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Increased Temporal Scanner Hospital Use Increases Medicare Reimbursement

Temporal Artery Scanner Only Method Satisfying 100% of Patients in Overnight Hospital Stays Says Exergen Corporation

A new national survey was recently conducted to explore methods of thermometry used in hospitals, patients' thermometry preferences and a possible correlation between the way patients had their temperatures taken and satisfaction with their hospital experience. The survey indicates that findings among patients ages 65+ have strong implications for Medicare reimbursement and hospital reputation. The survey was conducted among adults who had spent one or more nights in the hospital over the past 24 months, and answers were based on their most recent stay.

A disproportionally large number of older patients are going to hospitals that use the Temporal*Scanner*. Patients ages 65+ reported that Temporal*Scanner* was the method used most frequently to take their temperature. Notably, 68% of that group said that they would recommend that hospital to family and friends.

"Today, virtually all (92%) adults who are 65 years of age or older are enrolled in Medicare," said Francesco Pompei, Ph.D., CEO of Exergen Corporation. "They have tremendous power in determining the outcomes of Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys that link directly to Medicare reimbursement for the hospital. With more than two thirds of patients 65+ saying they would recommend the hospital which used the TemporalScanner, hospitals should take note and make sure they are listening to those individuals."

Patients reported a variety of methods hospitals used to take temperatures, but Temporal*Scanner* alone satisfied 100% of respondents of all ages. Every other method included individuals who were "not at all satisfied." No other method satisfied all the respondents.

"The 100% satisfaction with forehead thermometry (temporal artery thermometers) is not surprising, and it is significant," said Dr. Pompei. "The Temporal thermometer is preferred by medical professionals because its accuracy has been proven in more than 70 clinical studies. It's the patients' choice because it is noninvasive. Anything hospitals can do to improve the patient experience is crucial for the hospital to make a positive impression on the patient."

Of the 1,000 people surveyed, 23% had an overnight stay in the hospital within the past 24 months. Recall of how they had their temperature taken was very high, with 85% indicating that they recalled how it was taken.

"The fact that so many people remembered how their temperature was taken indicates that temperature taking has a great impact on them," added Dr. Pompei.

The online survey was fielded by Researchscape International from April 8 to 9, 2019 with 1,000 respondents and a modeled margin of error of +/- 4%. Results were weighted by age, gender, region, Hispanicity, ethnicity, and education.

Exergen manufactures and markets two series of the Temporal*Scanner* thermometer: a professional version for hospitals and clinics, and a Consumer Temporal*Scanner* version sold in major retailers nationwide. More than two billion temperatures are taken each year with Temporal*Scanners*. Used in thousands of hospitals and clinics across the country as well as in millions of homes, Temporal*Scanners* are the #1 preference of pediatricians, #1 preference of nurses and #1 selling retail thermometer.

The Exergen Temporal*Scanner's* accuracy is supported by more than 70 peer-reviewed published studies covering all ages from preterm infants to geriatrics and care areas from hospitals to homes.

Dr. Francesco Pompei is founder and CEO of Exergen Corporation, and holds nearly 100 patents in non-invasive thermometry for medical and industrial applications. Earning BS and MS degrees from MIT, and SM and PhD degrees from Harvard, Pompei also served as Research Scholar in the Department of Physics at Harvard in cancer research for 15 years.

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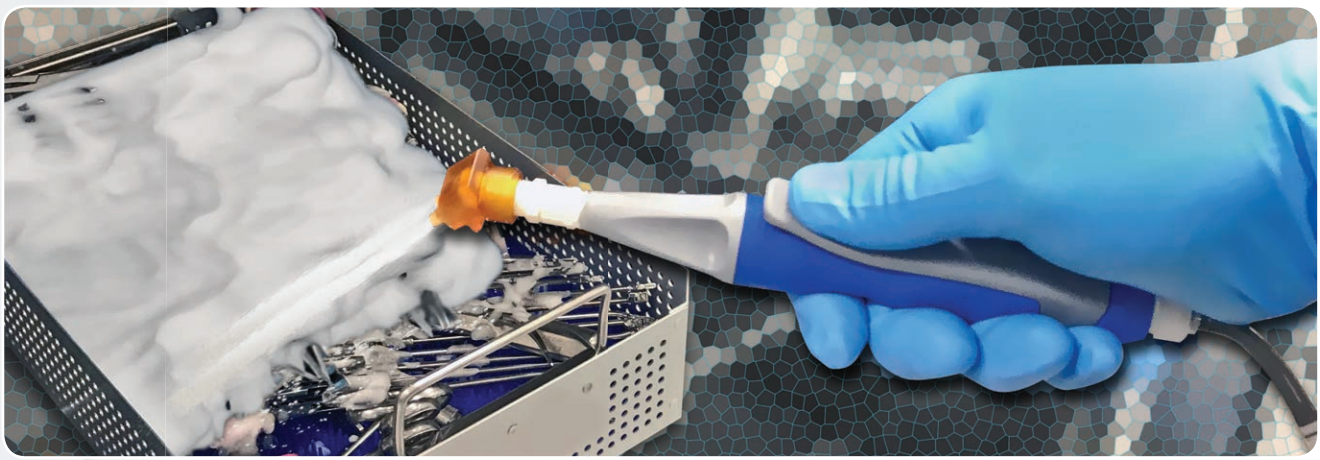

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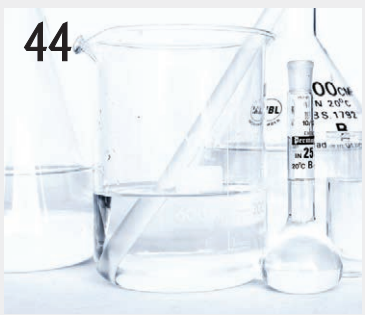

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SKU'd SCincentives

Back in the day you may have used coins or branded tokens to reward yourself at the local arcade with some Airheads, Bottlecaps and Gobstoppers as well as a few rounds of Asteroids, Pole Position and Q*Bert.

Fast forward to administrative, clinical, financial or operational executive life and you likely find life a bit more … complicated and less … dynamic. All teched out with budgets, projects, deadlines, responsibilities, life seems to be driven by that even more dreaded Scarlet Letter (with apologies to Hester Prynne and to anything Amazon-related): A … for Accountability.

During this Age of Automated Activity in healthcare operations, administrators and clinicians alike are besotted by buzzwords like augmented reality, blockchain, drones (no, not the staff in the trenches), holographic multi-dimensional imaging, self-driving or self-operating this or that. It's enough to motivate the fictional futuristic captain of the Federation Starship U.S.S. Enterprise to smirk, pat us on the heads and chime, "How quaint."

Perhaps for some of us there remains a fondness for those halcyon days of small prizes stuffed into cereal or Cracker Jack boxes, or acquired by mail for a stack of boxtops. How gleeful. Simple benefits brought great delight.

These days in the healthcare industry we get all jazzed up about cool tech, discounts, dividends, gainsharing, pay raises, "prebates," rebates and such. But they seem to add too much paperwork – electronic or otherwise – to the pure enjoyment of a transaction.

What if we could resurrect some of those rewarding schemes from our childhood as a clandestine way of modifying behavior? A few companies have emerged with reward programs to encourage patients to take their meds, make their follow-up doctor visits, complete and submit their paperwork. Think of it as Pavlovian patient care. Why, I'm salivating at the mere thought.

As part of these incentive programs, when patients follow their prescriptions and protocols they earn "digital tokens" they can "spend" on whatever the token provider offers them. Who knows whether this "token economy" (pun intended) will gain(share) in popularity as much as the so-called gig economy.

But what if Supply Chain were to offer a similar incentive (call it a SCincentive!) for performance improvement in the storeroom or warehouse, on the nursing floors, within the surgical suites?

Inventory management staffers who go a week without a stockout anywhere on the shelves earn a stack of digital SCitcoins. Clinicians who actively participate in value analysis projects involving product evaluation or process modification earn their own stacks that they could cash in on additional equipment-related consummables, for example. Yes, it's a bit like gainsharing but clearly not as fun. In fact, some gambler in the warehouse might even conceive a way to manage an internal black market of SCitcoin distribution. Of course, if Supply Chain were to operate this program using blockchain they could fulfill two aims: Make sure the SCincentive scheme remains honest and fair, and test out the validity and reliability of blockchain to boot!

The Supply Chain role in any healthcare organization can be boiled down to a simple algebraic expression that goes something like this:

Controlling expenses = Acquiring stuff + modifying behaviors + x^2.

Now solve for x.

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Source: FDA CDRH Safety Assessment of Di(2-ethylhexyl) Phthalate (DEHP) Released from PVC Medical Devices. FDA CDRH 1 –118,2003.

FAST STATS

Hurricanes, storms, floods, fires, and extreme temperatures have touched every region of the country along with widespread outbreaks of hepatitis A, measles cases, opioid overdose deaths, and community violence at schools, churches, and other public spaces. Results from the 2019 National Health Security Preparedness Index indicate that readiness for these and other emergencies continued to improve in 2018, but current levels of health security remain far from optimal and large disparities in readiness exist between regions across the nation.

6.7

is the current national index level reached (out of a possible 10) for disaster preparedness.

4

states experienced a decline in health security in 2018; 32 states and the District of Columbia improved; and 14 remained unchanged.

6

additional years will be required in an average state to reach the health security levels currently found in the best-prepared states if current trends continue; and at least 10 more years to reach a strong health security level of at least 9.

11

of the states that are significantly above-average cluster in the Northeast, Mid-Atlantic, Upper Midwest, and Central Rocky Mountain regions; clusters of below-average states exist in the South-Central, Upper Mountain West, Pacific Coast, and Midwest regions.

4.9

is the nation's average score in the Healthcare Delivery domain, which scored lowest compared to the other 6 domains (Health Security Surveillance, Community Planning and Engagement, Information and Incident Management, Countermeasure Management, Environmental and Occupational Health).

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was the price of the economic damage caused by disasters and emergency events in 2018; seven high-consequence natural disasters occurred that exceeded $1 billion each.

Source: Robert Wood Johnson Foundation, National Health Security Preparedness Index, May 2019.

NEWSWIRE

HealthTrust to acquire ROi

HealthTrust announced on May 31, 2019, the signing of a definitive agreement with Resource Optimization & Innovation (ROi), a recognized leader in healthcare supply chain management, to assume ownership and operations of the company. Headquartered in St. Louis, ROi is a provider-operated group purchasing organization and is accountable for the supply chain organization of Mercy, one of the nation's largest Catholic health systems.

Following the closing of acquisition, HealthTrust will become the exclusive national group purchasing organization (GPO) for Mercy and other ROi partner members Orlando Health, Inc. and Franciscan Missionaries of Our Lady Health System. In addition, ROi's co-workers will transition to HealthTrust and continue to support supply chain operations at Mercy facilities.

"Mercy founded ROi in 2002 to manage our supply chain and we've watched it grow and innovate to become a highly-recognized supply chain organization," said Lynn Britton, president and chief executive officer of Mercy, and ROi's first president and CEO. "As part of HealthTrust, ROi has the opportunity to accelerate its progress and strengthen its capabilities in support of Mercy, other ROi members and HealthTrust members."

ROi's Custom Pack Solutions division, offering customized surgical packs tailored for clinical end-users, will be established as an independent company owned by HealthTrust, with Mercy and other ROi owners maintaining a minority ownership.

HealthTrust's acquisition of ROi reinforces its commitment and connection to faith-based ministries, with Catholic health systems comprising a significant part of its member base. "We understand the needs of Catholic health systems and believe we are uniquely positioned to support them in delivering high-quality care, providing value and honoring their mission of caring for those in need," said Ed Jones, president and chief executive officer of HealthTrust.

Financial terms were not disclosed. The acquisition is expected to close by late summer pending customary regulatory approvals.

HFAP Quality Review reveals top deficiencies, provides tips

The Accreditation Association for Hospitals/Health Systems announced that the development of policies, alignment of procedures and completion of assessments continue to trouble all types of healthcare organizations seeking accreditation, which is according to the 2019 HFAP Quality Review. The findings are based on HFAP (Healthcare Facilities Accreditation Program) surveyors' ratings of compliance during 2018 onsite surveys of acute care hospitals, critical access hospitals (CAHs), laboratories and ambulatory surgery centers (ASCs) and that incomplete processes and insufficient documentation remain the main concerns cited during accreditation surveys.

The review focused and provided details on several areas, including the physical environment, patient care and safety, infection prevention, emergency management, and laboratory analytic systems.

"The Quality Review is designed to help healthcare organizations evaluate their performance in context with their peers by identifying trends from all surveys conducted throughout the year," said Meg Gravesmill, CEO of AAHHS/HFAP. "The review can act as a self-assessment guide with tips organizations can use to correct deficiencies they self-identify. Understanding the pattern of policy, implementation, evaluation and reporting for each set of standards supports development of a framework to boost survey performance — which leads to improved quality and safety across the organization."

- *Physical environment*: In acute care hospitals, CAHs and ASCs, deficiencies in standards focused on how the management of the built environment can impact patient, staff and visitor safety were commonly reported. Similar to results from previous years, the most frequently cited standards were those related to Life Safety Code compliance. Some common examples of these deficiencies include poor management of building controls and fire alarm systems, insufficient life safety policies, incomplete risk assessments of building services, and failure to comply with National Fire Protection Association (NFPA) codes.
- *Patient care and safety:* One aspect of the standards associated with patient care and safety found deficient across acute care hospitals, CAHs and ASCs was the development and implementation of a Quality Assessment and Performance Improvement (QAPI) plan that addressed all services provided — even those provided through contracts or agreements. The goal of the plan is to provide the foundation for ongoing quality improvement by identifying areas of low performance and deploying changes to enhance patient outcomes. QAPI plans should be broad-based and incorporate all aspects of an organization's operations. ASCs also struggled to provide complete patient admission, assessment and discharge documentation, which can increase patient risk due to inaccurate information.
- *Infections:* For deficiencies related to infection prevention and control, many acute care hospitals struggled to maintain an active surveillance program with appropriate interventions across all departments and failed to integrate the infection prevention

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1. Altimier, L., & Phillips, R. (2016). The neonatal integrative developmental care model: Advanced clinical applications of the seven core measures for neuroprotective family-centered developmental care. Newborn And Infant Nursing Reviews, 16, 230-244. doi:10.1053/j.nainr.2016.09.030

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NEWSWIRE

and control program with the hospital-wide QAPI plan. A wide range of citations were noted, including outdated policies, inconsistent cleaning methods and storage issues. While the percentage of infection control-related citations in ASCs dropped from 75 percent in 2017 to 23 percent in 2018, difficulty demonstrating consistent cleanliness practices throughout facilities persisted. According to HFAP surveyors, most deficiencies reflect infection control issues "hiding in plain sight" that are easily corrected with more thorough and consistent procedures based on the standards.

- *Emergency management:* Deficiencies in emergency management were most prevalent in acute care hospitals and CAHs. These standards call for the development of a comprehensive emergency preparedness program that complies with local, state and federal requirements and addresses protocols for any type of emergency or disaster. Citations in emergency management stemmed from an incomplete Emergency Operations Plan (EOP) that failed to meet a variety of standards requirements, including designating specific responsibilities and service capabilities, establishing nutritional services policies, ensuring sufficient medical supplies, and assessing specific needs of at-risk patients.
- *Laboratory analytic systems:* The top deficiencies cited in clinical laboratory facilities centered on the processes and procedures surrounding analytic systems and proficiency testing. Unsuccessful participation in proficiency testing can result in restrictions on a laboratory's ability to continue testing in areas of deficiency. In addition, laboratories' management of conditions and supplies were often found deficient. Many citations resulted from expired certification of instruments used for measurement, improper labeling of expiration dates and noncompliance with manufacturers' maintenance recommendations for equipment.

HFAP is hosting a series of webinars to discuss the findings of the 2019 Quality Review by organization type beginning July 11. To register visit https://register.gotowebinar.com/register/1670266313716306957.

World Health Assembly adopts health-improvement measures

The World Health Organization (WHO) reported several actions that transpired during the multi-day World Health Assembly meeting in Geneva, which concluded in May. Resolutions by the Assembly include:

- *Take steps to improve pricing transparency and access to medicines & Access*: WHO says the Assembly adopted measures to improve the transparency of markets for medicines, vaccines and other health products in an effort to expand access. The resolution urges member states to enhance public sharing of information on actual prices paid by governments and other buyers for health products, and greater transparency on pharmaceutical patents, clinical trial results and other determinants of pricing along the value chain from laboratory to patient.
- *Implement ICD-11:* Member states also agreed to adopt the eleventh revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-11), effective January 1, 2022. ICD-11 has been updated for the 21st century and reflects critical advances in science and medicine. It can be well integrated with electronic health applications and information systems, will allow more detail to be recorded and is significantly easier to use and to implement, which will lead to fewer mistakes and lower costs, and make the tool much more accessible, particularly for low-resource settings.
- *Expand patient safety initiatives:* The Assembly requested WHO to formulate a global patient safety action plan in consultation with countries and all relevant stakeholders, to improve and ensure patient safety globally. Patient harm due to adverse events is one of the leading causes of death and disability globally, said WHO. An estimated 134 million adverse events occur annually due to unsafe care in hospitals in low- and middle-income countries, contributing to 2.6 million deaths, while 1 in 10 patients is estimated to be harmed while receiving hospital care in high-income countries.
- *Strengthen emergency care:* Member States agreed to pave the way for better and faster services for time-sensitive health conditions, including injuries, heart attacks, mental health conditions, infections or pregnancy complications. Timeliness is an essential component of quality care, and that millions of deaths and long-term disabilities could be prevented if emergency care services exist and patients reach them in time. Member States also embraced the use of the WHO emergency care system assessment to identify gaps and context-relevant priorities.
- *Fight antimicrobial resistance:* The Assembly agreed on a resolution calling for continued high-level commitments to implement and adequately resource multi-sectoral National Action Plans to fight antimicrobial resistance. The resolution urges Member States to strengthen infection prevention and control measures including water sanitation and hygiene; enhance participation in Global Antimicrobial Surveillance System; ensure prudent use of quality-assured antimicrobials; and support multisectoral annual self-assessment survey. HPN

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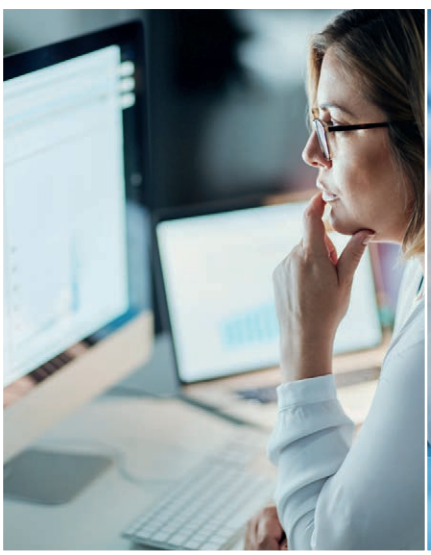
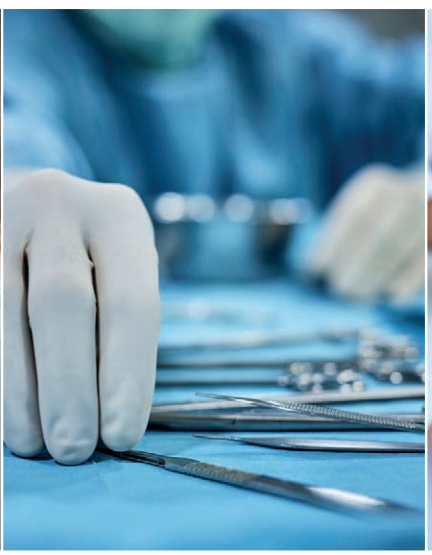


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2019 PURE AWARDS

Meeting in the middle to strive for optimal clinical outcomes

Four doctors promote how they bridge any divides between Supply Chain and Medical staff, teams

by Rick Dana Barlow

As healthcare economics and reform continue to tighten the grip on decision-making authority and autonomy physicians and surgeons have experienced and enjoyed for decades, doctor reactions have been swift and varied.

Within the last few years traditional consumer and trade media — as well as social media — has posted, aired and published tales of doctors burning out, selling out (to group practices, hospitals or healthcare systems) or simply getting out of practicing medicine altogether, due in large part to intensifying pressure from three key culprits: Declining reimbursement, increasing malpractice fees and claims, and shifting market referrals from payer-oriented managed care drivers.

Those who remain in the profession, however, whether employed or privileged to practice, increasingly are embracing a curious alternative to the fading status quo: Working directly with Supply Chain.

As *Healthcare Purchasing News* recognized the emerging and growing participation by genuinely engaged physicians and surgeons in the supply chain process it decided to identify and salute those key clinicians truly making a difference by presenting them with its annual P.U.R.E. award and profiling their points of view. P.U.R.E. signifies Physicians Understanding, Respecting and Engaging Supply Chain professionals. *HPN* bestows its P.U.R.E. award on those physicians and surgeons who have made solid contributions to supply chain operations — activities, practices and thinking. *HPN* designed it to further solidify and strengthen the clinical bonds between physicians and supply chain professionals.

Last year *HPN* selected three physicians to receive the third annual P.U.R.E. award. This year four more join their ranks, selected from noteworthy nominations submitted to *HPN*.

HPN's 2019 Supply Chain-Focused physicians are: **Ronald M. Benoit, MD,** Associate Professor of Urology, University of Pittsburgh School of Medicine, and Director of General Urology, UPMC, Pittsburgh; **John Cherf, MD,** MPH, MBA, Chief Medical Officer, Lumere Inc., and former Chief of Orthopedics, Advocate Illinois Masonic Medical Center, Chicago; **Patrick A. Kenney, MD,** MPH, MBA, Assistant Professor of Urology, Yale School of Medicine, Clinical Vice Chair, Yale Medicine Urology, and Medical Director, Supply Chain, Yale New Haven Health, New Haven, CT; and **John M. Mohart, MD,** Vice President, Cardiovascular Care Performance Acceleration, Mercy, St. Louis.

Benoit recognizes the "extremely delicate task" Supply Chain teams have when trying to work with doctors to manage physician preference items. Supply Chain simply needs a physician champion to nurture trusted relationships, foster transparency and promote a team-based culture with the physicians, according to Benoit. So that's what he volunteered to do in leading the value analysis team back in May 2016. Under his leadership and physician coaching, UPMC has generated hundreds of thousands of dollars in savings from removing high-cost, clinically equivalent items, tracking disposable product expenses and overall case costs.

Having earned an MBA, Cherf recognized several decades ago the importance and value of optimizing supply costs in a private practice environment, which he helped expand into a fully integrated musculoskeletal center offering a variety of services. He also helped set up two ambulatory surgery centers that "required meticulous attention to supply costs." At mid-career, Cherf helped found the orthopedic department at a private orthopedic surgery/neurosurgery specialty hospital in Chicago that involved working with administration and Supply Chain to control costs. Before joining Lumere where he worked with hospital and health system clients to manage PPI and reduce costly clinical practice variation, he served as Chief of Orthopedics at Advocate Illinois Masonic Medical Center where he collaborated with Supply Chain and helped evaluate and introduce new technology into the Advocate Health Care system.

As part of Yale New Haven's Corporate Supply Chain leadership team, Kenney reinforces the ongoing aim of improving clinical value by clinically integrating supply chain decision-making through value analysis for supply and service consumption. Through the Northeast Purchasing Coalition, a Vizient Member Business Venture comprising 19 members representing more than 100 acute care facilities across nine states generating $4.7 billion in annual purchasing volume, Kenney has fostered and maintained a system driven by regional clinician and physician input on clinical practices and product and service sourcing decisions. He and his team promote evidence-based decision-making related to supply and service selection and use. Kenney also is developing a national forum for Clinical Supply Integration Practice Sharing.

Mohart may be a Mercy-employed cardiovascular executive and cardiologist affiliated with multiple hospitals within the St. Louis metropolitan area, but he actually began his career as a CPA with the accounting and consulting firm Ernst & Young for nine years before switching to medicine.

Mohart's business background reinforces his clinical experience, which enabled him to meld a diverse group of physicians within the Mercy system to unify when evaluating products, protocols and services through a lens of fiscal responsibility, clinical quality and patient outcomes. His leadership efforts, for example, helped Mercy reduce CV product spending (including cardiac stents, balloons and implantable rhythm devices) by $10 million annually during the last two years. He also established a district council to focus on quality and outcomes, a ministry-wide CV summit three months ago to share best practices and strategic direction among facilities, and an electronic risk calculator for pre-cardiac surgery in which doctors can discuss with patients treatment options and protocols and determine together how to proceed.

HPN's traditional wide-ranging interview explored how all four recognized the need for and value of supply chain strategies and tactics as an integral component of effective and efficient patient care and a critical contributor to optimal outcomes.

RONALD M. BENOIT, MD

Associate Professor of Urology, University of Pittsburgh School of Medicine
Director of General Urology, UPMC
Pittsburgh, PA

HPN: Why do you feel it has been — and in spots still is — so difficult for physicians and surgeons to become more directly involved in supply chain issues? What are some of the challenges that doctors may have with Supply Chain (the department) that makes them so resistant to Supply Chain advice and recommendations?

BENOIT: I believe the main issue is physicians have not previously had to focus on the costs of the case they are performing. Their sole focus has been outcomes. Physicians see themselves as responsible only for outcomes, and the costs associated with the case is someone else's concern. As to the second part of your question, physicians have the experience in the OR and believe they know which equipment works best for them. They are quite resistant to being told by non-medical personnel which equipment they should use.

Let's reflect on the how, when and why you decided to get involved with supply chain issues? What motivated your interest?

I have an interest in healthcare costs and healthcare reform. I have used that interest to investigate areas we can decrease health care costs without impacting quality.

One major sticking point between Supply Chain and physicians has been product brand preference. Why do you believe physicians are so reluctant to change product brands if/when necessary?

Great question. Physicians, with good reason, concentrate entirely on outcomes. If a certain piece of equipment works for them, they are extremely reluctant to change devices. Brand preference oftentimes becomes more faith than reason.

Where do you see the physician's/surgeon's relationship with Supply Chain heading long-term?

I do believe the relationship will become more collaborative over time. As compensation becomes more value- and less volume-based, physicians will see the benefit of cost control providing we can realize cost savings without affecting outcomes.

How does having a physician or surgeon on the Supply Chain staff — or even leading the department — affect the dynamic between the two areas as well as the fiscal health of the organization?

Physicians serve an extremely valuable role as a liaison between Supply Chain and physicians. Our value is to explain the perspective of each side to the other and provide confidence everyone is acting in good faith. Progress cannot be made until these parameters have been established.

Dr. Benoit, as a urologist who leads value analysis efforts at your facility, how do you bridge the divide between your clinical peers and colleagues, Finance and Supply Chain so that everyone interlinks and works together?

Our goal is to focus on collaboration. We attempt to gain as much input from physicians as possible, and give them a range of options rather than dictating which equipment they need to use. Similarly, I also believe it is just as important to explain to Finance and Supply Chain the physicians' perspective.

JOHN CHERF, MD, MPH, MBA

Chief Medical Officer, Lumere
Former Chief of Orthopedics, Advocate Illinois Masonic Medical Center
Chicago, IL

HPN: Why do you feel it has been — and in spots still is — so difficult for physicians and surgeons to become more directly involved in supply chain issues? What are some of the challenges that doctors may have with Supply Chain (the department) that makes them so resistant to Supply Chain advice and recommendations?

CHERF: Many physicians and surgeons (physicians) are challenged running their own practices. Overwhelming demands for practicing medicine include government and payer compliance requirements, EHR, contracting, decreased reimbursement, etc. It is difficult for physicians to take on another responsibility that does not directly impact their workload, such as supply chain. Supply chain activities are also not part of most physicians training and are not a typical physician core competency.

Physicians rarely ask hospital administration to help control costs in their practices, and it is unclear if hospitals would deploy resources to help physician practices. We shouldn't be surprised that physicians do not welcome the opportunity to contribute to supply chain activities in many settings. However, hospital employment of physicians and new payment models, such as bundled payments, are incentivizing physicians to spend more time managing traditional hospital costs and they take on more longitudinal financial risk.

Let's reflect on the how, when and why you decided to get involved with supply chain issues? What motivated your interest?

One of the irrational expense problems I see in healthcare involves supply chain materials. The price discrimination we see in the global market is extreme with the U.S. paying some of the highest prices in the world. This occurs at a time when the cost of care is the single most important problem with our healthcare system. Many supply prices have increased much faster than inflation and substantially faster than physician reimbursement. This disconnect motivated me to learn more and participate in supply chain activities.

One major sticking point between Supply Chain and physicians has been product brand preference. Why do you believe physicians are so reluctant to change product brands if/when necessary?

Many physicians become entrenched with a particular device and manufacturer. This creates "stickiness" between the product and often the sales representative. The manufacturer also helps physicians with education and procedural support. The "switching costs" of changing brands can be significant. Physicians are often up on the learning curve for using a particular device. This may be a product of their training. There is also an established relationship with the rep and an overall comfort level for the physician.

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Giving this up can be difficult. Changing brands and devices may also adversely impact clinical outcomes as a physician moves up the learning curve with a new device. It is important to remember the physician is the stakeholder most responsible for outcomes and liable for suboptimal results. This often leads to a high threshold for physicians to change brands and devices.

Where do you see the physician's/surgeon's relationship with Supply Chain heading long-term?

As we transition to more overall integration between providers and increasing financial pressure to provide value-based care, physicians will likely have a greater role in supply chain activities. This will be driven by new payment models and the need to document value with optimal quality and cost to be competitive in a consumer driven market. Our conversation with physician involvement with supply chain will be very different in five and 10 years. We should expect much more physician involvement in supply chain activities and more published research in physician literature about cost of care, clinical variation and value.

How does having a physician or surgeon on the Supply Chain staff — or even leading the department — affect the dynamic between the two areas as well as the fiscal health of the organization?

Having a physician at the supply chain table is very important and extremely valuable. Physicians can provide sound clinical input to help drive supply chain efficiency. Forward-thinking organizations are integrating physicians in value analysis, clinical efficiency and other supply chain-related activities.

Dr. Cherf, as an orthopedic surgeon and clinical leader with an MBA, what do you feel is the biggest stumbling block Supply Chain has with orthopedic surgeons or even the weakest link that prevents them from working together and how might that be overcome?

I see two major stumbling blocks: Supply Chain staffs are territorial and may be intimidated by working with physicians. Ironically, the Supply Chain team knows significantly more than physicians about purchasing, inventory management, etc. The converse is true about clinical knowledge as physicians know more than the Supply Chain team. The two parties complement each other and are stronger working together rather than independently. The key is creating incentives for collaboration.

CHERF IN REAL LIFE

Unlikely source of inspiration: Not accepting or adopting the latest trend in healthcare (largely driven by stubbornness and luck).

Most creative thing he's ever done: Professionally, building a fully integrated orthopedic institute in the early 1990s — way before this became popular. And going to business school. Personally, marrying my wife.

What makes him laugh: People making fun of themselves.

Best and worst advice someone ever gave him: Best: Founding a surgery center; Worst: Founding a specialty hospital.

Favorite objects he keeps in his office: Trout Unlimited and Pheasants Forever calendars — Great outdoor photos that provide inspiration to balance work with favorite hobbies. Photos of my family — reminds me of what is most important.

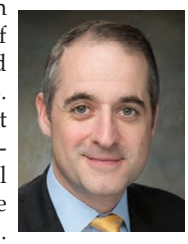
What he would tell himself if he traveled back in time to when he just started in healthcare: Think long-term rather than short-term.

PATRICK A. KENNEY, MD, MPH, MBA

Assistant Professor of Urology, Yale School of Medicine, Clinical Vice Chair, Yale Medicine Urology, Medical Director, Supply Chain, Yale New Haven Health
New Haven, CT

HPN: Why do you feel it has been — and in spots still is — so difficult for physicians and surgeons to become more directly involved in supply chain issues? What are some of the challenges that doctors may have with Supply Chain (the department) that makes them so resistant to Supply Chain advice and recommendations?

KENNEY: Physicians and surgeons are incredibly busy. We are in an era of declining reimbursements, electronic medical records, and physician burnout in the setting of ever-increasing time and productivity demands. Most physicians do not have training or experience in the operational aspects of running the healthcare business. Supply chain, as traditionally framed, is not front and center in the minds of physicians — despite the fact that it impacts every aspect of their work and the care of their patients. Moreover, many hospital systems have not recognized the importance of a clinically integrated supply chain with a clinician leader. Yale New Haven Health System has been a trailblazer in this area, with both a pharmacist and a physician helping lead our efforts.



Physician Preference Items are a challenging area. There are numerous reasons why physicians may be resistant to Supply Chain advice. In many instances, physicians may be insulated from the financial ramifications of the clinical decisions they make. We often cite the "value equation" when discussing healthcare decision-making, but this is a theoretical construct. The scientific literature is imperfect and much of it is not reproducible. In particular, the evidence to support one medical device over another is often nonexistent or of very poor quality.

Physicians also do not know the cost of the items they use — but it is not their fault. The system is really stacked against us. Costs vary from one hospital to another. Confidentiality clauses prohibit price disclosure. Rebates and other factors make the actual cost of the item potentially unknowable at the time an item is used. In addition, there are data to support the notion that physicians tend to overestimate the cost of inexpensive items and underestimate the cost of expensive items. This leads them to underestimate the cost savings that could be achieved by switching to a less costly device.

Good communication is essential. It is more common for physicians to have a close relationship with industry representatives than with Supply Chain. Communication and transparency are essential to driving change. If we look to the techniques of our industry partners, we can learn what it takes to drive physician behavior change — communication, relationships, and, where appropriate, financial alignment.

Ultimately, the problem comes down to the low-value decisions made by individual physicians for their own patients. These decisions are leading to catastrophically rising costs in the U.S., with spending approaching 20 percent of GDP, an unsustainable level. We have not linked the individual decision to the aggregate consequence — a concept known as the "tragedy of the commons." We need to resolve this problem through price and outcome transparency and by ensuring the physician incentives are aligned with value.

Let's reflect on the how, when and why you decided to get involved with supply chain issues? What motivated your interest?

I believe that physicians are uniquely qualified to help address the operational challenges we face in health care delivery. I've always been interested in process improvement and how structure and process design can be used to improve performance. Although I'm in academic medicine, I'm most interested in implementation of practical, real-world approaches that impact patients now. I jumped at the chance to join Yale New Haven Corporate Supply Chain, where extraordinarily talented and hard-working people are on the front lines

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AMPLIFY YOUR INFLUENCE

At HealthTrust, we use science supported by data. Others may claim big data. But they can't duplicate our experience and insight in guiding informed decision-making that supports improved care and lowered cost. Let us help you amplify your voice and turn data into action.

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solving practical problems to ensure we deliver the best care — care that is both innovative and high value.

One major sticking point between Supply Chain and physicians has been product brand preference. Why do you believe physicians are so reluctant to change product brands if/when necessary?

There are far more contributing factors than just reluctance on the part of physicians. Outside of supply chain, there is abundant and oft-cited literature documenting slow diffusion of practice change and poor compliance [with] best practices and guidelines. Nonetheless, I dispute the notion that physicians are generally reluctant to change. There are examples of seismic changes in clinical practice and very rapid adoption of new technology. We know that physicians can change practice rapidly — but we need to better understand what motivates these changes.

I suspect that high-quality literature and a desire to improve outcomes is a strong motivator of change. There are also nice data to show that physicians respond to incentives and to personal relationships — facts which are well-known to our partners in industry. We've all seen previously unwavering orthopedic surgeons switch to a new vendor when their rep changes employers. I definitely do not know the roadmap to solve PPI — but it most definitely includes better communication and engagement with physicians, potentiation of value-based decision making through transparency in cost and outcomes, and appropriate incentives to make the right choice.

Most importantly, though, we have to understand physicians and what informs their preferences. Physicians and surgeons work in a high-stakes environment. Every decision and every surgical maneuver can have profound consequences for our patients. Familiarity with a drug or device, and their nuances, brings a measure of stability and reproducibility. We are still trained as artisans. When a surgeon has performed a high-stakes operation, for instance, sewing a graft to a great vessel hundreds or thousands of times with good results, the proposed potential benefit of switching to a new, unknown suture for which there is little comparative evidence will have to be very high in order for the surgeon to be an eager participant.

Where do you see the physician's/surgeon's relationship with Supply Chain heading long-term?

Long-term, I envision a clinically integrated supply chain characterized by seamless communication and transparency in pricing, outcomes and relative performance. Supply Chain needs to do more than just procure what it is that physicians want — Supply Chain needs to provide decision support to help physicians establish or change a preference.

How does having a physician or surgeon on the Supply Chain staff — or even leading the department — affect the dynamic between the two areas as well as the fiscal health of the organization?

In part, a physician can act as intermediary between Supply Chain and the Medical Staff, and ensure that we are all working together toward a common goal. The hope is to create a very positive dynamic, to help advance the supply chain value and safety agenda, and to ensure that the needs of our physicians and patients are met. I often note that patients come to our medical center for our outstanding physicians — they rarely come for access to a device. It is our physicians that are the highly differentiated product — most of the devices are branded commodities. Sometimes it is easy to forget this.

Devices and new technology form a large portion of the rising cost of hospitalizations, and can be the dominant cost of some surgical admissions. Taming this area can produce dramatic results, and if appropriate processes and culture are put in place, the improvements can continue to bear fruit on a regular basis. More importantly, having a clinician leader in supply chain can help emphasize quality and safety. Similar to the great work done in pharmacy over the past several decades, there is an enormous amount of work to be done in supply chain with regards to safety and quality, including evaluation of new product requests, aftermarket surveillance, and regular communication with clinicians about the products we source.

Dr. Kenney, as a urological oncologist with extensive experience in robotic surgery, how do you interact with and relate to Supply Chain without intimidating anyone?

I am fortunate to be part of a great team at Yale New Haven. This organization is like sailing a big ship requiring many hands on deck — we all need to work together to chart the course, gauge the wind, and adjust the sails. Our patients benefit when we work well together as a team, and this is reflected in our organization's values. Professionalism is a necessary ingredient for safety, for great patient care, and to create a positive work environment. To reach our goals, we need to hear from every voice. It is essential to create an environment where high reliability behaviors flourish, such as clear communication, the concept of 200 percent accountability and embrace of questioning attitudes. My office door is always open.

KENNEY IN REAL LIFE

Unlikely source of inspiration: The greatest source of inspiration to our group is the individual patient — our efforts to improve care are inspired by an obligation to help patients achieve the best possible outcome and to do so in a manner that respects stewardship of resources.

What makes him laugh: My family. They are wonderful to be around.

Favorite object he keeps in his office: A vibrant, fun painting of a kidney with a bandage on it. It was painted by a friend of a patient on whom I performed a complex partial nephrectomy. It has a great energy to it — and is a daily reminder to me of the importance of the work we do every day.

What he would tell himself if he traveled back in time to when he just started in healthcare: Being a physician is the most rewarding job imaginable. It is a great privilege and honor both to care for patients and to work to improve our processes of care.

JOHN M. MOHART, MD

Vice President, Cardiovascular Care Performance Acceleration, Mercy
St. Louis, MO

HPN: Why do you feel it has been — and in spots still is — so difficult for physicians and surgeons to become more directly involved in supply chain issues? What are some of the challenges that doctors may have with Supply Chain (the department) that makes them so resistant to Supply Chain advice and recommendations?

MOHART: In general, physicians/surgeons are occupied with caring for patients and time constraints do not always allow the opportunity for additional involvement in supply chain related activities. Non-integrated supply chain efforts can also lead to a siloed approach, often creating confusion, misconceptions, and inconsistencies among multiple departments.

While I understand that clinicians may not want to get involved in supply chain-related activities — particularly if it takes them away from their primary mission of caring for patients — how do you advise clinicians to make the delicate balance work, specifically if working on business-related matters is no longer an option but a necessity?

The delivery of healthcare is changing rapidly with new entrants and disrupters. In order for organizations to thrive and survive in the future, physicians must lead in delivering the best care and outcomes at the lowest cost.

Let's reflect on the how, when and why you decided to get involved with supply chain issues? What motivated your interest?

We must create greater value in healthcare to our patients and our organizations. I realized the tremendous opportunity in supply chain in the cardiovascular (CV) arena.

Healthcare margins are very slim after accounting for total costs and vendors have had significant leverage over hospitals in the past. Reduction in supply costs creates dollars that flow directly to the bottom line, which can be used to invest in opportunities to deliver new and innovative ways to care for the patients we serve.

One major sticking point between Supply Chain and physicians has been product brand preference. Why do you believe physicians are so reluctant to change product brands if/when necessary?

Different physicians and healthcare professionals have varying preferences for the products that they use, and when a clinician uses a familiar product that works well and consistently delivers good outcomes, there could be some hesitancy to change that practice. Identifying product characteristics necessary for optimal care, understanding the costs associated with these products, and discussing alternatives can help uncover products or standardization efforts that will offer comparable or better outcomes with additional value.

Where do you see the physician's/surgeon's relationship with Supply Chain heading long-term?

Physicians/surgeons will most certainly become more involved in the supply chain process over time. Given the rising cost of healthcare coupled with the challenging reimbursement landscape, it will become essential to partner together with all departments to engage in a higher level of transparency and provide an increased focus on delivering value through a collaborative decision-making process.

How does having a physician or surgeon on the Supply Chain staff — or even leading the department — affect the dynamic between the two areas as well as the fiscal health of the organization?

Integrating a physician or surgeon on the Supply Chain staff can foster collaborative relationships to ensure patient care needs are met while deriving optimal value from the supply chain system. Having a physician or surgeon assist and support an evidenced-based decision-making process for the selection of products and standardization efforts can lead to increased clinical, financial, and operational efficiencies.

Dr. Mohart, you started your career as a CPA before changing gears to become a cardiologist. How has that accounting/financial background shaped your clinical career and helped you balance your business acumen as it relates to supply chain?

The business and accounting training has helped tremendously in analyzing options, understanding numbers and projections, P&L and realizing the impact supply chain can make on providing value to the organization. HPN

MOHART IN REAL LIFE

Unlikely source of inspiration: Physical labor
Most creative thing he's ever done: Rehab of an old church on our property
What makes him laugh: My kids
Best and worst advice someone ever gave him: Best: The days go by slow but the years go fast; Worst: Tech stocks too risky
Favorite object he keeps in his office: Pictures of family
What he would tell himself if he traveled back in time to when he just started in healthcare: Be patient

Pre-existing pressure injuries offer clinical clues

Pre-existing pressure injuries cannot replace sophisticated systems for scoring the severity of illness in critically ill patients, but their presence does quickly identify patients at greater risk for longer hospital stays and increased mortality, reports the American Association of Critical-Care Nurses (AACN).

AACN pointed to new research, published in the June issue of *Critical Care Nurse*, that finds that pressure injuries present upon admission to the intensive care unit (ICU) can serve as a predictive clinical marker for longer hospitalization and increased odds of mortality, especially when other data aren't available. "Pressure Injuries at Intensive Care Unit Admission as a Prognostic Indicator of Patient Outcomes" reports the results of a retrospective analysis of ICU admissions from 2010 to 2012 at Baystate Medical Center, Springfield, MA.

Many hospitals use the Acute Physiology and Chronic Health Education (APACHE) and Mortality Prediction Model, which automatically extracts information from a patient's electronic medical record, except for the patient's diagnosis at admission. However, the APACHE score is not available immediately since it relies on information such as vital signs and laboratory test results obtained during the first 24 hours of a patient's ICU stay.

In contrast, a clinical marker present at admission could be used to quickly and objectively identify patients who may require additional care and longer hospital stays.

"Our results show that pressure injuries can be a quick, unambiguous way to alert critical care nurses and intensivists to newly admitted patients who will be challenging in the ICU, so we can make more informed decisions faster," said co-author William T. McGee, MD, MHA, an intensivist at Baystate. "This study underscores the importance of a thorough skin examination upon admission to the ICU."

The researchers analyzed admissions of adult patients to Baystate's 24-bed medical-surgical ICU over a 17-month period. Of these, 180 had a pressure injury at admission.

The statistical analysis revealed that pressure injuries were associated with significantly longer hospital lengths of stay, regardless of mortality outcome. Patients with pressure injuries at admission had a longer mean length of stay of 3.1 days. They were not associated with mortality after adjusting for the APACHE score but may serve as a marker for increased risk of mortality if an APACHE score is not available.

Among patients with pressure injuries at admission, mechanical ventilation and dialysis were more common, as was the overall severity of illness. They also were more likely to show evidence of prior long-term care or physical rehabilitation. Readmission to the ICU during the same hospitalization occurred more frequently for patients with pressure injuries.

OPERATING ROOM

Ensuring safety in surgical suites

by Valerie J. Dimond

One of the greatest ironies of the operating room (OR) — where patients go for life-saving procedures — is its potential to also be one of the most dangerous, sometimes deadliest places inside a healthcare facility. Hazards of all types are waiting to happen to both patients and staff if proper safeguards aren't always in place. For example, administering the wrong medication or dose, leaving foreign objects inside of patients, using faulty equipment, dirty equipment, missed recalls, needlestick and scalpel injuries, wrong site/patient/procedure errors, wearing the wrong PPE or not enough, accidental fires, surgical smokes inhalation … and that's just the short list of what can go wrong.

Those and other complications are discussed continuously. Research is performed, articles and books are written, guidelines get updated, best practices are adopted, new technologies are developed, and clinicians try to do better.

What follows is a sampling of various solutions healthcare facilities can use to help prevent a variety of safety breaches. *Healthcare Purchasing News* asked these vendors two questions: How does your solution make a direct impact on improving OR safety and why is it a good investment for supply chain to consider?

First step: Follow the IFU

Following a manufacturer's instructions for use (IFU) is a fundamental safety step and most OR and sterile processing technicians are dedicated to the process. However, significant obstacles can get in the way. IFUs can be difficult to understand. Lack of time needed to follow every step in the IFU is another challenge. Poor collaboration or understanding between the OR and sterile processing department regarding who is responsible for what can also throw a wrench into the process. Sometimes the IFU is missing entirely, especially when using loaners.

oneSOURCE offers healthcare facilities current IFU documents via subscription to a comprehensive database intended to simplify the IFU process, foster compliance, and maintain accreditation effortlessly. "The need for our databases is driven by CMS regulations mandating that healthcare SPD, OR, HTM and Infection Prevention departments follow the IFU for patient safety. We provide the necessary tools professionals and facilities need to avoid typical failures such as improper cleaning, wrapping or loading in the sterilizer; incorrect reassembly of the device; and use of an incorrect sterilization process," said Heather Thomas, Chief Marketing Officer, Vice President of Sales and Marketing at oneSource. "Improperly cleaned instruments and/or medical devices have been linked to adverse patient outcomes as well as death. When facilities have access to a robust tool like oneSOURCE it arms them with the resources required to keep patients safe 24/7 and can assist them in avoiding fees for readmission due to HAI lawsuits associated with fatal results in addition to expensive citations from accrediting bodies. We are launching databases for Facilities Maintenance and Tissue & Implants later this year to meet the patient safety compliance needs for OR and Facilities Maintenance departments."

UDI & OR safety

UDI adoption remains challenging for most hospitals. In recent surveys by *Healthcare Purchasing News*, among the 43 percent of organizations stating they have not adopted the use of UDI in their supply chain data, respondents often cited there is "a lot of work involved and a lack of time to dedicate to the process." While the importance is recognized, capturing UDI data has remained a significant hurdle for provider organizations.

SteriTrack's Pat Cairn, COO and Michael Schiller, CMRP, VP, Healthcare Engagement, explained how SteriTrack UDI scanning solution delivers on patient safety, recall management, and regulatory compliance.

Everyone knows a recalled surgical instrument poses an immediate danger and should be removed from inventory but everyone knows also that it doesn't always happen that way — not without a system in place that can assist with the myriad challenges of staying on top of the

many surgical products that could lead to injury and death.

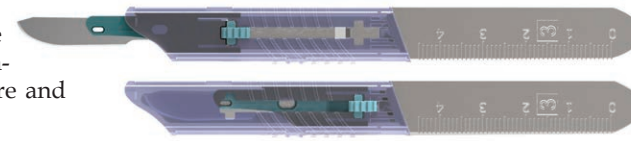
"SteriTrack has brought UDI scanning to the point of implantation, inside the sterile field, seamlessly integrating it within the workflow between the scrub tech and the surgeon. The Tractus platform leverages UDI data from regulatory databases including the GUDID and FDA Medical Recall Database to ensure device safety prior to use or implantation," explained Cairn. "By allowing devices to be scanned at the point of use, the OR team is notified if the product is recalled or expired immediately prior to implantation and not post-procedure. Patient safety becomes real-time, helping mitigate risk to the healthcare organization."

"The Tractus platform allows a clinician to specify anatomic regions involved in a procedure and the ability to document the exact location of each implant. Once scanned, UDI data resides within the patient's clinical record where the patient can be correctly notified in the future if a recall occurs," Schiller added. "This capability provides the most accurate and effective UDI documentation process and, is critical in eliminating potential data entry errors that could occur when manually entering the UDI information. Almost as important as notifying a patient of a recall is avoiding an inaccurate recall notification, as a result of UDI data being entered incorrectly. Tractus scanning technology eliminates risks of documentation errors resulting from manual data entry, which are reported at an average error rate of 30 percent.

"Data capture of the UDI still hasn't been widely adopted by hospitals. It would offer many patient safety advantages such as in the event of product recall and enhance the acuracy of patient records regarding the products used on them," continued Schiller.

"While minimal regulation exists today to propel providers to capture UDI data, there is tremendous benefit recognized in recording the UDI data for implants and supplies used during the course of a procedure, building a comprehensive patient clinical record within the EHR and moving healthcare organizations closer toward understanding the total cost of care, improving patient care and patient outcomes."

SteriTrack's Tractus



Anzen Safety Scalpel from Medipurpose

Sharps

Sharps safety has been a top priority for decades and it's paid off in many ways with better practices and technologies to support it. But it remains slow-going in some areas, and according to the Centers for Disease Control, approximately 385,000 needlesticks and other sharps-related injuries happen to hospital-based healthcare personnel each year.

"Since the Needlestick Safety and Prevention Act was signed into law in November 2006, sharps injuries in nonsurgical settings dropped by almost a third, while injuries increased by 6.5 percent in surgical settings," said Adeline Yi, Senior Manager, New Business Development, Medipurpose. "ORs face even greater risks than other departments, with the potential for scalpels to cause deeper and more serious wounds. Yet nationwide, the conversion to safety scalpels has been very slow as surgeons and surgical techs are unhappy with the limited safety scalpel options currently out in the market. During the development of our Anzen Safety Scalpel, we worked closely with surgeons and surgical techs to design a product to meet those needs: Reusable, metal-handle that provides surgeons with the weight, balance, and feel they are used to in a traditional scalpel; pushing on the slider moves the blade in a out of the cartridge (intuitive to use, like a box cutter); safety catch that prevents the blade from being extended when the cartridge is not mounted on the handle (prevents accidental sharps injuries during loading of the blade); and cartridge lock feature that prevents cartridge from being removed when blade is not fully retracted (prevents accidental sharps injuries during unloading of the blade).

"There are an estimated 1,000 sharps injuries occurring in U.S. hospitals every day," Yi continued. "This translates to over $1 billion in unnecessary healthcare costs. A report found that operating room scalpel injuries indirectly increase the cost of purchased conventional blades by at least $2 per blade. Safety scalpel cartridges like the Anzen Safety Scalpel are typically priced at $1.00/cartridge. This translates to $1 saved for every cartridge used over conventional blades (taking into account costs due to surgical sharps injuries). There are about 75 million scalpel blades used every year, which translates to $75 million in savings by switching to a safety scalpel."

Sam Kumar, President & CEO, Myco Medical, says he sees the same thing. "Scalpel blade injuries are in the top five common types of sharps injuries and second only to needle-sticks. An estimated 50 percent of OR Sharps injuries are preventable, however, the majority of the safety devices available are not adopted in the OR as they often require a change in surgical technique," Kumar said. "The Qlicksmart Blade Removal Portfolio is the only single-handed blade removal system. The Qlicksmart Blade Removal System allows the Surgeon to continue using their preferred reusable scalpel blade handles. Hospital Infections cited a staggering 662 injuries for every 100,000 blades used (includes OR, ER, Endoscopy, etc). The cost of even an uncomplicated injury can range from $1,500 to $5,000. A severe injury requiring microsurgery can cost upwards of $100,000, up to three months of rehabilitation and loss of salary. Not to mention the risk of infection."

Qlicksmart Blade Removal System from Myco Medical

Added protection

Adding to the sharps safety effort are surgical glove technologies that not only protect transmission of pathogens from hands to patient but will protect surgeons from injuries.

"Surgical glove protection is a primary factor that works to prevent sharps injuries, minimize risks associated with latex allergies and surgical site infections (SSIs)," said Judith Seltzer MS BSN RN CNOR, Clinical Director, National Accounts, U.S. Surgical Division, Mölnlycke Health Care. "Double-gloving is proven to reduce risks of sharps injuries and exposure to bloodborne infections by 71 percent. Data research reveals that on average, only 10 percent of glove punctures are noticed during surgery. At least 60 different bloodborne pathogens can be transmitted to healthcare workers due

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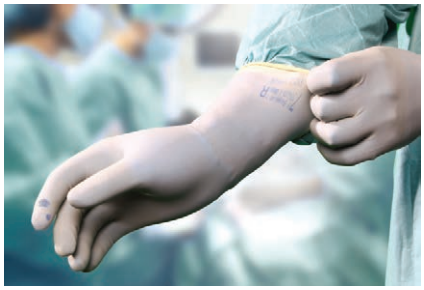
to accidental exposures with HIV, Hep B and Hep C accounting for most of the risk.

"Biogels Puncture Indication System, which includes as its most recent addition with enhanced tactile sensitivity, the Biogel PI Micro Indicator glove, can increase breach detection from 10 percent to 97 percent," Seltzer continued. "These gloves are uniquely engineered to work together with Biogel overgloves. The blue inner glove color was selected based on color physics to maximize visibility. It is designed to make the spot following a puncture visible as fast as possible and for the indication size to provide a large, visual alert from a distance in the room. Glove perforations can increase the risk of SSIs to 6.9 percent. With SSIs costing upwards of $25K, that can be a substantial loss to the patient and hospital. Data research reveals in an average facility performing 10,000 surgical procedures, an average of 442 SSIs could result from various factors which includes surgical gloves. With Biogel gloves potential savings for a 10,000 surgical procedure hospital could be reduced by $56 per surgery or approximately $560,000."

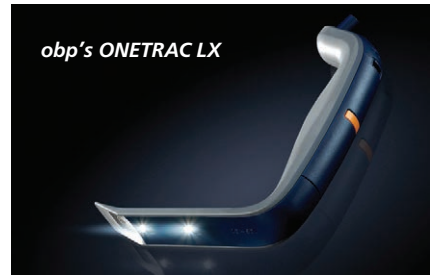


Biogel PI Micro Indicator glove from Mölnlycke

Smoke & fire

The Association of periOperative Registered Nurses (AORN) has done much work in recent years to raise awareness of the health and safety problems associated with surgical smoke inhalation. And some states are now passing laws requiring hospitals and surgical centers to implement strategies for reducing exposure, which makes sense. The National Institute for Occupational Safety (NIOSH) says surgical smoke contains toxic gases, vapors and particulates, viable and non-viable cellular material, viruses, and bacteria — all of which can cause a host of health problems, including asthma.

"OSHA estimates that 500,000 healthcare workers are exposed to surgical smoke each year which according to AORN is the equivalent to the OR team smoking 27 to 30 unfiltered cigarettes per day," said Jason Swift, CEO, obp. "obp's ONETRAC LX addresses this major health risk by featuring



a patent pending integrated dual smoke evacuation system coupled with onboard cordless multi-LED lighting enabling users to effectively remove smoke and maintain clear visualization throughout surgical procedures. ONETRAC LX virtually eliminates the potential risk of patient burns and fires caused by thermal hazards associated with typical fiber optic retractors. obp's ONETRAC LX features an all-in-one design in which the power source and illumination system is single-use, cordless and built into each unit eliminating the need for all additional accessories, components, and reprocessing associated with traditional systems.

"This all-in-one design enables healthcare facilities to stock all needed sizes and styles in each room without having to make any investment in depreciable capital equipment that often costs many thousands of dollars," Swift continued. "Additionally, healthcare facilities continue to transition to fully disposable systems to reduce cross contamination risks and mitigate the severe financial consequences associated with treating HAI's. ONETRAC LX is the logical next step in this effort."

Accidental fires during laser procedures are another hazard for which solutions are available.

"The GloShield safety cap provides a protective covering for the end of the fiber optic light cable that can reach over 550 degrees Fahrenheit," explained James K. Rains, PE, CEO, Jackson Medical. "GloShield is designed to prevent Never Events such as OR fires from occurring. This award-winning product is reliable and intuitive, making the hospital safer for patients and staff. GloShield is a simple way to mitigate the risk of 'never events' from occurring in

the operating room. Of over one hundred first-time users, 94 percent thought that GloShield offers reliable protection and would reduce the risk of fires."

Keeping tools safe & secure

Workflow interruptions cause stress and stress can lead to mistakes. For example, dropping an instrument on the floor — happens all the time — which leaves surgical teams scrambling for a replacement. Passing needles, electrocautery devices and other potentially hazardous equipment can also lead to cuts, burns and more. Alas, there is a solution.

"Based on firsthand experience, DropStop was designed by the OR Innovations team to solve a common problem facing surgical teams world-wide; costly surgical tools falling off the surgical field, leaving the circulator scurrying to get a replacement, if one is available!" said Alex Duy Bui, Chief Technical Officer, OR Innovations. "This event repeats itself daily in most surgical suites, resulting in hundreds of thousands of dollars annually of avoidable costs and unanticipated time delays. While the initial DropStop design goal was to prevent items from falling off the sterile field, DropStop also addresses other operating room challenges such as; securing the electrocautery holster in a safe, optimized position to minimize risk of patient burns, as well as positioning a suture pack on the user's sleeve to eliminate risk of needlesticks which can occur during passing of loaded needle drivers.

DropStop by OR Innovations

"Most notably, DropStop promotes hands-free transfer of all surgical tools to increase OR safety; reducing incident reporting and adverse outcomes for employees and patients. It optimizes workflow by safely and effectively securing sterile tools, cautery, and instruments close at hand, where and when the surgeon needs them, improving surgical on-time rates and improved resource utilization. DropStop also prevents avoidable costs by preventing delays associated with dropped or contaminated surgical tools, reducing unnecessary

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distractions, infection rates, and negative patient outcomes. DropStop allows the end-user to customize and maximize the benefits of use based on their needs. It can be placed anywhere on the surgical field, drape or surgical gown."

Retained surgical instruments

The horror of finding out that a foreign object was left inside of a surgical patient has lasting, far-reaching consequences for everyone involved. The patient, the surgical team, the facility suffers as a result of this "never event" which unfortunately is still too common. Implementing the latest technology is critical to reversing the trend.

"Currently in the United States the No. 1 reported surgical never event to the Joint Commission is retained surgical items (RSIs), of which the No. 1 contributor of RSIs is retained surgical sponges (RSSs) accounting for 69 percent of all RSIs," said Jason Davies, Senior Brand Manager, Stryker. "[And] 16.3 percent of patients that have a sponge left in them suffer a permanent injury, and it is a mortal event for 4.5 percent of patients. The average malpractice impact to a hospital on a national average is nearly $600,000 per occurrence, and the rate of occurrence of RSSs is between 1:5,000 to 1:7,000 surgeries according to studies. The surgical team currently has a deficit of technology by only using a whiteboard & marker to keep counts on their sponges. It's estimated that RSSs are left in patients 4,000 times a year in the U.S., or roughly 11 times a day. RSSs are a completely preventable surgical never event that add roughly $2.4B to the U.S. healthcare system

The SurgiCount Safety-Sponge System from STRYKER

"The SurgiCount Safety-Sponge System shows the surgical team in real-time when their manual count is right or when it's wrong," Davies continued. "It augments the nurses manual count by simply tracking the sponges IN and tracking them back OUT via a barcode that they scan underneath the SurgiCount Tablet that acts as a debit/credit tool. At the end of the case, the surgical team clicks the submit button on the tablet and all the sponge data (sponges used, when scanned in, when scanned out, etc.) is recorded in a cloud database so the institution has an evidence-based outcome. The surgical team can now have the peace of mind that no sponges are left inside patients. On average, SurgiCount adds only $8 to $10 per surgical procedure to use our technology and sponges, whereas without using our technology it adds $94.50 to each surgical procedure by not having technology in place due to high settlements paid out."

Opioid disposal

By now everyone is aware of the opioid crisis taking place in the U.S. and elsewhere. Concerted efforts are underway to help defeat the problem — patient advocacy groups, government, professional agencies, healthcare providers, insurers, pharmacist and medical supply manufacturers are all taking steps to help. Schreiner MediPharm's contribution is providing a safer way to dispose of narcotic pain patches.

Schreiner MediPharm's Patch-Safe

"When properly used, transdermal patches with high concentrations of active ingredients are an effective and safe means of drug delivery used in chronic pain management or hormone therapy; however, when patches that contain opioids come into contact with the skin of non-patients, this may lead to serious, even fatal health problems—especially for children," said Gene Dul, President, Schreiner MediPharm U.S. "Schreiner MediPharm's Patch-Safe is a multilayer specialty label applied to sachets that reliably seals a used transdermal patch between two layers. In the case of patches containing high concentrations of opioids, an accidental transfer of active ingredients via the skin — and the resulting health risks as well as potential for abuse — can thereby be prevented. Pain patches pose a high risk of abuse by those suffering from drug addiction and, in some cases, by patients with chronic pain," Dul continued. "This is because even used patches still contain large amounts of active ingredients.

The Patch-Safe solution allows a broad use in different hospital settings, since it helps to safely and efficiently dispose of used patches, which is especially important in the hectic environment healthcare professionals have to cope with. Due to its special construction, it secures patches and critical substances reliably. In addition, it is easy and intuitive, which facilitates work in hospital and healthcare settings and helps to optimize processes." HPN

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1. MHC Study #G09-005.
2. Scott,Douglas R II. The Direct Costs of Healthcare-Associated Infections In U.S. Hospitals and the Benefits of Prevention, March 2009
3. Data on file, MHC-2018-T00015.

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Push to develop world's first vaccine against the deadly Strep A bacteria

The International Vaccine Institute (IVI) and Australia's Murdoch Children's Research Institute (MCRI) is coordinating a global push to free the world of Group A Streptococcus (Strep A), the contagious bacteria that kills half a million people every year and is developing resistance to antibiotics. IVI says the British biomedical research foundation, the Wellcome Trust, has granted $2.25 million to IVI and MCRI to coordinate world efforts to develop a vaccine against Strep A and find manufacturers.

Director General of IVI, Dr. Jerome Kim, said that Strep A, a bacterial pathogen, is one of the most deadly infectious diseases ranking with tuberculosis (TB), HIV, and malaria but globally very little had been invested in Strep A research. "Strep A is one of the main causes of death from infectious diseases, claiming 500,000 lives per year; however few people are aware of it," Dr Kim said in the announcement.

"Strep A usually begins with a sore throat, but if left untreated it causes the immune system to become overactive, resulting in rheumatic heart disease, which damages heart valves and over time causes heart failure and death." Continued Kim. "This affects more than 33 million people around the world, and the vast majority of deaths are in low-and-middle-income countries. A vaccine would be the most effective and cost-effective way to control infection."

The World Health Organization prioritized a vaccine for Strep A in 2014, and in 2018 unanimously passed a resolution calling for action against rheumatic heart disease, including a vaccine against Strep A, IHI says. MCRI's Head of Infection and Immunity, Prof. Andrew Steer, says there were concerns in the scientific community about the effectiveness of antibiotics to treat Strep A in the future as groups of Strep A had evolved to be resistant to the antibiotics azithromycin and clarithromycin.

"Already invasive Strep A infections like the notorious 'flesh-eating bacteria' and 'toxic shock' kill 150,000 people around the globe each year," Steer said. "But there is little awareness of Strep A among the public, policymakers, and even scientists – and so there has been little incentive for major vaccine manufacturers to get behind vaccine development."

Work to raise awareness and build global support for the development of a Strep A vaccine is supported by the new Wellcome grant. "We will create the means to advocate internationally for increased vaccine research and develop the cases for investment in Strep A vaccines at business and policy levels," Dr. Kim said. "By the end of the project, we also hope to have identified a major vaccine manufacturer."

INFECTION PREVENTION

It takes a village

Preparing for outbreaks and catastrophes

by Susan Cantrell, ELS

The 2019 *National Health Security Preparedness Index*[1] brought good news and bad news. The bad news is that 2018 was an extraordinary year for disasters, with hurricanes, storms, floods, fires, and extreme temperatures throughout the nation. The nation also faced outbreaks of hepatitis A and measles, the continuing rise in opioid deaths, as well as mass violence at schools, churches, and elsewhere.

Because where or when these events will happen usually cannot be anticipated, nor can it be foreseen how destructive they will be, "protections need to be available 'everywhere' in order to prevent disease and injury 'anywhere.'"[2]

A number of factors contribute to the frequency and intensity of health-security threats, both in the U.S. and globally.[3]

- Extreme weather events such as storms, fires, floods, droughts, and temperature extremes
- Newly emerging and re-emerging infectious diseases such as Zika, Middle East Respiratory Syndrome, and Ebola
- Growing antibiotic resistance
- Incomplete vaccination coverage
- Globalization in travel and trade patterns
- Political instability, violence, and terrorism risks
- Aging infrastructure for transportation, housing, food, water, and energy systems
- Cybersecurity vulnerabilities

The good news is that, for the past six years, health security has improved in the U.S., with some regions moving ahead strongly and others still lagging behind. Contributing factors, according to the Index,[1] likely include "an updated National Health Security Strategy, clearly defined capabilities for key sectors involved in health security and preparedness, community-engaged planning and protocol development, and regular testing of plans and protocols through exercises, drills, and responses to real events."[1]

The 2019 *National Health Security Preparedness Index*[1] states that the U.S. scores a 6.7 on a 10-point scale for preparedness. While that indicates progress, there is still much work to be done.

Who needs to be involved?

You've heard the expression "it takes a village to raise a child"; well, it takes a village to respond to disasters and outbreaks, too. Some experts weighed in on what is needed and who should be involved in preparations for the unexpected on a large scale.

Beth Krah, Owner and CEO, activTek Health Solutions, commented, "By nature, the term 'disaster' explodes outside the confines of any box, so our strategy in planning needs to outwit any disaster. The key is not only establishing strong relationships between each department within the facility, but with first responders, United States Public Health Service Commissioned Corp officers, the private sector, etc.

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Aftermath of the May 2011 tornado in Joplin, Missouri
Photo courtesy Mobile Medical International Corp.

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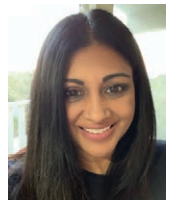
Gary M. Schindele, FHFI, President, Paladin Healthcare LLC, highlighted the importance of communication among those involved, "Unified command consists of all participants of an event being at a centralized command post with means to communicate directly with assets in the field. This includes hospitals, fire and emergency medical services, and law enforcement."

Krutika Kuppalli, MD, an infectious disease specialist at Stanford University School of Medicine and an Infectious Diseases Society of America (IDSA) Global Health Committee member, talked to *Healthcare Purchasing News* about hospitals' roles in precarious times. "Hospitals play a crucial role in providing medical care for communities during all types of emergencies and disasters. Any unexpected incident can overwhelm the capacity of a hospital and healthcare system at large.



Krutika Kuppalli

"To be best prepared," continued Kuppalli, "medical facilities should have a multidisciplinary hospital-incident command group that is activated in the event of a disaster or emergency. At the very least, this should include representatives from hospital administration, communications, security, nursing administration, human resources, pharmacy, infection control, respiratory therapy, engineering and maintenance, laboratory, nutrition, laundry, cleaning, waste management, and medical staff including intensive care, emergency medicine, internal medicine, pediatrics, obstetrics-gynecology, surgery, orthopedics, anesthesia, and radiology."

"It is critical for all departments to work together during a crisis," said Janet L. Lumbra, Director of Business Development, Mobile Medical International, Corp. Lumbra thinks it is most important that facilities and materials management, infection control, operating room, and sterile-processing management are involved, "to ensure ongoing safe service to patients and personnel."

"Engineers have a unique contribution as well, in how HVAC systems affect outbreaks, environmental hazards associated with biological agents, and appropriate handling of utilities during natural disasters," added Krah, activTek Health Solutions. "Knowledge gleaned from others' experience on the front lines is invaluable. Science matters greatly as well, and technology is often available to aid significantly in mitigating mass-casualty incidents or other disasters."

Advance planning

Obviously, the most important aspect of being prepared is planning ahead. Waiting until a disaster or outbreak strikes is dangerous for all. Alex Birrell, PhD, CEO, CleanSpace Technologies, noted, "In a crisis, prioritizing protection of healthcare workers (HCWs) can ensure a resilient frontline defense. In 2003, during SARS [Severe Acute Respiratory Syndrome outbreak], about 20 percent of the people infected in the U.S. were HCWs; in Canada, it was forty-three percent. There was little time for hospital preparedness policies to be implemented and resources scaled up."

Kuppalli advised, "I think the most overlooked component of emergency and disaster preparedness is planning and being ready for the unexpected. Oftentimes, as a society, we are reactive to events when they occur rather than being proactive. As a member of IDSA, we are constantly monitoring disease outbreaks and pandemics around the world. People can go to our society site, www.idsociety.org, to get more information about various infectious diseases and prepare appropriately. If we have learned anything from the past, it is that there will be another emergency or disaster. We just do not know when or where. It is for this reason it is important that, as a society, we all prepare and be ready."

Kuppalli, IDSA, described the main components of an emergency/disaster plan. "The essential components of an emergency/disaster plan are continuing essential services, developing an effective command and control, ensuring safety and security of staff and patients, clear and accurate internal and external communication, quick adaptation to increased demands on the system, efficient triage, appropriate use of scarce resources, effective human resource management, logistics and supply management, and a post-disaster recovery plan."

Stressing the importance of participating in drills, Krah, activTek Health Solutions, insisted, "Take all training and exercises seriously. Preparing for *if* a disaster happens just gives the pathogen or storm the upper hand. It's critical to approach training as *when* it will occur."

Schindele talked about the importance of maintaining HCWs' health and safety, so they can continue contributing their efforts to those who need them. "The first and foremost element of disaster management is to do no harm, to both responders and patients. Caregiver safety is the primary goal, to ensure that effective patient care can be delivered throughout the event. Keep in mind that disaster/mass-casualty events may involve damaged infrastructure, limiting re-supply and manpower reinforcements. Providers must be prepared to manage for extended periods of time in compromised conditions."

Lumbra, Mobile Medical International, Corp, stated that the most important thing is "having a knowledge of the plan, first and foremost, with cooperation of all. The main components and tools needed to ensure success in preparing and responding during an emergency are continued access to power, clean water, supplies, and personnel/manpower, to continue offering services to patients."

Krah continued, "Upstream strategic thinking is key to prevent infectious diseases from spreading. Diseases and contamination run rampant after natural disasters, and proper hygiene isn't a priority when mom is desperately searching for her three-year-old. Having technology already in place can go a long way in mitigating the spread of such diseases."

Product solutions are part of the strategy

Part of preparation for disasters/outbreaks is having on hand what is needed or knowing where to get what is needed. One of the things critically needed is safe air. Krah, activTek Health Solutions, talked about their solution. "For over a decade, activTek Health Solutions has been providing healthy living environments within the healthcare industry. Recently inducted into the Space Technology Hall of Fame, ActivePure Technology greatly improves indoor air quality by providing non-invasive, continual treatment of the entire facility, without chemicals and toxic by-products, while promoting LEED Certification points. By exploding the shell of pathogens, volatile

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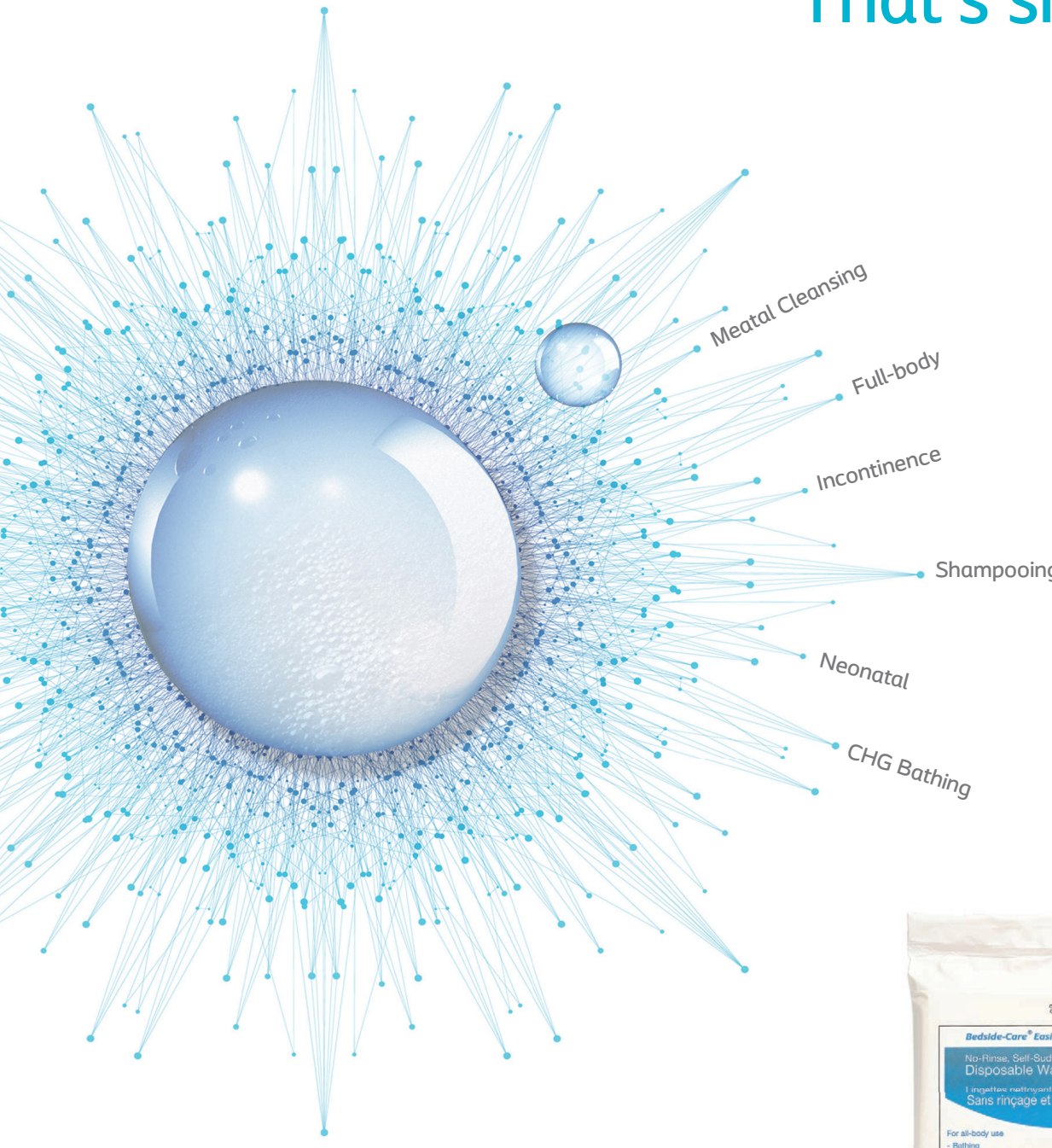

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Schindele, Paladin Healthcare, said, "Paladin Healthcare manufactures solutions that bring critical equipment and supplies to forward triage and non-traditional care sites such as lobbies, tents, parking areas, and public venues such as conference centers and sports venues. Paladin products have been successfully deployed in several scenarios including hospitals set up to manage special events and surge populations for emergency departments."

Delivery of oxygen for mass-casualty events, major fire incidents, or other catastrophes is a challenge. Paladin's Surge Gas Delivery System deploys in minutes, sets up in rough terrain, and can simultaneously supply eight victims with oxygen. It stores in a portable and easy to carry case.

Whatever the scenario, the need for personal protective equipment (PPE) likely will skyrocket. Birrell, CleanSpace Technologies, said, "PPE plays a critical central role in managing and containing infectious diseases. Globally, hospital PPE may be outdated, inconsistently adopted, and in short supply. There are 18 million HCWs across the 5,500 hospitals in the U.S., and 7.3 billion N95 masks are needed during a pandemic. Currently there are 60 million masks stockpiled."

Paladin Healthcare Forward Triage Cart system deployed in a hospital

Birrell noted that inhalation of unknown contaminants or respiratory-infection outbreaks present a high risk to staff. "To protect staff, the focus must be on respiratory equipment. For years, hospitals relied on N95 masks; however, there are challenges with N95 masks including discomfort, heat, difficulties to fit, fogging, and the fact that they are disposable. There is a call for hospitals to evaluate reusable systems that will remove reliance on stockpiling disposable masks. The second issue is to incorporate mask PPE into routine care, so teams are familiar and confident with their respirators prior to a disaster.

"CleanSpace HALO is the next generation in healthcare respiratory protection," averred Birrell, adding that some of the biggest attractions of CleanSpace HALO respirators are that they are a small and reusable system that can be incorporated readily into routine care at a lower cost than N95s, they eliminate stockpiling, and they reduce contaminated waste."

Birrell added that CleanSpace HALO is lightweight and has no belts or hoses as with traditional powered air-purifying respira-

CleanSpace HALO respirator without mask

tors. "Nurses love the cool, fresh air across their face, with no fogging, and the transparent mask means good communication with each other and the patients."

Highlighting the need to have optimal PPE in stock, Birrell pointed to past outbreaks. "During SARS, HCWs accounted for 1,707 of the people who contracted the disease. During the first Ebola outbreak, at least 600 HCWs contracted the disease, of which half died. These cases highlight the vulnerabilities around the use and supply shortages of N95 disposable respirators. With N95s, managers can be faced with sending staff in to care for patients with used masks, or without protection at all, and this can result in potentially high rates of HCW stress, infection rates, and absenteeism. Hospitals adopting CleanSpace have trialed HALO and have acted to ensure their staff are protected and comfortable, and that their preparedness plans are robust."

Mass violence and natural disasters can cause overload of the hospital's surgery department, if indeed the hospital is still standing and in operation. Lumbra described how their solution fills the gap when the disaster strikes the hospital itself. "Mobile Medical International offers on-site surgery unit, sterile processing, and water-quality solutions that can provide the continuation of surgery and surgical-instrument processing while ensuring water quality."

Citing a previous experience, Lumbra said, "Mobile Medical International provided two Mobile Surgery Units to ensure continuation of surgical services to St. John's Regional Medical Center patients in Joplin, MO, immediately following the F-5 tornado's destruction of their facility in May 2011. These units were utilized for a year while the hospital was being rebuilt." For more details on how Mobile Medical International's solutions allowed surgeons to continue operating after their hospital was destroyed, go to http://www.mmicglobal.com/Joplin.

Get ready

Catastrophes and outbreaks can happen anywhere. Small communities or large cities, none are exempt or spared, as we have seen time and again. Natural disasters are increasing. Mass violence is rising. Outbreaks are popping up with more frequency, with both old and new infectious diseases. There is no excuse not to be prepared. Information abounds. Use it. The next time an outbreak or disaster hits, you could be in the middle of it. Be ready. HPN

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Progress in reprocessing

Best practices and tools to optimize workflow

by Kara Nadeau

With growing procedural volumes, the increasing complexity of medical/surgical instruments, and a healthcare industry under mounting pressure to improve patient care and safety, the central sterile/sterile processing department (CS/SPD) is one of the busiest and most stressful places to work. CS/SPD professionals are expected to effectively reprocess instruments and get them back into the hands of clinicians as quickly as possible. The challenge lies in balancing the demands for quality work with the demands for speed.

In this article, we present advice and best practices from CS/SPD professionals and other industry experts on how to improve reprocessing workflow efficiency throughout the process without compromising patient safety.

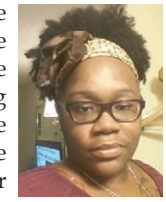
Best practices at each reprocessing stage

As with any process, efficient and effective reprocessing of surgical instruments requires staff members at each stage to perform their tasks correctly the first time, eliminating the need for time-consuming rework.

Point of use

When operating room (OR) staff members fail to clean instruments after use, it can lead to a snowball effect of reprocessing delays. In cases where blood, tissue and other organic matter dries and hardens on instruments from the time they are used to the time they reach decontamination, the CS/SPD team's job becomes even harder as they attempt to remove this bioburden.

"For reprocessing, everything begins at the point of use," said Andrea M. Harris, BA, CSPDT, Supervisor/Educator for AdventHealth Apopka in Apopka, FL. "As much bioburden as possible should be removed from the instrument(s) before they are returned to the reprocessing area. Instruments should be kept damp through the use of an enzymatic spray, or whatever approved wetting agent is available. This prevents any remaining bioburden from drying on to the instrument(s) and possibly causing damage or creating a biofilm."



Andrea M. Harris

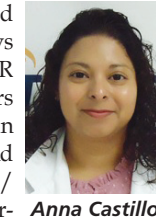
Arlene Bush CRCST, CER, CIS, CHL, SPD Educator at AdventHealth Orlando and Communications Director for the IAHCSMM Central Florida Association of Central Service Personnel (CFACSP) Chapter, explains how education of OR staff on the importance of point of use cleaning has played a huge role in improving her department's reprocessing workflow efficiency.

Arlene Bush

"CS/SPD staff identified opportunities for improvement related to point-of-use cleaning in the OR," said Bush. "This ultimately added a delay in reprocessing in decontamination. The OR and SPD must work together to implement best practices to remain compliant with ever changing standards in today's industry."

According to Bush, education started at the top with required in-services for department heads, supervisors and frontline staff to set expectations for required point-of-use cleaning. Bush and her team also opened a quality feedback option in their instrument tracking system to allow decontamination staff to enter feedback when point of use cleaning did not take place on items entering decontamination. Next they tracked compliance and reported it out in department huddles.

"Once staff understood the 'WHY' behind point of use cleaning, instrument thru put times increased dramatically," said Bush. "It was a move in the right direction for reprocessing workflow efficiency and staff satisfaction."



Anna Castillo-Gutierrez

Another challenge and cause of reprocessing delays that originate in the OR is how OR staff members place instruments back in their containers after use and before transport to the CS/SPD. Anna Castillo-Gutierrez, AA, CRCST, CSPDT, CIS, CFER, a Sterile Processing Instructor for Fortis College based in Houston, has faced

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this challenge first hand and was determined to find a solution.

"Imagine this: It's your turn in decontamination on second shift and you walk into a clean decontamination room at 3 p.m., your first case is coming down from the operating room and you're ready," said Castillo-Gutierrez. "It's a coronary artery bypass graft (CABG), you open the large case cart and all the instruments are thrown into the containers, and some baskets don't even have instruments in them. This is going to take awhile to sort, not to mention sharp hazards and trash can be seen throughout."

After shadowing a few cases, Castillo-Gutierrez and a team of nurses, OR techs and sterile processing technicians found one process, restringing instruments after cases, offered benefits to all parties involved. It helped the OR with last counts and made it easier for staff members to place items back into correct sets. For the CS/SPD, restringing reduced decontamination time by 30 percent, decreased the number of lost instruments, protected instruments from damage during transport (e.g., placing heavy instruments on top of delicates or lids crushing instruments due to poor organization), and it helped boost CS/SPD staff safety by allowing them to easily see sharps that had been inadvertently placed facing up.

"It took a lot of in-servicing for everyone but restringing gave both sterile processing and the OR great turn-over results, earning us commendation from the Joint Commission survey for the concept," said Castillo-Gutierrez.

Decontamination and cleaning

As Sharon Greene-Golden, BA, CRCST, CER, SME, FCS, Consultant for oneSOURCE Document Site, points out, the CS/SPD in many hospitals is not set up to facilitate efficiency. Often situated in a small area of the basement, the CS/SPD has traditionally been an afterthought when it comes to hospital design. Therefore, improvements in decontamination process workflow start with taking a step back to determine if CS/SPD professionals have what they need from a space and equipment perspective.

Sharon Greene-Golden

"One key area that CS/SPD professionals must address to improve workflow efficiency is the decontamination area where the set-up is important for instrument cleaning and processing to be completed correctly and according to instructions for use (IFU) specifications," said Greene-Golden. "The workflow in the decontamination area must allow for the removal of instruments to the sink and adequate professional sinks that can be used to properly rinse, soak and clean trays of instruments according to the IFU. Sonic machines, washer decontaminators, flexible inspection scopes and cart washers all need to have room to function correctly in a manner that allows workflow to be seamless. The standard requirements and design can be found in the ANSI/AAMI ST79:2017."

Michael DeFee, CRCST, CHL, SPD Manager, Riceland Healthcare, Beaumont, TX, has designed a decontamination space where technicians have everything they need close at hand.

"We are in a very busy day-surgery setting where instruments must be turned over quickly because we don't have a lot of inventory," said DeFee. "Designing our decontamination space took planning and experimenting to see how we could support a fast pace without compromising efficacy and safety. While our space is small, each person has exactly what he or she needs at arm's length and can work with minimal distraction."

Harris explains how effective and efficient practices in decontamination pave the way for streamlined cleaning in washers/disinfectors, stating:

"Instruments should be pre-cleaned in decontamination prior to being placed in the washer, and ringed instruments should be strung on an appropriate style stringer to keep them in an open position when they are placed in the washer. Best practice is to place those instruments with the finger rings down and the box locks up towards the spray arms of the washers. Instrument baskets should not be overloaded so that washer chemistries can make contact with all instruments."

Mike McCormick, Director, Corporate Project Development for STERIS, says the company has completed many capacity studies in the CS/SPD over the years and found the number of sinks in the decontamination area has an impact on productivity.

"When instrument washers were first introduced, they washed eight to 10 instrument trays per hour," McCormick explains. "A single, three-well sink can output 12 to 15 instrument trays per hour. Most SPDs would have one sink for two instrument washers. Current instrument washers output 18 to 20 trays per hour on average, yet many facilities continue to plan one sink for two washers. By increasing the number of three-well sinks to one per washer, it will help balance workflow and reduce backlog."

The washer/disinfectors themselves can make or break the effectiveness and efficiency of the entire process, according to Gene Ricupito, CRCST, CHL, CFER, PMP, Interim Director of SPD, UCSF Health.

"In my experience, one of the most critical process control points to address for efficiency is the throughput of mechanical washer/disinfectors," said Ricupito. "Lengthy cycle times, idle time and unplanned downtime can greatly impact the workflow from decontam to assembly. Short of replacing older equipment with efficient cutting-edge technology, organizations should also periodically collaborate with their field service engineer to ensure that variable cycle parameters are optimized specific to the processes and other technology assets in use. While there is a careful balance between effective cleaning and the length of the cycle, there are variables that can be tailored to meet the needs for repeatable quality outcomes without over-processing devices in decontam."

Inspection, assembly and packaging

While most of the "dirty work" is over once the instruments come out of the washer/disinfector and into the clean side of the CS/SPD, the process of inspecting, assembling and packaging instrument sets and trays prior to sterilization require proper planning, expert skills and the appropriate equipment to facilitate speedy turn around times.

"Once trays reach the clean side they should be tested for sharpness, cracks and any other types of damage that may be present," said Harris. "Best practice is to inspect and assemble trays in the order in which they will be needed. Priority trays should be assembled first. Once trays are sterilized they should not be transferred to their storage area until they have reached ambient temperature to prevent condensation from forming in the tray."

"Many techs assemble similar sets in the same group rather than assembling based on need," said James Marchisio, MBA, Business Manager, Perioperative Services, The Ohio State University Wexner Medical Center East Hospital in Columbus, OH. "The long-standing culture, of 'the sterilizer must be full' creates unnecessary inefficiencies. A focus on productivity is important; however, clean, sterile and accurate sets are factors that must be a priority for every SPD to run efficiently."

Sterilization

Whether a CS/SPD is using rigid containers, peel pouches or sterilization wrap, each comes with its own opportunities for workflow improvements.

With a background in medical device manufacturing, Charlie A. Webb CPP, Sterile Packaging Sciences, Van der Stahl Scientific, believes repeatability in pouch sealing is the greatest challenge facing CS/SPDs.

"The medical device original equipment manufacturer (OEM) must conform to a pouch sealing validation process that is much more robust, as all pouch sealing attributes are monitored," said Webb. "Systems such as self-sealing pouches and non-microprocessor controlled packaging systems are not used in

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manufacturing as we are not able to control, monitor, alarm and record individual pouch closing events. As healthcare packaging moves to a zero defect and risk to patient metric for the sterile barrier system, hospitals will need to reevaluate packaging and take a cue from medical device manufacturers."

Reprocessing instruments used in orthopedic procedures takes a great deal of time and labor among CS/SPD professionals because of the number of sets used per case and the growing volumes of orthopedic cases, including total joint replacements (e.g. knee, hip).[1]

A retrospective study published at the 2019 Association of periOperative Registered Nurses (AORN) Global Surgical Conference & Expo demonstrated how Turbett Surgical's Instrument POD system, with its 15-tray capacity, cuts instrument processing time by 45 minutes or more for orthopedic instrument sterilization, compared with the use of rigid containers and sterilization wrap. The results show that 20 percent of the time savings was achieved prior to the autoclave, 70 percent observed in the POD rapid dry time and 10 percent in the transfer from the autoclave's sterile racks to the case cart.[2]

"The time and efficiency savings, along with the reduction in rejected trays, makes this likely the biggest step forward in efficiency a department can make," said Turbett Surgical's President and CEO Rob Turbett. "Looking deeper into the study, this hospital shows how you can do more surgeries with less instrumentation."

"Ambulatory surgery centers (ASC) and hospitals struggle every day to support the rising number of surgeries with inadequate instrumentation," according to Barbara Ann Harmer, MHA, BSN, RN, Vice President of Clinical Services at Innovative Sterilization Technologies, LLC. "The use of ONE TRAY dramatically reduces the wait time for completion of the sterilization cycle, dry and cool times. Faster turnaround of instrumentation voids the need for hospitals to invest in additional surgical instruments. The absence of idle time when using ONE TRAY can also drive better employee productivity as staff members could be deployed for activities such as preparations for surgeries, equipment maintenance or quality control."

"ONE TRAY Sealed Sterilization Containers are intended to be used to hold temperature-tolerant medical devices during steam sterilization cycles and they meet the industry's definition of terminal sterilization as this product is sterilized within a sterile barrier system that permits storage for use at a later time," continued Harmer. "After sterilization, the container provides for the safe storage, transport and assured delivery of the enclosed devices in a sealed container with tamper-evident security and load record documentation."

The performance and intended use of the ONE TRAY Sealed Sterilization Containers should utilize the device manufacturers' sterilization exposure parameters and recommended practices/guidelines outlined by the Association for the Advancement of Medical Instrumentation (AAMI) and AORN.

Storage and transport

Following sterilization, CS/SPD professionals must transport sets either to a storage area, or to the OR for the next case. Melissa Lingle, MBA, BSN, RN, Director of Perioperative Services, The Ohio State University Wexner Medical Center East Hospital, comments on factors that influence workflow efficiency during transport.

"Transportation of instrumentation to and from sterile processing and the OR is different in each facility," she said. "The proximity logistics of the OR to SPD can create inefficiencies that are difficult to streamline. Most facilities have SPD in the basement; for those that are fortunate enough to have SPD on the same level of the OR, count your blessings! Many perioperative departments must creatively design a workflow that effectively navigates the challenge of having an SPD three to four floors below the OR. Factors to consider when designing the workflow include elevator wait times, sterile pathway, transport labor requirements, surgical volume and clean return rate."

A common concern among wrapped instrument sets during transport and storage is torn wraps which compromises the sterility of the set, explains Mitch Gerber, President of Pegasus.

"One of the things we hear a lot about in both the CS/SPD and OR areas is the number of torn sterile instrument packs," said Gerber. "This contributes to a high level of frustration when tears are found causing instruments sets to have to be re-wrapped and sterilized again. Not only does this cost time and money, but if this happens just prior to a surgical procedure beginning it can lead to delaying or even canceling that procedure. The impact on the patient emotionally cannot be understated. If this issue can be addressed and virtually eliminated it would have a major impact on workflow efficiency."

Best practices across the board

There are some best practices that a healthcare facility can apply throughout the entire reprocessing cycle to drive greater efficiency while maintaining patient safety.

Education

Proper education of staff — in both the OR and CS/SPD — lays the foundation for success and serves to boost process efficiency by reducing mistakes and rework.

"The biggest challenge to CS/SPD and workflow is education of staff in best practices of how to reprocess the select equipment," said Mark A. Leath, President, CS Medical. "Equipment manufacturers have varying IFUs and being fully versed on each is at times hard. Staff turnover and rush to turn instruments lead to healthcare-associated infections (HAI). Furthermore, any reduction in manual process to the workflow would be beneficial. For example, when reviewing reprocessing of transesophageal echocardiogram ultrasound probes (TEE), if you could automate cleaning prior to high-level disinfection with a validated process you could improve the workflow and solve a noted problem- cleaning of reusable instruments."

Communication

At every stage of reprocessing, communication is critical to success, explains Ralph J. Basile, Vice President of Healthmark Industries.

"There are many areas ripe for improvement and effective communication is key," said Basile. "Adopting methods to alert coworkers to the condition of devices (e.g., clean, dirty, processed, etc.) is one such example. Needless to say, it is critical that only processed devices are used and a used device is fully processed. There are too many documented incidents when a device was thought to have been processed, but wasn't, and ended up being used on a patient."

"High-tech tools are often favored (e.g., barcodes, RFID) and while these tools offer awesome benefits, sometimes simple is better (alone or in combination) than the high-tech," Basile added.

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Teamwork

Michele DeMeo

Michele DeMeo, CSPDT, CRCST, Independent CS/SPD Consultant at MDD Virtual Consulting, CS/SPD, performs assessments of CS/SPDs to help them set a baseline for improvements, create a priority list of critical needs, develop a correction plan, implement the plan and track progress in meeting their goals. In order for any plan to be successful, DeMeo says CS/SPD leaders must develop a team where they recognize each member's talents and areas for improvement.

"Each member must be able to produce the work tasks required of their position/role,"

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said DeMeo. "However, each person and technician will have both innate and learned skills and attributes, and equally differing levels of strengths and weaknesses. Leaders must be able to build a team that can function effectively and as naturally as possible. If you force a process it will likely fail. I have found that it helps to implement human factors elements or human factors engineering principles in addition to general CS/SPD necessities."

Collaboration

Because the actions of the OR directly impact the CS/SPD and its ability to turn around instruments quickly, effectively and safely, there must be close collaboration between the two teams, explains Jean Sargent, President of Sargent Healthcare Strategies (SHS).

Jean Sargent

"It is not so much about how the CS/SPD can improve efficiency, but how everyone else, particularly the OR, impact the process," said Sargent.

Sargent recently conducted a hospital assessment and found that while the CS/SPD team was performing its tasks correctly and working efficiently, the OR team was haphazard about its point-of-care cleaning. To educate both teams on their impact on one another and help overcome this issue, she recommends that hospitals implement cross training programs where OR technicians spend time in the CS/SPD, and CS/SPD technicians spend time in the OR.

Sargent says another key stakeholder in promoting the reprocessing of clean and safe instrumentation is infection control.

"It is really a three-legged stool: CS/SPD, infection control and the OR," said Sargent. "These parties should come together, review the AAMI standards and AORN guidelines to find out what they are doing right and where they have opportunities, then put together a strategic plan for improvements."

Data

"To make effective workflow improvements in reprocessing and disinfection processes, knowing where you have been is as important as knowing where you are going," said Russ Higgins, Manager, Product Software Solutions, Olympus America. "Having proper documentation on asset tracking, staff and equipment reprocessing compliance is critical to establishing data-driven key performance indicators (KPI). Good data allows managers to establish baselines that can be compared against a set of standardized KPIs. By establishing these KPIs managers can better measure improvements they make to processes and procedures, creating a predictable feedback loop that not only provides managers with a road map for change, but also promotes a staff culture of responsibility. The ultimate goal is to facilitate good practices that increase workflow efficiencies and enhance patient safety."

Documentation

DeFee says effective documentation is a key factor in the success of his department, stating:

"I've been through four or five state inspections and one of the factors that the inspectors find most impressive about our department is the level of documentation," said DeFee. "If someone on our team is looking for information to do their job they are able to easily find it. I am also sure to continuously update team members on changing standards that impact their work."

Standardization

"Standardizing workflows is one important way to improve efficiencies," said Susan Flynn, Technical Service Specialist, 3M Medical Solutions Division. "Establishing and communicating a standardized workflow can help ensure that staff on all shifts follows the most efficient and compliant method to complete a task."

"Take the example of routine sterilizer load release," Flynn added. "Many facilities have adopted the best practice of monitoring every sterilization load, whether steam, EO or VH2O2, with a biological indicator (BI). The standardized workflow is to release load items only after they are cool (for steam-processed items) and all quality control results, including the BI result, are acceptable. Adopting this standardized workflow can simplify staff training, improve quality, and reduce the need for rework."

Instrument tracking

Finding ways to efficiently process instruments is obviously a tremendous challenge — but what if you can't find the instrument to begin with? Missing or lost instruments is a major source of frustration and delays — in the OR and CS/SPD.

"I see the issue of missing/lost instruments as being an area most in need of improvement and is, in my opinion, the largest obstacle to workflow efficiency in a CS/SPD," said Todd Schojan, Laboratory Coordinator at High-power Validation Testing & Lab Services. "When an instrument is missing it can cause set down time, re-work and the biggest obstacle to efficiency — CS/SPD staff spending hours looking for an instrument if it is doctor-specific or one of a kind. Missing instruments have the potential to render a tray useless and can wreak havoc. They can cause case delay, rescheduling and even cancellation, leading to frustration not only to CS/SPD and OR staff but to the surgeon and the patient as well."

"There is no substitute for staff diligence and solid standard operating procedures to ensure that each instrument is accounted for and stays with the set it belongs to," added Schojan. "However, instrument-level tracking systems can help to keep instruments from going missing, or at least greatly reduce the time it takes to find ones when they do. RFID tags in conjunction with tracking systems can help staff locate instruments in real time and greatly reduce money spent on replacing lost instruments."

Special considerations

While the best practices highlighted in this article apply to most instruments flowing through the CS/SPD, some items present unique challenges when it comes to reprocessing efficiency.

Robotic instruments

"Sterile processing technicians are tasked with working safely and efficiently in order to deliver items to the OR which are 100 percent complete, 100 percent on time and 100 percent sterile," said Bob Straub, Director of Sales and Business Development at Cenorin. "Today they are challenged with processing more complex instruments than ever before. That complexity includes thoroughly cleaning and drying robotic instruments. CS/SPD teams must make a conscious effort to remove residual water from lumen devices and dry those devices without that process becoming a bottleneck itself."

Loaner trays

The delivery of loaner trays, and the condition in which they arrive at the facility, can make or break the reprocessing workflow. Mary K. Lane, MHA, CSPDM, CSPDS, CSPDT, MK Lane SPD Consulting, offers her advice on boosting efficiency in this area.

"The CS/SPD must implement a firm policy for vendors with surgeon buy-in that encompasses receipt to the pick up of the trays," said Lane. "Vendors are expected to have their trays to us not later than 24 hours prior to the surgery time, which is gracious on our part. Failure to do so means the vendor has to provide a written explanation and the surgeon is notified that they might encounter a surgical delay because of the late vendor trays. A repeat offense within 14 days results in a letter to the vendor advising them that if they are late a third time they are on a 30-day suspension from the hospital. Subsequent infractions result in more severe consequences, up to being banned from the hospital." HPN

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LEARNING OBJECTIVES

1. *List the types of cleaning brushes used in sterile processing departments.*
2. *Perform a brush risk assessment.*
3. *Describe how to assess and mitigate potential harms associated with cleaning brush use.*

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Brushing up on brushes

Instrument cleaning brushes and patient safety: Assessing and reducing risks

by Tamara Behm and Janet Strong

Every trained chef knows her tools and how to use and maintain them. When she reaches for a knife, for example, she selects the one most appropriate for the job at hand. Using a meat cleaver to cut bread or a butter knife to cut tomatoes damages the food and could injure the chef. Chefs keep a variety of knives available to optimize each of the many food preparation tasks they perform.

In addition, chef's knives must be maintained. Dull knife blades, loose handles and rusty edges all lead to poor performance that directly impacts the chef's ability to make great food safely.

At the sterile processing sink, technicians are the chefs. Their primary tools are water, cleaning chemistries and instrument cleaning brushes. As with chef knives, there are various brushes designed to do specific tasks, and improper brush use can lead to serious consequences for patients and providers, such as infections and instrument damage.

Despite the critical importance of brushes as an infection prevention tool, little published guidance has been directed towards them. It's important to know how to assess their associated risks and to develop risk-reducing procedures for proper use and maintenance.

Types of brushes

Brushes are defined as "implements having bristles, hair, feathers, wire or other flexible fibrous material, fixed in a handle or a back, used for sweeping, scrubbing, painting, cleansing, smoothing, etc."[1] Cleaning brushes used in healthcare are designed to reach and remove soils that have become adhered to surgical and diagnostic devices. When designing an instrument cleaning brush, important factors to consider include the intended medical instrument, specific components or accessories that need to be accessed for cleaning, and the soils that are likely to adhere to it during use. Brush types include general, toothbrush-style, burr, channel, valve, and acetabular reamer brushes. Each brush is designed for a specific purpose.

- **General cleaning brushes** have a wide plastic handle with nylon bristles. These brushes are used for cleaning larger smooth instruments, such as organ retractors, and instruments with hinges or box locks, such as clamps.
- **Toothbrush-style brushes**, as the name suggests, are thinner brushes with multiple rows of bristles at one end of a handle, like that of a toothbrush. The bristles can be metal or nylon bristles. These brushes are designed to clean fine surfaces of instruments.
- **Burr cleaning brushes** are a subset of the toothbrush style brush. They are designed to clean burrs and rasp style instruments, which are typically encrusted with orthopedic soils. This style of brush typically has rigid stainless-steel bristles and sturdier handles.
- **Channel brushes** are long-handled nylon brushes used to clean devices with lumens or channels, such as endoscopes. Typically, they are designed with twisted wire that fans the bristles 360° around, or flexible plastic tubing. They come in a variety of diameters and lengths. It is important to match the diameter of the brush to the diameter of the lumen. Using a brush smaller than the lumen prevents the bristles from contacting all inner surfaces. A brush with a larger diameter than the lumen causes the bristles to bend, preventing good contact with the inner lumen walls. Choosing the right diameter allows for the bristles to clean the lumen effectively.
- **Valve brushes** are short channel brushes having one or two circular rows of nylon bristles at the end. These brushes are used for cleaning the insides of valves and short lumens.
- **Acetabular reamer brushes** are either curved or round in design to fit into the reamers, which are often difficult to clean due to their shape and the many grater holes on each reamer.

Regardless of brush design, all function in a similar fashion: they are moved against the surface of the device while submerged in cleaning solution. The bristles physically dislodge soil and debris, which then become



lodged within the bristle material and suspended in the cleaning solution.

Brushes become contaminated with patient debris during use, which makes them a source for potential cross-contamination. Despite this risk, little guidance has been made available regarding appropriate infection prevention practices. According to ANSI/AAMI ST79, "Brushes should be checked for visible soil and damage following each use and should be frequently cleaned and disinfected. Brushes should be stored clean and dry."[2] What does "frequently" mean? There is even less guidance on how to inspect brushes, and on the associated risk from damaged instruments that could result in patient harm.

It is at the discretion of the facility to establish policies and procedures for managing brushes. The hospital-established policies must consider the specific harms and risks associated with the use of the various types of cleaning brushes within the facility. The first step in this process is a risk assessment.

Assessing the risks

In the most general sense, a risk is the probability of a negative event occurring. Healthcare workers commonly use risk assessments to identify the potential for a specific harm to occur and prevent it from happening.

Risk assessments have four steps: (1) identifying risks, (2) rating risks, (3) mitigating risks and (4) communicating any remaining risks. A facility's first step in the risk assessment process is to identify all the potential harms that may occur when using brushes.

The first step is to identify the risks. Assemble a multidisciplinary team that includes an infection preventionist, a risk manager, department managers and end users. It is imperative that the group includes those who use brushes and those who use the devices that were brushed. The group should then brainstorm as many ways as possible in which a brush can cause harm either directly or indirectly. Table 1 shows a list of examples of harms and the events that must occur to cause those harms.

Another way to identify risks is to map the process. At each step of the process potential changes, missed steps or other "defects" are identified. The team then determines what harm these events might cause. For example, brushes can be used on several devices. The team would identify all harms that could occur when the brush is used on more than one device. Examples may include cross-contamination of devices with *Clostridium difficile* spores that are not eradicated during high-level disinfection, brush wear that leads to damage that makes devices unusable, the formation of biofilm between uses that can be passed on to other devices, or weakened bristles that break from reuse, can be transported to the patient procedure site and can harm the patient. It's important to note that several of these harms could happen from a single event. Reusing a single-use brush can result in damage to the instrument and patient harm, infection or even death from loosened bristles and cross-contamination.

Risk can also include events that jeopardize the healthcare facility's accreditation. The Joint Commission (TJC) is an accrediting body that hospitals invite to evaluate processes for patient safety standards. The Joint Commission provides performance standards for safe patient care that align with CMS federal guidelines. The 2017 facility survey guidance for inspectors includes evaluation of variances in a healthcare facility's elements of performance. When a violation is observed, such as when a single-use brush is reused, TJC inspectors calculate the harm the finding could cause to a patient and typically cites the facility for that violation. For example, if they see an SPD staff member cleaning instruments with a wire brush that contradicts the instruments' instruction for use, they would assign that as a pattern with either medium or high risk. If in the same facility the inspector observes reuse of single-use brushes in another department, such as GI, it may lead to an immediate jeopardy finding from widespread misuse of brushes in the facility.

Severity

Although there are many risks associated with healthcare practices, not every risk has the same chance of occurring. A damaged brush is more likely to damage an instrument than it is to transmit microorganisms that cause a lethal infection. Additionally, some risks are more tolerable than others. A patient's death is intolerable, whereas replacement of a damaged instrument is more acceptable. The next step in the risk assessment process is to rate all risks using an assessment of occurrence probability and severity of harm.

Severity is a rating of the impact the harm has. Severities range from very serious harms, such as life-threatening events, to minor nuisances, such as a pinch that does not require medical intervention. A severity scale is developed by the facility. Several organizations, like APIC and CDC, can help provide guidance regarding severity scales. Regardless of the scale used, examples of harms associated with the brushes should be included to help the risk assessment team compare the various harms when assigning a severity rating to each one.

Table 1: Harms and Causes

Harm	Events that must occur to cause the harm
Unusable instrument due to damage	Use a metal wire brush on a soft surface
	Forced a brush that is too big for the channel through the channel
Patient infection	Brush forms a biofilm that transmits microorganisms to the lumen establishing a device biofilm that is resistant to high level disinfection or sterilization
	A damaged brush scratches the device providing a protective area for microorganisms against high level disinfection or sterilization processes
	Used the wrong brush resulting in residual debris that protects microorganism during sterilization.
Patient Death	Brush forms a biofilm that transmits microorganisms to the lumen establishing a device biofilm that is resistant to high level disinfection or sterilization
	A damaged brush scratches the device providing a protective area for microorganisms against high level disinfection or sterilization processes

Self-Study Test Answers: 1. A, 2. A, 3. D, 4. C, 5. D, 6. D, 7. A, 8. B, 9. B, 10. A

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Probability of harm

There is no question that a serious life-threatening harm must be addressed, but it becomes less obvious when the harm is minor. And investing a great deal of time and money to prevent a harm that is already unlikely to happen may not be prudent either. This is why the second part of the risk rating considers the probability that a harmful event will happen.

Probability is the likelihood of an event occurring. It can be stated as a fraction/decimal or as a scale of occurrence. A 90% chance of rain is an example of a fractional expression. It can also be expressed as 9 out of 10 places will receive rain. Regardless of the way it is stated, there is a high probability of rain. The same is true for predicting the probability that a harm will occur.

Several factors must be considered when assigning a probability. For example, patient infections caused by using the wrong brush to clean have six steps. Each step along the way changes the probability of the event occurring.

1. The technician uses the wrong brush
2. Bioburden is left on the instrument
3. An infectious microorganism is present
4. The microorganism survives the sterilization process
5. The microorganism is transferred to the patient
6. The patient develops an infection

The type of microorganism trapped within the bioburden can also influence probability. Examples of organisms that have been transmitted by gastroenterology scopes include *E. coli*, *Pseudomonas sp.*, *Klebsiella pneumoniae*, *Stenotrophomonas maltophilia*, and Carbapenem-resistant Enterobacteriaceae. One hospital outbreak of *Klebsiella pneumoniae* resistant to beta lactam drugs (ESBL) was linked to improper cleaning of a duodenoscope that infected 16 patients. It wasn't until repeated flushing and brushing that the source of the microorganisms was identified as the scope's channels.[3] Since these organisms have been associated with outbreaks, the probability of this event happening is increased when theses organisms are identified in the facility.

Determining a risk value

The probability of a harm occurring is considered in relationship to the severity of harm to determine a relative risk value. This value is typically presented using a grid but can also be expressed using a calculated value.

The last step is determining when the risk rating warrants mitigation. This reduces the probability of the event occurring or eliminates the risk altogether. In the example of Table 2, action must be taken to mitigate risk that can or did result in a serious or severe harm, and sometimes even cause moderate harms. It's important to note that industry benchmarks are an important resource for establishing mitigation scales.

Table 2: Example of risk value table*

Severity	>70% of the time	Between 30-70% of the time	<30% of the time
Severe (Life-Threatening / Death)	Mitigation Required	Mitigation Required	Mitigation Required
Serious (loss of limb or infection)	Mitigation Required	Mitigation Required	Mitigation Required
Moderate (Instrument is damaged and unusable)	Mitigation Required	Process Improvement	Process Improvement
Minor (Instrument must be recleaned)	No Mitigation Required	No Mitigation Required	No Mitigation Required
	Probability of occurrence		

Each facility must determine its own table.

Mitigating risk

Mitigation involves all steps taken to ensure that the chance of harm occurring is reduced to acceptable levels. The risk of harm can never be truly eliminated but it can be reduced so that it is unlikely to happen. Applying the chef analogy again; there is a possibility that our chef will cut her finger. However, by using proper cutting techniques, the correct knives and cut-resistant gloves, she can significantly reduce the possibility of being cut.

The first step in mitigating a risk is to remove the possibility of the events occurring. For example, one risk that may be associated with brushes is the development of biofilms on the brush itself that can be transmitted to all devices that it is used to clean. To reduce the potential of forming biofilms, the department can establish cleaning and high-level disinfection/sterilization frequencies that reduce or eliminate the microorganisms found on reusable brushes. Or, they can use single-use disposable brushes to eliminate the risk of biofilm formation caused by brush use.

The second step is training. This must be based on the department's written procedures to help reinforce performance consistency. Of course, the training is only as good as the follow-up auditing. Over time, shortcuts may evolve, or new staff may enter the workflow, both of which can cause inconsistent processes. Regular refresher training and audits are important tools for success.

Communicating remaining risk

After all attempts are made to reduce the potential of occurrence, all remaining risks must be communicated to the users. These can be communicated through wall charts, references and symbols that enforce the risks. For example, single-use brushes should not be reused. However, when both single-use and reusable brushes are used at the same sink, the probability of reusing a single use brush is high. Single-use brushes are typically labeled with a symbol that indicates they are to be used only once. The department can remind technicians with posters or other communication to confirm they have the correct brush by looking for the "single-use" symbol.

Tools to help you

Several organizations provide tools and training on risk management and infection prevention. One such tool is the Center for Disease Control & Prevention (CDC) Risk Management Plan. There are templates and training for this assessment available on the CDC website. The tool allows the end user or leadership team to walk through a process as if they were an end user. Their step-by-step process takes you through an evaluation to determine patient risk at each step of your processes.

Another tool is the APIC Risk Assessment. This tool begins with a multidisciplinary team like the one we have described above. The risk assessment evaluates the potential impact, probability, and the organization's preparedness, specific to the prevention of infections.

Do no harm

Cleaning brushes are critical tools designed to help assure the safety of reusable instrumentation. The lack of detailed guidance on proper use and maintenance of brushes places the responsibility on each healthcare facility to address the risks in their departments. This requires the engagement of not only the sterile processing professionals, but leaders from infection prevention and risk management functions as well. Performing a multidisciplinary risk assessment and developing a mitigation plan will result in specific guidance that will help each facility reduce its potential for brush-related patient harm. HPN

See references online at www.hpnonline.com/21084043.

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***Janet Strong**, RN, BSN, CNOR, CRCST, was a surgical nurse for more than 20 years. She has held various positions, including total joint coordinator, ortho trauma coordinator, OR educator, and surgery center manager. During her career, Strong learned to clean, decontaminate and package orthopedic instruments. Strong is a member of IAHCSMM, AORN, APIC and SGNA.*

CONTINUING EDUCATION TEST • JULY 2019

Brushing up on brushes

Instrument cleaning brushes and patient safety: Assessing and reducing risks

Circle the one correct answer:

1. **Channel, toothbrush, acetabular reamer and burr are all types of brushes.**
   A. True
   B. False
2. **Before using any type of brush on an instrument, what document should be referenced?**
   A. Instrument instructions for use
   B. Technical data sheet
   C. Ultrasonic cleaner manual
   D. None of the above
3. **Which of the following is NOT a potential harm?**
   A. Unusable instrument
   B. Patient infection
   C. Patient death
   D. None of the above
4. **How can you tell if a brush can be reprocessed?**
   A. All brushes can be reused
   B. It will have a 2 on it inside a circle with a line through it
   C. The brush packaging will give clear instructions on reprocessing.
   D. It will be listed in the washer's operator manual
5. **A multiple disciplinary team to review harm should include ALL of the following except**
   A. Infection Prevention
   B. End Users
   C. Risk Management
   D. Environmental Services
6. **What can happen when a technician uses the wrong brush to clean a medical device?**
   A. Damage the instrument
   B. Leave behind bioburden
   C. Miss crevices and important areas requiring cleaning
   D. All the above
7. **To determine the risk value, you should include the severity of the risk and the probability of occurrence**
   A. True
   B. False
8. **If a risk value is serious you should:**
   A. Tell the supervisor
   B. Take steps to prevent it from happening
   C. Do nothing, it is up to the supervisor
   D. Monitor the number of times it happens
9. **Policies and procedures should be developed by the facility to establish cleaning and disinfection of single use brushes to reduce risk of harm.**
   A. True
   B. False
10. **Training and Auditing are essential activities for decreasing the risk of harm**
    A. True
    B. False

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Online information increases

IAHCSMM's expanding web offerings aid process improvement, enhance education

by Julie E. Williamson

All Central Service/Sterile Processing (CS/SP) professionals should strive to improve their practices daily and make an ongoing commitment to professional growth and knowledge advancement. Because of the fast-paced, demanding CS/SP environment where time and other critical resources are often limited — and where CS/SP professionals must divide their time and attention across a wide range of tasks and responsibilities — it's essential that these individuals have easy access to information to help them perform their jobs most effectively and efficiently.

To assist in these important goals, the International Association of Healthcare Central Service Materiel Management (IAHCSMM) continues to add valuable educational content and other focused materials directly to its website, with the content available free of charge to active or associate IAHCSMM members.

Document library deepens

In 2016, IAHCSMM began posting on its website sample resource documents for departmental process and performance improvement. The documents are provided by different healthcare facilities and are offered as samples of reference to IAHCMM members. Thanks to IAHCSMM's active and ever-growing membership base, the list of sample documents shared by facilities has grown significantly. As of June 2, 2019, dozens of sample documents are available under the Competencies, Forms & Documents, Job Descriptions and Posters sections, and more than 50 are available under the Policies section.

Just some of the available sample documents under Policies/Procedures include: Meeting staffing needs; department access and workflow; volunteers working in CS/SP; water supply disruption and contamination; and maintenance of processing equipment. Of the 12 provided posters that can be made visible to staff throughout the department, some cover critical topics such as handwashing; patient support; dress code; and bullying. Competency documents address cleaning and handling of endoscopes; instrument assembly; surgical instrument inspection and evaluation; TEE probe cleaning; gas plasma sterilization; and more. The Forms and Checklists section covers a broad range of pertinent content, such as endoscope tracking; case cart quality assurance audits; sterilization load record quality assurance audits; committee goal progress reports; inservice record with sign-in sheet; loaned instrument check-in form; new item shelf tag; and preparation and packaging temperature/humidity record log.

Continued success of the Sample Documents section of IAHCSMM's website depends upon ongoing participation from IAHCSMM members. CS/SP professionals who have documents they wish to share should review the Frequently Asked Questions section (www.iahcsmm.org/resources/cs-sample-documents.html) for submission rules and requirement, and then complete the online CS Sample Document Submission form. *Note: Users must be logged in as a current IAHCSMM Member or Certified Member to review or submit sample documents.*

Webinar content grows

Recognizing the need for today's busy CS/SP professionals to fulfill their continuing education (CE) requirements on the go, IAHCSMM developed a series of webinars that can be accessed from a desktop computer, laptop, tablet or mobile phone. The webinars are available free to IAHCSMM members and for a small fee to non-members. Completion of any webinar provides 1 CE (following each webinar, the user will need to take a brief survey to receive credit toward their certification renewals).

To date, 17 webinars are available that cover a broad range of topics, including: Basic Instrument Inspection; Behind Closed Doors: The Role of the CS Department in Infection Prevention; Central Service Attire Overview; Developing Teaching and Training Skills; Environmental Cleaning; Fostering a Mentoring Culture in Your Department; Gamification in Central Service; General Safety for Central Service Departments; High-Level Disinfection in Central Service; Immediate Use Steam Sterilization; Implant Processing; Laparoscopic, Robotic and Insulated Instrument Inspection; Loaned Instrumentation; Risk Assessments; Sterilization Containers; Survey Readiness; and Understanding and Developing a Competency Program.

More webinars are currently in development and will continue to be added to the IAHCSMM website, so those interested in participating should check the Online Store for further information on the webinars and access to all the content. HPN

Note: The CS Sample Resource Documents compiled and posted on the IAHCSMM website have been provided by numerous sources. They are offered as samples for members' reference only and are not intended to represent the best or only approach to any particular issue. IAHCSMM is not a standards-making organization and these documents do not represent IAHCSMM requirements. IAHCSMM and the individuals or companies providing the samples do not guarantee the accuracy, completeness or suitability of any document, and they assume no responsibility or liability in connection with the use or misuse of any material. The samples posted should not be construed as standards or legal advice, and users should seek other appropriate professional guidance. Users should verify that any documents or portions of documents they choose to use meet current standards and federal regulations, as well as applicable state and local requirements. Commercial products or services named in these documents do not represent an endorsement by IAHCSMM.

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SUBMIT YOUR QUESTIONS: **editor@hpnonline.com**

Handling sharps and needles; weekend protocols

by Ray Taurasi, Principal, Healthcare CS Solutions.

Q I am the safety officer of a physician's group which operates three ambulatory care clinics and a surgery center. I am in the process of developing the policy and procedure for the safe and appropriate handling and disposal of contaminated sharps and needles. What are the key issues I should address in these documents?

A The Occupational Safety Health Administration (OSHA) is a federal agency which issues and governs regulations relative to worker safety. OSHA does have strict regulations which include those relative to the proper handling of sharps such as needles and other devices used in a clinical environment. The Environmental Protection Agency (EPA) is another federal agency which is focused on environmental safety and preservation. The EPA issues and monitors strict regulations geared toward protecting and maintaining a healthy environment. There are EPA regulations that healthcare institutions must follow relative to the disposal of biohazardous materials including medical waste (e.g., the disposal of medical devices, supplies and the like which are contaminated with blood, body fluids or other organic matter).

OSHA and EPA regulations are governed by law and must be enforced and implemented, violations are subject to severe penalties including fines and possible closures. All sharps need to be disposed of in an OSHA-approved containment device clearly identifiable (labeled or color coded) as a contaminated sharps disposal container. Sharps containers can be made from a variety of materials including cardboard or plastic. To be acceptable by OSHA the container must be closable, puncture resistant, and leak-proof on all sides and the bottom. Sharps containers must be easily accessible to employees and located as close as feasible to the immediate area where sharps are used such as patient-care areas, surgical suite and support areas such as, central sterile processing, laundry and the like. OSHA mandates that each sharps container must either be labeled with the universal biohazard symbol and the word "biohazard" (see figure 1) or be color-coded red. Sharps containers shall be maintained upright throughout use, replaced routinely, and not be allowed to overfill. When removing sharps containers from the area of use, the containers shall be:

- Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, and or shipping
- Placed in a secondary container if leakage is possible. The secondary container must also be closable and constructed to contain all contents to prevent leakage during handling, storage, transport, and shipment. Secondary containers must also be labeled and or color coded as previously noted.
- Upon closure, duct tape may be used to secure the lid of a sharps container. A solid lid must be used, the tape cannot serve as the lid itself.

If used, reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury. Biohazardous waste must be handled in accordance with OSHA and EPA regulations. EPA like OSHA requires biohazard materials and waste be clearly identifiable via labeling and or color coding. Biohazard waste cannot be disposed of in a landfill but must be rendered safe prior to disposal. While there are various means of rendering biohazardous materials safe for disposal including, decontamination, sterilization, incineration, chemical applications and other mechanical processes the process can be quite complicated and expensive. Therefore, most medical facilities utilize the services of a professional biohazard disposal company. It is critical that you verify that any services you employ are EPA compliant. It is also very important that you consult with your local and state departments of Public Health, EPA, and OSHA to ascertain if they have any additional regulations.

Figure 1

Q I am the lead tech of sterile processing and on Monday through Friday we run a Bowie Dick test on the first empty sterilization cycle every morning. We then run a BI test in the next cycle which contains instrument sets and supplies. On weekends the OR nurse and surgical techs do the processing and sterilization. Do they need to do a BI or not? So far, they have not been doing any testing. I want to be sure we are not doing anything wrong. I called the manufacturer and he wouldn't tell anything except to do what the facility tells us to do.

A The same sterilization and related quality control practices should be followed on weekends as are followed during the weekdays. You need to have precise policies and procedures for all aspects of your sterilization and QC process. Policies and procedures need to be documented, monitored and recorded accordingly. In developing policies and procedures, you should follow professional recommendation and guidelines such as those published by AAMI and AORN.

Ray Taurasi is Principal, Healthcare CS Solutions. His healthcare career spans over-five decades as an Administrator, Educator, Technologist and Consultant. He is a member of AORN, SGNA, AAMI and a past president of IAHCSMM. Taurasi has been a faculty member of numerous colleges teaching in the divisions of business administration Nursing, and health sciences. He is the author of numerous articles and textbook chapters; he is a frequent speaker at national and international healthcare conferences.

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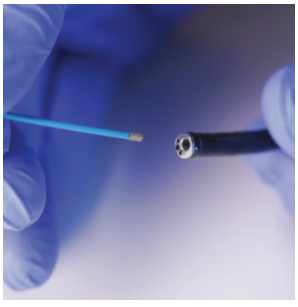

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Supply Chain's laboratory experiment

Understanding lab services leads to shared, improved experience

by Rick Dana Barlow

After the main story and a sequel or two finish their box office runs, Hollywood tends to follow up with a prequel, particularly if the "franchise" performs well among film goers. They simply contract for a product that looks back to show and tell a story about characters from the beginning as a way to squeeze out a little more cash from consumers.

Over the years, *Healthcare Purchasing News* has explored something of a niche franchise — the world of the clinical laboratory and its relationship to and need for supply chain expertise in the areas of contracting and product selection potentially.

HPN tagged the lab as the "final frontier" following the operating room and diagnostic imaging in terms of dollars expended on products and equipment as well as Supply Chain extending its contractual expertise, which clinicians tend to lack as a core competency.

While a small, but growing contingent of healthcare organizations have seen Supply Chain working with Laboratory on contracting and product management, many more have not.

So *HPN* reached out to a group of Laboratory supplier experts to gauge product demand and usage experience for Supply Chain professionals to extend an offer of service to help manage and reduce expenses via contracting and sourcing.

Where to start

Zachary Wert, Vice President of Instrument Manufacturing, Laboratory Diagnostics, Siemens Healthineers, identified a prequel of his own for Supply Chain to address first.

Zachary Wert

"Before trying to identify specific products, Supply Chain must first be willing to work with key stakeholders — lab managers, clinicians impacted by test menu changes, etc. — to understand the patient population the laboratory is serving and what testing menu would both benefit the laboratory and its patients," Wert said. Conducting some lab background homework gives Supply Chain efforts the necessary context on how to proceed.

Wert emphasizes three critical reasons for Supply Chain to gather lab intelligence.

First, laboratory testing plays a critical role in helping support patient care, particularly in the inpatient and emergency-care settings, with lab tests conducted on nearly all of hospital patients and more than half of emergency patients, according to Wert who cited a January 2017 article in *The Journal of Applied Laboratory Medicine* as his source.

Second, "producing test results quickly is increasingly challenging for laboratories," Wert noted. "The growing number of patients, the greater impact of diseases and the increased availability of new tests means more samples are headed to the laboratory."

Third, the lab industry currently is experiencing a shortage of staff to process the samples and keep up with the rising demand as noted by the Bureau of Labor Statistics analysis of medical and clinical laboratory technologists and technicians, he added.

"Conversations with these key stakeholders can help Supply Chain gain a better understanding of these challenges, and others unique to the institution the lab is supporting," Wert emphasized. "Open communication with key stakeholders can also bring to light ways in which the laboratory can optimize its operations — via the equipment it uses — to accomplish goals, such as reducing turnaround time for emergency tests or increasing productivity by reducing downtime spent on instrument maintenance. Having this information will help Supply Chain to identify the most appropriate laboratory equipment for its institution's unique setting and patients."

Wert cites one example where a laboratory that receives a high percentage of specialty testing requests may wish to bring that type of testing in-house if it currently outsources those services because it does not have the required assays or instruments. Or the laboratory may wish to gain better control over the point-of-care testing devices used throughout the health system by implementing an open connectivity informatics solution, he continued. "The laboratory may even have goals of modernizing its operations by implementing an automation track," he added.

Concentrating on processes and services for the lab can be just as effective — if not more — as Supply Chain focusing on products and equipment, according to several lab supplier experts.

"Balancing [point-of-care] lab strategy with a central/hospital lab strategy is key," indicated Patrick Bowman, Director, Health Systems, Lab, McKesson Corp. "With declining payments through PAMA [Protecting Access to Medicare Act of 2014] legislation coupled with the continued prevalence of value-based payments and outcome metric tracking create an urgent need to optimize a lab test menu and site of testing designation — near the patient or reference lab. If the organization has not conducted a lab strategy analysis citing clinical, operational and financial impacts of their current lab strategy and its impact to the enterprise level ecosystem in the past 24 months they should strongly consider doing so.

Patrick Bowman

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Bowman also singled out two areas in the POC and central/hospital lab space that should be investigated: Lab connectivity and molecular testing. "These solutions can help an organization run more efficiently with better direct and indirect financial outcomes," he added.

Assessing lab performance and designing a strategy to help the department manage expenses should be Supply Chain's aim, according to Lynn Glass, Vice President, Strategic Accounts, Lab, McKesson.

"Doing assessments of both centralized – capital equipment, bulk routine work with broad test menu – and decentralized lab testing – POC/waived testing – is important to be able to formulate a long-term strategy for sourcing and contracting," she noted.


Lynn Glass

Chris Gormley, CEO, MedPricer, urges healthcare providers to hone in on purchased services, which comprise approximately 20 percent of a hospital's total operating costs.

"U.S. hospitals are collectively overspending $39 billion each year on purchased services, which includes all outsourced contracts – both clinical and non-clinical," Gormley stated. No matter the area, Supply Chain "simply can't overlook purchased services anymore as it offers unmatched savings opportunities," he added.


Chris Gormley

Products vs. processes

Mark Krhovsky, Vice President of Laboratory Sales, Medline Industries, offers some key Supply Chain strategies for addressing products, starting with categorizing inventory into five buckets: Laboratory plastics and consumables, chemicals/solvents, equipment/instrumentation, reagents and manual micro/plated media.


Mark Krhovsky

"When it comes to standalone product cost, equipment/instrumentation and reagents will most likely make up a disproportionate amount of the lab's overall spend," Krhovsky indicated. "If costs can be controlled on these particular items then you put yourself in an advantageous position to save money and/or decrease spend for the entire lab. Diagnostic instrumentation platforms – chemistry, hematology, immunoassay – and reagents are often purchased manufacturer-direct in today's market, which means it is critical for Supply Chain teams to understand the brands that exist within their lab so they can build the proper relationships with those specific organizations and their sales leadership group. In some circumstances leveraging a distribution partner to help manage and oversee these product categories can help Supply Chain teams with overall organization and leverage."

Krhovsky admits that Supply Chain historically has had limited oversight and responsibility for laboratory product procurement, which may be reflected in departmental economics in terms of managing expenses and pricing.

"With that being the case we often find that general lab pricing has remained quite high in comparison to other areas of the hospital, and contract compliance is often less consistent, he observed. "There is no doubt that Supply Chain teams can have a tremendous impact on general vendor negotiation and contract admin-

The Lab and Supply Chain: Getting to know each other

The 1951 Rodgers and Hammerstein Broadway musical, "The King and I" may have featured the show tune "Getting to Know You" as a heartfelt but whimsical way to move the storyline forward, but that titular philosophy represents a successful business philosophy, too. And it's one that should not be lost on Supply Chain as it tries to work with their colleagues in the Laboratory to help them manage departmental expenses.

Supply Chain getting to know the Lab's operations may take some work but it's well worth the effort for the department, facility and patient care as a whole, according to a trio of lab industry suppliers.

"Understanding unique capabilities, such as lot track-and-trace and sequestration, are keys with lab products. Combined with the need for cold storage and delivery, smaller units of measure to individual clinic sites and the need for a different service model from the acute vs. the non-acute space within the enterprise [these all] are important for Supply Chain to understand when making lab decisions."

— Patrick Bowman, McKesson Corp.

"The ideal solution is one that offers a variety of functions that are centralized on one platform, that all parties – from sourcing team, to department stakeholder, to executive leadership, to suppliers – can access for instant transparency.

"To truly identify savings within the lab's cost management lifecycle, the sourcing teams should be able to develop a clear savings roadmap within the platform to define and implement a strong purchased services strategy. With an integrated approach to purchased services lifecycle management, platform users can easily spot savings opportunities, manage incumbent negotiations, go to RFP, and manage contracts all in one place. This approach ensures that, with a high degree of confidence, sourcing teams can negotiate great terms at the lowest rates available.

"Analytics and benchmarking both play an important role in identifying they best savings opportunities by purchased services category, evaluating current and soon-to-expire contract terms and comparing contract terms and prices to those against market standards, regardless of the healthcare organization's geographic location. By drawing on marketplace data [against which] to compare and measure a company's spend performance, Supply Chain is able to draw actionable conclusions that guide their negotiation strategy. Streamlining the entire process – from analyzing and benchmarking to running the RFPs – strongly unites the Supply Chain with Lab leadership and enables them to make the smartest purchasing choices for the greatest impact on their bottom line."

— Chris Gormley, MedPricer

"It's important to understand instrumentation platforms and workflow. Even small product decisions can have an impact on the inner workings of the lab. [The lab] is a critical unit of the hospital, so it's paramount nothing is done to interrupt or suspend the lab processes being run every day. Before any product conversion decisions are made the lab should be involved to validate and weigh-in on specific changes.

"Plated media for microbiology is the most difficult and finicky product to handle. It is short-dated, temperature-sensitive and has a propensity for manufacturer backorders. If you can control and stabilize this area of sourcing you have mastered one of the toughest elements of lab procurement.

"There are more high-quality, reliable lab manufacturing and distribution organizations than ever before. In many ways the lab has dealt with subpar service and support without understanding there might be a different way or a better option. Now is the time to seek out the right partners who are willing to go above-and-beyond to assist the Laboratory staff and Supply Chain teams alike.

— Mark Krhovsky, Medline Industries

istration — whether that be directly with the manufacturing community or with the laboratory distributors in the market. In the recent past there have been several new players entering both lab distribution and manufacturing, which means new options and the ability to shop business if the facility is not feeling fully supported by its current partners."

Krhovsky also singles out shipping and freight for certain high-touch items, such as hazmat chemicals and short-dated, refrigerated microbiology items, as opportunities to help drive down costs.

Gormley notes that his company has identified "plenty" of popular lab-related categories where Supply Chain can look for savings opportunities. They include immunochemistry equipment and consumables, reference lab testing services, blood products and services, laboratory device maintenance services, pathology and laboratory information systems.

"By uncovering lab-related purchased services opportunities, sourcing teams and stakeholders alike stand to gain tighter control and improved transparency within laboratory operations," he added.

Because of laboratory's "enterprise-level impact on a health system's operations, patient outcomes and financial outcomes," Bowman recommends aligning and incorporating laboratory with a multidisciplinary committee that spans administration, clinical, finance and operations.

"[This] will ensure that all decisions or change considerations around a lab strategy will be properly vetted and all potential impacts — positive and negative — will be identified, mitigated if needed, and executed with fewer surprises," he said.

Supply Chain should concentrate on reducing variation in the lab, according to Glass.

"Standardization of formulary, reduction in [stock-keeping units], bundling product to fewer manufacturers and vendors or test platforms and systems can provide clinical, financial and operational efficiencies," she noted. "Utilizing MMS delivery and service model to the non-acute space versus self-distribution through the hospital and out to the non-acute space may provide faster delivery, smaller units of measure, elimination of multiple shipping and delivery steps to insure integrity of product and can ultimately reduce costs while providing operational efficiency." HPN

Lab on Supply Chain: Walk softly as we carry the big stick

What are some of the common mistakes that Supply Chain can make when approaching the Laboratory with offers to help the department manage and reduce costs? Four supplier experts sound off about how Supply Chain may not recognize how deeply and widely lab services are integrated throughout a healthcare organization and a patient's experience.

"Lab needs to be looked at through a 'systemness' lens. It impacts nearly every corner of the enterprise. One of the most common mistakes we see is Supply Chain looking at lab as strictly a cost center or cost line item. It is much more complex than that, and in many cases, reducing costs by eliminating a test and outsourcing can have significant downstream impacts on patient care, patient access, reimbursement revenue and value-based reimbursement incentives or penalties. It is important to take a balanced scorecard approach around lab from a supply chain perspective. In many cases adding lab services may increase costs, but it can also improve operational, clinical and financial incomes when strategically implemented."

— Patrick Bowman, McKesson Corp.

"Laboratories regularly face budget cuts, and as a result, are unable to upgrade their technology as often as the increasing patient testing demand would encourage. Modern technology advancements afford laboratorians the opportunity to help keep up with the testing demands of today's patients while helping to improve turnaround time, quality of results, ease of use and safety when handling patient samples. The latest innovations and technological advancements also are helping to restore the clinical laboratory as an exciting place to establish one's career and address the pitfalls of understaffed laboratories. Anything Supply Chain can do to prevent budget cuts and support the laboratory in its efforts to upgrade its technology and could serve to benefit patients served by the institution."

— Zachary Wert, Siemens Healthineers

"The most common mistake Supply Chain makes in managing costs with stakeholders — laboratory leaders included — is that they don't consider purchased services sourcing as an avenue for savings. Historically, equipment and labor costs are the first to be evaluated. However, the cost benefits of re-negotiated purchased services contracts drop to the bottom line of an organization's profit margins. Beyond the cost savings, considerations for improved service level terms and deliverables can bring a positive impact to patient care.

"To prevent other mistakes from occurring, Supply Chain can take to following steps to best manage costs while working with lab leaders:

- Communicate the sourcing process and metrics that will govern the negotiation and award of contracts. By taking this step, your operations team will be positioned to act more nimbly in response to the laboratory's requests.
- Obtain industry benchmarks on laboratory purchased services contracts, such as reference lab testing. This allows organizations to determine the competitiveness of their spend in relation to similar providers in their region, and it guides the sourcing roadmap prioritization schedule.
- Maintain a stakeholder roster, making sure the lab contacts are senior enough to make supplier-based decisions and tradeoffs to support system-wide objectives and be able to clearly articulate the business requirements, such as scope of work, quality performance indicators, and identify preferred suppliers.
- Centralize the sourcing process so that lab stakeholders can work directly with the supply chain on one platform to house qualitative and anecdotal information, along with business requirements, contract redlines and current contract terms.

These steps create more transparency within an organization and enable cross-department teams to work together quickly and efficiently to identify and act on savings opportunities."

— Chris Gormley, MedPricer

"[For] Supply Chain professionals who are starting to work with their labs: One, do your best to understand their world before offering critical advice. Take a tour of your lab, get a sense for the workflow and products/brands being used and introduce yourself to the staff. The lab is a critical area of the hospital and it is complex in many ways. On top of that you will typically see some of your most long-tenured staff in the laboratory. To gain their trust and respect I find it's always smart to be a student of their world. They're typically quick to teach and explain — and they'll know you're committed to trying to understand even though you'll never fully grasp all of the inner workings of the department.

"Two, ease your way in. I find that coming in strong with forceful demands is not the best way to get started with the lab. Ensure they're part of the decision making process and explain to them the overall financial impact of buying decisions and potential changes in products or distribution service. The more collaborative you can make this working relationship the better your overall results will be in the long run."

— Mark Krhovsky, Medline Industries

WORTH REPEATING

"By allowing devices to be scanned at the point of use, the OR team is notified if the product is recalled or expired immediately prior to implantation and not post-procedure. Patient safety becomes real-time, helping mitigate risk to the healthcare organization."

Pat Cairn, COO, SteriTrack

"For reprocessing, everything begins at the point of use. As much bioburden as possible should be removed from the instrument(s) before they are returned to the reprocessing area. Instruments should be kept damp through the use of an enzymatic spray, or whatever approved wetting agent is available. This prevents any remaining bioburden from drying on to the instrument(s) and possibly causing damage or creating a biofilm."

Andrea M. Harris, B.A., CSPDT, Supervisor/Educator, AdventHealth, Apopka, FL

"Before trying to identify specific products, Supply Chain must first be willing to work with key stakeholders – lab managers, clinicians impacted by test menu changes, etc. – to understand the patient population the laboratory is serving and what testing menu would both benefit the laboratory and its patients."

Zachary Wert, Vice President of Instrument Manufacturing, Laboratory Diagnostics, Siemens Healthineers

"In a crisis, prioritizing protection of healthcare workers (HCWs) can ensure a resilient frontline defense. In 2003, during SARS [Severe Acute Respiratory Syndrome outbreak], about 20 percent of the people infected in the U.S. were HCWs; in Canada, it was forty-three percent. There was little time for hospital preparedness policies to be implemented and resources scaled up."

Alex Birrell, PhD, CEO, CleanSpace Health and Safety

PEOPLE & OPINIONS

Should experience carry an expiration date?

We should embrace failure as the spark toward success

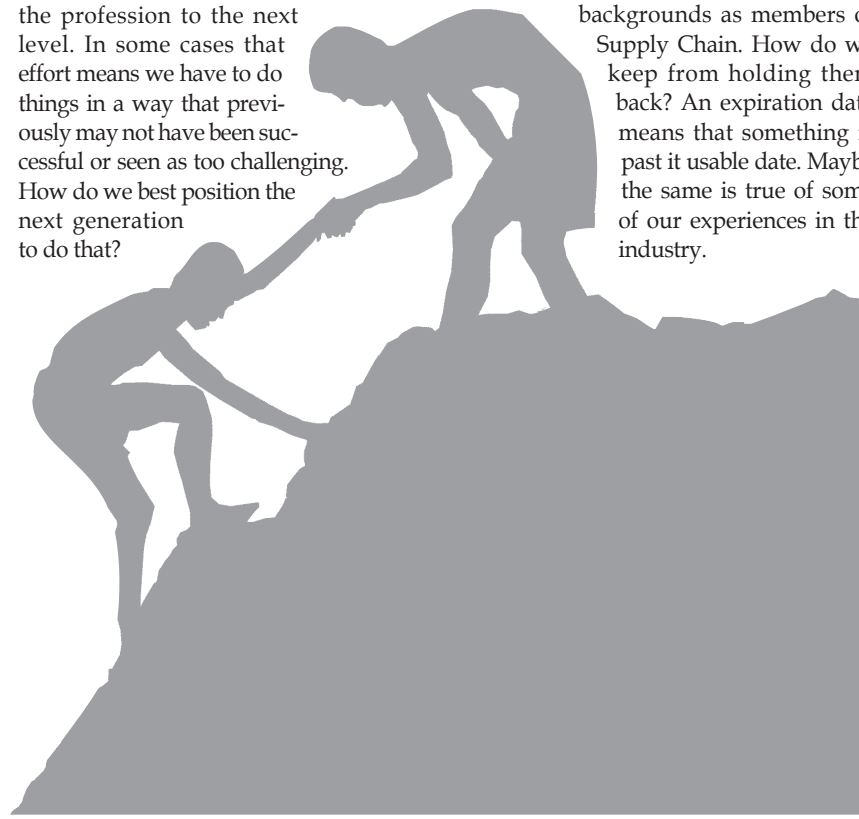
by Joe Colonna

We in this profession called "Healthcare Supply Chain" stand on the shoulders of those that came before us. Our predecessors took us from Procurement and Materials Management to what we now, almost exclusively, call Supply Chain Management. They took the profession from one of order takers and box movers to positioning us to be seen as a strategic partner for the success of the organization. They did this by challenging the previously held beliefs of leaders in those roles and the organizations they served. While this may not be true in all cases, it is certainly very true in many organizations.

We owe those who came before us a debt of gratitude. We also owe it to them to take the profession to the next level. In some cases that effort means we have to do things in a way that previously may not have been successful or seen as too challenging. How do we best position the next generation to do that?

We talk about what we have learned from our failures and that it made us stronger as leaders. How often does anyone talk about another person who tried the exact same thing again at a different time or place and this time it turned out to be a success? Can the experience of a failure also cripple us? Can it lock down a certain portion of our creativity or cause us to be overly protective? Worse yet, can the sharing of these experiences keep the next generation of leaders from trying the same things again with potentially better outcomes?

The healthcare industry and specifically our Supply Chain industry has made tremendous advances. We now have people with incredibly diverse backgrounds as members of Supply Chain. How do we keep from holding them back? An expiration date means that something is past it usable date. Maybe the same is true of some of our experiences in the industry.



What I am really starting to worry about is extinguishing the exuberance of the next generation of leaders. I think we can do this with the best of intentions because we think we are keeping the next generation from failure or trying to positon them for success. We can do this directly by saying things, such as, "I have tried that before, I know it won't work" or "Let me tell you how to do this." We also can discourage folks indirectly by just oversharing our opinions on the profession with comments like, "Leadership will never agree." We should think about what we are saying and how we are saying it. People are always listening, and words matter.

With 30 years in the Healthcare Supply Chain profession, I have amassed quite a few stories to tell. I, of course, love to share my "war stories" as part of the coaching process or anytime I can get someone to listen. However, I am learning that I should be careful not to squash new ideas or even old ideas revisited. I have also found that I must actively coach myself to be open to new ideas and concepts. Among those is that the times I tried and failed to meet a goal or just screwed something up, it may not have been the right time, the right place or honestly I may simply have not been the right person.

This also can be true of past success. Just because something worked out well here does not mean someone else should do it like me. Not everyone has the same skill set. People, process and technology are all improving and finding better and different ways to approach and execute on an opportunity. While on the surface a project may look like something I have tackled before, it may not have the same dynamics. I am trying hard to remember that when I share my war stories I temper it with, "this is what I learned from this, but it does not mean we cannot try it again." There may be other times when regardless of personal or professional experience it's probably best to keep my war stories to myself and just be a supportive leader. After all, words matter and maybe some of my experiences should have an expiration date. HPN

Joe Colonna serves as Vice President, Supply Chain, Atlanta-based Piedmont Healthcare, the 2018 Supply Chain Department of the Year, by Healthcare Purchasing News.

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The surprising truth behind UDIs and recall management

by Karen Conway, Vice President, Healthcare Value, GHX

When the Food and Drug Administration (FDA) published the UDI rule in 2013, it listed the ability to "provide for more rapid, more efficient resolution of device recalls" as a primary driver for the regulation. Meanwhile, the economic analysis published as part of the final rule noted the potential "to more effectively target and manage medical device recalls" as one of two benefits (the other being better adverse event identification and response). Given the rise in the number of medical device recalls, including those posing the greatest threat to public health, you would expect to see more use of UDIs in the recall process. Yet, despite many providers and manufacturers having incorporated unique device identifiers (UDIs) into their internal systems for inventory and recall management and adverse event reporting, the use of the identifiers for those purposes remains surprisingly low. In this month's column, we will explore the issue in greater detail and consider some possible reasons why UDIs for recall management has not gained more traction.

Recall trends

The number of recalls issued in 2018 was the highest in five years, while the average number of Class I units recalled per quarter increased more than 64 percent from 2016 to 2017. In 2018, Class I units recalled were even higher — by nearly 10 fold — but that was due to an unusually large Class I recall in the first quarter. According to a 2017 McKinsey report, a major recall can have a negative impact on perceived shareholder value, not to mention the significant risk to patient safety if the devices in question are not removed from the market and patients treated with those devices, especially implantables, cannot be identified.

Provider response

In the final UDI rule, the FDA noted that it "anticipates that providers will include UDIs in electronic health records (EHRs)… to identify the specific devices implanted into patients, and will improve…adverse event reporting and recalls." With nearly two million UDI device identifiers (UDI-DI) for medical devices now available to the public in the FDA's Global UDI database (GUDID) and additional UDI rules already or soon to be published in Europe, the Middle East and Asia, there is considerably more information available to providers to use them to manage recalls. The Learning UDI Community (LUC), operated by the Association for Healthcare Resource and Materials Management (AHRMM), also identified increased labor savings and improved patient safety by incorporating UDIs into both systems and processes to manage recalls.

For example, if providers store the UDIs for products purchased in their enterprise resource planning (ERP) or materials management information systems and concurrently track product recalls, they can be alerted if they scan a product that has been recalled. If they also record the UDIs for products used in patient care in electronic health records (EHRs), they can more effectively match a recalled product to a specific patient.

Few UDIs in recall management

While there are still limitations in many materials management and EHR systems, there appears to be a bigger problem: the lack of UDI usage in the recall process by both manufacturers and the FDA. When I reviewed the 19 Class I medical device recalls for 2019 featured on an FDA recall page,[1] only one company (Integra Life Sciences) included the UDI-DIs, along with the catalog numbers and descriptions. Other companies, including some of the most ardent proponents of GS1 product identifiers (one of the UDI compliant codes), only listed product codes or model numbers.

Another possible challenge to increased use of the UDIs for recall management may be the FDA itself. In its most recent (April 2019) publication on recall procedures, the agency only references UDI once, and as one of many ways to identify products in recall communications. Further, when searching for recalls in the FDA's medical device recalls database, there is only a place to list a product code, which could be interpreted as many things, including model numbers, catalog numbers, and part numbers. The lack of a specific field for UDI undermines the goal of having all stakeholders across the healthcare ecosystem identify products the same way, using UDIs.

The path to value

From the beginning, the FDA has stated that the benefits of UDI "will only be fully realized with the adoption and use of UDIs by manufacturers, distributors, payers, providers, patients, healthcare systems and other stakeholders." Even if manufacturers and the FDA only used the UDIs to manage recalls, it is still incumbent on providers to use the identifiers to not only record the UDIs for products used in patient care in EHRs but also to use the UDIs in purchasing and inventory systems. That way they can not only match patients to recalled products, but also determine if they purchased the products in question and if so, where those products are being stored. In this way, they prevent future usage of the products and resulting patient harm.

It's no surprise, it will take a village to realize the full value of UDI, but it seems to me that the first ones to the starting line should be the FDA and manufacturers. After all, the FDA was the first to recognize the value, and the manufacturers have invested the most to comply with the regulation. Now is the time to take the steps to begin realizing the benefits, while creating the path forward for others to take full advantage of the UDI system. HPN

Reference

1 https://www.fda.gov/medical-devices/medical-device-recalls/2019-medical-device-recalls

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Searching for your successor beyond trial-and-error

by Jamie C. Kowalski, LFACHE

If you are the executive leader of Supply Chain Management at your facility you hopefully should recognize the steps or sequenced activities that you need to know, understand and deploy effectively, if you are to increase your chances of finding your optimal successor.

As a reminder, those steps are:

1. Develop your personal Strategic Plan and timeline. This will help you determine how long you hope or plan to remain employed, and at your current employer.
2. Prepare a Strategic Plan for Supply Chain Management enterprise-wide. This will define where the supply chain is now and where it should go. Then you can determine what must be done and when, which will help identify what leadership resources are needed and the subsequent skill sets, knowledge and experience the leadership team and the successor will need.
3. Confer with your boss and the senior executives — if you don't report to the CEO directly. Make sure they understand and buy into the Supply Chain Strategic Plan.
4. Prepare the general and specific timeline and the sequence of activities and events that will lead to the execution of the Plan.
5. Develop a budget for the Plan and for the search for the successor.
6. Make sure policies and procedures are correct and current. If they are not, fix them. The successor will need this tool as a reference source and a guide when they take the helm.
7. Produce a Talent Profile for the leaders and successor that coincides and synchronizes with the Strategic Plan. How will you recognize and confirm those candidates that best match the Talent Profile? Stay tuned.
8. Identify talent sources. These include schools with soon-to-be graduates, professional societies, other "second lieutenants" in your local marketplace, regional and national markets, the military, etc.
9. Decide on a search firm or in-house effort. In-house may be a mistake. Does your internal HR team (and you) have the time to devote to a thorough but quick-as-possible search? Do you know or have connections with the external sources of talent? Realistically, not likely.
10. Get started when the time arrives that you defined in the Strategic Plan. Get the job done/hire the successor (or promote from within), mentor as needed, turn over the keys, and wish him or her all the best.

Igniting the talent profile

You might be familiar with the phrase, "you'll know a leader when you see one." Really? How?

Well, after you have completed steps 1-7 above, you will have a pretty good idea of the talent needed or preferred for the successor and the other leaders.

Then you begin the detective work of learning all you can about your internal prospects, as well as some selected external prospects. That means getting to know your current leader's team members.

Observe their interactions with their subordinates, peers, customers and superiors. Are they good listeners? How do they handle problems (process and people)? Do they see the big picture and will they get and support the Strategic Plan? How well do they write (a report) and speak to a group? Are they good thinkers that can cease deliberation, make a decision and execute it? Are they organized and good at following up?

Can and do they plan and follow it? Are they logical, analytical, fair, know when and how to have fun at work? Mature thinkers? And, maybe most importantly, do they "command respect" without demanding it, by their demeanor, their actions, their knowledge, their respect for others, their reliability and integrity?

But wait… before you get enamored with a candidate that seems to have it all or can quickly learn the ropes and settle in as the successor, have you considered others in your own organization? What about those that have learned some-to-many principles of supply chain management and operations management in their current positions? Think about Food Service, Pharmacy, Engineering, even the "Lean Team." What if someone in Administration might be interested and able to take charge of an operation that represents around 50 percent of the operating budget? Have they developed strong relationships with the managers and staff that will rely on them and vice versa?

Next, look at what is out in the market. A search firm can help you see what skills, knowledge, experience candidates have and their current and expected compensation. How does that compare with your requirements and the ability to execute the Strategic Plan? What about your own and the internal potential candidates' qualifications? Or what your employer likely is willing to pay?

If there is someone with many of the needed characteristics, but you are just not convinced, you can have candidates take aptitude and skill tests that can be administered and scored by HR or a third-party firm. Such tests also can identify the accuracy and reliability of your observations about their personal characteristics. Is he or she an introvert or extrovert? Thinker or doer? Decision- and action-oriented?

There is a lot to think about and do when advancing succession planning — from creating a plan to making the offer. Make sure to take the time to think it through, confer with those who have done more of this than you and even someone who has a different perspective than you do (internal source or external search firm). If you do most of the above, you stand a pretty good chance of making the right selection. Just remember: If the successor is not successful, it's not your fault. He or she still must do the job and do it right. HPN

Jamie C. Kowalski, LFACHE, has more than 40 years of experience in healthcare supply chain and expense management as a provider and supplier executive, strategic advisor, thought leader, frequent speaker, author, coach/mentor and supply chain advocate. Following his hospital supply chain career, Kowalski served in executive-level positions at several distributors after 23 years in supply chain consulting. Kowalski is the Co-Founder and Founding Chairman of Bellwether League Inc., and is a member of the Bellwether Class of 2017. He also earned the 2011 George R. Gossett Leadership Award from AHRMM. He can be reached at jamie.kowalski@jckcllc.com.

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