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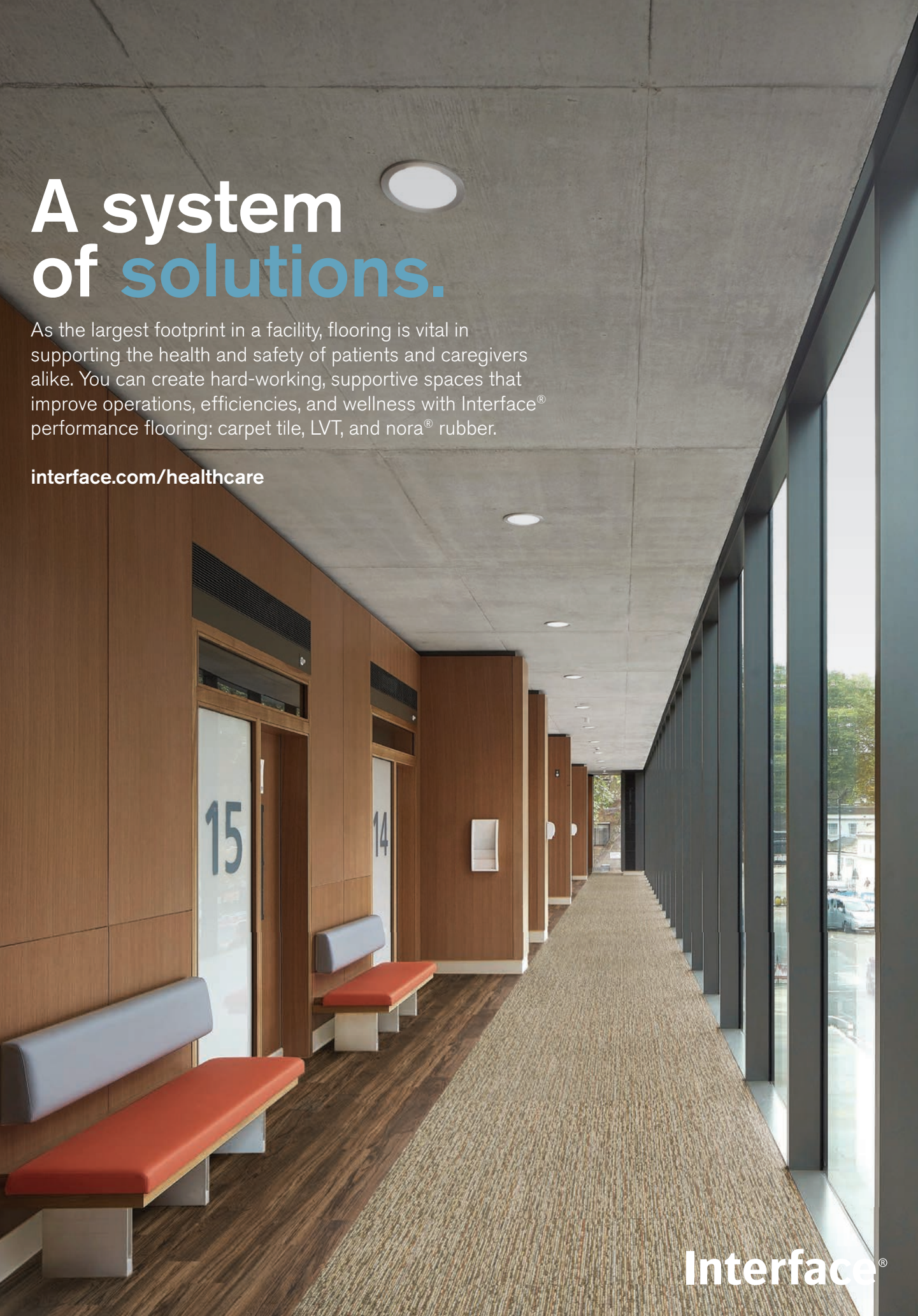

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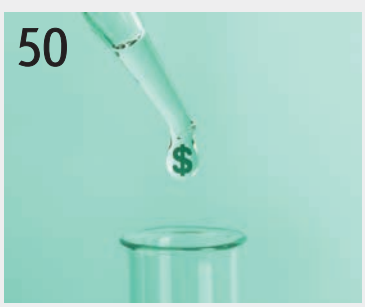

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1. European Heart Journal, Volume 34, Issue 37, 1 October 2013, Pages 2862–2872, https://academic.oup.com/eurheartj/article/34/37/2862/503604.

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GETINGE

SKU'd
Idle minds, idyll finds

When the goings get tough, the tough should innovate.

With a growing number of people working from home these days who aren't trained or used to the "freedom," you'd surmise that many succumb to idling along and "wasting" time (as in non-productive tasks for the boss and the corporation).

Idle minds tend to beget one of three things in a person: Ennui, crime or creativity.

If you're a first-moving forward thinker, being cooped up courtesy of the coronavirus during the last seven months hopefully motivates your creative bug – not only to search for ways to protect people from the pandemic or prevent it from perpetuating, but also to cope with it as we navigate "The New Nominal." (See August 2020 SKU'd.)

Like how, for example?

- Beyond investing in UV-C light sanitizer/sterilizer units on wheels to clean surfaces as well as portable UV-C light devices for environmental services staff to use, what about equipping drones with this capability, too? How about a smart-phone app that can emit UV-C light?
- Using the QR reader app on your smart phone to interact with touchscreen kiosks, rendering them "touchless?" What if the O.R., nursing floors and other internal departments could order supplies that way? Or even homecare/telehealth patients?
- Installing body-temperature monitoring devices in doorways and in freestanding kiosks akin to real-time location systems (RTLS) and radiofrequency identification (RFID) capabilities?
- Equipping staff with smart eyewear (e.g., Google Glass II?) or even wearable lapel sensors that can check body temperatures of people groups in minutes? And what if those wearable sensors could detect COVID-19 aerosolized particles suspended in the air in front of you?
- Installing a building fan system powerful enough to pull air up into the HVAC system, equipped with high-acuity filters and scrubbers that deactivate or nullify the COVID-19 virus, rendering it inert before expelling the air outside?
- Creating face masks woven with transparent microfibers that enable the facial expressions of people wearing them to be seen by those who thrive on visual emotional communications and connections, such as adults and children with special needs?
- Using computer-projected 3-D holography similar to what the Radiological Society of North America showed at its 100th Scientific Assembly and Annual Meeting nearly six years ago to augment virtual education and exhibition?
- Developing do-it-yourself COVID-19 testing (as a springboard for other virus testing, too), akin to home pregnancy tests, DIY DNA tests and DIY colorectal cancer screens? And then transmitting the results to your physician via secure email or electronic health record access?
- Installing a microdot sensor in the nasal/throat swab to detect the virus in real time without the caregiver having to shove the swab too deeply into the passages?
- Developing a hand sanitizer that functions effectively like a glove, solidifying by friction as you rub your hands together? It can be washed off with soap and water but not deactivated by water alone – or sweat?

Some call the 2020 pandemic a "black swan" event – or something unpredictable that sparks profound circumstances and consequences – or a "gray rhino" event – something largely predictable but dismissed or ignored until it was too late. Prevention and protection efforts by politicians and regulators so far seem to be more "white elephant."

Thankfully, within this crisis-oriented viral zoo noir, we have four-color clinicians, administrators and professionals who fight in the trenches for their patients and communities and subscribe to the three Rs. We are responsive, resolute and resilient.

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1. Stegmeier H. Alcohol-Based Nasal Antiseptic as Part of a Bundle to Reduce the Incidence of Contact Precautions and Surgical Site Infections. Open Forum Infect Dis. 2019 Oct; 6 (Suppl 2): S446. 2. Franklin S. A Safer, Less Costly SSI Prevention Protocol—Universal versus Targeted Preoperative Decolonization. AJIC 2020. Article in Press. 3. Whitaker J. et al. A Safe, More Cost-Effective Protocol: Universal Decolonization vs. MRSA Screening and Contact Precautions. Open Forum Infect Dis. 2019 Oct; 6(Suppl 2): S25. 4. Arden S. Does Universal Nasal Decolonization with an Alcohol-Based Nasal Antiseptic Reduce Infection Risk and Cost? Open Forum Infect Dis 2019 Oct; 6(Suppl 2): S26. Outcomes reported by actual users. Your results may vary. Nozin® Nasal Sanitizer® antiseptic is for nasal decolonization. Nozin® Nasal Sanitizer® antiseptic is an OTC topical drug. No claim is made that it has an effect on any specific disease. Patent nos.: nozin.com/patents.

FAST STATS

4.2%

was the increase in healthcare spending in the United States between 2016 and 2017 to $3.5 trillion, or $10,739 per person, and accounted for 17.9 percent of the Gross Domestic Product (GDP).

ONE-THIRD

of nearly all healthcare expenditures were for hospital spending, which rose 4.7 percent to $1.1 trillion during the same time period.

35 MILLION+

hospital stays, equating to 104.2 stays per 100,000 population, occurred in 2016.

$11,700

was the average cost per hospital stay, making hospitalization one of the most expensive types of healthcare utilization.

$13,600

was documented for stays among patients with an expected payer of Medicare, compared to $9,300 to $12,600 for other expected payers.

66.3%

of all hospital costs was accounted for government payers (Medicare and Medicaid combined) in 2017.

$38.2 BILLION

or 8.8 percent of aggregate costs for all hospital stays in 2017 was for septicemia, the most expensive condition treated.

$19.9 BILLION

or 4.6 percent of hospital stays was for osteoarthritis, $16.0 billion or 3.7 percent was for liveborn (newborn) infants, $14.3 billion or 3.3 percent was for acute myocardial infarction, and $13.6 billion or 3.1 percent was for heart failure.

Internet Citation: HCUP Home. Healthcare Cost and Utilization Project (HCUP). September 2020. Agency for Healthcare Research and Quality, Rockville, MD. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb261-Most-Expensive-Hospital-Conditions-2017.jsp

NEWSWIRE

SMI announces priorities for COVID-19 recovery in executive briefing and white papers

The Strategic Marketplace Initiative (SMI) introduced its new SMI Priorities for COVID-19 Recovery Executive Briefing and Corresponding White Papers, which can be downloaded at no charge on the SMI website as part of the COVID-19 toolkit.

Through collaborative work, a team of SMI members, all supply chain thought leaders from integrated healthcare providers, suppliers, manufacturers and distributors, determined five strategic priorities that will help the industry prepare for any additional waves of the virus, bolster supply chain operations, and maximize the lessons learned to-date. The strategic priorities are: (1) restoring supplier interfaces; (2) stabilizing and strengthening PPE programs; (3) expanding value analysis influence; (4) recognizing new supply chain leaders; (5) supplier business continuity.

SMI Board Member and Chief Supply Chain Officer at BJC HealthCare Tom Harvieux said, "these strategic priorities are based on insights from SMI members that focus on transparency, provider and supplier collaboration, communication and innovation. The SMI team wanted to quickly deliver a resource for the healthcare supply chain industry that sets priorities and outlines actions for organizations responding to COVID-19 and beyond."

The SMI Priorities for COVID-19 Recovery Executive Briefing and Corresponding White Papers can be downloaded, from the SMI website at: www.smisupplychain.com/tools as part of the COVID-19 toolkit.

2020 Chuck Lauer Award recipient announced

Ochsner Health's Chief Supply Chain Officer, Régine Honoré Villain, received the 2020 Chuck Lauer Award presented by the IDN Summit & Reverse Expo. This year the IDN Summit National Advisory Board nominated 14 individuals for the award.

These individuals include healthcare leaders from across the United States, including:

- Teresa Dail, Chief Supply Chain Officer, Vanderbilt University Medical Center
- Nick Gaich, CEO, Nick Gaich and Associates
- Maria Hames, Partner, HealthCare Links
- Ed Hisscock, SVP, Supply Chain Management, Trinity Health
- Brent Johnson, VP, Supply Chain (Ret.), Intermountain Healthcare
- Jay Kirkpatrick, VP, Supply Chain Operations, LifePoint Health
- Carl Meyer, EVP, Wetrich Group
- Dennis Mullins, SVP, Supply Chain Operations, Indiana University Health
- Ken Murawski, CEO, HealthCare Links
- Eric O'Daffer, Research VP, Gartner
- Jonathan Pumphrey, VP & Chief Supply Chain Officer, WellSpan
- Cathy Spinney, President and CEO, Yankee Alliance
- Mark Van Sumeren, Managing Director, Health Industry Advisor LLC
- Régine Honoré Villain, SVP, Supply Chain Network & Chief Supply Chain Officer, Ochsner Health System.

The prestigious Chuck Lauer Award is given annually to a member of the healthcare supply chain who best embodies the characteristics of its namesake, Chuck Lauer. Those characteristics include selfless care for others, a strong commitment to excellence in work and life, a healthy balance between work and life, eternally optimistic, strong ethical values, and unwavering patriotism and pride in the United States of America.

As a leader in the healthcare industry with over 25 years of experience, Régine certainly embodies these characteristics. Her current role is SVP, Supply Chain Network and Chief Supply Chain Officer at Ochsner Health System. Previously she served as the VP, Supply Chain Operations at NYU Langone Health System. She began her career in healthcare at New York Presbyterian Hospital, where she spent 10 years mastering her skills with increased responsibilities along the continuum of supply chain.

Vizient launches integrated solution to lower costs of PPI

Vizient, Inc. introduced its Integrated Clinical Preference Solution, a new program to help hospitals achieve sustainable value on physician preference items (PPI) in key categories.

Through a combination of expertise, technology and data, the solution enables supply chain leaders to build stronger alliances with physicians, service line leaders and key supplier partners allowing them to drive the organizational change required to reduce the total cost of care. The solution is designed to support organizations at every point along their journey to comprehensive category management. Through efficiencies gained from technology, organizations can reduce contract cycle time, access automated crowd-sourced cross references, and monitor newly implemented pricing and rebates.

"The Integrated Clinical Preference Solution connects the supply chain with experts that can help them align their goals with clinicians," Debbie Schuhardt,

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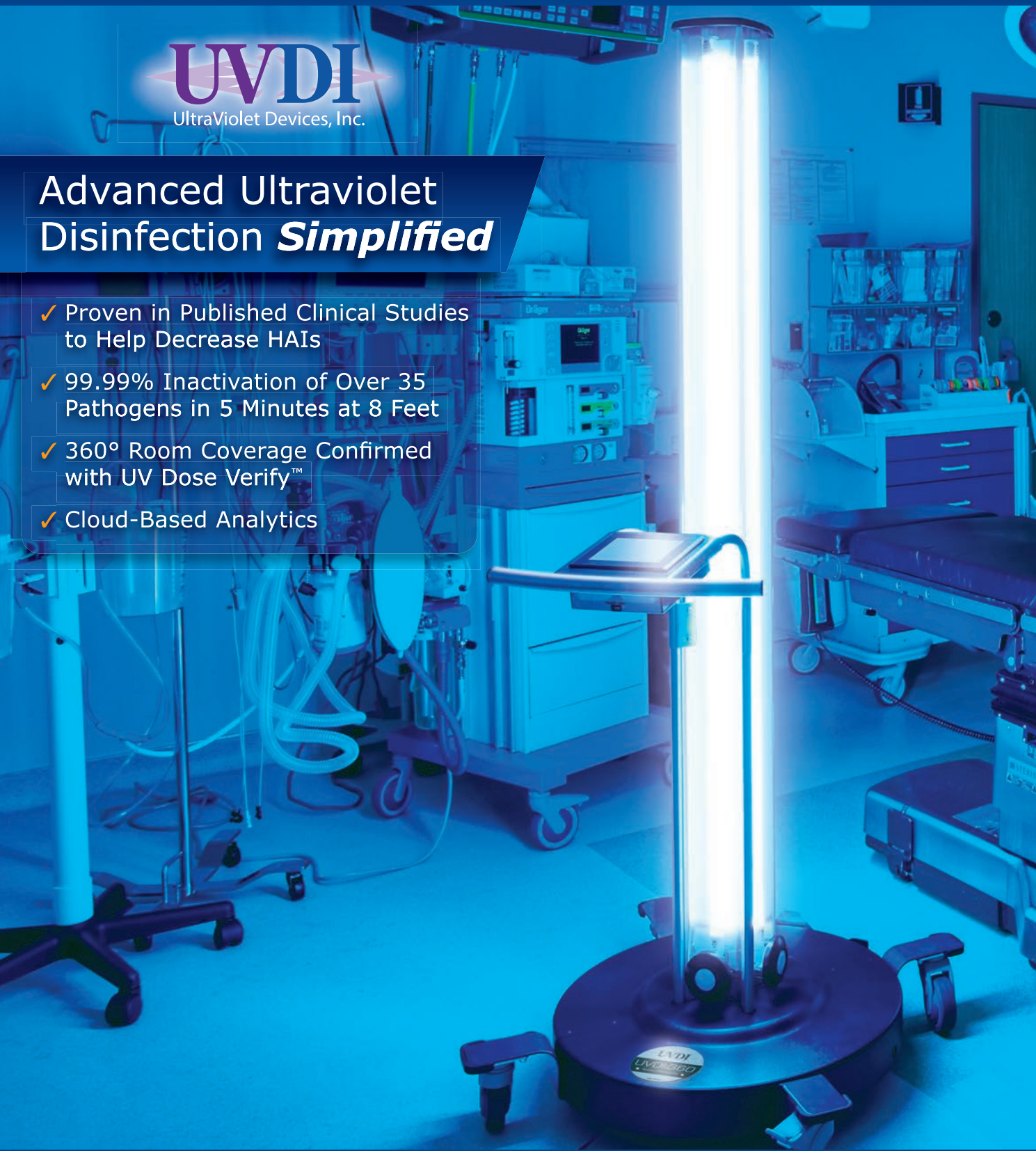

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-Hospital of the University of Pennsylvania, *Infection Control and Hospital Epidemiology* 2017

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(Pegues et. al.,Impact of Ultraviolet Germicidal Irradiation for No-Touch Terminal Room Disinfection on Clostridium difficile Infection Incidence Among Hematology-Oncology Patients. Infect Control Hosp Epidemiol. 2017;38(1):39-44.)

Senior Principal, said. "It allows supply chain professionals to have meaningful, engaging and informed conversations with physicians to identify opportunities for cost savings while ensuring clinicians have the items they need to care for their patients."

The Integrated Clinical Preference Solution brings together two of Vizient's assets — a services-led approach based on deep subject matter expertise and analytics delivered through the technological power of aptitude, Vizient's contracting platform. Vizient members who enroll in the new solution can expect:

- Clinical and market insight, including product category expertise and an experienced advisor in driving clinical alignment to support initiatives.
- Enhanced value analysis engagement, including access to automated cross-referencing capabilities that allow key stakeholders to quickly identify alternate products and compare their attributes, while also infusing perspectives from across the country through crowd sourcing.
- "Speed to value," including reduction in contract cycle time, an automated request for proposal process, and scenario modeling.
- Sustainable results, including utilization improvement, unwarranted variation reduction, price and rebate monitoring.

BSMA offers virtual event for Building the Next Gen Supply Chain of Life

The annual conference from the Bio Supply Management Alliance (BSMA) will be virtual. This year's theme is "Building the Next Gen Supply Chain of Life".

Experts of the global healthcare industry will address how the supply chain is being transformed in the USA for resilience, agility and sustainability after the apocalyptic COVID-19 pandemic of the century.

The organizations represented will be the major biotech companies, Gates Foundation (Vaccine distribution mission), COVID-19 vaccine manufacturers and distributors, international transportation companies, regulatory compliance and quality assurance, digital transformers, technology innovators, and exceptional change agents from academia.

The building blocks of themes of the four-hour virtual conference are the following:

- Ensuring supply of materials APIs and services from global suppliers
- Building the Next Gen Supply Chain of Life Sciences – the Ilumina Journey
- Preparedness for the distribution of emerging vaccines for COVID-19.
- Transportation network readiness for COVID-19 vaccines.
- Digital transformation of life sciences for resilience and agility.
- Virtual audits of drug manufacturers and their global suppliers.

The event will be followed by a day of online partnering between drug manufacturers and their service providers and technology enablers to explore implementation of solutions and services. More information is available at BSMA, https://biosupplyalliance.com/2020-virtual-conference/.

MEDICA 2020 converts to virtual platform

MEDICA 2020 has announced that this year's annual meeting will take place as a virtual platform, November 16 – 19, 2020.

Within the framework of "virtual.MEDICA" and "virtual. COMPAMED," decision makers from all areas of the healthcare industry can expect a comprehensive range of products and services consisting of three focal areas: The Conference Area (conference and forum program), the Exhibition Space (for exhibitors and product innovations) and the Networking Plaza (networking/ matchmaking).

Next year, MEDICA 2021 and COMPAMED 2021 will be held in a hybrid concept consisting of a combination of live platforms for trade visitors at the fairgrounds in Düsseldorf, Germany, plus digital offerings.

"Our hygiene and infection protection concept was positively received by the exhibitors and the successive relaxation of international travel regulations in early summer made the successful and safe staging of both trade fairs appear realistic. However, the development of the worldwide pandemic situation now had to be reassessed. Against the background of numerous travel restrictions and the very international demographic of MEDICA and COMPAMED on the exhibitor and visitor side, we had to decide to focus solely on the virtual format this year," explained Wolfram Diener, President and CEO of Messe Düsseldorf.

In recent years, over 80 percent of the exhibitors came from abroad - from around 70 different nations. The visitors travelled from about 170 nations, with the proportion of international visitors at 70 percent. Together, MEDICA and COMPAMED attracted more than 6,300 exhibitors and 121,000 trade visitors last year.

"We will work with the associations and partners involved to find the best streaming solution from the 600 sessions of the expert forums and conferences planned so far. Participants can expect to see highlights with high relevance to coronavirus in particular in these virtual formats. In addition, there will be a wide variety of web presentations from exhibitors on their innovations and an online matchmaking area for making valuable business contacts, including a video web meeting function," stated Horst Giesen, Global Portfolio Director for Health & Medical Technologies at Messe Düsseldorf.

The MEDICA digital program items will include technical, economic and healthcare policy trends and issues. The MEDICA forums will include: the MEDICA CONNECTED HEALTHCARE FORUM, the MEDICA HEALTH IT FORUM, the MEDICA LABMED FORUM, the MEDICA TECH FORUM, the MEDICA ECON FORUM, the COMPAMED HIGH-TECH FORUM and the COMPAMED SUPPLIERS FORUM.

IDSA launches COVID-19 website for frontline clinicians

With funding from the Centers for Disease Control and Prevention (CDC), the Infectious Diseases Society of America (ISDA) has launched the COVID-19 Real-Time Learning Network (RTLN) microsite (www.idsociety.org/covid-19-real-time-learning-network/).

The site brings together the latest clinical guidance, institutional protocols, clinical trials data, practice tools and resources from a variety of medical subspecialties around the world.

IDSA recognizes that a vigorous, multidisciplinary response is key to winning the battle against COVID-19. The information provided by the RTLN site is curated by medical experts with the goal to help clinicians from a variety of disciplines and other decision makers coordinate their response to this pandemic.

The RTLN site provides links to a variety of interactive programs and learning opportunities for clinicians not only practicing in infectious diseases, but also in critical care, emergency medicine, and other specialties. The information is curated by medical editors to make the information available in a succinct, easily accessible format for busy frontline clinicians. The site highlights resources on trending clinical and research topics. It also provides access to IDSA's COVID-19 Podcast Series as well as information on the weekly CDC/IDSA COVID-19 Clinician Calls.

In addition to its medical editors, the information on the site is guided by a multidisciplinary Advisory Group consisting of medical representatives from 11 medical societies. HPN

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SPECIAL FOCUS

Supply Chain endgame: No holds bare

Will advanced technology remain a niche or become a notch?

by Rick Dana Barlow

If anything, the 2020 pandemic inflicted three wounds on the healthcare supply chain: Stockouts, followed by shortages due to unexpected demand surges and the grim realization that the industry may not be prepared to handle the next big – and potentially worse – pandemic.

Thankfully, none is mortal or fatal to operations.

For the last two years, *Healthcare Purchasing News* explored the possibilities of a future-ready supply chain through available and emerging technology, including the promise of the latter's conceptual applications.

To access the 2019 story, visit https://www.hpnonline.com/21105835/.

To access the 2018 story, visit https://www.hpnonline.com/13001355/.

Yet sources showed *HPN* it remains painfully obvious that technology may not be enough. Of course, it never was (sorry, 3-D printing, which did come in handy for making face shields and masks this year).

At best, technology represents a means to an end – but what about the end from the means?

This year, *HPN* sought to explore the end game sought and the process – humans with ingenuity augmented by technology ... from raw materials to manufacturing to distribution to warehouse to hospital to bedside to the patient's home or trash bin.

A recent study found that nearly 50 percent of businesses say it will take a year or more before supply chains return to pre-pandemic levels and that higher costs will continue even as supply ramps up.

This raises at least five noteworthy questions: Will the Future-Ready Supply Chain call for:

- Access to more warehouse or storeroom space?
- Some type of hybrid hub-and-spoke system for suppliers to meet demand spikes?
- More investment in and implementation of cloud-based, real-time computer tracking?
- More investment in and implementation of voice recognition and real-time image capture?
- Fluid exchange of information that accelerates the adoption and implementation of blockchain capabilities among suppliers, providers and payers?

At minimum, experts agree that Supply Chain must master four areas to emerge from 2020's challenges a more responsive and visionary profession. They are, in random order, supply chain visibility; real-time data accessibility, analysis and transparency; supply network mapping and effective demand management. *(See figure 1 for explanations.)*

Figure 1

4 areas healthcare supply chain must master

- **Supply Chain visibility:** Everybody recognizes and values Supply Chain (including its data) as the go-to experts on sourcing and negotiations, including the C-suite and even if the C-suite doesn't invite Supply Chain within its executive ranks.
- **Real-time data accessibility, analysis and transparency:** This precludes that data on evaluation, ordering, contracting, purchasing, usage, outcomes and disposal patterns are accurate and reliable, and that colleagues trust and value the conclusions derived from them.
- **Supply network mapping:** This encompasses way more than just information technology. It involves tracing product development from raw materials as well as labor elasticity and flexibility throughout the production, usage and disposal channels.
- **Effective demand management:** This includes understanding consumption/usage patterns and being able to pivot (proactively versus reactively) during crises and disasters that could initiate demand spikes (short-term) and surges (long-term).

What should Supply Chain do?

You might surmise that products represent the primary responsibility of Supply Chain because, after all, people stereotype Supply Chain as *the* mover of stuff.

Technically, Supply Chain does that … and more.

By and large, one of the key elements of Supply Chain's success is data – pure and simple. Supply Chain requires access to accurate data that can be shared conveniently to enable and drive decisions – including managing demand as has been demonstrated this year amid the pandemic.

Sean Halligan, Senior Vice President of Pharma Supply Chain and Operations, Cardinal Health, agrees that all four areas to master listed above are "equally important in today's supply chain" but one stands out from others.

Sean Halligan

"Data accessibility, accuracy and transparency are key areas of focus in today's fast-moving supply chain," Halligan told *HPN*. "Leaders routinely utilize data to help make efficient and effective decisions about how to manage procurement, inventory placement and order fulfillment. Successful supply chains, and most progressive leaders in the industry, are continuously looking to improve the accessibility, accuracy and transparency of their information by digitizing activities and capturing data."

All four are closely related and interwoven, according to Steve Downey, Group Vice President, Supply Chain Operations, Vizient.

Steve Downey

"If you don't have the information on a network you can't manage demand, and you don't get transparency without the data on the network," Downey noted.

Supply chain visibility means supply chain has the resources, alignment, data and access necessary to do the best job they can, Downey explains, detailing successful organizations amid the pandemic.

"In working with our member hospitals during this pandemic, those with the most successful supply chains have C-suite access, alignment with clinical teams, and a single executive leader who is managing all of the supply chains within the health system with integrated data and technology. This structure and level of visibility with key stakeholders brings the right tie to strategy and organizational support," he said.

Downey calls for a cohesive fusion of supply mapping, demand management and real-time data, something on which Vizient has been working. "Other industries have leveraged these sorts of third-party network solutions to help supply resiliency, and that has proven itself to help solve all these together," he added.

Supply Chain first must focus on correct and timely data on which to base contracting and purchasing decisions, according to Downey. "Accurate, real-time data showing on-hand inventory is key to enabling health systems to adjust par levels as necessary to meet shifting clinical demand," he said. "If categories are set improperly, it's hard to source without price and spend.

"If demand management is wrong, then you will not have enough supplies no matter what," Downey continued. "Being able to predict needs and work with suppliers to establish agreements to meet those needs, leads to greater resiliency."

Downey also cautions providers to learn whether products are made or stored in a single facility located in a high-risk area because that should motivate Supply Chain to invest in additional inventory or work with a secondary supplier approved through a value analysis process.


Joe Pleshek

Joe Pleshek, President and CEO, Terso Solutions, recognizes the inherent value of each of the four areas as standalone initiatives but insists the most value can be extracted when they work together.

"To me it starts with visibility," Pleshek said. "Once key supply chain assets are visible they can be tracked and monitored. Visibility information is great, but if it isn't transparent and shared across the supply chain it doesn't do much good. I believe data analysis, including predictive analytics and [artificial intelligence] is the key to harness visibility data to enable proactive demand management."

But Jody Hatcher, Director, PartsSource, and former President, Supply Chain Services, Vizient, further qualifies the nature of data needed.


Jody Hatcher

"Building the future-ready supply chain requires understanding vulnerabilities with real-time or near real-time information," Hatcher indicated. "To connect and access that information, we need to better leverage our supply networks and partners along with their expertise, data and technologies. In doing so, we can create the transparency and robustness needed to better manage the healthcare supply chain across the industry."

Reliable data and advanced analytics can identify future potential supply bottlenecks and prevent shortages, as well as equipment and staffing needs, according to Hatcher. This includes forecasting bottlenecks and addressing them before they materialize or become acute, which requires precise information about the inventory available in the entire supply chain, not just an organization's own inventory, as well as the capacity of suppliers, demand patterns and rates of consumption.

"Clearly, getting that data requires transparency and visibility into channels with honest and open communication between providers, suppliers and distributors to support inventory planning," Hatcher said. "Without that visibility, healthcare organizations end up, as they did in the early days of COVID-19, ordering product not knowing how much was available and where it was going, which led to either under-ordering or hoarding."

Mark Wheeler, Director, Supply Chain Solutions, Zebra Technologies, relays the age-old axiom that inaccurate and unreliable data cast doubts on everything else.


Mark Wheeler

"Without reliable, repeatable real-time data from the edge, the rest of the supply chain planning and optimization will be suspect," Wheeler said. "If the decision support systems prove over time to be unreliable due to poor data, they won't be used. With reliable data, analytics engines can transform this data into useable information. This is what supply chain visibility is – useful information about the supply chain status. Once this visibility is established, information is distilled to key metrics tracking demand signals and the overall supply chain network."

Chaun Powell, Group Vice President, Strategic Supplier Engagement, Premier Inc., agrees.


Chaun Powell

"In order to be effective, supply chain professionals must first have transparency into the totality of the supply chain, including the upstream raw materials that go into finished products and ancillary supplies. Absent this vital information, the supply chain gets relegated to purchasing and logistics."

Powell attributes 68 percent of disruptions to "poor demand signaling to suppliers," which is why effective demand management and supply network mapping are critical components of supply chain preparedness.

"Alongside an understanding of any potential risks with their suppliers, supply chain professionals can then apply real-time data demand signals to accurately identify the intersection of their demand and sustainable supply," Powell said. "The icing on the cake is real-time access to usage, inventory and location information – rounding out the necessary improvements to transform the healthcare supply to the same level of sophistication that we see in the automotive, electronics and food sectors."

Hatcher warns providers, which may be trapped in a data quagmire, against casting blame on suppliers.

"The onus of supply chain opacity during COVID-19 is not resting on the shoulders of the suppliers alone," he argued. "Greater supply chain transparency requires open communication by all parties. Providers can help by being willing and able to provide better inventory visibility, better demand forecasts, faster order placement, and greater collaboration with their suppliers. For their part, suppliers can work with distributors and providers to manage to their historical ordering patterns and avoid stocking up outside of the norm, including previous spikes in demand."

Ultimately, Hatcher defines the future-ready supply chain as requiring visibility into the location, quality and availability of inventory across various members of the supply chain. "To accomplish that, providers need more sophisticated data, automation and analytics, and ideally an online marketplace to consolidate the hundreds of supplier relationships that most providers maintain," he added.

Standard foundation

To succeed now and in the future the marketplace needs a solid foundation, emphasizes Jeremy Owens, Vice President of Supply Chain Logistics, LeeSar. Standards matter.

"Drastic improvements in data management must be achieved before anything else can move forward," Owens noted. "Uni-

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versal data standards have to be widely adopted and implemented throughout the healthcare supply chain verticals. Without the data standards, data integrity will never be achieved, thus falling short of any goals for transparency, trust or value. Despite best efforts for organizations to normalize this non-standard data, there will always be doubt and problems that will hamper the real-time data accessibility."


Jeremy Owens

Owens points to mapping out the supply network channels as the logical next step or ground floor of the solution.

"From raw goods to the end users, this map tool now provides a complete picture of the path the product takes," he continued. "Having this information, an organization can now start to evaluate where risk points could occur should a disrupting event present itself. This exercise will help identify the needed contributors for data sharing when building out the visibility infrastructure."

Once an organization centers on standardized data with all collaborators identified from the mapping exercise, then it can build on the foundation and ground floor to reach the next level - visibility.

"Linking all the data together to gain visibility into the complete healthcare supply chain is a lofty goal," Owens admitted. "However, it's been something the healthcare industry has needed for a very long time. Many other supply chain sectors have been successful in achieving this goal. Why hasn't healthcare? Is it because of rapidly changing technology, the complexity of clinical preferences, or is it about transparency causing issues with insurance reimbursement? Regardless of the reasons, the healthcare supply chain sector is extremely behind. Considering we are literally talking about 'life or death' in some instances, we should have these visibility tools in place to mitigate risks where the stakes are high."

Owens also questions the hubbub around demand management without an effective framework in place.

"Each organization has its way of managing demand," he said. "However, despite the best efforts and methods, understanding high-level usage patterns cannot be fully achieved without all of the preceding steps in place. Data management must be solid, and considerations for all factors impacting production or demand must be mapped. Additionally, unobscured visibility to the complete supply chain must be present to fully understand consumption patterns and to nimbly determine strategy for mitigating any disruptions."

Healthcare isn't retail

Creating actionable change requires a thoughtful approach to tackling supply chain fundamentals, according to Tom Redding, Senior Managing Director, Healthcare Services, St. Onge Company.


Tom Redding

While some may see managing demand as the destination once other elements in the journey are implemented, Redding begins with demand and works backward.

"The priorities for implementing change starts with effective demand management and knowing what the customer needs, wants and uses on a daily basis as well as variability of demand," Redding indicated. "Since healthcare delivery does not mimic a 'retail transaction,' the ability to readily capture and collect information for planning purposes is many times limited. To effectively manage the supply chain, it is critical to understand the demand side of the equation since it drives many of the upstream decisions, such as manufacturing and distribution."

With effective demand management in place, sharing data transparently with others for analytical, cataloguing and decision-support purposes represents the next outcome, which enables optimal supply chain visibility, he noted. Anything short of that may lead to visibility that may not be in a positive light, he added.

"Taking the supply chain to the next level with end-to-end track-and-tracing once the foundational elements are in place enables health systems to realize long-term value and position themselves to be a leader in the industry," Redding said. "Supply network mapping will require a broader industry perspective and support to realize the inherent benefits – it goes beyond the internal circle of influence to building the case for industry change."

Dawn of a black swan

Effective demand management emerges from a chain of events focusing on supply chain visibility, supply network mapping and real-time data accessibility, analysis and transparency, according to Ranna Rose, Vice President, Operations and Customer Success, Resilinc.


Ranna Rose

"COVID-19 has been a black swan event of historic proportions and has opened the eyes of procurement officers and supply chain professionals who quickly realized they had limited information about their suppliers' global operations, and most dramatically, they learned they had little visibility to their suppliers' suppliers," Rose noted. "Many woke up to the fact they needed greater visibility into their second, third or fourth-tier suppliers. It took many unprepared companies more than three months to react to the impacts of COVID-19 and get their mitigation efforts stabilized and moving forward."

Rose insists that by analyzing data extracted from continuous monitoring of world events, supply chain experts can increase their visibility and get ahead of their competitors during major disruptions.

As with travel, the road to greater visibility requires a map that extends beyond the overt, Rose recommends.

"Supply chain mapping provides this visibility, which provides greater predictability on how to get materials from point A to point B, and, most importantly, identifies risks and failures in the supply chain while giving recommendations on how to mitigate them," she continued. "Mapping is critical for identifying where suppliers are located, the origins of parts and locating qualified and vetted alternate sites. Many companies manage their suppliers by giving priority to their highest-spend tier 1 suppliers. However, 80 percent of the largest disruptions in the supply chain stem from lower-spend and single-sourced suppliers. This is why mapping is so critical to ensuring greater visibility across all tiers of the supply chain."

For example, a $1 part may be the cause of the delay of a billion dollar product, Rose asserts. "This is one reason why Resilinc advocates for prioritization of suppliers based on revenue impact versus spend," she said. "By identifying tier 2 and tier 3 suppliers used by multiple tier 1 suppliers, the company can add any bottlenecks to their 24/7 monitoring to better prepare for an effective and speedy response."

Using monitoring and mapping tools effectively can provide Supply Chain leaders with the "peace of mind" that stems from real-time data accessibility, analysis and transparency, Rose surmises.

"In the context of the COVID-19 pandemic, some of the supply chain monitoring and mapping tools for risk monitoring and mitigation purposes involved early warnings via news monitoring, 'what-if' simulators, part-site mapping, alternate site recommendations and pandemic readiness supplier assessments," she noted.

Rose shared the example of an unnamed healthcare company that looked to supply chain mapping during the Mexico earthquake and Puerto Rico hurricane season in 2017 to predict the trajectory of hurricanes Maria and Irma. The company also developed "what if" scenarios to establish the various factors that might affect the supply chain,

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she recalled. Hurricane Maria threatened to disrupt materials provided by suppliers in Puerto Rico as the hurricane wrought power outages on the island. The healthcare company faced the possibility of production delays of IV bags made on the island. Supply chain mapping enabled the company to make advance purchases to avoid this delay and ensure there were enough IV bags for life-saving procedures needed during the hurricane's aftermath.

As the hurricane continued to swell, a massive earthquake struck Mexico. "By knowing how impact zones and their suppliers were affected, potential risks were mitigated in the same company's supply chain. Impacted employees were located and confirmed safe," Rose indicated. "The healthcare company was also able to identify the universities conducting the company's drug trials, facilities where manufacturing vials were stored, and any distributor warehouses in the impact zone. This gave the company the data and analysis necessary to mitigate potential risk caused by the earthquake by moving to alternate sites located outside the affected area."

Before an organization can effectively manage demand it must excel in mitigating risks from event disruptions, Rose advised. "Because just-in-time inventory is still the most prevalent practice among supply chain managers, it is critical to implement digital risk mitigation tools to provide effective demand management," she added.

The invisible supply chain

The basic elements of supply chain must be accurate and reliable before anything else can be accomplished, observes Deborah Templeton, R.Ph., who retired last month as Chief Administration Officer (CAO), System Support Services, Geisinger Health, which earned *HPN*'s Supply Chain Department of the Year award in 2008.

Deborah Templeton

Real-time data accessibility, analysis and transparency drive accuracy and reliability, she noted.

"This includes operating with accurate data from supply product cost and acquisition standpoint from two perspectives: Ease of use for the customer without delays in patient care and the fiduciary responsibility of the supply chain to ensure expense management, including aligned contracting and purchasing channels as well as efficient distribution systems," Templeton said. "This builds trust and confidence in the supply chain. The best supply chain in this regard is the 'invisible' supply chain; a clinician doesn't have to wonder how the supply gets to where it is needed and doesn't fear that the supply will not be there when needed. They have what they need when and where they need it and don't really give much thought to the process that got it there."

With the fundamentals in check, forecasting supply accessibility and availability to cover emergencies that cause spikes in demand naturally follows, according to Templeton. "Being able to anticipate needs is far more desirable than having to scramble during events that already are putting pressure on the organization and its resources," she added.

Templeton also urges Supply Chain to concentrate on data accuracy that can then be connected to patient outcomes coupled with supply utilization trends and supply costs as a piece of the total cost of care. "Tying supply chain data to quality outcomes data turns the focus to improvement of patient care, not just the unit cost of a supply," she said.

One key element Supply Chain must master is the ability to build and cultivate relationships with other members of the care team, including physicians, nurses, clinicians, revenue cycle and finance, all of whom play a part in determining the total cost of care, she recommends.

"Being able to contribute to driving successful risk-based healthcare models will make supply chain a valuable organizational asset," she noted. "Being able to tie supply information enabled by global trade item numbers to claims data becomes even more powerful in looking at supply performance."

Supply network mapping from raw materials through finished goods, consumption and recall can help Supply Chain "anticipate far in advance shortages" and enable them to "look for alternatives or to pivot to other sources," Templeton continued.

"Having flexibility to move as needed is not only necessary, but critical to manage in supply chain today," she said. "Resiliency can be enhanced by shortening the supply chain and operating on selections of products by specifications versus on brand or a sole manufacturer. Risk assessments on source of the supply will become a routine part of supply management."

Mastering all of these skills will lead to supply chain visibility, Templeton insists. "The supply chain doesn't have to be part of the executive suite in order to drive change and contribute value to an organization," she added.

"Supply chains operate best with predictability," said Nancy LeMaster, CEO, Nancy J. LeMaster Consulting. "They are built around assumptions related to demand, which in turn dictate the type and amount of inputs required. For supply chains to be responsive, they need to be able to quickly detect fluctuations in demand. To be able to understand and predict demand, providers must have real-time access to consumption data that is tied to the types of procedures and care being given – the medical equivalent to a bill of materials. Of course, it will never be as precise as in manufacturing environments, but we can do a much better job than we do today."

Nancy LeMaster

LeMaster served for 31 years at BJC HealthCare as Vice President, Supply Chain Operations, and as Vice President, Supply Chain Transformation.

"Once we improve the ability to forecast demand, then it is important to have visibility across the supply chain to be more proactive in identifying and making adjustments related to disruptions caused by raw material shortages or global demand fluctuations," she said. "The importance of supply network mapping was brought home when hurricanes ravaged Puerto Rico, and we had no idea which manufacturers' facilities were impacted – and they refused to be transparent about the impact."

Data in the details

Charlie Miceli, C.P.M., Chief Supply Chain Officer and Network Vice President, University of Vermont Health Network, remains stark but resolute, calling for meaningful informatics as Supply Chain "has a seat at the High Table by default," visible to the general public, boards and C-suite.

"If we do not have data accessibility, analysis and transparency we need to pick up our supply chain and go home," Miceli concluded. "We need to know and monitor our ever-changing demand signals, from analog to digital, and align with our suppliers. Knowledge and transparency of the manufacturing locations of our first-, second- and third-tier suppliers are critical. New suppliers may come from the third tier, leapfrogging primary [suppliers] as we have visibility."

Cory Turner, CMRP, Senior Director, Healthcare Strategy, Tecsys Inc., ranks data near the top of priorities as well.

Cory Turner

"In our industry, data is king, and supply chain leaders are lost without it," he said. "Real-time data accessibility, analysis and transparency are therefore a fundamental priority. Whether you're after supply chain visibility, supply network mapping or demand management, the quality and reliability of the data input is a

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precursor to meaningfulness of its output. Quite simply, garbage in, garbage out."

Reliable data then buttresses visibility.

"Only once your data is solid and trustworthy can we earn a spot at the table," Turner cautioned. "The supply chains of yesteryear were backroom cost centers. Today, supply chain is rightly positioned to guide strategy and lead digital transformation. Supply chain visibility plays a central role in that pursuit. Having true visibility is what gets us into the C-suite and keeps us in the conversations that matter to the patients. The visibility you afford your organization enables you to become a dependable resource for strategic business decisions and cost control initiatives."

From there, a health system's end-to-end visibility ushers in effective demand planning, according to Turner.

"Being able to successfully manage your organization's demand is something way too many supply chain departments simply cannot do," he observed. "Unlike supply chain departments in non-essential industries, we have to be able to adjust to every situation no matter the size and scope, including a global pandemic. The days of tribal knowledge for setting order levels and being reactionary to physicians' demands are gone. We have to be able to use all that rich data that we have been working on. With a pulse on all the moving parts from a real-time and responsive supply chain control center, the integrity of the demand chain can be trusted, and pivoting from spikes and surges becomes a data-driven effort rather than a 'gut feel.'"

Turner casts supply network mapping as something of a Holy Grail.

"Supply network mapping is an idea that eludes the vast majority of healthcare supply chains," he noted. "Most rely on a distributor to keep up with this, but with the growing number of health system IDNs adopting a [consolidated service center] model, they are becoming more aware of the possibilities. Some health systems are even managing their own sourcing directly from overseas manufacturing, but this remains the exception, not the rule. My perspective is that mastering the other three areas first enable to you to get more value out of supply network planning. Once the house is in order, supply chain leaders are better positioned to look at external dynamics."

Turner previously served as part of the award-winning supply chain team of Greenville (SC) Health System, which earned *HPN's* 2013 Supply Chain Department of the Year award. **HPN**

Delay, ignore changing? What then?

Status quo offers little-to-no get-up-and-go

Healthcare Purchasing News asked supply chain executives and leaders about the long-term effects of doing little or nothing to improve operations and how that might affect future readiness and resilience, particularly in the face of another crisis or disaster like a pandemic – including what might be killing it. Here's what they shared.

"Currently, healthcare supply chains are not future-ready, as supply reliability is just in its infancy in implementation. Health systems are now working to figure out how to balance cost and resiliency, and suppliers and health systems are coming together to help solve the challenges in unison. Transparency is beginning to take shape, but it's [in the] early days. The supply chain needs continued focus from C-suite executives with their support and resources for technology solutions that will bring improved data for informed decision making, greater cooperation across all the components of the supply chain and willingness to learn from both other industries and our mistakes." ***— Steve Downey, Vizient***

"The COVID-19 pandemic has provided insight into the profound gaps in today's healthcare supply chain. The problem can be traced to two primary challenges: A lack of data and lack of transparency. Healthcare systems, distributors and group purchasing organizations, along with state and federal governments, rely on real-time data to manage supplies and model their equipment and staffing needs. To generate reliable data, it's important to build and maintain open communications between providers and suppliers. Doing so ensures appropriate access to critical equipment when and where it's needed most.

To create lasting change leading to a true future-ready healthcare supply chain, healthcare organizations need to adopt:

- Broader use of analytics supported by real-time data to forecast supply bottlenecks and proactively prevent shortages of supplies, equipment and personnel.
- Visibility into channels with open communications between suppliers, distributors and customers so hospitals can order product understanding how much is available, preventing under-ordering and hoarding.
- Better inventory visibility by hospitals along with more accurate demand forecasts, faster order placement and greater collaboration with their suppliers and distributors.
- Automation and decision support tools to digitize the medical device supply chain and drive better value-based decisions that diversify and expand the supply base.
- Online communities enabling hospital supply chain leaders to share insights and best practices with their peers in other hospitals." ***— Jody Hatcher, PartsSource***

"Healthcare supply chain would not successfully thrive if we were to enter into another period like COVID-19 has brought us. The amount of disruption that initially occurred has settled down some, but that is because it's becoming a new norm, and many non-traditional suppliers were jumping into the market. The healthcare supply chain may never get back to pre-pandemic norms. This event could have been much worse than what we have seen thus far. If the pandemic had been more severe, the industry would not have been able to get by.

"One positive from this pandemic is that it has illuminated the vulnerability of our industry's supply chain. Ultimately, it comes down to the money necessary to invest in the systems and resources needed to adopt data standards, network mapping and data sharing integration tools. Also, I feel there is barrier to sharing data from entities up and down the vertical. I don't think this pandemic generates enough motivation to get all manufacturers, distributors and healthcare networks on board with moving forward on a complete supply chain visibility initiative. It will take federal mandates, like with electronic medical records (EMR), to get the industry moving in the right direction." ***— Jeremy Owens, LeeSar***

"One challenge specific to healthcare is that the purchaser of critical products and supplies is not always the decision maker. Many supply chains are becoming more mature in terms of value analysis and clinical integration, in which physicians and other stakeholders work with the supply chain on purchasing decisions, and have conversations around an item's cost and potential impact on patient outcomes. However, in some instances, physicians work independently with suppliers to procure preferred items. Very few other industries face a potential disconnect like this between decision makers and purchasers.

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"Finally, the lack of accurate demand signaling and the spirit of two-to-three-year contracts with 30-to-90-day turnover post-contract awarding lend themselves to just-in-time manufacturing. This practice works nearly flawlessly in times of steady state. COVID-19, however, acted as the harbinger that we must prepare for uncertainty and potential crises. With improved demand signaling, suppliers will have greater ability to secure vital materials and products and more effectively and sustainably.

"Suppliers will also be enabled to drive greater transparency with their supply, raw material, sterilization and packaging locations, which in turn will help supply chain professionals identify gaps and proactively alter purchasing patterns where necessary. Further, the development of an industry-standard product disruption communication template, similar to an example authored by Premier, HIDA and SMI, would be immensely valuable so that all stakeholders could rely on consistent information at times of disruption." ***— Chaun Powell, Premier***

"Until the beginning of 2020 the healthcare supply chain for the most part was 'working as designed.' Supply chain executives were focused on running lean supply chains, geared more to just-in-time deliveries and lean investments in inventories, with emergency stock not necessarily a prime focus and run in a very lean manner, sometimes unmanaged. The challenges driven by the needs that COVID-19 presented pushed the need for resilient and responsive supply chains to the forefront. The need for having good data to drive forecasting and monitoring burn rates that supports proactive approaches to supply needs is critical. This will also drive more 'independence' within supply chains, no longer relying solely on GPOs or national suppliers to fulfill needs, but moving quickly to more direct-to-source contracting and non-traditional contracting to help secure mission critical products. The criteria to vet these new agreements with non-traditional suppliers were rapidly developed during the COVID-19 peak but will continue to mature over time. The need for a responsive distribution network and ability to store product have become critical.

"Supply Chain leaders will need to develop new tools and skills to manage their workforce. Many roles will move to work-from-home environments. It hasn't been too bad for teams right now as most members knew each other before the need for a remote work environment quickly accelerated. As the workforce continues to turnover, and work-from-home becomes a new norm, new tools and methods to engage a team will be necessary. Also, the provision of tools needed to work from home need to be planned and deployed. Mental and emotional support of employees also are needed and new methods and approaches to work-life balance when the distance between the two environments is minimal or non-existent . Structuring routine work should be done in such a way that temporary labor can step right in to help with tasks at times of peak need. ***— Deborah Templeton***

"Right now, there is plenty of supply chain tech that is high up on the hype cycle, but low on the maturity scale. Some will fizzle out, no doubt, but others will carve out important roles in the future of our business. When I started as a supply technician, my tools were paper, pen and a lot of tribal knowledge. Computers talking to computers, RFID chips and AGVs were the stuff of sci-fi movies. In a few years, if you're not leveraging at least one of these things, you're rowing with one paddle in the water.

"Supply chains of the future are agile in every way. Being able to produce the right supplies at the right time for the right procedure before clinicians know what they need is likened to fantasy, but the reality is that this is exactly what we need to accomplish to be future-ready.

"Adopting technology that supports this level of decision-making capability will enable us to stand up to the invisible enemies of the future. The global pandemic is revealing to us the weak links in our supply chain, once thought to be unbreakable. We must overcome our fear of change, battle the legacy cultures and begin to be the changemaker in our organizations." ***— Cory Turner, Tecsys Inc.***

This sidebar was edited for space. Visit https://hpnonline.com/21153705 for full version plus "Future-ready starts with chip off the old blockchain."

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Pandemic PPE evolution

Spotlighting ingenuity, ramp-up, planning and reinforcement of safety

by Ebony Smith

COVID-19 disease, caused by the SARS-CoV-2 virus, has transformed the healthcare supply chain, population health and patient care as we knew it. Infections first struck people in China, then popped up in other countries across the world.

The United States reported its first case in December 2019. Many months passed and infections surged on. This public health emergency-turned pandemic propelled an upheaval in the production of personal protective equipment (PPE) critically needed for staff in hospitals and healthcare facilities to adequately and safely care for patients.

"As has been well reported in *HPN* and elsewhere, when the COVID-19 pandemic hit, it placed terrific pressure on the supply of PPE, particularly face coverings and gowns," emphasized Ralph Basile, Vice President of Marketing & Regulatory Affairs, Healthmark Industries Company, Inc. and a Sub-chair of ASTM International committees. "The first indicators of this came in January, when Chinese companies were contacting distributors of PPE outside of China, as there was inadequate supply in China. As time moved along and the virus spread across the globe, supply shortages of PPE were experienced by market after market, country after country. Come March, when the virus became widespread in the United States, this country experienced these shortages."

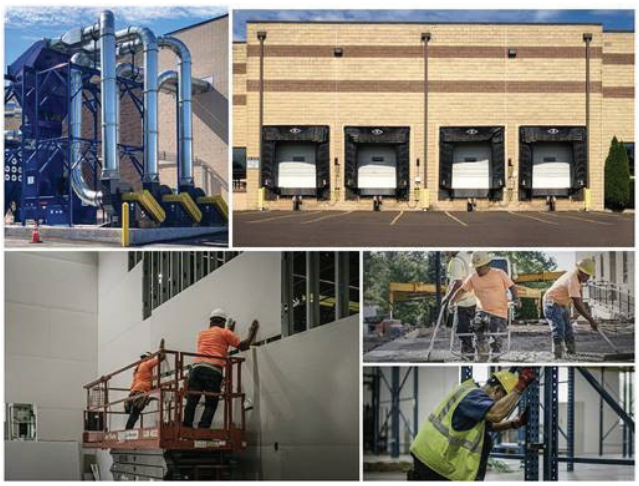
Pandemic changes

Basile shared his insights on the trajectory of PPE development this year, ahead of the September 9-10, 2020, ASTM International virtual Workshop on Fast-Tracking Standards Development to address Personal Protective Equipment (PPE) Shortages Due to the COVID-19 Pandemic.[1]

"Attempts to adapt to the shortage of N95 masks have included efforts to reprocess and reuse these masks that are labeled for single-use and also to acquire alternative masks that have not undergone regulatory review and clearance," Basile noted.

"Changes have included expanded recommendations/mandates requiring the wearing of face coverings in public places and new entities manufacturing these coverings," he continued. "Many of these face coverings have limited or have no filtering properties, so they could prove useful for healthcare workers with duties that did not put them at the highest risk of being exposed to COVID-19. During this time, many organizations that had never made masks, face shields, or gowns pivoted and turned their resources to make such PPE. This included existing cut and sew shops, material convertors, 3D production facilities and other such organizations."

The ASTM International committees aim to meet and "identify the needs and opportunities to either modify existing ASTM standards or to author new ones, to help the industry, regulators and healthcare professionals, based upon the experiences in responding to the COVID-19 pandemic, better prepare and respond to the existing PPE challenges and future ones, should we be faced with a challenge like this again," Basile explained.



Dräger's new production facility in Montgomeryville, PA

Expanded production

The resourcefulness and ramp-up of PPE remain an ongoing priority for supporting the health and protection of healthcare workers and patients. What are the latest developments in PPE manufacturing and distribution in the healthcare landscape?

Recent examples include:

1. Dräger opened a new production facility in Montgomeryville, PA, that will manufacture and distribute N95 respiratory protection masks announced the company in a press release.[2] "The facility will have three employee shifts throughout the day, operating 24/7 to ensure the mass production and supply of National Institute of Occupational Safety and Health (NIOSH)-approved N95 respiratory protection masks to frontline workers. Additionally, the facility will support Dräger's recently announced contract with the U.S. Department of Health and Human Services to produce N95 masks in the fight against COVID-19," the release stated.
2. "In just a matter of weeks, we opened two new manufacturing production lines in the U.S. to help address the demand for high-quality, USA-made, NIOSH-certified N95 respirators," shared Allison Pearsall, Senior Customer Marketing Leader for Healthcare, Honeywell Safety Products. "Millions of our N95s have been flowing

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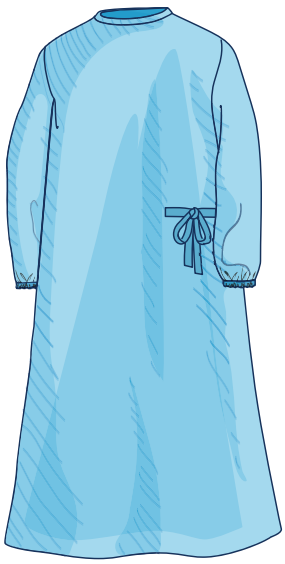

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out of our facilities in Rhode Island and Arizona, as well as other global locations where we have expanded capacity to help protect healthcare professionals, first responders and other workers."

Honeywell's N95 respirator

3. "We recently added reusable bouffants, skull caps, shoe covers and face masks to our product line in response to requests from our customers," indicated Richard Stewart, Corporate Vice President, Product Innovation, Standard Textile. "We introduced the first reusable synthetic surgical gowns to the market back in 1988 under our ComPel brand. Isolation gowns and lab coats made from this same revolutionary fabric technology soon followed."

EasyRelease Iso Gown by Standard Textile

4. "We had the ability to provide PPE (coveralls, scrubs, etc.) to dozens of hospitals across the country during the critical initial wave, when supplies were the most challenging to acquire," expressed Bryan Zediker, Executive Vice President, RepScrubs. "This required our company to pivot from our normal business model of servicing the vendor population alone. We were able to adjust and support the frontline providers along with the vendor population. Our disposable scrubs are manufactured by FDA-certified facilities that meet all industry requirement as safe attire. They are dispensed on site and disposed of onsite, further mitigating quality risks."

5. "When COVID-19 hit, we were approached by government ministers to produce PPE, specifically gowns," addressed Donnie Hodge, President & COO, Kitex USA. "There was an urgent need for these products in India (globally as well). The gowns are more difficult to put into large scale production than masks, so that is where we concentrated our efforts. We set up initially to produce 35,000 per day, but quickly expanded that production and set up to export to other markets, including the US. We decided to start our production with Level 1 and 2 gowns and now are expanding that to include 3 and 4 gowns. We are FDA approved for 1 and 2 and the process for 3 and 4 should be completed very soon."

Donnie Hodge

6. "In response to the COVID-19 pandemic and critical supply shortages, Key Surgical expanded our PPE product portfolio that was historically focused on equipment used in the Sterile Processing department to include PPE designed for frontline staff throughout the facility," said Brandon VanHee, CRCST, CIS, CER, CHL, AGTS, Clinical Education Manager. "In addition to expanding our PPE product portfolio, we significantly increased our production capacity to provide high-quality PPE products to other essential businesses outside of healthcare facilities."

Key Surgical's face mask and face shield

7. "CleanSpace Respirators have been widely adopted in hospitals globally during the pandemic, particularly for those healthcare workers most at risk of infection, such as ICU staff and anesthetists conducting intubation on COVID-19 patients, where a higher level of protection is required," stated Jon Imms, Global Technical & Product Director, CleanSpace Technology. "CleanSpace Respirators with the active airflow, offer high-level protection, provide cool, fresh air on the face, no fogging of eyewear, and clear transparent masks to allow patients to see the face of their carer."

Disposables versus reusables

As new PPE is produced, many in the industry weigh the pros and cons of items that can be disposed of or can be repurposed after disinfection. How do these PPE items rank in value, effectiveness, comfort and safety for healthcare staff?

"The recent unprecedented demand for PPE has made clear that sole reliance on single-use products is an ineffective supply strategy," Stewart stressed. "Reusable PPE offers significant advantages with respect to continuous and manageable availability, proven performance, lower cost-per-use, and, in the case of apparel, a documented preference by end users with respect to comfort."

Pearsall further points to the benefits and challenges of disposable and reusable respirators and face masks.

"PPE, such as disposable N95 respirators and face masks, which are intended to be used one time and discarded after every patient encounter, were designed to be easy to use, save time, improve productivity, and reduce risk of contact transfer of pathogens," she indicated. "Reusable PPE, for example, elastomeric facepiece respirators or PAPRs, can be an alternative and offer benefits, including easier breathing and potentially higher filtration efficiency depending on the filter selected. Reusables require decontamination after each use. This adds an additional step for reprocessing into the workflow. In addition, they cannot be used in all clinical areas."

Imms suggests that function, size, fit and accessibility matter with reusable equipment.

"Reusable devices have considerations for cleaning and reprocessing," he noted. "Looking for simple and compact devices that minimize the time and effort for staff are important to implementation and ongoing care. It is important to consider

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PPE projections for the next pandemic

How can healthcare providers, supply chain and logistics departments and manufacturers begin to prepare for the next major health crisis and PPE needs? Industry professionals shared their predictions with HPN.

"From our experience this year, we expect to see seismic shifts in a few areas: Telemedicine is having perhaps the fastest revolution in the history of healthcare. The very important role of infection control and infection preventionists is taking center stage, not just in acute care but across the spectrum of care. There will be more attention to the global supply chain for pharma manufacturing, but also for critical supplies, such as PPE. There will be a renewed focus on resilient supply chain and an appetite for adding near-shore manufacturing to a diversified manufacturing base. We many also see healthcare providers having closer scrutiny of the quality and performance standards for their PPE, with end users possibly even conducting their own testing to confirm compliance.

The next few years should hopefully usher in a new era of renewed innovation for PPE. A greater appreciation of the vital, irreplaceable role of PPE as a last line of defense should spur renewed investment in finding better solutions to protect our healthcare professionals and their patients. The last 20 years have seen little innovation in healthcare PPE, as there has been more emphasis on cost reduction. It's been a while since we had significant advancements, like past inventions of electrostatic filtration media or fluid-resistant nonwoven gowns or nitrile gloves."

Allison Pearsall, Honeywell Safety Products

"Many lessons can be derived from the experience of the past six months. Among these are the need to have in place a system of products that can be trusted for performance and a supply chain that assures a continuous stream of availability in the quantities necessary. We are of the opinion that recyclable, multi-use PPE provide the best options. Accordingly, preparation for future, similar demand surges requires the establishment of a system for processing reusable PPE products that is connected with a manufacturing/supply network that can scale upward as required to meet demand. Current ongoing advancements in material science, novel woven and knitted fabric structures, and fabric finishing technology will enable and inform the development of products that enhance market acceptance and preference for reusable PPE options."

Richard Stewart, Standard Textile

"I believe we will see a diversification of manufacturing of goods across the board. The pandemic has highlighted an issue and the world is responding."

Bryan Zediker, RepScrubs

"Long-term planning to include contingencies and redundancy are critical in the diversification of the supply chain. That should include pre-approval and pre-certification of facilities, such as Kitex, who have the ability to scale up quickly."

Donnie Hodge, Kitex USA

"There have been a multitude of lessons learned in every aspect of preparedness; from how healthcare providers and facilities use and source PPE, to how manufacturers produce and distribute it. Many manufacturers learned the importance of flexibility in production capacity in 2020. The ability to ramp up production on critical items has been crucial to success in the COVID-19 pandemic. Manufacturers will need to continue to focus on identifying key product categories (PPE, disinfectant chemistries, etc.) that require more flexibility in production capacity."

Brandon VanHee, Key Surgical LLC

that disposable N95 masks must be fitted correctly to be effective. One major risk for users and employers after fit testing, is that if the hospital cannot source the correct brands on an ongoing basis, staff will not have access to their mask type without retesting. With positive pressure reusable respirators, there are no ongoing issues with stock or model availability – your wearers always have access to reliable, high-level protection."

Another consideration is the choice between disposable or reusable clothing, notes Zediker.

"There have been several articles written that illustrate the risks associated with home-laundered scrubs and the resilience of pathogens," Zediker said. "Specifically, a study done in the *Journal of Hospital Infection* by Tammelin concluded that disposable, polypropylene scrubs are more effective in reducing airborne bacterial counts when compared to reusable options."[3]

VanHee urges that all guidelines be followed when cleaning or disinfecting any reusable items.

"Cleaning and disinfection of reusable PPE (or single-use PPE in emergency situations) is a vitally important, but often underappreciated component of PPE use," he explained. "Although best practices dictate that single-use PPE should never be reused, supply shortages have required significant adaptation of PPE reuse practices. No matter the type or PPE, strict adherence to cleaning and disinfection protocols that have been validated by the PPE manufacturer and/or the manufacturer of the disinfection equipment is fundamental to the safe reuse of PPE. It is of particular importance to stay up-to-date on FDA emergency use authorization (EUA) for any approved disinfection protocols being used for single-use PPE."

Planning and preparation

In light of this pandemic, it is clear that hospitals and healthcare providers must be vigilant in their pursuit of PPE to ensure the safety of staff and patients. What are the best practices for existing and future PPE evaluation, sourcing and other decision making and planning?

Planning:

Pearsall brings forth the need for effective knowledge and tools for supply chain decisions and implementation.

"A best practice for planning PPE supply needs is to understand changing protocols and how that drives utilization changes and product selection all the way down to the SKU level," she expressed. "While much of our pandemic preparedness has historically been centered around the expectation of a flu pandemic, we've learned that the threat also exists from other viruses with different, potentially unknown modes of transmission. Healthcare providers need greatly improved tools for the complex challenge of planning, sourcing, procuring and stocking the proper PPE with the appropriate levels of protection for whatever the threat may be. This is a tremendous need that supply chain technology could help with in the future."

All plausible constituents should be integrated into planning, explains Zediker.

"Do not forget about the ancillary population(s) (salespeople, contractors, consultants, etc.) that will need to be factored in," he described. "Then look at channel partners that focus on these groups as a solution outlet. For example, RepScrubs is solely focused on the extensive visiting vendor population. We can support planning efforts by eliminating the cost and quantity requirements that a hospital has for that population. We do this by taking on the workload and inventory and shifting the cost of providing those products to visiting sales professionals."

Past planning should guide the planning for future emergency events and needs, says VanHee.

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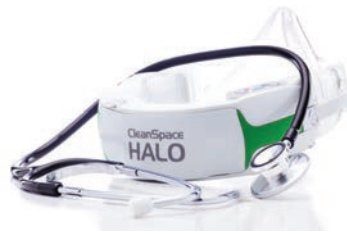

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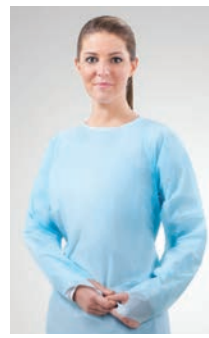

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OPERATING ROOM

"The COVID-19 pandemic has proven that contingency planning for emergencies is of utmost importance," he stated. "The real challenge is to balance the worst-case inventory scenario with appropriate budgeting and inventory holding costs. When modeling and testing inventory planning protocols, historical information and references should be used to develop the model and evaluate the impact."

Evaluation:

With PPE at the forefront of the pandemic, care and safety, it should be scrutinized closely, urges VanHee.

"Historically, PPE may not have required high-level product evaluation, but it has become increasingly important to have an effective product evaluation process in place for PPE," he expressed. "PPE evaluation should consist not only of the characteristics of the products, but also the characteristics of the manufacturer. Evaluation of the manufacturer should ensure both product quality and appropriate quality systems that meet ISO standards for the manufacture and distribution of healthcare products."

Stewart recommends making evaluations according to suppliers' length of time in the market and connection to the healthcare-specific industry.

"Evaluation of PPE should be based upon not only the documented performance of the products, but also the track record and credibility of the supplier," he said. "To the extent possible, healthcare organizations should endeavor to source products from suppliers with longstanding and reliable records of manufacture, distribution, and sale of the specific PPE to the institutional healthcare marketplace."

Zediker suggests checking out what's new in the market and adhering to guidelines.

"I would always recommend examining new technologies, ensuring cost effectiveness, cleanliness, and efficiency," he indicated. "Also, many Risk or Infection Prevention departments have specific protocols that they require team members to follow. I would recommend knowing and following those guidelines."

Sourcing:

Supply should be sourced from manufacturers who are reliable, authentic and regulated, sums up VanHee.

"The COVID-19 pandemic has highlighted the need for reliable and compliant sourcing for not only PPE, but for healthcare products in general," he shared. "Recently, issues with counterfeit facemasks, respirators, and other PPE have been brought to the attention of the general public, but this is not a new problem."

Zediker emphasizes sourcing should be based on timespan and diversity of manufacturing.

"Look for longevity (five years or more) of suppliers," he noted. "Look for folks who were delivering value prior to the panic. Ask for samples of everything you buy. If you can't wait for your current supplier, then you need someone who has a relentless focus on worldwide sourcing."

Manufacturing safety and product support also can be helpful with sourcing, according to Imms.

"For reliability on quality and approvals, hospitals should be sourcing from manufacturers that have a track record in workplace safety, specifically, working within a healthcare setting, and can support with training and technical advice," he said. This will save time and costs and build a relationship with the providers that will assist with supporting your team at the front lines." HPN

Visit https://hpnonline.com/21153862 for references

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Hands up for hygiene

Hand washing, disinfection and compliance monitoring merge for staff and patient safety amid lingering pandemic era

by Ebony Smith

When it comes to decreasing the risk of infection spread in the community and in healthcare, routine and proper hand washing and sanitizing rise to the top of best hygiene practices.

During today's COVID-19 crisis, hand washing and disinfection is making an even bigger splash as means to help protect staff and patients from this potentially deadly disease caused by the SARS-CoV-2 virus.

Infections abound

Still, the basic, but essential act of hand washing remains a health barrier and danger for various populations, including school children in disadvantaged regions.

The World Health Organization (WHO) recently reported, " As schools worldwide struggle with reopening, the latest data from the WHO/UNICEF Joint Monitoring Program (JMP) reveal that 43 percent of schools around the world lacked access to basic handwashing with soap and water in 2019 – a key condition for schools to be able to operate safely in the midst of the COVID-19 pandemic."[1]

Like schools, healthcare providers want to help wash away germs and protect people against infections.

The Association of Professionals in Infection Control and Epidemiology (APIC) stated, "No matter where you are — a hospital, a long-term care facility, an outpatient surgery center, a dialysis center or a doctor's office — you are at risk for infections. The most common infections associated with healthcare facilities include catheter-associated urinary tract infections; central line-associated bloodstream infections, surgical site infections, and pneumonia. *Clostridium difficile* infection (also known as deadly diarrhea) is another harmful illness that can develop from antibiotic use. According to the Centers for Disease Control and Prevention (CDC), 1 in 25 hospitalized patients will get an infection as a result of the care they receive. An estimated 75,000 patients will die each year."[2]

Consistently cleaning hands

Hand washing and disinfection serve as a universal health and safety protocol in healthcare environments.

"Keeping up with good hand hygiene is essential to help workers and patients stay safe and healthy," emphasized Tom Bergin, Marketing Director, Health Care, Essity Professional. "All healthcare workers should use hand sanitizers or wash their hands with soap and water at five critical moments – as prescribed by the WHO's 'My 5 Moments for Hand Hygiene':

1. Before touching the patient
2. Before a clean/aseptic procedure
3. After body fluid exposure risk
4. After touching a patient
5. After touching patient surroundings."

Bergin continued, "If their hands are visibly soiled, doctors, nurses and other healthcare workers should wash their hands with soap and water. You should ensure that hand hygiene supplies are readily available to all personnel in every care location in your hospital, doctor's office or other healthcare facilities. Engaging staff in training is also important. Tork has launched the Tork VR Clean Hand training app to help. The app is avail-

Tork VR Clean Hand training app from Essity

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able for free and helps reinforce the proper moments of hand hygiene in a safe and interactive way." The Tork brand is part of Essity.

Additional educational resources should be placed into the hands and minds of healthcare staff to enhance cleaning and sanitization, urges Bergin.

"By empowering EVS with the right tools, education, and effective products, they can help mitigate the risk of infection spread and keep operations running efficiently," he said. "Tork has launched the COVID-19 tool kit for healthcare. This document summarizes tools, education materials, and recommended products that help maintain a safe and hygienic care environment."

David Cassidy, BSN, RN, Mölnlycke, looks to the CDC's guidance for hand washing and stresses hand washing as a number one practice to defend against contagion.

Mölnlycke's Hibiclens antimicrobial skin cleanser

"As a nurse I focus on proven standards of care," Cassidy addressed. "The most important part of being a healthcare professional is to do no harm. Hand hygiene is the first step in patient care that frontline medical staff can do to prevent the spread of potentially harmful pathogens and adversely affecting the health of our patients. I always practice the 'wash in-wash out' concept in my approach to hand hygiene. Simply stated, I perform proper hand hygiene when entering a patient's room and before exiting a patient's room. As always, clinicians and staff should refer to the CDC's recommendations around handwashing as a preventive action."

Martin McGonagle, General Manager, SC Johnson Professional, Healthcare, points to the WHO's guidance for handwashing and the company's hand sanitizer and hand hygiene system for staff disinfection and patient safety.

"The spotlight on proper hand hygiene has never been brighter," McGonagle expressed. "SC Johnson Professional's Alcare Extra Foaming Hand Sanitizer contains 80% Ethanol and moisturizing agents to leave the hands feeling smooth and refreshed after use. This ABHR product is proven to eliminate up to 99.9999% of tested organisms in 15 to 20 seconds when used correctly. With the use of our DebMed System, healthcare facilities are provided with a trusted method of monitoring hand hygiene during direct patient care. The stand-alone system uses monitoring-enabled, point-of-care and wall mount dispensers to register events and measure compliance with the WHO's 'My 5-Moments for Hand Hygiene' and other best practice guidelines."

SC Johnson Professional's Alcare Extra Foaming Hand Sanitizer and DebMed System

Antibiotic cleansers, like those from Mölnlycke, help decrease the risk of pathogen spread.

"Hibiclens is an antiseptic skin cleanser used for hand hygiene as well as patient bathing," Cassidy called out. "Hibiclens' proprietary formulation contains four percent CHG for a broad antimicrobial effect. We are excited to be partnering with Georgia-Pacific to introduce Hibiclens in an automated dispenser solution – Hibiclens Antimicrobial Soap System by GP PRO. The automated, touchless dispenser can help reduce cross-contamination risk and can be positioned at every hand washing station to ensure easy access."

*Hibiclens Antimicrobial Soap System by GP PRO**

Ongoing education and ample supplies for hand hygiene are critical for compliance, expresses Caitlin Stowe, MPH, CPH, CIC, CPHQ, VA-BC, Clinical Affairs Research Manager, PDI.

"Continual education and staff reminders are important in improving and maintaining compliance," Stowe noted. The most important practice is to ensure that hand hygiene products are readily available. If the product is not easily accessible or available, there is a chance that staff could miss vital hand hygiene opportunities. Our PDI's Sani-Hands wipes are formulated with 70% ethyl alcohol and meet the CDC and the WHO hand hygiene requirements for use when hand washing is not possible."

PDI Sani-Hands Family

With the heightened risk of COVID-19 spread, the CDC recommends additional hand hygiene measures for the safety of healthcare personnel (HCP), patients and visitors, including, "HCP should remove their respirator or facemask, perform hand hygiene, and put on their cloth face covering when leaving the facility at the end of their shift. Educate patients, visitors, and HCP about the importance of performing hand hygiene immediately before and after any contact with their facemask or cloth face covering."[3]

Hand hygiene compliance

How can healthcare providers work to achieve hand hygiene compliance and safety in care? Cassidy suggests professional education, visual monitoring and monitoring systems for support.

"Healthcare institutions have multiple ways to measure the efficacy of current hand hygiene protocols," he said. "One of the most effective methods gets back to basics. Proper education and simple observation by infection prevention professionals works as well as audit tools and monitoring systems that seem to improve with every new iteration. Several vendors of hand hygiene solutions employ professionals to teach and implement facility-specific practices and protocols. Hibiclens is very gentle to skin and has a low potential for skin irritation in repetitive use. This benefit of being gentle to skin drives compliance with caregivers."

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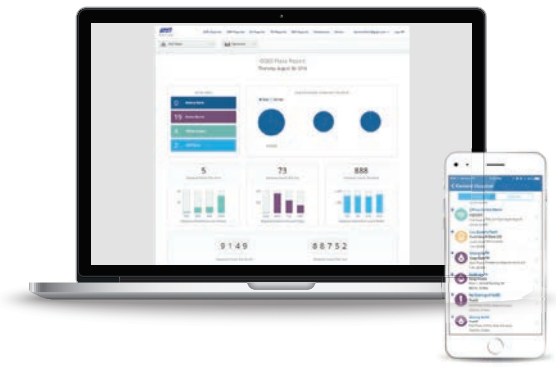

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1. Altavita Village, Time and Waste Reduction Study, June – December 2016. Data on file.

McGonagle turns to a solution-based approach for tracking, evaluating and sharing information about hand hygiene and compliance.

"For example, Leapfrog's new hand hygiene standard includes five domains: monitoring, feedback, training and education, infrastructure, and culture[4]," he indicated. "The standard encourages facilities to adopt this multimodal approach to hand hygiene, emphasizing the importance of monitoring and feedback. The solution, therefore, is to measure hand hygiene compliance with an evidence-based and validated electronic hand hygiene monitoring system that can track every hand hygiene event and provide the data needed to support ongoing improvements and compliance."

The Hand Hygiene Compliance Monitoring system by Ecolab Healthcare provides added accountability and extra security in care, brings forth Linda Homan, RN, BSN, CIC, Senior Manager of Clinical Affairs, Ecolab Healthcare.

"The pandemic has reinforced the importance of fundamental infection control practices, such as hand hygiene," Homan explained. "Ecolab's system has enabled our customers to ensure hands are washed before and after every patient. It allows hospitals to record hand hygiene events automatically and accurately by individual and provides immediate feedback to keep staff accountable, driving a two-times average improvement in hand hygiene compliance and resulting in sustained post-implementation compliance levels of 80 to 90 percent. To quote one customer, '*If I didn't have this system, I wouldn't have a clue about what is going on with hand hygiene! We are trying to restart our 'usual' activities, but with staffing cuts it is difficult. The beauty of the system is I can send reports to those above me to get my point across – I don't have to depend on manual observations.*'"

Hand Hygiene Compliance Monitoring System by Ecolab Healthcare

Further, Ecolab's product-level tracking keeps hand dispensers stocked and its digital direct observation app enables situational coaching and monitoring of all '5 Moments', added Homan.

COVID-19, however, may disrupt the flow of monitoring compliance, or, on the other hand, may open the door to new improvements, observed Stowe.

"While direct observation is the gold standard when it comes to evaluating proper hand hygiene, this may not be possible during the pandemic[5]," she stated. "Staff normally responsible for monitoring hand hygiene compliance are increasingly relying on alternative methods, such as hand hygiene product usage calculations and secret shopper observations performed by other staff members to monitor compliance. While none of these are perfect, any of these methods can be used to benchmark current performance and identify opportunities for improvement."

Disinfecting equipment

In addition to hand hygiene, computer keyboards and other equipment touched by staff are critical to clean and disinfect in healthcare facilities.

"All work environments have varying degrees of shared spaces and opportunities for cross-contamination, and many of them are commonly overlooked," said Matt Dombrowski, Sales Manager, WetKeys Washable Keyboards. "Now more than ever, the mindfulness for cross-contamination has made WetKeys Washable Keyboards essential personal protective equipment (PPE). We are thrilled that our products are being used to outfit hospitals and other healthcare facilities with sanitary typing equipment. Our hospitals partners are now purchasing washable keyboards and mice for administrative areas and patient intake zones because these have previously been blind spots in their infection prevention plans."

Just as healthcare workers strive to achieve hand hygiene compliance and safe care settings, so do the WetKeys staff in their workplace, Dombrowski expressed.

"At WetKeys, we are adamant about good hand hygiene, and each team member has a favorite song they hum while washing their hands for the recommended twenty seconds," he shared. "While our team is hypervigilant about hand hygiene, we also use a standard washable ABS plastic keyboard, like the KBWKABS104-BK, at our desk and in our conference room to ensure a hygienic, safe work environment. They (hospitals and healthcare facilities) have put out hand sanitizer and hand washing guide signs above sinks, but monitoring and measuring is a

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75,000 deaths occur annually in US hospitals due to HAIs

(It's time to take proven infection prevention further)

Figures released from the CDC make stark reading for Infection Preventionists. An estimated 722,000 healthcare-associated infections occur annually, resulting in 75,000 deaths and billions in additional costs.[1] More than half of these occurred outside of the intensive care unit.

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Reference: 1. Magill SS, Edwards JR, Bamberg W et al. Multistate Point-of-Prevalence Survey of Health Care-Associated Infections. N Engl J Med 2014; 370: 1198-208. Add additional references: **2.** Rodriquez, P. Reducing Infections and Increasing Patient Satisfaction: One Hospital's Journey. Infection Control Today June 2018. **3.** Climo MW, Sepkowitz KA, Zuccotti G, et al. The effect of daily bathing with chlorhexidine on the acquisition of methicillin-resistant Staphylococcus aureus, vancomycin-resistant Enterococcus, and healthcare-associated bloodstream infections: results of a quasi-experimental multicenter trial. Crit Care Med 2009; 37:1858-1865 **4.** Rupp M, et al. Effect of Hospital-Wide Chlorhexidine Patient Bathing on Healthcare-Associated Infections Infect Control Hosp Epidemiol 2012;33(11):1094-1100

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hurdle. It is much easier to maintain and enforce hand hygiene for the usual high-risk environments, like operating and examination rooms. Our SaniType keyboards, designed for these specific areas, have a 'sanitize for prevention' reminder printed on them."

Next wave of hand hygiene

What's in store for the future of hand hygiene practices and compliance? Homan predicts that technology will advance to allow better tracking of hand washing activity and compliance.

"New wearable technology, for example, is advancing quickly," she noted. "In fact, Apple has recently enabled the iWatch to recognize when you are washing your hands and provided a timer to ensure they are washed for the full 20 seconds. We see this type of advancement being especially useful in acute care facilities, but it will also be helpful in making people mindful of hand hygiene across many different environments, such as schools, offices and sports arenas – and that's really exciting."

Stowe agrees technology must develop and climb to the forefront of hand hygiene in care.

"The next generation of hand hygiene should be fully automated and more accurate than direct observation," she said. "This could be accomplished through the use of enhanced radio frequency identification (RFID) technology. This will be able to track compliance down to the specific person and hand hygiene dispenser and at what specific indication hand hygiene was performed. Future hand hygiene compliance technologies will allow facilities to collect robust hand hygiene observations and monitor intervention effectiveness in real time."

Dombrowski envisions continued focus on disinfecting devices and surfaces touched in public spaces.

"The next generation of hand hygiene is community-based protection. Hand hygiene is personal and can be tricky to enforce in all areas," he stated. "One set of dirty hands using a shared keyboard at a data entry station without cleaning contaminates all the clean hands. Washable keyboards and mice help to combat this human element and reinforce the hand hygiene of the entire hospital. It is hard to monitor and measure personal hygiene. Broadly deploying washable keyboards and mice, a commonly shared surface, becomes a keystone in making a robust infection prevention plan." **HPN**

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Kit, tray and kaboodle

Getting and keeping your assets together

by Kara Nadeau

In a hospital, ambulatory surgery center (ASC) or other healthcare facility, many take for granted the process by which clean, sterilized surgical instruments reach the hands of surgeons and other clinicians for use on a patient. Two very important elements of the process are the storage of instruments until they are needed, and the transport of instrument sets and trays from the Central Sterile/Sterile Processing Department (CS/SPD) to the procedural area and back again, both of which must be performed with safety and efficiency.

Take a team approach

While the operating room (OR) is essentially the customer of the CS/SPD, that doesn't mean OR staff members hold no responsibility for the handling and transport of instruments. In reality, both the OR and CS/SPD teams must play a collaborative role in these processes in order for the healthcare facility to deliver safe, effective and efficient care to patients.

Troy Scroggins, Product Manager, Sterile Packaging for Aesculap, comments on the challenges CS/SPD and OR teams face with regards to timing (delivering instruments where they are needed when they are needed) and ensuring the clinicians have the right instruments in right/proper conditions.

"Factors that cause case delays include holes in sets, missing or incorrect instruments (lack of organization/optimization) and dull or broken general and specialty instruments," said Scroggins. "The mishandling of instruments can also lead to higher repair costs. Standardizing on a single container brand that is durable and includes a variety of options to accommodate a broad range of instrument types can help address these issues."

Mary K. Lane, MHA, CSPDM, CSPDS, CSPDT, MK Lane SPD Consulting, has built and redesigned many CS/SPD departments and sterile storage areas during her career. She says some of the biggest challenges related to instrument storage and transportation are associated with OR turnover efficiencies, the distance between the OR and CS/SPD, storage space allocation, the surgical set inventory levels and turnover time in CS/SPD to reprocess the sets.

Mary K. Lane

For those facilities wanting to improve the storage, transportation and containment of instruments, she recommends they establish a multidisciplinary team to determine the goals and define the available "real estate" in terms of storage space.

"Investing the time and energy into designing or redesigning the sterile storage space can be time consuming; however, the benefits of a well-planned, well-designed area cut down on the stress and tension, as well as the overall efficiencies," said Lane. "The collaboration between the departments (CS/SPD and OR) when implementing changes results in a much stronger relationship with all involved taking ownership for the process and success."

She offers the following advice to facilities when taking a team approach to CS/SPD department and sterile storage area redesign:

- Secure surgeon buy-in to "trim down" the number of instruments in their sets, while increasing inventories when needed.
- Secure C-suite buy-in for additional surgical set inventory, rigid containers and additional storage space when needed.
- Design adequate storage in CS/SPD and the OR, ensuring that all areas are labeled clearly and that the items are not placed too close together or stacked, which creates clutter and confusion.
- Have OR and CS/SPD stakeholders walk through the proposed modifications multiple times over a few months prior to setting them in stone to ensure that they will be able to achieve the goals they have outlined.

The Aesculap JS Series containers, for use with Low Temperature, Et0 and PreVac Steam sterilization

Space-saving storage practices

Hospitals and other healthcare facilities that were designed and built decades ago typically find themselves outgrowing the instrument storage spaces originally designed to support them, explains Dave Salus, Market Manager, Healthcare Division, InterMetro Industries Corporation.

"Budgets are tight, so building in/on new spaces is not always an option, and when it is there is never room for waste,"

MetroMax from Intermetro can be configured in track system or freestanding

said Salus. "Storage solutions need to be flexible in design and configuration to deliver high density, protective storage."

Salus says CS/SPDs must take steps to reduce wasted space above and beside stored packs; install shelves that are rugged enough to hold metal containers, yet delicate enough to eliminate rips and tears in packs; and select partitions that are movable to adjust to varying pack sizes.

"Storage design choices should be flexible to provide high density storage like in track systems, or space reclaiming configurations that can utilize [typically wasted] space, like above case carts or other equipment," Salus added.

Keep separate for safety

Darwin Asa, Marketing Manager, Midmark, stresses the importance of establishing and maintaining separate spaces for each CS/SPD function to boost efficiency and safety. He explains how department design can play a significant role in maintaining consistent and effective instrument processing practices that help safeguard the wellbeing of patients and staff.

"Ideally, the instrument processing space should be a separate, discrete area designed specifically for instrument processing and sterilization. It should not share space with the staff break area or be located in the facility's storage room," said Asa. "Rather, it should be centrally located within the facility to allow for easy access from all patient areas. This separation allows organizations to more easily control and manage the process and ensure safety."

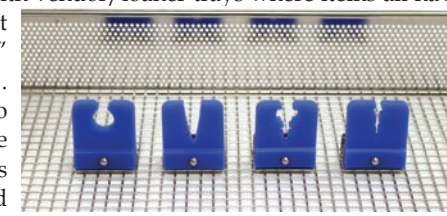
The Ritter M11 Steam Sterilizer from Midmark can optimize the supply of available sterile instruments by reducing the time and effort required.

"Additional attention should be given to ensure the size and layout of the instrument processing area fits the needs and workflow of the facility, allowing caregivers to treat patients effectively and efficiently," Asa added. "The right design can help strengthen infection prevention programs and initiatives."

Staying organized

Kevin Anderson, BSN, RN, CNOR, CSSM, CRCST, CHL, CIS, CER, Clinical Education Coordinator, Healthmark, says one way for CS/SPDs and ORs to improve instrument containment and transport is to simply organize their trays.

"We see this with vendor/loaner trays where items all have a specific spot within a tray," said Anderson. "This makes it so much easier to see when an item is missing, or to find what you need. The same concept could be accomplished with many of our trays if we use simple tools like Secur-Its or other organizing tools within our trays. Having a streamlined design for our trays makes life easier for the end users in the OR, and for techs in SPD throughout the process. Organizing instruments within the tray may also improve the life of your expensive instrument assets."

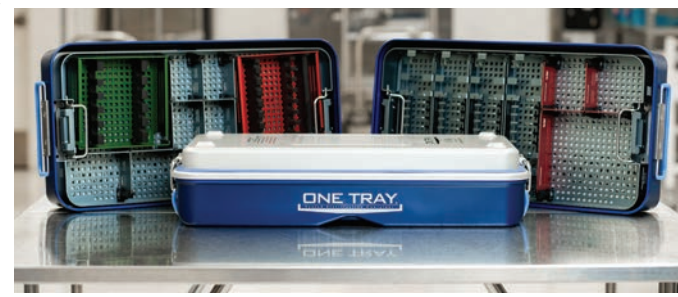


Healthmark Inudstries' Secur-Its.

Turnaround times

Time is of the essence when it comes to the delivery of needed sterilization trays. The ONE TRAY Sealed Sterilization Container was cleared by the U.S. Food and Drug Administration (FDA) to be used to hold temperature-tolerant medical devices during steam sterilization cycles and then be stored up to 48 hours.

Barbara Ann Harmer, MHA, BSN, RN, Vice President of Clinical Services, IST, states that with the elimination of dry time when using ONE TRAY, the CS/SPD staff can react quickly to any changes or issues during the day's schedule or address on-call situations when dealing with emergent needs.



ONE TRAY Sealed Sterilization Container from IST

"Add-on cases with insufficient instrumentation can now be scheduled knowing that a timely solution is available with the use of ONE TRAY," said Harmer. "Torn wraps or other container systems that are found to be wet when needed are two other examples that are problematic for the timely delivery of sterilized trays. Late vendor trays, not a problem for ONE TRAY. ONE TRAY provides an efficient, economical and effective solution for CS/SPD daily concerns."

Inventory tracking

Inventory tracking systems are an extremely valuable tool for maintaining visibility into surgical instruments inventory. Terso Solutions Senior Product Manager John Kuehl comments on the operational and clinical benefits of using radio frequency

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identification (RFID) technology for instrument tracking.

"Using technology, such as RFID, enables hospitals to benefit from a real-time inventory system that reduces delivery delays of critical items to avoid delaying or canceling surgeries, helps reduce labor costs in documenting used items and restocking any unused items, and shares information between departments or inter-network facilities," said Kuehl. "RFID tracking also reduces overall inventory levels through knowing what is physically at the hospital, eliminates the hoarding of hard to get items for the OR, and tracks expiration dates, and in some cases, temperatures of critical items so only valid items are being used."

The Large RFID Refrigerator from Terso Solutions.

Instrument tracking systems also protect patient safety by enabling these teams to track patient usage for infection prevention, and the number of reprocessing cycles to keep unusable instruments out of the hands of clinicians.

"CS/SPD professionals should pay close attention to the tracking and management of instruments coming in and out of the OR," said Christopher John, Field Marketing Manager, Getinge. "By tracking which cases and patients these instruments are being used on, facilities can ensure that patient infection is kept to a minimum and tracking of trays and instruments have a full end-to-end documentation."

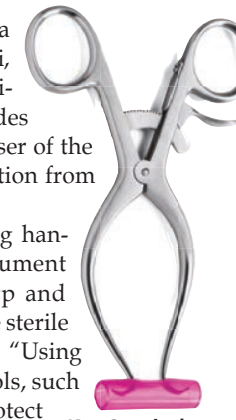
"By using the T-DOC Sterile Supply Management Solution from Getinge to keep track of these trays/equipment, facilities can track usage and ensure that instruments in circulation are not being kept past their useful life, thereby keeping patients safer and staff happier by not using outdated equipment," John added. "Tracking the movement of these instruments and trays helps keep track of units while they're in use, dirty or being sterilized with estimated completion times."

Torin, Getinge's OR Management solution

Protection during transport

As clean and sterilized instruments make their journey from the CS/SPD to the procedural area and back to the CS/SPD for reprocessing, there is always the risk for damage, particularly for delicate instruments that are not properly contained.

"Although there are many factors that contribute to the safe transportation of surgical instruments, instrument protection in the preparation and packaging area is a crucial component," said Jamie Zarembinski, CCSPD, SPD Clinical Educator, Key Surgical. "Instrument protection not only provides an additional layer of safety for the end user of the instrument, but also protects instrumentation from damage during transportation.



Key Surgical instrument protectors

"Surgical instruments often shift during handling and transportation of sterile instrument trays, which can cause damage to sharp and delicate instrument tips or compromise the sterile packaging integrity," Zarembinski added. "Using a wide variety of instrument protection tools, such as tip caps and instrument sleeves, to protect surgical instruments from damage during transportation is a critical but an often-overlooked component of safe transportation of surgical instrumentation."

Linda Condon, MBA, BS, RN, CRCST, Director of Clinical Services, Censis Technologies, explains how a stringer and tray liner are not always enough to protect instruments during transport because they can shift in the inner basket each time a container is handled.

"I highly recommend the use of positioning devices to hold instruments in place so they are protected during transport," said Condon. "If the same positioning device can be used to protect instruments during the decontamination process that is even better. Different container manufacturers have positioning devices to help secure instruments. Taking the time to configure the inner basket before putting a set into circulation is critical in preventing damage to these expensive assets. Having instruments secured decreases this risk and can also protect the container filter from being compromised."

CensiTrac Advanced from Censis provides real-time surgical instrument tracking

Endoscopes in particular are vulnerable to damage during transport because of their delicate nature and high price tags, according to Aaron Lieberman, InstruSafe Product Group Manager, Summit Medical. He states:

"Organizing and protecting surgical instruments throughout the entire use cycle from decontamination, sterilization preparation, storage and transportation to the OR and back is what Summit Medical designs products for and the biggest areas of opportunity we see is the containment and storage of endoscopes. Taking care of your endoscopes can have a tremendous impact on your instrument repair and replacement budget."

"Right now, we see a lot of rigid endoscopes, flexible endoscopes and robotic endoscopes being transported in plastic trays and metal baskets and these instruments are too delicate to be bouncing and sliding around during transportation resulting in expensive repair costs," Lieberman added. "Using trays and transport containers that are specifically designed for

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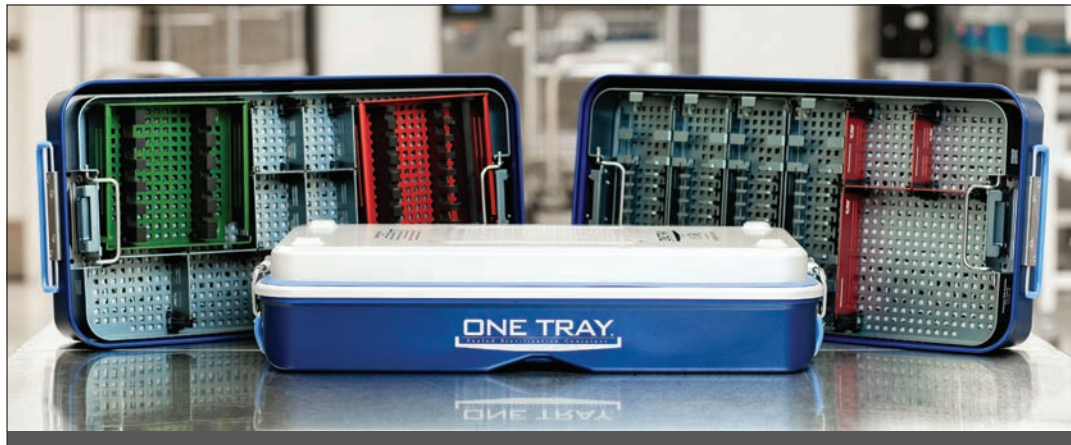

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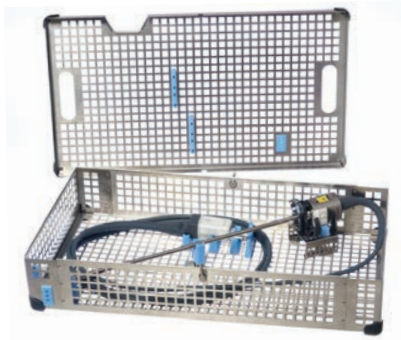

InstruSafe Single Scope Tray from Summit Medical

each specific endoscope will protect them while they are most vulnerable, during transportation."

Transport through public areas

One critical area in instrument transport that is often overlooked is the transportation of contaminated instruments through public areas, says Casey Stanislaus Czarnowski, BA, CRCST, CSPDT, CIS, CER, Sterile Processing Educator, Stanford Health Care. Czarnowski points out that while CS/SPD and clinical teams might come up with a plan and policy around safe and efficient transport of surgical instruments in their facility, including "an iron-clad path of travel for soiled instruments between semi-restricted areas" aligned with regulations (e.g. OSHA), in the dynamic care environment they can find it challenging to comply.

Casey Czarnowski

"When surgeries come up unexpectedly and CS/SPD and OR staff members are trying to get instruments where they are needed in the heat of the moment, they quickly realize that their transport plans are unworkable, causing stress for everyone involved," said Czarnowski.

Czarnowski explains that when that path of travel is blocked, disrupted or changed, the safety of patients, families and visitors may not be addressed, or may be overlooked. He says two common causes of disruption in the instrument transport path are construction and mechanical failure.

"As everyone who works in a hospital knows, construction is a constant fact of life," said Czarnowski. "When hallways are blocked, new avenues for contaminated instruments must be found, or the instruments must be contained according to strict measures to protect the public.

Another instance is mechanical failure. The dedicated OR to SPD elevator is a common feature in hospitals. A contingency plan for when the elevator goes down must be made policy, trained for all roles involved, rehearsed regularly and enforced."

When developing a transport path and plan, Czarnowski recommends that CS/SPD and clinical staff members take the time to test it out before implementing a policy.

"Come up with a potential plan and then have the people involved walk it and trial it on a low volume surgery day, for instance," said Czarnowski. "Walk the path, see visitor areas, public areas, unrestricted areas and other areas you will encounter and adjust the plan from there before making it policy."

Staff training

Even with all of the technologies on the market today to help improve instrument containment, storage and transport, per-

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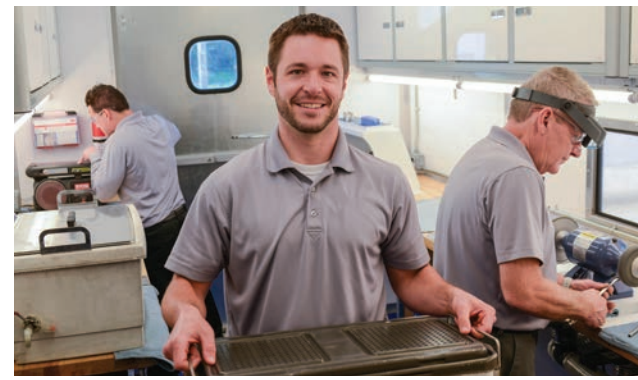
haps the most critical element to success is CS/SPD and OR staff member training.

"Containers represent a significant expenditure for the hospital," said Lawrence J. Slattery, Senior Consultant, Strategic Projects & Mobile Solutions, STERIS IMS. "This investment is intended to provide secure, sterile handling over time; however, container components are often mishandled and damaged resulting in questionable integrity. Whether wrapped or containerized, tray handling is critical. Instruments must arrive at the OR sterilized and ready for use."



STERIS IMS onsite container inspection, maintenance and repair

"Several hands touch the container components during the reprocessing cycle journey," Slattery added. "Each touchpoint allows for mishandling, increasing the likelihood of holes in wrappers, which compromises sterility or allows possible content damage. Train staff on the importance of proper handling of trays and containers, and work to reduce touchpoints. Proactively maintain container components to ensure integrity." HPN

Custom tray pilot project eliminates ophthalmic instrument repairs

One instrument category that requires meticulous protection is ophthalmic instruments. Nuffield Health is the UK's largest healthcare charity with 31 award-winning hospitals, 112 fitness and wellbeing clubs, healthcare clinics, and over 200 workplace wellbeing services.

Gordon Allan, Nuffield Health's Hospitals Sterile Services Unit (HSSU) Surgical Instrumentation Manager, has been working on a project to reduce damage to fragile ophthalmic instruments through rationalization of sets and moving the instruments to custom Microwash instrument trays from Altomed.

"As an offsite sterile processing provider, our instrument sets are transported throughout the country and it's therefore essential that we work to reduce the potential for damage to instruments in transit," said Allan. "Not only do damaged instruments have a cost implication in terms of the repair/replacement budget, they also pose a significant risk to patients during surgery if not identified, increase turnaround time at SSD, reduce availability of sets and can ultimately increase the time a patient spends in surgery."

Allan and his team implemented the Microwash instrument trays from Altomed in the health system's Wolverhampton hospital at the end of 2019. This has resulted in a reduction in ophthalmic instrument repairs from 14 in 2019 (total cost £700, $910.69 U.S.) to zero in 2020. Based on these results they are projecting a saving of £3500 ($4,553.49 U.S.) over five years in repair costs alone.

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October 2020
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LEARNING OBJECTIVES

1. *Examine the goals of sterilization and options for the sterile processing department*
2. *Compare and contrast steam and vaporized hydrogen peroxide sterilization processes*
3. *Review quality control tools and procedures for sterilization processes in healthcare facilities*

SELF-STUDY SERIES

Breaking the chain of infection

Sterilization options for the SPD

by Craig Wallace, President, Wallace Sterilization Consulting, LLC

Sterilization of medical instruments began in the 1870s with rudimentary heat and moisture-based systems and has evolved into the highly complex and effective processes used by healthcare facilities today. Sterilization of instruments is critical to infection prevention and patient safety. The sterilization process breaks the chain of infection by preventing transmission of pathogens between patients. New processes and equipment technology have been developed to accommodate the evolution of medical device designs and materials, as well as increasing demands for lower costs and increased throughput from the Sterile Processing Department (SPD).

Sterilization basics

The term "sterile" means "*free from viable organisms*".[1] While this certainly seems straightforward, the science behind "sterile" is actually quite complex. For medical devices, sterile is expressed as a probability that any given device is non-sterile (has at least one viable organism on it). The accepted probability for medical devices is no more than one chance in one million that a device is non-sterile after the sterilization process. This is called the Sterility Assurance Level or SAL and is typically written as 1×10^{-6}. The term "sterilization" means "*validated process used to render product free from viable microorganisms*".[1] In the United States, sterilizer manufacturers are required to demonstrate that each programmed sterilizer cycle is validated under laboratory conditions and demonstrate to the FDA that the process achieves the required SAL of one in one million probability of a non-sterile device.[2]

The effectiveness of the cleaning process is critical to the overall success of the sterilization process. The CDC Guidance for Disinfection and Sterilization states: "Cleaning reduces the bioburden and removes foreign material (i.e., organic residue and inorganic salts) that interferes with the sterilization process by acting as a barrier to the sterilization agent."[3] Careful adherence to cleaning instructions provided by the sterilizer manufacturer or the medical device manufacturer will help ensure that the sterilization process will perform as intended and the processed devices will meet the required one-in-one-million probability of a non-sterile device.

Packaging, sometimes called the sterile barrier system, is also an important factor in the sterilization process. The sterile barrier system is intended to protect the sterile medical device from any environmental contamination until it is presented for use on the patient. Per AAMI ST 79, the sterile barrier system selected should address the following:[4]

a) allow air removal to permit sterilant penetration of the package contents;
b) provide a barrier to microorganisms during sterilization processing, handling, distribution, transport, and storage;
c) resist tearing or puncture;
d) allow a method of sealing that results in a complete seal that is tamper-evident and provides seal integrity;
e) maintain protection for the sterile contents during storage and transportation to the point of use;
f) allow for aseptic presentation;
g) be free of toxic components and non-fast dyes;
h) be non-linting;
i) be compatible with the intended methods of sterilization, sterilization parameters, and the devices to be sterilize

The healthcare facilities' packaging procedures should be based on instructions for use (IFU) from the sterilizer manufacturer, medical device manufacturer, and packaging system manufacturer.

Sterilization quality control

So, how do you know if the sterilization process has been successful? You can't see if the device is sterile, and there is no

no practical way to do lab sterility testing on enough devices to ensure that the required SAL of no more than one contaminated device out of every one million devices has been met. However, you can perform other types of tests on each sterilizer cycle to provide information on whether the expected and required conditions were achieved in that cycle. While these quality control (QC) tests cannot confirm an SAL, they can provide information on the sterilizer cycle performance that can be used to make a decision on whether or not the devices in that cycle can be considered safe and ready for patient use.

The quality control programs for healthcare sterilization processes are typically based on testing the sterilizer and process with a combination of physical monitors, chemical indicators (CIs), and biological indicators (BIs). Each of these monitoring tools provides different information about the sterilization process that, when combined and evaluated by a knowledgeable individual, can provide the information needed to decide whether to release the load contents for patient use.

The physical monitors are sensors that are located in the sterilizer chamber and measure physical parameters, such as temperature and pressure, and provide a cycle printout. This information is useful for ensuring that the correct cycle was selected and confirming that no gross cycle errors occurred. The physical monitors provide basic information from distinct points in the chamber wall and are not able to provide information related to loading or information from inside the sterilizer load. Chemical indicators use reactive inks that will respond to specific sterilizer process conditions with a chemical or physical change that can be interpreted by the user (e.g. a change in ink color or a moving front). Chemical indicators are placed on both the outside and inside of packages and provide information on the physical quality of the process from those locations in the load. Biological indicators are placed inside process challenge devices (PCDs) in the most challenging location in the chamber and provide the only direct measurement of the lethality (killing power) of the cycle. A "pass" result for all these indicators provides a sound rationale that the process was correct and effective, and the load contents are safe for patient use.

Sterilization options for the SPD

There are two general types of sterilization processes available to the SPD. The first is high temperature sterilization, which in healthcare means moist heat or steam. The second is often called low temperature sterilization. The most common processes for low temperature sterilization in healthcare are vaporized hydrogen peroxide (VH202), and ethylene oxide. VH2O2 is much more common now and will be the focus of this discussion.

Steam was the first technology used for sterilization of medical devices and is still the most heavily used process in hospitals today. It is fast, highly effective, and cost efficient. The development and use of the low temperature processes were driven by the development of medical devices with materials or design that were not compatible with the high temperature, high pressure, and/or high humidity of the steam process.

Steam sterilization

Steam sterilization is considered a physical sterilization process. It relies on saturated steam, that is, water vapor that is in a state of equilibrium between the gas and liquid phases. Steam condenses on surfaces and releases energy that will kill the microorganisms present on the surface. Steam will transfer heat energy to a medical device and can kill the microorganisms on the device, even if it does not contact them directly. Residual air in the sterilization chamber or device container can reduce the level of saturation and therefore the amount of energy transferred, thus reducing the effectiveness of the sterilization process.

The critical variables of a sterilization process are the physical aspects of the process that have the greatest impact on the effectiveness of that process. The critical variables for a steam sterilization process are temperature, exposure time, and steam quality (level of saturation). Typical steam sterilization processes in healthcare today operate at 132°C or 134°C and remove air from the chamber with a series of vacuum or steam pulses at the start of the cycle. Cycles that operate at 121°C and use gravity to remove the air are also used but are less common.

Vaporized hydrogen peroxide sterilization

Hydrogen peroxide sterilization is a chemical sterilization process that uses hydrogen peroxide vapor as the sterilizing agent. These cycles typically operate at approximately 50°C to 55°C and are commonly called low temperature sterilization (as compared to the temperatures in steam cycles). The critical parameters for VH2O2 sterilization processes are temperature, exposure time, and concentration of hydrogen peroxide. The concentration of hydrogen peroxide is more critical and complicated than it sounds. VH2O2 sterilization is a chemical process, which means that hydrogen peroxide molecules must directly contact a microorganism to kill it. So, to sterilize a device, every microorganism on the device must be contacted directly by the hydrogen peroxide vapor. Hydrogen peroxide is in a vapor state, which means it tends to condense easily into liquid on surfaces, like water vapor on the mirror in the bathroom after a hot shower. The condensed liquid hydrogen peroxide will not further penetrate into the devices and may reduce the amount of vaporized hydrogen peroxide available in the rest of the chamber. In addition, hydrogen peroxide itself is a somewhat unstable molecule, and will tend to break down into other chemicals. (For example, the hydrogen peroxide solution in your home medicine cabinet is in a light-proof, brown bottle and must be stored in a cool place to protect the unstable hydrogen peroxide molecule).

There are many different VH2O2 cycles available in the varied VH2O2 sterilizers used in healthcare today. Some cycles use a gas plasma exposure to reduce the amount of residual hydrogen peroxide after the cycle is complete. Each cycle is intended for a specific set of medical devices, and careful adherence to sterilizer manufacturer and medical device manufacturer IFU is critical.

Comparison – steam vs. VH2O2

Steam and VH2O2 sterilization processes are both completely effective at achieving the required SAL when they are run under the same conditions as their original validations. However, the challenges and variability presented by rigorous daily use in a busy SPD can expose the inherent differences between these two processes.

The physical action of the steam compared to the chemical action of VH2O2 leads to some practical considerations in the real-life use of these processes. While exposure time and chamber process temperature are critical variables in both

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

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processes, these variables are relatively easy to measure and control. Achieving the correct "quality" or concentration of the sterilant itself (steam or VH2O2) in the medical device load is the greatest challenge and presents the most significant risk of process failure and unsafe instruments.

Steam processes rely on the basic physical action of steam condensation and heat transfer to kill microorganisms. Steam processes are designed with an excess of saturated steam available and therefore can compensate for normal variations in load size, load temperature, and device mix. The chemical action of VH2O2 and reliance on adequate concentration for all microorganisms present on the device, coupled with the complex and unstable nature of hydrogen peroxide, present some unique practical challenges with these processes. VH2O2 processes do not typically operate with the same excess of sterilant as steam, so they can be more sensitive to variations in load size and composition. Too much material in the load, or a load that is too cool, can cause an excess of H2O2 condensation, resulting in poor distribution or inadequate sterilant in the chamber. VH2O2 can also interact with certain packaging or medical device materials that can absorb or degrade the hydrogen peroxide, again resulting in poor distribution or inadequate concentration in the chamber.

While following the IFU is imperative for any sterilization process, it is particularly important for VH2O2 processes. The unique nature of the hydrogen peroxide chemical process makes this technology approach much more technique sensitive than steam, that is, packaging, loading, and load composition must be carefully managed by the SPD staff to ensure effectiveness of the process.

Quality control recommended practices

AAMI standards provide recommended quality control monitoring practices for load release for steam and VH2O2 cycles.[4,5] The recommendations are summarized in Table 1.

The monitoring recommendations for load release for steam and VH2O2 are quite similar. It should be noted that BI/PCDs are optional for testing of non-implant loads in steam while BI/PCD testing is preferred for every load in VH2O2. This fits well with the possibility of more variability in VH2O2 processes. Many healthcare facilities monitor every cycle in both processes with a BI in a PCD to provide the highest level of quality control and a uniform standard of care for all patients.

A few words about biological indicators

Performance and labeling requirements for biological indicators for steam are well defined in ISO standards, but at this time there are no standards defining the performance requirements for biological indicators for VH2O2 processes. This means that the end user should rely on regulatory clearances by the FDA to provide confidence that the biological indicators they are using will perform appropriately in the labeled cycles. The FDA makes the determination regarding suitability of BIs for specific VH2O2 cycles. This determination is not made by the sterilizer manufacturer.

Biological indicators are placed inside of PCDs to monitor sterilization cycles. The BI spores are intended to represent the microorganisms on the medical devices. The PCD is separate and represents the challenge to the process provided by the device packaging and the load. The BI/PCD combination then provides a representative challenge to the process like the organisms on devices inside of the load, yet the BI/PCD is easy to retrieve and test without opening any packaged devices.

Summary

By breaking the chain of infection and preventing cross contamination between patients, sterilization processes used in healthcare facilities are critical to patient safety. Steam and vaporized hydrogen peroxide processes are both effective when used properly. Vaporized hydrogen peroxide processes are more technique sensitive, however, and require strict adherence to packaging and loading recommendations. Quality control testing using physical monitors, chemical indicators, and biological indicators inside of PCDs provides information on the quality of the process, which can guide the decision on whether devices can be released for patient use. HPN

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Craig Wallace, president of Wallace Sterilization Consulting, LLC, has over 26 years of experience in the field of medical device disinfection and sterilization.

Craig is the Convenor of the ISO Biological Indicator Working Group (TC 198, Working Group 4), the ISO committee responsible for international biological indicator performance standards, as well as a U.S Technical Expert for Chemical Indicators (ISO WG 6) and Moist Heat Sterilization (WG 3). He is also the Co-Chair of the United States (AAMI) Biological Indicator Working Group, and an active member of several other AAMI working groups including chemical indicators, vaporized hydrogen peroxide sterilization, and ethylene oxide sterilization.

Table 1 – AAMI Monitoring Recommendations for Routine Release of Loads

	STEAM	VH2O2
Physical monitoring	Every cycle	Every cycle
Chemical indicators - external	Every package	Every package
Chemical indicators - internal	Every package	Every package
Biological indicators inside a PCD	Optional[a] Every cycle[b]	Daily, preferably every cycle[a] Every cycle[b]

a. Non-implant loads
b. Loads containing an implant

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Breaking the chain of infection

Sterilization options for the SPD

Circle the one correct answer:

1. **"Technique sensitive" is a term to describe potential variability introduced by packaging or loading procedures that can have a significant impact on the outcome of the VH2O2 sterilization process.**
   A. True
   B. False
2. **Sterilizer manufacturers determine which biological indicators can be used to monitor their sterilizers.**
   A. True
   B. False
3. **AAMI ST58 states: "A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle"?**
   A. True
   B. False
4. **Inappropriate loading may not be detected by the physical monitors of the sterilizer (cycle printout).**
   A. True
   B. False
5. **Sterilization is a process that can break the chain of infection by preventing cross-contamination between patients.**
   A. True
   B. False
6. **Steam is a chemical sterilization process.**
   A. True
   B. False
7. **"Sterile" actually describes a probability that any given device is contaminated with a viable organism.**
   A. True
   B. False
8. **The original technology for sterilization of medical instruments was a chemical process.**
   A. True
   B. False
9. **AAMI ST79 requires a BI in a PCD to be used with every load containing an implant.**
   A. True
   B. False
10. **Vaporized hydrogen peroxide processes are dependent on the concentration of hydrogen peroxide, as well as the temperature and exposure time.**
    A. True
    B. False

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Removing biofilms; using indicators in sterilization assurance

by Ray Taurasi, MBA, CRCST, CHL, FCS, ACE, Principal, Healthcare CS Solutions

Q Over the past few years I have heard a lot about biofilms and how bad they are in sterile processing, but I have to admit I really don't understand what they are or why they are so bad for us. I have worked in sterile processing for over 20 years and now we have biofilms to worry about. Why is that and what's next?

A Over the years we have made many scientific discoveries and advances and have developed lots of new technologies that have changed and improved the way we do things. While biofilms have existed forever, through more advanced study, we have learned more about them and how they can present a significant challenge to effective cleaning and sterilization.

So, what is a biofilm? Well, just as the name implies it is a biological film. This film, or slime, often consists of diverse colonies of tiny microorganisms bound together in a "matrix," or a thick, sticky substance. This "matrix" consists of both living and dead cells as well as polysacharides or carbohydrates.

Biofilms often are not detectable by touch or visible to the naked eye. However, in extreme cases and with multiplication, biofilms may become more visible and become slippery to touch. Biofilms form when single microorganisms attach to a hydrated surface and undergo a "lifestyle switch," giving up their life as a single cell to live on a surface in an adhesive cell formation (matrix) with other microorganisms.

When soiled medical devices and surgical instruments are left for prolonged periods of time soaking in water or a water-based substance, the formation of biofilm is likely (see figure 1). Biofilms can irreversibly attach to the surfaces of these medical devices and instruments and, once attached, it is extremely difficult and very challenging to remove them. Our standard cleaning protocols may not be effective. If biofilms are not thoroughly removed, they will present a barrier to intimate disinfectant and or sterilant contact, resulting in processing failures and the potential for cross contamination and transmission of infectious agents, placing patients at risk.

Figure 1: 579 x 326 magnification biofilm on medical device

Q I am a second-year nursing student and have been working part time in sterile processing. I recently listened to a podcast on sterilization quality control. I believe I heard one of the speakers say that neither a chemical indicator nor biological indicator ensure that the contents of a sterile package are sterile. I, as well as my co-workers, found his comment very confusing and contradictory. How can a "sterile package" not contain sterile items? If that were so, it would not be a sterile package. Further, why do we use these indicators and tests if they cannot ensure the items are sterile?

A The sucess of a sterilization process is dependent on many factors. Foremost, the sterilizer must be functioning properly, and the sterilization cycle must meet the required conditions and sterilization parameters of proper steam, temperature, pressure, and time; together these elements assure the effectiveness of this sterilization process.

There are six different types of chemical indicators – each type monitors or measures one or more specific parameters or critical variables of the sterilization process (see figure 2). A biological indicator (BI) is a challenge test, which consists of vial that contains active spores. The BI is placed within the sterilizer and/or in containers and packages to be sterilized. Post sterilization and incubation, the BIs are evaluated to verify that the spores were adequately exposed to the required sterilization parameters and destroyed.

Chemical and biological indicators tell us that the sterilization parameters were achieved within the sterilization cycle, thus providing confidence that the conditions were adequate to sterilize all contents in the sterilizer, pending the efficacy of the human element performance, e.g. cleaning, following the device manufacturer's IFU, packaging, and loading the sterilizer. If there are failures in staff performance, it could be possible to have an unsterile item next to a passed BI in a sterile container or package. **HPN**

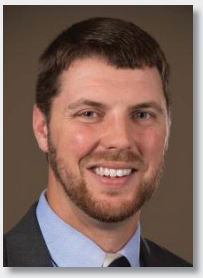
Figure 2

Type 1: Process	One or more critical variables in the sterilization process The unit has been exposed to the sterilization process	Autoclave tape or chemical indicator strips Located inside or attached to the outside of packs
Type 2: Specific-Use	Defined in relevant sterilization standards for specific test procedure	Test air removal in a prevacum steam sterilization cycle
Type 3: Single-Variable	One critical variable in the sterilization process Exposure to a sterilization process at a stated value (SV) of the variable	Demonstrates the steam sterilization process has achieved a specified temperature
Type 4: Multi-Variable	Two or more critical variables in the sterilization process Exposure to a sterilization cycle at stated values (SVs) of the variables	Change color only when exposed to a given temperature for a specified time in a steam sterilization application
Type 5: Integrating (Integrators)	All critical variables in the sterilization process Stated values (SVs) meet or exceed performance requirements in the ISO 11138 series for biological indicators	Respond to all critical process parameters
Type 6: Emulating (Cycle Verification)	All critical variables for specified sterilization cycles Stated values (SVs) are generated from the critical variables of the specified sterilization process	Cycle-specific indicators Respond to all critical process parameters for a specified sterilization cycle

Leading for success

Boosting quality, morale during trying times

by Nicholas Schmitz, PMP, LSSBB



During these uncertain times, when worry and anxiety are high and staff morale can be quite low, it is especially important for healthcare professionals to take care of themselves and their teams. We have all seen the inspiring ways so many healthcare professionals, including those in Sterile Processing (SP), continue to rise above to take care of their customers and patients. But when stressful work environments are coupled with the challenge of being physically distanced from friends, family members and colleagues, it's understandable how it can take a toll on morale.

Uncertainty is uncomfortable for everyone. What should SP leaders do – and how can they keep themselves and their teams focused on their important roles, while also coping with the feelings that change and ambiguity often bring? What follows are some top tips:

Take care of yourself first

A leader can only support the team and model resiliency if he/she acknowledges and manages his/her own stress and anxiety. Taking time to understand one's own feelings and identify and address emotions is essential. It may be necessary to briefly distance oneself from others to make a conscious decision about how one's actions can stay in step with personal values. Consider asking these questions: *Who do I want to be in this situation?* If the leader wants to model collaboration, for example, he or she can ask, *"How can I help employees feel more like they're part of the team?"*

Acknowledge the uncertainty

Our current experience is very real and can't be ignored, denied or repressed without consequence. Although a leader's intention may be to keep the team focused on tasks to distract from the uncertainty, bottling emotions and expecting employees to do the same won't help. Some may feel uncomfortable voicing their feelings or concerns, so it can be helpful to directly address the issue rather than jumping straight to how he/she is feeling. A leader might acknowledge that things seem chaotic and unpredictable at the moment; however, it's important not to dwell on the negative, which could prolong discomfort and low morale for the team. Acknowledge how people are feeling, but then move on to discuss how the team needs to work together to meet critical goals.

Encourage self-compassion

Some people may wonder how others are keeping it together while they're struggling to stay focused and productive. Everyone reacts to stress and change differently; however, self-compassion and open conversations can help normalize emotions and reduce stress. If anyone on the team is feeling stressed, they should be encouraged to admit it. Talking about previous situations in which anxiety was felt (and, ideally, overcome) can also help remind the team that challenges arise, but don't endure.

Ask employees what they need

SP leaders should consider having one-on-one conversations with their employees to allow them to describe what they're feeling. Leaders should aim to better understand what their employees think and feel, even if they don't agree or feel the same about the situation. Empathy forms the basis of trust and allows the team to move into problem-solving mode. Dialog could be something like, *"It seems like a tough time. What would be most helpful for you at the moment? Let's problem-solve together, so we can stay focused on your critical tasks."* Employees may benefit from extra guidance on how to reduce distractions, prioritize their work or stay flexible during uncertain times.

Focus on what can be controlled

Research shows that even small rituals and positive, team-led changes can reduce stress and improve performance. If circumstances allow, a leader might give employees more flexibility in their work schedule, for example (as long as they plan in advance and understand that performance expectations remain the same). Leaders should focus on their individual and organizational values as well. Even when some power and choices are being taken away, a person still gets to choose who they want to be. It's important to help team members clarify what's important, too. Consider asking, *"How do we want to act during these times? How do we want to treat one another?"* Employees might state they want to continue delivering a quality product to customers, while being respectful and kind to one another, for example. Reaffirming goals can help the team stay grounded in a shared sense of purpose.

Reduce secondary traumatic stress

Secondary traumatic stress (STS) is the name for emotional duress that results when an individual hears about the firsthand trauma experiences of another. This can certainly be witnessed in healthcare professionals, who are more closely tied to the pandemic and its impact on patients, families and fellow teammates; however, STS can impact anyone. It is important to learn the physical and mental symptoms (e.g., fatigue, illness, fear, withdrawal and guilt), allow time for the individual and their family to recover, and encourage employees to ask for help if the pandemic is overwhelming them with worry and making it more difficult to care for their family or serve customers and patients.

Encourage and model self-care

Sleep, exercise and good nutrition are proven stress relievers and productivity enhancers. Encouraging all employees to take care of themselves can be as simple as encouraging them to take walks outside during breaks, bringing in healthful snacks for the break room, or teaching the team about mindful breathing. Self-care should also be promoted off the clock. Managers could consider putting tips in writing and sharing them with employees. Tips could include limiting the amount of time spent watching/listening to the news and setting aside more time for family, personal hobbies (reading, gardening, etc.) and outdoor activities performed at a safe distance. HPN

Nicholas Schmitz is President of Schmitz Consulting LLC. He holds two master's degrees in organization development and change management, and project management, and is a certified Project Management Professional and Lean Six Sigma Black Belt.

Empowering the lab's supply chain

Where and to whom should the lab turn for expert help?

by Rick Dana Barlow

Due to financial and operational disruption brought on by the pandemic, the hospital's C-suite executives call for enormous budget slashing across the board in order for the organization to survive and continue providing patient care service to the community.

Supply Chain faces this scenario routinely. But professionals in the Laboratory feel they're taking it on the chin (instead of one for the team) by being ordered to cut $5 million in expenses without sacrificing essential services. Naturally, labor, products and equipment and purchased services remain prime targets.

Empathetic, Supply Chain offers to help the Laboratory meet this mandatory goal.

Is such assistance warranted? Wanted? Appreciated? And finally, accepted and used?

The short answer: It depends. Some laboratory departments prefer to operate on their own, so to speak, under the guise that they know their own unique circumstances, processes and technology, regardless of rudimentary skills in contracting, negotiating and procurement.

Protecting turf as part of the corporate line may only go so far as concerns about the bottom line cross the line on maintaining overall operations.

But there's a way for both Supply Chain and the Lab to toe the line – together.

"Before looking at bankable strategies and concrete measures that can be taken by Supply Chain to assist hospital labs, it's important to understand the foundational aspects of every true partnership—trust and relationship," advised Mark Krhovsky, Vice President of Laboratory Sales, Medline Industries. "As is the case with most clinical disciplines in the hospital, lab is unique and particularly technical. Additionally, if you look at the tenure and experience level of most lab employees, it typically ranks in the top of both categories across the hospital network. With all that being said, I always encourage our Supply Chain partners to spend time in the lab before making any drastic changes or suggestions. Meet and get to know the various staff members—most notably directors, managers, supervisors and pathologists. Get a sense for workflow and technologies as well as goals and pain points.

Mark Krhovsky

"If you do these things, while making an effort to learn and understand their environment, your solutions and suggestions will have a better chance of being heard and ultimately adopted," he closed.

Eric Jurinic, Vice President, Corporate Supply Chain, Accumen, reframes the "trust" issue a bit.

Eric Jurinic

"I don't necessarily think it's a trust issue," he indicated, "[but] more of a second or third set of eyes to ask questions from a different perspective. This also stresses the importance of a cross-functional team who can bring these different perspectives. As humans, we don't know everything, we don't know what we don't know and others can bring a fresh perspective to avoid pitfalls."

Basic instincts

Executives with lab supply chain experience offer at least a dozen ways for Supply Chain to help Laboratory control, manage and reduce expenses or even areas for Lab to concentrate on its own.

Jurinic starts with the fundamentals.

Revisit all contracts and analyze compliance. "Are you exceeding contractual commitments, are you leveraging boilerplate pricing, are your contracts year-to-year or evergreen [renewed automatically unless canceled by either party]? If so there is an opportunity," Jurinic insisted. "This sounds like a basic approach but, believe it or not, we see that contracts are neglected more often than not."

However, if Laboratory negotiated its own contracts and monitored its own compliance how might they know if they even need help in these areas?

"Often times they may not know what to look for, questions to ask, etc.," Jurinic said. "Supply Chain, Finance and third-party organizations can help. Chances are the Lab is being told by the supplier, 'this is the best deal I've ever seen.' If you hear that, proceed with caution."

Look at leases and reagent rentals. "There could be a hidden opportunity for a buyout, lease renewal or other hidden costs," he advised.

Consider low-cost alternatives. "Many times these are only private-label items but ultimately [from] the same manufacturer you are using today."

Rethink "big-box closed systems" that require you to use a supplier's reagents and consumables after buying the supplier's analyzer. "Many hospital labs who are using 'the big-box closed systems' solutions are having supply issues right now because suppliers oversold, thus forcing the lab to send COVID testing out to a reference lab at [higher costs]. Labs can actually turn this into a win to save money by bringing the testing back on site, have redundancy and qualify for the higher reimbursement," Jurinic indicated. "You do this by adding a higher complexity test on an open channel instrument. Why don't they? It's a scary thing that seems to be synonymous with reference labs or academics. It's actually not that hard and it's not scary. We are helping to bring up three labs, and the ROI is fantastic – less than a two-month payback. [Costs for big-box closed systems] vary by supplier and quantity, but we've seen labs spend anywhere from $100,000 to over $1 million on instruments that still have not showed up, can't be used to full capacity or even at all because of [COVID-19-related] shortages."

Jurinic encourages Lab to focus on patient care and leverage Supply Chain without worrying about losing control.

"Make sure Supply Chain is engaged early as they will do the work for you and 'package up' all the details so the Lab can do the comparative analysis based on the objective data comparisons of all the various options Supply Chain puts together," he said. "The process works kind of like this: Engage Supply Chain, identify clinical viable suppliers, go to market. Work smarter, not harder, and leverage your team!"

Standardize products, services

Medline's Krhovsky lists three primary areas.

Consumable standardization. "The hospital lab is notorious for product variation," he noted. "The lack of purchasing oversight has allowed each individual clinician [his or her] own procurement power leading to a more fragmented sourcing approach. There are undoubtedly areas where high brand preference is excusable and even necessary, but many of the general consumable categories offer prime opportunity for standardization. Examples of these categories range from basics like microscope slides to slightly more complex products like pregnancy tests.

"I've consulted facilities in the past that were using 10 different pregnancy tests across their network, and those tests – in instances – varied in price by more than 20 percent," he continued. "These are scenarios where Supply Chain can step in to help address variation and drive standardization savings as they have visibility system wide and the bandwidth to give these projects focus.

Instrumentation and capital contracts. "Instrumentation, and their subsequent reagents, are typically one of the highest spend categories within any hospital lab," Krhovsky said. "This includes, but is not limited to, chemistry, immunoassay, hematology, molecular, centralized urinalysis and blood bank. The majority of these contracts are manufacturer-direct, run five-plus-year terms, and amount to spend that can quickly get into the tens of millions of dollars. Incredibly clinical in nature, there is undoubtedly a technical element to these decisions that is rooted in the needs, dynamics and testing requirements for that particular lab. That being said, there is always room for Supply Chain to be involved with product negotiations and contract review. These are elements where Supply Chain has a particular skillset and level of experience that should always be leveraged. And as one of the largest areas of spend, even small, incremental improvements or adjustments to a pending deal can prove to be financially vital."

Distribution programs. "If you compare lab distribution to the current standard of medical/surgical distribution – where Supply Chain has been an integral partner for decades – the disparity is hard to ignore," he noted. "And yet the lab is as important as any clinical department at the hospital, so why the lack of change to the status quo? I believe lab clinicians and leaders are busier than ever, and also experiencing the pressure of more impactful outside stressors. Their focus has been on turnaround times, staffing, reimbursement changes and other tangible elements that are paramount to their long-term relevance and viability.

"There is a crop of newer organizations, both regional and national, who are rethinking the models and levels of service around lab distribution," Krhovsky continued. "That choice and the involvement of Supply Chain in these decisions will have two critical impacts on the market. One, it will raise the competitive level of all distributors in the market including the historical incumbents. Two, it gives hospitals a realistic option to take business elsewhere if it makes sense to their bottom line."

Deep dive

Iris Jungherr, Vice President, Automation and Diagnostics IT, Siemens Healthineers, homes in on specific lab-centric operations and processes where Supply Chain can be tapped.

"During the pandemic most core laboratories were seeing a decrease in overall test volume and a shift in assay menu mix," Jungherr observed. "Knowing this information and even predicting these trends can have profound impact on the operations of the lab and hence bottom line. For example, by knowing the menu shift and predicting volume fluctuations, suppliers can advise clients on an improved menu structure between instruments that is better balanced, thereby reducing the time spent performing [quality control] and calibration and the costs associated. Suppliers can also advise on creating a new operating/staffing model based on the new volumes."

Jungherr recognizes that the shift in menu and volume will impact ordering frequency and associated commodities.

"Solutions, such as inventory monitoring and management, can be adjusted to address the new testing and volume requirements, thereby reducing the potential of over or under ordering a component," she added.

"Finally, Supply Chain inquiring about the COVID-19 clinical pathway and associated testing schemes can prove instrumental to support laboratory activities that can have enormous impact on length of stay," she continued. "For example, the cascade of testing and reflexing testing in the clinical pathway can be managed with rules written into a middleware

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program, ensuring proper adherence to protocol and quickening the decision-making process. Supply Chain supporting the need for digitalized solutions can have an overall impact to the hospital's bottom line."

Roll up your sleeves

Dedicating departmental resources can make a big difference, too, according to Barbara Strain, MA, SM (ASCP), CVAHP, Principal, Barbara Strain Consulting LLC, and formerly Director of Value Management, University of Virginia Health System. Strain has experience in helping Lab apply value analysis to its decision making.

Barbara Strain

"Assign specific buyer and contracting staff to the clinical laboratory, including but not limited to the Core Laboratory and specialty testing laboratories, [such as] Microbiology, Molecular, Immunology, Toxicology, Pathology, Phlebotomy and Blood Bank," Strain recommended. "This assures that the supply chain values the laboratory operations and wants to have a firsthand understanding of their needs."

Together, they should set up a lab-centric inventory management program.

"If one does not already exist, co-designing an inventory management system to guarantee laboratory reagents, test kits, PPE and other products needed for patient testing are ordered and delivered on time every time is key," she continued. "Supply Chain and the Laboratory might also draw on internal process improvement coaches or use services offered by laboratory supplier contracts to assist in 5S and other LEAN activities to organize workflow and create nearby supply availability locations."

The laboratory should be included in the organization's Value Analysis program, according to Strain, and a value analysis coordinator should be assigned to work directly with the laboratory team.

"Laboratories are cautious about doing this as they typically have established meetings to discuss new testing methods, clinical-based evidence, equipment capacity and requirements, make-or-buy lab testing services as well as laboratory information system (LIS) and electronic health record (EHR) enhancements all in an effort to provide clinicians with accurate, timely results to treat patients effectively," she acknowledged.

Labs that have embraced value analysis, according to Strain, recognize that the process helps to keep initiatives on track by:

- presenting contracting options
- organizing supplier meetings and presentations
- assisting in collecting and providing product evaluation reports
- scheduling end-user reference account calls
- analyzing current versus estimated new costs, ROI and other analytics
- facilitating consensus decision making
- establishing key performance indicators (KPIs) to monitor efforts in meeting their goals. HPN

Visit https://hpnonline.com/21153856 for sidebars: "Managing contracts, expenses not second nature to lab," and "Supply Chain must up its credit score with Lab"

Third in a four-part series

SPECIAL REPORT

How high-quality medical supplies can help improve the health of populations

The term "population health" has grown in recognition since the Institute for Healthcare Improvement (IHI) included it as a key component of its Triple Aim initiative, calling on healthcare organizations to improve the health of populations in an effort to optimize health system performance.

In order to truly impact the health of a specific population (e.g., patients with heart disease, diabetes), the health system or hospital must transition from addressing specific episodes of care (e.g., physician office visits, hospital admissions) and broaden its focus to how it can impact cost and quality throughout the care continuum.

There is increased recognition of the impact of supplies on patient care quality and outcomes. Where in the past a hospital might purchase the cheapest product to cut upfront costs, today they are leveraging value analysis committees (VAC) and other key stakeholders to analyze the long-term impact of supply choices. They have learned that, in some cases, paying a little extra for a higher quality product at the time of purchase can lead to significant savings in the long run as a result of less waste, improved performance and enhanced safety.

One area for savings that is often overlooked is the acquisition and use of high-volume, low-cost medical supplies and accessories. The individual upfront cost of these products, encompassing everything from IV tubing to blood pressure cuffs, may seem minimal, but the collective spend in this category resulting from their frequent use and repeated replacement during the course of care adds up. Furthermore, their close contact with patients has a direct impact on outcomes and satisfaction.

Here are some factors to consider when purchasing medical supplies to support the care of populations at multiple points along the continuum.

Compatibility

Patient transportation and transfers between departments often call for switching monitoring accessories to suit different devices in each of those care settings. This wastes product and money, and adds time and inconvenience for everyone involved. Select disposable and reusable supplies that are compatible with a variety of manufacturers' devices when used with appropriate adapters and trunk cables, such as ECG leads that can remain with the patient from admission to discharge.

Durability

Medical supplies used throughout the patient's journey must be designed for durability, with the ability to withstand usage over hours or days with a low margin or error of failure. Look for manufacturers that use high-quality materials and invest time and resources into product design, as opposed to cutting corners. For example, a blood pressure cuff that will travel with the patient from the operating room to the intensive care unit to the step down unit, must be built to withstand the rigors of transport and consistent use over an extended time period.

Photo credit: Stuart Miles | stock.adobe.com

Comfort

Medical supplies that touch a patient's body or come into close proximity during a patient's entire stay must be not only durable, but also comfortable. When selecting products in this space, avoid hard plastics and opt for pliable materials. Also, look for manufacturers that offer a variety of options to meet individual patient needs, such as anatomical sizing.

For more information on how high-quality medical supplies and accessories can help your organization simultaneously address all three goals of the Triple Aim, read this Frost & Sullivan white paper: When Can a "Commodity" Advance Clinical Care? Achieving Triple Aim Goals With the Help of High-Quality, Innovative Medical Supplies. HPN

1. The IHI Triple Aim, http://www.ihi.org/engage/initiatives/TripleAim/Pages/default.aspx
2. The IHI Triple Aim, http://www.ihi.org/engage/initiatives/TripleAim/Pages/default.aspx

Last in our series will be about high-quality medical supplies.

4 ways high-quality medical supplies can help reduce the cost of care

The shift from volume to value-based care, with declining reimbursements and penalties for hospital-acquired conditions (HAC) and readmissions, have forced health systems and hospitals to find ways to improve quality of care while reducing costs. Reducing the per capita cost of health care is a pillar in the Institute for Healthcare Improvement's (IHI's) Triple Aim initiative....

More in November

Lessons in disaster and demand planning

by Karen Conway, Vice President, Healthcare Value, GHX

In last month's issue of *Standard Practices,* we explored the growing interest (if not imperative) for demand planning in the healthcare supply chain. Given the importance of standards in this pursuit, we will periodically explore this topic through interviews with key industry leaders. This month, I had the opportunity to speak with Donna Van Vlerah, Senior Vice President of the Support Division for Parkview Health in Indiana about her organization's work in this area, especially around disaster planning.

A retired United States Marine Corps logistician, Van Vlerah takes a very deliberate approach, incorporating key process improvement methodologies such as DMAIC, which stands for **D**efine, **M**easure, **A**nalyze, **I**mprove and **C**ontrol. In the context of emergency or disaster planning, defining the problem included an assessment of potential vulnerabilities faced by the healthcare system and its respective facilities. Such vulnerabilities – both imminent (e.g. a snowstorm or tornado) and visible (e.g., a pandemic) – are prioritized based on their probability and severity (measured by the magnitude minus the ability to mitigate).

Imminent threats are considered much more probable, but their magnitude is usually limited to a specific geographic area and with a shorter duration compared to a pandemic, which can last a couple of years. Most regulatory requirements are geared to the former. For example, The Joint Commission requires hospitals to keep a 96-hour supply of products required to combat their highest threats. Clearly 96 hours is not enough of a safety stock to combat pandemics, which usually last a couple of years. But even if a health system were to build out a year's supply, it would not have been enough based on prior utilization levels.

Van Vlerah explains: "Our N95 usage was much lower prior to COVID-19, with the respirators used mostly in patient isolation rooms. With the surge, the need was much higher. Demand planning played a significant role in Parkview Health's preparedness and response to the COVID-19 situation."

Solving for a problem of this magnitude, Van Vlerah requires foundational capabilities that can also be applied to crises of less scale and even to demand planning in general. Below are some of Van Vlerah's recommendations for those who wish to shore up their capacity to respond to emergencies.

Create supply lists by disaster type

While both Ebola and COVID-19 require personal protective equipment (PPE), the types of PPE required differed based on the way the disease is spread. In the same way, there are differences in the supplies needed to support a response to a tornado compared to a pandemic. The good news is, numerous organizations, from the World Health Organization to the Occupational Safety and Health Administration, create such essential lists that health systems can use as a starting point. Van Vlerah recommends bringing the relevant experts to the table to customize the lists for your organization. For example, to address COVID-19, Parkview enlisted the help of respiratory disease and infection control specialists.

Standardize on commodities/ identify substitutes in advance

While standardization is always a good idea in order to reduce both variation and costs, it is even more critical for emergency preparedness. By standardizing on products and identifying acceptable substitutes in advance, hospitals can help avoid some of the concerns expressed by clinicians when forced to use alternative products in the wake of shortages. Ideally those substitutions, if not by brand, then by relevant attributes, can make it easier to source and less stressful for clinicians. Health systems should also develop reference lists with alternative vendors or supplies identified if traditional channels dry up.

Establish emergency access and usage protocols

Preplanning around protocols for how products are accessed and used can also help minimize waste during times of critical shortage. As Van Vlerah explains it, if N95 respirators were used during the pandemic like they are in normal times, e.g., donned and doffed and tossed each time a clinician enters a patient room, the health system would have run out very quickly.

Critical supplies also need to be stored centrally versus potentially hoarded at every facility, with pre-determined quantities that can be accessed in an emergency. Additional quantities can be requested to meet extraordinary circumstances, but require additional authorization steps.

Van Vlerah warns that centralizing stock can drive down inventory turns. She recommends prioritizing products with longer or no expiration dates.

Plan centrally/implement locally

Parkview Health does its demand planning and emergency preparedness at a system level, but it makes both the plans and visibility to critical inventory levels accessible by each facility at the local level. That way, individual hospitals can respond directly to Joint Commission requests for information on their compliance with emergency preparedness requirements. Individual facilities should also have a say in the development of the disaster response plans.

Hardwire emergency stocking practices and par levels

Once the critical supplies are identified based on the type of threat, Van Vlerah advises establishing appropriate stocking practices, including location (e.g., centrally or locally managed) and PAR levels based on actual usage or anticipated surge demand. At Parkview Health, these emergency protocols are hardwired into the system, enabling the emergency protocols to be activated in a matter of hours.

Plan based on the unique characteristics of supplies

Regardless of whether you are demand planning for a disaster or for the normal course of business, Van Vlerah emphasizes the need to understand the unique characteristics of different supplies.

- What are your anticipated usage levels (normal and surge)?
- How critical are the products and for what use(s)?
- How difficult are they to acquire?

- Are there suitable alternatives (vendors or products)?
- What are the vendor's lead times, fill rates?

Van Vlerah believes Parkview Health's investment in a central distribution center (DC) has been a foundational capability to support many of the practices outlined above. But a DC is not feasible for all organizations. In such cases, hospitals and healthcare systems can partner with peers or distributors to share in the acquisition, management and allocation of critical resources in the event of an emergency. But just like so many other things, those partnerships and that planning need to occur now, long before the next disaster rolls into town. HPN

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Running out of price and standardization savings?

7 new workable rules can create double-digit results

by Robert T. Yokl

Based on our discussions with hospitals, systems and integrated delivery network (IDN) supply chain executives, it appears that price savings are now harder to find, contain, negotiate or even identify now that their vendors have little more to give in concessions and most of your healthcare organization's supply standardization efforts are substantially completed.

What does this mean to you? If you are betting your career on easily finding lower prices for the commodities you buy and more standardization savings as you did in prior years, you are going to be in for a rude awakening. It isn't going to happen based on our in-depth research that documents that most hospitals, systems and IDNs are only saving 0.5 percent to 1 percent on their price savings (annual savings/total supply chain expense budget) versus 7 percent to 15 percent on their supply utilization. That's why you need to look beyond price and standardization so you can make a quantum leap forward with supply utilization savings that are never-ending and right in front of your eyes just waiting to be harvested.

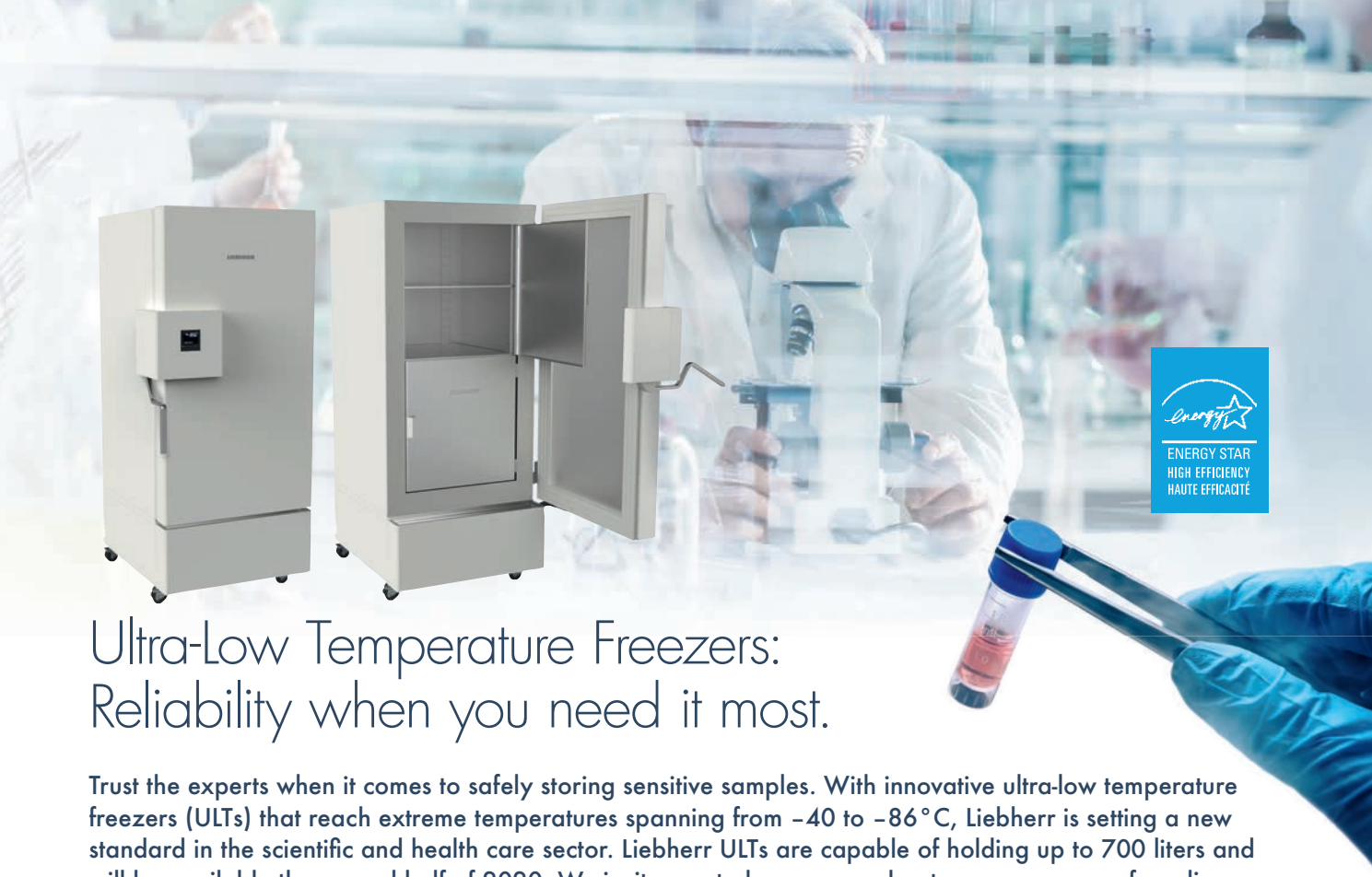
7 new workable rules

Based on our empirical experience over the last 15 years, for supply chain professionals to tap into this new and better savings source (supply utilization) they will need to follow 7 new workable rules to create this quantum leap forward and the double-digit supply utilization savings I just talked about. Here are those 7 new rules you need to follow to obtain the desired results:

1. *Change your mindset* from price thinking to supply utilization thinking to increase your savings yield by 200 percent, 300 percent or even 600 percent almost overnight. Believe it or not, price savings only represent about one-tenth of the total lifecycle cost of a product, service or technology. Correspondingly, your product, service or technology utilization costs over their life span represent nine-tenths of their total cost. So I ask you this question: With these facts in mind, where should you be spending your time and resources to reduce your supply expenses?
2. *Make it a team effort* to uncover these supply utilization savings because you need the buy-in and ownership of your department heads and managers to make change happen. We have found that value analysis teams are the perfect vehicle to attack these supply utilization costs because they generally include the customers, stakeholders and experts of the product, service or technology under investigation, making it a collaborative effort to save money.
3. *Follow the money* and where it is misspent on your commodities by employing analytics to identify where your supply utilization savings reside. Generally, you can't see your utilization misalignments (e.g., wasteful and inefficient consumption, misuse, misapplication and value mismatches) in your supply stream with the naked eye. Therefore, you will need to rent, buy or develop your own clinical utilization management system to do so.
4. *Measure, then observe* where your supply utilization savings opportunities reside. One of the biggest errors that value analysis teams can make regarding your utilization misalignments after they have been uncovered by measurement, is not to shadow the customers of the product, service or technology to understand how it is employed. We have found that this one step alone can answer 90 percent of questions about why any product, service or technology is being over-consumed.
5. *Discover why you are different* from your peers when you identify an unfavorable variance through benchmarking. For instance, why are you using twice as many Oxisensors this year over last year when your census has remained stable? What are your peers doing different from you to conserve their Oxisensors? Maybe, your nurses think your Oxisensors are disposable?
6. *Build in controls* to hold your gains by employing a utilization dashboard to continuously measure and manage your supply utilization. Once you have eliminated one or more of your utilization misalignments, you want to ensure that your misalignments are still under control because things – and people – change. Therefore, you must continuously monitor that your wasteful practices don't return. Our clients have found that a utilization dashboard showing where you stand monthly, quarterly and yearly with your past, current and future utilization misalignments, represents the easiest and best way to monitor your progress.
7. *This remains a never-ending journey* as circumstances change. Consequently, there always are supply utilization savings opportunities to be addressed. For example, one of our clients saved $100,000 annually when we flagged that their contrast media usage was twice that of other hospitals their size and characteristics. Once this utilization misalignment was corrected (a higher contrast media dose was being used than was medically indicated) this same hospital's contrast media consumption rates repeatedly spiked over the years because the hospital staff reverted to their old bad habits. That's why this vigilance of your utilization misalignments is never over!

As these guidelines suggest, supply utilization management is a new discipline with new rules that need to be followed for optimal performance. To shortcut any of these rules will limit your utilization management savings success. HPN

Robert T. Yokl is President and CEO at SVAH Solutions. Yokl has four decades of experience as a healthcare supply chain manager and consultant, and also is the co-author of Supply Utilization Management: The Future of Supply Chain Expense Management 2nd Edition and co-creator of Clinical Utilization Management software powered by Utilizer Dashboard that moves beyond price for even deeper and broader clinical utilization savings. Yokl is a member of Bellwether League's Bellwether Class of 2018. For more information or to receive Yokl's latest free supply utilization management book, visit www.svahsolutions.com. Email Yokl at bobpres@strategicva.com.



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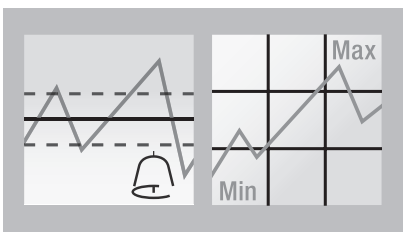

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