New Independent Studies Show Exergen Reduces Hospital Costs by 90% Compared to Other Thermometers

“Yielded clear-cut cost savings that increased exponentially with increasing duration of use and increasing bed numbers per device.”

WATERTOWN, Mass., May 25, 2017 (GLOBE NEWSWIRE via COMTEX) -- Two new studies from Postgraduate Medical Journal indicate that when used throughout a hospital, Exergen TemporalScanners deliver substantial cost savings while providing accuracy and ease of use, as supported by more than 70 peer-reviewed published studies for all ages and clinical settings.

The first study, “Cost minimisation analysis of thermometry in two different hospital systems [1],” was conducted at University Hospital Centre Zagreb (UHCZ) and University of Michigan Hospitals (UMH), each of which used the Exergen TAT-5000 to evaluate cost savings. Results dramatically favored TAT over tympanic thermometry at UHCZ, where the cost of consumables per measurement would be more than 10 times cheaper for TAT, leading to considerable budget savings within a year of hospital-wide implementation. The UMH study concluded that routine use of Exergen TAT-5000 would lead to cost savings over three years at UMH.

The second study, “Minimising the costs of temperature monitoring in hospitals [2],” revealed that Exergen TAT-5000 savings exceeded $1.7 million when there were 10 beds per device used for five years. In addition, the study indicated that other forms of thermometry such as oral, axillary and rectal are not favored by hospital staff due to numerous factors including time commitment needed from the healthcare provider, patient discomfort and the potential to wake a sleeping patient.

“We appreciate how cost is a critical consideration in hospital purchasing today, and we are committed to providing a product, the Exergen TAT-5000, that delivers significant cost savings,” said Francesco Pompei, Ph.D., CEO of Exergen Corporation. “This has wide implications for maximizing savings, as our thermometer is the single standard of uniform care in hospitals nationwide, giving more healthcare professionals and patients access to its many benefits.”

The above, along with other independent studies, confirm suitability among all patient groups, including premature infants, adults and geriatrics, and under all medical conditions. For a complete list of studies visit www.exergen.com/c.


Renewing the oldest vital sign
Temporal Artery Thermometer validated by more than 70 published clinical studies

BY FRANCESCO POMPEI, PH.D.

Fever was known as a vital sign to ancient Egyptians at least 5000 years ago, using the hand as measuring instrument. Galileo invented the first thermometer 500 years ago. Carl Wunderlich, ‘Father of Clinical Thermometry,’ proposed 98.6°F (37°C) as the mean normal temperature 140 years ago. Until very recently we have been taking patients’ temperatures more or less the same way for more than 500 years, circa 10 billion measurements per year worldwide (approximately half in the US). Can we improve on what we have been doing for thousands of years and countless billions of times? Emphatically yes.

Today’s patient expectations

Importantly, today there is a much higher patient expectation of non-invasiveness. After all, the 10 billion temperatures mean a similar number of probe insertions into a body cavity, causing discomfort and unnecessary indignity, as well as some risk of harm. Patients undergoing cancer treatment are grateful for a reprieve from things that hurt, when their temperature is taken with the latest non-invasive methods. It is not uncommon today for a parent to refuse to permit a rectal thermometer to be used on their child.

Non-invasiveness is unachievable if the vital sign lacks the necessary clinical accuracy. The scientific and engineering challenge is to accurately measure the temperature inside, from the outside. From medical science we have learned that certain external locations have useful properties for ascertaining internal temperature. The ear, for example, has a 50-year history of investigation for thermometry, and in the last 20 years devices developed on this principle have been widely used. Although perhaps less invasive than older methods, inserting a probe into an ear is not what patients consider non-invasive. Further, there are accuracy problems, particularly with small children.

Back to the future

As inventor of much of the ear thermometer technology in use, Exergen was asked by physicians to reconsider non-invasive thermometry, since ear thermometers were not an acceptable solution to the patients’ requirement for non-invasiveness and the clinicians’ requirement for accuracy. Within this context we re-examined the medical science of fever assessment, going back not 50 years, but 5000 years, to the hand on the forehead.

Although never precise enough for clinical accuracy, laying a hand on the forehead provided useful fever indications under certain conditions, and was safe, gentle and a reassuring caress for the patient. Preserving these desirable attributes while making the measurement robust and reliably accurate for clinical use for all ages was the challenge. Our mathematical models indicated we needed to find an easily accessible external skin surface with high and consistent perfusion. We found this property at the superficial temporal artery, where it traverses the forehead. A measurement modality was developed based on scanning the temperature of the skin over the temporal artery, and with proprietary algorithms we could then accurately compute the internal core temperature, for all ages, under essentially all clinical conditions, as validated by more than 70 published clinical studies.

In the past ten years Temporal Artery Thermometry has become widely accepted and is responsible for about 2 billion temperatures per year by medical professionals in the US, a very good start in reducing the number of probe insertions into body cavities and improving the clinical experience for both patients and clinicians. Nearly ten million consumers have home versions for their personal use.

Future with zero cost and zero waste

An unexpected benefit of Temporal Artery Thermometry is that without insertion into a body cavity there is no requirement for disposable probe covers, and simple wiping is adequate. Thus, future operating budgets for thermometry in institutions using only Temporal Artery Thermometers are zero. Furthermore, with disposable waste eliminated, the institution contributes significantly to ‘green’ operations, while reducing storage space and handling costs. In the past ten years, US institutions have saved approximately $500 million in disposable costs, and nearly 50,000 tons in disposable waste. With Temporal Artery Thermometry initial cost is about the same as other thermometry devices available and acquisition cost is typically less than one year of disposables cost, thereby not requiring capital budgeting.
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ASCs, outpatient facilities shouldn’t have to fish for hospital contracts.

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Too many professionals in the healthcare supply chain industry fret about Amazon entering and thriving in the healthcare industry. They should. I apply the previous two-word sentence to both groups mentioned in the lead sentence. Call it a double entendre.

Amazon should jump in and succeed; everyone else swimming in the giant process pool between the buyers and sellers of products and services should be concerned. That’s called competition. Free enterprise. It’s business. And let’s face it: We’re in the business of delivering high-quality healthcare. Consumers expect, demand high-quality healthcare; it’s up to clinicians and administrators in the provider, supplier and payer communities to figure out how to pay for it all and remain comfortably operational.

Indeed, Amazon might drive distributors, dot-coms, GPOs, third-party logistics companies and consulting/service companies out of business because that sea between the shores of the buyers and sellers seems heavily stocked with fish. Amazon might even obviate the need for supply chain departments as we know them, particularly if everyone can make their own cost-effective and cost-efficient purchases online.

Doubtful. Since the late 1980s, a variety of disruptive concepts, ranging from healthcare reform implementations to mergers and acquisitions to integrated delivery networks, dot-coms and supply data standards, were supposed to thin the herd of midlemmen between buyers and sellers.

And yet, here we are experiencing the perceived benefits and liabilities of a well-stocked system of economic transactions.

Healthcare’s proper answer to Amazon: “Bring it on.”

Looking back on 40 years shows so many improvement opportunities smothered by seemingly endless debate and discussion. From the debut of bar coding in the mid-1970s to the Common Category Database in the late 1980s to the Monarch UPN initiative in the late 1990s to electronic health/medical records, GS1 and the UDI within the last 10 to 15 years. We could have been so far along by now instead of so far behind.

Apparantly, nothing short of government fiat will force us to become more efficient and improve. After all, federal authorities legally made us all to switch to digital television sets and pay for content! Instead of debating and protesting, we embraced it and now aim to satisfy our content appetites by feasting on Internet access — easily and readily accessible for convenient consumption.

Like that old more declares: “It’s never too late to be what you might have been.”

Perhaps Amazon can give the healthcare supply chain industry the swift kick it needs to make some progress.

In New York City, Amazon is testing a food store with no cashiers, checkout lines or visible inventory managers. You carry your Amazon-chipped bag through the turnstile, which scans your bag, and your Amazon account is accessed. You pull products off the shelves and place them in your bag. Sensors in the shelves notify the storeroom to replenish stock and sends alerts back through the supply channel. Meanwhile, your Amazon-chipped bag records the selection (even deletes it if you return the item to the shelf) and when you walk back through the turnstile to exit your Amazon account is charged. Linking this to your bank account closes the transaction loop.

Usage data is recorded; replenishment orders are made; theft seemingly is thwarted.

Healthcare facilities easily could affix sensors to shelves and doorways to do the same thing. Such technology has been available for years. Want case studies showcasing success? Call Amazon. Of course, there’s no word on what happens if someone purposefully misplaces product or leaves unwanted product on the floor just to mess with the system.

Amazon makes it relatively comfortable and easy to order products and receive deliveries through 3PL services, too. Who wouldn’t want that from their MMS/ERP or distributor?

Some might say Amazon doesn’t have the clinical expertise to facilitate product, service and technology discussions with doctors and nurses. With the resources of Berkshire Hathaway and Chase behind it, such expertise can be bought through acquisition and/or recruitment.

Instead of expending energy and resources devising ways to defend against Amazon’s perceived encroachment, perhaps the healthcare industry — and patients — would be better served by letting Amazon do the heavy lifting as the first mover and follow their lead?

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FDA warns duodenoscope manufacturers postmarket surveillance study compliance

The U.S. Food and Drug Administration issued warning letters to all three duodenoscope manufacturers for failing to comply with requirements of federal law under which they were ordered to conduct postmarket surveillance studies to assess the effectiveness of reprocessing the devices.

As part of an ongoing effort to prevent patient infections associated with the transmission of bacteria from contaminated duodenoscopes, the FDA in 2015 ordered U.S. duodenoscope manufacturers Olympus, Fujifilm and Pentax to conduct a postmarket surveillance study to determine whether healthcare facilities were able to properly clean and disinfect the devices.

Specifically, as part of their approved study plans, all three manufacturers are required to conduct a study to sample and culture reprocessed duodenoscopes that are in clinical use to learn more about issues that contribute to contamination, as well as a human factors study to assess how well trained hospital staff are following the reprocessing instructions.

“The FDA has taken important steps to improve the reproprocessing of duodenoscopes, and we’ve seen a reduction in reports of patient infections, but we need the required postmarket studies to determine whether these measures are being properly implemented in real world clinical settings and whether we need to take additional action to further improve the safety of these devices,” said Jeff Shuren, M.D., director of the FDA’s Center for Devices and Radiological Health.

The FDA has worked with all three duodenoscope manufacturers that market duodenoscopes in the U.S. to review validated processing instructions and to take corrective actions to remove and replace models from the market with faulty designs that made them difficult to clean and reproces.

On February 26, 2018, the FDA, Centers for Disease Control and Prevention (CDC), and the American Society for Microbiology (ASM) released voluntary standards for duodenoscope surveillance sampling and culturing.

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On February 26, 2018, the FDA, Centers for Disease Control and Prevention (CDC), and the American Society for Microbiology (ASM), together with other endoscope culturing experts, released voluntary standardized protocols for duodenoscope surveillance sampling and culturing.

For healthcare facilities that choose to implement duodenoscope surveillance sampling and culturing, these protocols can be used to help monitor the quality of a facility’s endoscope reprocessing procedures. Adequate monitoring may reduce the risk of infection.

FDA expected Olympus, Fujifilm and Pentax to submit a plan in late March that outlines how study milestones will be achieved. The agency expects 50 percent of testing to be completed by May 31, 2018 and 100 percent by June 30, 2018. If the companies fail to adequately respond to the warning letter, the FDA may take additional action such as seizure, injunction and civil money penalties.

HIMSS Analytics announces collaboration to advance supply chain capacity in global health systems

HIMSS Analytics announced a collaboration with Dr. Anne Snowdon, Professor of Strategy and Entrepreneurship, Chair of the World Health Innovation Network (WIN) and CEO of the Supply Chain Advancement Network (SCAN Health) located at the University of Windsor, Ontario, Canada.

Through this unique initiative HIMSS Analytics will accelerate the development and launch of evidence-based tools to support supply chain transformation in global health systems.

“As technology solutions become increasingly integrated the ability to leverage supply chain tools, processes and information across global health systems becomes essential to improve performance and population health outcomes,” said Hal Wolf, III, HIMSS, President and CEO, HIMSS.

Dr. Snowdon is leading an extensive program of research at WIN, creating empirical evidence of the impact and value of supply chain maturity in health systems. Through her research she works with industry and health systems to design predictive artificial intelligence tools that support clinicians and assess the maturity of supply chain infrastructure across healthcare organizations.

Dr. Snowdon has developed a groundbreaking supply chain maturity tool Health Supply Information Maturity Management (H-SIMM) to support health organizations to assess their progress towards a strategic supply chain infrastructure that contributes to quality, safety and sustainability.

HIMSS Analytics will collaborate with Dr. Snowdon working with her research team to validate the innovative tool, disseminate the findings, and launch the H-SIMM.

Partnering with HIMSS gives us tremendous reach into healthcare systems to accelerate the adoption of leading supply chain best practices and to amplify knowledge exchange to improve performance, safety and health outcomes,” explained Dr. Snowdon.

Dr. Snowdon’s presentation included experiences of global supply system leaders: AHS, Canada — Jitendra Prasad; NHS England — Dr. Charles Alessi; and Mercy, St. Louis, Supply Chain Director, Curtis Dudley.

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and is under-developed in the health sector. This is in spite of the fact that medical error is the leading cause of death in the USA, UK and Canada.

Emerging findings of the global initiative include:

- Transparency of what care patients receive by who, using what products linked to outcomes, cost, safety, quality in real-time.
- Transparency of variation: reduces variation in cost, care processes by patient outcomes.
- Labor savings: 16 FTEs at NHS, 30 per-cent reduction cost/case at Mercy.
- In the USA, Mercy Health System estimated a $1 billion direct outcome of optimizing and transforming supply chain processes across Mercy.

HGPPI chief aims to set GPO record straight about new, innovative product access

If you believe group purchasing organization critics during the last few decades, you likely get the impression that GPOs hold their provider members hostage to contractual relationships with selected suppliers, denying them access to perceived “new and innovative” products, services and technologies available to others outside of a particular GPO.

And those perceptions could not be any further from the truth, according to Phil English, National Coordinator, the Healthcare Group Purchasing Industry Initiative (HGPPI) and a former member of the U.S. House of Representatives (R-PA).

In an exclusive interview with Healthcare Purchasing News, English promoted HGPPI releasing its 12th report in March that touts GPO ethics, fairness and competitive business practices.

“The latest annual report finds GPO organizations participating in HGPPI continue to illustrate a strong commitment to maintaining the highest ethical and business conduct practices in the healthcare supply chain sector,” English said. “Through a variety of measures — interviews, questionnaires, field visits — HGPPI concludes that its members are acting with openness and transparency.”

As GPOs remain focused on their goal to reduce the cost of healthcare products and services to their membership, they also will continue to be on the cutting edge in identifying ways to respond to emerging trends in the healthcare industry that allow them to remain responsive and adaptive.

“In the report, we document in detail the approach that individual group purchasing organizations, as well as the HGPPI compliant parts of the supply chain, apply to making available new products and technologies,” English continued. “The availability of innovation is a founding principle of the initiative, and we have reviewed how competing GPO networks have pursued this access with sustained effort. The process is familiar: Modified contract lengths and review committees, bolstered by technology fairs and internet forums. The results encourage our belief that GPO networks are providing pathways for many new products to enter the healthcare supply chain swiftly and to good effect.”

English argued that HGPPI GPOs grant the access desired by hospitals and other healthcare organizations to companies that claim to offer “new and innovative” products, services and technologies.

“We believe that GPO firms embracing HGPPI are providing innovators with a predictable path to the marketplace based on their value to healthcare providers,” he said.

“Our signatories stress that the evaluation of new products is driven by member input through a developed assessment process and a standing committee structure. The competitive marketplace within the supply chain creates strong incentives for GPOs to make new products available on contract promptly.”

English dismissed accusations that HGPPI-compliant GPOs, regardless of business model, restrict member access to suppliers that don’t have contracts with them.

“To be clear, group purchasing organizations interact extensively with innovative vendors who are not ‘under contract,’” he told HPN. “Hospitals have the opportunity to purchase products directly from vendors who are not part of a GPO. They just don’t get pricing advantages.”

“Participation in group purchasing organizations is voluntary by healthcare providers, and vendors have multiple avenues to sell their products,” English said. “While I have heard and reviewed concerns about innovator companies lacking access to GPO contacts, the reality is that vendors with new products and services have extensive opportunities to participate, as our questionnaires detail.

“While no system is flawless,” English continued, “we see little evidence that the cost saving networks mediated by modern GPO operations are locking out technological advances. To the contrary, we have found that GPO innovation reviews have created access opportunities for breakthrough technologies. We would stress though that this is an ongoing process requiring effort, expertise and a very high level of participation from member hospital systems and other providers. In coming years the ability of GPOs to balance innovation and cost savings will play a significant role in the quality of care.”
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Keep supply lines fluid

ASCs, outpatient facilities shouldn’t have to fish for hospital contracts.

by Rick Dana Barlow

Much of the concentration and focus on supply chain operations in non-acute care settings centers on class-of-trade complaints, ranging from contract pricing to distribution costs to effective but efficient inventory management.

Many participants in supply chain operations recognize and understand (even if they don’t agree with it) the argument behind suppliers charging more for the same products delivered to acute care facilities because they’re generally distributing product in small quantities to geographically dispersed and far-flung facilities. Economically, it makes some logical sense that it costs more to deliver a case of widgets to a remote ambulatory surgery center 100 miles away from a prominent city than a pallet of widgets to a suburban hospital. The service simply costs more.

A number of provider organizations have fought against the pricing and cost differentials by forming integrated delivery networks (IDNs) and launching a centralized warehouse or consolidated service center, assuming the responsibility for remote deliveries as a way to demand and cost-justify unified unit pricing regardless of location.

But these types of ventures as well as sound inventory management per facility type require data that streams from materials management information systems (MMIS) or enterprise resource planning (ERP) systems on the hospital side, fortified by data analytics and supply data standards. As today’s healthcare organizations adopt and adapt to a continuum-of-care mindset, coupled with population health concerns, they are migrating more patient care processes — and responsibilities — to the ASCs and outpatient facilities/departments. Consequently, these sites must have a better handle on their supply chain capabilities.

Clearly, hospital and IDN-based Supply Chain leaders increasingly are assuming responsibility for managing product and service flow through non-acute care facilities, as demonstrated in two separate industry surveys by Strategic Marketplace Initiative (SMI) and Healthcare Purchasing News.

As part of a provider survey of supply chain across the continuum of care in 2016, SMI learned that nearly 95 percent of supply chain executive respondents were servicing non-acute care sites in their provider systems with about 75 percent of that group having done it for at least five years and up as part of their departmental duties. Moreover, nearly half have dedicated a manager or director to oversee the non-acute care program, the survey showed.

ASCs, clinics, urgent care centers and physician offices dominated the list of sites served by Supply Chain, with about 53 percent listing on average up to 100 locations being served, but few involve direct-to-home delivery post discharge, according to the survey.

Nearly 84 percent indicated their non-acute care supply chain program used a common information system that allowed customers to order products and services and manage other related tasks.

Meanwhile, HPN found that supply chain managers directly manage the purchasing and distribution of products and services to nearly 9 non-acute care facilities on average, according to its 2016 Supply Chain Management Compensation Survey, with nearly 37 percent overseeing outpatient surgery centers and nearly 31 percent citing clinical offices.

Last year’s Supply Chain Management Compensation Survey results showed the number of facilities remained on par, but outpatient surgery centers grew to nearly 41 percent and clinical offices nearly 32 percent. For this year’s survey, preliminary results indicate continued reach into the outpatient realm with the number of facilities holding firm for the third year at almost 9, according to the 2018 survey results, with nearly 42 percent servicing ambulatory/outpatient surgery centers. HPN also replaced “clinical offices” as a survey response selection with “physician practices” and “retail/urgent care clinics” for the first time. Nearly 25 percent of survey respondents noted that they provide supply chain services to physician practices and nearly 16 percent provided supply chain services to retail/urgent care clinics. HPN will publish complete results from the 2018 Supply Chain Management Compensation Survey in the June 2018 edition.

How should ASCs and other outpatient facilities/departments pay attention to supply chain operations, specifically in the area of IT and data management?

HPN reached out to a number of supply chain executives with deep ties to the non-acute care segment, asking them to list and explain some of the obvious and obscure supply chain challenges that may be unique to the non-acute or outpatient segment.

Obvious

Ben Winfield, Vice President, Non-Acute and National Accounts, Intalere

“If supplies are generally in the area of one-third of the overhead costs in running an ASC or clinic, it would stand to reason, that supplies would be a focus area in terms of reducing or controlling costs. But in many cases surgery centers and smaller facilities cannot be as strategic regarding supply chain because of resource constraints — that could be anything from manpower, education, training, time, etc. Just keeping up with the day-to-day functions, because many employees are wearing several hats and purchasing may be dispersed, makes it difficult to bring more strategy around that area. Many centers use their nursing staff or administrator for this duty, and many times, multiple people. This leads to no time to explore best price options, off-contract purchasing, no formulary and “rogue” ordering. They recognize the need and they want to be proactive, but they are too busy putting out fires to engage proactively.”

“In the case of a group of facilities, or multiple sites, the issue seems to multiply. Each center does their own ordering and there is no easy way to pull data to aggregate their spend and drive savings by tier level or contracting as a service.”

“Following from these points is the difficulty in thinking beyond just price for products and services. Because they lack resources, data, etc., there can be a lack of understanding in cost vs. quality concerns, the value of standardization and the actual total cost of ownership.”
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SPECIAL FOCUS

Jeff Lawrence, Vice President, Business Development, Inventory Optimization Solutions (IOS)

“Many ASCs share the persistent supply chain challenges of disconnected systems, process gaps, highly manual tasks, and disparate data sets. For these organizations in particular, too much paper and too many manual processes make it very difficult for managers to perform even foundational tasks well. For example, it’s hard to know if they’re getting the best price on purchased products. Limited reporting and analytic capabilities make it difficult to run their multi-facility business efficiently. And often, using paper-based processes means there’s no way to run an integrated supply chain throughout the continuum of care.”

John Cunningham, D.Sc., Chief Client Officer, Lumere

“Data ordering/management systems: Supply Chain needs meaningful system-level insights to make the best purchasing decisions. However, when disparate software systems aren’t integrated across facilities, collecting and aggregating the right data can be extremely difficult. A lot of ASCs use multiple methods outside of the materials management information system (MMIS) — when one exists — to acquire products. For example, they may call in for overnight delivery or same-day trunk stock from sales reps. This can lead to unnecessary shipping and freight costs as well as higher, off-contract pricing. I’ve seen many outpatient facilities that track products ordered over the phone and using a pen and legal pad. Clearly, that kind of analogue tracking is a roadblock to effectively analyzing order history and product need.

“Inconsistent or nonexistent item masters/formularies: As we see healthcare systems increasingly shift toward value-based care, widespread, unwarranted clinical care variation makes it impossible to effectively control costs and provide consistent care. However, without the right focused initiatives, sustainable product standardization can be difficult to achieve, regardless of location. Outpatient facilities often don’t have visibility into what products are on contract and or on formulary. This inevitably leads to greater variation, especially when physicians are accustomed to having access to a range of products from multiple vendors.

“Inventory management: In some inventory processes, outpatient facilities have to wait longer to receive supplies. This can lead to ‘just-in-case’ ordering and stockpiling — meaning that clinicians will order products whether the need currently exists or not, unintentionally causing excess or duplicate inventory. Because supplies are usually housed in multiple locations and infrequently audited, you end up with a large carried expense and the potential for expired stock.”

Michael DeLuca, Executive Vice President, Operations, Prodigo Solutions Inc.

“Large IDNs — with some exceptions — that have huge non-acute care business units are using visualization technologies like Tableau or Business Intelligence solutions like IBM Cognos to report out. But what are these providers doing with the data? How are they effectuating change in their organizations? I still believe that some basic blocking and tackling is missing in the healthcare supply chain. Average contract utilization is still 57 percent, and only a handful of IDNs are using demand planning and thinking about forecasting demand to lower the cost curve, and an average of 30 percent of spend is not tied to a purchase order. These are the basics and represent the first inefficiencies and cost savings initiatives that should be used from the data being gathered. And these basics should absolutely apply to the non-acute continuum. Non-acute care operations should not be immune from the same contract compliance, procure-to-pay efficiencies, and cost savings goals as their acute care counterparts.”

Scott Jackson, General Manager, Healthcare Services, Henry Schein Inc.

“Twenty-five percent to 30 percent of an ASC’s budget is consumed by supplies. This compares to just 10 percent to 15 percent in the hospital setting, and 3 percent to 5 percent in a clinic setting. An ASC’s overall financial performance is significantly impacted by how well they manage their supply chain.”

Obscure

Winfield: “Something we are hearing more often from members is lack of systems’ interoperability. Those who are maybe ahead of the curve and have initiated some sort of automation or technology solution are finding, in some cases, that systems are not able to communicate with each other, causing new challenges they had not anticipated. So in automating and hoping to take steps forward in becoming more strategic about supply chain, they have actually been faced with new challenges.”

Lawrence: “Many of the Supply Chain managers I talk with will say their supply chain processes aren’t particularly good. But the hard part is defining what ‘good’ — or especially best-in-class — might look like. Among ASCs, there aren’t easy ways to obtain and share best practices. In my role, I work across many organizations, and have found I can offer industry perspective to help determine specific supply chain objectives, then compare those to best practices. Once an organization has objectives clearly defined, a roadmap can be developed, and the work to improve supply chain efficiencies by implementing new technology and business processes can begin.

“The key to ensuring success is getting executive support as objectives are defined, systems are evaluated, and finally, new technology is selected. Through executive leadership, effective communication to the entire organization can take place, letting team members know of the strategic decision to more effectively manage supply chain. In many organizations, it helps to leverage leadership to present the value to the organization, the value to the individual, and to reinforce the need for regular reviews for compliance and success. Having top-to-bottom organization alignment of this key initiative drives toward a stronger supply chain.

Cunningham: “To optimally drive efficiency and manage variation, Supply Chain must have focused conversations with physicians that are driven by patient outcomes, not cost. Historically, physicians and Supply Chain have at times struggled to align on these issues, and Supply Chain is often hesitant to leverage the work they are doing with acute care clinicians to make positive changes in the ASC space. Overcoming this mindset can be a huge cultural shift, requiring the resources of the organization’s outpatient facility presence, supply spend and utilization data can have a significant impact on system-wide decisions. However, outpatient facilities typically are not stakeholders in the strategic sourcing process and aren’t involved in decision-making. Additionally, the data that they use when considering product contracting or conversion are often incomplete, resulting in unmet needs.

“Freight and shipping costs often only appear on invoices and are notoriously difficult to manage and mitigate when data are lacking or inaccessible. For ASCs receiving high-dollar implants and devices, these costs add up quickly. Supply Chain regularly addresses these costs in the acute setting; however, outpatient facilities frequently have products arriving via multiple avenues, which means that Supply Chain must ensure no fees are paid that unless they were previously negotiated.”
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**DeLuca:** “The distribution network typically used by IDNs to service their non-acute care operations drives toward a low-volume distribution provider. The network is typically not served by a Consolidated Service Center. However, the control and compliance goals are the same. Providers must use the same rigor around formulary management with their non-acute business as they use with their acute care business. This ensures committed volume to their distributor of choice (e.g., Amazon, McKesson, Seneca, etc.). However, a challenge does present itself in the non-acute care arena — switching costs — which are often times as low as a new distributor walking in the front door and asking, ‘What are your top 15 items by volume?’ I’ll lower the price by X percent, and you can buy directly off my eCommerce site.” The progressive [Supply Chain leader] understands this challenge, and uses the economies of scale provided by their ERP system and online marketplace to thwart it and add control and compliance. The footprint of items in a physician’s office should look the same in office 1 as it does in office 400. Drive formulary control across the non-acute care setting to achieve further savings.”

**Jackson:** “ASC staff members are not trained on how to effectively manage a large and complex supply chain. Hospitals have Materials Management departments, staffed by trained Materials Managers. An ASC likely has a nurse who has been given the responsibility to manage supplies, but was trained to be a nurse, not a materials manager.

“ASCs also may have limited use and adoption of available supply chain technology. Effective supply chain technology platforms are available for ASCs, yet there has been a limited rate of adoption by ASCs to either fully utilize their existing operating system supply chain functionality, and/or utilize existing bolt-on materials management systems, which can interface with their current operating systems. Adoption rates are low due to the perception that the extra technology costs do not outweigh the benefits, or just lack awareness that they are available.”

“ASCs transact with multiple layers of vendors, which creates challenges related to effective price management, [purchase order] management and invoice reconciliation. This is exacerbated by limited adoption of supply chain technology. ASCs also tend to have very limited stocking and storage space, which creates a demand for just-in-time inventory replenishment, which leads to stockouts and expedited shipping rates.”

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**Tips, tools for managing ambulatory/outpatient facility supply chain**

Healthcare Purchasing News asked supply chain executives working in the ambulatory/outpatient arena for overt and covert ways to help an ASC or outpatient facility/department improve its supply chain operations. They shared more than 40.

**Overt**

**Ben Winfield, Intalere**

Most simply, software, through even a basic materials management information system, can provide benchmarks and goals for organizations to use to reduce extreme variability in pricing in both commodities and implants. Data derived from a materials management information system (MMIS) can also assist in:

- **Aggregation** — Systems can collect the proper data to aggregate spend across multiple facilities. Today, many work in silos and aren’t leveraging their buying power.
- **Tier Optimization** — An IT platform provides the data to assist facilities in optimizing tiers and adjusting spending to achieve the higher, more cost-effective tier levels.
- **Purchase Orders** — Today, many organizations have multiple POs from possibly hundreds of vendors at each site. With an IT platform, facilities can assure POs are pulled in one system and paid more efficiently and correctly.
- **Formulary Purchasing** — Many facilities do not have a purchasing manager, therefore, there are many people ordering. With an IT platform, a formulary can be built and pre-approved to ensure purchases are contract-driven. This can also minimize off-contract or rogue spending.
- **Contract Compliance Purchasing** — An IT platform will help drive contract compliance, which will lead to better vendor relationships and offer better negotiation leverage with those vendors.
- **Comparable Items** — An MMIS system can also provide alternatives, clinically equivalent comparables that can possibly be purchased at a better price. This will drive better purchasing decisions and savings.
- **Paying the right price** — Just because you placed an order for an item at a given price does not mean you will be invoiced for that price. MMIS can ensure a 3-way match so that you realize the savings you are projecting on the front end.

**Jeff Lawrence, Inventory Optimization Solutions (IOS)**

- **Order preparation** — I’ll go out on a limb and say we agree pen, paper and Post-Its might not be the best method for capturing products that need to be reordered. Bar-code scanners that easily capture barcode labels on all needed products from all vendors can save a tremendous amount of time.
- **Order approval** — Getting purchase order (PO) approval before submitting to suppliers is critical to saving money, and while conceptually this makes sense, it doesn’t always get prioritized. Shifting approval to the front end of the purchasing process can drive significant reductions in orders for products that aren’t needed. Example: An approver may know there’s more product in the nurses’ closet or that a sister facility is overstocked a particular item. People often believe they don’t need to approve orders before they’re submitted — that approving an invoice is doing the same thing, but that can cause an organization to purchase products that aren’t needed, so always shift approvals to the front end of the purchasing process.
- **Order submission** — We need to streamline order submission, so supply chain personnel aren’t logging into multiple websites, standing by fax machines or waiting on hold with customer service. Technology that places orders via electronic data interchange (EDI), email or autofax is a huge time saver.
- **Two-way vendor communication** — By leveraging EDI technology, users can establish a pipe from their system to their supplier network that exchanges information both directions. Send out a PO and receive back an electronic order acknowledgement, know when that product has been put on the truck and is on its way, and get an electronic invoice.

**Mobile apps** — 92 percent of Americans have smartphones, and constantly have their device in their hand — even at work. With this, business apps on mobile devices are game changers. New supply chain apps can help by supporting the user wherever they are. Users can submit orders electronically from an app that in turn, an approver can approve and instantly submit. Mobile apps can help users complete an accurate ordering process easily and seamlessly.

**Tracking costs for better business management** — I recently spoke with a large surgical department director who used two numbers to manage his business: Total revenue and total cost. We have to run our businesses with numbers. As we push more patient interactions outside of the hospital, we need to capture information to know costs by location, department, specialty, physician, patient, case, etc. Today, technology can help managers at ASCs manage their business plans against real numbers, performing tasks like tracking the movement of inventory across the entire non-acute network.

**Product formulary** — One of the biggest challenges for multi-location organizations is defining a list of best practice/contracted products and enforce purchase compliance across multiple locations. Users can work with a GPO to define products that can be standardized and make sure contracts are activated. A GPO can help work with the suppliers to make sure contracts are activated and the ASC is receiving contracted prices. Then items can be loaded into the procurement system so all locations and departments are buying off the same list of contracted products. It’s key that the procurement system includes all vendors and all products, and makes the shopping experience easy for all locations.

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**SPECIAL FOCUS**

From page 14

standardized at the organization level — without having to install hardware or go through a rigorous implementation at every location will greatly reduce staff time and investment.

**John Cunningham, Lumere**

- **Materials management information system** — A materials management information system will enable the ASC to, at minimum, address its order processing and inventory and data management needs with automation. By doing so, the ASC will increase the reliability and effectiveness of its Supply Chain as well as provide the data necessary to manage the Supply Chain.
- **ASC-specific EMR** — An EMR should be tailored specifically to the unique needs of an ASC, without features and functions that are not relevant to the facility. With the growing types of procedures that ASCs are licensed to perform, the need to document and retain electronic records for patients is even more important. For example, in the future, when ASCs are performing primary arthroplasty procedures on Medicare covered lives, the longer-term retention of implant records will be required.
- **Instrument tracking** — With these new procedures will come a whole new set of instrumentation and, like the inpatient surgical suites in the mid-80s, ASCs will require IT to aid in the management of the instrumentation, thus a tracking system can provide benefit to the ASC.

**Michael DeLuca, Executive Vice President, Operations, Progido Solutions Inc.**

- Extend the footprint of your ERP into your non-acute care setting. Leverage the economies of scale it provides.
- Use a marketplace to extend the ERP and provide the same level of e-Commerce shopping the non-acute care employee desires, but with added compliance and controls in the background.
- Use Inventory/PAR management where needed. Do not let it be a decision for company business. It likely is overall in most non-acute care settings.
- Use hardware agnostic technology to drive efficiencies and for track and trace purposes. This will decrease your technology footprint, but provide the same level of control and sophistication.
- Apply the same big data, analytics and visualization technologies for non-acute care, non-clinical spend as you likely already do with clinical spend.
- Integration of technology costs money and makes upgrades harder...decide on the right mix of “best in breed” versus “good enough.” Non-acute care settings are not a supply chain mystery. They are a smaller version of acute care that in aggregate make a similar impact.

**Scott Jackson, Henry Schein Inc.**

Here are five examples of Materials Management functionality that can be adopted by ASCs. This functionality can come by either fully adopting existing ASC operating system’s inventory functionality, and/or investing in bolt-on MMIS technology platforms that interface into existing operating systems.

- **EDI Functionality** — EDI functionality, when utilized, allows for multiple vendor electronic ordering from one platform, automatic invoice reconciliation and effective price management with pricing acknowledgments and advanced price change notifications
- **Manage Perpetual Inventory** — Always know how much inventory is on hand by utilizing available technology
- **Manage PAR Levels** — Set mins and maxes so that you don’t stock out, have too much or too little inventory on hand
- **Incorporate Bar-code and or RFID technology** — Utilize your smart phones to automate the ordering process with highly efficient barcode and RFID ordering as this can cut ordering time in half

**Cunningham:**

- **Preference cards** — Regardless of care setting, updating preference cards often feels like a daunting task. However, given the lean margin space of ASCs, using technology to aid in working with high-volume physicians to review and update cards can significantly reduce cost per case and clinical variation. It also leads to better inventory management.
- **Broader device catalog** — Because ASCs have historically had a more limited portfolio of procedures and less device intensity, they largely have not needed access to a broad catalog of medical devices for comparison of equivalence, attributes and safety data. However, with the growth in device-related outpatient procedures, ASC will require and benefit from technology that provides greater insight into the selection of devices.
- **Learning management system** — ASC have traditionally been able to operate with a much smaller compliment of staff who perform multiple functions rather than the specialization that we see in the inpatient surgical suite. For example, an ASC may have surgical technicians that perform scrub nurse, instrument technician and supply chain functions. However, as the complexity of ASC procedures increase, these functions are becoming more and more difficult to not specialize, leading to broadening education and training backgrounds of the ASC staff.

**DeLuca:**

Not much obscure about it: Use your centralized supply chain organization to decide how to best service the non-acute care entities, then drive compliance and control by extending your existing IT footprint into the setting, leveraging existing economies of scale, and driving the most efficient, cost justified distribution process. Put contracts in place with pricing that represents committed volume, and use the process you have designed to live up to those commitments. If your users want an Amazon experience, give them one that is controlled by leveraging a marketplace that provides the shopping experience of Amazon, but the control content of Google.

**Lawrence:**

- ** Electronic 3-way match and invoice approval** — I started my career as an auditor/CPA, so electronic three-way matching as an afterthought causes me pain. How many organizations just pay an invoice and hope that the quantity and price are accurate? The CPA in me wants to stand on my chair and shout, “make a three-way match!” Create a PO with accurate pricing, make sure you record the receipt transaction so you know the quantity that should be paid for, and ensure the invoice matches the confirmed price and quantity. Stop hoping the invoice is accurate. Know that it is! And if it isn’t, stop and save the money.
- **Automate a high percentage of order confirmations** — Hidden within the EDI discussion is the very important order confirmation process. Often ASC team members need to shift among multiple roles, so it’s hard to find time to confirm that orders are received and being processed. By combining EDI technology and advanced email confirmation tools, users can confirm a very high percentage of orders electronically. When this information is delivered back into the supply chain system, users can simply manage orders by exception.

**Jackson:**

- Invest in auto-replenishing technology that knows what your PAR levels are, and that automatically creates POs that are electronically sent to your vendor partners, thereby eliminating the manual component of ordering.
- Invest in a Physician Preference Item (PPI) Benchmarking platform. There are new, cloud-based PPI Benchmarking systems that allow hospitals and ASCs to better understand how their PPI costs for PPI items compare to those costs at other hospitals and ASCs. This can be an excellent negotiating tool when you are attempting to drive down the high costs of implants and devices.
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Clinical assessments help ASC’s reach target goals

Advances in medical technology, pain management, and anesthesia now make it possible for surgeons to perform outpatient operations that were once considered too risky to do anywhere else but in a hospital OR. Last year, for example, the Centers for Medicare & Medicaid Services (CMS) finalized the removal of total knee arthroplasty from its inpatient-only list, indicating that some ASCs will experience higher patient volume, require additional surgical supplies, and take on more inventory management responsibilities than usual. To succeed, some ASCs may need to modify current processes and practices.

“More complex procedures are moving to the ASC requiring more supplies and technology to support those services, including instruments, sterile processing support, etc.,” said Bilinda Garlock, RN, BSN — Manager of Clinical Operations at Cardinal Health, Ambulatory Surgery Centers. “There’s more competition, more ASCs being opened that are connected to hospitals to reduce the strain on hospitals.”

New research suggests a 4 percent decrease for inpatient surgery with outpatient procedures expected to increase by 11 percent now through 2022.1 The 2016 21st Century Cures Act, which gives Medicare beneficiaries a public database to compare the costs of surgical procedures at outpatient and ambulatory surgical centers, also adds to the competitive dynamic. Plus, as more complex surgical cases continue to shift from hospitals to ASCs, these smaller facilities will also need to comply with new and changing regulatory requirements, reimbursement rules, and patient satisfaction expectations.

Gearing up for future growth

For ASCs to thrive in a changing healthcare climate there are many significant factors to consider. ASCs and surgical hospitals need dedicated supply chain management practices to guide and sustain good clinical outcomes, optimal workflows, and keep a positive reputation amongst a rapidly increasing patient population. Is your ASC poised to embrace what’s coming? Consider a few questions:

• Are the medical supplies in your ASC used only where and when they are required?
• Is the charge-capture process accurate on every case, or are there too many missed billing opportunities?
• Are preference cards current and custom packs filled exactly right?
• Do you have appropriate technology in place to collect and analyze the data needed to make strategic decisions, standardize items and maximize purchasing?
• Are patient satisfaction scores where you want them to be?

If you can answer these questions affirmatively and accurately, that’s great news. But for many ASCs — maybe even yours — the answers to some of those and other questions are either unknown or nebulous at best. What the majority of ASCs do know is that they could probably do better if they knew how, and could find the time needed to focus on making improvements. If you can’t measure what you don’t know, you can’t determine the necessary steps to achieving better outcomes. Which means realizing progress first can be quicker to make decisions.

“ASCs are different

While ASCs and hospital ORs do share some common ground, there are distinct operational and purchasing differences between them. A clinical assessment by the supply chain and clinical experts at Cardinal Health help those working in the ASC arena determine those dissimilarities and better understand why processes that work well for one facility could actually be a disadvantage to the other. “These are two entirely different environments,” said Garlock. In fact, under certain circumstances, Garlock says ASCs are in a somewhat better position to implement lasting improvements faster and with less difficulty than a hospital would. “ASCs are more streamlined and less complex,” she said. “They can change practice and process quicker with less layers of complexity to get through and can be quicker to make decisions.”

Strategies that work well in the hospital environment don’t always produce the best results when practiced in the ASC. For instance, outpatient settings rely on fewer staff to manage varying responsibilities. To achieve efficiency and savings requires that ASCs take

Identifying your needs

A comprehensive, no-cost2 to you clinical assessment of your ASC from Cardinal Health can give you the answers — and the solutions — you need to identify problem areas, implement effective solutions, and accomplish your goals. Supply chain and clinical experts from Cardinal Health know how to help increase quality and advance the bottom line with inventory management processes designed to work in your ASC’s favor, not against it. The clinical assessment process helps ASCs find ways to support safety standards, increase compliance, optimize procedure packs and eliminate surgical waste. You will learn how to maximize your existing space and capitalize on current or new technology. A clinical assessment with Cardinal Health can also point out and address inefficiencies that you may not have been aware of before. You might discover ways to reverse poor turnover time, enhance physician satisfaction and more — all while keeping costs down and patient satisfaction scores up.

“We can bring our vast knowledge from being in many ASCs across the country to offer solutions to issues identified; inventory management, case pick, custom pack solutions, and standardization opportunities,” said Marvella Thomas, RN, MSN — Sr. Consultant of Clinical Operations at Cardinal Health, Ambulatory Surgery Centers.

A clinical assessment by the supply chain and clinical experts at Cardinal Health help those working in the ASC arena determine those dissimilarities and better understand why processes that work well for one facility could actually be a disadvantage to the other. “These are two entirely different environments,” said Garlock. In fact, under certain circumstances, Garlock says ASCs are in a somewhat better position to implement lasting improvements faster and with less difficulty than a hospital would. “ASCs are more streamlined and less complex,” she said. “They can change practice and process quicker with less layers of complexity to get through and can be quicker to make decisions.”

Strategies that work well in the hospital environment don’t always produce the best results when practiced in the ASC. For instance, outpatient settings rely on fewer staff to manage varying responsibilities. To achieve efficiency and savings requires that ASCs take
a different approach. “Hospitals have more defined roles, where ASC staff wears many hats,” said Garlock. “ASC staff must accomplish more with less. This can narrow the amount of time ASC staff would ordinarily take to focus on supply chain management activities. As a result, it’s not uncommon for ASCs to rely on manual processes (e.g., using pen and paper or visual eyeballing) to order supplies instead of ordering based on actual usage. Hospitals, on the other hand, have dedicated IT teams that can access and utilize data and technology to manage their inventory.”

Leveraging your uniqueness
The clinical assessment process is designed to help ASCs recognize their strengths and use them to their advantage. But even ASCs are unique and can differ widely. “Every ASC is different and identifying issues in one center doesn’t mean all centers are having the same issue,” said Thomas.

One example is Madison Outpatient Surgery Center, a Mississippi provider that realized it was generating lots of waste and relying on too many off-the-shelf items during procedures. Yet, they had trouble pinpointing just how much waste they were creating and why. Cardinal Health performed a clinical assessment and found that the ASC was using procedure packs modeled after the ones used by a sister ASC, despite the differences in procedures each one performed. After making changes recommended by Cardinal Health the facility was able to save several thousands of dollars a year by reducing per-case supply costs, standardizing products, improving room turnover time and other changes.3 ASCs that undergo a clinical assessment also learn to maximize existing space — an ongoing challenge for most facilities — with a variety of creative solutions including ideas that may seem simple at first but only thought of during evaluation. “For example, hanging instruments on the wall using something as simple as a peg board instead of storing them in drawers results in better space utilization and decreases the potential for breaks in sterility,” Garlock said. “We also find some ASCs with limited time could benefit from adopting a different process for following regulatory requirements. We might remind them of certain processes they need to take during a clinical assessment and suggest solutions that will ensure they stay consistently on track.”

More specialized surgeries taking place in the ASC — right now and in the future — also means there will be a need for more medical equipment and supplies. A clinical assessment can help determine where to focus your cost-cutting strategies. For example, “What resources can an ASC lease, consign or borrow to lessen financial burden of a new specialty?” said Garlock. “There are enhanced IT offerings available for the ASC space; many vendors are offering barcode technology to order supplies, etc.,” added Thomas. “Tap into IT vendor resources, especially if you have new staff, or materials managers, who have never been trained on how to use technology to manage inventory.”

As you can see, numerous opportunities for improvement exist — it’s just a matter of discovering what they are. If you want your ASC to do better, a clinical assessment from Cardinal Health can show you how. For more information, or to request a clinical assessment for your facility, visit cardinalhealth.com/surgerycenter or email Cardinal Health directly at ASC@cardinalhealth.com.

References:
1 Sg2 Impact of Change (IoC) 2017
2 If customer receives any “discounts or other reductions in price” under Section 1128B(b)(3)(a) of the Social Security Act (42 U.S.C 1320-7b(b)(3)(a)) from Cardinal Health, Customer may be required to disclose the discounts or reductions in price under any state or federal program which provides cost or charge-based reimbursement to Customer for the products or services Customer buys from Cardinal Health, or as otherwise requested or required by any governmental agency.
OPERATING ROOM

Savvy scheduling in the surgical suite

Today’s technology boosts productivity, satisfaction and revenue

by Valerie J. Dimond

Getting prepped and rolled into the operating theater for a surgical procedure is one of the most important days — if not the single most important day — in a patient’s life. That’s according to Erin Kyle, DNP, RN, CNOR, NEA-BC, Perioperative Practice Specialist, Association of periOperative Registered Nurses (AORN). For a variety of reasons, this is probably an accurate assessment. However, it’s probably true also that most patients aren’t thinking about (nor should they have to) the many variables that go into scheduling their case that day and how fundamental the process is to the operation’s success or failure. “The complexity of surgery is now at a level where changes can happen on a daily basis,” Kyle said. “Coordinating all of the people, equipment, and supplies at the time of scheduling can literally look different from day to day for the same procedure type with all of the advances in technology. In today’s technologically advanced society and especially in healthcare, many details are inputted into scheduling programs that feed into workflows for all that coordinate care of the patient,” said Kyle, citing an automated internal defibrillator implant procedure as an example: “Scheduling is responsible for inputting information and informing all of the specialists and caregivers who are needed for the procedure. In this case, the imaging department and the device representative must be present for the procedure for device placement and programming. If accuracy in scheduling breaks down, all of the key players may not be present with all of the needed tools, supplies, and implants needed for the case at the right time.”

Scheduling mistakes and their consequences

Consistent accuracy and throughput requires the successful management of many interlocking components. As Kyle pointed out, miss just one and it has the potential to create a negative ripple-effect on surgical outcomes, time, patient satisfaction and money; and it most certainly frustrates surgeons and causes undue stress and anxiety for the entire surgical staff. “The top three challenges facing perioperative professionals are on time starts, room turnover and add-on cases,” asserted Eric Burch, Associate Principal, Vizient, Inc. “Failing to start on time throws your schedule off and even one delay has a cascading effect on every procedure that comes after. Optimal surgery scheduling is one which keeps all required staff informed and ready to meet the needs of the patient and the surgeon.”

Gavin Fabian, CEO, Casetabs, believes if OR staff is struggling to keep cases organized and on track then communication and coordination are probably the top culprits that need to be addressed. “There are many moving parts when scheduling a case and seeing it through completion,” said Fabian. “Ensuring everyone involved is properly scheduled and kept up-to-date on any changes or

PATIENT CONNECTION

AORN Syntegrity, Inc., and IMO create consolidated surgical scheduling procedure list

AORN Syntegrity, Inc., provider of the premiere perioperative documentation system, and Intelligent Medical Objects, Inc. (IMO), the developer of the most widely-accepted medical terminology solution for the management of medical vocabularies and software applications at healthcare organizations worldwide, have announced a technology partnership in conjunction with the launch of a new product, PeriopIT.

PeriopIT combines AORN’s perioperative care expertise with IMO’s clinical terminology expertise to create a surgical scheduling solution that works behind the scenes in operating room scheduling systems and EHRs to improve patient outcomes and increase revenue.

As a surgical scheduling solution, enhanced with AORN Syntegrity, PeriopIT is mapped to healthcare code sets, aids in meeting regulatory requirements thus ensuring maximum reimbursement, accurate scheduling, and defining workflow efficiencies for the perioperative setting. It will enhance claims and reporting workflows, optimize communication and patient outcomes, improve procedure scheduling, and reduce operation and IT workloads.

Minimally invasive surgeries underused in older patients

A study of more than 200,000 Medicare patients who had common surgical procedures shows that, compared to the general population, they underwent far fewer minimally invasive operations, whose benefits include lower rates of complications and readmissions, along with older patients.

Minimally invasive surgeries—such as those for cholecystectomy (gallbladder removal), bariatric, colectomy, hysterectomy, inguinal hernia, thoracic and ventral hernia.
updates is a difficult task, especially considering many of these people work outside of the facility."

Getting it right requires taking a multi-pronged approach fueled with smart people, processes and technology. And while advanced technologies are available to mitigate challenges and support scheduling tasks, some departments still rely on inefficient, antiquated tools and methods to schedule cases. “It is usually a fatal combination of technological backwardness and improvised, sometimes haphazard, processes,” suggested Justin Rockman, Vice President, Sales and Development, Surgimate. “The irony is that in the U.S., the world’s most advanced surgeries rely on the least-advanced back-offices. We’re talking about an industry that still considers the fax machine a daily workhorse! Not once have we encountered cutting-edge practices still using typewriters and couriers to shuttle paperwork between facilities. They’re decades behind the curve when it comes to real-time communications, cloud-based applications, and digital collaboration tools.

“Surgeries have become hugely complex events, with up to 50 individuals involved in a single surgery. These stakeholders experience major challenges sharing patient data as there is no interoperability between systems,” Rockman added. “Even though groups are entering information into digital systems, sharing that information still means generating mountains of paperwork.”

It would seem unrealistic then — even risky — for a surgical department to continue storing case-related data in separate silos and using error-prone methods to disseminate it.

For those who are ready to invest in an upgrade, plenty of sound solutions exist.

The cloud with the silver lining
Among the surgical teams that have adopted advanced OR scheduling software, most will choose a cloud-based structure — and for good reason, according to suppliers and end-users. Unlike traditional phone, fax and text delivery, methods that are still in use at many hospitals, cloud-based scheduling systems collect all inputs and simultaneously deliver up-to-date communications to everyone involved in a surgical case, provide robust predictive analytics, and other useful components that can help facilities discover opportunities for substantial growth and savings.

“Similar to a project management tool, a cloud-based surgery coordination system simplifies tasks by providing an at-a-glance view of where a patient is at each step of the case, from scheduling all the way through discharge,” explained Fabian, Casetabs. “These systems allow case teams to be easily added, enabling communication and coordination to ensue around the case. Phone, fax and text updates are replace by automated alerts sent to every person involved in the case, including vendor reps, each time an update or request is made which ensures everyone remains current on case details. When using a cloud-based system, information is easily accessible to those who need it, regardless of location, either through a laptop or mobile device such as an iPhone or Android.”

Casetabs tested their scheduling technology with participating surgery centers which Fabian says relied on a system that entailed a near-total of 25 touch-points, including calls, texts, emails and whiteboard updates. The Casetabs system whittled it down to just five touch-points and a central hub that gave everyone involved in the procedure universal access to case information in real time.

“Crown Point Surgery Center is a great example,” said Fabian. “With 450 cases each month, the center’s clinical and business office teams were spending significant labor hours on surgical case communication and coordination. Simply trying to ascertain where each patient was in the pre-op process was labor intensive and prone to error when relying on traditional manual methods. After implementing Casetabs, Crown Point was able to greatly reduce communication touch points. The result was more than $6,500 in savings per month in labor hours (82 front office hours and 123 nursing hours per month)."

The technology also connects physician offices with surgery centers and hospitals, which in turn increases case load and revenue.

“Buena Vista Surgery Center’s Medical Director, Dr. Raymond Raven, cites a 10 percent increase in case volume since deploying Casetabs,” continued Fabian. “He attributes this increase to the ease of which physician office staff can conveniently and safely schedule cases at his center. According to Dr. Raven, the center has seen a direct path from cloud-based surgery coordination to increased caseloads.”

Sanjeev Agrawal, President and Chief Marketing Officer, LeanTaaS, says seamless surgical scheduling means employing technology that will deliver a marked improvement to existing workflows. “It’s one of optimized scheduling through predictive analytics, which technologies like mobile, cloud and machine learning make possible,” Agrawal said. “Identify and make available block inventory to surgeons and clinic schedulers needing block time. Let them easily discover and request/release blocks with a single click on their mobile device. Eliminate the need for phone calls, emails and faxes. Monitor booking patterns to identify blocks that are likely to be underutilized.”

Agrawal says UCHealth implemented the LeanTaaS system and was able to increase overall financial performance by more than $450,000 per OR per year. “Average aggregate block utilization is up by over 4 percent; 11 new surgeons have been hired into the system despite a lack of permanent block time for them,” he said. “Release lead times have lengthened to almost 27 days, allowing more surgeons access to the OR more often. Block allocation is a fairer and more data-driven process. Surgeons and administrators have more trust in the data upon which block allocation decisions are made.”
For facilities using the Surgimate product, they too are enjoying impressive results. “One practice was able to cut booking time by 47 percent, which directly lead to surgical volume growing by 24 percent,” said Rockman. “Another practice was able to more than double their MD team from 19 to 43 surgeons simply by implementing a uniform workflow that allowed them to scale economically. Other clients have used our software to quickly rebook surgeries cancelled due to unavoidable circumstances, thereby capturing revenue that would otherwise have been lost. In addition to the tangible benefits Surgimate delivers, it also improves the everyday working environment of thousands of doctors and staff by reducing confusion, stress, and friction.”

“Hospital IQ offers hospitals a cloud-based operations planning and management software platform that enables hospitals to leverage their existing data to improve the delivery of perioperative services,” said Jason Harber, Vice President, Product Management. “A leading hospital in Boston used Hospital IQ’s perioperative solution to enable surgical service managers to better manage and measure individual surgeons. Within two weeks, all of the hospital’s data was loaded and the hospital was ‘mapped’ in the data analytics system. Service managers have ‘dedicated views’ of their departments that allow them to monitor and manage services on a daily basis. OR managers share bi-weekly reports that accurately track performance and utilization. This shared accountability framework for both service managers and individual surgeons has led to volume increases and improved OR utilization. The hospital has increased OR volume by 3 to 5 percent annually, resulting in an incremental annual revenue increase of $3 million, without adding cost.”

Better building blocks

Today’s OR scheduling systems are clearly changing the way facilities organize surgical cases and can provide vast improvements across the board, especially when used properly and options are explored thoroughly to identify additional areas for improvement.

“Technology can help, or it can be a barrier; it is up to the team to ensure that process and technologies complement one another to facilitate accurate surgical scheduling,” said Kyle, AORN. “An example of technology coordination could be interface between scheduling software and physician procedure cards. Naming of procedures and selecting the appropriate procedure card can be extremely challenging for schedulers.”

Harbor added, “Once the technology is in place, leadership can look at new strategies, such as service line management, to appoint leaders to manage scheduling and drive volumes for each of their services. And it’s not just about discarding the old way of crunching data: leadership must have progressive views to engage surgeons and hold them accountable for their use of OR time.”

Kyle says facilities can also make collaborative efforts between stakeholders an enjoyable process in which traditional methods actually do continue to work well. “One organization scheduled quarterly breakfasts that included surgery schedulers, schedulers from clinics, and perioperative nursing leaders to address any changes to processes and to field questions from clinics,” she said. “This created a very collegial environment that literally brings key players together and was extremely helpful in humanizing teamwork among those who communicate almost exclusively via phone and email.”

**SurgiMate scheduling software**

**Hospital IQ scheduling software**
## Explore the Benefits of ATP Cleaning Verification

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<tr>
<th><strong>Verify Cleaning</strong></th>
<th>Ensure the effectiveness of your cleaning program</th>
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<td><strong>Prevent HAIs</strong></td>
<td>Increase cleaning thoroughness and improve patient outcomes</td>
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WHO says Disease X could be the next global pandemic

The World Health Organization (WHO) recently listed a range of lethal diseases that have a potential to cause global outbreaks, including a new one they’ve termed “Disease X.”

In February, during the 2018 annual review of the Blueprint list of priority diseases, a Geneva-based group of renowned medical scientists used a special tool to determine which diseases and pathogens to prioritize for research and development. The tool seeks to identify those diseases that pose a public health risk because of their epidemic potential and for which there are no, or insufficient, countermeasures, stated the WHO.

The scientists say they do not know what Disease X is exactly – because it hasn’t developed yet – but did hypothesize that a variety of factors have created conditions that could cause its development, resulting in a serious pandemic. Factors such as climate change, deforestation, and increasing human-animal contact are exposing new organisms. The increased use of chemical weapons made from viruses, bacteria and poison gases and rogues who purposely create pathogens via gene-editing (e.g., Crispr) are other serious concerns.

“Disease X represents the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human disease,” the WHO said in a statement. Other priority diseases on the 2018 list include:

- Ebola virus disease and Marburg virus disease
- Lassa fever
- Crimean-Congo (CCHF) hemorrhagic fever
- Nipah and henipaviral diseases
- Rift Valley fever (RVF)
- Middle East respiratory syndrome coronavirus (MERS-CoV)
- Severe Acute Respiratory Syndrome (SARS)
- Zika

“These diseases pose major public health risks, and further research and development is needed, including surveillance and diagnostics,” the WHO stated.

Unfortunately, the WHO fears the threat of a new disease could be crippling because the world is not prepared to defend against another pandemic, particularly one that hasn’t been identified or dealt with before, and which the human immune system has no previous exposure or resistance.

The hope is that Disease X will guide a formal designation, with no known effects or treatment, to encourage scientists worldwide to conduct rigorous research that could help populations prepare for a rapid response should a worldwide outbreak happen.

“As there are concerted efforts to address antimicrobial resistance through specific international initiatives,” the WHO stated. “The possibility was not excluded that, in the future, a resistant pathogen might emerge and appropriately be prioritized.”


Communication is key

When sepsis is suspected, minutes count; so, quick and easy communication is critical among those involved in the patient’s care.

Calvin K. Janney, RN, MSN-L, Ascrom Clinical Application Specialist, noted, “Sepsis is a complicated and challenging condition to diagnose. Both patients and healthcare providers often don’t recognize the early symptoms, which can mimic common ailments such as the flu, and therefore do not fully recognize or understand that the real problem is sepsis. Most cases of sepsis occur in the intensive care unit (ICU), where the patient population is older, has weakened immune systems, often has drug resistance to certain types of bacteria, and has multiple invasive lines or tubes. These conditions can lead to the types of infection most likely to lead to sepsis.”

Bart Abban, Data Scientist, VigiLanz, added, “Because of its complexity, it has historically been difficult to find consensus in the definition, diagnosis, and treatment of sepsis among the medical community. A major reason for the lack of awareness is that sepsis is often secondary to other diseases and conditions. Although sepsis might be what delivers the coup de grace to a patient, the initial hospitalization is often for another illness or condition.”

Along the same vein, Rose Mary Casados, MBA, BSMT, ASCP, WW Marketing Manager, BD Life Sciences, said, “Sepsis is a secondary condition, usually the final common pathway to death. The challenges lie in driving education beyond first-line infections—such as pneumonia, urinary tract infection, and wound infection—but rather to the outcome of these diseases, which could include sepsis.”

Sepsis is a puzzle to healthcare workers, so it is no surprise that the public knows little about it. The flu epidemic of 2017-2018 has drawn more attention to sepsis, according to Phillip Chan, MD, PhD, Chief Executive Officer, CytoSorbents Corporation. “The most recent influenza epidemic and the daily highly publicized stories of otherwise healthy individuals dying rapidly of the flu and associated complications due to ‘cytokine storm’ and excessive inflammation has likely improved awareness of sepsis.”
The Ascom Healthcare Platform software captures, tracks, and records vital signs, alarms, and other data from patient-room equipment, ICUs, operating rooms, and other wards. Information is continuously analyzed and presented as meaningful data in a controlled, secure manner to the right person or system at the right time and at the right place, resulting in faster responses to individual patient events.

“Because time is of the essence when treating sepsis,” said Janney, “Ascom’s Clinical Consulting Service and portfolio of products, such as the Ascom Myco smart phone with the Unite Context clinical collaboration application, allow hospital staff members to communicate and collaborate at a time when speed is critical.”

Rhonda Collins, Chief Nursing Officer, Vocera Communications, agreed, saying, “Time is of the essence when diagnosing and treating sepsis. Real-time communication between clinicians is critical. To help care teams identify sepsis sooner and initiate treatment quicker, Vocera technology can integrate with a hospital’s electronic health records system and predictive analytics tool.”

Collins provided an example of how their product works to thwart sepsis. “At Halifax Health in Florida, Vocera teamed up with Wolters Kluwer Health to arm care teams with a high-powered sepsis surveillance and alerting solution. Wolters Kluwer’s POC Advisor analyzes 250+ data points within a patient’s medical record to identify early signs of sepsis, warn caregivers of escalating risks, and empower them with evidence-based guidance at the point of care. When early signs of an infection are detected, an alert with situational information is sent directly to the patient’s care-team members via their Vocera badges and smartphone apps. This clinical workflow and proactive communication can result in faster diagnoses and treatment of sepsis, which leads to reduced severity, decreased mortality, and lower costs.”

Steve Claypool, MD, Medical Director for Wolters Kluwer Clinical Software Solutions, concurred. “POC Advisor can detect and alert the clinical staff to sepsis cases faster and provide guidance on the right course of treatment. It does that accurately, early, and effectively.”

“Identification and communication are key to expediting diagnosis of sepsis,” declared Tim O’Malley, President, EarlySense Inc. “For every hour a patient is septic, their mortality rate will increase by almost 8 percent; therefore, any infection needs to be determined earlier and treatment initiated. As time goes by, acuity of these patients increases. Left undiagnosed and untreated, these patients will become more complex, requiring more time in a higher acuity environment.”

O’Malley explained that the EarlySense System is a contact-free, continuous monitoring system employing a small sensor under the patient’s mattress that collects the heart rate and respiratory rate twice per second. “The goal of the EarlySense System is to identify the earliest warning signs, so providers can expedite action, diagnosis, and treatment. One of the first signs of infection, and concurrently sepsis, is an increase in these key vital signs,” said O’Malley. “This system helps alert clinicians that a patient is experiencing an increase in heart rate and respiratory rate and should be evaluated. We introduced a multi-parameter alert recently that warns caregivers if heart rate combined with respiratory rate is elevated over a period of time. If both of these parameters are elevated for, say, 4 hours, it merits a check of other parameters to determine if the patient is developing a more advanced infection or is pre-septic.”

In a study of more than 7,000 patient outcomes, using the EarlySense System, the number of ICU days for transferred patients decreased by 46 percent, the overall hospital length of stay decreased by 9 percent in the intervention group, and the number of code-blue events decreased by 86 percent, all because patients were treated as soon as they began to deteriorate.

Chan, CytoSorbents, highlighted the importance of all healthcare professionals being alert to sepsis, “particularly when patients have signs and symptoms of infection, exhibit fever, or have instability, especially concerning blood pressure, oxygenation, or kidney function. CytoSorbents’ CytoSorb blood-purification technology is designed to control the deadly inflammation that kills patients in severe sepsis and septic shock, helping to round out the spectrum of treatment approaches for sepsis that include rapid detection, antibiotics, supportive-care therapy, and active control of inflammation.”

Blood cultures are an important component in diagnosing sepsis. “A key component is promoting best practices in blood culturing and offering proven performance in the diagnosis of sepsis,” stated Casados. “BD’s integrated blood-culture solution includes the BD BACTEC blood-culture media, BD BACTEC FX Series Automated Blood Culture Instrument, and the BD Synapsys informatics solution. BD recognizes the key role of data-management solutions in measuring quality metrics and workflow efficiencies. BD Synapsys Microbiology Informatics Solution connects data from BD blood-culture instruments in disparate systems and settings, which expedites communication to clinicians and pharmacists, facilitating accurate, timely diagnosis and appropriate therapy for patients.”

**Connecting the dots between sepsis and readmissions**

The Centers for Medicare and Medicaid are required to reduce payments to certain hospitals that have excessive readmissions within 30 days of the patient’s dismissal, so it is vital that sepsis patients are stable before leaving the hospital. Abban, VigiLanz, cited some readmission statistics. “More than 12 percent of all unplanned 30-day readmissions are associated with a sepsis...
INFECTION PREVENTION

diagnosis during the previous admission and patients who are readmitted with an infection within 30 days of discharge are at risk of sepsis.”

Abban described how the VigiLanz platform’s tools can lead to prevention and reduction of HAIs, sepsis, and readmissions. “The Infection Control Module services, including cluster detection, provide early detection of hospital outbreaks that lead to HAIs; HAI identification provides the data analytics needed to help understand population risk factors and opportunities for improvement; a prevention tool box helps in preventing infections; and drug-bug mismatch rules automate the process of identifying patients who are on ineffective anti-infective drugs. Sepsis Discrete Service provides highly-sophisticated customizable rules to detect cases of sepsis that are present on admission and monitors to ensure protocols are followed. The Sepsis Predictive Machine Learning Algorithms predict the risk of sepsis for inpatients.”

Claypool, Wolters Kluwer, observed, “Sepsis is the most common condition resulting in readmission.” He explained that electronic surveillance could help by catching the condition early, when it is most treatable, so the patient’s condition doesn’t escalate, and the patient isn’t discharged while their health is still compromised. “Wolters Kluwer’s POC Advisor aggregates, normalizes, and analyzes patient data from disparate clinical systems to drive early, accurate sepsis detection and treatment,” said Claypool. “Hundreds of rules are built into the platform to account for possible comorbidities and medication abnormalities. This enables prescriptive alerts that have scientifically demonstrated unprecedented levels of sensitivity and specificity, alerting clinicians to at-risk patients without alert fatigue.” According to Claypool, POC Advisor reduces sepsis mortality by half, reduces related 30-day readmissions by 30 percent, and lowers lengths of stay.

Chan, CytoSorbents, noted, “Sepsis is a two-part equation consisting of a serious infectious trigger followed by an overzealous immune response that can lead to un-

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controlled inflammation, organ failure, and death. “If these patients survive, they are often severely debilitated and often wind up back in the ICU or dead in the first year after hospital discharge.”

Chan described how CytoSorb works to combat deadly inflammation in septic patients. “CytoSorb is an extracorporeal cytokine adsorber that reduces cytokines and cytokine storm, as well as many bacterial toxins and other mediators that contribute to uncontrolled systemic inflammation. In doing so, CytoSorb has helped to stabilize and turn patients around, reducing organ injury, and restoring adequate blood pressure during septic shock.”

CytoSorb is compatible with existing dialysis, renal replacement, and extracorporeal membrane oxygenation machines found in hospital ICUs today. It is approved in the European Union but not yet in the U.S.

“By reducing the severity of illness,” added Chan, “CytoSorb helps to reduce the debilitating effects of sepsis, helps patients get out of the ICU faster, controls costs, and potentially reduces the incidence of readmissions later.”

Bob Gerberich, CCO, Magnolia Medical Technologies, talked about the importance of accuracy in blood cultures when diagnosing sepsis: “Blood-culture contamination introduces substantial uncertainty about accurate diagnosis, as well as a lack of clarity for patients and their families. Forty percent of positive results are actually false positives due to blood-culture contamination.

“Steripath is a patented closed system that mechanically diverts and sequesters the initial 1.5 to 2.0 mL of blood, which is known to contain contaminants, into an isolation chamber. Once diversion is complete, an independent second sterile blood-flow pathway mechanically opens, allowing only pure, contaminant-free venous blood to flow into the culture bottle.”

“Using standard techniques of the past, hospitals have strived to meet the blood-culture contamination national benchmark of 3 percent. By comparison,” Gerberich said, “Steripath is clinically proven to virtually eliminate blood-culture contamination.” This is important, because an accurate diagnosis of sepsis helps differentiate between patients who need treatment and those who do not, meaning unnecessary use of antibiotics can be avoided.
Gerberich referred to recently published results from a prospective, controlled trial of Steripath, versus standard phlebotomy procedures, in the emergency department at the University of Nebraska Medical Center (UNMC), which showed a 92 percent reduction in false positives with a 12-month sustained contamination rate of 0.2 percent when using Steripath.1 “Results from the UNMC study of Steripath conservatively estimated $4,850 as the cost of a blood-contamination event resulting in a false-positive test result for sepsis,” said Gerberich. “Using this conservative estimate, infection control expert and study author Mark Rupp, MD, said the use of Steripath would save his single hospital $1.8 million per year by preventing 373 cases of contamination leading to false positives.”

Casados, BD Life Sciences, stressed the importance of understanding the link between HAI, antimicrobial therapy, readmissions, and sepsis. “HAI’s can lead to many complications during hospital admission,” she said. Casados offered an example: immunocompromised patients initially admitted with pneumonia or for surgery, etc., may be placed on antimicrobial therapy for a prolonged period of time, increasing the chance of building resistance to the antibiotic, which increases the chance of contracting an HAI, which, in turn puts the patient at risk of acquiring sepsis.

Shane Cooke, Chief Strategy Officer, Cheetah Medical, referred to a study published in JAMA indicating that the proportion and cost of readmissions due to sepsis are even higher than those more widely known conditions. In the U.S., one person every 20 seconds is diagnosed with sepsis, and 28 percent to 50 percent of these patients die.17 “Achieving the proper fluid balance during sepsis is critical to avoiding complications and even death,” said Cooke, noting that balance between too little and too much fluid for sepsis patients may sometimes be delicate. “More than 80 percent of patients within a hospital are receiving fluids intravenously, especially in emergency situations such as with low blood pressure. Unlike prescription medicines, however, infusion fluids are often prescribed without measuring a patient’s ability to absorb or respond to them. Receiving too little fluid intravenously, or too much for a patient’s specific needs, can lead to serious complications, even death.”

“Studies have shown Cheetah Medical’s non-invasive technology equips clinicians with the information needed to guide fluid-management decisions accurately, which may lead to improved clinical and economic outcomes,” stated Cooke. He alluded to sepsis studies from the University of Kansas Health System demonstrating that stroke volume variation, “guided by Cheetah technology, led to a reduction in ICU length of stay of 2.9 days and reduced the risk of both mechanical ventilation and initiation of acute dialysis.” Additionally, the data show total hospital cost savings of over $1.4 million during the six-month study.18

The staggering cost of sepsis

O’Malley, EarlySense, brought out an astounding fact. “The financial burden of sepsis is incredibly costly. In 2015, Medicare paid $6 billion to treat sepsis.”19, 20 “Sepsis carries an estimated annual financial burden of nearly $24 billion, with the average hospital bearing nearly $19,000 per case for a primary diagnosis,” contributed Claypool, Wolters Kluwer. “Yet, the Advisory Board notes that the typical Medicare reimbursement for sepsis and sepsis with complications is just $7,100 to $12,000. POCC Advisor helps to lower these costs by reducing lengths of stay, as well as sepsis-related 30-day readmissions.”

“Globally, sepsis is one of the leading causes of mortality and critical illness, contributing to 25 percent to 30 percent of hospital mortality rates,” said Casados, BD Life Sciences. “Clinical studies have demonstrated a two-fold increase in mortality caused by sepsis when inappropriate antimicrobial therapy is given.”21 Sepsis is the No. 1 cost of hospitalization in the U.S., consuming more than $24 billion each year.22

Collins, Vocera Communications, talked about a 2016 study,24 which revealed “the annual costs for treating sepsis in hospitals increased over $3.4 billion during a two-year period. While sepsis can have a significant impact on a hospital’s bottom line, the impact it can have on the lives of patients and families is staggering. Every year, sepsis kills approximately 258,000 people in the U.S., or one person every two minutes. For every hour that passes without treating sepsis, the likelihood of death increases. The best way to beat sepsis is by beating the clock. Time is a key factor in the battle against sepsis. So, an integrated clinical workflow with mobile communication, intelligent alerting, and real-time situational awareness is essential for reducing sepsis-related complications and costs.”25

References


4/18 Health Care Purchasing News
Solutions to reduce HAIs

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- TEEZyme enzymatic sponges are lint-free, latex-free and dust-free

QwikDry™ TEE Probe Drying Cloths

QwikDry TEE probe drying cloths have been developed to give healthcare professionals the added confidence of properly dried ultrasound TEE probes prior to re-use or storage. The super absorbent pad effectively removes moisture from TEE ultrasound probes without damaging the probe or sticking to the ultrasound probe during the drying process.

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The elevation revelation

Salary surveys shows CS/SPD continuing to strive for higher status

by Kara Nadeau

The average annual salary for central sterile/sterile processing department (CS/SPD) professionals increased by 6 percent — from $57,029 in 2017 to $60,633 in 2018 — according to the results of the 2018 Healthcare Purchasing News CS/SPD Salary Survey. The majority of respondents (60 percent) reported an increase in pay over last year.

- **OR Liaison and Educator salaries soar:** The OR Liaison position saw the biggest salary gains, rising 32 percent: from $43,350 in 2017 to $57,500 in 2018. The next highest pay hike was for Educators who reported a 22 percent average salary increase since: from $44,773 to $54,808. When digging into the data, this year’s respondents in both categories reported higher education levels compared with 2017, including post-graduate degrees, which could account for the significant salary increases.

- **CS/SPD Directors still lead the pack:** As with previous years, the CS/SPD Director position reported the highest average annual salary: $102,824, which was up 15 percent from 2017.

- **Modest increases for Managers, Lead CS/SPD Techs and Surgical Instrument Techs:** CS/SPD professionals in these positions reported modest salary increases from last year, with salaries for Managers and Lead CS/SPD Technicians up 4 percent, and Surgical Instrument Techs up 3 percent.

### Survey history

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### Salary by education & gender*

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### Salary by region & gender*

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</thead>
<tbody>
<tr>
<td>Pacific</td>
<td>9%</td>
<td>5%</td>
</tr>
<tr>
<td>Mountain</td>
<td>8%</td>
<td>3%</td>
</tr>
<tr>
<td>Central</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Northeast</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>Southeast</td>
<td>9%</td>
<td>7%</td>
</tr>
</tbody>
</table>

### Salary by number of beds

<table>
<thead>
<tr>
<th>Number of Beds</th>
<th>Salary ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-25 beds</td>
<td>$44,615</td>
</tr>
<tr>
<td>26-49</td>
<td>$49,722</td>
</tr>
<tr>
<td>50-99</td>
<td>$56,477</td>
</tr>
<tr>
<td>100-199</td>
<td>$51,722</td>
</tr>
<tr>
<td>200-299</td>
<td>$60,330</td>
</tr>
<tr>
<td>300-399</td>
<td>$75,933</td>
</tr>
<tr>
<td>400-499</td>
<td>$82,000</td>
</tr>
<tr>
<td>500-749</td>
<td>$67,429</td>
</tr>
<tr>
<td>750-999</td>
<td>$96,200</td>
</tr>
<tr>
<td>1000 beds</td>
<td>$49,318</td>
</tr>
</tbody>
</table>

* 3 percent of respondents did not report their gender, and are therefore not included in the gender breakdown. All respondents are included in the overall averages.
the CS/SPD. The job process in CS/SPD is an important part of the patients surgical journey because the surgical instruments being processed correctly or incorrectly can impact a procedure. The CS/SPD technicians are the unseen team members of a surgical case whose expertise is needed for the OR team to complete their part of the surgery. We provide the instruments that are needed for a team to perform surgery. Those instruments must be clean, working, assembled in some order and then processed all according to the instructions for use (IFU). We have a lot of knowledge that does not require that you hold a MBA but you need to understand the ‘how to and why’ when it comes to sterile processing as well as the parameters that must be met to obtain sterility. In a nutshell, no, the pay in this field is not equitable to the job.”

“From what I hear and observe SPD tech wages remain pitiful, with salaries typically falling into the exempt versus nonexempt wage paying category,” said Chuck DePreker, CRCST, CIS, CHL, Operating Room/Sterile Processing Supply Chain Manager at Eisenhower Army Medical Center. “A new and inexperienced tech is brought in at the lowest wage range and it can take a very long period of time — as many as 20 years — to reach the top wage.”

“In many areas of the country, those where certification is not the law of the land or sterile processing departments are not unionized, compensation has remained flat and dismal,” said Casey Czarnowski, a SPD Educator in Fargo, ND “In regions without post-secondary programs readily available, new technicians can start at about that same rate as full-time night closers at fast food restaurants. Cleaning and sterilizing the instruments that improve the quality of life for people should be worth more than preparing food that decreases it!”

“It is no secret we have a compensation problem in our industry,” said Weston “Hank” Balch, BS, MDiv, CRCST, CIS, CHL, Co-Founder and Host for Beyond Clean Podcast. “As with all economic issues however, there is no ‘easy fix’ to bring compensation of CS professionals in line with the value they provide to hospitals. Part of the problem is that many of the organizations that could speak on behalf of CS professionals in the field have decided to instead focus on credentials, recognition and respect. While those are noble causes, recognition obviously does not pay the bills.”

“CS/SPD salaries are not where we should be but our organization is improving,” said Albert Huether, Director of the Sterile Processing Department at Methodist Healthcare System, San Antonio. “It has been a struggle the last seven years, but we are competitive to the local market in most job descriptions. We do have a few areas in need of improvement, such as entry level. We are working in collaboration with Human Resources to bridge this gap.”

Job security
Job security held steady, with nearly half (49 percent) of respondents reporting they are “very secure” in their positions, and an additional 46 percent stating that they are “somewhat secure.”

“In Northeast Ohio there is currently a huge demand for CS staff,” said Randy Bigler, Manager of Sterile Supply for Summa Health in Akron, OH. “From Aultman and Summa in the Canton and Akron markets, to Cleveland Clinic and University Hospitals in Cleveland, there are endless opportunities for CS/SPD professionals. The biggest challenge is finding qualified, experienced and certified staff.” Huether attributes job security in his city — San Antonio — to the lack of experienced personnel available in the area to meet the open job market demand. He notes that this has contributed to an “employee’s market.”

Czarnowski states that the job market for sterile processing professionals is strong in his market of Fargo, ND as well, stating: “With high turnover being the norm, a medium or high performer can expect to stay in the job for as long as he or she wants”

Are you a member of any of the following organizations?

<table>
<thead>
<tr>
<th>Organization</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>IAHCSMM International Association of Healthcare Central Service Material Management</td>
<td>73%</td>
</tr>
<tr>
<td>CSBPD Certification Board for Sterile Processing and Distribution</td>
<td>26%</td>
</tr>
<tr>
<td>AAMI Association for the Advancement of Medical Instrumentation</td>
<td>22%</td>
</tr>
<tr>
<td>AST Association of Surgical Technologists</td>
<td>7%</td>
</tr>
<tr>
<td>AORN Association of periOperative Registered Nurses</td>
<td>6%</td>
</tr>
<tr>
<td>SRCM Certification Board</td>
<td>4%</td>
</tr>
<tr>
<td>SGNA Society of Gastroenterology Nurses &amp; Associates</td>
<td>2%</td>
</tr>
<tr>
<td>AHRMM Association for Healthcare Resource and Materials Management</td>
<td>1%</td>
</tr>
<tr>
<td>APIC Association for Professionals in Infection Control and Epidemiology</td>
<td>1%</td>
</tr>
<tr>
<td>Other</td>
<td>2%</td>
</tr>
<tr>
<td>None</td>
<td>7%</td>
</tr>
</tbody>
</table>

Which certifications do you hold?

<table>
<thead>
<tr>
<th>Certification</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRCST - Certified Registered Central Service Technician</td>
<td>64%</td>
</tr>
<tr>
<td>CHL - Certified In Healthcare Leadership Strategies</td>
<td>23%</td>
</tr>
<tr>
<td>CSPDT - Certified Sterile Processing Distribution Technician</td>
<td>21%</td>
</tr>
<tr>
<td>CIS - Certified Instrumentation Specialist</td>
<td>19%</td>
</tr>
<tr>
<td>CST - Certified Surgical Technician</td>
<td>9%</td>
</tr>
<tr>
<td>CFER - Flexible Endoscope Reprocessor Certification</td>
<td>8%</td>
</tr>
<tr>
<td>Certified IAHCSMM Instructor</td>
<td>6%</td>
</tr>
<tr>
<td>SPD Technician Certification</td>
<td>6%</td>
</tr>
<tr>
<td>CSPDM - SPD Manager Certification</td>
<td>5%</td>
</tr>
<tr>
<td>RN - Registered Nurse</td>
<td>5%</td>
</tr>
<tr>
<td>CSPDS - SPD Supervisor Certification</td>
<td>3%</td>
</tr>
<tr>
<td>CNOR - Certified Nurse Operating Room</td>
<td>3%</td>
</tr>
<tr>
<td>CMDRT - Certified Medical Device Reprocessing Technician</td>
<td>2%</td>
</tr>
<tr>
<td>CSIP - Surgical Instrument Processor</td>
<td>2%</td>
</tr>
<tr>
<td>CHMMC – Certification in Healthcare Material Management Concepts</td>
<td>1%</td>
</tr>
<tr>
<td>CNA - Certified Nursing Assistant</td>
<td>1%</td>
</tr>
<tr>
<td>LPN - Licensed Practical Nurse</td>
<td>1%</td>
</tr>
<tr>
<td>CORT - Certified O.R. Technician</td>
<td>1%</td>
</tr>
<tr>
<td>CPHIQ - Certified Professional in Health Quality</td>
<td>1%</td>
</tr>
<tr>
<td>CASSPT - Certified Ambulatory Surgery Technician</td>
<td>&gt;1%</td>
</tr>
<tr>
<td>CMRP – Certified Materials &amp; Resource Professional</td>
<td>&gt;1%</td>
</tr>
<tr>
<td>State Certification</td>
<td>&gt;1%</td>
</tr>
<tr>
<td>Other</td>
<td>1%</td>
</tr>
<tr>
<td>None</td>
<td>6%</td>
</tr>
</tbody>
</table>
Health Care Professionals, Have You Heard About FLUAD®?

A flu vaccine for adults 65+. FLUAD® is the first FDA-approved seasonal flu shot made with an immune-enhancing adjuvant, which is proven to provide a strong immune response in adults 65 and older.1,2

Pre-order FLUAD®. Help adults 65+ prepare for flu season.

The CDC recommends FLUAD® as an acceptable option to other vaccines licensed (or indicated) for people 65 years of age and older for immunization against influenza.*

*The CDC has not made a preferential recommendation for any flu vaccine formulation directed toward this age group.*

Find out more at FLUAD.com/HCP

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Manufactured by: Seqirus Vaccines Limited Speke, Liverpool, L24 9GR, UK
Distributed by: Seqirus USA Inc., 25 Deforest Avenue, Summit, NJ 07901, USA

INDICATIONS AND USAGE
FLUAD is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in persons 65 years of age and older.

CONTRAINDICATIONS
Severe allergic reaction to any component of the vaccine, including egg protein, or after a previous dose of any influenza vaccine.

WARNINGS AND PRECAUTIONS
- If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks.
- The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.

ADVERSE REACTIONS
- The most common (≥10%) local (injection-site) adverse reactions observed in clinical studies were injection site pain (25%) and tenderness (21%).
- The most common (≥10%) systemic adverse reactions observed in clinical studies were myalgia (15%), headache (13%), and fatigue (13%).

Please see accompanying US Full Prescribing Information for FLUAD
http://hcp.fluad.com/Common/docs/FLUAD_Package_Insert.pdf
1 INDICATIONS AND USAGE
FLUAD is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in persons 65 years of age and older. Approval is based on the immune response elicited by FLUAD. Data demonstrating a decrease in influenza disease after vaccination with FLUAD are not available. [see Clinical Studies (14)]

4 CONTRAINDICATIONS
Do not administer FLUAD to anyone with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine, including egg protein, or after a previous dose of any influenza vaccine.

5 WARNINGS AND PRECAUTIONS
5.1 Guillain-Barré Syndrome
If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks. The 1976 swine influenza vaccine was associated with an elevated risk of GBS. Evidence for a causal relationship of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1 million persons vaccinated. [see References (1)]

5.2 Preventing and Managing Allergic Reactions
Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.3 Latex
The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions in latex sensitive individuals. [see Description (11)]

5.4 Altered Immunocompetence
The immune response to FLUAD in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals. [see Concurrent Use With Immunosuppressive Therapies (7.2)]

5.5 Syncope
Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD. Ensure procedures are in place to avoid injury from falling associated with syncope.

5.6 Limitations of Vaccine Effectiveness
Vaccination with FLUAD may not protect all vaccine recipients against influenza disease.

6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect rates observed in clinical practice.

Solicited adverse reactions were assessed in a multicenter, observer-blind, randomized controlled study (Study 1) conducted in the United States, Colombia, Panama and the Philippines. The safety analysis set included 3545 FLUAD recipients and 3337 AFRIFLU (Influenza Vaccine) recipients. The enrolled subject population in Study 1 was 65 to 97 years of age (mean 72 years) and 64% were female. Within each treatment group, 53% were Asian, 28% were Caucasian, 18% were Hispanic, 1% were Black, and fewer than 1% each were Native American/Alaskan, Pacific Islander/Hawaiian, or Other. Solicited local (injection site) and systemic adverse reactions were collected from subjects in Study 1 who completed a symptom diary card for seven days following vaccination. The reported frequencies of solicited local and systemic adverse events from Study 1 are presented in Table 1.

Table 1. Percentages of Subjects ≥ 65 Years of Age With Solicited Local and Systemic Adverse Reactions in Days 1-7 After Administration of FLUAD or AFRIFLU (a U.S. Licensed Comparator) NCT01162122

<table>
<thead>
<tr>
<th>Study 1</th>
<th>FLUAD (N=3418-3456) Percentage</th>
<th>AFRIFLU (N=3420-3488) Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection site Pain</td>
<td>Any</td>
<td>25.0</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>3.9</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>Any</td>
<td>21.1</td>
</tr>
<tr>
<td>Tenderness</td>
<td>Moderate</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0.1</td>
</tr>
<tr>
<td>Erythema</td>
<td>Any</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>25 to ≤ 50 mm</td>
<td>1.1</td>
</tr>
<tr>
<td></td>
<td>51 to ≤ 100 mm</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>&gt; 100 mm</td>
<td>0.0</td>
</tr>
<tr>
<td>Induration</td>
<td>Any</td>
<td>1.3</td>
</tr>
<tr>
<td></td>
<td>25 to ≤ 50 mm</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>51 to ≤ 100 mm</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>&gt; 100 mm</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling</td>
<td>Any</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>25 to ≤ 50 mm</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>51 to ≤ 100 mm</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>&gt; 100 mm</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td><strong>Systemic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td>Any</td>
<td>14.7</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>2.6</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0.3</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Any</td>
<td>13.3</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>3.1</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0.4</td>
</tr>
<tr>
<td>PLT</td>
<td>Any</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>&gt; 100 mm</td>
<td>0.0</td>
</tr>
<tr>
<td>Headache</td>
<td>Any</td>
<td>13.2</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>PLT</td>
<td>0.0</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>Any</td>
<td>8.5</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0.2</td>
</tr>
<tr>
<td>Chills</td>
<td>Any</td>
<td>6.7</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>PLT</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>Any</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>1.3</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>PLT</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Fever</td>
<td>Any</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>≥ 38.0°C to &lt; 38.4°C</td>
<td>1.8</td>
</tr>
<tr>
<td></td>
<td>≥ 38.5°C to &lt; 38.9°C</td>
<td>1.3</td>
</tr>
<tr>
<td></td>
<td>39.0°C to &lt; 40.0°C</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>≥ 40.0°C</td>
<td>0.1</td>
</tr>
</tbody>
</table>
**Important Safety Information:**

**CONTRAINDICATIONS**

- Severe allergic reaction to any component of the vaccine.
- The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.

**INDICATIONS AND USAGE**

FLUAD is indicated for active immunization against influenza disease caused by influenza virus A (H1N1) and (H3N2) virus strains, and influenza virus B (Victoria) and (Yamagata) variants. FLUAD is approved for use in persons 65 years of age and older.

**ADVERSE REACTIONS**

**Local (injection-site) Adverse Reactions**

- Injection-site reactions observed in clinical studies were injection site pain (67.2% FLUAD vs. 61.6% Active Comparator).

**Systemic Adverse Events (AEs)**: The clinical safety of FLUAD was assessed in fifteen (15) randomized, controlled studies. The total safety population in these trials included 10,952 adults 65 years of age and older, comprising 5,754 who received FLUAD and 5,198 who received other US licensed influenza vaccines. The percentage of subjects with an unsolicited AE within 30 days following vaccination was similar between vaccine groups (16.9% FLUAD vs. 18.0% active comparator).

**Serious Adverse Events (SAEs)**: In Study 1, in which subjects were followed for SAEs and deaths for one year following vaccination (N=3,545 FLUAD, N=3,537 AGRIFLU), the percentages of subjects with an SAE were similar between vaccine groups (7% FLUAD vs. 7% AGRIFLU). Four SAEs (1 FLUAD and 3 AGRIFLU) were assessed as related to study vaccination over one year of observation and 2 of these occurred (1 FLUAD and 1 AGRIFLU) within 21 days following study vaccination. There were 98 deaths (n=52 FLUAD, n=46 AGRIFLU) over one year of which none occurred within the first 21 days following vaccination.

In 14 additional randomized, controlled studies, SAEs were collected over a 3 to 4-week period in 4 studies, over a 8-week period in 1 study, and over a 6-month period in 9 studies (N=2,209 FLUAD, N=1,661 US licensed influenza vaccines). The percentages of subjects with an SAE within 30 days (1.1% FLUAD vs. 1.8% AGRIFLU) or within 6 months (4.3% FLUAD vs. 5.9% AGRIFLU) were similar between vaccine groups. The percentages of deaths within 30 days (0.3% FLUAD vs. 0.6% active comparator) or within 6 months (1.0% FLUAD vs. 1.5% active comparator) were also similar.

**Adverse Events of Special Interest (AESIs)**: Rates of new onset neuroinflammatory and immune mediated diseases were assessed in a post hoc analysis of the 15 randomized controlled studies over the time periods specified above for SAEs. The percentage of subjects with an AESI at any time after vaccination was similar between vaccine groups (0.9% FLUAD vs. 0.9% active comparator). There were no notable imbalances for specific AESIs.

**Safety of Annual Revaccination**: In 5 of the randomized, controlled trials, subjects were followed for SAEs and deaths for 6 months following revaccination (N=492 FLUAD, N=330 US licensed and non-US licensed influenza vaccines). After the second annual vaccination, the percentages of subjects with an SAE were similar between vaccine groups (6.1% FLUAD vs. 5.5% comparator influenza vaccines); 23 deaths (n=17 FLUAD, n=6 comparator influenza vaccines) were reported. Causes of death included cardiovascular events, malignancy, trauma, gastrointestinal disorders, and respiratory failure. Clinical characteristics of the deaths, including the variable causes, timing since vaccination, and underlying medical conditions, do not provide evidence for a causal relationship with FLUAD.

**6.2 Postmarketing Experience**

The following adverse events have been spontaneously reported during post-approval use of FLUAD in Europe and other regions since 1997. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

**Blood and lymphatic system disorders**: Thrombocytopenia (some cases were severe with platelet counts less than 5,000 per mm3), lymphadenopathy

**General disorders and administration site conditions**: Extensive swelling of injected limb lasting more than one week, injection site cellulitis-like reactions (some cases of swelling, pain, and redness extending more than 10 cm and lasting more than 1 week)

**Immune system disorders**: Allergic reactions including anaphylactic shock, anaphylaxis and angioedema

**Musculoskeletal and connective tissue disorders**: Muscular weakness

**Nervous system disorders**: Encephalomyelitis, Guillain–Barré Syndrome, convulsions, neuritis, neuralgia, paraesthesia, syncope, presyncope

**Skin and subcutaneous tissue disorders**: Generalized skin reactions including erythema multiforme, urticaria pruritus or non-specific rash

**Vascular disorders**: Vasculitis with transient renal involvement

**7 DRUG INTERACTIONS**

**7.1 Concomitant Use With Other Vaccines**: There are no data to assess the concomitant administration of FLUAD with other vaccines. If FLUAD is to be given at the same time
certain vaccine(s), the vaccine(s) should be administered at different injection sites.

**7.2 Concurrent Use With Immunosuppressive Therapies**: Immunosuppressive or corticosteroid therapies may reduce the immune response to FLUAD.

**8 USE IN SPECIFIC POPULATIONS**

**8.1 Pregnancy**: Pregnancy Category B: A reproductive and developmental toxicity study has been performed in rabbits with a dose level that was approximately 15 times the human dose based on body weight. The study revealed no evidence of impaired female fertility or harm to the fetus due to FLUAD. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this vaccine should be used during pregnancy only if clearly needed.

In a reproductive and developmental toxicity study, the effect of FLUAD on embryofetal and post-natal development was evaluated in pregnant rabbits. Animals were administered FLUAD by intramuscular injection twice prior to gestation, during the period of organogenesis (gestation day 7) and later in pregnancy (gestation day 20). 0.5 mL (45 mcg)/rabbit/occasion (approximately 15-fold excess relative to the adult human dose based on body weight). No adverse effects on mating, female fertility, pregnancy, embryofetal development, or post-natal development were observed. There were no vaccine-related fetal malformations or other evidence of teratogenesis.

**8.4 Pediatric Use**: The safety and effectiveness of FLUAD in the pediatric population has not been established.

**8.5 Geriatric Use**: Safety and immunogenicity of FLUAD have been evaluated in adults 65 years of age and older. [See Adverse Reactions (6.1) and Clinical Studies (14)]

FLUAD is a registered trademark of Seqirus UK Limited or its affiliates.

Manufactured by: Seqirus Vaccines Limited
Speke, Liverpool, L2476R, UK

Distributed by: Seqirus USA Inc. 25 Deforest Avenue, Summit, NJ 07901, USA
1-855-358-8966
wishes. Some hospitals in our region require certification, while others unfortunately do not. So, a technician can continue to serve in the career as long as the salary is manageable to him/her, and he/she is able to pass a certification test, if required by their healthcare system.”

More set their sights on certification
The percentage of certified CS/SPD professionals continues to rise, with 90 percent of survey respondents stating they have achieved certification (up from 88 percent last year), and an additional 8 percent are either in the process of certification or considering it. The number of CS/SPDs requiring certification of their staff rose slightly — from 63 percent in 2017 to 64 percent in 2018.

The states of New Jersey, New York, Connecticut and Tennessee currently require central service technicians to be certified. According to Heidi Melnyk, Executive Director of the Certification Board for Sterile Processing & Distribution (CBSPD), New York is the only state so far to specifically cite in their statute that the certifying organization for certification must be accredited.

“The CBSPD has three of its certifications accredited by the National Commission for Certifying Agencies (NCCA): Technician, G1 Scope and Management. Our Technician certification has been accredited since 1997,” said Melnyk.

Josephine Colacci, Esq., Government Affairs Director for the International Association of Healthcare Central Service Materiel Management (IAHCSMM), provided this update on additional legislative efforts around certification requirements.

“In January, IAHCSMM introduced legislation in Rhode Island for the first time,” said Colacci. “Rhode Island’s legislative session ends in June and we are hopeful about having a committee hearing soon. Our Massachusetts bill successfully passed out of the Joint Public Health Committee and is awaiting a vote in the Joint Health Care Financing Committee. Our Massachusetts bill must be voted out of the Joint Health Care Financing Committee by March 28th to continue to move through the legislative process. We do not think that will be an issue as we have successfully passed out of this committee before. We are hoping this bill will pass the legislature in 2018.”

“Our Pennsylvania legislation has struggled over the last couple of years due to opposition from the hospital association,” she added. “We have a House bill that was introduced in 2017, and are hoping to introduce a Senate bill soon. Pennsylvania’s legislative session runs through the end of 2018.”

“Certification is key for advancement in our profession,” said Bigler. “Certification shows not only advanced knowledge, but also commitment and dedication to the job long term. In the future, one certification may not be enough for advancement. Techs will need to continue on and become a certified endoscope reprocessor, instrument specialist and managers would benefit from becoming certified healthcare leaders through IAHCSMM or managers through CBSPD. Taking some Six Sigma or other Lean courses is also a good way to advance career and salary. CS is very similar to manufacturing, one large assembly line constantly turning out the same product.”

Higher education equals higher pay
As in past years, the higher level of education achieved, the higher the average salary in the CS/SPD profession. Those with post-graduate degrees reported the highest pay, an average of $88,190. As a CS/SPD professional climbs the education ladder from a high school diploma, to an associate’s degree and next to a bachelor’s degree, his/her average salary increases approximately $10,000 according to the survey results: $51,716, $61,500 and $70,582 respectively.

“All of us didn’t grow up and say, ‘Hey, I think I want to be a sterile processing professional,’” said Loraine Durigan, CRCST, CHL, CISS, Materials Manager and CS Supervisor, Florida Hospital. “Many of us stumbled into this in some way, shape or form. I was in retail management for 10 years before I became a surgical tech and that’s how I came into sterile processing. Everybody has a different story about how they entered the profession.”

According to Bigler, there are many local community colleges in his market of Northeast Ohio offering programs that are one year or less for CS/SPD certification. Students get placed at a clinical site during the program to gain knowledge and real world experience in CS/SPD. He says many of these students end up becoming employees once they have completed the program and pass their certification. But a downside is that colleges use their CS/SPD certification programs as a feeder for their nursing, respiratory therapy and surgical assisting programs. Bigler explains that students are often on a waitlist for those programs so they complete the CS/SPD program in order to open the door for them to get hired by a hospital.

“I have also had staff move onto the larger healthcare systems that are only a 20 to 30 minute drive and can pay dollars more an hour,” said Bigler. “Also, this job is not for everyone because it can be very stressful and physically demanding at times. Instruments sets can get heavy and it’s a workout pumping 25 loaner sets. I think the work hours are a drawback for most people as well. The majority of the work is performed, after the surgery schedule, which means afternoon shift. It’s hard to find staff to work 3-11 p.m. Most expect to work day-shift right away.”

Those progressive states that have instituted laws regarding CS/SPD certification have enjoyed an increase in post-secondary offerings for sterile processing, but the rest of the country will not match that until public opinion changes,” said Czarnowski. “Area colleges and tech schools will not initiate programs without a strong financial incentive to do so, which means students signing up for their programs. In areas without the requirement for certification, or the presence of unions for
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CS CONNECTION

SPD workers, higher learning institutions have little incentive to offer programs that feed into the profession.”

Continuing education remains a priority
The survey results point to continuing education as a top priority among CS/SPD professionals, with 80 percent of respondents participating in 10 or more continuing education courses/lessons each year, of which 35 percent participate in 20 or more (up 5 percent over 2017).

“Sterile Processing and the healthcare field itself, is constantly altering with updated standards, practices, products and technologies. Therefore, it’s important to keep abreast of these changes by focusing on continuing education,” said Melnyk. “Keeping current in education is vital to the profession, as well as ensuring patient safety. Moreover, it enables the certificant to increase his/her fluency within SPD while maintaining, as well as earning, education relevant to his/her respective certification.”

“Change is the one constant in today’s healthcare. Central Service (CS)/Sterile Processing professionals need a solid background in processing basics to enable them to adapt to changes, make good decisions and meet the needs of today’s healthcare providers,” said IAHCSMM’s Education Director Natalie Lind. “We see a constant need for education as CS technicians and managers strive to keep abreast of new information and technologies.”

But despite the profession’s commitment to continuing education, only 12 percent of respondents said their hospitals give them higher levels of compensation for obtaining certified education units/points.

CS/SPD as a profession: stuck below or rising above?
“As the CS/SPD profession gains more internal recognition in their respective hospitals and outpatient surgery centers, the role that is played by those professionals gets noticed by the local community,” said Greene-Golden. “Safety is the number one job of the CS/SPD professional and we strive every day to meet that requirement for our patients. We want every patient to have a great outcome and here at Shady Grove Medical Center we do our work using the best practice standards of the industry.”

“Fifteen years ago the CS/SPD professional was unheard of in the hospital in which they worked,” she added. “With increasing SSIs (surgical site infections) and the act to get those numbers under control this group has come to the forefront as having a stake in the game. One driving force is that most hospital administrators want to know all of the players in the game in their effort to combat SSIs.”

Secrets to a successful career in Sterile Processing
When asked what CS/SPD professionals can do to advance the field, climb the career ladder and achieve salary gains, those interviewed offered the following advice.

Build your brand
“I am a big proponent of recognition starts with yourself — if I don’t look at it as a profession, if I don’t look at it as an actual field, then no one else is going to do that,” said Lorane Durgan, CRCST, CHL, CIS, Materials Manager and CS Supervisor, Florida Hospital.

“One of the most powerful tools available for climbing the CS/SPD career ladder is the ability to build your own personal ‘brand’ in the world of social media,” said Weston “Hank” Balch, BS, MDiv, CRCST, CIS, CHL, Co-Founder and Host for Beyond Clean Podcast. “What makes you different from the other certified technicians in your department? Why are your five years of experience more valuable to an organization than someone else’s five years? How do you demonstrate that? Social media provides a powerful outlet for you to differentiate yourself, your ideas and your professional brand from those around you.”

“While it’s true that recruiters utilize social media to fill their vacancies, the reality is that many positions are filled before they are even posted in public,” Balch adds. “Creating a presence on social media allows you to tap into this hidden job market, and ensures you are the person folks think about when advancement roles become available.”

Get certified
“If you are interested in moving out into the larger world of sterile processing and surgical instrumentation, seek advance certifications through IAHCSMM, SGNA or CBSPD,” said Casey Czarnowski, a SPD Educator in Fargo, ND. “Those extra letters after you name make a big difference to instrument repair companies, national professional organizations and device and instrument manufacturers. The discipline of flexible endoscope reprocessing is especially newsworthy these days, and any certification or education that you can achieve will be of great value to potential employers. Most importantly, studying for advanced certification contributes to your development as a professional in our field, to the ultimate benefit of your patients.”

Continue your education
After Chuck DePreker, CRCST, CIS, CHL, Operating Room/Sterile Processing Supply Chain Manager at Eisenhower Army Medical Center, left the Army, he earned the “Triple Crown” of IAHCSMM certifications: Certified Registered Central Service Technician (CRCST), Certified Instrument Specialist (CIS) and Certified in Healthcare Leadership (CHL). During his career he has also earned Six Sigma belts and completed a distance-learning course from Purdue. He stresses the importance of education in the profession, noting how his own resume has attracted interest from “high-level, upper echelon SPD director” positions, stating:

“While the career path for SPD techs is perceived to be a dead one, there is always the aspect of job security and the opportunity for upward movement — I am living proof of that,” said DePreker. “SPD is a niche that one can hone and develop. Those in the profession should always keep learning, be assertive and present themselves as experts and leaders. I have found ways to present myself as an expert in this profession and become the type of individual that any organization would want to hire.”

“Be a voice of education, not demand,” said Albert Huether, Director of the Sterile Processing Department at Methodist Healthcare System, San Antonio. “Pass your education to others and with humility. The ideal team player starts with you. Continue to educate yourself by understanding the science, business and leadership of Sterile Processing. Then apply all these methods strategically to better service the department, hospital and community.”

Communicate
“In our healthcare system, CS/SPD professionals are gaining greater recognition thanks to the efforts of leadership in the SPD and the OR, and in upper administration,” said Czarnowski. “Through constant communication, transparency and cross-education we have created a good rapport with our OR managers and surgeons, clinic managers and executive staff. Constant communication means that leaders from all areas and at every level get together regularly and frequently to discuss problems, successes and new initiatives. Transparency takes the form of reporting problems immediately and in all directions.”
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SELF-STUDY SERIES

The science of speed

Today’s rapid readout biological indicators

by Craig Wallace, Senior Technical Specialist, 3M Infection Prevention Division

B
ingenious indicators (BIs) are an important part of a quality control system for hospital sterilization processes. The information on the quality of the sterilization process supplied by biological indicators, when combined with the information from physical monitors and chemical indicators, provides the basis for the decision on whether or not to release the medical devices for use on patients.

Biological indicators are defined as a test system containing viable microorganisms providing a defined resistance to a specified sterilization process. A key point in this definition is "viable microorganisms," as biological indicators are the only sterilization monitoring device that directly tests the effect of the sterilization process on microorganisms. The Centers for Disease Control and Prevention describe the value of biological indicators in their 2008 Guideline:

"Biological indicators are recognized by most authorities as being closest to the ideal monitors of the sterilization process because they measure the sterilization process directly by using the most resistant microorganisms (i.e., Bacillus spores), and not by merely testing the physical and chemical conditions necessary for sterilization. Since the Bacillus spores used in biological indicators are more resistant and present in greater numbers than are the common microbial contaminants found on patient-care equipment, the demonstration that the biological indicator has been inactivated strongly implies that other potential pathogens in the load have been killed."

The primary biological indicator design used in healthcare facilities is the self-contained biological indicator, or SCBI (see Figure 1). Self-contained biological indicators contain the critical elements of the biological indicator: the bacterial spores on a carrier, and the growth media required to culture the test organisms to determine if the BI is positive or negative. The self-contained design eliminates the need for a microbiological laboratory to complete the BI test.

Before we go much further into biological indicators we need to take a minute and review a little bit of microbiology. The term “spores” is short for bacterial endospores. There are a few types of bacteria that have developed the ability to change from an active, growing cell (or vegetative cell) to a highly protected, dormant cell (endospore), and back again depending on their environment. These bacteria will change to a spore when faced with a shortage of food or other conditions that are harmful to the cell. The spore itself is like a plant seed or hard nut — it is biologically dormant (or “sleeping”), it has a highly protective dry shell, and it is capable of withstanding extreme conditions for prolonged periods of time without ill effect. If the spore senses that conditions have improved and will support life, it goes through a series of biological steps called activation and germination, to shed the hard coat and become a regular, active bacterial cell once again. Biological indicators use the spore form of Bacillus bacteria because of the toughness of these spores and the challenge they present to the sterilization process. Each sterilization process requires a specific Bacillus species proven to be the most resistant to that process. For example, steam sterilization processes are tested with Geobacillus stearothermophilus spores.

Spores require a source of nutrients and an optimized temperature and pH to begin the activation, germination, and outgrowth processes. Self-contained biological indicators contain growth media that has been specially formulated to support outgrowth of the spores used in that BI. All biological indicators require incubation, during which the spores are exposed to the growth media and the biological indicator is heated to the optimum temperature for spore outgrowth. Any surviving spores will first activate and germinate to become vegetative cells, and then these cells will begin to “grow," which means they will replicate (one becomes two, two become four, and so on).
Incubation time
The incubation time for a biological indicator is the amount of time that the BI must be incubated before a decision can be made that the BI is negative (i.e., the spores are all dead) and the test is complete. This concept takes a little more explanation... if a biological indicator turns positive, it has completed its “task” of providing information on the quality of the biological indicator system (in the case of a positive control) or of the sterilization process itself (a positive BI test indicates a sterilization process failure). If a biological indicator turns positive you will end the BI test at that point and take appropriate action. But, how long must you incubate a BI before you can decide that it is truly negative and end the test? This time frame is called the incubation time.

The international biological indicator performance standards state that the reference incubation time for a biological indicator is 7 days. This incubation time was established in the early days of biological indicators, and was based on the technology available at that time. An incubation period of seven days is not at all practical or useful in today’s healthcare environment. So, for biological indicators, there was a need for speed.

Biological indicator evolution
The first generations of biological indicators consisted of spores applied to some sort of carrier, such as a piece of suture material. These early BIs evolved into spore strips, where the spores were applied to a small paper strip that was enclosed in a glassine envelope which allowed sterilant penetration while protecting the spore strip from outside contamination. After the sterilization process the indicators were transferred to a test tube containing the growth medium using a process called aseptic transfer. This was typically done in a microbiology laboratory equipped with special laminar flow hoods to try and prevent any environmental organisms from contaminating the spore strip or the media, which would create a false positive result. (Note: This process is not required with self-contained biological indicators). The test tubes were then incubated at the proper temperature for up to seven days. So, how could you tell if the BI was positive or negative? The user needed to look for a “signal” from the spores that they were alive (positive BI), or dead (negative BI).

The original signal used to determine a positive or negative result was the development of turbidity, or cloudiness, in the test tube. If the BI placed in the medium had viable spores (either a positive control or a sterilization process failure), the spores would convert to vegetative cells, and begin to grow or replicate. Over time, the number of cells in the test tube would increase to the point where the density of cells in the tube was high enough to scatter light passing through the test tube, making the medium appear cloudy. While effective, this process required a significant amount of incubation time (up to 7 days) to allow the spores to germinate and the cells to grow for enough generations to be able to scatter light.

The next advance in technology introduced a color-based pH indicator into the growth media, to make the biological indicator signal a color change rather than cloudiness. A pH indicator is a chemical that responds to the acidity of the solution, and will typically be one color at an alkaline pH and change to another color as the solution becomes more acidic. Biological indicators utilizing the pH color change system have growth media that is specially formulated so that bacteria growing in the medium will produce acidic by-products. As the bacteria continue to grow, the growth medium will continue to become more acidic until the pH indicator changes color. This technology enabled the development of self-contained biological indicators in the 1970s. The glass media ampoule in the SCBI was too small to see development of turbidity, but a color change was readily apparent. The optimization of the media in SCBIs and the user’s ability to detect the color change signal faster than the cloudiness signal reduced the incubation time from 7 days to 2 days. This was much faster and easier than spore strips, but still required incubation times that were not optimal for healthcare.

The next major leap in reduction of biological indicator incubation time came from new technology that enabled detection of biological signals from viable spores much earlier in their germination and outgrowth process. To understand this, we need to understand a little more microbiology. The spore activation and germination processes may sound simple but they are actually complicated, multi-step processes. A good analogy is the steps that occur when a computer powers up. Once the power button is pushed the computer goes through a series of actions that turn on many programs and sub-systems in the computer in a specific order, until the computer is fully operational and ready for use. In the spore, the cell’s “sub-systems” are created and activated by many biochemical reactions. Specialized proteins called enzymes act as catalysts that make these complicated reactions happen much more quickly. The first rapid readout biological indicators used the actions of some of these “boot up” enzymes to produce a signal that could be detected earlier in the spore outgrowth process, reducing the required BI incubation time from days to hours.

The enzymes used to produce a signal for rapid readout biological indicators are enzymes that become active early in the activation and germination processes. These enzymes have a specific natural role for the cell, but their catalytic actions can also be utilized to produce a signal that can be detected and analyzed as a positive response. Rapid readout biological indicator technology uses a special indicator in the growth medium that can interact with the enzyme. This chemical is like the pH indicator discussed earlier, except that instead of turning color based on a change in acidity this indicator changes from a non-fluorescent molecule to a fluorescent molecule when it is acted on by the enzyme. Fluorescence means that it will “glow” or emit light at a certain wavelength (say, Wavelength B), if it is first exposed to light of a different wavelength (Wavelength A). So, rapid readout BIs use a biological indicator reader that shines Wavelength A light onto the incubating biological indicators, and has a detector that is sensitive to Wavelength B light to look for a fluorescent signal. If the enzyme is active in the biological indicator (i.e., a positive control BI or a positive BI from a sterilization process failure), the sensors will detect the fluorescent signal and the reader analyzes this signal and indicates a positive BI result.

Rapid readout biological indicator technology has reduced incubation times from days to hours. Continued improvements of the physical design of these biological indicators concentrated the fluorescent signal to make it easier to detect. These changes, coupled with improved sensors and electronics in the readers, have now reduced biological indicator incubation times to less than an hour, and in some cases, less than 30 minutes. This dramatic improvement in incubation time, from 7 days to less than 30 minutes, means that this important quality control information regarding the efficacy of the sterilization process is now available in a timeframe that fits with the healthcare facilities’ workflow.
Quality control of sterilization processes

You can’t see sterility. This basic fact drives the need for a quality control system that provides information on the quality of a sterilization process, so a decision can be made on whether or not the processed instruments are safe for patient use. The American National Standards for the key healthcare sterilization processes: steam, ethylene oxide, and vaporized hydrogen peroxide, all recommend the integrated use of three quality control monitoring tools: physical monitors, chemical indicators, and biological indicators.\(^4,5,6\) The information provided by each tool is different. Physical monitors are electronic sensors inside the chamber that provide data on the environment inside the sterilizer chamber such as the temperature or pressure. This data is recorded on a printout that can also be used as a record of the cycle. Review of cycle printouts from the physical monitors can confirm that the proper cycle was selected. The second quality control tool, chemical indicators, utilize specially selected chemicals that respond to the effects of the sterilization process. Chemical indicators that are used on the outside of packages (Type 1 process indicators) can provide visual evidence that an item has gone through the sterilizer. Common process indicators include indicator tapes and chemical dots printed on packages. Remember that process indicators are only designed to indicate exposure to the sterilant, and they do not provide evidence that the process was effective. The more sophisticated chemical indicators (Type 5 and Type 6 indicators) that are used inside of containers and packages are designed to respond to all the sterilization process variables. These chemical indicators provide more detailed information on whether the required process conditions were achieved on the inside of the packages.

As we have discussed, the third quality control tool, biological indicators, are used to directly measure the effectiveness of the sterilization process by measuring its effect on live microorganisms. Let’s take a closer look at the role of biological indicators in the quality control of sterilization processes.

The role of biological indicators in quality control

Biological indicators are placed with the load inside of the sterilizer chamber in the location determined to be the most difficult to sterilize. The typical biological indicator placement location for large steam sterilizers is over the drain; for ethylene oxide sterilizers, in the center of the load, and for hydrogen peroxide sterilizers at different chamber locations specific to the sterilizer, cycle, and load. The instructions of the sterilizer manufacturer regarding the recommended placement location for the biological indicator in their sterilizer should be followed.

Biological indicators are typically used inside of process challenge devices (PCDs) or other items that can represent the sterilizer load. Placement of biological indicators inside of the containers or packages would give direct information on the lethality of the sterilization process inside the device packaging, but this placement is not practical as even today’s rapid readout biological indicators require incubation time that would not be feasible in the OR. So, biological indicators are placed into PCDs or other devices that are intended to have the biological indicator perform as if it was placed inside of containers or packages in the load. Reference PCDs that can be constructed in healthcare facilities are described in the standards.\(^5,6\) Commercially available PCDs that have been cleared by the Food and Drug Administration (FDA) with performance equivalent to the reference PCDs are also available. These devices eliminate the need for staff time to assemble test packs, and are typically more consistent because of automated assembly processes and quality control procedures required of medical device manufacturers.

The recommended frequency of use of biological indicators in healthcare facilities varies by the sterilization process. For steam, the recommendation from AAMI is weekly use, but preferably daily use, for routine efficacy monitoring. Also, a biological indicator should be used to release any load containing an implantable device. Implant-loads should be quarantined until the biological indicator test result is available.\(^4\) Per AAMI, a biological indicator should be used to monitor every load for ethylene oxide sterilization processes. Again, any implants should be quarantined until the biological indicator results are available.\(^1\) Finally, for vaporized hydrogen peroxide processes, the AAMI recommendation is that biological indicators be used daily, but preferably in every load. The same requirement of BI monitoring with load quarantine until the BI results are available is applied for implants.\(^6\)

As you can see, there is some variability in the current recommended practices regarding frequency of use of biological indicators. It is interesting to note that this type of variation is not allowed for medical device manufacturers that are supplying sterile, single-use devices to healthcare facilities. National and international standards for medical device manufacturers require the same level of quality control for every sterilization load, regardless of the device, intended use, day of the week, etc.\(^4,5,6\) It is curious that reusable medical devices reprocessed in a healthcare facility do not have to meet the same level of safety as those sterile devices received directly from manufacturers. Many healthcare facilities are now leveraging the significant reductions in biological indicator incubation time to increase their frequency of use of this important QC tool, without negatively affecting their work flow. For example, rapid readout BIs make the quarantine of implantable devices until the biological indicator test result is available much more realistic. Many hospitals have moved to monitoring of every sterilization load with biological indicators even where the current healthcare standards do not require it, such as for steam and vaporized hydrogen peroxide. Load items from these processes are not distributed until a negative BI result is obtained. The criteria often cited for making this change include a desire to improve quality control to assure a uniform standard of care for all patients, avoidance of the extra work required in the event of a recall, as well as reduction of errors in the sterile processing department caused by varying requirements for biological indicator monitoring.

Summary

Biological indicator technology has continued to evolve with faster detection of the biological signals produced by the bacterial spores that provide the direct challenge to the sterilization process. These technologies have resulted in biological indicators with incubation times of less than 30 minutes for some sterilization processes. These short incubation times now make it possible to obtain biological test results in time for optimized instrument workflow, including shorter quarantine periods for implantable devices, and in many facilities, for all instruments. These indicators can facilitate improved quality control of sterilization processes by enabling increased frequency of biological monitoring.**HPN**

References:


6. ANSI/AAMI ST58:2013. Chemical sterilization and high-level disinfection in healthcare facilities. Association for the Advancement of Medical Instrumentation, Arlington, VA.
CONTINUING EDUCATION TEST • APRIL 2018

The science of speed
Today’s rapid readout biological indicators

Circle the one correct answer:

1. Biological indicators utilize bacterial spores because spores are difficult to kill and present a significant challenge to the sterilization process.
   A. True  B. False

2. Biological indicators with rapid readout technology rely on a biological signal from germinating and replicating spores.
   A. True  B. False

3. The reference incubation time for a conventional biological indicator is seven days, but rapid readout technology has enabled biological indicators with incubation times of less than 30 minutes.
   A. True  B. False

4. The most effective quality control system for healthcare sterilization uses a combination of physical, chemical, and biological monitoring.
   A. True  B. False

5. Sterilizer printouts from the electronic sensors in the chamber can prove that a sterilization cycle was effective.
   A. True  B. False

6. Chemical indicators on the outside of packages are used to test all the sterilization process parameters and prove that the process was effective.
   A. True  B. False

7. Chemical indicators can provide a direct measurement of the lethality of the sterilization process.
   A. True  B. False

8. Biological indicator manufacturers’ IFUs are the best reference for where biological indicators and PCDs should be placed in the sterilizer chamber.
   A. True  B. False

9. Rapid readout biological indicators can make it easier to quarantine implantable devices until the BI test is complete.
   A. True  B. False

10. For biological monitoring of steam sterilization, AAMI ST79 recommends weekly, but preferably daily testing, as well as use of biological indicator PCDs with all implant loads.
    A. True  B. False

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Craig Wallace is a Senior Technical Specialist in the 3M Infection Prevention Division laboratory. Craig is the Convener of the ISO Biological Indicator Working Group (TC 198, Working Group 4), the international committee responsible for biological indicator performance standards. He is also the Co-Chair of the United States (AAMI) Biological Indicator Working Group. Craig leads the 3M Sterilization Technical Service and Education Team, and has given lectures on a wide range of sterilization-related topics in North America, South America, Europe, and Asia.
CS SOLUTIONS

Soaking solutions; hand sanitizer violations; identifying mysterious gray stains

by Ray Taurasi

Q I work at an ambulatory surgery center and at the end of a surgical procedure our OR team has always placed used instruments into a ring stand basin which contains irrigating saline. The ring stand with instruments are then moved across the hall to the OR instrument workroom and are left soaking in the basin until they can be washed. The surgery center was recently acquired by a large healthcare organization and we are being scrutinized by a group of consultants who have mandated many changes on how we do things, including processing instruments. One such mandate was to discontinue placing our soiled instruments in saline immediately. They are really nitpicking on many small things like this. I can appreciate change when it is warranted but does it really matter if instruments are placed in the irrigating solution? We are just keeping them moist to prevent soil from drying.

A It is very important to keep soiled instruments moist to prevent organic matter from drying on them. However, saline solution should never be used as an instrument soak as it is extremely caustic and can cause corrosion and damage to the instruments. For the same reason blood, which consists of saline, and organic matter should always be wiped from instruments during the surgical procedure. Soiled instruments can be kept moist by:
- placing a water-moistened towel over the instrument and then placing them in a closed transport container or sealed plastic bag;
- utilizing a treatment solution such as an enzymatic spray, gel or foam; and
- placing in a commercial package designed to create and maintain moisture.

Q Our Safety council recently conducted an inspection of the SPD and found many changes on how we do things, including processing instruments. One of the mandates was to discontinue placing our soiled instruments in saline immedi-ately. Are really nitpicking on many small things like this. I can appreciate change when it is warranted but does it really matter if instruments are placed in the irrigating solution? We are just keeping them moist to prevent soil from drying.

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A. placing a water-moistened towel over the instrument and then placing them in a closed transport container or sealed plastic bag.
B. utilizing a treatment solution such as an enzymatic spray, gel or foam.
C. placing in a commercial package designed to create and maintain moisture.

Q As a result has required us to remove all alcohol-based, hand-sanitizing products and dispensers throughout the entire department. We were told that the products were in violation with municipal fire code regulations. At the same time, I have noticed that other departments still continue to use hand sanitizers and dispensing stations. Why the double standard?

A Alcohols are flammable. Flash points determine the temperature at which a particular organic compound gives off sufficient vapor to ignite in air. The Flash Points of alcohol-based hand rubs range from 21°C to 24°C (70°F to 75°F), depending on the type and concentration of alcohol present. Alcohol-based hand-hygienic agents must have an alcohol concentration of 60 percent to 95 percent to be effective. State or municipal regulations might dictate when and where such agents may be used and be placed within a facility. You might want to discuss your situation with the appropriate source from your safety council to grasp a better understanding of why your hand sanitizer was in violation and others within the hospital were not. It seems as though it would make sense for the council to establish a detailed policy on this important matter and for the hospital to consider product specification and standardization.

Q We have been experiencing intermittent issues with a mysterious gray-colored staining on our packaging materials, tray liners, peel pouches and wraps. What is perplexing is that the stains only appear on some packages in the same load, some of the staining is on the inner wrappers while other staining is on the outer wraps. Our Biomed has assured me that our steam and water quality is excellent. Some lab samples of the stained packages have tested positive for aluminum. I have noticed that some new aluminum trays, containers and cassettes we recently purchased are also discoloring and I was wondering if they might have something to do with our problem.

A Certain chemicals, detergents and sterilants can have a caustic affect on certain metals such as aluminum; the metals can degrade and slough off and deposit on wraps and other items in the sterilizer. I don’t know enough about your situation to determine if that is indeed the cause of your problem. The fact that your aluminum cases, etc. are discoloring is indicative of some problem which may be relevant. You need to verify that you are following the manufacturers’ IFUs for the aluminum devices you are using, including cleaning protocols, proper use of chemical agents and sterilization processes. I would investigate and document what is being packaged in the stained packages – do they contain the aluminum products in question? You also want to be certain that you use quality aluminum products as there are different grades and types of aluminum. Anodized aluminum is superior but like all other devices proper care and handling must be applied to ensure and maintain its serviceability. Anodizing is a process, which gives aluminum a protective surface of aluminum oxide, which is scratch and corrosion resistant and is not electrically conductive. A non-anodized metal is not corrosion resistant and it can become reactive having an adverse impact on other metals, which come into contact. An electrolytic couple reaction dissolves and corrodes other metals. Further, a non-anodized aluminum material will oxidize when exposed to steam or water during routine cleaning, decontamination, and sterilization, producing a white powdery film. In addition, non-anodized aluminum scratches easily and will discolor through routine use becoming cosmetically unsightly. Surgical instruments can also corrode, rust and stain when they come in contact with the non-anodized material. What is imperative is to keep metals protected from corrosion. In fact, aluminum material has a MilSpec for corrosion resistance that all manufacturers of sterilization containers need to meet in order to sell products to the federal government. That is why pH-neutral detergents are necessary for cleaning aluminum containers to avoid corrosion when the caustic or acidic cleaning agents or chemicals remove the anodized surface.

Ray Taurasi is Principal, Healthcare CS Solutions.
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The International Association of Healthcare Central Service Material Management (IAHCSMM) is calling upon qualified members to push their professionalism to new heights and embark upon the rewarding Fellowship journey. Fellowship status is among the highest honors professional organizations can bestow upon their members. IAHCSMM’s Fellowship program formally recognizes the competence of its members and provides members with a measure of achievement that will be meaningful even to those outside the organization.

Earning the prestigious Fellowship designation requires hard work, determination, a commitment to professional advancement, and a strong desire to raise the bar as both an IAHCSMM member and a contributor to the CS profession. Currently, only 25 professionals have earned the IAHCSMM Fellowship distinction; however, several individuals are actively pursuing Fellowship at this time. The Association remains confident many more individuals have what it takes to cross the Fellowship finish line. Often, all that’s needed is a willingness to demonstrate knowledge of the information presented in the research paper. If Fellowship is granted, the recipient will be recognized at the IAHCSMM Annual Conference.

Applying for Fellowship and completing the IAHCSMM Fellowship process is a journey that can take many months and, for some, a year or more; however, each step is one that can help sharpen the applicant’s written and verbal communication skills, and advance one’s knowledge and professionalism.

Laying the foundation
Before one embarks upon the IAHCSMM Fellowship journey, it is essential to ensure that all requirements can be met. These requirements include the following:

- Must be an active IAHCSMM member in good standing for at least five years and hold the Certified Registered Central Service Technician (CRCST) designation.
- Must be responsible for directing a Central Service (CS) department of a healthcare facility or have an interest by virtue of practice.
- Must submit a research paper on a topic pertinent to the CS profession, such as processes and/or practices that led to targeted, quantifiable improvements within the department or facility. Research papers should be extensively researched and, generally, at least 10 pages in length, not including charts, graphs or other illustrations/images. Papers should be written in a professional manner, much like a journal article or college thesis, and include references to support statements, data and other content. Careful attention must also be paid to proper writing style, formatting, punctuation and grammar.
- Must submit a Curriculum Vitae and two professional letters of recommendation.
- Must complete an in-person interview with the IAHCSMM Fellowship Committee to demonstrate knowledge of the information presented in the research paper.

Several examples of previously accepted Fellowship papers include:
- Reducing Immediate Use Steam Sterilization: SPD’s Role;
- Boiling: The Answer to High-Level Disinfection of Surgical Instruments in a Third World Country; Factors Affecting the Leadership Process Improvement Teams in Sterile Processing; and
- Managing the Steam Sterilization Process.

Steps to Fellowship
IAHCSMM members who meet the aforementioned criteria and are interested in pursuing Fellowship will then complete the following steps.

Step 1:
Submit the following to IAHCSMM headquarters:
- Fellowship application;
- Curriculum Vitae;
- Research paper topic and detailed outline.
- Two letters of recommendation; and
- Research paper draft and cover letter.

Step 2:
The Fellowship Committee will review the application and research paper outline. The candidate will be contacted regarding the next steps in the Fellowship process.

Step 3:
Submit final research paper and cover letter to the Fellowship Committee.

Step 4:
Final research paper will be reviewed by the Fellowship Committee.

Step 5:
The applicant will sit for an interview with the Fellowship Committee during the IAHCSMM Annual Conference to demonstrate knowledge of the information presented in the research paper. If Fellowship is granted, the recipient will be recognized at the IAHCSMM Annual Conference.

To learn more about the Fellowship process, explore several previously-accepted Fellowship papers and review Fellowship writing tips and materials, visit www.iahcsmm.org/about/fellowship.html. Those attending the 2018 IAHCSMM Annual Conference and arriving to Phoenix early are also encouraged to attend the April 28 pre-conference workshop “Writing for Publication and IAHCSMM Fellowship.” This one-hour session will be held at 10:15 a.m. and then will repeat at 1 p.m. Full conference attendees may attend the pre-conference workshop at no extra charge; however, space is limited and available on a first-come, first-served basis. For more information about the IAHCSMM Annual Conference & Expo, visit www.iahcsmm.org/events/annual-conference-expo.html.
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PRODUCTS & SERVICES

Anatomy of a surgical suite

Make no bones about the technology needed to run the OR

by Rick Dana Barlow

If beds and patient transport equipment epitomize the workhorses of a hospital or healthcare facility, then surgical tables, lights and booms represent the skeleton of the surgical suite. (For a report on beds and patient transport equipment, see the February 2018 edition of Healthcare Purchasing News.)

Just as clinicians, administrators and supply chain professionals have witnessed numerous ergonomic improvements and technological developments in beds and patient transport equipment during the last 40 years, they surely have noticed similar developments and improvements in the workhorses of the OR.

Much of what happens in the traditional or integrated surgical suite revolves around the center of the room where the surgical table is positioned with the patient atop. Lights and booms that hold electronic equipment, such as audio and video consoles, and power outlets (as well as the lights themselves) also may occupy both types of surgical suites. Diagnostic and directional imaging and robotics added to the suite converts the traditional to the integrated model.

“We’ve heard consistent feedback from OpenMarkets Exchange users that when it comes to OR innovation ‘it all comes back to navigation and robots.’ I couldn’t agree with this more,” said Tom Derrick, Senior Vice President and Co-Founder, OpenMarkets. “For OR tables, this means tables are much more niche and configured to the mini scale, whether as small as a mobile imaging suite.”

For example, the STERIS Surgigraphic 6000 is a purpose-built table for guided surgery. They key innovation here is a ‘fluid top’ that allows smoother positioning of the patient. This lets the surgeons better align the patient and the surgical robots. This is a huge innovation for patient safety.

“For forty years ago it was common to see clinicians picking up the sheet to reposition patients in surgery!” Derrick added.

One of the foremost design progressions for surgical tables enables imaging in the OR. “Surgical C-Arm tables using isocentric lateral roll motion are relatively new to the industry,” said Richard Schubert, MPA, BS, RT(QM), Senior Product Sales Manager, Biodex Medical Systems Inc. “We engineered our latest Surgical C-Arm Table 840 with this unique movement enhancement because it does wonders for minimizing image distortion during cardiac procedures by maintaining image center while the table moves. The creation of carbon fiber tabletops were another very significant innovation from the last 15 years or so that we included in our Surgical C-Arm Tables. Instead of requiring metal support on the sides of the table, they allowed for a complete radiolucent area. Both of these innovations have made positioning more convenient and helped improve image quality.”

“It’s all about functional flexibility and mobility over fixed and stationary room functionality. “Image Diagnostics’ primary focus involves X-ray imaging systems that require table designs to present artifact-free imaging over as large an area as possible,” said Remo Rossi, President, Image Diagnostics. “In the early 90s Image Diagnostics pioneered fully cantilevered table top designs to allow imaging systems to access patients for head to toe imaging.

“The main thrust of our product development since then has focused on improving mobile table designs to the point where they provided virtually all the same functions as one would find in a floor-mounted product,” Rossi noted. “Creating a stable yet fully mobile platform for imaging procedures has allowed hospitals, imaging centers, etc., to narrow the investment required to just capital equipment in lieu of room constructions and infrastructure improvements. With the dramatic improvements in mobile X-ray technology, many procedures that were once only completed in fixed rooms can now be accomplished using a mobile imaging suite.”

Two decades ago in 1997 the intraoperative magnetic resonance imaging (iMRI) project was established in Winnipeg, Canada, recalled Andy Flanagan, CEO, IMRIS. The goal was to introduce a high field magnet into the OR to give neurosurgeons access to brain image detail during surgery that would result in greater precision and accuracy, reducing the need for additional operations as well as eliminating exposing patients to possible infection when moving in and out of the OR, according to Flanagan.

“The founders of IMRIS understood that to minimize the need for additional surgeries and improve patient outcomes, surgeons would need access to high-quality image detail while the patient was on the table,” Flanagan said. “They also understood that keeping the patient stationary while moving the MRI would be safer than moving the patient to the magnet. The result of this innovative thinking and development was the world’s first ceiling-mounted, moving intraoperative magnet, which has since evolved into what is now the IMRIS Surgical Theatre — a comprehensive suite of advanced imaging technology, OR configurations and equipment.”

Today’s surgical tables include an increasing array of Trendelenberg positions, flexible table-top switching, the ability to support bariatric patients as heavy as 700 pounds, incorporate mobile drives and plug-ins for vital signs monitoring. Like beds, surgical tables seem to be en route to being an extension of both the patient and the clinician.

Ask industry experts about surgical light progression and they undoubtedly will home in on one aspect: Bulb type.

“Without a doubt the biggest innovation in surgical lights has been the conversion from halogen to LED,” insisted OpenMarkets’ Derrick. “We’re now using run-cool lights that are 40 to 60 times more efficient than bulbs used just a decade or so ago.”

Image Diagnostics’ Rossi agrees. “For decades, halogen has been the source of choice for surgical lighting, despite several drawbacks,” he indicated. “Light emitted from halogen bulbs have a yellow/green appearance and do not emit in the spectrum of natural daylight required for an ideal working environment. Halogen lights have a high-power consumption and cause an increase of temperature in the operating field. Halogen lights also have a short lifetime and inferior performance in red color rendering index (R9).”

Since the introduction of LED technology in 2006, according to Rossi, surgical lighting has overcome most of the drawbacks from
When it comes to supporting quality OB/GYN care, Brewer offers you much more.

Aside from the variety of functional tools to add to a boom as surgeries become more complex, sources indicate that the ceiling and floor mounts (no wall mounts) and mobile varieties capstone boom development. Wireless capabilities, however, offer an intriguing “what if” scenario for boom development and progression.

Lights, on the other hand, may offer some possibilities.

“In the past, developments in the medical industry have been influenced by developments in other sectors, such as the automotive sector,” Rossi said. “This trend could continue and we could see developments such as gesture or voice control for surgical lights. Also, an alternative way of how surgical lights are installed within the operating room could be one of the innovative developments in the future.”

Meanwhile, Derrick points to more administrative issues.

“We aren’t aware of any fundamental innovations coming down the pike for surgical lights and booms,” he indicated. “However, as providers merge and get better at consolidating their capital data, we expect to see a more proactive approach to purchasing lights and booms. This equipment is often bought at the same time, and providers with good data can collaborate with manufacturers on both purchases easier. This makes it more efficient to not only contract but also to evaluate all the options in the market.”

Expect more development and innovation to emerge with tables, experts agree, particularly targeting clinical specialties.

ROSSI: “Image Diagnostics will be launching an advanced urology table in 2018,” Rossi revealed. “New products will refocus on capabilities that are more closely aligned with the increasing emphasis on endoscopic procedures. Our new urology table will feature a more ‘camera-centric’ design and integrated video processing and visualization. We have also recently introduced an upgraded line of advanced vascular tables with a 600-pound patient capacity as well as enhanced ranges of motions.”

Flanagan anticipates expanding the applications of intraoperative imaging with MR compatibility within the surgical theater and outside the traditional imaging suite.

“Bringing intraoperative MRI to other disease states will certainly require innovative solutions,” Flanagan noted. “For example, nearly 85 percent of neurosurgical procedures involve the spine. The challenge with imaging the spine is that you must insert the patient much deeper into the MRI scanner while carefully monitoring the patient and managing the sterile field, drapes, and anesthesia. One of the benefits of the current IMRIS MR neurosurgery future or voice control for surgical lights. Also, an alternative way of how surgical lights are installed within the operating room could be one of the innovative developments in the future.”

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PRODUCTS & SERVICES

Sweet surgical suite
What follows is an alphabetical listing of the leading manufacturers of surgical tables, lights and booms, along with links to key product lines worth noting with all the necessary details.

Biodex - www.biodex.com
  • Tables: https://www.biodex.com/medical-imaging
  • CV Medical - www.compviewmedical.com
  • Booms: https://compviewmedical.com/our-products

Getinge - www.getinge.com
  • Booms: https://www.maquet.com/us/products/moduvel/
  • Lights: https://www.maquet.com/us/workspaces/operating-room/?filter=12
  • Tables: https://www.maquet.com/us/workspaces/operating-room/?filter=5

GETLIN - www.getinge.com
  • Booms: https://www.maquet.com/us/products/moduvel/
  • Lights: https://www.maquet.com/us/workspaces/operating-room/?filter=12
  • Tables: https://www.maquet.com/us/products/moduvel/

Hill-Rom - www.hillrom.com
  • Booms: https://www.trumpfmedical.com/us/products/support-units/
  • Tables: https://www.allenmedical.com/ and https://www.trumpfmedical.com/us/products/or-tables/

IMRIS - www.imris.com
  • Booms and Tables: https://www.imris.com/explore-the-surgical-theatre/

Karl Storz - www.karlstorz.com
  • Booms, Lights and Tables: https://www.karlstorz.com/de/en/karl-storz-or1.htm

Midmark - www.midmark.com
  • Lights: http://www.midmark.com/products/medical/lighting

Siemens Healthineers - www.healthcare.siemens.com/
  • Booms and Tables: https://usa.healthcare.siemens.com/clinical-specialities/surgery

STERIS - www.steris.com
  • Booms: https://www.steris.com/healthcare/products/surgical-booms
  • Tables: https://www.steris.com/healthcare/products/surgical-tables

Stryker - www.stryker.com

Image Diagnostics: www.imgediagnostics.com
  • Booms: http://imgediagnostics.com/suspension-systems/
  • Tables: http://imgediagnostics.com/c-arm-tables/

Noteworthy products

BIODEX: The NEW Surgical C-Arm Table 840 from Biodex is designed for image-guided fluoroscopic procedures where stability, access, and precise, quiet, vibration-free positioning are essential. Latest model includes a stainless steel base, larger radiolucent area, exclusive SmoothGlide movement and isometric lateral roll motion to help ensure a clear image.

IMRIS: The iMRI capability necessitates a surgical table that meets several challenging requirements: It must seamlessly integrate with the workflow of the surgical staff, allow for precise positioning of the patient within the magnet, have sensors integrated within the control system that are monitoring the magnet, and be compatible with the high fields produced by the magnet. Since the first iMRI case was performed in 1997, IMRIS has developed four generations of unique surgical tables, the newest in collaboration with Hill-Rom (Trumpf Medical), and that combines an IMRIS MR-compatible surgical table top with the Trumpf TruSystem 7500 platform. Fully integrated with the IMRIS Surgical Theatre, the system also offers an interchangeable tabletop to accommodate multiple specialties.

Image Diagnostics: S.I.M.E.O.N. Medical has learned how to further increase the light performances of high-end surgical lights while reducing overall power consumption. The result of this development was the patented Sim.POD technology – an aluminum-coated reflector that is formed around a base with 3 LEDs. Sim.POD technology allowed SIMEON Medical to manufacture the first LED surgical light with natural white LEDs, outstanding technical specifications and a maximum light intensity of 160,000 lux that offered a power consumption of less than 90 Watts. Image Diagnostics and S.I.M.E.O.N. are partnering to launch this surgical lighting technology in the U.S. in 2018.

Brewer Company: Are you looking to install a multi-tasking procedure table in your OR? Brewer’s AssistPRO Power Procedure Table offers 4-function programmability that accommodates multiple positions for a variety of procedures. The easy-to-use two-step programming method relies on a standard hand pendant and foot control pad. The AssistPRO can be lowered to 19 inches, facilitating wheelchair transfers, and can accommodate larger patients courtesy of its 450-pound weight capacity and a 5-inch leg extension and sports a 3-point pivot headrest. The AssistPRO is available in 12 standard seamless upholstery colors, carries a standard 3-year warranty and requires a 7-day lead-time, customary with all Brewer Power Tables.
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Is offsite sterile processing for me?
Eight factors to consider before moving your operation offsite

by Derrick Bransby

The market for healthcare services is rapidly changing; consumers are savvier, competition is fierce, and laws and policies governing the market are in a near-constant state of flux. Such pressures have forced healthcare leaders to think differently about the organizations they lead and identify creative solutions for increasing efficiency, improving quality, and cutting cost. Most recently, one such solution gaining momentum in healthcare systems throughout the country is relocating ancillary operations, specifically sterile processing, to offsite facilities.

Relocating sterile processing operations to a centralized offsite facility, whether owned internally or operated by a third party, is a rapidly emerging trend. While some systems have already successfully implemented offsite processing, many others are actively considering a move, citing benefits such as increased efficiency and equipment utilization, improved regulatory compliance, enhanced quality, decreased processing cost, and opportunities for new revenue generation in the recovered facility space. However, the move to an offsite facility also comes with risk. From a clinical perspective, one must be concerned about infection prevention, quality assurance, and availability of instruments and supplies at a moment’s notice. From an administrative perspective, there are issues related to transportation, compliance, inventory management, operations planning, and other crucial supply chain functions.

Unfortunately, there is no easy answer; the case for offsite sterile processing is unique for each hospital and healthcare system. The best offsite sterile processing operations are engineered solutions—facilities sized and designed to meet the dynamic needs of the healthcare systems they serve. Too often, leaders simply view offsite facilities as a “silver bullet” for space constraints within the four walls of a hospital. If footprint reduction is the key motivator for creating an offsite facility, then proceed with caution. The reduction alone will likely not be enough to justify a move off site. Instead, consider the following eight factors to determine if an offsite sterile processing facility is right for your organization.

1. Demand for processing
In general, offsite operations make the best business case when demand from multiple facilities can be combined for processing (e.g., a hub and spoke model). However, that is not to say that offsite operations are limited to large healthcare systems. Partnerships between multiple hospitals, surgery centers, etc. are not unheard of when considering offsite operations, although they can introduce their own unique complexities.

2. Geography and transportation requirements
Systems with a compact geographic footprint are often better suited for offsite operations than those spread over a large area. Time is of the essence when collecting soiled instruments and delivering sterile material to clinical staff. As such, transportation systems must meet the required service criteria and be well managed. The expense and expertise associated with operating a successful transportation system must not be overlooked.

3. Data integrity and process standardization
Visibility to accurate, near real-time data is a must. Reliable item masters, preference cards, tracking data, etc., should be available prior to moving operations off site. Without access to reliable data, successfully managing an offsite facility is nearly impossible. Furthermore, standard processes and systems are required to en-
PEOPLE & OPINIONS

Offsite Sterile Processing Readiness

4. Inventory management and service level
Balancing the quantity and location of inventory within the system is a crucial aspect of offsite planning, and one that must not be overlooked. Offsite operations may require a net increase in inventory to accommodate longer processing times, as well as transportation time. Availability of instrumentation and supply when needed, often referred to in the industry as the fill rate, must be nearly perfect to ensure success. A robust inventory management system is vital.

5. Clinical environment
Any offsite operation must be designed to complement clinical operations and improve outcomes. Systems with a significant volume of predictable, elective procedures planned far in advance are typically the best candidates for offsite processing. On the other hand, hospitals such as academic medical centers that see frequent emergent cases or highly complex procedures are not as ideal because they must often retain a significant processing and storage capability on site, thereby diluting the business case for an offsite facility.

6. Supply chain expertise
Running an offsite sterile processing operation means not only managing the processing engine itself, but also managing transportation, inventory, etc. While some health systems have individuals with these skills in house, many do not. Experience indicates that the most successful offsite projects have strong leadership who have, or are willing to obtain, supply chain talent. Running a successful offsite facility is a full-time job and should be treated as such.

7. Integration with a strategic vision
The rise of consolidated service centers (CSCs) has had an important impact on offsite sterile processing operations. The business case for offsite processing, coupled with that for other ancillary operations like supply chain, equipment storage, pharmacy, clinical lab, etc., is often more compelling than that of sterile processing alone. It is important that leaders consider a broader strategic vision to include future centralization of shared services, acquisitions and mergers, etc.

8. Buy-in from leadership
Buy-in from all levels of leadership is crucial. If key players are not on board, moving off site is not likely the best course of action. However, it takes more than executives and senior management to make the offsite operations run efficiently and effectively. It is prudent to identify a project champion and involve key leaders from the OR and sterile processing department early in the process. If buy-in from end-users (e.g., nurses, surgeons, technicians, etc.) is lacking, experience suggests the outlook is dim.

If effectively analyzed, the eight factors presented above should lead to more questions than answers—and that is a good thing! Offsite operations are complex, multifaceted systems that require thorough analysis and planning. It is crucial that healthcare leaders consider each facet carefully. Offsite operations have unique challenges that make the planning and design process fundamentally different from designing an onsite operation. Not only does scale necessitate a more detailed approach to facility layout and equipment planning, but it also requires prudent consideration of advanced technology, transportation, inventory management, and long-term strategic plans with regards to growth, real estate, and finance. That said, complexity need not be scary. The potential benefits of offsite processing can be realized when facilities and processes are engineered to meet the needs of the hospitals and healthcare systems they serve.

Derrick Bransby is an engineer and project manager at St. Onge Company (www.stonge.com), an independent engineering firm based in York, PA. He specializes in applied industrial engineering and actively studies the application of systems thinking to the delivery of affordable, high quality, patient-centered health care. Bransby received his BS in Engineering from the University of Pittsburgh and is enrolled as an MBA candidate at the Johns Hopkins Carey Business School. You can contact him by email at dbransby@stonge.com.
R

egulatory and market demands for more real world evidence (RWE) on product performance and changing reimbursement structures are necessitating changes in how providers have traditionally managed product item data. The drive for RWE on medical devices has been enabled by the U.S. Food and Drug Administration regulation requiring manufacturers to label their products with unique device identifiers (UDIs). It was further strengthened by regulations from the Office of the National Coordinator for Health IT (ONC) and the Center for Medicare and Medicaid Services (CMS) requiring electronic health records to hold UDIs for implantable devices in electronic health records (EHRs) and providers to share that data as part of the Common Clinical Data Set (CCDS). With data on products used in patient care in EHRs and subsequently registries, researchers can study how specific medical devices perform in routine clinical practice. Their research can assist providers in sourcing the best products for specific patient populations and more effectively managing recalls, while helping manufacturers design and market products based on real world performance.

Effectively capturing and managing data about products used in patient care can deliver a range of benefits for providers, from more complete charge capture to calculating costs for delivering care. Bill Mosser, vice president of supply chain services for Franciscan Missionaries of Our Lady Health System (FMOLHS), says hospitals and health systems have traditionally not been required to understand the true cost of an episode of care. They were simply paid based on the services performed. As a result, he says, they have not historically built systems to enable that capability.

That approach no longer works with advanced payment models, such as bundled payment where providers will be paid a target price lower than what CMS has historically paid. To manage toward a target price, hospitals and other providers involved in the episode of care need to understand not only their actual costs but also how variation impacts both cost and quality. Knowledge about what drives that variation, e.g., the patient, the physician, the products used, etc., can inform care pathway redesign. The process begins by collecting data at the individual patient level. As healthcare systems gather data across many patients and procedures, they can explore relationships between multiple factors, including but not limited to patient co-morbidities, physicians, facilities, products used, lengths of stay, complication and infection rates, readmissions, etc., all of which lay the groundwork for more advanced predictive and prescriptive analytics to further improve the cost and quality of care.

Supplies can make up a significant portion of the cost of some procedures, making data on products consumed critical to patient-level cost accounting. To ensure that its EHR has up-to-date and comprehensive data about all of the products used in patient care, FMOLHS chose to use a cloud-based or virtual industry item master as the source of the data as opposed to its on-premise ERP item master. To do otherwise would have required FMOLHS to increase the size of its ERP item master nearly five-fold. Instead, FMOLHS follows best practice and limits the products in its ERP item master to those most frequently purchased.

The product data needed by the health system to perform various functions comes from a variety of internal and external sources. The virtual item master provides the external data, which includes attributes published by manufacturers to the Global UDI Database (GUDID), as well as additional attributes not typically provided by manufacturers but which are relatively standard across the industry, such as UNSPSC and HCPCS codes that are used for classification and claims, respectively. But this data is still not enough for hospital systems to perform all of the necessary activities and analytics related to product usage. For that reason, FMOLHS has also deployed technology to bring in additional data elements that are specific to its own organization, such as contracted unit price, revenue and charge codes, and flags indicating whether a product is billable. Getting this data right has important downstream impacts, e.g., ensuring complete charge capture.

Another critical component is the ability to accurately scan product barcodes at the point of care and ensure those scans link to the data needed by the healthcare system. To address this issue, FMOLHS undertook a concerted effort to make sure it could scan every product used in the perioperative environment. FMOLHS is now getting more than a 98 percent successful scan rate with linkages to needed product data. Mosser, who previously worked in the automotive industry, believes the healthcare industry has to go back to fundamentals and embrace what the manufacturing industry has known for decades – that the only way for an organization to be profitable is for it to know exactly what it is spending to deliver its product/service and the value that the consumer, in this case the patient, received. By integrating supply chain, clinical and financial data on the products used in patient care, FMOLHS has taken important first steps toward answering those questions.
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The long tail of Supply Chain’s expense continuum

Why stay on the narrow path to savings when you can achieve more going long?

by Robert T. Yokl, President and Chief Value Strategist, SVAH Solutions.

For more than 50 years, hospitals, healthcare systems and integrated delivery networks have depended on price concessions, standardization and their group purchasing organizations to provide the fire power necessary to keep reducing their healthcare organization’s supply chain expenses.

This strategy has worked superlatively up to a point, but now all healthcare organizations have reached what is called “The Law of Diminishing Returns” where even more effort to save money translates into less savings being generated from these three savings sources that I just mentioned. We consider this scenario the narrow path to supply chain expense savings, while the “long tail” should be regarded as supply utilization.

Narrow path

Unfortunately, these tried-and-true savings tactics (price, standardization and group purchasing) are clustered close to the Y-axis (or narrow path) of the “long tail” shown in Exhibit A resulting in only a trickle of savings because these sources of savings have greatly matured.

Yes, I know that all healthcare organizations have worked even harder over the last few years on group buys, reverse auctions and committed volume programs, etc., to improve their price position, but these tactics haven’t moved the needle on savings at these healthcare organizations. As proof, just look at your healthcare organization’s profit and loss statement.

The “long tail, a concept developed by Wired magazine editor Chris Anderson, and explained by Margaret Rouse of Whatis.com, “is a frequent distribution pattern in which occurrences are most densely clustered close to the Y-axis and the distribution curve tapers along the X-axis. The long tail refers to the low-frequency population displayed in the right-hand portion of the graph (Exhibit A) represented by a gradual sloping distribution curve that becomes asymptotic to the X-axis. In most applications (of the concept), the number of events in the tail is greater than the number of events in the high frequency area, simply because the tail is long.”

Now that we have examined the theoretical long tail, let’s see how this concept can be applied to the supply chain expense continuum.

Long tail

Moreover the “long tail” or X-axis in Exhibit A provides a greater number of new utilization savings opportunities in the range of seven to 15 percent, than the number of new savings opportunities in the high frequency area or the Y-axis, which calculates to be 1 percent to 3 percent annually.

For example, I’m sure you receive 500 or more new or renewal GPO contracts annually from your GPOs that may save you 1 percent to 3 percent of your total supply chain expense budget. Similarly, 100 utilization misalignments (i.e., wasteful and inefficient consumption, misuse, misapplication or value mismatches) could be identified over a longer period that will save you 7 percent to 15 percent of your total supply chain expense budget. Get the idea? The “long tail” provides a greater number of big savings opportunities in the long-term for your healthcare organization, than the higher frequency area.

This begs the question, where should Supply Chain/Value Analysis leaders be spending their limited time? It is obvious that you should be focusing on the “long tail” of supply utilization. This doesn’t mean that you ignore the high frequency areas price and standardization, but you also focus your value analysis teams’ efforts on utilization management.

Supply utilization/value analysis connection

After 17 years of specializing in supply utilization management, we have discovered that value analysis teams have the best opportunity to investigate and then eliminate their healthcare organization’s utilization misalignments, looking at the lifecycle cost (birth to death) of the product, services and technologies they are evaluating or studying.

We need to more than investigate whether products, services and technologies are safe and appropriate for their intended use.

Meaning, value analysis teams need to look deeper and broader into how the thousands of products, services or technologies their healthcare organization is buying annually are being utilized as opposed to how much they cost initially. Remember, the unit cost of a product, service or technology is only one-tenth of its in-use cost when you add up all the direct and indirect costs associated to its use. For example, if an I.V. set costs $1, then its in-use cost could be $10 once you add in all storage, delivery, stocking, tagging, inventorying, charging and removal cost of getting it to the end-user.

Pathway to greater savings

The healthcare marketplace is rapidly changing to value-based contracts from fee-based, and that's why supply chain/ value analysis strategies, tactics and techniques need to be continually evolving to meet these new challenges. How you look at your products, services and technologies’ “long tail” or utilization could be the difference between your hospital, system or IDN continuing to be profitable in the new healthcare economy we all live and work in.
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