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HEALTHCARE PURCHASING NEWS

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Green Cash Flow Offer

Q: How does the $100 upgrade credit work?

A: For every new TAT-5000 thermometer purchased, Exergen will credit the hospital $100 each for every hospital grade ear or electronic thermometer taken out of service and sent to Exergen.

Q: Can I purchase through a distributor and still qualify for the $100 upgrade credit?

A: **Yes.** If the TAT-5000's are purchased through an authorized Exergen distributor, proof of purchase needs to be sent to Exergen to qualify for the $100 upgrade credit (or direct payment) to the hospital.

Q: What thermometers will be accepted for the $100 trade in credit?

A: Any hospital grade ear or oral/rectal electronic thermometer that is in currently in use at the hospital.

Q: What does a 1 year payback mean?

A: Since ear and electronic thermometers have operating costs of $300 or more per year per thermometer, and a TAT-5000 with the $100 upgrade credit will cost much less than $300 to purchase, payback on the Exergen purchase will be well under 1 year.

Q: What does the 100% reduction in waste mean?

A: Studies show that each staffed bed produces more than 30 pounds of waste per day. Included in that total are thermometer probe covers, broken probes/cables, and discarded thermometers.

Exergen requires zero disposables. If the TAT-5000's are returned for replacements, the returned units are recycled into refurbished units. The refurbished units are also covered by the Lifetime Warranty. The hospital has zero costs and zero waste after purchasing the Exergen TAT-5000.

Q: What does 100% reduction in operating costs mean?

A: Ear and electronic thermometers have annual operating costs to use, including probe covers necessary for each use, probe replacements from breakage, repair charges from limited warranties, user abuse, and significant biomed costs for in house service. This can run about $300 per year or more per thermometer in use.

Exergen TAT-5000 thermometers have zero operating costs. Disposables are optional and can be reused on the same patient. Under the Lifetime Warranty, Exergen will repair or replace at no charge.

Q: How often are the optional disposable probe caps used?

A: On average, the optional disposable covers are used on about 5% of temperatures taken. This is a negligible cost and waste compared to ear and electronic thermometers.

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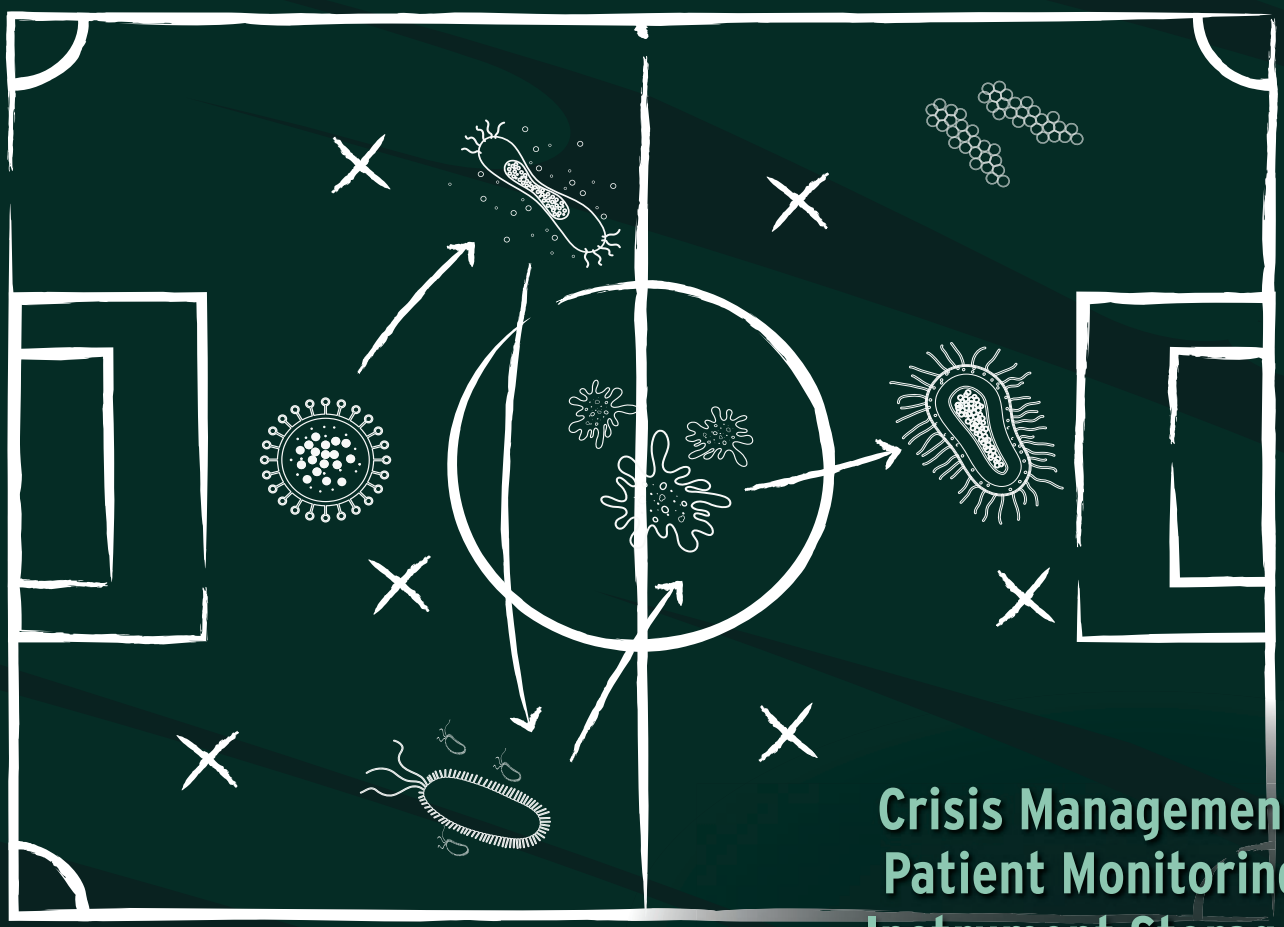

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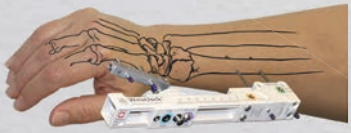

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BUYLINE

O sole meta

Rick Dana Barlow
Senior Editor

Think of the headline as a metapolitan version of a famous Neapolitan song.

What about meta? For the healthcare industry, meta symbolizes technologies available but not quite in universal practice. The metaverse represents a computer-generated make-believe "reality," either a conjuring of creative fictional worlds or an existing environment, footprint or landscape on which you can add, manipulate or remove components and elements.

Healthcare as an industry remains chock full of technology on the clinical and pharmaceutical sides where doctors and nurses take as much advantage of digital and electronic tools as possible. Yet on the operational side, of which supply chain is a large part, the players are more analog, if not quasi-digital, unlike many of their colleagues and counterparts in food service, manufacturing and retail, for example. At least they're not Luddite.

While technologies can't always avert crises or solve problems they can aid and assist in performance improvement and productivity, bringing efficiency to effectiveness, if not guaranteeing effectiveness.

Granted, some of the technology options employed by healthcare has been around or even known for decades – from tracking and tracing modalities (e.g., bar coding, RFID, etc.) to mobile devices (e.g., smart phones, data readers, etc.) to automated supply cabinets/dispensaries (e.g., closed or open shelf options) and even wayfinding devices (e.g., digital flatscreens/interactive touchscreen or voice-activated signage and kiosks, etc.) are surging in interest in popularity. Thanks to the global pandemic and worldwide supply chain disruptor, most everyone knows about demand management/predictive analytics software, cloud computing, artificial intelligence (AI), Internet of Things (IoT) and machine learning (the latter three continuing to simmer as buzzwords), which leads to concerns about cybersecurity.

Beyond that, widely adopted and implemented options seem spotty. Outside of healthcare, Supply Chain embraces them; inside of healthcare only a small number recognize their value and see their functional applicability. What are they and why do they matter?

- Augmented reality (AR) (e.g., for directions, instructions, locating, mapping, teaching, training, etc.). Imagine wearing a pair of computer-chipped eyeglasses connected to the cloud that can direct you on where to find a certain product in the warehouse.
- Automated guided vehicles (AGVs) (including "mother-daughter" and remote-control tugs). Do you need to transport a passel of boxes and cartons of varying products to the nursing floors from the storeroom? A motorized sidekick can help or can handle it independently via ceiling- and/or doorway-mounted wi-fi sensors.
- Robotics (including "co"botic arms, exoskeletons, etc.). Arms can be helpful in SPD to maneuver and/or transport soiled instruments or conversely sterilized instruments during reprocessing. Staffers in the warehouse can don an exoskeleton jacket to help them pickup large, heavy boxes without a forklift or can ease physical and mental stress from repetitive motions.
- Virtual reality (VR) (e.g., for demonstrations, designing, inservice training and education, etc.). This can help educate and train supply chain staffers through crisis/disaster drills and can be used to design and redesign storage space throughout a facility.
- 3-D printing. This can be used to fabricate buildings, cars and the like, but legal concerns about patent protection and privacy prevent its use in the fabrication of medical/surgical devices and implants. Still, 3-D printing can be used to fabricate components for "lower class" products and basic commodities for the storeroom and /or warehouse that likely shouldn't trigger an organization's risk radar and potential litigation.
- Drones. These "toylike" tools can be used for convenient pan-campus deliveries to multiple buildings or even to patient homes within relative proximity of the healthcare organization.
- Self-driving vehicles (e.g., cars, trucks, vans, shuttles). They simply can shuttle patients and visitors to multiple buildings on sprawling campuses for appointments and meetings.

Are we there yet? No. Is it possible? Yes. But like "O sole mio" or even "O sole meta," it's now or never.

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FAST STATS

If there were any doubts about the vital and growing role of telehealth in our lives, living through the pandemic certainly erased them all. Just like everything else in 2022, healthcare has gone virtual. Here are some interesting statistics concerning telehealth and remote patient monitoring:

52% of consumers indicated they would use a connected health device if it was recommended by a physician when asked in 2019, well before the pandemic.

In 2020, **23.4 MILLION** U.S. patients utilized remote patient monitoring services; by 2024, that number is projected to reach 30 million.

In the last 12 months **88%** of patients surveyed stated that they had healthcare performed remotely.

80% of Americans, according to a June 2021 MSI International survey, are in favor of using remote patient monitoring, and nearly one-half are very favorable towards incorporating it into medical care.

Patient satisfaction scores over **90%** were achieved when University of Pittsburgh Medical Center equipped patients with remote patient monitoring equipment and tablets.

About **25%** of consumers stated they would switch to a new physician to access telehealth.

https://blog.prevounce.com/27-remote-patient-monitoring-statistics-every-practice-should-know

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NEWSWIRE

FDA Safety Alert: Reports concerning breast implants

The U.S. Food and Drug Administration issued a safety communication informing patients and providers about reports of squamous cell carcinoma (SCC) and various lymphomas located in the capsule or scar tissue around breast implants.

After an initial extensive review, we currently believe that the risk of SCC and other lymphomas occurring in the tissue around breast implants is rare. However, in this case, and when safety risks with medical devices are identified, we wanted to provide clear and understandable information to the public as quickly as possible.

In some reported cases, patients were diagnosed years after having breast implants and presented with findings such as swelling, pain, lumps or skin changes. These emerging reports of lymphoma in scar tissue are different from Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), which the FDA began communicating about as a potential risk more than a decade ago.

Read on: https://hpnonline.com/21280185

AHRMM elects new members to its Advisory Board

The Association for Health Care Resource & Materials Management (AHRMM) is a dedicated leader of health care supply chain professionals. Each year, AHRMM holds member elections for open positions on the AHRMM Advisory Board.

This year, AHRMM Members voted for two (2) healthcare provider and one (1) affiliate seat(s) for terms beginning January 1, 2023.

AHRMM is pleased to announce the results of the 2022 AHRMM Board election. Thank you to all members who voted and thank you to the candidates who participated in the election for their leadership and dedication to AHRMM. All newly elected advisory board members will serve three-year terms, which start on January 1, 2023.

Read on: https://hpnonline.com/21279931

FDA approves updated, bivalent boosters

The U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following primary or booster vaccination.

The bivalent vaccines, which we will also refer to as "updated boosters," contain two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2.

The Moderna COVID-19 Vaccine, Bivalent, is authorized for use as a single booster dose in individuals 18 years of age and older. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent, is authorized for use as a single booster dose in individuals 12 years of age and older.

The monovalent COVID-19 vaccines that are authorized or approved by the FDA and have been administered to millions of people in the United States since December 2020 contain a component from the original strain of SARS-CoV-2.

Read on: https://hpnonline.com/21279487

Walmart and UnitedHealth joining forces

Walmart Inc. and UnitedHealth Group announced the beginning of an initial 10-year, wide-ranging collaboration, bringing together the collective expertise of both companies in serving millions of people with high-quality, affordable health services that improve health outcomes and the patient experience.

The collaboration will start in 2023 with 15 Walmart Health locations in Florida and Georgia and expand into new geographies over time, ultimately serving hundreds of thousands of seniors and Medicare beneficiaries in value-based arrangements through multiple Medicare Advantage plans.

Optum, a UnitedHealth Group business, will help enable Walmart Health clinicians through analytics and decision support tools to deliver comprehensive value-based care that can help drive positive health outcomes for seniors and Medicare beneficiaries. These capabilities will enhance the care already provided at Walmart Health centers, which deliver quality, accessible care through a collaborative, team-based delivery model, and will help accelerate the transition to value-based care by enabling clinicians to focus on patient outcomes.

Read on: https://hpnonline.com/21280070

CVS and Signify enter into agreement

CVS Health and Signify Health ("Signify") have entered into a definitive agreement under which CVS Health will acquire Signify Health for $30.50 per share in cash, representing a total transaction value of approximately $8 billion.

Signify Health is a leader in Health Risk Assessments, value-based care and provider enablement. With a network of more than 10,000 clinicians across all 50 states and a nationwide value-based provider network, combined with its proprietary analytics

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and technology platforms, Signify Health is improving patient engagement, patient outcomes and care coordination for stakeholders across the healthcare system. Signify Health's clinicians and providers can have an even greater impact by engaging with CVS Health's unique collection of assets and connecting patients to care how and when they need it.

"Signify Health will play a critical role in advancing our healthcare services strategy and gives us a platform to accelerate our growth in value-based care," said CVS Health President and CEO, Karen S. Lynch. "This acquisition will enhance our connection to consumers in the home and enables providers to better address patient needs as we execute our vision to redefine the healthcare experience. In addition, this combination will strengthen our ability to expand and develop new product offerings in a multi-payor approach."

Read on: https://hpnonline.com/21279785

Study confirms the lethal potential of fentanyl

In research conducted by investigators at Massachusetts General Hospital (MGH) and published in PNAS Nexus, tests of the brain's electrical activity revealed fentanyl's effects over time and indicated that the drug stops people's breathing before other noticeable changes and before they lose consciousness.

Electroencephalogram (EEG) tests revealed fentanyl's effects on the brain and indicated that the drug stops people's breathing before other noticeable changes and before they lose consciousness. This explains why fentanyl has been so deadly during the opioid epidemic.

Fentanyl produces a specific EEG signature, which could allow clinicians to monitor its effects to enable safer, more personalized administration during and after surgery

Fentanyl is used to supplement sedation and to relieve severe pain during and after surgery, but it's also one of the deadliest drugs of the opioid epidemic.

In the study, electroencephalogram (EEG) tests were run for 25 patients undergoing general anesthesia for surgeries lasting two hours or more. The researchers discovered that certain EEG patterns were associated with respiration, sedation and loss of consciousness.

Read on: https://hpnonline.com/21279800

New rule on noncitizens health coverage

The U.S. Department of Homeland Security (DHS) issued a final rule applicable to noncitizens who receive or wish to apply for benefits provided by the U.S. Department of Health and Human Services (HHS) and States that support low-income families and adults.

The rule, which details how DHS will interpret the "public charge" ground of inadmissibility, will help ensure that noncitizens can access health-related benefits and other supplemental government services to which they are entitled by law, without triggering harmful immigration consequences. By codifying in regulation the "totality of the circumstances" approach that is authorized by statute and which has long been utilized by DHS, the rule makes it clear that individual factors, such as a person's disability or use of benefits alone will not lead to a public charge determination.

The final rule applies to noncitizens requesting admission to the U.S. or applying for lawful permanent residence (a "green card") from within the U.S. When assessing whether a noncitizen is "likely to become primarily dependent on the government for subsistence," DHS will not penalize individuals who choose to access the vast majority of health-related benefits and other supplemental government services available to them, including most Medicaid benefits (except for long-term institutionalization – such as residing in nursing home – at government expense) and the Children's Health Insurance Program (CHIP). DHS will also not consider non-cash benefits provided by other government agencies including food and nutrition assistance such as the Supplemental Nutrition Assistance Program (SNAP); disaster assistance received under the Stafford Act; pandemic assistance; benefits received via a tax credit or deduction; and government pensions or other earned benefits. Receipt of cash-based benefits, such as Supplemental Security Income (SSI), Temporary Assistance for Needy Families (TANF), and other similar programs, will not automatically exclude an individual from admission or green card eligibility, and will instead be considered in a "totality of the circumstances" analysis.

Read on: https://hpnonline.com/21280195

Domestic manufacturing vital to a healthy healthcare supply chain

According to a release from Vizient, for two years, half a million dollars in disposable isolation gowns sat unused in Encompass Group's Georgia-based warehouse.

Demand for the gowns had diminished to the point that the company had stopped producing them — since most providers were ordering them from offshore private label manufacturers, Encompass Group instead shifted its attention to higher-demand categories.

But one month into the COVID-19 pandemic, those boxes of gowns were gone, snatched up in a single order. For health systems, acquiring personal protective equipment had become not just a matter of quantity, but speed — they needed a lot of PPE, and they needed it fast.

The overwhelming demand for PPE may have stabilized for now, but Vizient's efforts to head off shortages of essential supplies have only surged. In fact, an early-pandemic agreement between Vizient and Encompass Group to relaunch production of disposable isolation gowns in Encompass Group's Mexico-based facilities led to a collaboration that hit even closer to home: If Vizient members committed to 5 million gowns annually, Encompass Group would open a U.S.-based manufacturing facility near its Georgia headquarters. That new facility is set to open at the end of this year, with the ability to scale manufacturing as needed (members committed to the program essentially own the line and receive substantial discounts on the gowns).

Read on: https://hpnonline.com/21279509

Glaring, global increase in early onset cancers

A study conducted by researchers from Brigham and Women's Hospital, a founding member of Mass General Brigham, reveals that the incidence of early onset cancers (those diagnosed before age 50), including cancers of the breast, colon, esophagus, kidney, liver, and pancreas among others, has dramatically increased around the world, with this drastic rise beginning around 1990.

In an effort to understand why many more younger individuals are being diagnosed with cancer, scientists conducted extensive analyses of available data in the literature and online, including information on early life exposures that might have contributed to this trend. Results are published in Nature Reviews Clinical Oncology.

"From our data, we observed something called the birth cohort effect. This effect shows that each successive group of people born at a later time (e.g., decade-later) have a higher risk of developing cancer later in life, likely due to risk factors they were exposed to at a young age," explained Shuji Ogino, MD, PhD, a professor and physician-scientist in the Department of Pathology at the Brigham. "We found that this risk is increasing with each generation. For instance, people born in 1960 experienced higher cancer risk before they turn 50 than people born in 1950 and we predict that this risk level will continue to climb in successive generations." HPN

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Managing supply chain crises calls for elementary equation

Which comes first: People, process or technology?

by Rick Dana Barlow

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Since early 2020, the healthcare supply chain seemed to recoil from the just-in-time (JIT), modified stockless and stockless distribution methods that defined advanced, forward-thinking operations until they were tested by global supply chain challenges ignited by the COVID-19 pandemic.

From there, providers and suppliers alike shifted into pandemic (some say "panic") mode, scrambling to source and deliver product amid mounting backorders, delays and shortages, overordering and overstocking to protect themselves.

By mid-2022, sensing – if not hoping for – an end to the pandemic and accepting COVID-19 as more endemic as influenza, the industry yearned to pivot to some kind of recovery mode, translating lessons learned to reshape how to handle future crises.

Arguably, the building blocks of any supply chain, regardless of industry, centers on three elements of an equation: People, processes and technology.

Back in August at the annual conference of the Association for Healthcare Resource and Materials Management (AHRMM) in Anaheim, there were plenty of educational sessions heavy conversations promoting people as key value providers in new roles, promoting technology as options to explore and promoting process improvements that involve both people and tech.

To optimally prepare to handle future crises for minimal impact on supply chain operations the question remains as to how to order the equation for the desired results. Do you:

- Invest in people to plan process improvements and use tech to ensure progress (People, Process, Tech)
- Invest in process (including improvement planning), assembling the tech for people to use (Process, Tech, People)
- Invest in tech and then train people to use it so that they improve processes (Tech, People, Process)

Supply chain experts among providers, suppliers and technology companies offer mixed and varying perspectives on how to order the equation. Among the noteworthy observations: Not every tech company executive encouraged starting the equation with tech and not every supplier encouraged starting with process.

People process

Pundits may point to ongoing labor challenges, regardless of industry segment or type, but in healthcare experts emphasize that people should be priority one to prepare for whatever looms ahead.

While Jeff Jochims, Executive Vice President, COO and President, Products Healthcare Service, Owens & Minor, thinks at first glance the overarching perspective may be obvious, the fundamental indicator becomes resoundingly clear.

"It is of course correct to say that all three matter, but in our view at Owens & Minor, people remain at the heart of strong operations," Jochims insisted. "The past several years have demonstrated over and over again that supply chain management is incredibly dynamic. While technology and processes are vital, people are the part of the equation that cannot be overlooked or undervalued. Empowering teammates with a framework for making decisions with technology tools allows for the optimal balance between tech and touch, whether we're operating under normal business conditions or responding to something unexpected. After all, it is people that perform scenario planning, that exercise subjective judgment, that balance availability with options, that identify potential failure points, that identify countermeasures and so much more.

Jeff Jochims

"At a most basic level, we can remove technology and processes, and still run supply chains," Jochims continued. "We cannot remove people. I think that the pandemic demonstrated this beyond our wildest expectations."

For Cory Turner, CMRP, Senior Director, Healthcare Strategy, Tecsys, with a background in provider-based supply chain at an award-winning healthcare system, a particular order makes the most sense.

Cory Turner

"People, Process, Tech is, in my opinion, the optimal approach to managing crises

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in the supply chain as healthcare logistics teams move forward post-pandemic," Turner noted. "We work with health systems across the nation to design and implement the technology backbone for more resilient supply chain practices, but I believe that our technology should underpin effective people and processes, not the other way around. The last thing you want to do is throw good money after bad, and investing in technology that speeds up or automates inefficient ways of doing business is exactly that.

"It reminds me of a conversation we had recently with Dr. Randy Bradley, in which he said, 'the healthcare supply chain is not broken, it is performing as it was designed, we are just trying to use it in a way it wasn't designed to be used and I think that has caused both supply chain leaders and other healthcare administrators to really rethink and try to reimagine what should our supply chain operations look like,'" he recalled.

People can represent a positive and a negative, according to Turner.

"Something to be cognizant of is that people – whether in attitude or aptitude – may unwittingly become a roadblock to navigating supply chain crises. On the flip side, it's also people that make effective processes work. Investing in people is such an important priority," he continued. "Ultimately, it's a three-legged table. Each component is critical and relies on the other two. While there is an effective order of operations, it should not be conflated with an order of importance. Only when a supply chain organization builds its strategy around all three elements will they be best equipped to hug the curves of disruption."

Angie Haggard, CEO, RDA, emphasizes the inherent connections between people, processes and technology.


Angie Haggard

"People are and will always be needed," she indicated. "Even though fewer people are required with technology, people are still needed to operate and/or manage the technology. In addition, when you invest in people with training and career growth plans, the probability of employment retention increases. Retention is further increased when employees connect to the cause that supply chain impacts patient's lives, and their actions can make a difference in that patient's life – positively or negatively."

But those connections must be precise and concentrated on accuracy, Haggard maintains.

"Technology is wonderful and helps to automate manual processes; however, if technology is automating bad processes, the technology has just automated and magnified the problems … faster," she noted. "Process improvements need to be streamlined and standardized prior to a major technology implementation, especially if it's a technology automation of cross-functional processes. Granted, some technologies limit flexibility and extensive custom design, which is a good thing as you don't want your organization's implementation to be so customized that technical support cannot be provided.

Haggard supports an order of events, too, beyond people.

"When organizations do not optimize or evaluate processes first, the end result is higher costs with little improvements," she said. "Utopia is to optimize processes first and then automate those processes, while fostering a culture of continuous improvement. In our current state of traveling and remote clinicians, high turnover rates and doing more with less, the more processes are standardized within a department, within a facility and across facilities, the better patient outcomes will be. Once people are in place and processes are optimized, it's time for technology to be utilized to automate and monitor progress and performance."

Tom Redding, Senior Managing Director, Healthcare, St. Onge, stresses that people form the foundation from which process and technology build an operation.


Tom Redding

"The first step is understanding if the organization has the right people with the right skills in the right job to adapt and drive the supply chain forward," Redding said. "Investing in people is a critical factor to handle the ever-changing requirements for healthcare supply chain leaders.

"Secondarily, supply chain leaders need to have a clear understanding of their primary processes and all of their supporting processes that may impact their ability to function effectively and efficiently," he continued. "Too often, upstream process changes are made in a vacuum by other stakeholders and unfortunately impact the downstream process(es) of others. Once a supply chain leader is confident in their team and processes, then they should explore options for technology and systems. We have all seen health systems purchase new technology and systems, and fast forward a couple years, are worse off than when they started. Don't be a statistic."

Investing in people to plan process improvements and use technology to ensure progress is the most optimal strategy for crisis management in supply chain, according to Bonnie Lai, General Manager, GHX Lumere.


Bonnie Lai

"As a leader at a company that builds technology solutions for health systems, I very much recognize technology's power and limitations," she said. "Technology is great for automating well-defined and repeatable processes. However, we're not yet at the point where technology can replace the critical thinking and problem solving you get from your best team members. For example, the COVID-19 pandemic was such a new and unpredictable problem that expecting technology to have solved all the related supply chain issues would have been foolish and misguided. Technology is also good at enabling efficient and repeatable processes that allow supply chains, clinicians and other key stakeholders to spend more of their time collaborating and problem solving to address patient needs.

"Despite advancements in artificial intelligence (AI) and machine learning (ML) in healthcare, I still believe these technologies are best deployed on more operational challenges than in clinical decision making at present," Lai added.

Keith Lohkamp, Senior Director, Industry Strategy, Workday, acknowledges that all three models can be successful, particularly depending on the starting point of an organization, but one rises to the surface first.


Keith Lohkamp

"People are the optimal place to start," he insisted. "Identifying the key skills and capabilities needed – analytical, adaptiveness, creative thinking, and ability to execute – and putting in place the right people is a critical first step. With the right team, even if processes put in place do not work, the supply chain organization can pivot and adjust more easily. So, with people and processes in place, the right technology can be implemented. But like with investing in people, it is critical to select technology that can adapt with the unique consideration of each crisis or change in the industry."

An organization's people experts are the foundation of a strong crisis management strategy, recommends Kyle MacKinnon, Senior Director, Operational Excellence, Premier.


Kyle MacKinnon

"They are the ones who think, continuously learn and innovate – identifying and framing the challenges, root causes, as well as the design of optimal solutions," he said. "These

experts should work alongside stakeholders to define the ideal business process (desired state), at which point the appropriate technology solution should be decided upon and used to effectively enable and streamline that process. Once the model is deployed, it continuously improves through innovation in all 3 areas (people, process, technology) based on needs of the organization and customer. Over time, the efficiencies gained with technology can free up workforce capacity, allowing your organization to deploy people in other value-added areas.

Process for people

Even though some contend that with people in place the process can be improved, others highlight on process improvement with optimal technology to fortify people.

"The best strategy would be to start investing in process improvement planning, assembling the tech for people to use," said Marlin Doner, Vice President, Data Analytics and Product Strategy, Prodigo Solutions. "Strategic responses should start by asking why, then investigate the how? As we look back at lessons learned, we can see that surge demand was driving product shortages in the early chaos of the pandemic. Now, as we have moved into recovery phase, labor disruption is still impacting availability in the supply chain. As supply chain practitioners, these are things we do not control; however, as leaders we can control our ability to respond and align supply with demand based on real-time data we are collecting.

Marlin Doner

"Better transparency into what is happening across our supply channels will help us manage our response," Doner continued. "Process re-engineering from the point of demand to the source of supply will help an organization identify and eliminate weaknesses in their business processes. Tracking vendor performance data, such as fill rates, backorders and substitutions as well as operational metrics such as inventory turns and days of supply coverage, should let us benchmark and forecast demand based on variables such as patient caseloads and community infection rates."

Brandon Reeder

Even though Brandon Reeder, Vice President, Operations, Supply Chain Optimization, Medline Industries, suggestes starting with process improvement he transposes people with technology.

"There is an order that I recommend, and that is investing in process improvement, then people and finally assembling the technology for people to use," he said. "It is important to scope out what you're trying to accomplish first. From there, you can create a team to fulfill your identified needs. Then that team can identify the technology needed."

If anything, the pandemic taught the supply chain industry two key lessons, according to Atul Vashistha, CEO and Founder, Supply Wisdom.

Atul Vashistha

1. The supply chain models we have relied on inherently underestimated risks of disruption in the demand planning and fulfillment process.
2. Our reliance on periodic assessments to understand the health of our suppliers and supply chains leave us in the dark and unable to support proactive disruption avoidance.

"Take for instance, the just-in-time inventory model built on the assumption that there will be no disruptions in the supply chain," Vashistha explained. "Even beyond the pandemic with the war in Ukraine and now escalating tensions between China and

Taiwan, this assumption appears increasingly unreasonable as supply chain disruptions increase exponentially in terms of frequency and severity – with no end in sight.

"Furthermore, building our risk programs around periodic assessments, incorrectly assumed that the risk landscape doesn't change much between assessments," he continued. "The pandemic proved this assumption to be false and demonstrated that data from a single point in time was quickly stale in the rapidly evolving crisis. During the early days of the pandemic crisis, decision makers were forced to respond reactively without a clear or current view of the true health of their suppliers or supply chains."

Vashistha recommends the first step to address these shortcomings should involve identifying what in the process needs to change.

"I believe it would be a mistake to consider today's dynamic risk environment as a temporary crisis that will pass, and risk and inventory models should be adjusted accordingly," he noted. "Today and going forward, proactive disruption avoidance requires access to current intelligence; therefore, we need to modernize processes away from legacy assessments with a point-in-time view of the supply chain to continuous monitoring and real-time risk intelligence."

From that point, supply chain leaders should search for technology that will enable what Vashistha calls "radical transparency" and "proactive vigilance.

"The good news is that technology exists today that can enable this 'always-on' continuous monitoring with accurate real-time supply chain and risk intelligence," he said. "The right solution enables proactive vigilance through radical supply chain transparency across all potential sources of disruption including financial, cyber, location, operations, ESG, compliance, and Nth parties. Better yet, now it's possible to operationalize this intelligence and automate mitigation actions based on preprogrammed triggers or thresholds that align with an organization's supply chain disruption mitigation strategy. In this way, organizations can realize significant improvements in risk management efficiency and effectiveness to better secure supply chains all while reducing costs."

Vashistha emphasizes the need for "agile intervention," whereby "people need to be trained not to reactively respond to disruptions but instead proactively respond before a disruption occurs for an agile intervention that minimizes the impact or even avoids the disruption altogether."

Margaret Steele, Senior Vice President, Med/Surg, Vizient, warns that "it is not a matter of if there will be another disruption, but when it will occur. Therefore, healthcare organizations should start investing in process improvement planning and assembling the right technology for supply chain employees to use.

Margaret Steele

"To prepare for the next disruption, organizations should ensure they have the appropriate processes in place, the technology to assist in early notification and rapid deployment of resources," Steele continued. "These are critical to ensuring that people can not only manage through a disruption, but that staff do not burn out in the process.

Steele adds that high-performing organizations will focus first on process, but with an eye toward what can be enabled by technology and then ensure they have the right people. "Focusing on technology first often results in automating a bad process," she reflected.

Tech drives process, enables people

In an ideal world, the industry standard approach is to start with hiring the right people, aligning them on the processes, and then layering on technology to make them most efficient, according to Shawn McBride, Vice President and General Manager, WaveMark Solutions, Cardinal Health. But the current operating environment is anything but idea, he adds.

"Given the present-day economic downturn and staffing shortages following the pandemic caused by burnout, turnover, and increasing labor costs, health systems may need to invest in technology solutions that unlock value across an enterprise," McBride observed.

Shawn McBride

"While implementing technology, health systems are smart to hire supply chain and clinical leads with diverse experience who possess skills like curiosity, critical reasoning and interdisciplinary thinking," he continued. "These leaders can build out teams to own, operate and extract value from the technology. Finally, having a process in place for department-level leads to come together to draw insights and act based on the information extracted from the technology is key."

But McBride remains realistic within a less-than-ideal marketplace.

"Motivation meets purpose when staff understand how, despite the initial pain of change, technology improves the efficiency of their jobs over the long term," he said. "It's important to underscore that technology is not a replacement for people; it augments the jobs of people to make them more efficient. Eventually, the industry will shift back to where people are driving the processes to evaluate new technological needs for the healthcare ecosystem to navigate future crises that have yet to occur, be it extreme weather events, security threats, or future pandemics."

Ashok Muttin, Founder & CEO, SupplyCopia, emphasizes the need for technology implementation first because of the analog nature of many providers.

Ashok Muttin

"There is a significant portion of the health systems – mainly small and mid-size – [that] conduct their business in a manual or semi-automatic manner," he indicated. "Yesterday I saw an assistant director of supply chain manually creating a PPE estimate report for their management. He manually takes the data from multiple systems, puts them into an Excel spreadsheet, and prepares this report. Investing in technology that automates these processes will yield a significant amount of productivity gains. This is especially true in the current environment where there is a significant shortage of people in the market. A significant percent of the current supply chain leadership is retiring in the next 1 to 3 years."

Mark Wheeler, Director, Vertical Marketing Practice Lead, Zebra Technologies, recognizes a blurring of the lines between models that may improve process efficiency and people skills.

Mark Wheeler

"It used to be taboo to talk about investing in technology first, but much of the new technology coming to the supply chain requires a degree of experimenting and learning by doing," he said. "I would propose start investing in tech and training people to use it so they can improve processes. From autonomous mobile robots (AMRs) to machine vision, to RFID and temperature-sensing devices, the industry is teeming with new technologies that will prove to be disruptive to longstanding supply chain practices. Those who try new things, learn fast and will have a significant early advantage in understanding how these new technologies can be profitably applied to unique business operations to drive value." HPN

Editor's Note: To explore further product/technology, process and people options, along with recommended priorities within each category, visit https://hpnonline.com/21280371 for exclusive additional content.

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SURGICAL/CRITICAL CARE

Scope and scale of patient monitoring

by Scott Tomko

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Monitoring patients effectively and efficiently is as important to hospitals and health facilities as watching the market is to stockbrokers.

However, the potential problems in patient monitoring are numerous; when these problems are not managed and/or eradicated, they can evolve from pests into plagues.

Some of the most common problems in patient monitoring today come with alarm settings, complicated artifacts, information overload, tangled cables, issues switching between monitors made from different manufacturers, and difficulties arising from human performance.

Fortunately, many companies are continually stepping up with new and better solutions to handle inefficiencies in patient monitoring.

Staying flexible

Neal Sandy, General Manager, Monitoring Solutions, GE Healthcare, talked about the evolution of patient monitoring over time, and, in particular, how the COVID-19 pandemic prompted the need for change.

"In the past, patient monitors were generally purchased for a specific care area. For example, hospitals had specific monitors for the intensive care unit (ICU) and different monitors, typically with fewer capabilities, for the emergency department (ED). However, the COVID pandemic highlighted the need to have flexible patient monitoring technologies that could easily adapt to meet a patient's acuity level. As hospitals had to quickly adjust from normal to surge operations to respond to the increase in COVID cases, it would have been ideal if the monitors deployed in lower acuity settings had the capability to provide ICU level monitoring.

Sandy proceeded to highlight one of the main complications in patient monitoring today, resulting from the need for various types of connections and ports, and how GE Healthcare's FlexAcuity provided answers for this all-too-common dilemma.

"Most monitoring technologies require different connections and ports for each new patient vital sign, which can create confusion and prevents institutions from leveraging new clinical capabilities easily. Standardized medical USB connections and flexible software on GE Healthcare's vital sign monitoring devices allow them to be used at any bedside to deliver the accuracy healthcare teams need to help make proactive clinical decisions. GE Healthcare calls this FlexAcuity, and has been investing in tools and technologies that enable hospitals to standardize patient monitors that can be flexibly deployed across their enterprise.

This FlexAcuity capability has an even bigger impact on patient care when paired

GE Scalable monitoring technologies with standardized medical USB connections and flexible software

with clinically advanced parameters that give clinicians flexibility to acquire precise and clinically relevant patient information required to make confident clinical decisions. These technologies specialize in having fewer false alarms and provide advanced indirect calorimetry measures that can aid in personalizing nutrition and reducing a patient's length of stay."

Vitally important

Mindray is a company whose patient monitoring solutions are designed to provide bedside, transport, and ambulatory monitoring functionality along with practical software applications, thus providing caregivers immediate access to real-time patient data in any setting or location within the hospital enterprise.

Beth Aquaviva is the Sr. Marketing Product Manager - Monitoring Solutions at Mindray.

"Mindray's BeneVision N-Series and VS Series, in combination with the BeneVision Distributed Monitoring System (DMS), ensures caregivers have access to comprehensive, meaningful patient data at the bedside and beyond. From the highest level of acuity in the ICU to the mid and lower acuity needs of the MedSurg floor, our portfolio fully meets a hospital's patient care needs."

Mindray's solutions focus on increasing productivity and efficiency to help offset declining clinician-to-patient ratios, improving staff satisfaction, and enhancing clinical workflow.

Aquaviva continued, "the BeneVision N1 Monitor/Module is a 3-in-1 solution designed to adapt to the patient monitoring needs across the hospital enterprise. N1 is a compact, comprehensive multi-parameter module, a powerful transport monitor, and a versatile bedside monitor – all in one. Its patient-centric design allows the robust onboard parameter-set to move with the patient, supporting full bedside monitoring functionality even during departmental transitions and maintaining data continuity.

Mindray N1 and V59 monitors

As part of the BeneVision N-Series premier patient monitoring platform, the N1 features multi-gesture, capacitive touchscreen technology that works like a smartphone and incorporates a surprisingly new level of ease and speed into clinical workflow."

The clinical need for continuous monitoring coverage on the general care floor has largely become the norm.

According to Maria Capuano-Weachock, Sr. Marketing Manager, Vital Signs Monitoring, "Mindray's newest VS9 Vital Signs Monitor brings vital signs to life with a powerful, portable patient monitoring solution designed to provide the flexibility to quickly shift from episodic spot-checks to continuous monitoring based on a patient's condition. The VS9 is loaded with functionality and parameters that provide tools, including CO2 monitoring, to support clinical decisions and help clinicians get a complete picture of patient health."

From security guards to remote surveillance

ivWatch is a company committed to providing continuous IV monitoring technology to patient IVs everywhere, so that in time, IV surveillance is ubiquitous as home security cameras.

Gary Warren is the President and CEO of ivWatch.

"Over many decades of constant evolution, continuous patient monitoring has transformed the healthcare field in clinical efficiency and workflow. The evolution of patient monitoring has expanded its utility beyond only physiological measurements such as pulse and oxygen levels. Advances in technology now allow the monitoring of therapeutic measurements even as specific as how well patients are complying with a discharge plan and monitoring how well medication is being delivered in an IV. This advancement is demonstrated by the issuance of reimbursement codes by CMS for RPM (remote patient monitoring) and RTM (remote therapeutic monitoring)."

An analog of how RPM and RTM technologies are augmenting the mundane, but still extremely important tasks of healthcare, is the smart security camera industry. Today, smart security cameras occupy the homes of hundreds of millions of people and with a real-time notification, you can see a package that has been dropped off, the name of the person that dropped it off, and even communicate with them. No longer does one have to sit and wait for a package wasting time. You can be away from home and have real-time notifications of what is happening – the same goes for continuous patient monitoring. When it comes to your pulse, blood pressure, and now IV status, you have real-time information at your fingertips, whether you are at a patient's bedside or not.

A common but underreported healthcare crisis

Warren continued, "peripheral IVs are the most common invasive hospital procedure performed around the globe, but they do not come without significant risk and complications such as thrombosis, occlusion, and infiltration/extravasation. A delayed or missed IV diagnosis can lead to drug dosing errors, necrosis, scarring, compartment syndrome, and even amputation in severe instances. For the patient, every second counts when missing essential fluids, medications, nutrition, or blood products. It is imperative for populations like neonates or patients that are intubated and are unable to communicate with their nurse that their IV hurts, to have a voice – a medical device – that can speak for them.

One of the most common misconceptions in IV therapy is that widely adopted infusion pumps can detect infiltrations, but this is not accurate. ivWatch technology is the world's only continuous IV monitoring device that helps to detect infiltrations and extravasations at the earliest stages to decrease patient harm."

ivWatch patient monitor

With ivWatch continuous monitoring, clinicians are informed with real-time clinical data that can allow for swifter decisions by the bedside when an IV goes bad and before it's too late, when patient injury is preventable. We are now able to accelerate diagnoses and improve patient outcomes."

From sophisticated to actionable insights

ivWatch has taken sophisticated mathematics and designed a miniaturized optical sensor and a monitor with an intuitive user interface, that can assess and perform at the bedside whether the clinician is in the room or not. The proprietary algorithm will notify clinicians with a real-time visual and audible alert if the optical properties around the IV site have changed, indicating that the IV fluid is leaking outside the vein, so that the IV can be assessed promptly.

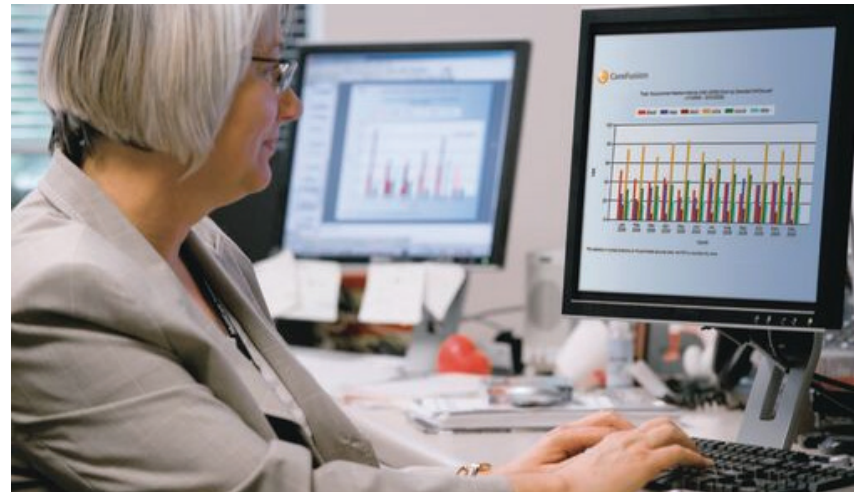
Periodic monitoring vs. continuous monitoring

"Periodic monitoring of IVs is considered the standard of care with IVs varying in the frequency of how often they need to be assessed by a clinician – from every 5-15 minutes for caustic, vesicant drugs, to every hour for populations that are at an increased risk like neonates, pediatrics, and critical care patients, to every four hours for less complex IVs. With ivWatch, a single IV site receives 18,000 checks per hour (or 5 measurements per second) compared to the standard of care, which can be problematic as clinician to patient ratios are strained.

Automating better care

Masimo is a company dedicated to providing innovative monitoring solutions that help clinicians improve patient outcomes and reduce the cost of care. With clinically proven Signal Extraction Technology (SET), Masimo invented solutions to pulse oximetry confounders that now allow clinicians to gain accurate pulse oximeter saturation (SpO2) readings even during challenging conditions including motion and low perfusion, and for all patients regardless of skin pigmentation. From there, Masimo expanded its technology to include other advanced health parameters (rainbow Pulse CO-Oximetry) that are designed to support oxygen, blood, and fluid management protocols.

Masimo Root patient monitor



BD HealthSight Clinical Advisor

William C. Wilson, MD, MA SVP is the Chief Medical Officer at Masimo

"Masimo has introduced additional technologies with the Root patient monitoring and connectivity platform, including brain and capnography solutions, for truly comprehensive multi-modal monitoring across all care areas. The Masimo Hospital Automation platform continues to grow, offering a variety of connectivity solutions wherein the types of patient data can be collected and moved through the continuum of care. In addition, Masimo has developed innovative solutions for data display and understanding, helping clinicians gain a better understanding of a patient's condition and empowering them to deliver superior, evidence-based care.

Most recently, as the COVID-19 pandemic increased demand for non-traditional care solutions, we adapted our technologies in real time to meet the rapidly evolving needs of the healthcare landscape—providing a remote monitoring and telehealth system that includes both "hospital to home" and "hospital at home" solutions."

A good advisor

Becton Dickinson has an analytical platform, HealthSight Clinical Advisor, which is a comprehensive solution combining ongoing clinical surveillance of healthcare-associated infections (HAIs) with clinical support and educational tools.

Kalvin C. Yu, MD, FIDSA at BD, is well experienced with the platform; in fact, Yu helped to introduce the solution into one of the largest integrated healthcare systems in California 15 years ago.

"HealthSite Clinical Advisor combines ADT feeds, pharmacy orders, and laboratory information and with those three feeds, you can create visibility to clinical situations that most likely need to be acted upon and in near-real time. The platform also monitors the liver, kidney function, and blood sugar. The end user can create their own alerts predicated on their specific quality initiatives and patient population."

In today's healthcare community, where increasing emphasis is placed on antimicrobial stewardship, infection prevention and helping healthcare workers ingest copious disparate data sources, these types of platforms are vital to help collate the most relevant clinical decisions cadences and in a timely fashion. churn of workflows.

It can also help measure important levels of crucial laboratories such as potassium.

Yu continued, "potassium is an important electrolyte, and, when you're sick, it can get too high or too low, and cause problems. Most medications use the liver or kidney to activate or clear the body, and if not working properly things like potassium levels can change quickly. Providing visibility to clinician derived thresholds gives healthcare providers like nurses and pharmacists a "safety net" so that they can concentrate on patient care with as little distractions as possible. This in turn can help manage the daily churn of patient care and hopefully facilitate managing their daily workflows."

Staying connected

Monitoring and documenting a patient's vital signs is a fundamental part of providing quality care. These vital signs parameters include blood pressure, body temperature, respiration rate, blood oxygen level and pulse rate, and may also include blood pressure and body weight – all of which help paint a picture of the patient's health. Connectivity that enables automated

documentation of information into the EMR is also an important consideration that can help reduce burden on clinicians while also improving the timeliness and accuracy of information in the patient's record – providing better information for the entire care team.

Baxter's patient monitoring devices are designed to be accurate, fast, easy-to-use, and adaptable to workflows both inside the hospital and in primary care clinics, so clinicians can spend less time collecting and documenting information, and more time with patients.

For example, the Welch Allyn Connex Spot Monitor can capture a full set of vital signs in less than one minute. A vivid touchscreen display is designed to be easy-to-read and use, and secure wireless electronic medical record (EMR) connectivity allows vitals data to be sent directly from the bedside to the patient's chart. Capabilities including the ability to enter additional patient information such as pain scale and "I's & O's" (intake and output) can help clinicians further streamline documentation workflows. Additionally, automated early warning scoring (EWS) can help clinicians identify signs of patient deterioration more quickly.

Increased patient acuity in the general care environment may also bring about the need for forms of continuous monitoring. To help clinicians adapt to that need, The Welch Allyn Connex Vital Signs Monitor offers basic vital signs monitoring, plus the ability to transition to continuous monitoring of measurements such as etCO2 and ECG. This includes visibility of monitor information as well as patient alarms remotely at a central station display.

With added cost pressures and a constrained supply chain since the start of the pandemic, healthcare systems require added visibility, customization and new options to reduce cost and increase efficiency.

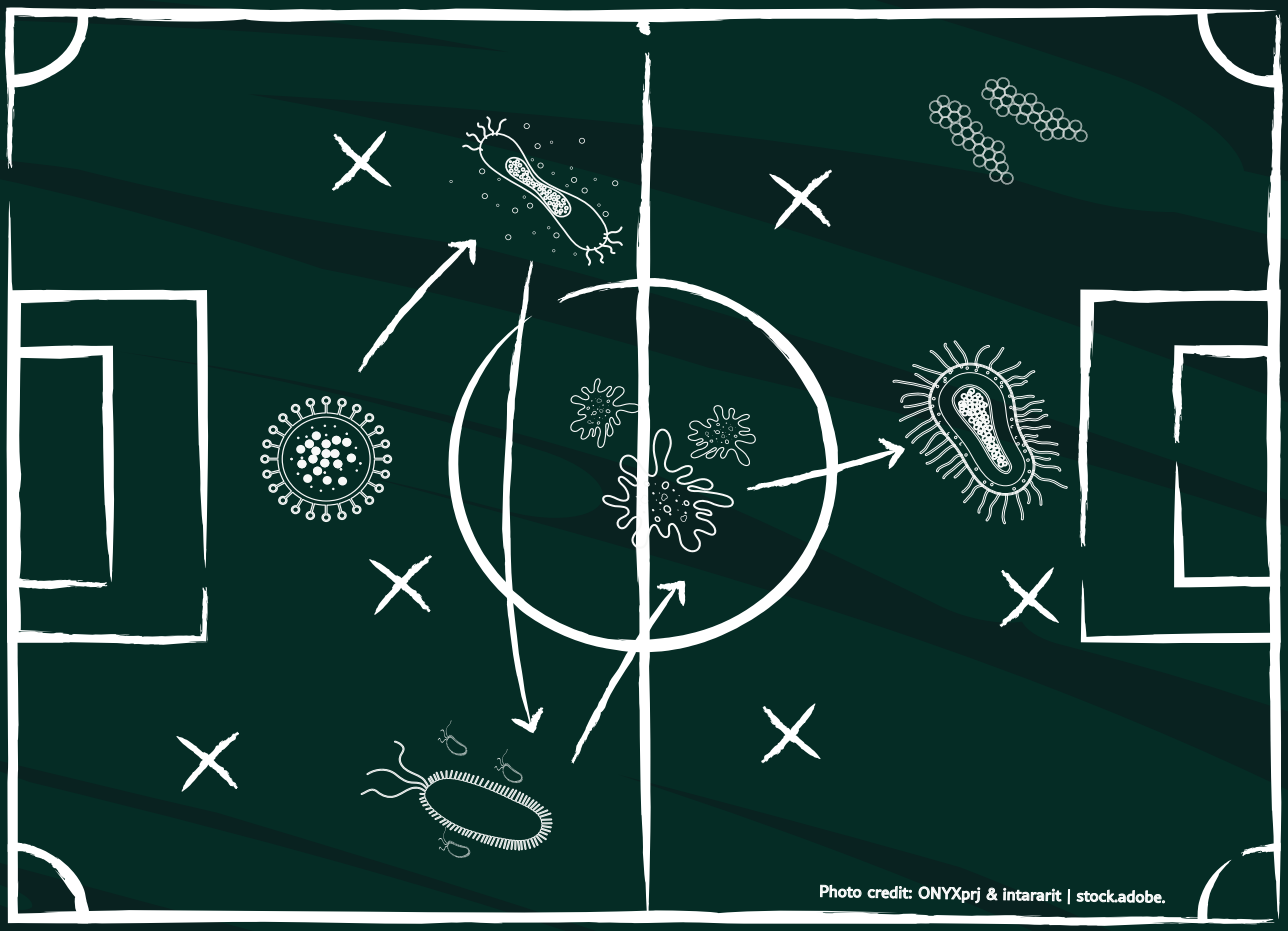
A one stop shop

PartsSource's platform and strong relationships with original equipment manufacturers (OEMs) and suppliers provide hospitals a one-stop shop to make data-driven procurement decisions and offer pricing discounts for equipment, parts and service options to save time and budget.

"The PartsSource platform shows equipment options across multiple OEMs and other vetted suppliers," said David Olexa, director of biomedical sales at PartsSource. "Our hospital clients have found this extremely helpful given the recent factory shutdowns and lithium, steel and other supply shortages in the past couple of years."

The PartsSource platform curates numerous supplier options and shows high-quality alternatives for cables and other patient monitoring equipment, as well as infusion pumps and batteries. If a specific type of equipment is unavailable or on backorder, PartsSource can provide a comparable option with the same functionality.

High-quality alternatives are common with replacement cables. For example, if a technician is looking for a four-foot cable but this size is unavailable in the desired timeframe, the platform will show the buyer an available, high-quality eight-foot cable in the catalog with deliverability details. "Another trend that we are seeing is more providers choosing disposable cables as they are single-use and reduce the possibility of cross contamination and healthcare-associated infections between patients," said Nishit Shah, strategic category manager of supply chain at PartsSource. HPN



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Zone defense to prevent infection

by Kara Nadeau

In his recent article, Health Care Environmental Hygiene: New Insights and Centers for Disease Control and Prevention Guidance, Philip C. Carling, Department of Infectious Diseases, Boston University School of Medicine, describes how "patient zone environmental hygiene" plays a critical role in "mitigating the transmission of health care-associated pathogens (HAPs)."[1]

He stresses the importance of implementing "horizontal interventions," aimed at reducing the "risk of infections caused by a broad range of pathogens by the implementation of standard practices that are effective regardless of patient-specific conditions."

Let's look at two of these interventions, hand hygiene and hygienic cleaning, within the scope of the U.S. Centers for Disease Control and Prevention (CDC) 2020 guidance: Core Components of Environmental Cleaning and Disinfection in Hospitals, which Carling cites in his article. Infection preventionists (IP) and suppliers of hygiene products and solutions share their insights on driving compliance and accountability.

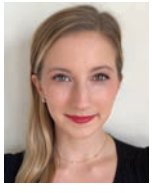
Hands as a component of hygiene

A recent survey on hand hygiene practices, conducted by GP PRO, a division of Georgia-Pacific, found just 39% of healthcare workers consistently comply with hand hygiene protocols primarily due to five common barriers: emergencies that require immediate attention; a busy workload; malfunctioning, broken or empty hand sanitizer dispensers; full hands; and difficulty during the glove on and glove off process.[2]

As Carling notes in his article, "further consideration must be given to viewing both environmental hygiene and hand hygiene as being interdependent interventions." Because they are "intrinsically relevant," he refers to the two together as "hygienic practice."

At Dartmouth Hitchcock Medical Center in Lebanon, N.H., Morgan Kuhnly, MSN, RN, CIC, Infection Preventionist, Quality Assurance & Safety, works toward compliance with Leapfrog's hand hygiene standard, which includes five domains: monitoring, feedback, training and education, infrastructure, and culture.[3]

"I think of hand hygiene as the overarching umbrella theme and under that are electronic monitoring and direct observation," said Kuhnly. "Direct observation, which is the gold standard, is where I have the most passion. I find motivating a culture of safety is the most important factor to compliance and continued patient safety."



Morgan Kuhnly

Kuhnly's approach is to motivate people to speak up when they see a "missed opportunity" for hand hygiene and give positive reinforcement when proper

hygiene is observed. Her team has set a goal of 100 direct observations per unit, per month. To help drive accountability, they send out monthly reports to unit leadership and department managers with both electronic and direct observation data and engage in bi-weekly meetings to target compliance goals.

When a unit falls behind, Kuhnly works with the team to understand barriers and take steps to overcome them.

"We all grow up knowing how to wash our hands but there are so many potential flaws in the technique. For example, if you lathered for 5 seconds instead of the recommended 15 seconds, or don't fully friction rub hard-to-reach areas, you may not be completing hand-hygiene correctly," said Kuhnly. "So sometimes it is reiterating the importance of the technique."

Hygiene focused on the patient

Kathleen M. Vollman

"Maintaining patient cleanliness by providing appropriate skin and oral care is not just a menial task, but a core nursing intervention," said Kathleen M. Vollman, MSN, RN, CCNS, FCCM, FCNS, FAAN Clinical, Nurse Specialist/ Consultant, Stryker. "As medical interventions have increased in technology, some of the most fundamental nursing practices remain a low-tech activity."

Amanda Thornton

Patient hand hygiene protocols have not been a priority, notes Amanda Thornton, RN, MSN, CIC, VA-BC, Clinical Science Liaison, PDI; however, studies have shown that they can potentially reduce the rate of healthcare acquired infections (HAIs), including *Clostridioides difficile (C. diff)*.[4]

"Patient hand hygiene can be challenging for those who are bedbound and unable to wash with soap and water," said Thornton. "Researchers found that washing a patient's hands using pre-saturated hand hygiene wipes may assist in controlling these events. Although alcohol is not considered to be an effective agent for killing the spores, it can be theorized that alcohol wipes provide mechanical cleansing of the patients' hands, removing organic debris from the skin's surface.

A study performed in a 495-bed university-affiliated medical center showed that providing bedbound patients with pre-saturated hand hygiene wipes resulted in a statistically significant decrease in the number of *C. diff* observed hospital onset laboratory identified (LabID) events in the first two quarters after implementation.[5]

According to Vollman, patient bathing is another nursing activity that often doesn't follow a standardized protocol. Each hospital, unit, and even the caregiver determines the method in which patients are bathed. She states:

"An easy way to improve hygiene compliance is to standardize the method and products used for patient bathing. Eliminating bath basins and use of tap water and choosing a skin-friendly prepackaged bathing product can help hospitals improve the patient's bathing experience, potentially decrease the bioburden on the patient's skin, and ensure that every patient is receiving the same hygiene intervention."

"Oral care is another simple intervention that can positively impact patient outcomes," Vollman added. "For independent patients, brushing teeth 2-4 times a day can help address risk factors of infection. For ventilated patients, using sequential specialized systems and kits that are designed to remove plaque, debris and oral secretions can improve compliance and address infection risk. For both skin and oral care, when process variation is decreased, quality may increase."

Hand hygiene compliance and monitoring

"With the initial COVID-19 crisis behind us, many healthcare facilities are refocusing on basic patient safety metrics such as hand hygiene and are wondering where to start (or re-start)," said Megan DiGiorgio, MSN, RN, CIC, FAPIC, Senior Clinical Manager, GOJO. "It's easy for hand hygiene leaders to assume that healthcare workers (HCW) know when to perform hand hygiene. But HCW can know conceptually what they need to do and when they need to do it and have difficulty following through with behaviors once inside the context of their busy workday."

DiGiorgio says periodic hand hygiene education is insufficient to ensure hand hygiene is performed at the right moment, while proximity can have a very powerful impact on behavior in the moment.

"Unit-based programs for norm setting, speaking up and encouraging everyone on the front lines to provide reminders for missed opportunities can help create and sustain a new set of habits and practices," DiGiorgio explains. "Improving and sustaining hand hygiene performance is work that spans over years, not months, but it's a worthwhile journey."

To ensure collection of meaningful hand hygiene compliance monitoring data, Linda Homan, RN, BSN, CIC, Director, Clinical Affairs, Ecolab, says first choose a monitoring system that provides meaningful data. She states:

Linda Homan

"There are three methods to measure compliance – direct observation, product tracking or electronic hand hygiene monitoring. Each of these methods has advantages and challenges. However, an electronic hand hygiene compliance monitoring system that captures hand hygiene opportunities associated with the patient zone rather than room entry/exit can provide the volume and type of accurate data needed to drive targeted, actionable results and meet Leapfrog requirements."

Homan says second, select a monitoring method that is accurate. "While direct observation is critical to provide feedback on hand hygiene technique, it is well-known that it is subject to bias due to Hawthorne effect, observer bias, and selection bias," she commented. "These factors make direct observation less accurate in compliance. Most electronic hand hygiene compliance monitoring systems will capture compliance data continuously and objectively. However, be sure to look for studies that support the accuracy of the system. If the data isn't accurate, healthcare workers will lose confidence in the feedback they receive about their performance."

Novant Health Matthews Medical Center leveraged the SwipeSense electronic hand hygiene monitoring system to increase hand hygiene compliance by nearly 30%. As a result of the success at Matthews Medical Center, Novant Health has implemented SwipeSense at nine additional hospitals and 10 ambulatory surgery centers.

SwipeSense Hand Hygiene automatically captures hand hygiene data and provides hospitals with actionable insights on a simple dashboard. A SwipeSense dedicated account manager diligently works with the infection preventionist to develop data-driven, personalized approaches to improve compliance, says Ali Grampp, Marketing Manager at SwipeSense. She states:

Ali Grampp

"According to the CDC, on any given day, about 1 in 31 hospital patients has at least one HAI. The best way to prevent HAIs is to increase hand hygiene compliance. On average, healthcare providers clean their hands less than half of the times they should. Many hospitals currently track compliance manually, which can be time-consuming and inaccurate. Monitoring hand hygiene compliance electronically has

proven effective in preventing HAIs and creating lasting behavior change."

Grampp says SwipeSense's mission is to empower hospitals to make data-driven changes that lead to predictable outcomes to help them save lives, improve the patient and clinician experience, and create operational efficiencies. The SwipeSense platform consists of Hand Hygiene, Nursing Insights, Asset Tracking, and Contact Tracing.

Judith Fine, MSc, MPH, M (ASCP), CIC, Infection Preventionist, says while most acute care facilities must submit hand hygiene observations to a regulatory agency, most do not have the staffing for direct observations, and most do not want to observe their peers and colleagues. Therefore, she believes a quality electronic hand hygiene monitoring system is currently the best option.

Judith Fine

Fine's healthcare system has been using Vitalacy's Automated Hand Hygiene Monitoring Solution for 2 ½ years. She comments on its use:

"We have experienced significant increases in our performance and have plateaued at certain times. The significant improvements were highly associated with the visibility of the team members on the unit and the direct relationship of the lay staff with the leadership involved, especially the IPC."

Fine offers the following recommended steps when exploring an automated monitoring system:

- Evaluate systems with an interdisciplinary team
- Form working groups inclusive of the lay staff
- Decide on a pilot unit and the timeline for implementation and expansion
- Determine what the team wants to capture: Observations, events, dispenses, etc.
- Contact references/referrals for all the systems

Environmental hygienic cleaning

In his article on the CDC's latest insights on healthcare environmental hygiene, Carling cites recent research that has "significantly clarified the impact of optimizing patient-zone environmental hygiene," noting how "new insights into the environmental microbial epidemiology of many hospital-associated pathogens, especially Clostridioides difficile, have clarified and quantified the role of ongoing occult pathogen transmission from the near-patient environment."

"The importance of environmental hygiene has never been greater than it is today," said Doe Kley, Senior Infection Preventionist, Clorox Healthcare. "The healthcare environment is a reservoir to a diverse population of microbes with 80% being transmitted by contact (or touch). While important, hand hygiene alone is insufficient to stop the recent increases in healthcare HAIs, multidrug resistant organisms (MDROs), and emerging pathogens."

Doe Kley

Collaborate on clean

Component #1 of the CDC's guidance calls on hospitals to integrate environmental services (EVS) teams into their safety culture. Carling notes how the CDC's reference to "EVS staff involved in patient-zone cleaning and disinfection as 'healthcare personnel' represents a reflection of the relevance these activities have to safe patient care."

"I think a lot of times support and ancillary teams are left out of the equation, so I try to target those groups too and make sure they feel empowered and motivated to participate," said Kuhnly. "They are boots on the ground just like everybody else. This speaks to the fact that we are all involved in patient safety, no matter what our role is. Traditionally people think it's just nurses and doctors that are responsible in patient care, but there are so many other team members involved. We wouldn't be able to do anything without all the people that work to support patient care."

"A multi-modal approach is necessary and IPs and EVS need to work together to ensure high-compliance to a cleaning and disinfection program," said Kley. "The five core components of environmental cleaning and disinfection are: education and training; product selection; standardized protocols; quality monitoring, and feedback. Regarding education and training, competency assessment is key."

At Hackensack University Medical Center in Hackensack, N.J., the IP and EVS teams work closely together on initiatives to provide the highest level of hygiene for patient care and safety. One of the latest is around cleaning compliance. They are piloting the use of a color additive (Kinnos Highlight) to bleach wipes used for terminal cleaning of patient rooms to train EVS staff members and reinforce cleaning effectiveness.

"We are a first-class hospital not only in the state of New Jersey but also in the United States and the world at large," said David Olonilua, EVS Director at Hackensack University Medical Center. "We are constantly looking for better ways to improve outcomes and the Kinnos product is another layer in removing bioburden and improving disinfection."

David Olonilua

By adding the liquid blue indicator to bleach disinfectant wipes, EVS staff members have a visualization of wiping surface coverage in the form of a temporarily visible bright blue trace, which fades away to clear in minutes. They can literally see what they have wiped down and what has yet to be cleaned.

Jerry M. Zuckerman, MD, Vice President of Infection Prevention & Control, Hackensack Meridian Health, notes how the proactive use of the solution drives greater EVS staff efficiency compared with reactive surface testing (e.g., ATP assay, fluorescent marker).

Jerry M. Zuckerman

"It has really been very valuable in the training and onboarding process so that people are learning the correct techniques and skills at the beginning," said Dr. Zuckerman. "In contrast, finding areas of cleaning failure through ATP testing or using fluorescent markers results in EVS staff members having to reclean those areas."

"It gives them a visual perspective of how thorough they are cleaning, which is critical to everything that we do in infection prevention," Dr. Zuckerman added. "It is all about making the invisible visible so they can enhance their performance and improve it over time in a more efficient way."

They started the three-month pilot in isolation rooms and have moved to areas of the hospital with high patient discharge rates. They are tracking patient experience data related to cleanliness and if they see improvements, they will next expand use of the product beyond terminal cleaning to daily cleaning of patient rooms.

"The value will be more in the future when we can incorporate it into daily cleaning because that is when the patient will actually see the color changes," said Dr. Zuckerman.

When asked to describe the benefits of this collaborative work for both the EVS and IP teams, Olonilua stated:

"It is all about teamwork and respect and understanding what we do not just from infection prevention but from multiple perspectives. Clinical leadership bought into this initiative, and it is always good for them to see something new done in their units. The reception and collaboration have been huge, and we look forward to building on existing relationships."

"This for me has been an excellent opportunity to reach out to the EVS team and

engage them in the process of infection prevention," Dr. Zuckerman added. "I think their work frequently gets overlooked and underappreciated. I think this really helps make the connection between what they are doing and the value they have for improved patient safety."

Plan, train, do, review

CDC component #2 is to "educate and train all healthcare providers responsible for cleaning and disinfecting patient care areas."

Larinda Becker

"Having a clearly defined process that the team understands is the first step," said Larinda Becker, Executive Director of Marketing - Infection Prevention, Diversey. "This includes roles and responsibilities of who does what, and when/how often."

"A certified 'train the trainer' program is imperative to ensure both current and new team members in Infection Prevention and Environmental Services are trained on cleaning processes and proper use of chemicals/equipment," said Rich Prinz, Global Vice President of Sales, EvaClean Infection Prevention Solutions.

To help train staff in proper cleaning techniques and maintain cleaning efficacy, Becker recommends use of a fluorescent marking spray to mark frequently touched surfaces. After staff members have cleaned the surfaces, an auditor can use a black light shined on the surfaces to determine if the marking spray was removed.

"Random environmental surfaces are marked prior to cleaning, and then reviewed after cleaning to provide an objective review of compliance," she explains. "Providing this visible, ongoing feedback can engage the staff and show them where there may be variability in performance. This provides actionable data for targeted training and continuous improvement."

Product selection

Selecting appropriate cleaning and disinfection technologies and products is component #3 of the CDC's core components of environmental cleaning and disinfection in hospitals.

The agency recommends hospitals use a "prospective 'systematic process' for product evaluation, incorporating "analysis by relevant leadership personnel to consider the clinical value, as well as direct and indirect costs, before implementing new programs and technologies."

"One of the critical issues that plague infection preventionists is the inefficiency of evaluating new products and removing products that do not perform," said Sarah Beatty, MHSA, MLS(ASCP), founder and CEO of Culturewell. "It can be frustrating to all parties involved when products and quality improvements are pitched to purchasing committees when there is little evidence of efficacy aside from a vendor's white paper."

Beatty says IPs need ways to rapidly test products within their facilities, along with quantitative data and charts that can be shared with stakeholders. She states:

"We need to make it easy for stakeholders to say 'YES.' Culturewell helps infection preventionists with quantitative pre-and post-implementation testing of ANY product or process, with results delivered on digital dashboards that allow for easy comparison, annotations, and sharing with stakeholders."

When evaluating products, Kley stresses the need for IP teams to select EPA-registered healthcare-grade disinfectants that target the pathogens of concern in their facilities.

"For standardization, strive to carry no more than 2-3 disinfecting products with one being a sporicide like bleach," she said. "Ready-to-use products are ideal as they eliminate the risk of dilution error. Last, be sure to have a structured quality monitoring process in place and provide immediate feedback to staff."

Monitor, evaluate and provide feedback

The last three of the CDC's core components are focused on standardization, monitoring, and feedback on cleaning and disinfection:

- Component #4: Standardize setting-specific cleaning and disinfection protocols
- Component #5: Monitor effectiveness and adherence to cleaning and disinfection protocols
- Component #6: Provide feedback on adequacy and effectiveness of cleaning and disinfection to all responsible healthcare providers as well as relevant stakeholders

Beatty says knowing the specific germ hotspots (not just generic high-touch surfaces) can make a world of difference in breaking the chain of transmission:

"Routine monitoring of surfaces, water and air provides insight into germ hotspots in our facilities, allowing us to prioritize cleaning and disinfection of those areas, especially in facilities with resource constraints and labor shortages," she commented. "Cleaning insights platforms like Culturewell provide routine monitoring, data analysis, shareable visualizations, and expert-level recommendations tailored to the specific clinical setting, allowing infection preventionists to focus on the implementation of best practices."

To hold teams accountable for hygiene compliance, Beatty recommends IP teams publicly post compliance data on each ward so team members, patients, and visitors can see the information.

"The best ways to encourage compliance are initiatives that allow for individual and group ownership of compliance results," Beatty added. "Leadership-driven initiatives created with input from infection prevention that teach and enforce a Culture of Safety are critical. Finally, including HAI outcome measures in performance reviews and bonus calculations (a % of total compensation related to an individual and group's ability to directly influence compliance rates) are essential." HPN

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5. Pokrywka et. al. "Can improving patient hand hygiene impact Clostridium difficile infection events at an academic medical center?" American Journal of Infection Control, Volume 45, Issue 9, 959 – 963.

Choosing products for compliance

Rich Prinz, Global Vice President of Sales, EvaClean Infection Prevention Solutions, suggests hospitals consider the following factors when choosing products to improve surface cleaning and disinfection compliance:

- **Safety:** Safer chemistry with a non-hazardous Hazardous Materials Identification System (HMIS) rating and neutral pH
- **Efficacy:** EPA registered chemistry for a wide range of bacteria/viruses, particularly HAI-causing pathogens and biofilm, continuously active disinfectant, and approved for enhanced disinfection with electrostatic sprayers
- **Standardization:** Versatile chemistry that serves as cleaner, sanitizer, disinfectant, and sporicidal for terminal clean and discharge, and can replace multiple other products, which simplifies processes, removes risks of harmful chemical mixtures, and reduces human error

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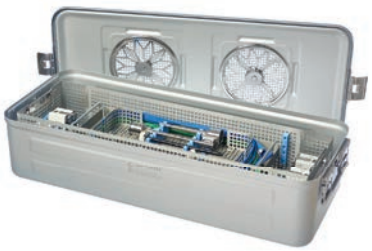

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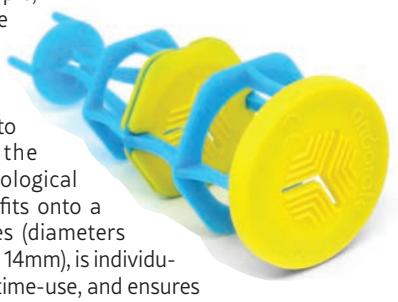

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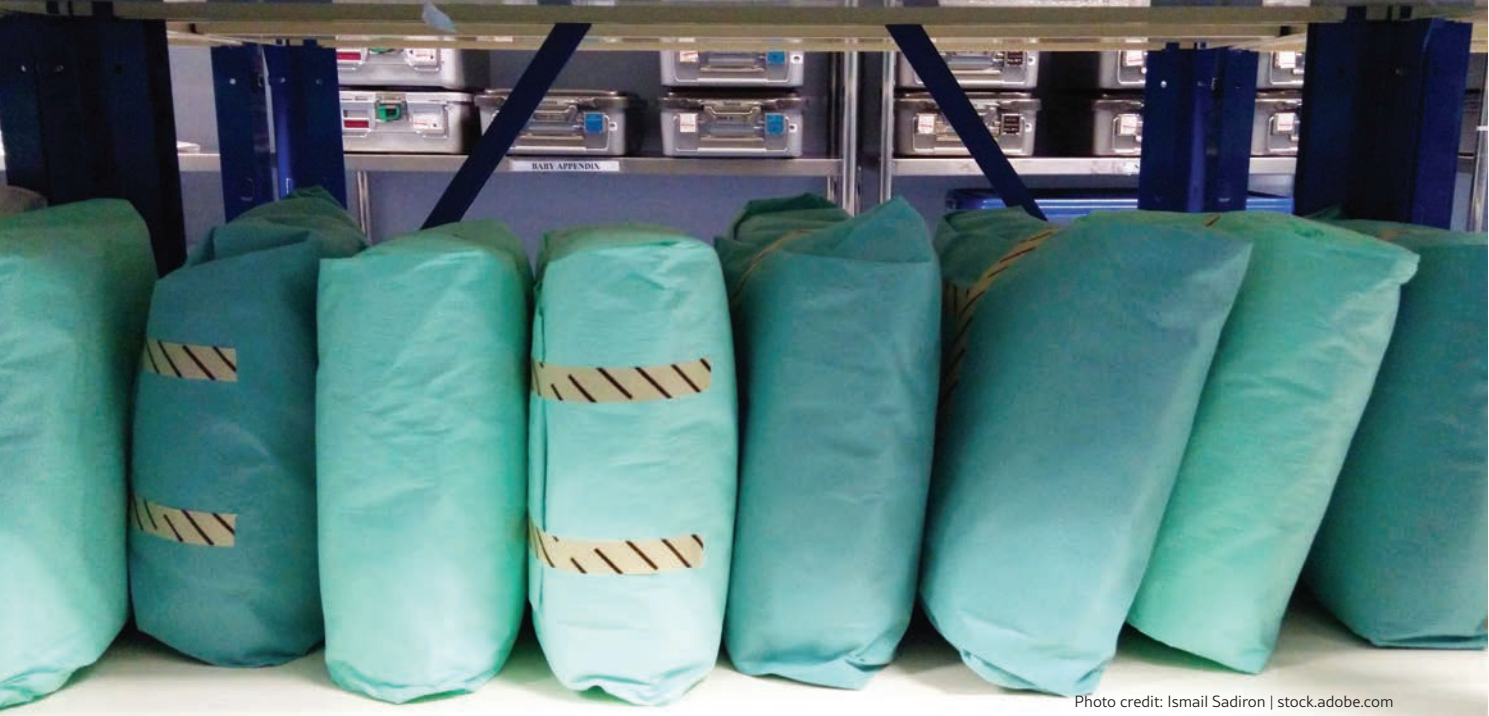

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Air-tight and under wraps

Sustainable sterile instrument storage and containers

by Kara Nadeau

Keeping surgical instruments and supplies organized, protected from harm/contamination and easy to find is a top priority for both Central Service/Sterile Processing & Distribution (CS/SPD) and clinical teams. But it is also a significant challenge given the growing number of items needed for patient procedures, the path they must travel to and from the CS/SPD department, and space constraints faced by most healthcare organizations.

Here is the story of one CS/SPD team's efforts to transform storage for the benefit of patient care and safety, a look at instrument storage regulatory and industry guidance, and insights from storage and container vendors on products and solutions to keep instruments protected and free of contaminants during storage and transport.

Cincinnati Children's Hospital & Medical Center storage to support growth

S. Dwayne Taylor

In 2019, when S. Dwayne Taylor, PA-s, CST, CFA, CRCST, CHL, CIS, CFER, ACE, SME, joined Cincinnati Children's Hospital & Medical Center as Director, Sterile Processing & Distribution, the healthcare organization was in the process of building a tower that would house a new and improved CS/SPD department. Both the main

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hospital's surgical instruments and those of select clinical areas would be stored in this new space.

"The existing sterile processing department was small, compact and cramped," said Taylor. "We are a Level 1 facility performing about 120 surgeries per day and had no room to properly store and house our sterilized instruments. It was a chronic issue where mishandling, improper storage and stacking of trays led to downstream effects such as compression of wrapped items and holes."

Taylor called in DSI to design a storage space in the new CS/SPD department that would not just accommodate current surgical inventory but be large enough to accommodate future growth.

"DSI used CAD design and configured shelving units to help us maximize every square inch of the space," said Taylor. "They submitted several designs, and we selected the design we liked based on the shelving units, parameters and footprint."

In new CS/SPD storage area, each surgical specialty (e.g., orthopedic, spine, general surgery, etc.) has its own aisle for instrument and supply storage. Each cart and shelf are assigned a dedicated location that corresponds to a location within the instrument tracking system so CS/SPD team members know exactly where to go when retrieving and returning items.

Since moving into the new CS/SPD, using the DSI-designed storage configuration, and beginning a transition from wrapped trays to containers, there has been a 68% reduction in holes in wraps reported by the perioperative team. Taylor and his team have also decreased delays in delivering needed items to the operating room (OR), as he explains:

"Before the new storage configuration, we averaged 27 delays per month ranging from 30-60 minutes when looking for instruments requested by the OR. Our latest report in July 2022 showed only two delays for the month. The new space is very open, well organized, well lit, and clean, making it far easier to find items."

Taylor designated an aisle for vendor trays where each vendor has been assigned its own cart. "Vendor trays are typically a huge problem for most departments because they tend to get stuck in any crack or crevice when CS/SPD has no place to put them. The space allocated in our storage area for vendor trays has greatly helped us," he commented.

When asked for his advice to other CS/SPD teams when renovating an existing storage space or designing/building a new one, Taylor says to always keep future growth in mind.

Storage guidance for hospitals

The Centers for Disease Control and Prevention (CDC), the Joint Commission (TJC), American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), and Centers for Medicare and Medicaid (CMS) are just a few of the organizations providing guidance to hospitals of sterile storage of instruments and supplies. Some of the key requirements and guidelines are as follows.

Temperature and humidity

Temperature and humidity can compromise the sterility of instruments in storage by promoting microbial growth. The CDC recommends sterile storage "be a limited

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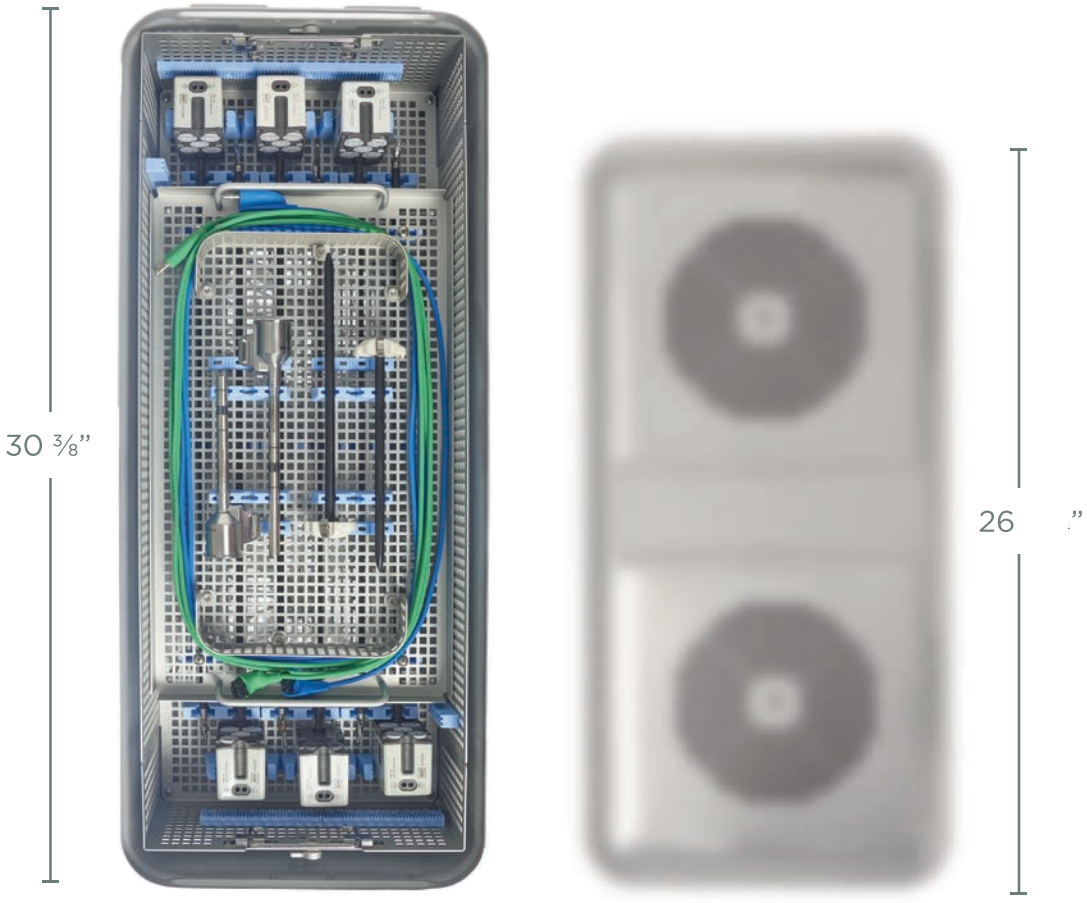

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access area with a controlled temperature (may be as high as 75°F) and relative humidity (30-60% in all works areas except sterile storage, where the relative humidity should not exceed 70%)."[1]

With regards to temperature and humidity of sterile storage areas, TJC[2] says to first ensure the hospital is compliant with all building code requirements. CMS ventilation requirements outline criteria for both new and renovated existing facilities (constructed or plans approved on or after July 5, 2016).

Ventilation

The ANSI/ASHRAE/ASHE Standard 170, Ventilation of Health Care Facilities[3] provides a "mandatory minimum requirement" for health care ventilation design, including the following ventilation requirements for sterile storage in central medical and surgical supply areas:

- Positive air pressure relationship to adjacent areas
- Minimum outdoor air exchange 2 per hour
- Minimum total air exchange 4 per hour
- Maximum relative humidity 60%
- Temperature range 72° to 78° F or 22° to 26° C

Storage conditions and monitoring

The CMS Hospital Infection Control Worksheet[4] lists the items that a state agency must assess during an on-site survey to determine compliance with the Infection Control Condition of Participation. Areas of assessment for the storage of sterilized medical devices and instruments include:

- 3.B.15: After sterilization, medical devices and instruments are stored so that sterility is not compromised
- 3.B.16: Sterile packages are inspected for integrity and compromised packages are repackaged and reprocessed prior to use

Similarly, the CDC guidance says to store sterile items in a way that protects packaging from compromise, evaluate packages before use for loss of integrity (e.g., torn, wet, punctured), and repack and reprocess packs that are compromised.[5]

In addition to temperature, moisture and ventilation controls, the CDC says hospitals must ensure the sterile storage area provides protection against dust and insects.[6]

Sterilized item shelf life

"Safe storage times for sterile packs vary with the porosity of the wrapper and storage conditions (e.g., open versus closed cabinets)," states the CDC, noting how "any item that has been sterilized should not be used after the expiration date has been exceeded or if the sterilized package is wet, torn, or punctured."[7]

It offers the following examples for time-related sterilization management:

- Heat-sealed, plastic peel-down pouches and wrapped packs sealed in 3-mil (3/1000 inch) polyethylene overwrap have been reported to be sterile for as long as 9 months after sterilization
- Supplies wrapped in double-thickness muslin comprising four layers, or equivalent, remain sterile for at least 30 days

The CDC goes onto note how some hospitals have switched to an event-related shelf-life practice from a time-related one, providing the following examples

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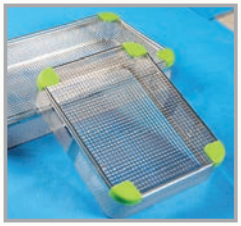

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of event-related factors that contribute to product contamination: bioburden (i.e., the amount of contamination in the environment), air movement, traffic, location, humidity, insects, vermin, flooding, storage area space, open/closed shelving, temperature, and the properties of the wrap material.

As for the effectiveness of this approach, the agency cites a study where items in sterile storage were microbiology tested two years from the date of sterilization. All items were found to still be sterile. Based on research such as this, the CDC suggests "contamination of a sterile item is event-related, and the probability of contamination increases with increased handling."

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Solutions for safer and more effective storage

Manufacturers are constantly innovating ways to better protect and organize instruments at each stage of their journey, including each step of processing and storage in the CS/SPD department, transport to procedural areas and use, and back to the CS/SPD space. From providing effective sterile barriers for instrument trays, to storing all sizes of supplies, here is a look at just a handful of the solutions on the market today.

Reduced touchpoints for sterile barrier protection

"While sterilization wrap offers tremendous properties to allow sterilant to enter and escape during a steam or other type of sterilization process, some products can experience tears, cuts or holes," said Cory Ezell, North America Sales Director for Belintra, partnering with O&M HALYARD. "To greatly reduce these breaches, it's not only about having a wrap that's durable, but it's also about limiting the number of times a tray is touched or handled post sterilization."

Ezell notes how tray touchpoints are an important consideration during tray storage and transport to the OR, and points to the combined HALYARD* SMART-FOLD* Sterilization Wrap with the BELINTRA STERIYSTEM storage and transport system as a way to minimize touchpoints during these processes. He describes how it works:

"A wrapped instrument tray is placed on an enhanced shelving unit that's used to store and transport the tray during its journey to the OR. With the shelving unit on the receiving end of any touchpoints, the wrapped, sterilized instrument tray is not touched again during the transport process until it reaches the OR."

"When trays are being stored, it's also important to eliminate stacking," Ezell added. "This common practice can create more opportunities for breaches, but with the height-adjustable and space-saving HALYARD and BELINTRA STERISYSTEM, all the wrapped packaging and soft goods necessary for one procedure can be accommodated without stacking."

The HALYARD SMART-FOLD* Sterilization Wrap with the BELINTRA STERIYSTEM storage and transport system*

Drying out microbial dangers

"Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces," says the CDC states in its Guideline for Disinfection and Sterilization in Healthcare Facilities (2008).[8]

The last thing anyone wants is for a surgical team to open a sterile set and find moisture. The resulting snowball effect of finding a wet pack can lead to wasted time and effort, increased workload, increased cost, potentially contaminated instruments, infection risk to the patient, poor patient outcomes, and delayed or cancellation of procedures.[9]

The potential causes of "wet packs" varies, including poor quality of wrapping materials, faulty valves of rigid container, faulty loading and packaging technique, poor steam quality, sterilizer malfunction, and design related problems in the CS/SPD storage area.[10]

To help ensure the dryness of sets that undergo steam sterilization, Aesculap recently launched its AESCULAP Aicon

Sterile Container System, which offers 100% container and basket synchronization and up to 47 percent less dry time with the Enhanced Drying System (EDS).[11]

Storage solutions large and small

A large, academic medical center performing 20,000 operative procedures per year, compared with a small, community hospital with an average surgical volume of 1,500 procedures annually will have very different requirements when it comes to surgical instrument and supply storage.

When asked for his best practices for instrument storage and surgical set storage, Craig Crock, President, Southwest Solutions Group recommends larger CS/SPD departments use automated carousel storage systems designed for the sterile core.

"Our sterile core vertical carousels for surgical kits and medical supplies save space and provide automated retrieval," said Crock. "These picking carousels hold rigid containers and surgical sets in the sterile core area. The units go tall and bring everything to an ideal ergonomic height."

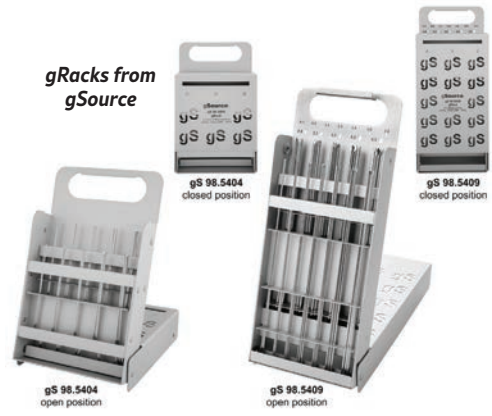
For smaller CS/SPD departments, Southwest Solutions Group offers sterile surgical instrument carts designed to reduce or eliminate perforations, tears and wet packs.

"They reduce manual handling, eliminate stacking by providing every wrapped kit with its own storage space, and safely store and transport blue wrap kits throughout the entire logistics flow," Crock added.

Small item organization

Orthopedic procedures often require wires and pins to hold bones in place, which can be challenging to manage given their small diameters. To help CS/SPD teams achieve optimal organization and convenient storage of Kirschner wires (k-wires) and bone pins, gSource offers its gRacks, with features that aid in easy access and identification

gRacks from gSource securely organize common diameter sizes of 4" and 6" k-wires (gS 98.5404) or 9" k-wires and pins (gS 98.5409). K-wires and pins are held in place when racks are closed, helping to prevent any shifting. gRacks fold close for convenient storage but convert to tabletop stands for use in the OR when open. Made in the USA from anodized aluminum, they are lightweight yet built for rigorous and repeated use; handles provide convenient transportation. gSource K-wires and pins are sold separately. **HPN**



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HEALTHCARE PURCHASING NEWS

SELF-STUDY SERIES

What's new in AAMI ST79:2017? A review

Adapted from the original article published in October 2017

by Susan Flynn, BESc, CSPDT

October 2022
The self-study lesson on this central service topic was developed by 3M Health Care. The lessons are administered by Endeavor Healthcare Media.

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LEARNING OBJECTIVES

1. *Review changes to the HVAC recommendations provided in AAMI ST79:2017.*
2. *Discuss key changes to the quality control recommendations in AAMI ST79:2017.*

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AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* is a go-to resource for all healthcare facilities that have steam sterilizers. The standard is as relevant and applicable to clinics with table-top sterilizers as it is to ambulatory surgery centers and acute care hospitals with larger steam sterilizers. AAMI ST79 is also referenced throughout The Joint Commission's High-Level Disinfection (HLD) and Sterilization BoosterPak.[1] Accreditation surveyors are tuned into the practice recommendations included in the document and expect to find a current copy of this evidence-based guideline accessible to front-line staff. AAMI recently published a new edition, ST79:2017,[2] and this self-study article reviews some of the new information and key changes in the revised document.

Customers sometimes call the 3M Sterilization Tech Line knowing that a particular recommendation is somewhere in ST79 but are unable to locate it to show their colleagues. The 2017 edition was designed to be more accessible to the reader, with recommendations in clear "should" statements (often bulleted) rather than buried in long paragraphs. The document explains that, "'Should' indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited." (Foreword) When you begin reading your copy of ST79:2017, remember that the verb "should" is a cue to an upcoming recommendation. Beyond the formatting changes designed to provide critical content in a consistent format, the changes in this edition of the document are rather subtle and incorporating these new guidelines into your practice should be relatively painless.

HVAC

Section 3 of AAMI ST79 provides design considerations for sterile processing areas Heating, ventilation and air conditioning (HVAC) parameters for operating rooms and sterile processing areas have been a recent source of discussion. These discussions have led to an industry consensus around the use of the American Society of Heating, Refrigeration, and Air Conditioning Engineers' (ASHRAE) Standard 170, *Ventilation of Health Care Facilities*. Eliminating specifying recommended temperature and humidity ranges altogether, the revised AAMI ST79 instead refers the reader to the HVAC parameters given in ASHRAE 170, thus harmonizing the recommendations between the two standards. This may make for easier discussions with your facility engineers. ST79:2017 recommends, "The health care organization should identify which version of ASHRAE 170 will be used based on when the HVAC system was initially installed or last upgraded." (Section 3.3.5.5) The burden of monitoring compliance with the HVAC parameters is slightly modified, with ST79 now recommending:

- "Facility engineering personnel or designated responsible personnel should establish policies and procedures for monitoring and maintaining HVAC parameters within the sterile processing areas.
- Procedures should include maintaining records of monitoring results that are retrievable either from a central system or a local log." (Section 3.3.5.5)

You may wish to initiate a discussion with your Facilities Engineering team to verify their ability and willingness to comply with these recommendations.

Guidance on response measures to any excursions from the desired operating parameters is also addressed, with ST79 recommending: "If a variance in the HVAC parameters occurs, sterile processing personnel in combination with a multidisciplinary team (e.g., facility engineer, infection preventionist, risk manager, sterile processing manager or designated personnel) should conduct a risk assessment." (Section 3.3.5.5)

Recognizing that the design temperature recommendations for decontam in ASHRAE 170 (60-73°F)[3] may cause anxiety, a new Annex Q, *Alternatives for keeping cool in the sterile processing environment*, was added to ST79:2017. The annex explains that our bodies use evaporative cooling to help regulate body temperature when a person's core temperature becomes too high. As the PPE worn in decontam can reduce the ability of sweat to evaporate, the annex provides strategies for improving employee comfort including short-

ening work periods and increasing rest periods; staying hydrated; and wearing cooling devices under PPE.

Personnel considerations

AAMI ST79:2017 continues to recommend that both Sterile Processing supervisors and personnel be qualified and competent. It is recommended that supervisors complete a sterile processing management certification exam and that other personnel "performing sterile processing activities should be certified within two years of employment." (Section 4.2)

Loaners

Expanded guidance on loaned or borrowed instrumentation is included in AAMI ST79:2017. (Section 5.2.3) This includes establishing a formal procedure with industry representatives for the receipt and use of loaned instruments and having a comprehensive facility policy. The policy should include processes to ensure that: applicable IFUs are provided before the loaner is received; the weight of loaned sets does not exceed 25 pounds; loaners are provided such that the facility has sufficient time to process them upon receipt; and records of loaner transactions are maintained. This section has a new recommendation: "Late receipt of loaned instruments should not be used to justify IUSS."

IUSS

And that takes us nicely to the next topic! ST79:2017 features a new definition and clear guidance on immediate-use steam sterilization (IUSS). IUSS of unwrapped items is no longer an option as it is recognized that rigid containers protect sterilized items from contamination. Section 10.2.3 states:

"IUSS should not be used for purposes of convenience or as a substitute for sufficient instrumentation. Instrument inventories should be sufficient to meet anticipated surgical volume and permit the time to complete all critical elements of reprocessing.

IUSS should be kept to a minimum and should be used only in urgent clinical situations.

Items processed by IUSS should:

a. be decontaminated as specified in Section 7;
b. be placed in a rigid sterilization container system that is intended for the cycle parameters to be used;
c. be used immediately and not stored for later use or held from one procedure to another; and
d. be identified as IUSS."

Loading and unloading sterilizers

The section on preparing instruments for sterilization is broadly similar in this edition. As accreditation surveyors sometimes overinterpreted the word *open* in the sentence "All jointed instruments should be in the open or unlocked position with ratchets not engaged," this statement has been simplified to read: "Ratcheted instruments should be unlatched" in the 2017 edition. (Section 8.2)

Updated figures in Section 10.1 depict the recommended loading of sterilizer carts, with rigid containers placed below absorbent materials.

What cycle should be run for Device X?
Follow the validated sterilization parameters provided in the device manufacturer's IFU.

One significant revision is the removal of the reference tables that provided typical sterilization parameters for gravity-displacement and dynamic-air-removal steam sterilization cycles. Instead, the reader is reminded to reconcile the validated cycle parameters found in the device, sterile barrier system (aka packaging) and sterilizer manufacturers' written IFUs. (Section 10.2) ST79:2017 also states, "Sterilization cycles used by the health care facility should be FDA-cleared and should incorporate sterilization monitoring accessories (e.g., CI, BI, PCD) and sterilization packaging labelled and cleared for that sterilization cycle." (Section 10.2.2.1)

ST79 continues to recommend that terminally sterilized load items be allowed to cool before being touched. A new statement reads, "The use of an infrared gun or temperature sensing device and a defined temperature (i.e., 24°C [75°F]) may be used." (Section 10.3.1)

Quality control

Cleaning Verification

One key change is the frequency at which mechanical cleaning equipment, such as automated washer-disinfectors and ultrasonic cleaning equipment, should be routinely monitored. A rationale statement explains, "Steam sterilization cannot be assured unless proper cleaning of the device and reduced bioburden and soil was achieved. Verification and documentation of automated cleaning processes through objective means is an important aspect of quality control."

It is now recommended that mechanical cleaning equipment be monitored daily.

It is now recommended that mechanical cleaning equipment be monitored daily and the results be documented. (Sections 7.6.4.5 and 13.2) ST79 states that, "Methods of verification include: a) directly testing individual instruments for residual soils (e.g., ATP, protein, hemoglobin); b) employing a test device that is a consistent and repeatable challenge to the cleaning effectiveness of the equipment; and c) monitoring critical parameters to evaluate the performance of the mechanical cleaning equipment." (Section 13.2)

Is your automated washer equipped with a printer? ST79:2017 recommends that such printers be located on the clean side of pass-through washers and that the printout be checked and initialed by operators.

With manual cleaning, it is important that cleaning agents be appropriately diluted. ST79:2017 recommends that, "When using an automated chemical delivery system/device or sink proportioner, the automated doser should be routinely verified or calibrated." (Section 7.6.3)

Sterilization monitoring

AAMI ST79 continues to recommend a steam sterilization quality assurance program which includes the use of physical monitors, internal and external chemical indicators, and biological indicators. A high-level overview of the sterilization process monitoring recommendations contained in AAMI ST79 is provided in Table 1, next page. The table includes the familiar column headers: routine load release; routine sterilizer efficacy monitoring; qualification testing; and product quality assurance testing.

Chemical indicators

When preparing sets for sterilization, have you noticed that most chemical indicators (CIs) are now labeled by 'type' rather than 'class' of CI? ANSI/AAMI/ISO 11140-1:2014 specifies the performance requirements, test methods, and labelling requirements for CI manufacturers.[4] Since this standard was released in 2014, CI manufacturers have been busy testing their products against the performance specifications and then updating the devices and labelling to reflect the new categorization term 'type'. AAMI ST79:2017 also uses this new terminology. In general, the use and application of chemical indicators did not change (see sidebar next page.) but the 'type' designation in ST79 now aligns with the labeling on the CIs actually available on your prep and pack stations.

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

Nonimplant load release

Routine load release guidance is split into two buckets: nonimplants and implants. Loads that do not contain an implant should be monitored using physical monitors (i.e., the print-out), chemical indicators, and may be monitored with a Process Challenge Device (PCD) containing: a BI; a BI and a Type 5 CI; a Type 5 CI; or a Type 6 CI. The use of the verb *may*, rather than the verb *should*, indicates the use of a PCD is optional for nonimplant loads. The decision about whether to release a load is made after evaluating the available data.

Implant load release

As biological indicators are the only monitoring tool that demonstrate the lethality of the sterilization process, AAMI ST79:2017 continues to recommend that implant loads be monitored with a PCD containing a biological indicator and a Type 5 integrating indicator. The implant should be quarantined until the BI result is available. (Sections 13.5.3.2 and 13.6.3) In defined emergency situations, the implant can be released on the basis of the Type 5 integrator contained with the PCD but the BI should still be incubated and the result documented. (Section 13.6.3) An example Exception Form for emergency load release documentation is provided in Annex K. This form continues to be a good tool to collect the reasons for emergency release. The collected data can be reviewed during quality improvement meetings so that mitigation measures can be identified and implemented.

Routine efficacy monitoring

The recommended frequency of monitoring steam sterilizers with a BI PCD did not change. AAMI ST79:2017 states: "A BI PCD should be used at least weekly and preferably daily." (Section 13.6.1). Also unchanged is the recommendation that each type of cycle used be routinely monitored.(Section 13.7.1) While smaller clinics and dental offices elect to monitor daily or weekly, many larger facilities have adopted the best practice of every load monitoring to: ensure all implant loads are monitored; ensure each cycle type is monitored; simplify staff training; and minimize the impact of a recall. A small change to the guidance on routine biological monitoring of sterilizers larger than 2 cubic feet is that this section now recommends the use of commercially available PCDs with the rationale statement explaining that, "Commercially available disposable PCDs (BI challenge test packs) provide standardization and reduce variability and potential for error." (Section 13.7.2.1)

Monitoring IUSS Cycles

Does your CSSD test the IUSS sterilizers located in the OR? AAMI ST79:2017 removed the separate section on routine biological monitoring of IUSS cycles. Other than dry time, for pre-vac cycles these sterilizers typically have the same sterilization pa-

MONITORING IUSS STERILIZERS

Previous editions of ST79 recommended end-user assembly of a representative BI PCD (typically a BI and a CI placed in an IUSS container) to monitor IUSS cycles. **This new edition recommends use of a commercially available BI PCD for sterilizers larger than 2 cubic feet, which includes IUSS sterilizers.**

Bottom line: Routine efficacy monitoring of dynamic-air-removal IUSS sterilizers should be done with a commercially available disposable BI PCD.

Testing a loaded chamber is recommended, however, as described in Table 1, for IUSS cycles, monitoring may be done in an empty chamber.

Routine efficacy monitoring of gravity **IUSS sterilizers** is done using a representative BI PCD assembled using the same type of tray that is routinely processed. (Section 13.7.4.1)

INTERNAL CHEMICAL INDICATORS

The guidance on the use of internal chemical indicators is slightly modified and now reads, "One or more internal chemical indicators should be placed within each package, tray, or rigid container. These indicators can be any type (Type 3, 4, 5, or 6) but preferably a Type 5 or Type 6 indicator as these types of CIs provide the user with more information on the critical steam sterilization parameters." (Section 13.5.2.2.2)

This section goes on to state: "Internal CIs should be placed so that:

a. one CI is visible to the person opening the package;
b. CIs are in the area or areas considered least accessible to steam penetration; and
c. all applicable written IFU are followed."

Table 1—Sterilization process monitoring recommendations

Routine load release (see 13.5 and 13.6)		Routine sterilizer efficacy monitoring (see 13.7)	Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures) (see 13.8)	Periodic product quality assurance testing (see 13.9)
Nonimplants	**Implants**			
Physical monitoring of cycle External and internal CI monitoring of packages Optional monitoring of the load with a PCD containing one of the following: • a BI • a BI and a Type 5 integrating indicator • a Type 5 integrating indicator • a Type 6 emulating indicator	Physical monitoring of cycle External and internal CI monitoring of packages Monitoring of every load with a PCD containing a BI and a Type 5 integrating indicator	Physical monitoring of cycle External and internal CI monitoring of packages Weekly, preferably daily (each day the sterilizer is used), monitoring with a PCD containing a BI. (The PCD may also contain a CI.) For sterilizers larger than 2 cubic feet and for table-top sterilizers, monitoring is done in a fully loaded chamber. in IUSS cycles, monitoring may be done in an empty chamber. For dynamic-air- removal sanitizers, daily Bowie-Dick testing in an empty chamber, if applicable (see 13.7.6).	Physical monitoring of cycle External and internal CI monitoring of packages For sterilizers larger than 2 cubic feet and for IUSS cycles, monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.) For table-top sterilizers, monitoring of three consecutive cycles in a fully loaded chamber with a PCD containing a BI. (The PCD may also contain a CI.) For dynamic-air- removal sanitizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack, if applicable (see 13.7.6).	Physical monitoring of cycle Placement of BIs and CIs within product test samples
Note: See Section 15 for general guidelines on how to assess the specific label claims of new products that become commercially available.				

rameters as those programmed on sterilizers located in the CSSD. For guidance on routine monitoring of IUSS cycles, readers should now refer to Section 13.7.2, *Routine monitoring of sterilizers larger than 2 cubic feet*. Qualification testing of dynamic-air-removal IUSS cycles is done by running a commercial BI PCD in an empty chamber in three consecutive cycles, followed by three consecutive Bowie-Dick tests.

Routine Bowie-Dick testing

For dynamic-air-removal sterilizers, AAMI ST79 continues to recommend that: "A Bowie-Dick (Type 2 CI) test should be performed each day the sterilizer is used, before the first processed load." (Section 13.7.6.1) As with BI PCDs, note that while facilities may assemble their own towel test packs, the standard now recommends the use of commercially available preassembled Bowie-Dick test packs. (Section 13.7.6.2)

Summary

All health care facilities that utilize steam sterilization should have a copy of this latest edition of ANSI/AAMI ST79 on hand and accessible to staff. The publication of this new edition provides a great opportunity to revisit your facility's policy and procedures to ensure they are aligned with current guidance. In particular, policies that may need refreshing include:

- with your facilities engineer, alignment of sterile processing area temperature and humidity operating parameters with the applicable ASHRAE 170 standard and a plan on who will monitor these parameters
- loaners
- frequency of testing mechanical cleaning equipment
- the use of internal chemical indicators
- the monitoring of pre-vacuum sterilizers used for IUSS HPN

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CONTINUING EDUCATION TEST • OCTOBER 2022

What's new in AAMI ST79:2017? A review

Circle the one correct answer:

1. **ANSI/AAMI ST79 is the go-to resource for steam sterilization in all healthcare facilities.**
   A. True B. False
2. **AAMI ST79:2017 recommends that staff performing sterile processing activities be certified within two years of employment.**
   A. True B. False
3. **AAMI ST79:2017 recommends that mechanical cleaning equipment be monitored weekly.**
   A. True B. False
4. **HVAC parameters for sterile processing areas should be based on the version of ASHRAE 170 that was applicable at the time the facility HVAC system was initially installed or last upgraded.**
   A. True B. False
5. **AAMI ST79:2017 recommends that one or more internal CIs (preferably Type 5 or Type 6) be placed within each package.**
   A. True B. False
6. **AAMI ST79:2017 recommends that all loads containing implants be monitored with a PCD that contains a BI and a Type 5 chemical indicator.**
   A. True B. False
7. **In documented emergency situations, the Type 5 integrator within the BI PCD may be used for early release of an implant.**
   A. True B. False
8. **Strategies to improve employee comfort in Decontam include staying hydrated and shortened work periods.**
   A. True B. False
9. **For automated washers equipped with a printer, the printer should be located on the clean side of pass-through washers.**
   A. True B. False
10. **Receiving loaner instruments late is a valid reason to perform IUSS.**
    A. True B. False

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The approval number for this lesson is **3M-HPN 21509.**

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The MAUDE Reports

by Stephen Kovach

Q I keep hearing the term MAUDE. What does it mean, is it a report, and why would a medical device reprocessing professional want to know this term?

A Last month, I briefly mentioned the MAUDE Reporting System. Let's focus on that. Simply put, it means **Manufacturer and User Facility Device Experience** (MAUDE). This searchable database (within the U.S. FDA's site) represents reports of adverse events involving medical devices. Many professionals think it is just for manufacturers but that is not true; anybody can fill out a MAUDE report.

"Each year, the FDA receives several hundred thousand medical device reports (MDRs) of suspected device-associated deaths, serious injuries, and malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as health care professionals, patients, and consumers."[1]

Customers often tell me about various equipment not working properly (malfunction of the device) and they feel companies are not listening to them. By filing a MAUDE report, the user (you and your facility) is not identified in anyway in the public data base, thus protected. I also believe before a user submits a MAUDE report, they should in good faith and effort work with the manufacture to try and resolve the issue of concern.

Here are just a few examples I have found in the MAUDE data base. Please note, for this article, I have redacted the reports' information for dates using "xx" and specific companies' names and products with em dashes.

"It was reported initially that the — mono cable had failed. Additional information received on 11/2019 indicated that the incident occurred on xx/xx/xx. It was reported that the nurses stated that the product failure was the plug in the generator, the cord separated and then arced. A 10-minute surgery delay was noted. The patient was prepped for surgery, and the device was in contact with the patient, however, there was no injury reported."[2]

"xx/xx/2019, — company became aware of an issue with one of the washer-disinfector: —. As it was stated, a wrong detergent was used during washing disinfection procedure. There was no injury reported, however with the information available we were not able to confirm how long a wrong detergent was used. We decided to report this issue based on the potential and in abundance of caution as incorrect detergent was used and could affect the final effect of the process."[3]

"— multi-level sonic does not pass efficacy tests when enzymatic detergent is used and dosed at 1 ounce per gallon. Efficacy test and active enzyme test not passing with — enzymatic detergent and check valve on detergent lines were plugged with debris. Once check valves were replaced, efficacy tests were still not passing in all levels, however active enzyme test strip passed. A specific product to test for cavitation did not pass in all levels consistently. Based on the efficacy tests and cavitation test device, this multi-level sonic machine design doesn't have enough sonication power to reach every level when all lumen baskets are tested together."[4]

In all my years of doing Critical Practice Review (CPR), I have seen so many issues that should be reported, and facilities just will not file a MAUDE report. If you have an issue (e.g., malfunction of your equipment) and have tried to work with the manufacture without resolve, using the MAUDE report to share your issue it is one way you can make a change (i.e., a difference in a positive way, not punitive toward any manufacture); at least in this author's opinion. Manufactures are and should be our partner in making a difference, and the better ones are.

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Screen capture:
MAUDE - Manufacturer and User Facility Device Experience

Education nation: the sterile processing renaissance

by Sarah B. Cruz, CSPDT, CRCST, CHL

The Sterile Processing (SP) profession has undergone notable changes in recent years. Veteran SP professionals may recall days when instrumentation was simpler in design and easier to clean and sterilize, personal protective equipment (PPE) involved little more than a pair of scrubs and gloves, and autoclaves had a submarine-door locking mechanism, to name just a few examples.

Today, changes impacting healthcare delivery and the complexity of cutting-edge procedures—and the devices and equipment needed to perform them safely—are stimulating growth opportunities in the SP discipline. The availability of new and emerging information, science and technology is creating a major shift from the "way we have always done it" and instead igniting an educational revolution.

Electronic communication via web pages, email, social media and direct messaging have allowed SP contributors to more readily access new information as it becomes available; as a result, information barriers and education silos that historically existed have begun to crumble. The ease of accessibility has created limitless seats at the information table and is allowing more SP professionals to broaden their knowledge and expertise and improve their services to their healthcare customers and patients.

Professional responsibilities, personal upbringing, and hands-on experience all contribute to the way individuals seek and interpret information. Take, for instance, the implementation of an SP electronic tracking system. An upper-level executive may consider such a system too costly and unnecessary, however, a perioperative nurse may see it as a way to help perform their end count, a manager may view it as a way to assess productivity, an instrument coordinator might consider it the most effective way to track instrument use, maintenance and repairs, frontline workers may see it as a more streamlined way to perform quality checks, and so on. Therefore, the benefits of all big decisions (including capital equipment purchases and educational endeavors) must be carefully explored, with decisions factoring in far more than just the initial expense.

Quality SP educators needed

Education passes on the knowledge and values of a group of individuals and can bridge the gap between one profession's goals and priorities and another's ability to help them achieve them. This exchange and flow of internal information and knowledge creates a multidisciplinary group culture.

An educator's responsibility is to relay information about the group's new shared understanding and how each of their roles impact patient safety. Put simply, an educator serves as a leader, but without traditional management responsibility; this dynamic can promote a more relaxed and trusting relationship between the SP professionals and the educator. In most healthcare professions, the use of an educator/preceptor has become expected. Professions that hire qualified and skilled educators have seen success in multiple areas—including their ability to create more consistent practices, onboard more effectively, and improve employee satisfaction. Still, the dedicated educator is a fairly new role for many SPDs, and one that isn't always easy to fill. While many facilities search for experienced candidates, the positions frequently go unfilled due to a limited pool of educators with critical SP experience. On the other hand, some organizations are forced to hire an educator from a non-SP-related background. Neither result is ideal.

Professional development in the SP space is necessary for both the educator and employees who serve as students. This ensures that educators have the knowledge, tools and resources to develop an effective career ladder program and ensure that all SP team members receive the training and support needed to stay ahead of industry, standard, technology and policy changes, and attain and maintain certifications. Quality educators also define goals and incorporate objectives.

New SP educators must remember that everyone plays a different role in the quest for patient safety, and challenging the way the department has always done something will be necessary and, at times, difficult. SP technicians and leaders will count on the educator to teach and translate new information effectively and consistently across all shifts. Educators may also experience personal biases in the role, so it is important to be aware of that risk and avoid judgmental statements such as "they ought to know," "It's common sense," or "Why can't they just—." Moral uprightness and high mindedness are unfortunate side effects of an SP educator who has used their own professional experience (as opposed to science-based data and information) to propel employee education and training. Personal biases can perpetuate the "this is how we have always done it" mindset and prevent positive changes and knowledge advancement that can benefit the team and the organization.

The fact that healthcare involves many overlapping roles and responsibilities throughout the facility brings pros and cons. While the doctor is held accountable for surgical site infections, the surgical tech maintains a sterile back table, the SP technician assures devices are clean, sterile and well-functioning, and the Infection Preventionist monitors statistics and creates policies to help prevent infections; however, each may lack an understanding of the others' roles and how they contribute to patient outcomes. A skilled and competent educator can help bridge those gaps and promote greater interdisciplinary understanding and perspective, all while helping ensure that SP technicians have the knowledge, training and support needed to grow and thrive in their roles and better meet the needs of their customers.

Conclusion

The SP revolution is making a significant turn toward quality and excellence within the profession. Hiring dedicated, skilled educators is an essential part of this trend, as is ensuring that all available educational resources are utilized to their fullest potential. With the amount of challenging ideas, new information, and pertinent data more readily available, facilities cannot afford to ignore the importance of quality SP educators and the need for greater interdisciplinary teamwork and knowledge sharing. HPN

Pandemic should motivate Laboratory to manage expenses more effectively, efficiently

What might they learn from Pharmacy, Supply Chain expertise?

by Rick Dana Barlow

Photo credit: Paulista | stock.adobe.com

When it comes to expense management within a healthcare organization, three specific departments handle it in three somewhat different but also somewhat familiar ways – particularly involving supply chain and purchased services, which includes segments of labor.

Some may give the highest marks to Pharmacy for how it manages supply chain and purchased services with a specific knack for drug inventory management, tracking and tracing through product and service codes and relationships with distribution partners. Others give considerable credit to Supply Chain for the breadth and depth of sourcing, contracting, purchasing, inventory replenishing, warehousing, tracking and tracing and other related areas on a much larger scale even if they do not have the data standards enjoyed by Pharmacy.

Certainly, Pharmacy and Supply Chain could work together in a complementary way and to an extent, learn from one another. But historically it's more likely for Supply Chain to share expense management expertise with other departments, such as the Operating Room/Surgical Services and Diagnostic Imaging/Radiology, that may be revenue-generating but also carry higher expense streams.

Another similar department in terms of revenue generation coupled with higher expenses is the Laboratory, which has attracted expense management coaching and consulting over the decades by a small and growing number of Supply Chain departments. *Healthcare Purchasing News* has profiled some of these efforts that have yet to reach as much of a fever pitch as it has in the OR, for example.

In recent years, several distributors, payers and service companies have launched programs to help manage the Laboratory expense stream that includes reducing process and product waste; improving product logistics and procurement (e.g., sourcing, selection, contracting, shipping, tracking and tracing); and incorporating clinical value analysis and management in product and technology selection, use and maintenance.

Short of relying on external sources to control, maintain and reduce expenses, Lab could look internally to two examples: Pharmacy and Supply Chain.

How might Pharmacy help?

Experts remain mixed about the contributions of Pharmacy beyond mere observation by the Lab leadership and staff on Pharmacy inventory management and logistics techniques.

Eric Jurinic

Eric Jurinic, Vice President, Corporate Supply Chain, Accumen, presumes that Pharmacy's procedures for negotiating local price agreements and utilizing best practices in process improvement might draw interest.

For Doug Heywood, Managing Partner, RDA, it's the inventory management technology.

Doug Heywood

"It's possible that the automated stations used in Pharmacy could provide support for managing lot numbers and expiration dates," he noted. "However, Supply Chain information systems can also provide similar information."

Pharmacy information systems, by and large, may be directly linked to the systems of their primary distributors for managing orders, pricing and stock. Depending on Lab's supplier agreements, this option may not be available. But Heywood recommends Supply Chain serving as a more appropriate example for Lab when it comes to procurement, logistics and inventory management.

Nichole Hukill

Nichole Hukill, Director, Contract Services, Vizient, however, thinks Lab could learn from and work with Pharmacy's techniques.

"There are a few parallels in inventory management between pharmacy and the lab," she said. "One such similarity is around automated inventory management as both the lab and pharmacy departments have this technology. This provides a seamless approach to both usage and inventory management. Many lab

suppliers offer an inventory management tool that assists in overall lab inventory. It is up to each lab to utilize the inventory management software and weigh the balance of cost versus benefit. One thing about laboratories, to keep in mind, is their incredible ability to have their finger on the pulse of their demands and equally their needs. Due to the regulatory environment for pharmaceuticals, there is much more stringency on who in a hospital can access drugs and different levels of approval."

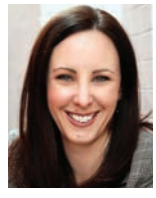
But Hukill pinpoints a notable disconnect in functionality.

"The most distinct difference between the two departments is how they function," she said. "Pharmacy operates to administrate treatment to patients, while laboratory operates to retrieve, analyze and diagnose. Progression in patient care, like that with cancer treatment and effectiveness, can correlate greatly with pharmacy. The formularies of cancer treatment can change based upon testing results."

How might Supply Chain help?

Experts see more of a correlation between Supply Chain and Lab in the area of procurement, logistics and inventory management.

"Because of Supply Chain's visibility across the full hospital system, they are well-positioned to drive purchasing standardization across the various Laboratory sites within their network while collaborating with the Laboratory to ensure clinical efficacy," said Emily Berlin, Vice President, Laboratory Products, Cardinal Health.



Emily Berlin

"Supply Chain typically has more experience in conducting RFPs [requests for proposals] and administering contracts," she continued. "This experience can translate to additional value for the system while allowing the Lab to focus on the clinical aspects of patient diagnosis and testing. Supply Chain's inventory management expertise can be leveraged to provide better system-wide visibility to short-dated materials that are approaching expiration. After these items are identified, they can be reallocated across their sites of care to minimize waste associated with expired inventory. Finally, Supply Chain can use their knowledge of inventory management technologies and solutions that could help labs manage their inventory more effectively."

Accumen's Jurinic questions Lab's resident expertise in supply chain processes.

"We feel that the lab lacks transparency to pricing," he noted. "Lab Directors and higher titles are involved in sourcing activities; however, they are not the people who order products. This is done at the bench tech level who do not always understand [the] cost and impacts of too much inventory, nor have they been trained in proper material management. This is important because when ordering supplies, it's critical to understand the cost implications of ordering too much – spoilage, shipping costs, holding costs, cash flow, etc. Therefore, transparency and training can influence better ordering patterns based on actual demand versus bulk orders or blanket orders because it's 'easy' and 'hands-off.' In some instances, we have seen labs that let their sales rep manage their inventory. For obvious reasons, this is not an acceptable practice."

The flip side involves dedicating lab staffers to do it in much the same way that nurses may search for and order supplies, according to RDA's Heywood.

"Most Labs are using expensive Lab Technicians to order and manage reagents and chemistry items for the analyzers," he said. "Supply Chain techs typically only manage commodity items. The Lab technicians are ordering by 'gut.' Reagents and chemistry items are never optimized for the accurate amount they should be ordering. This exposes the Lab to waste and sometimes missing key utilization criteria to support the analyzer agreements."

Heywood recommends that Lab enable Supply Chain technicians to expand inventory management beyond commodity items in the lab to all items – including chemistry and reagents. In fact, they should "perform inventory optimization on these items to ensure the reorder points and reorder quantities support the terms of the analyzer agreements and don't impact QA testing upon lot number changes," he added.

Expanding Supply Chain's approved influence in Lab shouldn't be a challenge either way, according to Heywood, because "most [materials management information systems] applications can already manage it like any other PAR inventory location. To track lot numbers, you would need a system overlay, similar to what they already use in the Cath Lab or Surgical Services," he said.

Vizient's Hukill indicates that the COVID-19 pandemic brought to the surface additional challenges for the Lab.

"The pandemic brought to light many issues around supply chain that ranged from supply disruption, raw material shortages and overall decrease in supplier and hospital workforces," she said. "The largest disruption in lab has been COVID

What are Laboratory's top cost drivers?

While every department within a healthcare facility maintains its own collection of expense line items in the budget, they all share categorical overlaps when they involve procurement and logistics.

Bottom line: The products may be different, but the process tends to be similar – or at least it likely should or will be, depending on the organization's management. Hence, pharmacy, nursing and laboratory all may acquire products unique to their activities but they may share a standard sourcing and contracting process.

Healthcare Purchasing News identified nearly 20 potential expense issues within the laboratory department and asked a small group of supply chain experts working among providers, suppliers and technology companies to highlight what they feel are top cost drivers in that area. Here's what they shared.

1. Product and equipment pricing
2. Freight/shipping issues (e.g., too many costly same-day deliveries, overnight service, etc.)
3. Budget/expense management in general
4. Data accuracy, analytics, management, science
5. Working with bad/erroneous data (actual or suspected)
6. Waste (e.g., unnecessary product use, testing, etc.)
7. Labor (e.g., shortages, lab techs doing supply chain work)
8. Branded product/preference item demands
9. Clinical decision support services/system (e.g., determining proper testing, procedures)
10. Demand management/predictive analytics
11. Inventory backlogs, delays and shortages due to external supplier issues
12. Inventory backlogs, delays and shortages due to internal supply chain issues
13. Product/service RFP/contract terms
14. Competition from outsourcing/reference labs

What didn't garner votes from among the choices offered: Access to new product and technology, lack of influence within the C-suite, lack of control over sales rep access to organization and managing product recalls effectively and/or efficiently

testing and blood collection tubes. While the market has been better for COVID tests, that is not the case for blood collection tubes and needles. The demand for these supplies was exacerbated by unfilled backorders that took months for distributors to completely resolve or clear out."

If anything, the pandemic-driven supply chain complications only reinforced the importance of Laboratory to healthcare, Hukill insists.

"What these shortages brought to light is that laboratory departments are critical to the overall healthcare system," she asserted. "Quite simply, if tests cannot be conducted, patient care essentially shuts down. With that, the Laboratory department has been and will continue to be fundamental in educating hospital personnel on conservation strategies, such how to limit or stop duplicate testing in order to conserve supplies, as well as limiting additional test-supply orders unless truly needed."

Historically, the laboratory has done very well around logistics and supply chain, according to Hukill. "Due to regulations around testing in the lab, most supplies are kept on a six-month on-hand supply, which helps with the logistical challenges surrounding same lot/expiration dates. Every time lab personnel utilizes a product with a different lot/expiration date, they must revalidate their testing equipment. This causes delay/downtime, extra paperwork and compliance/accreditation issues. It's not uncommon for a lab to purchase a six-month-plus product supply to avoid this extra work, which distracts from patient care and laboratory functions. This means they need a storage area, and [because] many reagents and testing supplies need to be kept cool, refrigeration as well."

Hukill contends the Lab can learn four key tactics from Supply Chain to benefit the department. They include:

- "Automated inventory processes (depending on the laboratory). Currently in the lab these processes are minimal and not as sophisticated – most are manual versus pharmacy with carousels, automated dispensing management and inventory management systems.
- "Differing storage locations for clean/new supplies and patient samples.
- "Contracts for lab equipment designed with specific utilization and purchase requirements for its consumable products so that part of the price for the reagents or consumables is written into the acquisition cost of the equipment (reagent rental). This reduces overall cost;

Status quo in Laboratory should be a no-go from the get-go

Laboratory, for the most part, has operated independently of fellow department "encroachment" (as in Supply Chain) for decades so what might be the harm in Lab continuing the status quo for the time being, if not long-term?

Experts say, plenty.

"We view the way the Lab operates as an evolution to more effective collaboration. We see a three-way collaboration between the Lab, Supply Chain and the Laboratory distributor. Each has an important role to play, with the distributor bringing a broad view across the supply base to help Supply Chain and Lab leaders understand the latest trends and opportunities that exist in the marketplace.

"Labs are looking at implementing best practices and greater adherence to specimen collection protocols, which is a vital step in the diagnostic process and can reduce costs while also improving efficiency. For example, Cardinal Health has a new Laboratory program to address the uncertainty of respiratory testing season, including supply chain constraints, by identifying the level of inventory needed. The program enables healthcare providers the ability to order their identified level of testing products and supports a more consistent supply of respiratory testing products reducing the variability experienced with seasonal testing supplies.

"Effective systems leverage the distinct capabilities of the lab and supply chain. The Laboratory will guide the clinical inputs and requirements while Supply Chain takes the lead on contracting and negotiations. This provides a win/win for patient care and operating budgets."

Emily Berlin, Vice President, Laboratory Products, Cardinal Health

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"The harm is lost opportunity, but also the inflation the Lab has seen over time. With reimbursements rising over the course of 30 years the Lab was left alone to do their own thing. Suppliers took advantage of that, hence the rampant inflation factors [year-over-year] of 2%,3% or even 5% historically. So, in the long term it has and will continue to create massive cost increases, the largest the economy has seen across all product categories.

Today, with reimbursements going down and PAMA [Protecting Access to Medicare Act of 2014], there has been some attention because many labs are now turning into cost centers versus profit centers. The Lab is still a relatively small piece of spend for an IDN [but] it still doesn't get the attention it should. Also from a labor aspect, there is not enough new talent coming into the Lab. There are staffing shortages across the board. It is critical to manage attrition and implement process improvement initiatives so you can operate more efficiently and close out positions as they attrition out."

Eric Jurinic, Vice President, Corporate Supply Chain, Accumen

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"Short term, expensive Lab Technicians are performing inventory management functions instead of spending their valuable time running lab tests that support patient care. Long term, Supply Chain will need to add the required resources to support the inventory management functions in the Lab.

"[Supply Chain] would need to look at labor and current inventory levels in the Clinical Lab. At [a large Texas teaching facility where] we are at, Finance trends Clinical Lab supply expense against tests and noticed peaks throughout the year. Finance wanted to smooth out the trend. The Lab can often order 90 to 120 days of inventory at a time to manage lot numbers."

Doug Heywood, Managing Partner, RDA

"The pandemic highlighted the importance of hospital laboratories and the professionals working and supporting the critical determinates of patient diagnosis and care, who have significantly adapted and ramped up their abilities to meet the challenge during COVID. 'Encroachment' from other departments is welcome as well as a deeper understanding for supply chain and pharmacy colleagues of lab functions. This comes by way of sharing information around supply shortages (e.g., blood collection tubes) and understanding correct coding for proper and full reimbursement. The recruiting and retaining of lab personnel is incremental in the success of hospitals keeping their laboratories in-house rather than being forced to outsource to a third party. The decision to outsource a laboratory should be carefully weighed and takes insight from multiple departments and executive level understanding and support."

Nichole Hukill, Director, Contract Services, Vizient

however, it requires storage space for the consumables and does not allow the institution to switch equipment.

- "Space. Laboratories are short on space for many reasons – equipment size has changed, added automation lines for samples, addition of new service lines, rapid growth in molecular area with covid testing. Space that was previously used for storage are now new laboratory areas. In some instances, storage has taken over hallways/conference rooms, and other areas in central supply."

Lab's priority one for supply chain ops

What's the best first step for the Laboratory to get on track for expense management and supply chain operations? Two contend that it involves selecting an optimal distributor.

"Foundationally, it is critically important that laboratories select a distributor who has the Laboratory-specific expertise necessary to effectively guide them through their product selection and implementation decisions – while serving as their trusted advisor," advised Cardinal's Berlin. "After choosing the right distributor for their lab, to maximize the value of the contract, the Lab's first steps to consider are [to] gain clear visibility into the system's Laboratory purchases across various sites of care, [then] identify opportunities to standardize purchases within the system without sacrificing clinical efficacy. This standardization helps reduce complexity and allows the system to maximize purchasing scale to secure the best price. [Finally,] examine opportunities to convert to private-label offerings where appropriate."

Accumen's Jurinic concurs that an "unbiased third party" can be an asset.

"Companies like Accumen have identified and implemented 15% to 25% savings above and beyond [group purchasing organization] contracted pricing, and they do so 'at risk,' meaning if you don't implement and realize savings Accumen doesn't get paid," he said. "Most labs are accessing GPOs and most IDNs don't have dedicated lab experts in supply chain. Therefore, they are merely accessing GPO pricing, and arguably the GPOs are not experts in the lab. We've found that you can still purchase through your GPO contracts and remain compliant but enhance pricing at the same time utilizing local contracts.

"At the very least, all hospitals should look from the top down at major contacts and assess the opportunity, but this takes diligence and focus because after all it's only going to be about 3% of the total health system spend," Jurinic continued. "But an IDN could have $20 million, $30 million, $40 million in untouched supply and purchased service spend and 'sitting in the basement,' which could equate to millions of savings opportunities. You must be focused though and ready to change an area of the hospital that has historically operated on their own and can be resistant to change!"

RDA's Heywood recommends Lab to analyze their data, inventory optimization and compare utilization against the analyzer agreements to ensure terms are being met.

But he realizes that such strategies require consulting with Supply Chain.

"Supply Chain would have to meet with the Clinical Lab Director to gain access," Heywood admitted. He referred to an RDA consulting contract at a large teaching facility in Dallas. "For our engagement in Texas, it was the Vice President of Ancillary Services that made the request. There is currently a severe shortage of Lab Techs. It was a strategy to remove a task from their daily routine. The system we are working with has 13 clinical labs spread out throughout the city.

Inventory management is just one part of the equation for laboratory costs, according to Vizient's Hukill. In fact, labor and reimbursement also matter.

"While labor is the largest cost for a lab, understanding reimbursement is also key," she indicated. "The Protecting Access to Medicare Act of 2014 (PAMA) has been delayed for quite some time, but changes in reimbursement are scheduled to occur in 2023. Appropriate reimbursement is essential to prevent labs from eliminating tests, laying off employees and reducing services for patients who rely on quality testing. Overall laboratories need to have a clear understanding of coding, billing, compliance and true unit costs for accurate expense management." HPN

ADVERTISER INDEX

VALUE. DELIVERED.

Rise in recalls and paperwork highlight a missed UDI opportunity

by Karen Conway, Vice President, Healthcare Value, GHX

This month, we return to a perennial topic, recall management, prompted in part by the latest Sedgwick Recall Index[1], which shows significant increases in the number of medical device recalls, as well as a conversation I had recently that highlights the continued missed opportunity to use unique device identifiers (UDIs) to expedite and streamline the recall process.

Let's start with the conversation. It occurred during the first meeting of the Strategic Marketplace Initiative (SMI) Clinical Integration Council's data enablement subgroup. On the call, I noted that a primary driver for the US FDA UDI rule was to improve recall management. When calculating the economic impact of the regulation, as required under the Paperwork Reduction Act, the federal government justified the cost to manufacturers by noting how UDIs "could more effectively target and manage medical device recalls." On the call, Jack Koczela from Froedtert Health showed the subgroup the stack of recall notices he had received in just a matter of days. (See photo below.) Clearly, as subgroup co-chair Ginger Henry from Legacy Health noted, "We have not reduced the amount of paperwork."

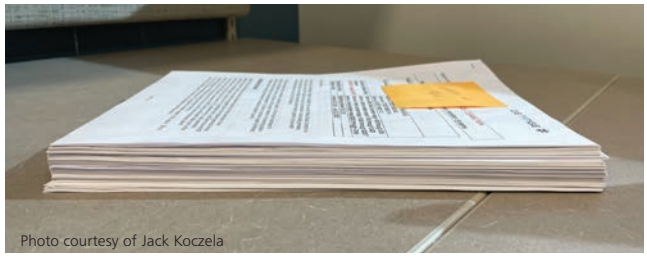

Photo courtesy of Jack Koczela

Part of the problem is that the vast majority of recall notices are still paper-based documents physically sent to providers and distributors, according to the UDI Impacts on Recall Management Work Group Report from the AHRMM Learning UDI Community.[2] Also, while some progress has been made over the years, many notices still do not include UDIs. The FDA only lists the UDI as one of several ways that manufacturers can identify recalled products, and as the AHRMM report notes, manufacturers say a lack of an "explicit requirement from the FDA and/or health care providers" is a primary barrier to their greater use of the UDI in recall notices.

Let's explore why this is a problem. To realize the full value of UDIs for recall management, both providers and suppliers need to incorporate the standard identifiers in their technology systems in order to automate processes. On the hospital side, that would entail using UDIs in purchase orders, in inventory management systems, and (at a minimum in the case of implantable devices) in electronic health records. That way, in the event of a recall, providers could rely on technology, not people, to search the records to determine 1) if the product in question had been purchased, 2) if it is being stored somewhere and/or 3) if it was used on a patient and if so whom. Unfortunately, when the UDI is provided in a paper-based document, such as a pdf, providers must at a minimum manually transcribe the information into their internal systems or databases to generate a query. But automated matching is still dependent upon the hospital having used the UDI as a standard way of identifying and documenting products.

In light of the continuing labor shortages plaguing hospitals, the use of UDI to reduce manual processes and associated paperwork takes on even more significance, especially given the recent increase in the number of recall events. The Sedgwick Recall Index found that in the second quarter (Q2) of 2022, the number of medical device recall events grew 34 percent over the prior quarter, hitting the highest per quarter number in five years. Among those recall events, the primary reason was safety, marking only the second time in six years that safety has topped the list. More importantly, the number of Class I recalls, in which the FDA believes there is a "reasonable probability" use of the product could cause "serious adverse health consequences or death," grew nearly 25 percent compared to Q1 and reached the highest level in more than 15 years. Unfortunately, early July data also raises alarm bells, with increases in both the monthly average for the number of recall events and in the number of units impacted.

That said, there is some good news to report. Since 2016, there has been a marked increase in the use of UDIs in recall notices, from virtually none to up to 25 percent in 2021. But inconsistencies remain in how that data is displayed. For example, in a recent defibrillator recall, one manufacturer identified the recalled products in a pdf by listing several GS1 Global Trade Item Numbers (GTINs), which are UDI compliant device identifiers, followed by a listing of the serial numbers associated with each GTIN. A much more effective approach would have been for the manufacturer to provide the information in a in a standardized digital electronic format and to have included the full UDI, which includes not only the device identifier, but also the production data, such as lot or serial number and expiry date.

While disappointing, this is not the time to give up on UDI. The vast majority of medical devices, regardless of class, now bear UDIs, and clearly from the increased inclusion in recall notices, the market is more aware of what they are and their value. Now it is a matter of encouraging greater use by providers and helping manufacturers understand why and how their customers can use the identifiers. It's both a labor reduction and response timing issue for providers, a matter of reputation management and customer service for manufacturers, and most importantly, a safety issue for patients and clinicians. We've got the tool; now we just have to use it. HPN

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[1]2017-2021 IQVA data and MicroAire sales figures.