Lean's kanban may be answer to efficient OR supply management

Surgical supplies not only account for a big chunk of the OR's budget, but they're also critical for safe and efficient care. The burning question—will supplies be there when they're needed in the right quantity without excess inventory?

There's no money to waste in expired and hoarded inventory. And there's certainly no time for nurses to leave the OR during a case to hunt for items that should be at hand.

For some, the answer has come in Lean's kanban system.

Advocates say kanban is a simple yet effective method for managing supplies using standard work and visual cues. The concept may be simple, but execution is critical.

This issue has advice from ORs that have laid a foundation for kanban and sustained the effort.

A surgeon blasts dangerous care, calls for ‘transparency revolution’

Does your OR have a Hodad, a Raptor, or a Shrek? These are handles for dangerous surgeons that Martin Makary, MD, MPH, describes in his scathing new book, Unaccountable.

Dr Makary, a surgeon and patient safety leader at Johns Hopkins, advocates a “transparency revolution” to make data public and motivate physicians and hospitals to clean up their acts.

He also tells about “health care heroes” and promising programs that are making a difference.

The book starts with dramatic stories of bad practice that Dr Makary has seen himself or learned about from colleagues.

Hodad—Hands of Death and Destruction—is a congenial surgeon with a warm bedside manner who’s a disaster in the OR. The Raptor is the opposite, hell on
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Editorial

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he recalls it as one of her worst days as an OR director. She was paged to the postanesthesia care unit. When she got there, the surgeon told her there had been a horrible mistake. He had performed a total knee replacement on the wrong side.

The surgeon asked if she would participate in the discussion with the patient once the patient had sufficiently recovered from anesthesia.

After the disclosure, she recalls, the patient looked up at her and said, “How could you let this happen?”

The OR director said she was devastated. She wanted to quit then and there. She had a long talk with the chief nursing officer who challenged her: “You can leave, or you can stay and help us fix this.”

She stayed and went on to lead a statewide collaborative on preventing wrong-site surgery.

The OR director says she still tells this story when she works with teams on patient safety projects.

Stories touch the emotions

We focus on data to target faulty processes, guide decisions on improvement, and monitor progress.

But don’t overlook stories as a way to engage teams and pull them in.

Data speaks to the brain, but stories capture the heart.

Most have probably heard the story of Josie King, the toddler who died from a catheter-related infection at Johns Hopkins Hospital while recovering from severe burns. Josie’s story galvanized Peter Pronovost, MD, and his colleagues at Johns Hopkins to become national leaders in patient safety.

A story you tell from your own experience can be a powerful catalyst for change.

Johns Hopkins is encouraging hospitals signing up for the new Surgical Unit-based Safety Program (SUSP) to identify their own stories. SUSP, funded by the Agency for Healthcare Research and Quality to target surgical site infections, is patterned after the successful project that reduced central line-associated bloodstream infections (CLABSIs) by 40% in 1,100 ICUs.

“When you tell a personal story face to face, it’s powerful because people can see in your eyes what it was like on that day,” says Annette Simmons, who speaks on the role of storytelling in group process (www.anettesimmons.com/storytelling/).

“It saves a tremendous amount of time because you do not have to convince them based on logic.”

Telling a story doesn’t take special skills, but it has to be genuine.

Tips for patient safety stories:
- Tell a story only if it changed you.
- If it didn’t change you, it won’t resonate with people,” the OR director says.
- Write and practice your story. Be succinct, but speak with feeling. “It has to come from your heart, or don’t even bother,” she says.
- The story will be more powerful if nurses and physicians hear it together.

If you want to learn more about storytelling, Simmons has books that can help: The Story Factor and Whoever Tells the Best Story Wins, a workbook.

—Pat Patterson

More about SUSP is at www.hopkins-medicine.org/quality_safety_research_group/our_projects/action_II/SUSP/
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wheels with colleagues and staff but a master of surgical technique. And Shrek is the surgeon the residents dread will be on call in the emergency room.

Then there are the hospitals that the author says cover up bad practice and act like they care more about the bottom line than they do about preventing complications.

Why read the book?
OR managers and directors might think, “Why do I need to read this book? I’ve lived it.”

The reason, Dr Makary tells OR Manager, is that accountability “is one of the defining topics of our era.”

Transparency—the public reporting of data that allows patients to make better decisions—is where he thinks reform lies.

He also points to encouraging stories of “heroes of American health care.” Mark Chassin, MD, pioneered the cardiac outcomes reporting program for hospitals in New York State that has made a difference in patient deaths and complications. He now heads the Joint Commission. Bryan Sexton, MD, fostered development of a widely used safety culture questionnaire that hospitals can use as a barometer of their environments.

Guy Clifton, MD, resigned from Memorial Hermann Hospital in Texas after the administration rebuffed his plans to fix problems behind a high complication rate in the neurosurgery ICU. The cause was taken up by a colleague who refused to take the post until the administration delivered on Dr Clifton’s requests. Today, says Dr Makary, Memorial Hermann is recognized as a top neurosurgery center.

Group efforts
The author also cites group efforts that contribute to better outcomes. The American Board of Internal Medicine’s Choosing Wisely campaign highlights tests and procedures physicians and patients should question.

Dr Makary lauds the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), which measures surgical outcomes, calling its rigorous protocol the health care equivalent to “landing a man on the moon.”

He tells of hospitals that have had success in addressing disruptive behavior, clinicians and professional groups that are seeking to understand and improve the wide variations in practice, and organizations with cultures that support teamwork and internal error reporting.

He applauds AORN for its campaign encouraging nurses to speak up when something doesn’t seem right.
Patient safety

Continued from page 5

Transparency revolution
If the root cause of all these problems is a lack of accountability, Dr Makary sees transparency as the solution.

“I think public reporting of hospital performance, using the measures professional societies have created, is the best next step,” for surgical quality improvement, he says.

User-friendly metrics
He proposes a set of metrics any consumer should be able to look up on any hospital:
• Bouncebacks: Percentage of patients readmitted within 90 days by discharge diagnosis.
• Complication rates for major treatments and procedures.
• Never events: Avoidable events such as retained surgical items, wrong surgery, and death during elective surgery on a healthy patient.
• Safety culture scores, such as the staff’s response to the question, “Would you have your operation at the hospital in which you work?”
• Hospital volumes: Annual volumes for medical conditions and procedures.
• Transparent records, open notes, and video recordings, giving patients streamlined access to written and video records.

Videos for peer review and for patients
Sure to be controversial is his proposal to make greater use of video for peer review, monitoring behaviors like use of checklists, and providing patients with information about their care.

Dr Makary says he routinely offers his patients a video of their laparoscopic surgery on a flash drive. He advocates sampling of procedure videos for external peer review and to sample when complications occur.

“It’s the same principle as traffic cameras, he says.

“When someone is watching, compliance with guidelines radically improves.”

He challenges colleagues and hospitals to take a transparency pledge that he himself has signed (sidebar).

Dr Makary lures readers in with his horror stories about shoddy care. It’s his way to call attention for his bold message about building a more accountable health care system through transparency.

For OR leaders, the book shows how the volumes of data they and their hospitals are collecting could be the path to greater transparency and better, safer care. ❖

—Pat Patterson

The Transparency Pledge for Healthcare Providers

To increase transparency and trust with patients and community, I pledge to engage in the following best practices with my patients:

- I pledge to disclose medical errors to patients as soon as I know about them.
- I pledge to disclose any money I receive from a pharmaceutical or medical device company related to a patient’s treatment options directly to the patient.
- I pledge to use internal hospital reporting systems to report hazards that I believe can harm patients.
- I pledge to openly and freely share a patient’s medical record with the patient.
- I pledge to offer our patients a copy of their procedure video when video technology is used for medical care.
- I pledge to participate in the safety culture survey offered at my medical center.

Medical center/institution__________________________
Health care provider _______________________ Degree ______
Date __________

Return to: TransparentMillenium@gmail.com
A kanban system seems like a logical method for managing surgical supplies. But it needs a strong foundation to be successful.

Kanban, a Lean manufacturing method, relies on visual signals and standard work (related articles). The idea is to be able to tell at a glance that you have what you need to carry out your work.

A typical kanban system uses 2 bins stacked one on top of the other for each supply. Here’s how it works:

- Each bin has half of the supply’s on-hand quantity.
- When a staff member uses the last item in the top bin, she puts the bin in a designated place to signal the need to replenish it.
- She then uses the supplies in the bottom bin.
- The top bin is restocked and replaced under the second bin.
- Each bin carries a standardized label with the product information, quantity, and home location.

But kanban takes more than bins.

“It takes active management and time to make the transition,” says Lewis Lefteroff, whose firm, Opus Solutions, LLC, consults with hospitals on Lean and process improvement.

Here is his advice:

**Plan the kanban system**
The kanban system must be well planned, with decisions about the:

- type of visual signaling system
- calculation of supply quantities
- mapping of the standard workflow.

Training is needed to make sure every person who uses the system is oriented to the workflow.

For a guide on setting up kanban, see Supplies Management in the OR by Gerard Leone and Richard R. Rahn (www.flowpublishing.com).

Be aware that “making the bins is the easy part,” Lefteroff says. Managing the transition and behavior change are key.

**Conduct a trial**
Conducting a trial in one part of the supply room or in 1 or 2 ORs demonstrates that the system can work and builds confidence.

**Reliability builds trust**
No supply system will work if clinicians don’t have what they need when they need it for a patient.

Conversely, the most well planned system won’t work if everyone who uses it doesn’t follow the process.

Though clinicians may think they don’t have time to follow the process, the result is an unreliable system no one can depend on.

**Manage the transition**
Count on challenges as the kanban system takes root. Managers must be on hand daily to coach, reinforce, and give feedback until everyone adapts to the standard work process.

“In the first wave, bins will disappear, cards will disappear; the system will be under heavy stress,” Lefteroff says. “If you don’t work through that, people will revert to their old patterns, and the system will fall apart.”

**Have a champion**
A champion advocates for the system and troubleshoots.

“Someone needs to take ownership,” says Lefteroff.

But avoid having kanban become just one person’s project.

“If the system relies on Sally, and Sally leaves, no one else will know how it works.

“Once you get a system going, it has to be reliable enough that it doesn’t rely on the champion.”

**Set clear expectations**
Everyone who uses the system must be accountable for the standard work.

Most likely, 80% of the staff will take to kanban and actually love it. But a few holdouts can break the system, Lefteroff notes.

At some point, he says, “You have to hold people accountable.”

**Supplies are more than a cost**
Supplies consume a big part of the OR budget, but managing them is more than a money issue. It deserves strong management support and accountability, Lefteroff points out.

“Beyond the dollar amount, it’s about patient safety.”

Having—or not having—the right supplies has a major impact on surgeon and staff satisfaction. A poorly managed system with missing and outdated supplies can delay cases, require circulating nurses to leave the OR to retrieve supplies, lengthen anesthesia time, and increase infection risks. That serves no one’s interests, especially the patient’s.

—Pat Patterson
Opening a new hospital gave a New York health system an opportunity to take a fresh approach to the OR supply chain. The 483-bed Orange Regional Medical Center, with 12 ORs, opened in 2011, consolidates surgical volume from 2 smaller hospitals. The Orange Regional Medical Center is part of the Greater Hudson Valley Health System (GHVHS), Middletown, New York.

The system faced a familiar OR supply challenge: having needed supplies on hand without tying up money in excess inventory.

One objective—get away from “the blitz mentality” for building case carts. That entailed waiting until the next day’s OR schedule was final and staging a “blitz” to pick all of the next day’s case carts. With 35 to 50 case carts, that created a big demand for labor, generally during the second or third shift, notes Luis Soto, MHA, CMRP, administrator for supply chain for GHVHS.

GHVHS turned to Lean management for a solution, specifically, kanban, which uses standardized work and visual cues to streamline the workflow and reduce waste.

Kanban for case carts
In the new kanban approach, the first 12 case carts for the next day’s schedule are picked the night before and lined up (photo).

As soon as those carts are delivered to the OR, the staff assembles the next 12, the next 12, and so on.

All of the day’s case carts are picked by late morning or early afternoon.

“If they have 30 cases or 60 cases, the same rhythm and productivity level are maintained throughout the day,” Soto says.

The rhythm and productivity are maintained.

Three-stage assembly
Case cart assembly is organized into 3 stages: Pick 1, Pick 2, and Pick 3, “basically like an assembly line,” he says. Carts move from one location to the next until completed.

- Pick 1: The process starts in the sterile processing department (SPD) where the staff adds the instrument trays and any surgical packs to the case carts.
- Pick 2: The carts are moved to the surgical storeroom where the staff picks the soft goods. They remain there until 6 am on the day of surgery.
- Pick 3: The carts are moved to the OR where surgical technologists (STs) take over, picking the items stored in the sterile core.

On the day of surgery, the first 12 case carts are placed outside the appropriate ORs. After the case is set up in the OR, the cart is moved back outside the OR door.

That serves as a visual trigger. “When a cart is outside the OR, you know the room is in progress,” he says.

What if the schedule changes? Soto says that rarely happens once it is finalized. “But this does require good communication by the schedulers and surgeons’ offices.”

Collaboration with the OR
Close partnership with the OR was crucial in designing and executing the new process, Soto stresses.

The OR inventory manager and team, who report to supply chain, are responsible for all of the supplies used in surgery, including implants, custom items, and consignment.

It’s a collaborative process.
“Everybody has a stake in making sure the system works,” Soto says.

The OR, SPD, and materials management must work together to make sure:
• preference cards are continuously updated
• the materials management and OR information systems are synched
• the correct supplies are in the right locations for Pick 1, Pick 2, and Pick 3.

OR teams invested time in updating preference cards. The supply chain team made sure all supplies on the preference cards were properly linked in the materials management database.

**Daily meeting**

The OR’s inventory manager meets with the OR staff daily.

“It’s like a shift report,” Soto says. “They communicate any issues they have and make sure anything outstanding is resolved.”

Behind the scenes, the supply database is maintained in the information systems, McKesson for materials management and Epic’s Optime for OR documentation.

When a case is picked from the preference card, the items are automatically charged to the patient and decremented from inventory, Soto notes.

Items added during a case are journaled in Optime by the circulating nurse. Items not used are credited back to the patient later.

**Gaining efficiencies**

The case cart kanban system, in place since August 2011, has reduced the need for additional labor on the second shift.

“When we opened, we were short-staffed, but we have gained efficiencies to the point where service levels are high, and we seldom have issues in the OR,” Soto says.

“We can manage by having 1 shift that comes in on a staggered basis and ends by 7 pm.”

With case cart picking finished late morning or early afternoon, the staff has time to order and replenish supplies and work on quality improvement projects.

So far, he says, with consolidation of the hospitals, the inventory value has been reduced from over $4 million to $3.3 million. He forecasts that OR inventory turns will be 6 to 7 in 2012 because of streamlined supply management and a planned shift to a low-unit-of-measure system with the distributor.

Of the case cart kanban system, “I’ve never seen this done before, and it actually works,” says Soto, whose experience includes more than 20 years in materials management and hospital administration. He particularly credits the facilitation by the system’s director of process excellence, Jeyaparakash Kathiresan, and the staff.

“It takes a tremendous amount of partnering,” Soto adds. “As long as people realize that everyone is a stakeholder and has something valuable to bring, and you work collaboratively, it can be successful.”

—Pat Patterson

Soto credits Emil Layacan, value analysis/systems director; Allison Diuguid, OR supervisor; Maria Quigley, OR director; Eileen Lake, systems analyst; Jonathan Schiller, COO; and Mitch Amado, CFO, as well as the surgical and supply techs for collaboration in the project.

**References**


**A simple program helps to improve postoperative pulmonary outcomes**

A simple, inexpensive postoperative pulmonary care program can reduce the likelihood of life-threatening and costly complications such as pneumonia and ventilator dependency after major surgery, a study finds.

The “I Cough” program includes coughing and deep breathing, getting out of bed at least 3 times daily, and elevating the head of the bed.

Within a year after the program was started, the odds of pneumonia dropped from 2.13 to 1.58, and odds of unplanned intubation fell from 2.10 to 1.31.

The study from Boston University Medical Center was presented October 4, 2012, at the American College of Surgeons Annual Clinical Congress.

If you opened a supply cabinet in one of your ORs, what would you find? For many, the answer might be, “a mess.”

That was the situation for Martin Memorial Health Systems, Stuart, Florida.

Even though the supply cabinets had par levels, when a supply was running low, clinicians would often grab a handful of the item and stick it in the cabinet.

“They were going for one item but would pick up five just to save a trip,” notes Valerie Ruby, MBA, BSN, RN, CNOR, assistant vice president, perioperative services.

Yet despite the full cabinets, the staff still spent time running for supplies during cases.

“It seemed like there was too much of what we didn’t need and not enough of the right stuff,” she says.

A simple exercise dramatized the need for a better system. In the target ORs, nurses were asked to drop a red poker chip in a jar every time they left during a case to pick up a supply.

“That was an ‘aha’ moment for the nurses,” Ruby says, because they could see by the number of poker chips that even with full cabinets, the needed supplies often weren’t there.

In search of a better system, 3 surgical locations piloted a new kanban system for stocking the OR supply cabinets: the ambulatory surgery center, cardiovascular (CV) ORs, and 1 neurosurgical OR.

After the year-long pilot, which Ruby says was successful, a broader implementation was planned for Summer 2012. Plans were placed on hold during implementation of a new OR information system.

Two-bin kanban
The new inventory system for the OR supply cabinets uses the 2-bin kanban method, which relies on visual cues and standard work (illustration). This is how it works:

- Each supply has 2 bins, placed one on top of the other. If the maximum par level for a supply is 10, each bin has 5 items. (Some items have only one bin.)
- Each bin is labeled for the item location, item number/information, and number of items in the bin.
- When all of the items in the top bin are used, the nurse removes that bin and places the empty bin on a case cart (or for the surgery center, in the bottom of the supply cabinet).
- OR assistants take the empty bins back to the central service area, where they are cleaned, restocked, returned to the OR, and placed back in their assigned spots behind the front bins.
- Different-colored bins are designated for items that were picked for cases but not used so they can be returned to inventory.

Determining room stock
To determine exactly which supplies needed to be stocked in the cabinets, managers and staff tracked when nurses were leaving during cases for supplies and which supplies those were.

From that, they developed a list of room-stock supplies and set minimum and maximum par levels. The list continues to require tweaking.

“We wanted to make sure we weren’t overstocking because we didn’t want to increase inventory,” Ruby says. “The idea was to decrease inventory when possible but make sure we had what we needed.”

Visual management
“The 2-bin system is an easy visual management tool,” Ruby says. “It has stopped a lot of hoarding. It has helped us to reduce the items in those rooms that really didn’t need to be there.” The system has also reduced the number of times nurses leave the room for supplies.

Ruby says nurses in the pilot ORs have become comfortable that supplies will be there when they need them. Plus, with the 2-bin system, they no longer need to restock the cabinets at the end of the day. When nurses found the cabinets’ original bin layout didn’t fit what they expected, the layout was modified to make it easier for the staff to find things quickly, Ruby notes.

Periodic checks are performed to ensure supplies in the bins are maintained at the correct level.

Martin Memorial’s ambulatory surgery center, by converting to the kanban system, was able to remove 118 unneeded items from inventory.

The Martin Memorial project was conducted with the Leonardo Group and partially supported by AORN.

—Pat Patterson

The Martin Memorial project was conducted with the Leonardo Group and partially supported by AORN.
**Standard work for room supplies**

- All bins are labeled on the front.
- Pull items from top bin only.

All items are kept in bins

Items with only one bin are identified on the shelf with 1.

The back of each bin contains:
1. Item location information
2. Item number and information
3. Number of items in bin.

All items picked but not used for a case should be put in the blue bin for restocking.

When you take the last item, place the empty bin on the bottom row of that cabinet.

Each time a glove package is taken, the card in the front must be placed in the red bin on bottom shelf.

Source: Martin Memorial Health Systems, Stuart, Florida
Stock-outs were the “burning platform” that caused staff and managers to jump into a 2-year project to overhaul a 22-room OR’s supply management.

The previous “system” had been a dissatisfier for OR clinicians and supply staff. Supplies in the OR storeroom weren’t kept in any order. Reordering was hit or miss. “It was incredibly frustrating for folks to go to the shelf and not find what they needed,” says Brian Whorley, who fostered the project at 400-bed Boone Health Center in Columbia, Missouri.

It was also urgent because the OR represents a large part of the hospital’s operating expense, and a significant chunk was spent on supplies.

Supply ‘supermarket’

Two years later, supplies are neatly arranged in a supply “supermarket.” Supply ordering relies on a kanban system that uses divided bins, making it easy to see what needs to be ordered.

Not only is frustration down, but the inventory value also has been reduced by several hundred thousand dollars. Stock-outs now are fewer than 4 or 5 a day for the 1,200 supply items.

Credit goes to the OR Supply Redesign Team, a dozen nurses and surgical technologists (STs) who developed the new system. Whorley facilitated the project as manager of surgical services for business and supply chain, drawing on his background in engineering and quality management. Executive support came from Julie Miller, RN, director of surgical services, with partnership from OR clinical supervisors George Henstorf, Heidi Woods, and Kevin Hall.

“Improving how we manage supplies in the OR was foundational to our strategic goals of cost management and sustainable growth. It made sense to get a team together and start making change happen,” says Miller.

A supply ‘pick path’

The supply supermarket is organized in the order the preference cards are picked, termed a “pick path.” Previously, items were stored in 4 or 5 different locations, Whorley says.

After the team agreed on a plan, 16 to 18 staff members volunteered to come in over a weekend to set up the new “Robmart,” nicknamed for the senior distribution tech, Rob Myers, and Rob Dunn, the materials coordinator.

At Boone, nurses and STs pull their own cases. Initially, Whorley thought that was inefficient. Now he thinks it’s a good strategy. “It creates a vested interest in maintaining the preference cards and in only picking what they need most of the time,” he says.

When the materials management staff pick cases, he notes, nurses tend to request everything on the card to be sure they have it.

“There’s no ‘moral hazard’ in keeping the cards neat and tight,” he notes. “With this system, we have nice, neat cards.”

Kanban for supplies

To create a more reliable system for supply reordering, the team decided to trial “kanban,” a Lean manufacturing method that relies on visual signals and standard work.

This is how the trial was set up:

• Several hundred products were organized into plastic bins, divided into left and right halves.
• Each product’s par level was divided in half, with half placed on the left side of the bin, and half on the right. Each bin has a
barcoded supply card kept in a pocket on the front.

- The supply room has 3 pegs labeled "order," "ordered," and "on back-order."
- Staff were instructed to pull supplies only from a bin’s left side. When the left side is empty, staff remove the supply card, hang it on the “order” peg, and then pull supplies from the right side. Picking their own cases gives them an incentive to pull the cards as a trigger to reorder products.
- Every afternoon, a supply tech takes the cards from the order peg and walks through the storage area to make sure no other bins are empty. He scans the barcodes on the backs of the cards into the computer to place an order and hangs the cards on the “ordered” peg. That way, the staff can see what supplies have been ordered.
- When the items arrive, Myers pulls the cards off the order peg and puts the supplies and cards in the proper bins while refilling the bins from right to left, effectively rotating the stock. Cards still hanging on the “ordered” peg are placed on the “back-order” peg so the staff can tell the status.

The trial proved successful. “It started to build confidence that this could actually work,” says Henstorf.

The trial showed that the most arduous tasks in setting up the kanban system were sizing the bins to the OR’s great variety of products and determining the products’ lead time for ordering, Whorley notes.

An engineering intern, Kara Bono, from the nearby University of Missouri helped with the original quantity and bin-size calculations. Though instrumental, this plan needed tweaking. For example, some bins were too tiny and hard to manage. The team decided to standardize to 3 bins sizes for the full implementation.

To help sustain the kanban system, colored stickers with the month’s abbreviation (eg, a red dot with JAN for January) are periodically placed on every box or package of a high-dollar item.

“It’s pretty obvious then what isn’t moving or being rotated,” Whorley says.

**Supply chain reporting**

Along with the overhaul of the supply area and ordering process, a clearer reporting structure for the OR supply chain was created.

The former structure with multiple reporting paths had proved inadequate. The clinicians, who were users of the supplies, reported to the OR director. An OR buyer, responsible for specialty items, reported to an off-site purchasing manager. The supply techs reported to the materials management director, whose office was in the hospital’s warehouse. The information services department maintained the supply interfaces.

The new structure consolidates accountability and has built a more cohesive team. Surgical supplies come directly to the OR storeroom, rather than being routed through the warehouse. Whorley, previously a project manager reporting to the COO, is now dedicated to the surgical supply chain, reports to the OR director, and oversees the personnel who manage OR supplies.

Through the new systems and reporting structure, says Whorley, “We’ve been able to achieve the paradox: Reduce cost and inventory while improving the availability of supplies.”

———Pat Patterson
As financial pressures grow, ORs are adding business managers. That’s particularly true for teaching hospitals, where 64% now have a business manager, and for larger ORs with 10 or more rooms, where 55% do, according to the 22nd annual OR Manager Salary/Career Survey.

In contrast, 5 years ago, just 47% of teaching hospitals and 41% of larger ORs had business managers.

Well over a third (37%) of responding facilities say they have an OR business manager, on a par with 2 years ago. That’s a big increase from the 24% in 2004, when the survey first reported on the position.

**Reporting structure**
The reporting structure is roughly the same as 4 years ago, with 73% of business managers reporting to the OR director, followed by a vice president (15%). Fewer than 1 in 10 reports to a senior administrator such as the nurse executive or CFO.

**Annual salaries**
OR business managers earn a mean annual salary of $81,900. Pay is higher at teaching hospitals, where the average is $89,100, while community hospitals pay an average of $77,400.

**Degree requirements**
Educational expectations are higher. Of the 73% of facilities that require a specific degree, 41% call for a master’s, with most calling for an MBA. That’s up from 34% who stipulated a master’s in 2008. More than half (55%) of this year’s respondents require a bachelor’s degree.

*Continued on page 19*
Surgical video displays and booms
ECRI Institute answers your questions about selection and installation

OR leaders are striving to make evidence-based decisions about new technology. OR Manager, Inc., and ECRI Institute have joined in a collaboration to provide technology management advice from the Institute’s Health Devices program to OR Manager readers. ECRI Institute is an independent nonprofit organization that researches best approaches to improving patient care.

If you’re renovating your operating rooms or constructing new ones, you probably have a lot of basic questions about device requirements and the purchasing process. Do devices need to meet electrical safety standards? Is equipment described as “medical grade” better? Is it important to buy your displays from your surgical boom vendor or your integration provider? ECRI Institute is regularly asked for advice about choosing and installing surgical video displays and booms. Here are answers to those and other questions we’re often asked.

Specifications and requirements

What are the basic specifications we should look for in our video displays to ensure compatibility with current and future requirements?
Consider the following three factors when selecting surgical video displays (especially those mounted in the vicinity of the patient):

- Whether they can be sanitized in an OR environment (e.g., whether they are compatible with cleaning and disinfection agents, whether their crevices are easily cleaned)
- Whether they are splashproof (see the question about IP Code ratings below)
- Whether they have cooling fans, which can move foreign matter such as dust in or out

The following specifications represent those of a typical installation; the requirements you choose to look for will be based on your facility’s needs:

- 21- to 26-inch diagonal measurement
- 16:10 or 16:9 aspect ratio
- High-definition video (e.g., 1920 × 1200 or 1920 × 1080 native pixel resolution)
Multiple video input connections/formats

Serial communication port (e.g., RS-232, USB) to permit remote selection of the display’s video inputs via the integration system

Some suppliers are touting their “medical grade” equipment. What exactly makes equipment medical grade?

It depends. There is no widely accepted definition among medical device manufacturers or users for the term medical grade. Hospital personnel often assume that equipment identified as medical grade is suitable for use in the OR; this is not always the case. In fact, the characteristics on which manufacturers base this designation vary widely. For example, a product may be designated as medical grade because it has better electrical safety than some other equipment, or is less flammable, or has better structural integrity, or is easier to clean and disinfect, or offers better splash or contamination resistance.

The medical-grade designation does not necessarily mean that equipment has been tested for use in a patient environment. For example, such devices may or may not have been tested by independent laboratories for compliance with accepted medical device standards (such as Underwriters Laboratories’ [UL] or the International Electrotechnical Commission’s [IEC] 60601-1 standard). And in any case, those standards address device safety only and do not indicate a given level of performance.

The question of whether a video display is medical grade is generally not significant. Many display manufacturers use the medical-grade designation to indicate that their products provide a level of performance and image quality that is generally accepted in healthcare. But in fact, except for high-resolution displays used for diagnostic picture archiving and communication systems, the image quality of most commercially available video displays touted as medical grade is no better than that of many consumer-grade video displays. If a supplier’s claim of offering medical-grade (or hospital-grade or surgical-grade) equipment seems likely to be a factor in your decision about a video display for use in a surgical environment (that is, a cart- or boom-mounted display), the supplier should specify the details of what that claim means.

In particular, don’t attach too much importance to a manufacturer’s claims of being FDA cleared. Few surgical video displays have FDA clearance, but some vendors will still seek it even if it is not necessarily required. This is often done to demonstrate that they have adequately considered the medical environment in the design of their product. To be safe, check to see if UL or IEC 60601-1 compliance is listed among the manufacturer’s specifications.

Additionally, surgical video displays should be examined by the clinical engineering department for overall quality and electrical safety; issues such as fluid resistance and ability to withstand cleaning and disinfection should also be looked at as part of this examination.

Is compliance with electrical safety standards, such as those in NFPA 99, required for video displays?

Some hospitals look for compliance with specific standards; others take a less formal approach.

For healthcare facilities in the United States, the primary standard on electrical safety is NFPA 99: Health Care Facilities Code. NFPA 99 largely stresses grounding and leakage current concerns. According to the standard, patient-care-related equipment used in the patient care vicinity must be grounded or double insulated and must meet appropriate leakage-current requirements—no more than 500 µA (NFPA 99 defines the patient care vicinity as “a space, within a location intended for the examination and treatment of patients, extending 1.8 m [6 ft] beyond the normal location of the bed, chair, table, treadmill, or other device that supports the patient during examination and treatment and extending vertically to 2.3 m [7 ft 6 in] above the floor.”)

Devices tested to UL or IEC 60601-1 standards will meet NFPA 99 requirements. Devices that are intended to be used within the patient care vicinity but that are not tested to these standards will need to be assessed for safety by the clinical engineering department. In some cases, a device may be safe to use even though it does not strictly meet standards requirements. For example, a good-quality wall-mounted display that is positioned where the patient is unlikely to contact conductive surfaces, and where the clinician is unlikely to contact the device and the patient simultaneously, may pose little risk to the patient; a facility might consider allowing this type of device.

And if the display is located outside the patient care vicinity, then even NFPA 99 allows the use of “household or office equipment not commonly equipped with grounding conductors” and does not set a leakage current limit for such devices.

In all cases, ECRI Institute recommends that the device be listed by UL or a similar testing lab (though not necessarily to IEC 60601-1 requirements).
Must OR equipment other than video displays be FDA cleared?

Not always. Off-the-shelf commercial-grade equipment can be used for many components (e.g., nurse's touch panel, AV routers, wall-mounted cameras). Some OR integration vendors claim that certain parts of their system meet FDA 510(k) requirements, but FDA clearance is not required unless the integration system controls certain medical devices located in the OR. For this reason, such claims can largely be ignored.

In addition to building new ORs, we're updating and integrating our existing ORs, replacing endoscopic cameras and defective surgical displays. Should we buy the surgical displays that the integration vendor, camera vendor, or original display supplier is trying to sell me?

Not necessarily, though in some cases you may find that it's a good idea.

Buying OR equipment from a variety of vendors is common because most integration and camera vendors do not manufacture displays, but instead buy them from a third-party supplier for resale. When choosing replacement surgical displays, you should certainly consult with the integration, camera, boom, and light vendors that are currently involved with your installation. But keep in mind that their recommendations may be based primarily on business partnerships, rather than on which displays are best or most cost-effective. You'll need to weigh that fact against the possible advantages of having one of these vendors provide your displays, including easier installation, better compatibility, and the cost savings (in both equipment purchases and post-warranty service contracts) that can result from bundling your purchases.

You may also want to consider purchasing your displays from an unrelated video equipment supplier. You can either install them yourself or have them installed by your boom vendor or integration vendor, but keep in mind that you may need customized mounting hardware for a particular boom/display combination. Also, don't forget to consider costs for warranties and future service contracts. Be sure to check the numbers before you buy.

What is an IP Code rating, and what IP Code rating is appropriate for use in an OR?

The IP Code is sometimes referred to as the International Protection Rating or Ingress Protection Rating. Defined in IEC 60529, “Degrees of Protection Provided by Enclosures (IP Code),” it is a means of classifying how well electrical equipment is protected against foreign objects and moisture. It consists of the letters “IP” followed by two digits—the first digit indicates its protection against foreign bodies, the second its protection against moisture; the higher the digit, the greater the level of protection. A code of IP33 would be appropriate for a surgical video display; it means the equipment is protected against solid foreign objects 2.5 mm or more in diameter and against sprayed water.

Just because a specific display doesn't have an IP Code rating, that doesn't mean it has no ingress protection; not all manufacturers of surgical video displays specify an IP Code. If a surgical display is lacking an IP Code, it's best to ask the supplier what ingress protection the display has. (Some surgical video displays have ingress ratings as low as IPX1—“X” indicating that the device has not been rated for protection against foreign solid objects and “1” indicating protection only against vertically falling drops of water.)

A complete listing of IP codes can be found at: www.ul.com/global/eng/pages/offering/industries/powerandcontrols/industrialcontrolequipment/ipcode/.

Installation considerations

Why is it important that booms be prewired for video by the manufacturer?

Because it's much easier to install the necessary video cables before the boom is in place and everything is closed up. This prewiring should, when possible, include extra cables for various video formats to accommodate future changes/expansion. You should make this an objective from the start. Include this specification in your RFPs and push for compliance during later discussions. Don't assume that boom vendors will perform prewiring without being asked.

Recognize, however, that not all boom have sufficient room in their articulating arms for all the cables you want. So there may be limits to how much prewiring is possible. One solution is to add cables through other paths later (e.g., above the ceiling), but that approach presents its own problems if spare cabling or above-the-ceiling conduit is not in place between the boom and the OR integration system's equipment rack. It's important to confer closely with the vendor while you're selecting equipment and designing your configuration, not after the boom is purchased and certainly not after they are installed.

Continued on next page.
Why should booms be prewired for low-voltage routing to displays?

Surgical video displays intended for boom mounting are usually designed to be powered from 24 volts DC rather than 120 volts AC. We believe this is done so that it isn’t necessary to route high voltages through the boom’s articulating arm, where the constant flexing and normal wear to the cable could possibly pose an electrical safety hazard for staff and patients. The 24 volts DC passing through the articulating arm can be fed from a separate power supply, which can be located as far as 100 feet from the display. So don’t forget to include this low-voltage wiring through the boom and articulating arm in your specifications.

When, why, and by whom should booms be rebalanced?

The initial counterbalancing of booms is typically done when they are first installed; once the surgical displays and other AV equipment are installed, the booms must be rebalanced to accommodate the added weight.

The initial gross counterbalancing is usually performed by the boom vendor and is done to keep the boom’s articulating arms, unencumbered by equipment, from rising toward the ceiling, possibly damaging the boom and other nearby equipment. Once displays and other devices are added, the booms must be rebalanced. Although this is often performed by the OR integration or video display vendor, the boom vendor may sometimes be asked to return to perform the task. This step should be accounted for when scheduling the installation of booms and displays. Remember to consider who is responsible for rebalancing if you buy displays separate from the purchase of booms or the integration system.

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Salary/Career Survey

What are the OR business manager’s responsibilities?

<table>
<thead>
<tr>
<th>(n = 68)</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Financial analysis/reporting</td>
<td>82%</td>
</tr>
<tr>
<td>Annual budget</td>
<td>78%</td>
</tr>
<tr>
<td>Billing/reimbursement</td>
<td>59%</td>
</tr>
<tr>
<td>Value analysis/product selection process</td>
<td>51%</td>
</tr>
<tr>
<td>OR scheduling</td>
<td>50%</td>
</tr>
<tr>
<td>Surgical information system</td>
<td>49%</td>
</tr>
<tr>
<td>Materials management</td>
<td>47%</td>
</tr>
<tr>
<td>Purchasing</td>
<td>47%</td>
</tr>
<tr>
<td>Strategic planning</td>
<td>37%</td>
</tr>
<tr>
<td>Quality improvement</td>
<td>13%</td>
</tr>
<tr>
<td>Other</td>
<td>13%</td>
</tr>
</tbody>
</table>

Examples of others: Capital budget, payroll, inventory, sterile processing, OR contracts, preoperative center, statistical reporting.

Business managers

Continued from page 14

Job responsibilities
The top 3 job responsibilities reflect surgery’s financial importance to the hospital:
• financial analysis/reporting
• the annual budget
• billing/reimbursement.

Duties aren’t limited to finance. An array of other duties is reported, from OR scheduling, to materials management, to oversight of the surgical information system.

About the survey
The OR Manager Salary/Career Survey was mailed in March 2012 to 800 OR Manager subscribers filtered to include only the 185 respondents who work full time in a hospital. The margin of error is ±6.3 percentage points at the 95% confidence level. Results on compensation and management were in the October OR Manager, and staffing findings appeared in the September OR Manager.

❖—Pat Patterson

In elderly, preop falls predict worse outcomes

Reoperative falls in older surgical patients are a powerful predictor of complications, longer hospital stays, and higher disability rates, in a study.

Of 208 elderly patients having colorectal or cardiac surgery, 34% reported preop falls within the past 6 months. Patients who fell spent nearly 3 times as many days in the hospital, and many more needed institutional care after surgery.

The study’s authors say simple tests could help surgeons forecast how patients will do after surgery.


Is a clinical background required for business manager position?

No (n = 51) 75%
Yes (n = 17) 25%

How many direct reports does the business manager supervise?

None (n = 14) 21%
1-3 (n = 12) 18%
4+ (n = 41) 61%
See 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 expected. 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.

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.”

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). 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
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• Lean Management in the OR and SPD: Changing Culture
• Targeting Zero Surgical Site Infections
• Implementing the WHO Surgical Safety Checklist
• Driving Beyond the Speed Limit with Surgical Dashboards

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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 sterile 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 log10 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 log10 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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Steris. Verify Chemical Indicator for SYSTEM 1E Processor, LCC016-20r03. Received by mail from sales representative. August 14, 2012.
A new villain has emerged in the struggle against drug shortages that continue to plague health care: the single-use vial.

When a vial of injectable medication contains more than a particular patient needs, if the vial is designated “single-use,” the remainder must be discarded, according to recommendations from the Centers for Disease Control and Prevention (CDC). The recommendations have been adopted by the Centers for Medicare and Medicaid Services (CMS) under its infection control regulations.

Clinicians have begun to challenge the rule, which they say leads to waste and expense. Until recently, most challenges have been aimed at regulatory agencies such as the CDC and the Food and Drug Administration (FDA).

Now there is talk of bringing the pharmaceutical industry into the discussion. Regulators say they generally accept drug manufacturers’ protocols for use.

The risk of reuse
CDC records show that between 2001 and 2011, there were 18 known outbreaks of viral hepatitis associated with unsafe injection practices in outpatient settings, affecting 358 patients and potentially exposing 100,000.

Among these, 2 outbreaks were in ASCs, and 4 were in endoscopy clinics.

In a 2008 random survey of ASCs in 3 states, the CDC found 28% of ASCs were cited for deficiencies related to injection practices or medication handling, including reuse of single-use vials. The following year, CMS instituted its infection control survey-reporting requirement.

A pair of outbreaks early in 2012 renewed concerns. The CDC, in its Morbidity and Mortality Weekly Report of July 13, 2012, reported that patients at an Arizona pain management clinic and a Delaware orthopedic clinic were infected with methicillin-resistant Staphylococcus aureus (MRSA) after sharing medication from single-use vials, even though needles and syringes were not reused. The outbreaks, in which 1 person died and 10 were hospitalized, bring to 20 the number the CDC has recorded since 2001—after tracking a half billion procedures in ambulatory settings of many kinds.

At the Arizona clinic, reports indicate that it was standard procedure to mix contrast media with saline solution each morning and store the diluted media in 10 mL vials for use during the day. Three patients required inpatient treatment for MRSA infection, and a fourth subsequently died after receiving injections from 1 of the refilled vials.

In the Delaware case, a hospital-affiliated orthopedic clinic had been reusing vials of the anesthetic bupivacaine. Of 7 patients who developed MRSA infections, 26

ASCs seek dialog on drug shortages, single-use vials

“A request to revisit requirements.”

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5 had been treated on the same day.

The CDC notes that difficulties obtaining vials in the appropriate sizes, either because of a drug shortage or because the vial size needed was not manufactured, might have led to the deviation from recommended practices.

Request to revisit requirements

Members of the ASC industry are asking regulators to revisit single-use-vial requirements in the hope of conserving medications without compromising patient safety. Of the 20 outbreaks the CDC reported during the 10-year period it collected data, 2 were associated with Medicare-certified ASCs—the only providers studied that were subject to CMS’s health and safety standards.

“Those outbreaks occurred under the current rules,” explains Bill Prentice, chief executive officer of the Ambulatory Surgery Center Association (ASCA). “But to say we couldn’t construct a process to protect patients is false logic.”

Few good substitutes

One alternative to running out of medications is to find other drugs that will do the same job.

According to pediatric anesthesiologist Keith Metz, MD, medical director of Great Lakes Surgical Center in Southfield, Michigan, that is not always easy. For example, he prefers fentanyl for postoperative pain relief because it is both effective and short acting.

When Dr Metz runs out of fentanyl, he turns to morphine, which is longer acting and can depress breathing. “We have to monitor patients for a longer time,” he says, “and that’s silly, because we have better drugs.”

“It’s one of the drugs that is most frustrating to us,” he says of fentanyl, “because when we can get it, we don’t have a choice of container.” Most ASCs order the 2 mL size, which is the average dose for both adults and most children. Lately, they have had to settle for larger vials, he says. “So we get 5 mL, use 1 or 2 ccs, and have to dispose of the rest.”

To have the drug repackaged at a local compounding pharmacy costs 3 to 5 times the original manufacturer’s price.

The preferred preoperative drug midazolam (Versed) is also in short supply. A common alternative is diazepam (Valium) to reduce anxiety. Diazepam, however, is longer acting and the injection is painful, Dr Metz says.

Worst is the case of ondansetron (Zofran), used to prevent nausea after surgery.

“It’s simply unavailable,” Dr Metz says. “Unfortunately, there aren’t even any good alternatives, so we have had to do without it and have more postsurgery nausea.”

Meeting with CDC, FDA

Prentice and other ASCA officials met in July and August with CDC and FDA officials to express their concerns. According to Prentice, the CDC officials were not aware that, unlike hospitals, ASCs do not have pharmacists on staff.

The ASCA officials also raised the concern that the CDC’s suggested alternative to discarding single-use injection vials—repackaging the drugs into smaller-dose containers—is not always practical for ASCs because of the controlled environment required.

Outsourcing the procedure to compounding pharmacies is also impractical in many cases, they said, because of the cost and, in certain locations, lack of access to such facilities.

Plus, with the fall 2012 meningitis outbreak from spinal injections linked to medication from the New England Compounding Center, more focus on the oversight of compounding pharmacies is sure to arise.

In a statement following the CDC meeting, ASCA said that it had voiced concerns from its members about the single-use rules and asked for clarity from the agency about whether “a more-nuanced process” could be developed that would protect patients while eliminating waste that occurs currently.

Meanwhile, ASCA urges members to comply with the current injection recommendations.

CMS reinforces requirement

Prior to the ASCA-CDC meeting, on July 13, 2012, the Government Accountability Office (GAO) issued a report revealing some contradictions in the way the single-use rules are being enforced.

On June 15, 2012, CMS sent a memo to state surveyors say-
Continued from page 27

ing that despite complaints from ASCs about hardship related to scarce drugs, it did not plan to relax the single-use rule.

The memo states in part: “CMS shares the concerns of providers and suppliers about patient access to critical medications that are in short supply and appreciates the efforts of health care facilities to meet the needs of their patients. However, CMS is equally concerned about health-care associated infections caused by unsafe medication preparation and injection practices, including using [single-use vials] for multiple patients in the same manner as vials labeled as multi-dose. Such reuse is not compliant with infection control requirements and must be cited as a deficiency. We are not changing our policy on this matter.”

The memo goes on to say that ASCs using medications that have been properly repackaged should not be cited.

**GAO: Continue tracking**

Since 2009, CMS also has had a policy of requiring surveyors to report deficiencies using its Infection Control Surveyor Worksheet. The worksheet includes a section on injection practices including disposition of single-use vials.

CMS stopped collecting the worksheets in late 2011 in response to surveyor complaints about the administrative burden they presented, despite the concern for patient safety.

The GAO recommends that CMS find a more efficient way to collect data, such as random sampling or less-frequent reporting, rather than stopping altogether.

“Without some form of continued data collection, CMS will lose its capacity to monitor ASC compliance with its health and safety standards related to safe injection practices and to monitor how well the state surveyors collect and assess information about unsafe injection practices,” the GAO report concludes.

**Lack of awareness**

In 2010, the Premier Healthcare Alliance surveyed 5,446 registered nurses in hospitals about their injection practices, and 6% reported “sometimes or always” using single-use vials for multiple patients.

The Institute for Safe Medication Practices (ISMP) attributed the results to a “lack of awareness regarding safe injection control practices.” Some respondents thought a larger vial meant the contents were intended for more than one patient.

Often the reason medications are labeled as “single dose” or “single use” is the absence of preservatives.

According to CDC associate director for infection control Michael Bell, MD, the MRSA outbreaks occurred in part because of a lack of awareness of the danger of contamination in preservative-free medications.

“Because injections were prepared with new needles and syringes and, in one of the clinics, in a separate ‘clean’ medication preparation room, providers thought they were being safe,” he explains in his blog.

ASCA would like to see more use of preservatives, according to Prentice. “The question is, Why couldn’t there be preservatives? We’re not presuming there is [a way]; we’re just asking the question.”

ISMP executive vice president Allen Vaida, PharmD, has an answer: “Because of where they’re being used. For example, ASCs do a lot of pain treatment, with spinal and epidural injections. Those can’t have a preservative because they will be toxic to the body.”

Other medications, such as lidocaine, are available with or without preservatives, giving physicians a choice.

“Many of those products are preservative free because that’s how the physician wants them,” Vaida says.

**Going to the companies**

In its analysis of the MRSA outbreaks, CDC noted that proper repackaging using a laminar-flow hood based on US Pharmacopeia standards might have prevented the infections, while smaller vials would have made repackaging unnecessary.

In his experience as a pharmacist, Vaida says it is possible to convince pharmaceutical companies to redesign vials to avoid waste. Similar efforts in the past yielded an increase in premixed medications, he says.
As for the difficulty in finding affordable compounding pharmacies, Vaida says there are FDA-approved outsourcing manufacturers with nationwide distribution. “We often go out and visit compounding pharmacies around the country. They ship.”

He acknowledges that cost is a factor. “Availability is not the issue, but it’s going to be more expensive” to repackgage, he notes.

Is there a better way?

Now, packaging is based on the “average” dose, but patients differ. “I think the problem is they have major concerns with certain drugs,” Vaida says of ASCs. “They should approach the manufacturer. With these products, it’s basically what the market wants.”

At their meeting in mid-August, the ASCA and FDA came to a similar conclusion. FDA officials advised ASCs to email drugshortages@fda.hhs.gov to report drug shortages and to contact drug suppliers directly to discuss their vial size preferences.

The FDA also has begun questioning vial sizes in its approval process, they said.

According to Dr Metz, who chairs ASCA’s government affairs committee, the point of the meeting was to begin involving the pharmaceutical industry. It may be possible to change a drug’s formulation to make it less susceptible to contamination or to provide a better range of vial sizes to avoid waste.

Meanwhile, he stresses, ASCs should never reuse single-use vials or repackage drugs except according to CDC protocols.

ISMP doesn’t dispute the need for discussion, according to Vaida, but safety must remain the highest priority.

“We are striving for the best, safest practice,” he says, “but we understand the need to be affordable. Yet, all you need is one outbreak, and there goes the money you saved. You really have to err on the side of safety. One infection costs tens of thousands of dollars to treat.”

—Paula DeJohn

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Reduction surgical readmissions
Surgical patients can develop significant complications after discharge, with long, difficult, and expensive recoveries, finds a study.

One in seven procedures resulted in a complication within 30 days of surgery in the analysis of 4 specialties in 112 Veterans Affairs hospitals.

The overall complication rate was 15%. Gastrointestinal (27.5%) and vascular (20%) surgery had the highest rates. Rates for orthopedic and gynecologic surgery were lower at 7%.

Most complications were surgical site infections.

The study was presented October 2012 at the American College of Surgeons Annual Clinical Congress.


New preop guidelines for elderly
The first guidelines for preoperative assessment of geriatric patients have been issued by the American College of Surgeons and American Geriatrics Society.

The guidelines include recommendations and 13 key issues in preoperative care for this population.

A driving force behind the guidelines is America’s expanding geriatric population.

The guidelines were published in the Journal of the American College of Surgeons.


Study finds wide variation in blood use
Lack of scientific evidence for blood utilization leads to wide variation in hospitals, finds a study by Premier. The analysis of 7.4 million patients shows hospitals could save $165 million a year by reducing blood use while maintaining outcomes.

Among recommendations are:
- forming a blood stewardship team
- working collaboratively to find alternative products and procedures
- implementing evidence-based transfusion guidelines
- providing education and tools
- monitoring guideline adherence and providing feedback
- monitoring utilization and measuring improvement.

—www.premierinc.com

Update: Injection-related fungal meningitis
Fungal meningitis linked to spinal and joint injections totaled 170 cases with 14 deaths in 11 states as of October 11.

Cases were linked to 3 lots of methylprednisolone acetate 80 mg/mL from the New England Compounding Center, Framingham, Massachusetts, the CDC reported.

The potentially contaminated injections were given starting May 21. Officials say symptoms can take up to several months to develop.

The fungus Exserohilum was found in 10 patients and Aspergillus in one patient with meningitis. This is the first time the CDC says it has seen fungal meningitis with Exserohilum.

Officials estimate 14,000 patients in 23 states may have been exposed to the 3 lots of the medication and said 90% had been contacted.

The FDA recommends facilities pull all medications received from NECC. NECC ceased operations and voluntarily recalled all products.

❖

—www.cdc.gov/HAI/outbreaks/meningitis.html