an indication, compared to 33% of patients under age 20.

Focusing on Texas, they discovered testing patterns varied widely in the Medicare population.

"You would expect that 80-year-olds having hernia repair in an elective setting would be similar no matter where they live," she says. Yet chest x-ray rates ranged from 10% in some locales to 90% in others. ECGs and other tests showed similar variations.

"This suggests physician or facility practice patterns and not patient characteristics are driving the use of laboratory testing," she says.

## Communication gaps?

Dr Riall has observed that there's often miscommunication about which tests are needed. In her organization, 80% of the tests are ordered by surgeons.

"A lot of surgeons we talk to say, 'We wouldn't order the tests, but the hospital or facility requires it,'" she notes. "Or they say, 'The anesthesiologist will cancel the case if we don't order them.' Then the anesthesiologists will say, 'We don't require these tests, but the surgeons order them.'"

"Many are ordered by residents. They do it because they're afraid the case will be canceled if they don't," she says.

The researchers plan to survey surgeons in Texas about tests they are required to perform.

Though many hospitals and health systems have developed their own consensus guidelines on testing, Dr Riall believes a national effort is needed.

"I think we have to develop clear and consistent guidelines that all of the groups would agree on," she says. That might also help to alleviate worries about malpractice suits. ❖

—Pat Patterson

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# VI. Retained Surgical Items



# Focus shifts to device fragments, small miscellaneous items in RSIs

**T**hough retained surgical items (RSIs) cases are rare, they do happen, and they take a heavy toll throughout the system in terms of steep fines, malpractice claims, and compromised patient safety. Estimates of RSIs range from 1 in 1,000 to 1 in 7,000 procedures. And a 2003 study by the Agency for Healthcare Research and Quality found that patients with RSIs had a mortality rate 2.14% higher than controls, excess hospital stays of 2.08 days, and excess costs of \$13,315.

There is no national reporting system for RSIs, but state and federal agencies along with accreditation organizations have recommended action to prevent such events.

RSIs are considered a serious reportable event (SRE) by the National Quality Forum and a sentinel event by The Joint Commission. The Centers for Medicare and Medicaid Services lists RSIs among the hospital-acquired conditions for which it will no longer provide payment under the Inpatient Prospective Payment System.

The state of California in 2007 began mandating that hospitals report cases of RSIs and other SREs and levying administrative penalties in cases where serious harm has occurred ([www.cdph.ca.gov/Pages/NR13-005.aspx](http://www.cdph.ca.gov/Pages/NR13-005.aspx)).

In February 2013, the California Department of Public Health (CDPH) issued penalties against 2 hospitals for RSI cases:

- One hospital was fined \$100,000 for failing to develop and implement a surgical count policy and procedure specifying that small items would be accounted for prior to closure. A Raney clip was left inside a patient's skull after brain surgery.
- Another hospital was fined \$75,000 for leaving behind a stiffener stylet (guide wire) from a Groshong catheter.

Interestingly, these fines were for retained small miscellaneous items and device fragments.

## 'Surgical junk' on the rise

The variety of small miscellaneous items and unretrieved device fragments (UDFs) that are being left in patients has increased, and they are gaining attention, says Verna Gibbs, MD, who developed the NoThing Left Behind® project for RSI prevention ([www.nothingleftbehind.org](http://www.nothingleftbehind.org)).

Dr Gibbs has termed these items "surgical junk."

Orthopedic surgery cases account for the largest number of these small miscellaneous items and UDFs, which often are the result of breakage of tools when used against bone. New to the scene are items such as guide wires, catheters, stents, and sheaths, which are left in patients whose procedures are performed in cardiac catheterization labs, interventional radiology labs, and hybrid ORs.

For example, problems can occur when a guide wire gets tangled around a stent and the wire fractures, leaving behind a small part of the wire, or a subcutaneously placed catheter snaps upon removal and part of it is left interstitially.

Device fragments can result from instrument failure that develops from extensive use (burrs, loose parts) or faults in new instruments, such as poor welds or rough surfaces.

## FDA takes notice

In 2008, the Food and Drug (FDA) Administration issued a medical device safety alert warning of serious adverse events associated with UDFs and provided recommendations to mitigate these events ([www.cdph.ca.gov/Pages/NR13-005.aspx](http://www.cdph.ca.gov/Pages/NR13-005.aspx)).

The FDA characterized a UDF as "a fragment of a medical device that has separated unintentionally and remains in the patient after the procedure."

The FDA's Center for Devices and Radiologic Health (CDRH) receives nearly 1,000 adverse event reports each year related to these items.

Among the patient consequences of retention are:

- local tissue reaction
- infection
- perforation or obstruction of blood vessels
- death.

RSI-related safety notices on the FDA website reflect a range of consequences. For example, in 1 safety notice, the FDA describes the fracture of the distal tip of an epicardial pacing lead. The tip was left in the patient without any adverse consequences ([www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm203731.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm203731.htm)). In another instance, a fractured guide wire lodged in a coronary artery during a cardiac catheterization, resulting in the patient's death from cardiac tamponade

([www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm070187.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm070187.htm)).

In addition, during MRI procedures, magnetic fields may cause metallic fragments to migrate, and radiofrequency fields may cause them to heat, which can lead to internal tissue damage and burns.

“What’s important to point out about these miscellaneous small items and unretrieved device fragments is that physicians may not think they need to disclose to patients that they have left something behind if they decide not to take them out,” says Dr Gibbs, professor of clinical surgery at UCSF and a surgeon at the San Francisco Veterans Affairs Medical Center.

“This is bad practice,” she says. “Physicians have a moral and ethical obligation to tell the patient. It is important for the patient to know in case an MRI is needed in the future.”

### Data show need for action

A 2012 study led by Susan Moffatt-Bruce, MD, PhD, chief quality and patient safety officer and associate professor of surgery at Ohio State University Wexner Medical Center in Columbus, examined risk factors for intravascular retained small miscellaneous items and device fragments.

The retrospective study of 83 RSIs found that 13 cases involved intravascular small miscellaneous items and device fragments—8 guide wires, 4 catheter/catheter fragments, and 1 coil.

Locations included:

- 3 catheter fragments were retained in the pulmonary arterial tree. Of those, 1 broken catheter tip embolized into a distal pulmonary arterial branch, and 2 catheter fragments were located in the heart.
- 1 guide wire was retained in the subclavian vein
- 2 guide wires were extending between the heart and iliac vein
- 2 guide wires were extending between the inferior vena cava and the right atrium
- 3 guide wires were extending between the superior vena cava and the inferior vena cava
- 1 catheter and the coil were located peripherally in smaller vessels.

Procedural factors significantly associated with the retained intravascular items included:

- technically difficult procedure—a procedure that did not proceed as planned (ie, took more than 1 attempt)
- unfamiliarity with the equipment—new equipment or equipment that did not work as expected or malfunctioned
- difficult/emergent setting—a procedure done emergently, often without enough time to go through the usual safety steps, in a less than optimal environment.

“One of the things we found was that radiology under-reads, or the item is missed on the ini-

tial read in a significant number of cases,” says Dr Moffatt-Bruce. Seven of the 13 items were missed on confirmatory postprocedural x-rays. Most of the retained items were found within 48 hours and were removed the same day. They were detected by means of interventional radiology procedures. Some items, however, were indwelling up to 6 weeks before being identified.

“Though all of the patients did well, it is a significant patient dissatisfier to have to undergo another invasive procedure,” she says.

Strict adherence to protocols and stringent radiographic review, along with standardized team training, checklists, and documentation, are needed to prevent these incidents.

### Technology alone won’t work

Another of the penalties issued by CDPH in February 2013 was a fine of \$100,000 for a surgical lap pad left in a patient despite the use of a 2-D matrix computer sponge counting device.

Stanislaw Stawicki, MD, and Dr Moffatt-Bruce led a multicenter study to gain a better understanding of why RSIs continue to occur, despite the use of radiofrequency tagged sponges and wand systems and mandatory x-rays, and how to reduce such events.

One of the analyses combined data from 2 previously published case-controlled studies on RSIs (Gawande et al, 2003; Lincourt et al, 2007) with data from their study on 59 RSIs and 118 matched controls from 5 institutions gathered over a 6-year period.

“Many variables that were not significantly associated with RSIs when data from the 2 previous studies were combined became significant when our data was added,” says Dr Stawicki, director of research for the division of trauma/critical care and associate professor of surgery at Ohio State University Wexner Medical Center.

Results showed that counts had been documented as correct in 45 of 59 cases, even though a sponge was later found inside the patient. In 13 of 27 cases an RSI was missed on initial confirmatory x-rays. In 2 of 32 cases in which radiofrequency tagging systems were used, RSIs were missed.

The biggest risk, says Dr Moffatt-Bruce, is that humans are doing the operating and humans are doing the counting. “Our goal is to minimize that risk as much as possible through the adherence to and enforcement of a standardized process for counting,” she says.

“All technology does is layer on another practice,” notes Dr Gibbs. “Humans are making errors in counting without technology, and humans will continue to make mistakes with technology added.”

Dr Gibbs has been testing and teaching a simplified, transparent standardized manual sponge management practice, called Sponge ACCOUNTing System, which she says is being used in hundreds of hospitals across the coun-

try. The practice requires the nurses to manage the sponges only in multiples of 10 and to account for them at the end of the case rather than just count them.

### **Teamwork, training essential**

Each member of the OR team plays a part in minimizing the risk of losing small miscellaneous items and generating UDFs, says Dr Gibbs.

- Surgical technologists should inspect any device before handing it to the surgeon and again when it is passed back after use.
- Surgeons should perform a methodical wound exam before closing every wound.
- Circulating nurses should direct the activities to account for all 4 classes of surgical items—soft goods (eg, sponges, towels), sharps (eg, needles, blades), instruments, and small miscellaneous items and device fragments.

Dr Gibbs says she would like to see a checkbox added to nursing operative records to signify a correct count of all small miscellaneous items. Currently nurses are bundling small miscellaneous items either with sharps or instrument counts.

In cath labs and procedural areas, proceduralists have to develop and adopt practices to account for all surgical items at the end of the procedure. One example would be to have a memory aid added to the central line-associated bloodstream infection (CLABSI) procedure list to visually confirm that the guide wire is in the kit at the end of the insertion. This would ensure that it wasn't inadvertently left in the patient.

"Instead of trying to assess the risk of an RSI based on the type of case or characteristics of the patient," says Dr Gibbs, "it would be better to look at the risk of the providers performing and assisting with the surgical procedures. The risk is in the personnel and the environment in which they work.

"An RSI means the OR team has poor practices and is not working together. I call an RSI case a canary in the surgical coal mine," she says.

A lot has been learned from wrong-site surgery, says Dr Gibbs. By implementing timeouts and using checklists, OR staff began to standardize practice, communicate, and work together. Similar systems are needed for prevention of RSIs.

Dr Moffatt-Bruce notes that because of their study, Ohio State University Wexner Medical Center invested in team training through crew resource management. Some 38,000 staff have been trained.

Crew resource management speaks to the basic premise of sharing the same mental model in the OR, whether it's during the procedure or during the counts, she says. The model makes the surgeon responsible for doing the timeout as well as the debriefing at the end of the case to ensure nothing is left behind. ♦

—*Judith M. Mathias, MA, RN*

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# VII. Wrong Patient, Wrong Surgery, Wrong Site



# A clearer, more robust surgical consent process

A large Chicago-area health system has built a clearer, more robust process for resolving any discrepancies in the surgical consent prior to the day of surgery. Consent discrepancies are a risk factor for wrong-site surgery.

"We realized that by the time the patient arrives in the surgery area, it is too late. Most of the work is done preoperatively," says Beverly Beine, BSN, MS, RN, NE-BC, vice president for perioperative services, for Evanston, Illinois-based NorthShore University HealthSystem, which has 4 hospitals and performs about 40,000 procedures a year.

After a couple of near misses in ophthalmology, a team of nurses began working on a quality improvement project to ensure consistency among the signed consent, the surgical schedule, and the surgeon's update note.

"We looked at the whole process—what were the key failure points?" she says.

Surgical scheduling is centralized for all 4 hospitals. Scheduling requests are called in, faxed, or for some offices, scheduled via computer. A challenge is that consents do not follow a standard workflow. Some offices submit them via Epic, the health system's electronic health record. Others fax the forms. Or patients bring them to their preop appointment.

After the QI project was completed and changes introduced, within a year, consent discrepancies fell from about 8% of cases to about 0.3%.

## A refined process

Among the changes in the consent policy:

- Consents for elective procedures must be received in the preop area at least 24 hours before surgery.
- The attending surgeon, not the physician assistant (PA), must either obtain the patient's consent or enter the consent order in Epic.

Using Epic, which all surgeons' offices can access either directly or through a web portal, surgeons can enter the consent order as soon as the patient encounter is completed and append it to the patient's record. When the patient arrives for surgery, the consent order is released, and the nurse can perform the formality of having the patient sign the consent form.

"We are seeing some surgeons doing them more than 24 hours in advance, which is good," Beine says.

- The consent information is verified with the patient during the preop phone call, again on admission, and again with the patient during the surgical site marking.
- Abbreviations were reviewed to make sure they were standardized and added to the list of those approved. Some, such as TLIF (transforaminal lumbar interbody fusion), were sent to the health information management department for approval.
- On the day of surgery, patients are not taken to the procedural area until any discrepancies in presurgical documents are resolved.

During the Universal Protocol to verify the patient's surgical site before the procedure, the team checks again to make sure the consent order matches the OR schedule and the surgeon's update note.

"If those 3 elements are not consistent, we stop the process," Beine says. "Phone calls are made, and the information is clarified until we have the correct information."

## A learning curve

As with any process change, there was a learning curve. NorthShore has a number of midlevel providers, such as PAs, who work with the surgeons in preparing patients for surgery.

The Surgical Quality Committee was instrumental in getting the buy-in of surgeons because they analyze near misses as part of the peer review process.

"They got the information out," she says. "We shared it with the staff so they would understand why we were doing this."

The administration supported the decision not to take patients to the procedural area until discrepancies are resolved.

Though there are still some challenges, Beine says, "At this point, I don't believe the surgeons would want to go back. It's becoming part of their workflow."

She adds: "The focus really is on creating a culture of safety. We drove that message home with the surgeons, anesthesia, and the OR staff." ♦

—Pat Patterson

*This article originally appeared in OR Manager, April 2012;28:20.*

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# 'Just Culture' encourages error reporting, improves patient safety

**D**uring a procedure in the OR, a medication is retrieved from the automated supply station and introduced onto the sterile field. The sterile field is then, unknowingly and unintentionally, contaminated by an unsterile medication.

This example could happen in any operating room setting. In this case, the circulating nurse spoke up and brought the situation to the attention of the manager, providing a learning opportunity for herself and her peers. An immediate survey within the department revealed that the majority of nurses would not have questioned if the contents of a medication or solution from the supply station could possibly be nonsterile. Often, the packaging with this information is removed before a medication is placed in the machine.

This incident illustrates how a "Just Culture" practice environment, in which an organization's leadership embraces a systems approach to error reporting, results in safer patient care. Research demonstrates that the root causes of most errors in health care systems are organizational issues. Still, it is common for management to blame individuals when errors occur. This blaming approach leads to missed opportunities to learn from the error, to better educate clinicians about their practice and situational awareness, and to improve systems and processes to help prevent future errors. As Lucian Leape, MD, a leader in the prevention of health care errors, states, "The single greatest impediment to error prevention is that we punish people for making mistakes."

## ***Safer Surgery series***

This series of articles covers Ten Elements for Safer Surgery developed by Advocate Health Care, a 10-hospital system in the Chicago area.

Previous articles in the series focused on:

- OR governance: January 2013
- Safer surgical scheduling: February 2013
- Presurgical assessment: March 2013
- Excellence in sterile processing: April 2013
- Checklists: May 2013
- Daily huddle: June 2013.

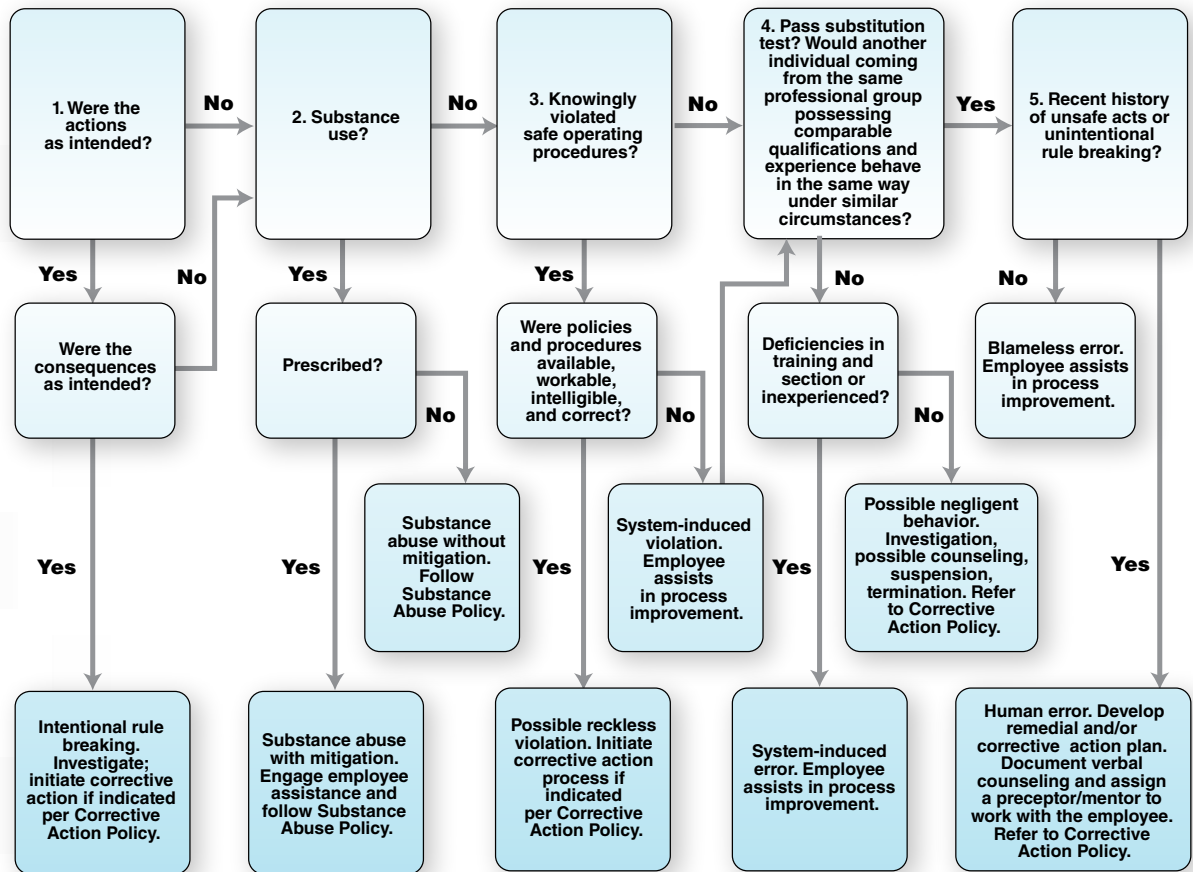
In recent years, perioperative services in the Southcoast Hospitals Group has evolved into a Just Culture. Southcoast has adopted a definition of Just Culture based on the description by David Marx, JD, the safety engineer who developed the concept: "Our culture is an environment that encourages reporting and puts a high value on open communication—where risks are openly discussed between managers and staff. We create an environment where staff members feel safe and supported in voicing concerns, while also holding them accountable for behaviors and practice. We learn from mistakes and strive to improve processes, recognizing that good outcomes are a result of a shared accountability for both good system design and personal responsibility."

With the change in leadership structure and the addition of a new nursing director 5 years ago came a leadership philosophy of open communication and transparency regarding the reporting of both errors and near misses. It was a new concept for the OR staff. Unlike many other organizations, errors didn't often surface because of a lack of reporting by members of the care team.

To introduce the Just Culture approach and hardwire it throughout perioperative services, the perioperative director adopted a hands-on strategy with her leadership team. When an unsafe incident occurred, the director closely mentored managers throughout the process of reporting and resolving the issue. As a guide, they use the Unsafe Acts Algorithm as a consistent framework to explore each occurrence. The algorithm, adapted from James Reason's research on errors in complex, high-risk areas, provides an objective tool that embeds the following elements:

- intent to harm
- incapacity
- foresight
- the "substitution test."

The substitution test involves substituting the individual(s) involved in the incident with a peer from the same clinical domain with similar experience and skills and asking how the peer would deal with the situation. This test was useful in the example involving the automated supply station because it showed



Reprinted with permission from Reason J. *Managing the Risks of Organizational Accidents*. Farnham UK: Ashgate, 1997, and Roesler R, Ward D, Short M. *Supporting staff recovery and reintegration after a critical incident resulting in infant death*. *Adv Neonatal Care*. 2009;9:163-171.

that someone else faced with the same situation clearly could have done the same thing. Using the substitution test helps to identify whether there are deficiencies in the system or staff education.

The algorithm is part of the standard approach to error management at Southcoast. There is a formal electronic reporting system, which staff members use to document any safety concern they observe or in which they are involved. The incident reporting system allows the person completing the report to forward the message to appropriate managers or directors, including physician leadership, who are needed to complete the investigation. It is an interactive system that fosters communication and collaboration around the event. The risk management department views all incidents in the system. In addition, staff can and often do talk directly with their manager. The manager then uses the algorithm to explore the incident, the root cause, and possible courses of action that may be needed.

New managers are coached by the director until the manager is skilled and comfortable

with the error-reporting process. This includes co-managing investigations and following through all of the steps. This process facilitates navigating the investigation through possible contributing factors such as human error, at-risk behavior, or reckless behavior. Outcomes of this process range from consoling the staff member to coaching or reprimand.

Managers continue to consult with their director and peers when incidents occur to gain insights and to learn from one another. When talking with staff, managers use an empathetic and blameless communication style and avoid a potentially punitive tone. Often, the staff members who are involved are encouraged to develop their own collaborative solutions and improvements, which are then shared (anonymously, if warranted) with the entire team.

The Southcoast Hospital Group's perioperative leadership team meets monthly as a group, and the agenda always includes a discussion about incidents that have occurred throughout the system. This allows for broad-based learning from team members, another facet of the open and transparent culture that has emerged over time.



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Just Culture doesn't replace individual accountability for safe practice; rather, it encourages management to focus on system and organizational contributions to patient safety incidents. Integral to the success of this approach is the support of leadership, the human resources department, and the medical staff. The outcomes of the Just Culture include stronger teamwork, increased reporting, a change in culture, and ultimately a safer practice environment.

—*Deborah Rideout, BSN, RN, CNOR, is director of perioperative services, Southcoast Hospitals Group, New Bedford, Massachusetts.*

*For more about Just Culture, visit the Just Culture Community at [www.justculture.org](http://www.justculture.org).*

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