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Rick Dana Barlow **Senior Edior**

BUYLINE

SPD is critical

The 30th anniversary of anything good tends to be special, except maybe if you just turned 30 and finally have to embrace (begrudgingly) the niggling discomfort of this thing called adulthood and leave "adulting" behind.

Honestly, if Neil Sedaka could pen a follow-up to his famous 1960 song, he likely would title it, "Growing Up Is Hard To Do."

Three decades ago, Hospital Purchasing News (our name just before the Clinton Administration's healthcare reform sent the industry all atwitter) wanted to recognize a key reader-

ship demographic it had been covering since the magazine's inception as *Purchasing* Administration back in April 1977 - Central Service. Today, we refer to the profession as Sterile Processing & Distribution (SPD).

And, before we continue, if you do the math, that makes Healthcare Purchasing News 45, which equates to the longest-running, independent and unaffiliated, continually published chronicle of SPD in the industry. With pride, HPN remains the undisputed grandaddy of SPD editorial coverage - even as many have fallen away or emerged and then re-imagined.

In short, you're holding a piece of history in your hands.

This edition profiles and salutes the 30th recipient of HPN's SPD Department of the Year Award, NorthShore University HealthSystem. We consider it a proud distinction and we are thankful that so many respect this honor - as well as the concerted and considerable effort that goes into it. That includes crafting and completing a detailed nomination to submit for editorial staffers and editorial advisory board members (who are veteran SPD professionals in their own right), as well as the leader of the previous year's SPD Department of the Year to read and assess.

When a winner is chosen from a small group of finalists selected from the pool of nominations received (and we read ALL of them), then the leader(s) of that venerable SPD department participates in a series of detailed interviews (30-plus questions minimum) that will serve as fodder for the written profile of the winner. In case you doubt the previous sentence, just ask any leader of an award-winning SPD department (we update the list annually and post it online) and it would be shocking if he or she doesn't chuckle, harrumph, and roll their eyes in exasperation like after an Olympicstyle competition.

It's that important; it's that meaningful; it's that necessary.

We may be biased, but we feel the annual SPD Department of the Year reveals what is best within the industry - beleaguered as it is by a media and public that really does not comprehend or understand the complexities, dedication and stringent adherence to administrative, financial, operational, biological and clinical regulations and requirements. In many cases, failure to comply can lead to death. Outside of random acts of violence, not too many professions can lay claim to such a pressurized existence.

NorthShore, as well as its three respectable and respected finalists - HonorHealth, Stony Brook Medicine, and Terrebonne General Health System (which also happens to be HPN's first Supply Chain Management Department of the Year Award winner back in 2004) represent SPD quality across the board.

The SPD professionals assessing this year's quartet of finalists marveled at their focus and resolve as they navigated through crises and other obstacles, such as management changes and operational and process upheaval. All dealt with the pandemic, of course, but one worked through a hurricane. Some chose to excise the use of ethylene oxide sterilization and immediate-use steam sterilization (flashing). They cross-trained people amidst labor shortages, but also strove for career development, diversity, and solidifying teamwork as they progressed.

Through it all, recognize this: These organizations should be celebrated for what they did and do. But they are not alone, nor are they exceptions to the rule. There are many others doing their best work but perhaps receiving little to no recognition.

Change that.

Know this: No matter what anyone says, healthcare cannot exist without Supply Chain and healthcare certainly cannot persist without SPD.

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FAST STATS

According to a study conducted by the University of Michigan, Americans are falling more every year (approximately 1.5%). The reasons for this and what we can do to mitigate the problem are not quite as clear, however. Indeed, one cause for the increase in falls could relate to the fact that we are getting more active in our senior years. The UM study, which was based on an analysis of insurance claims for adults 65 and older from 2016 to 2019, illustrates the following:

4.5 MILLION

older adults in the U.S. are affected by falls based on studies from 2016-2019.

106,000

average new fall injuries annually in adults aged 65 and older from 2016-2019.

\$15-\$30 BILLION

is the Medicare cost annually for the injuries and trauma resulting from falls.

1.5%

increase in falls in the U.S annually. However, there is a wide variance in terms of geography, with persons in the Central Plains and Southern states reporting the most falls.

1.8%

average annual increase in fall injuries per 100,000 person-quarters in counties in the 90th percentile and a 5.6% overall increase since 2016.

1.5%

average annual increase in fall injuries per 100,000 person-quarters in counties in the median percentile and a 4.5% increase since

2.1%

average annual increase in fall injuries per 100,000 person-quarters in counties in the 10th percentile and a 6.4% overall increase since 2016.

75%

higher rate of falls in countries that are in the 90th percentile for injury rates than in countries in the 10th percentile.

https://news.umich.edu/more-adults-are-falling-every-year-despite-prevention-efforts/#

https://www.hpnonline.com/surgical-critical-care/article/21257986/more-adults-are-falling-every-year-despite-prevention-efforts

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NEWSWIRE

ECRI annual report emphasizes COVID's impact on healthcare workforce

Staffing shortages and healthcare workers' mental health top a list of patient safety concerns released by ECRI. While the annual list is typically dominated by clinical issues caused by device malfunctions or medical errors, Emergency Care Research Institute (ECRI) researchers say the most significant concerns at present are caused by crises that have simmered, but COVID-19 exponentially worsened.

While both trends were known, their effect on patient care was not well documented. Now, ECRI researchers say inadequate staffing is actively jeopardizing patient safety. Due to staffing shortages, many patients are waiting longer for care, even in life-threatening emergencies, or simply being turned away.

With reports of more healthcare workers planning on leaving the industry, ECRI experts say patients could face even higher risks without proactive solutions. Without intervention, the chaos and understaffing in hospitals and other healthcare settings seen over the last two years could become the new normal for the foreseeable future.

"ECRI's report is a roadmap to help prioritize patient safety initiatives and allocate necessary resources that accelerates organizations in their total system approach to safety," said Brigitta Mueller, MD, executive director of patient safety, risk and quality at ECRI. "We are here to help healthcare and government leaders as they finally address these longstanding issues in a comprehensive, forward-thinking way."

To identify the most pressing patient safety threats, ECRI analyzed a wide scope of data, including scientific literature, patient safety events or concerns reported to or investigated by ECRI, client research requests and queries, and other internal and external data sources.

The top 10 patient safety concerns for 2022 are:

- 1. Staffing shortages
- COVID-19 effects on healthcare workers' mental health
- 3. Bias and racism in addressing patient safety
- 4. Vaccine coverage gaps and errors
- 5. Cognitive biases and diagnostic error
- 6. Nonventilator healthcare-associated pneumonia
- 7. Human factors in operationalizing telehealth
- 8. International supply chain disruptions
- 9. Products subject to emergency use authorization
- 10. Telemetry monitoring

APIC reports alarming rise in HAIs

As the world enters the third year of the COVID-19 pandemic, the Association for Professionals in Infection Control and Epidemiology (APIC) is issuing an urgent call-to-action to shore up the nation's infection prevention and control (IPC) infrastructure.

Even before the pandemic, hospital IPC programs were underfunded and understaffed. The pandemic exacerbated those patient safety weaknesses, leaving healthcare facilities with insufficient capacity to prevent common, often deadly, healthcareassociated infections (HAIs).

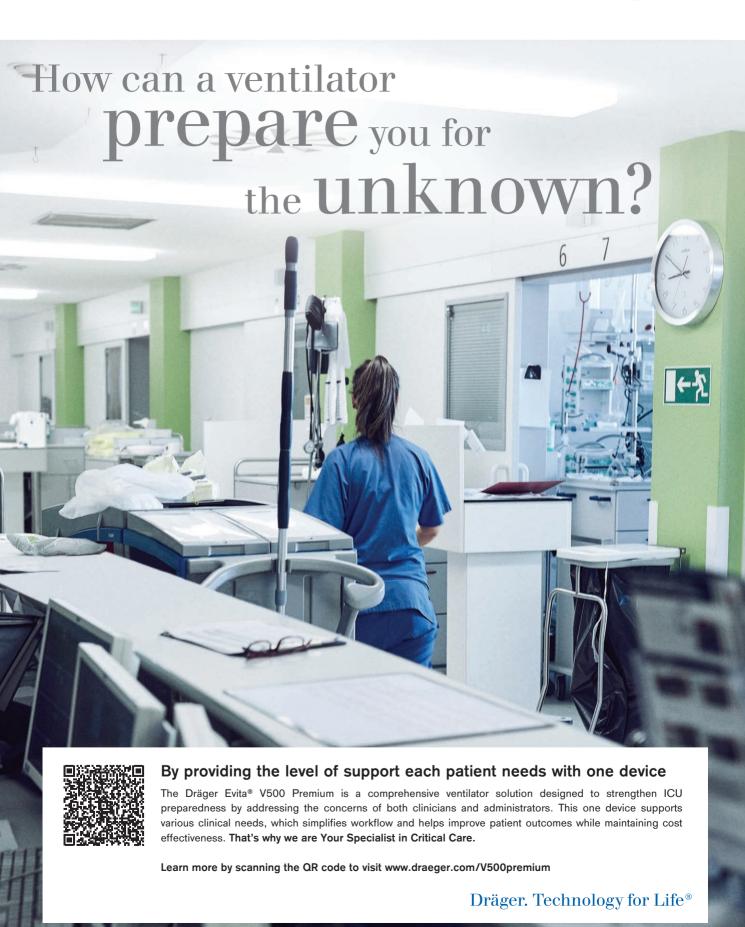
APIC published the report, BETWEEN A ROCK AND A HARD PLACE: Recommendations for Balancing Patient Safety and Pandemic Response, provides an extensive set of strategies to increase the IPC workforce, strengthen prevention programs, and build resiliency for future pandemics.

"APIC is issuing this call-to-action as we all recall the nightmare of extensive supply shortages and overworked health-care workers," said APIC 2022 President Linda Dickey, RN, MPH, CIC, FAPIC. "Especially troubling to APIC is how many preventable infections were transmitted inside hospitals during COVID because that resilience was not built into our healthcare system."

In the report, APIC urges policymakers to allocate funding to build IPC surge capacity to ensure the continuity of safe patient care during a pandemic. The specific recommendations from the 66-page report include:

- Develop next-generation universal PPE for a one-size-fits-all device to protect healthcare workers
- Normalize the use of masks by the public during outbreaks of infectious diseases, building trust among the American people of their effectiveness
- Address supply chain failures to ensure greater diversity in production locations and expanded ease of access
- Require that health facilities include personnel with IPC expertise on emergency response teams to ensure the safety of response practices
- Protect nursing home residents ensuring that each nursing home has at least one dedicated infection prevention expert on staff
- Build and implement IPC surge capacity to ensure the continuity of safe patient care during a pandemic
- Increase capacity for testing and contact tracing to control disease spread during a pandemic





NEWSWIRE

- Ensure rapid healthcare data collection and sharing to optimize strategies to prevent disease transmission
- Build vaccine confidence to combat misinformation and dissuade hesitancy
- Fund pandemic preparedness workforce capacity and training with incentives for universities to create a pathway to the infection prevention profession

In 2021 the Centers for Disease Control and Prevention (CDC) documented a sharp rise in healthcare-associated infections (HAIs), which had been steadily decreasing prior to the pandemic.

Because of the strain that the pandemic put on the entire healthcare system, central line-associated bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), ventilator-associated events (VAE), and Methicillin-resistant Staphylococcus aureus (MRSA) have increased exponentially.

HAIs can often be prevented through careful monitoring and safety protocols overseen by IPC specialists, but only when there are sufficient resources and trained personnel in place to support these efforts.

"For the U.S. to create a safer, more resilient healthcare system, policymakers should make the substantial investments recommended by the hands-on infection

prevention experts who had a unique vantage point as the pandemic overwhelmed hospitals, nursing homes and clinics nationwide," said Dickey.

"We need to build capacity so we can surge when we need to," said APIC CEO, Devin Jopp, EdD, MS. "I won't sugarcoat it; fortifying our nation's IPC infrastructure isn't free, but the cost of ill-preparedness in lives and dollars is incalculable."

To help healthcare facilities assess their IPC capacity, APIC is launching a new campaign called HAI Fast Forward: Accelerating HAI Prevention. It will include a series of initiatives to help organizations make headway in reducing their HAIs back to pre-pandemic levels.

WHO launches new healthcare database

The World Health Organization's new Global Health Facilities Database will be a key resource to help countries provide access to healthcare services for all populations.

The COVID-19 pandemic has revealed urgent gaps in countries' current ability to locate health facilities, impeding progress to provide equitable access to therapeutics, diagnostics, and vaccinations through the ACT-Accelerator and other initiatives.

As a standardized and open access repository of health facility information, the database will provide critical insights to deliver primary healthcare, especially during emergencies. It will also leverage the power of geospatial data to map health facilities in relation to communities and help bridge long-standing inequalities in access and use.

The database will include a digitized master list of health facilities with name, location and type coded by a unique identifier. At the start, it will host data for 46 countries representing 40% of the world's population with the aim of including all 194 WHO Member States by 2027.

It will be regularly updated and maintained by WHO in line with best practices on data governance, data sharing and WHO's data principles in agreement with participating countries.

The database is being established in response to the Eleventh Session of the United Nations Committee of Experts on Global Geospatial Information Management (UN-GGIM) which underscored the need for this resource to be made available as a global public good. The database will be made publicly available by the end of 2022. HPN











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upply Chain consistently strives to control costs and expenses as much as possible, based in part on C-suite demands for the department's functionality and role. One over-arching way to accomplish that is to know the organization's total costs through tracking, tracing and linking to clinical, financial and patient care systems one of which is the electronic health record/ electronic medical record (EHR/EMR), where asset consumption and usage is (or should be) noted.

Imagine being able to apply supply and service consumption data to a single patient that extends to the item master and inventory management on one hand and to billing, reimbursement and revenue cycle on the other? That's closing the loop.

Imagine Chevy Chase's Clark Griswold character in "National Lampoon's Christmas Vacation" connecting the elaborate house lights for the first time. If you remember that pivotal scene, you have a decent grasp of the healthcare supply chain's universal link to EHR/EMR systems - not as widespread as it should be among healthcare organizations yearning to rein in costs, but plenty of room for illumination and improvement.

Standard interfloperability?

Short of an intricate (and dangerous) array of plug-in extenders dangling from the fuse box in the Griswold family garage, questions continue to linger as to why - nearly two decades after President George W. Bush created a sub-Cabinet position to promote national adoption and implementation of EHR/EMR systems that became a mandate

a decade later - healthcare organizations are not farther along in the process.

Further, questions remain beyond simple adoption and implementation of EHR/EMR for patient and payer benefits - the clinical and revenue side of the financial component - but generally fall short of the expense side of the financial component.

What will it take for healthcare organizations to compare the challenges of linking Supply Chain systems to the EHR/EMR system versus the challenges of keeping them separate? Are the benefits of interfacing or integrating too operationally painful to endure or are the perceived benefits not yet worth the pain?

Supply Chain IT experts agree.

"The challenges of linking the item, its

identifiers, metadata, and cost data or what we refer to generically as supply chain data, are limited to only technical obstacles and data quality barriers," said Marlin Doner, Vice President, Data Analytics



Marlin Doner

and Product Strategy, Prodigo Solutions. "These are obstacles Supply Chain should be overcoming in its pursuit of modernization and transformation. As an industry, healthcare needs to be adopting data standards and employing best-of-breed technologies that enable the seamless sharing of digital assets. We refer to this as interoperability of data.

"Supply chain is the entry point not just of the 'physical' product; it is also the custodian of the 'virtual' item, the associated attributes,

and the contracts that define the item cost," Doner continued. "As a result, data needs to be accurate (connected to a source of truth), managed (kept updated throughout the chain of custody), and connected (shared) across the organization's technology ecosystem."

Doner posits that the problem may wrest within the systems themselves or even the data. But in the face of delivering quality patient care that should not be an excuse.

"Admittedly there are challenges to making this happen - systems don't talk to each other in a common language, item identifiers are not consistent, data is not complete or accurate, item costs are variable, and the list goes on," he noted. "Whatever the challenges are that we've identified, the risk to patient care, where we manage data independently within the operating silos of supply chain and the clinical enterprise, are far greater. The foundation of the Cost, Quality, and Outcomes [CQO] movement is compliance. Without seamless integration of data across the entire ecosystem you cannot control the point of entry for new items, record accurate procedural costs, drive clinician efficient at the point of care, or audit your clinical practice."

Ashok Muttin, Founder and CEO, SupplyCopia, believes cost and revenue represent two faces of the same coin so healthcare organizations should not stumble over any manufactured barriers.



Ashok Muttin

"Unless and until both are addressed with the same

amount of commitment, cost and revenue remain lopsided," Muttin said. "It's not a

PRODUCT & SERVICE LINE REPORTS

question of whether they should be integrated but when. If we believe a human body needs to be treated in its entirety for longevity, then in a similar way, the health of an organization will depend on treating the cost and revenue at the same time."

Muttin points to cost-related data residing in multiple systems, such as order management and contract management, while other vital information concerning procedure, utilization per procedure, patient demographics and procedure outcomes are captured in the EMR/EHR. He lists six hurdles that complicate any necessary connectivity.

- Lack of data standardization: "Different software vendors provide these critical systems, so no shared data standards can be used to integrate the systems."
- System integration: "While the ERP [enterprise resource planning] providers have been very open to publishing their data standards and APIs [application programming interfaces] to hook into their systems, the EMR/EHR vendors have been less receptive to this option. It remains difficult for third-party vendors to integrate systems."
- Lack of in-house skill sets: "Even large IDNs have difficulty hiring and retaining top-level IT talent, so they often rely on third-party integrators. The situation is even more severe for smaller organizations, with neither skill nor budget."
- Legacy systems: "Some hospitals are still using ERP or EMR/EHR systems that are behind firewalls, i.e., not on the cloud. In these situations, it becomes even more challenging to integrate the data, systems and processes."
- Cost: "Even for some of the larger organizations, the cost of integration tends to be relatively high, and change management requires serious commitment."
- Mindset and compliance: "We see an openness in supply chain management to integrate with the EMR/EHR systems but less so in the clinical and financial side. This may be due to keeping the revenue/reimbursement as 'need to know' or regulatory requirements."

The benefits of connecting your ERP to

your EHR/EMR significantly outweigh the challenges of implementing, linking and maintaining that integration, according to Melissa Amell, Director, Industry & Solution Strategy, Infor.



Melissa Amell

"Most of the time it comes down to challenges of technology, data standards, knowledge-skill set, FTE-time to build, maintain and monitor, and expense both internally from an ownership perspective or if you buy an annual managed service who implement and maintain the connections," Amell indicated. "So many data and business processes efficiencies can be gained throughout dayto-day healthcare business operations and ultimately a positive effect on patient care and safety, to include not only patient safety, but caregiver safety. By understanding business process and defining a system of record up front, your data will be more consistent, you will reduce manual workarounds and be able to standardize and streamline work so that FTE times can be focused on providing value, not performing non-value-added tasks that could be automated."

Amell envisions the ERP to serve as an organization's supply chain, finance, and HR system of record and the EMR should be the clinical and patient system of record. For example, in Supply Chain the ERP should be the system of record for all product and product pricing information and should send that information to the EMR, keeping it updated with any add/changes and deletes, she notes. "Once that it is in place the product data in the EMR can be used on preference cards, patient charting, documentation and charging. This example is just the beginning of what can be done, and with today's technology, we should be exchanging more and more data within these systems to support defined business processes," she added.

Keith Lohkamp, Senior Director, Industry Strategy, Workday, stresses the "master data"

concept overshadowing the data pocket viewpoints of the past.

"Interoperability among systems for master data is vital to supporting efficient and effective delivery of care as well as accurate charting and billing," Lohkamp



Keith Lohkamp

said. "As providers move their supply chain systems to the cloud, we see them taking advantage of this effort to link these systems to their EMR system to ensure that item master data and cost data is regularly sent over. This automation of master data ensures that both the ERP and the EMR have the same definition of an item and the same cost. In addition, any analytics that pull from either system will have a common definition.

"When these systems are separate, providers risk incomplete billing, inaccurate costing and more manual steps to reorder," he added. "Closing the loop becomes much more difficult as data will need to be cleansed and standardized before analytics become useful."

Chris Luoma, Senior Vice President, Global Product Management, GHX, urges looking at the big picture and backdrop of this IT connectivity. He posits that the average item master comprises about 70,000 SKUs.

"When the ERP and EHR/EMR are integrated, the item master expands easily to 600,000 SKUs due to the greater number of products that may need to be documented in a clinical environment," Luoma said.



Chris Luoma

"Systems integration at this level requires more sophisticated data management capabilities to create and support an enterprise-wide item master that can fuel business processes. This will require either staff, resources and budget that many hospitals don't have or a partnership with a third party that has systems and data integration expertise."

Not surprisingly, when the ERP and EHR/EMR aren't linked, they operate in silos so greater levels of data synchronization are required to ensure data integrity, according to Luoma. "The work is tedious and requires significant budget and staffing resources to mitigate the errors that arise from different data formats, multiple databases and many users," he noted. "Additionally, a lack of standards like UDI [Unique Device Identification] prevents organizations from performing downstream analytics that require merged data sets, such as cost-per-procedure analysis."

Luoma recognizes the need to move to a "value-based care model" but acknowledges that that requires an understanding of the true cost of care.

"We can't do this efficiently, accurately or effectively with siloed data and unintegrated business processes," he asserted. "Integrating systems helps ensure the integrity of the data feeding financial, operational and clinical systems and better align business processes. The long-term benefits outweigh the initial effort and investment of linking systems together."

Risk versus reward

While Supply Chain IT experts acknowledge that the rewards and benefits of EHR/EMR systems integration far outweigh ignoring or postponing the actions, they also lament the challenges may be discouraging to some – not unlike dieting and/or working out to improve fitness and physique.

SupplyCopia's Muttin recognizes the advantages of integrating the supply chain procurement to EMR/EHR as being so "huge" that he hails the strategy as the "holy grail of future organizations."

PRODUCT & SERVICE LINE REPORTS

With such connectivity, a healthcare organization can achieve five tenets, according to Muttin. They can:

- "Flawlessly implement a CQO process and integrate the stakeholders including supply chain, physicians, finance and contracting."
- "Gain 360-degree visibility into every procedure cost, then tightly integrate patient outcomes with cost to proactively measure and manage both."
- · "Work with physicians to manage physician preference item costs, and even change physician behavior."
- "Leverage a working platform and process model for increased visibility to spend and better demand management.
- "Deliver improved patient care," he listed. Prodigo Solutions' Martin Doner applies a consumer-minded analogy to the process to illustrate the tension.

"Think of your frustration in the grocery store self-checkout line when you scan an item that the system does not recognize," Doner noted. "Now translate that experience to healthcare. We should expect no less level of service when it comes to the accuracy of our 'bill' when it comes to the healthcare we receive."

According to Doner, while price transparency may have been required for healthcare only a small percentage of hospitals were compliant with the Centers for Medicare and Medicaid Services (CMS) mandate. He cited a February 2022 report titled "Semi-Annual Hospital Price Transparency Compliance Report" from Patient Rights Advocate.org (https:// www.patientrightsadvocate.org/semiannual-compliance-report-2022).

"Every industry must know its costs to understand the relationship between the cost to deliver its goods and services and the price it sells those goods and services to its consumers," he insisted.

But Doner quickly pivoted from blaming hospitals alone.

"Transparency is not wholly the responsibility of the provider," he said. "This is an industry challenge, from product identification to complex pricing incentive programs built into contracts, to technology limitations around data management and the lack of industry-wide adoption of data standards. We all share responsibility to solve these industry challenges. These are not technical obstacles. We need to establish open channels for data to flow between the manufacturer and care provider, we need to be more transparent within supply channels to align supply with demand, we need to adopt standards which enable interoperability and reduce friction across the supply chain."

Joerg Schwarz, Director, Industry &

Solution Strategy, Infor, injects some realism into the mix that probably should have been addressed by this point in the 21st century.

"It is harder to connect



Schwarz encourages providers to develop use-cases that demonstrate the value of connecting the two worlds so that manufacturers of clinical systems and operational systems can build the necessary interfaces and provide insight into business operations and improved usability.

data interchange] standards on the supply

chain side, but there is no standard crosswalk

between clinical and operation interoper-

ability," he added.

He foresees this connected world generating at least four specific benefits that enable providers to do the following:

- "Utilize clinical data as a predictor for supply needs. Many elective procedures are scheduled weeks in advance, so it is possible to utilize the data from the clinical system to inform the supply chain about required supplies."
- · "Deplete on-hand stock based on clinical data. Instead of dual data entry or manually tracking down supplies, activity recorded in the EMR can be utilized to re-stock supplies, while also preventing provider burnout from unnecessary clerical tasks."
- · "Predict workload and skills required for nursing staff based on clinical data - which helps to optimize resource allocations and provider satisfaction."
- "Assess the actual cost of delivering a specific service/DRG by combining clinical data with financial and HR data for activitybased cost analysis. This allows not only root cause analysis of cost overruns, but it also allows providers to contract for bundled payments and risk/value-based models." Infor's Melissa Amell also calls for "holistic product standards" to join interoperability

standards. "Currently in today's environment there are multiple standards, which contribute to variability and the lack of visibility in the healthcare supply chain," she added.

The primary advantage of linking these systems is unlocking the value of data, according to GHX's Chris Luoma.

"Data only serves the business when it is integrated into every business process across the care continuum and healthcare operations so that providers can make data-driven decisions aimed at balancing cost, quality and patient outcomes," he indicated.

Adopting a "modern item data strategy" that links the ERP to the EHR/EMR will improve the order management process, making it more efficient by reducing waste and costs, Luoma notes.

"It helps ensure clinicians will have the items they need when they need them. And it can capture more charges in the revenue cycle because a complete record of items used at the point of care is synched with the EHR/ EMR," he said. "Further, this level of integration will help advance the evolution of care outside the four walls providing a data strategy foundation that will support demand for new supplies - in new, dispersed locations - as well as point-of-care systems that enable accurate capture and sharing of data."

Yet Luoma acknowledges that securing the staffing resources and expertise to "build an item master that supports 'just-in-time' inventory for ERP systems and 'just-in-case' inventory for EHR/EMR systems remains a key barrier. This is why many providers are turning to data services organizations to support their integration efforts, he adds.

"Data services organizations curate information from a wide variety of sources - suppliers, providers, industry repositories such as GUDID, contract catalogs - and deliver the appropriate items with the appropriate attributes at the right point in time," Luoma said. "Without question, integration of business processes requires a strong foundation of item data. And, as more hospitals move to a cloud-based ERP environment, they will need the ability to efficiently manage a massive body of data without having a team of 30+ experts managing item data. Given this, choosing a data service to support the depth and breadth of item management allows the investment in supply chain systems systems to serve as the source of truth and feed the EHR/EMR." HPN

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Respiratory care in critical times

Profession struggles to catch its breath in approaching crisis

by Kara Nadeau



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he respiratory care profession and field of medicine have been under siege over the past two years with the COVID-19 pandemic driving unprecedented patient volumes at a time when there is a severe shortage of respiratory therapists (RT).

The National Board for Respiratory Care (NBRC), the American Association for Respiratory Care (AARC) and the Commission on Accreditation for Respiratory Care (CoARC) released the results of a recent survey of respiratory care leaders on their joint MoreRts.com website. Nearly 9 in 10 respondents agreed or strongly agreed there is a current, local shortage of RTs, and 84% think a shortage of RTs in the future is likely or very likely.¹

In a healthcare environment where there are increasingly more patients with respiratory conditions, not only COVID-19, but also chronic illnesses such as asthma and chronic obstructive pulmonary disease (COPD), the number of RTs is rapidly shrinking. The survey also found:

- 93% of RTs say burnout is a major issue with 72% saying they are feeling the effects
- 92,000+ RTs will retire by 2030, while healthcare needs to retain more than 155,000 RTs to meet current patient needs

• 27% decrease in RT education program enrollment, with only 10% of programs at capacity, while there is a 19% projected increase for RT jobs by 2029¹

While respiratory industry associations, healthcare organizations, and RT schools are working to retain current RTs and recruit new people into the field, there is also a role and responsibility for respiratory care suppliers to help support and sustain the profession.

"Equipment providers and manufacturers can raise awareness of the profession by recognizing its employees who are respiratory therapists," said AARC President & CEO Sheri Tooley, BSRT, RRT-



Sheri Tooley

NPS, CPFT, AE-C, FAARC. "Furthermore, we encourage them to participate in community activities, which will also increase awareness of the respiratory therapy profession. Thinking beyond the hospital, highlighting the value of respiratory therapists working in non-traditional settings, such as clinical specialists and product development, will help our communities understand the depth of the profession's skills and its prevalence in caring for patients."

"As we look ahead, our basic need is to have more persons aspire to become respiratory therapists. This growth can only happen if career seekers are first aware of the existence of our profession," Tooley added.

Why are suppliers important to the RT profession?

On the surface, the role of suppliers in respiratory care is clear; they provide the supplies, equipment and services needed for patient care delivery. The AARC and Boston Scientific conducted an online survey of 87 hospital-based respiratory therapists, managers and directors in the U.S. from July 9 to August 9, 2021. When asked what their barriers to patient care were, the top answer was talent/being understaffed at 67%, which is no surprise. The other top responses were associated with technology and workflows, with 65% of respondents naming technology availability/functionality/performance as a barrier, 45% operational inefficiencies, and 37% lack of training.

When asked for three procedures where they want to see advancements, RTs named:

- Mechanical ventilation to decrease barotrauma and improve modes (50%)
- Secretion management to provide smaller, more effective removal solutions (41%)
- Aerosol therapy to deliver higher quality nebulizers with shorter deposition (35%)²

How can suppliers help?

Clearly technological innovation is important to alleviating the burden on RTs and helping them deliver patient care more effectively and efficiently, but supplier support of education, training, and leadership development may be just as important.

Innovate with technology

"No one party can solve the current RT shortage crisis, it will take multiple stakeholders coming together to determine how to retain experienced RTs and attract a new generation of individuals to the profession, including healthcare organizations, industry associations, colleges and universities, and those who provide products and services to the field," said Edwin Coombs, MA, RRT, NPS, ACCS, FAARC, Senior

Marketing Director for Portfolio Solutions Training, Clinical Affairs & Intensive Care in North America, Dräger.



Edwin Coombs

One way that respiratory care equipment and supply manufacturers can

help the RT profession is through technology that streamlines workflows, according to Coombs. He points to closed loop ventilation strategies, such as Smartcare/PS, for automated/protocol-based weaning, and airway pressure release ventilation (APRV) with Autorelease, as technologies that make it easier and more efficient for RTs to care for patients in respiratory distress. He also recommends a comprehensive ventilation workstation approach that accommodates invasive, non-invasive, and 02 therapy.

A February 2022 analyst insight report from Signify Research cites healthcare facilities' increased adoption of disposable respiratory consumables during the pandemic to reduce infection risk. But with facilities facing increased financial pressures, analysts say vendors will have to prove their products representative of the best combination of cost and performance to remain competitive.3

Alan Haynie, RRT, Clinical Educator,

Verathon, says RTs are seeking ways to increase staff efficiency to compensate for staff shortages and that single-use devices can help, stating:



Alan Haynie

not require reprocessing, which reduces workload and has the added bonus of patient safety benefits. One possible solution is to consider utilizing single-use devices to streamline workflow to save time as reprocessing an endoscope takes up valuable staff time."

Verathon offers single-use GlideScope Spectrum video larvngoscopes and singleuse BFlex bronchoscopes as part of its Total Airway Solution. Its GlideScope Core airway visualization workstation is compatible with both devices, enabling clinicians to perform video laryngoscopy, bronchoscopy, and dual-view airway procedures through a single system.

"BFlex and Spectrum can be used simultaneously to help with difficult airways and provide timely and effective patient care in the OR, ICU and ED," said Haynie. "Verathon has a staff of clinical educators that will help with product education and implementation. We also offer an education program to familiarize your staff with product offerings and to optimize workflow."

It is not only the respiratory device itself that can spread infection but also how it is stored. For hospitalized patients requiring ongoing delivery of medication via a nebulizer for treatments such as pneumonia, the RT often administers the therapy using a reusable nebulizer that must be stored between use. In most cases, the storage receptacle is a clear, polyethylene plastic bag.

Research has shown that dangerous microbes (e.g., MRSA, VRE) can survive on polyethylene plastic for up to 90 days.4 Considering the RT must handle the plastic bag and the nebulizer multiple times per day to administer therapy, it is easy to imagine how microbes could spread to these items - and subsequently to the RT and other patients.

"Polyethylene plastic bags allow bacteria to thrive and are a conduit to HAIs throughout healthcare facilities," said R. Scott Hatfield, President and CEO, Infection Prevention Products.



Scott Hatfield

"Consider an RT providing treatment to several patients, some with COPD or asthma, and others with pneumonia. If the pneumonia bacteria remain on the hands of the RT, who then handles the plastic bags containing the nebulizers for the other patients, there is a risk that the bacteria will be retained and even grow on and in the plastic bag, increasing the risk for cross contamination."

Recognizing this risk, Meredith Lloyd, LVN, invented the WikiPouch (formerly IP-Pouch) while working as an Infection Control Nurse at a healthcare facility in California. Made from a breathable wicking material that removes moisture and allows microbes to die naturally, WikiPouch serves as a replacement technology for the plastic bags used for storing reusable nebulizers and other respiratory devices, such as nasal cannulas.



Nurse switching to WikiPouch polypropylene mesh bag

A study at California State University found a 62% reduction in Staphylococcuscontaminated cannulas immediately after transfer from polyethylene plastic bags to WikiPouch polypropylene mesh bags.5 Hatfield says the product's manufacturer, Infection Prevention Products, offers hospitals samples of the WikiPouch for testing at no charge.

Generate awareness

Raising public awareness for the respiratory profession is one way to help address the current crisis, and is a key pillar of the AARC, CoARC and NBRC's multi-year, national campaign to bring more respiratory therapists into the profession and advance specialization.

As Quan Golomb, Senior Director,

Ventilation Global Marketing, Medtronic, explains, manufacturers can play a central role in supporting these types of awareness initiatives. She states:



Quan Golomb

"Medtronic partnered with the AARC in their effort to recruit new talent through our sponsorship of their Thank an RT campaign, designed to raise awareness of the profession. We also offer best-in-class education with our on-demand, product-agnostic ventilator training - Ventilator Academy (www. ventilators.com) - to help the onboarding

process for new RTs. We understand RTs have large demands on their time. The suite of software features on the Puritan Bennett 980 ventilator can help clinicians manage patients, from adults to neonates."

Support RT education

In response to the RT shortage crisis, multiple stakeholders are investing in RT education to boost enrollment in programs and provide RT students the resources they need to enter the profession quickly, effectively, and safely upon graduation.

For example, the Pittsburgh-based Community College of Allegheny County's Respiratory Therapy Associate of Science Degree program recently announced that it has partnered with the University of Pittsburgh Medical Center (UPMC) on a joint initiative to help fill the RT shortage. Program participants receive \$6,000 in tuition assistance and paid work opportunities while enrolled in the 18-month program, as well as a guaranteed job at UPMC upon successful program completion.⁶

From the manufacturer side, Dräger has made annual device donations to U.S. RT schools to help advance RT education with

over 110 devices donated to date. Coombs comments on the program:

"Equipping RT schools with advanced technologies is important to preparing students for real-world application of their skills. Students should be training on the same caliber of ventilators and other respiratory care devices and supplies they will be using in healthcare facilities upon graduation."

With regards to continuing education, Dräger offers complimentary continuing respiratory care education (CRCE) courses and live webinars through its website *A Breath Ahead*. Additionally, Dräger's agreement with the Intensive Care Online Network (ICON) provides all Dräger ventilation customers access to online continuing education and a real-time support system 24x7 staffed by clinicians through ICON's Critical Care Resource Center.

The future of respiratory care

With an ever-increasing population of patients with respiratory conditions, and the trend towards treating patients in lower acuity and lowering cost settings outside of the hospital, the future of the respiratory care field and that of the RT professional will continue to evolve in the years ahead.

COVID-19 patients with lingering respiratory challenges are often transitioned from the intensive care unit (ICU) to nonacute facilities (e.g., long-term care center, skilled nursing facility). But as McKesson states its recent Roadmap to Respiratory Season Success in Non-Acute Settings eBook:

"In most cases, non-acute care clinicians have never had to manage patients with this level of clinical complexity. For example, while they care for patients requiring supplemental oxygen, the respiratory needs of some COVID-19 patients often exceed a facility's resources."

"Whereas a facility may have only had a handful of patients on two liters of oxygen in the past, they are now administering flows higher than six liters, probably closer to 15, to prevent COVID-19 patients from being re-hospitalized," said Patricia Reni, registered respiratory therapist (RRT), homecare account manager for McKesson. "This requires an entirely new skill set and thought process among clinicians."

One solution that is growing in popularity is remote respiratory monitoring. Researchers from the Worcester Polytechnic Institute Department of Electrical and Computer Engineering published a study



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on the current state of respiratory monitoring and future methods in today's "smart and connected health" era. Their research found:

"Continuous and accurate remote monitoring, along with other physiological data, can help caregivers improve the quality of care and allow patients greater freedom outside the hospital. Such monitoring systems could lead to highly tailored treatment plans, shorten patient stays at medical facilities, and reduce the cost of treatment."

Spire Health specializes in remote patient monitoring (RPM) for patients with chronic respiratory conditions. The company's Vice President of Commercial, Phil Golz, comments on how RPM has grown exponentially during the past two years because of the COVID-19 pandemic and RPM code requirements from the Centers for Medicare & Medicaid Services (CMS).

"Chronic respiratory patients were some of the highest risk patients and often isolated to their homes due to their conditions," said Golz. "Early in the pandemic, we saw most pulmonology offices close for routine care and doctors spending most of their time in the ICU treating COVID-19 patients. RPM and telehealth together

allowed providers to keep a close eye on their patients and enrich their telehealth appointments with physiological data to

Spire Health remote patient monitoring Health Tag



help make informed treatment decisions remotely."

According to Golz, many practices have continued using RPM for patients with chronic respiratory conditions because of its clinical value and ease of use, and the peace of mind it offers to providers and patients alike. He said Spire Health has seen a growing number of practices adopting remote monitoring systems and building clinical pathways to incorporate their daily use into patient care.

"As with all new fields, there are a lot of players at the beginning," Golz added. "Throughout the pandemic we have seen insurers and CMS look at adding additional requirements to ensure RPM is providing clinical value to patients. We see this trend continuing with a focus on proving technology solutions such as RPM have a clinical impact on patient outcomes. Further, we see these remote monitoring tools offer ancillary services such as at home pulmonary rehab programs for patients to help live their best quality of life at home." HPN

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OVID-19 is the third-leading cause of death in the United States following heart disease and cancer, according to the Centers for Disease Control and Prevention (CDC)¹. Furthermore, roughly 1 in 25 hospital patients catch a hospital-acquired infection (HAI) each year in the U.S². Globally, close to 100,000 people die from HAIs³, costing hospitals and health systems billions of dollars. The significant rise in HAIs over the past two years has brought increased attention to the importance of disinfection.

Against the backdrop of the pandemic, now lingering into its third year, *Healthcare Purchasing News* asked several manufacturers for insights about cleaning and disinfecting the air and surfaces of bacterial and viral microbes.

No ESKAPE

More than 40% of HAIs are due to ESKAPE pathogens (Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter species)⁴. In response to pathogens' capability to recontaminate surfaces or equipment over a 24-hour period, PDI Healthcare, a manufacturer of infection prevention products and services,

recently launched Sani-24 wipes that protect against pathogens in one minute.

"This product helps solve several common problems encountered within healthcare disinfection, including the inability to disinfect surfaces/equipment as often as they need due to constrained resources (i.e., FTEs, time, or supplies). Additionally, this product's formulation can also help with high-touch surfaces within high-traffic areas (i.e., elevators, waiting rooms, public bathrooms, ATMs/kiosks, etc.) by providing 24-hour disinfecting coverage. Lastly, when used as a routine disinfectant, repeated applications of Sani-24 wipes can provide coverage for areas that may have been missed during a previous cleaning process or subsequent uses therefore reducing potential gaps," according to Debra A. Hagberg, MT(ASCP), CIC, Director, Clinical Affairs, PDI.

Kinnos, a specialized developer of disinfectant applications, noticed that disinfection could only be calculated after it was done, with microbial sampling, ATP [adenosine triphosphate] testing, or fluorescent markers. Ready-to-Use (RTU) wipes are ubiquitous, but spots on surfaces are often missed, according to Katherine Jin, Chief Technology Officer, Kinnos.

"Research shows that inadequate disinfection is the root cause of a huge portion of healthcare-associated infections.

Disinfectants and readyto-use (RTU) wipes are all transparent on application, so workers can't see what they are wiping and what they've missed. Our colorant for bleach and RTU wipes lets workers finally



Katherine Jin

see where they've wiped, and empowers them to self-monitor their own coverage," she said. Kinnos launched its Highlight for



Kinnos Highlight for bleach wipes colors your wipes blue for visual confirmation of coverage

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Bleach Wipes in mid-2021, a lid and cartridge addition to bleach wipes. The wipes are then used to clean a surface and the Highlight will color it blue. If the area is thoroughly disinfected, the blue will fade.

Jin suggests doing multiple passes while disinfecting a surface. "Our teams have seen a real gap in consistency of how everyone wipes with these tools. Some wipe in a zig zag, some circle their hand, but few do multiple passes. Wipe manufacturers don't instruct on this. Our research indicates that multiple passes doesn't take longer but improves the removal of dirt and reduction of microbes," said Jin.

While healthcare facilities are dedicated to effective and thorough disinfection, they also strive to achieve quick turnover times. Facilities are experiencing unprecedented shortages in staff and increased turnover, which can increase the risk of error, according to Larinda Becker, Executive Director of Marketing, Infection Prevention for Diversey, a manufacturer of cleaning and hygiene products. She suggests that "Suppliers can help address these issues with turnkey solutions that can simplify and streamline processes, allowing facilities to make it easier for staff while reducing the risks of transmission and infection."

Diversey designed Oxivir 1, a wipe that is bactericidal, virucidal, fungicidal and tuberculocidal in one minute. Diversey also developed a four-step cleaning process approach to help customers reevaluate their practices:

- 1. Access facility needs and objectives
- 2. Select cleaning methods and products
- 3. Validate cleaning effectiveness
- 4. Implement training program and materials

We're just not compatible

Compatibility with medical devices is one of the most challenging areas for surface disinfection, according to Hagberg, PDI. She highlights two focus areas:

- 1. Compatibility of the disinfectant chemistry with the actual material of the surface
- 2. Compatibility of the disinfectant solution with the actual functionality of medical devices that the disinfectant is used on

"The U.S. Food and Drug Administration (FDA) requires manufacturers of medical devices to test at least one disinfectant on the medical device for compatibility against corrosion/visual impact and impaired functionality. If the medical device manufacturer tests a specific brand of disinfectant, that product(s) is then listed in the cleaning/

disinfection instructions for use (IFU) in hardware and machinery is crucial. With the product manual. hardware and machinery is crucial. With the correct dilution of chlorine, this can

"The healthcare facility must then comply with the medical device IFU and comply with the disinfectant IFU. Problems can arise when the facility does not use the specific brand listed in the device manual because this can lead to either a non-compliance issue, if another disinfectant brand is used, or the required purchase of several different disinfectants to meet the needs of the medical device instructions," she said.

Healthcare's numerous medical devices continually complicate the practice of surface disinfection. "Each device may have a different disinfectant listed, or the instructions for the disinfectant contact time may not be correct," Hagberg continued. "This can result in a compliance concern, especially if the user follows the device IFU correctly, the disinfectant IFU is not complied with, or vice versa."

Medical equipment surfaces can be costly to replace and Clorox cleaner disinfectant Spore Defense has a broad surface compatibility to protect medical equipment, according to Kristina Vannoni, Associate Marketing Director, Clorox Healthcare. "Healthcare facilities have and will continue to be challenged with preventing the spread of pathogens that contribute to healthcare-associated infections (HAIs), especially with the rise of antibiotic resistant pathogens, such as drug-resistant Candida auris (C. auris). Drug-resistant C. auris can survive on surfaces for prolonged periods and its primary route of transmission is contact with contaminated environmental surfaces such as medical equipment, fomites and person-to-person. Continued focus on routine cleaning and disinfection of high-touch surfaces is critical to keeping healthcare facilities as safe and healthy as possible," she emphasized.

Michele Padovan, Product Education Specialist for Angelini Pharma, a producer of dialysis infection control products, says that a dilution wipe is a good choice disinfectant for a dialysis area. "Consideration for avoidance of degradation of the expensive hardware and machinery is crucial. With the correct dilution of chlorine, this can be avoided, and a ready-to-use wipe is an obvious choice," she said.

Scratching beyond the surface

Three-quarters of surfaces in rooms remain untouched after cleaning with only mops, buckets and rags⁵. "The sanitation industry has been fraught with challenges due to a long-standing reliance on traditional tools that take an unrealistic amount of time to effectively clean, sanitize or disinfect surfaces well enough to eliminate pathogens," according to Rich Prinz, Global Vice President of Sales, EvaClean Infection Prevention Solutions by EarthSafe. He further emphasized that the use of toxic cleaning and disinfectant chemicals cause more harmful health hazards.

Prinz's colleague, Gabriella Cimarelli, Director of Account Development, EvaClean

Infection Prevention Solutions by EarthSafe, points to more natural cleaning for staff safety. PurOne and PurTabs NaDCC disinfectants dissolve to produce HOCl, the same chemistry the human body produces to



Gabriella Cimarelli

fight infection. NaDCC chemistries kill pathogens while keeping a low toxicity profile and reducing turnover time.

"By eliminating 90% of the chemicals used to clean and disinfect and replacing them with a safer solution, EvaClean is able to standardize processes and simplify training, thereby reducing the risk of errors. Standardization also increases compliance and safety for staff and patients. Standardizing chemicals and dilution rates means fewer protocols to learn resulting in less margin for error, and replacing hazardous chemicals with safer solutions eliminates exposure risks and mixing mistakes," Cimarelli said.

COVID-19 caused more disinfection products to emerge, but many of them use harsh chemicals, according to Brittany Buchman,



Finsen Technologies' THOR UVC Halo disinfects the floor and its own wheels.

Vice President of Marketing, TOMI Environmental Solutions. Pathogens are easily spread through the air and surfaces. Current methods such as manual cleaning and Quality Assurance Technicians (QATs) have issues with human error (missing spots) as well as harsh chemicals destroying sensitive equipment," she said. TOMI manufactured the SteraPak, the most portable SteraMist system that uses ionized hydrogen peroxide (iHP) technology and removes the hassle of mixing hazardous solution.

Halosil, a provider of surface and water disinfection products and services, designed a portable fogger, the HaloFogger POD, which runs without electricity.

Additionally, Maryalice St. Clair, Chief Commercial Officer of Halosil International Inc. stresses that Environmental Services

> (EVS) managers and Infection Preventionists should educate themselves on disinfection products. "Read the EPA label and challenge the efficacy claims of the manufacturer to be sure they are not false or exaggerated and that the product is being used according to Front view the instructions on of Halosil's the EPA label," she HaloFogger

example, I have seen products that are only approved and effective for wet spray applications, being sold as fogging products without having EPA fogging use approval."

POD

It's in the air, in the shadows

The area underneath all ultraviolet-C (UVC) robots is shadowed directly by the verticality of the unit, according to Brian Donahue, Director, Corporate Accounts for Finsen Technologies, a designer and manufacturer of UVC disinfection systems. "The dirtiest surface within any healthcare environment is the floor. It is the highest traffic area and airborne bioburden can settle there. So, you must clean the square footage under your UVC unit," he said. Finsen recently launched the new THOR UVC robot, with unique UVC emitters placed directly underneath to disinfect the floor and its wheels.

Before purchasing a UVC unit for your facility, Donahue suggests researching the products. "Follow the science, especially the physics. Check the numbers on the UVC -wattage, wavelength and the manufacturer of the emitter itself - and inspect the design of the unit and details of any studies. Some of the new innovative ideas seem whizbang revolutionary, but most are vaporware and cannot perform to the stated claims. Demand a live webinar that will show the product in use, not a YouTube demo or panel discussion," he said.

Mark Stibich, PhD, Co-founder and Chief Scientific Officer of Xenex Disinfection Services, says to consider evidence and experience when evaluating UV technologies. "It's not enough to simply create a UV device. A very large number of companies have launched UV devices that were unsuccessful. To produce a UV device that meets the needs of the healthcare customer, a thorough understanding of the physics associated with





Xenex LightStrike germ-killing robot in use at nurse station

UV, microbiology and hospital workflow is necessary. We partner with our customers to understand their goals and help them develop a disinfection strategy that easily fits into their existing processes," he noted.

UVDI recommends healthcare professionals vet how simple or easy a product is to operate and to integrate it efficiently in an existing workflow. "Healthcare teams have been under tremendous strain in the last two years and the last thing they have time for

is to take on clunky or cumbersome new products to use," said Peter Veloz, Chief Executive Officer. "Products that are exceedingly simple and safe to operate are a must."

Less focus is paid to the risk of air contamination than to surface disinfection, according to Karen Hoffmann, RN, MS, CIC, FAPIC, FSHEA, University of North Carolina School of Medicine.

"Untreated air samples in healthcare facilities on average range from 2 to 8

times more contamination than surfaces. Pathogens become aerosolized from routine activities like bedmaking, walking and flushing toilets, and take flight, presenting a risk of breathing in microscopic particles that contain potentially infectious material. Immunosuppressed and immunocompromised patients are at the highest risk in the hospital setting. Contaminated air is a risk to healthcare workers as well. Vidashield UV24 draws airborne contaminates and pathogens into the system through a discreet vent opening on the face of the fixture in the ceiling and eliminates 97% of the contaminates in the treated air resulting in a cleaner healthier environment," she said. HPN

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THE FUTURE OF DISINFECTION

Healthcare Purchasing News asked infection prevention suppliers for their thoughts on what is next for disinfection. Here are their predictions:



"COVID-19 has created what I call the new normal. Not only are healthcare facilities aware of the need for adequate disinfection, the public at large realizes that we'll continue to deal with current and emerging pathogens in our future."- Maryalice St. Clair, Chief Commercial Officer, Halosil International

"Healthcare facilities have and will continue to be challenged with preventing the spread of pathogens that contribute to healthcare-associated infections (HAIs), especially with the rise of antibiotic resistant pathogens, such as drug-resistant *Candida auris*. It is also important for everyone in healthcare to continue playing a role in cleaning and disinfecting. While EVS are required to clean given areas once a day, all staff such as nurses should clean and disinfect their workspaces,



including high-touch surfaces such as telephones and printer control panels, at least once per shift as well as clean and disinfect any patient care equipment after each use. Given the high traffic in hospitals, a sanitary environment is key to infection prevention and control efforts and to achieve this will mean continued collaboration among disciplines, Infection Preventionists (IPs) and EVS professionals." - *Kristina Vannoni*,

Associate Marketing Director, Clorox Healthcare

"The future of disinfection includes products that easily and effectively eliminate bacteria biofilms on wet and dry surfaces while providing continu-



ously active disinfection over longer periods of time (i.e., beyond 24 hours). In addition, there is an opportunity to provide a more accurate method of compliance monitoring. This type of technology could provide bacterial identification from surface samples in real-time while determining if the bacteria are alive or dead. Advanced technology will certainly come into play with surface

disinfection." - **Debra A. Hagberg, MT(ASCP), CIC, Director, Clinical Affairs, PDI**



"The future is in technologies that are increasingly easy and fast to use — that adapt to and simplify workflow versus the other way around. UV technologies that can address multiple healthcare needs — supply chain sustainability, lessen labor strain through improved efficiency and proven effectiveness against multi-drug resistant organisms and emerging variants

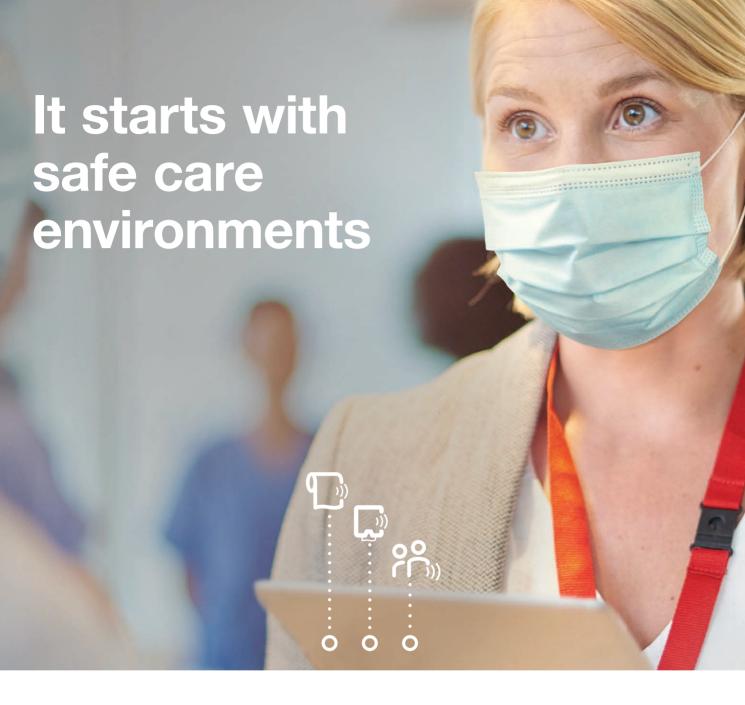
- will take hold." - Peter Veloz, Chief Executive Officer, UVDI.

"A manufacturer should be mindful that new technology often comes with an extra cost. The healthcare world looks for effective, science-

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1. Based on survey results conducted in March 2021 of 34 current Tork Vision Cleaning customers in Europe and North America. NOTE: Tork Vision Cleaning was formerly known as Tork EasyCube®.





THE FUTURE OF DISINFECTION, CONTINUED...



based products that manage the critical need for products that decrease hospital-acquired infections (HAIs) and the ever-evolving number of antibiotic-resistance pathogens. Chlorine can provide customers with a product, in various dilutions, that can meet their surface disinfection requirements economically."

- Michele Padovan, Product Education Specialist,

Angelini Pharma

"As SteraMist continues to assist in the fight against the COVID-19 coronavirus pandemic, history shows that there are many pathogens in this world that pose a substantial threat. TOMI continues to develop and



add SteraMist products to the ever-changing world, and industry. All SteraMist products are built with iHP technology to eliminate threats, and TOMI remains innovating for a safer world. TOMI has fought Anthrax, Ebola, MERS-CoV, SARS-CoV-2 and will always be prepared for the next outbreak to ensure those at the forefront are fighting with the global standard of disinfection and

decontamination." - Brittany Buchman, Vice President of Marketing,
TOMI Environmental Solutions



"The next evolution is to establish hospital level disinfection processes for every industry, and promote safer and more sustainable infection prevention practices." - Rich Prinz, Global Vice President of Sales, EvaClean Infection Prevention Solutions by EarthSafe.



"Patients and families expect to have a safe environment. They will demand to see a facility's "visible commitment" to infection prevention, and they will expect to have access to safe and effective disinfectants that care givers and loved ones can use at the point of care to keep the environment safe during the patient's stay." - to Larinda Becker, Executive Director of Marketing, Infection Prevention for Diversey

"With emergence of SARS-CoV-2 requiring use of disinfectants from the EPA registered List K, and norovirus and C difficile requiring registered disinfectants from List G, healthcare facilities have ever more



concerns about the future of emerging and remerging resistant organisms. Because Vidashield UV 24 disinfection is entirely physical, the development of resistance of microorganisms is not possible. There is no potential for microorganisms to develop resistance in the same way that they do to chemical disinfectants over time or have selective effectiveness to specific pathogens."

- Karen Hoffmann, RN, MS, CIC, FAPIC, FSHEA, University of North Carolina School of Medicine

"Finsen has launched several overlapping platforms and will continue



to lead with integration and workflow solutions to make workplaces safer while also embracing antimicrobial stewardship. Our industry partners are all experts in their respective componentry, and Finsen brings synergy to create more than the sum of the parts for surfaces, air and objects. Teltonika, Verizon, Panasonic, Philips, to name a few global leaders."

Brian Donahue, Director, Corporate Accounts for Finsen

"I really appreciate that we've seen an increased demand for evi-



dence-based solutions. As a result of the pandemic, dozens of UV companies emerged touting all sorts of ridiculous claims. Sophisticated buyers now ask for validation that the UV technology works -- are there peer-reviewed and published studies validating that the technology can do what the sales rep says? I expect to see further demand and sophistication from UV buyers in the coming years." - *Mark*

Stibich, PhD, Co-founder and Chief Scientific Officer of Xenex Disinfection Services

"I think that disinfection will be recognized as a step we need to invest a little more time and technique into. We all understand its importance, but we haven't been able to visualize a slightly better wiping technique, a little more friction, and not missing a spot. If you can't see it, to what degree did you really clean it? Now that we can visualize it, we can improve it and see those efforts translate into fewer HAIs." -Katherine Jin, Chief Technology Officer, Kinnos

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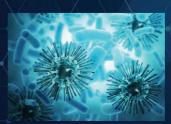
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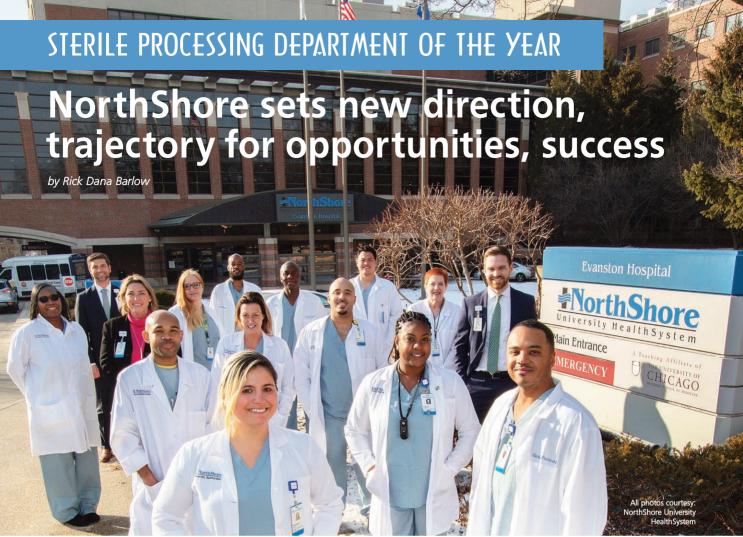
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(Front row left to right): Donielle Horn, Patrice Williams, Lex Bland; (Second row left to right): Elvis Sutherland, Cynthia Bradich, Embry Alvarez; (Third row left to right): Bonnie Young, Courtney Mace Davis, Jennifer Isdale, Johnny Kukom, Caryn Moore, Matt Belanger; (Fourth row left to right): Gus Granchalek, Jeremy McGaha, Jose Oregel Mesa

hen Courtney Mace Davis arrived at NorthShore University HealthSystem's Sterile Processing department as Director in 2019, she brought to the multi-hospital system's team extensive experience in quality improvement and process management and immediately put those skills to work by observing operations.

Her keen, trained eyes spotted something worth noting: "SPD wasn't always set up for success due to the way the instruments were arriving in decontamination," she recalled.

"There was already a process in place to provide feedback to the OR when this happened, but SPD staff was not following the process – just as the OR wasn't following the process to report issues back to SPD," she said. "I knew that tackling this was one of the first steps to compliance [and] in building a strong collaborative relationship with our OR partners."

She targeted point-of-use (POU) instrument care and pre-treatment in the OR as an

area that needed measurable and sustained improvement.

Mace Davis and the SPD team embraced and pursued compliance to Association for the Advancement of Medical Instrumentation (AAMI) standards and Association of periOperative Registered Nurses (AORN) guidelines to the point that 99.5% of the trays that come to decontamination from the OR comply with POU AAMI standards and AORN guidelines every day, according to Mace Davis.

How? Through education and regular communication with SPD's "perioperative partners," she insisted. "It's the trust that was really improved throughout this process and acted as a catalyst for other improvements," she added.

"I've found it helps to provide the why behind what we do," Mace Davis told Healthcare Purchasing News. "The standards and guidelines are there for a reason and the rationale really helps people understand what the goal is and if there are other ways to achieve that goal. Infection Prevention was also involved in, and supported these discussions, which helped with alignment. It's rewarding to see how SPD technicians, who have worked other places, react when they see how case carts arrive in decontamination. They are very impressed with our perioperative team!"

For the leadership team overseeing NorthShore's multi-facility SPD team, which includes Mace Davis and extends to Matt Belanger, Director, Clinical Operations, and Gus Granchalek, Vice President, Perioperative Services & Anesthesia, success represents more than just a hard-earned seven-letter word.

It's more like two seven-letter words because the first leads to the second. The root word? Respect.

NorthShore's SPD team learned how to engender respect for what it does by concentrating on the pursuit of quality service through partnerships, by actively collaborating with fellow departments through multi-disciplinary "Connections" meetings, by educating and demonstrating

STERILE PROCESSING

the critical importance of what they do and by streamlining processes through automation, integration and specialization to deliver quality, reliable and uninterrupted service - even during a massive construction project and a global pandemic. For these reasons, NorthShore earned the 2022 SPD Department of the Year Award by HPN, the 30th organization to be honored for providing exemplary service.

NorthShore, based in Evanston, IL, the suburb perched just north of Chicago, comprises four hospitals in as many suburbs north-by-northwest of the city - Evanston, Glenbrook (in Glenview), Highland Park and Skokie.

Recently, NorthShore, which also includes Chicago-based Swedish Hospital (acquired in January 2020), and Northwest Community Healthcare, Arlington Heights, IL (acquired in January 2021), finalized its merger with Edward-Elmhurst Health, a three-hospital system based in Naperville and Elmhurst, west of the city. Continued integration of SPD operations will become a major project for Mace Davis, Belanger and Granchalek throughout 2022 and into 2023.

Device care at POU

Pre-treating instruments at the point of use, namely, the OR, has been an emotionally charged issue between SPD and OR for many years and has intensified in recent years due to the increasing complexity of minimally invasive surgical devices and media reports of surgical infections linked to sterile processing issues.

NorthShore's SPD and OR teams broached and blunted the topic right away in a detailed but effective process.

It works like this: If SPD notices a POU care issue, such as instruments not being sprayed, SPD sends an email or text message to the OR educator using a bar code scan via its Sonar instrument tracking system, according to Mace Davis. The OR educator then verifies the issue with the decontamination team. Both teams work together "to better define and update training materials as needed," Mace Davis indicates.

"We track and present these metrics monthly which serves to reemphasize the importance of treating the instruments at point-of-use for our OR and SPD teams," she continued. "This simple and ubiquitous task of consistent POU instrument care was one of the most challenging initiatives to work on with the OR. However, we were able to show that these findings had a direct correlation to the quality of trays the OR received from SPD. Through this process we demonstrated metrics are not punitive, but instead can be used as a roadmap for improvement and an objective way to understand what's working and what's not."

Through this process, SPD established metrics and accountability, and demonstrated compliance and an improvement of 19% from a previous system average of 126 occurrences in a month, Mace Davis notes. This contributed to the 99.5% tray processing accuracy throughout 2021, she adds.

Prior to this process being implemented, friction between SPD and the OR ensued due to challenges with tray error reporting.

"Because SPD did not consistently report or act upon the data, the OR was resistant to communicate any tray issues," Mace Davis recalled. "When SPD took the initiative to focus on reporting, the clinical staff didn't believe the accuracy of the numbers. And they were right to question the accuracy. What we learned together is that SPD was reporting everything we were aware of, but the OR wasn't reporting all of the issues. Through SPD's monthly report-outs of issues to both the OR and Infection Prevention, as well as

SPD's root cause analysis and action plan for resolution, the OR started to see value in reporting. SPD, in turn, was able to focus on the most important issues, notice if there were special circumstances contributing to quality issues, and address issues with particular team members on a more a timely basis."

Both SPD and OR knew that quality events, unrelated to patient safety, were under-reported, according to Mace Davis. Therefore, when reporting accuracy improved, the situation appeared to be worsening.

"We had to accept and work through that in order to build trust," she acknowledged. "Today, the reporting is much more accurate and representative to what the OR is experiencing. This is monitored during our monthly multi-disciplinary 'Connections' and Infection Prevention and Control Committee meetings where we share the data from the most recent month."

Mace Davis recognizes that this always will be a work in progress. "Trust takes many months/years to build and can be lost so quickly," she said. "Unfortunately, quality events will happen, but it's SPD's responsibility to communicate and learn from these events."

Banking big wins

NorthShore SPD banked two more big wins for the organization last year, addressing two prominent sterilization processes: Ethylene oxide (EO) use and



Leadership trio responsible for NorthShore's SPD transformation: Courtney Mace Davis, Gus Granchalek, Matt Belanger

Fast Facts on NorthShore's Sterile Processing team					
SPD FTEs	122	Number of OR suites*	46	Outpatient visits*	1,286,215
Percent of FTEs certified	88%	Hospital admissions*	40,986	Births*	4,982
Number of acute care hospitals serviced*	4	Emergency depart- ment volume*	108,539	Surgeries*	34,445
Number of non-acute care facilities serviced*	Approximately 70 unique addresses (includes physician offices, immediate care locations and other outpatient sites)				
Number of beds (operating)*	Staffed beds including newborn bassinettes, 764; staffed beds excluding newborn bassinettes, 726				
Annual Performance and Production**					
	Produc-	2019	2020	2021	2022 to date
tion**		2019 37,923	2020 31,202	2021 34,478	
tion** Number of surgical cases su Number of sets/trays proces	pported				date
tion** Number of surgical cases su Number of sets/trays proces sterilized	pported	37,923	31,202	34,478	date 10,909
tion** Number of surgical cases su Number of sets/trays proces sterilized Instruments processed	pported	37,923 203,053	31,202 203,506	34,478 218,979	date 10,909 64,655
	pported	37,923 203,053 unknown	31,202 203,506 unknown	34,478 218,979 6,402,136	date 10,909 64,655 2,359,506

the SPD Department of the Year determination

Source: NorthShore University HealthSystem, March 2022

STERILE PROCESSING



immediate-use steam sterilization (IUSS), otherwise known as flashing.

In short, SPD worked closely with the OR to eliminate both in 2021.

"NorthShore has long been committed to sustainability and environmental stewardship, and our perioperative team proactively decided to move away from this method of sterilization," Mace Davis noted. These decisions involved identifying alternate instruments that could be processed in a different manner as well as investing in instruments that could be used in existing sterilization methods, according to Belanger.

"From a fiscal perspective, we were fortunate to work with leaders in the organization that appreciated the trade-offs and cost of purchasing – or not purchasing – new instrumentation," he said. "We approached these questions with data and partnered with colleagues in our perioperative business services team to understand volume projections and scheduling practices."

SPD also conducted a "meticulous review" of the device instructions for use (IFU) to determine validated alternate sterilization methods.

SPD implemented the use of OneTray to cease IUSS practices because they recognized how quick turnovers could contribute to "quality events" in the OR.

"A review of perioperative services drew attention to an elevated IUSS rate at one



Checking sterilizer load tape on the sterile side of pass-through sterilizers: Lesya Matsuk, Melissa Gawerecki , Carlo Delos Reyes

of our hospitals, and it became an area of focus," Belanger said. "Within a 90-day period, OneTray technology was implemented across our hospitals to more safely support 'quick turns' and eliminate IUSS."

Using OneTray, SPD demonstrated to the OR that they could turn over instruments quickly if needed, but the OR also had to provide accurate feedback as to when a tray actually was needed, according to Mace Davis. "Most of the time, a quick turnover was not needed, but there was a just-in-case mentality we had to overcome through trusted performance on the SPD side," she added.

"Prior to 2021, if a quick turn was needed the instruments traveled several floors down to decontamination in the basement and then back up again to the OR for sterilization," Mace Davis said. "All of this tray movement between floors, in conjunction with the heavy tray volumes, created an environment of confusion and inflated urgency. When everything is a priority, nothing is a priority. By working with our OR partners, we were often able to find alternatives to expedited processing. Now when there is a quick turn request, it is clear to all this is a priority."

As a result, SPD improved quick turn rates for the OR by 67% to just under 2% for the system.

Not surprisingly, instrument access and availability represented SPD's top-quality

event to tackle in 2021. Incidents of missing and wrong instruments dropped by more than 23% once SPD improved loaner tray delivery compliance, courtesy of its Sonar instrument tracking system matching count sheet accuracy and completion via part numbers and pictures, according to Mace Davis. No more relying on memory to assemble trays.

"As the POU compliance numbers improved in decontamination due to the OR keeping sets together, the number of opportunities for SPD staff to assemble trays

with wrong instruments was reduced," she noted. "We are dependent on each other for our success!"

SPD also depends on vendor participation. "It is nearly impossible to manage loaner tray delivery compliance without vendor cooperation," Mace Davis said. "Without vendor collaboration, any wins are temporary and not sustainable. We are actively working with a couple of our largest vendors and are close to having some major improvements in delivery compliance. We need our vendors to trust our SPD team to process their trays appropriately and completely, and our SPD team needs the correct and complete information – including IFUs – from our vendors."

Working with OR, SPD installed an electronic display of vendor performance that shows such data as on-time delivery, check-in compliance and volume, for complete transparency.

"To take this a step further our SPD team is leading monthly multi-disciplinary meetings with our tray vendors, loaner tracking system, the OR, and procurement to drive improvements – similar to what we've seen internally – with this same approach," she said. Casechek serves as NorthShore's loaner management system. SPD is working with DePuy Synthes and Zimmer Biomet to launch this data-driven project. "I'm really impressed with the cooperation these two vendors, in particular, have provided and am excited to see how this project evolves!" she added.

This project also will help SPD as it processes more than 2,000 loaner trays a month at NorthShore's orthopedic hospital in Skokie alone, according to Mace Davis, as they must be processed twice – once before they can be used and again before they can be returned.

SPD makes 'Connections'

Emphasizing that SPD doesn't co-exist on an island or in a vacuum, Mace Davis and her team parlayed their joint accomplishments and trust-building with OR to reach out to other departments, including











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Ernesto Rodriguez manages set inspection/assembly using the Sonar instrument tracking system and STERIS IMS mats that help with instrument inspection criteria.

Infection Prevention (IP), Environmental Services (ES), Clinical Engineering (CE) and Facilities Management Systems (FMS), for routine meetings under the "Connections" banner.

Mace Davis extols the value between SPD and IP working together.

"Our teams weren't collaborating," she said. "Getting all stakeholders at the same table is so important! IP has been such a valuable resource for our SPD team as they bring in other standards that we may not be aware of. In turn, SPD is a valuable resource for IP as we are often closer to the standards and upcoming changes. As experts in our workflow, SPD may also be able to provide a variety of ways to meet a particular standard. Not everything in SPD is black and white, and we need partners who can critically think through compliance scenarios with us. SPD leaders have a responsibility to become familiar with the regulations, standards and guidelines that affect their department. Sitting back and letting others tell us how to run our departments doesn't work as our devices, equipment and chemicals are all different and it's our responsibility in SPD to know

what makes our individual departments compliant.

["]In my career, I have been fortunate to work with very knowledgeable and supportive IP professionals," she continued. "If that trusted relationship is not established, IP may not have realistic expectations about how to operationalize the standards. If that happens, SPD may not be as transparent with issues or workflow changes [that] could lead to unsafe practices - and surprises during Joint Commission surveys. The IP relationship is key to a successful SPD department."

the "Connections" meetings with OR and IP to foster collaborative solutions. In fact, ES leaders often add to discussions involving SPD and IP that are not related to ES.

"This is a great reminder that we all have something to contribute," Mace Davis assured. "The advantage is that we can help promote consistency (high reliability) through metrics. The disadvantage is that when metrics are lacking, these discussions can feel blame-oriented. Our approach has been to offer assistance in working together and to showcase the improvements our teams have made collectively. This approach has ultimately promoted continued collaboration."

Against the grain

As centralization of services and off-site reprocessing has grown in popularity, NorthShore detoured to explore something different that has proven successful for the organization and beneficial to the participating teams.

SPDs commonly struggle with outdated preference cards, poor workflow and equipment capacity issues, and face challenges with process standardization, staff

education and oversight, according to Mace Davis.

"Off-site centralization of SPD may make some of this easier due to one physical location, but there are additional costs and risks with that model, as well," she said. "At NorthShore, we have a hybrid model where some things such as clinic instruments are centralized, but each hospital has its own SPD department which reduces the dependence on transportation resources. As technology evolves and there's a continued focus on minimally invasive procedures, medical devices themselves are getting more challenging to process. This is happening at a faster pace than the expectations and qualifications of our SPD professionals. The result can be poor quality as we're expected to expertly process thousands of medical devices that are getting more complex."

Instead, NorthShore trains specialized SPD technicians to align with their hospital's specialty. For example, NorthShore's Orthopaedic & Spine Institute (Skokie) not only includes high-tech surgical suites and specialized surgeons and clinicians but also an SPD team comprising experts in reprocessing orthopedic and spine instruments.

"Our team will have basic skills in decontamination, set assembly, sterilization and case carts to help other pavilions as needed," she noted. "Specializing allows our SPD staff to become experts in the care and handling of those particular instruments. This specialized model is the same model we will follow as SPD prepares for the opening of a new NorthShore Cardiovascular Institute."

Mace Davis cautions against perceiving specialization as somehow limiting.

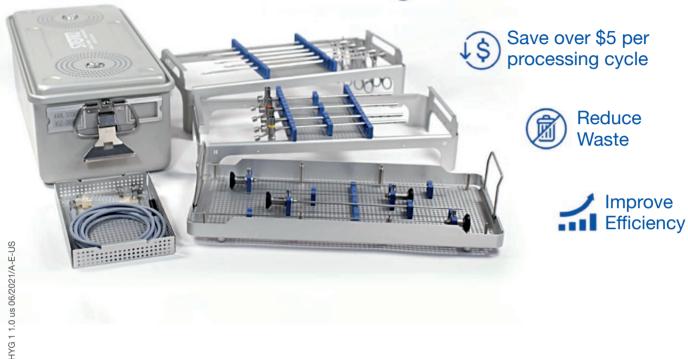
"All team members are cross-trained in basic decontamination, set assembly, sterilization and case carts," she countered. "Specialization is by location. If a hospital SPD team is short-staffed one day, a team member from another hospital may travel to that location to help out but not in a specialization different than they are trained in. Instead, they would backfill a less specialized position and allow one of that hospital's team members fill in for the more specialized tasks in which they are trained."

NorthShore believes minimizing variation and developing experts in SPD have been keys to the department's success, according to Mace Davis. The benefits of this model include built-in contingency, reduced instrument inventory needs due to shortened lead times and no long-term dependency on resources – trucks, people, dock space – for transporting instrument trays, she says. "People, process, and product are crucial attributes to any high









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functioning sterile processing team – but it's our people in particular who set us apart from other organizations," she added.

SPD's management team includes four location-specific SPD managers, a high-level disinfection/sterilization (HLDS) manager, and a manager of quality and education, representing a "flattened organizational structure" that emphasizes valuable peer-to-peer support. "The advantages of this horizontally aligned team of six managers are that they are all peers and there to support each other every day," she added. "Even though we

are physically located at different hospitals up to 14 miles apart, we work very closely together." The Director, HLDS manager and Q&E manager are system positions and travel between sites. NorthShore is in the process of securing office space for the system leadership team out of the Skokie hospital that is the most centrally located and highest-volume SPD to further solidify collaboration.

We, not me

Mace Davis remembers one SPD manager uttering a refrain about their philosophy

that has become something of a motivator, if not a motto: It's all about "we, not me." Such an attitude makes standardizing processes and equipment across a multi-hospital system easier, she adds.

During the last half of 2021, NorthShore had to "decompress" the orthopedic specialty hospital during a massive 14-month SPD construction project that expanded SPD (footprint to 11,400 square feet from 6,000) to service up to 16 new ORs in addition to the existing 12 at one of the system's highest-volume hospitals. After exploring every conceivable option, one of the vendors - Agiliti - stepped up to support SPD by transporting clean trays to another pavilion for processing and returning sterile trays back for storage. SPD organized a multi-disciplinary team that included the OR, IP, procurement and Agiliti to establish a transportation process with temperature and humidity monitoring.

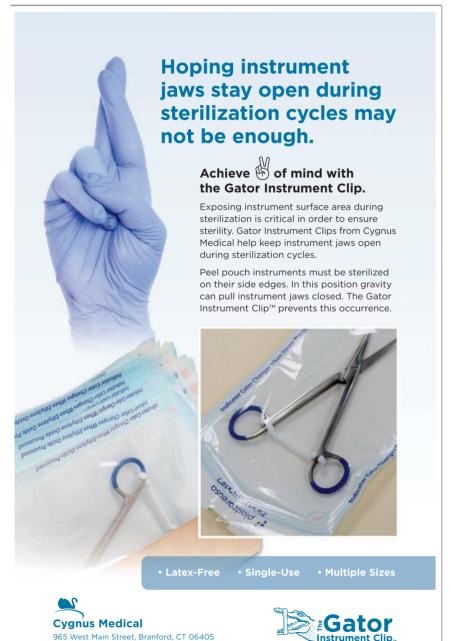
"Through this exercise, we were also able to define a systemwide contingency plan based on a transportation solution that better prepares us in the event it is ever needed," she said. "Not only did our vendor work closely with us to understand and meet our needs, we leveraged our strength as a system to ensure this change in assembly and sterilization didn't adversely affect the OR."

SPD standardized a host of processes, including the reprocessing of specialized instruments such as robotic arms, ophthalmology instruments and flexible endoscopes in addition to water quality testing, borescope testing and quality checklists.

Peel pack processing was a particular win, according to Mace Davis. "We not only standardized within the hospitals but also started transitioning the instrument processing from our clinics to SPD," she said. "We know there is a lot of focus on the way these instruments are processed (opened, no staining, appropriate size pouch, no broken seals, etc.) and this centralization allows our SPD team to own the process as experts in cleaning, packaging and sterilization."

Mace Davis admits that existing workflows, such as how SPD reprocessed robotic instruments, were the most difficult to standardize.

"Change can feel personal, and we not only included our SPD teams in the process reviews, but also the OR teams," she said. "Specific to this project, there was a lot of debate over wrapped or peel pouched arms and which process was better. When multiple solutions are acceptable, consensus can be challenging! Getting the other side to try the new way often helps ease concerns



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- and presenting data whenever it's available helps. Otherwise, we can spend a lot of time discussing all of the 'what ifs' instead of the problem at hand. Perfection can't be the enemy of progress."

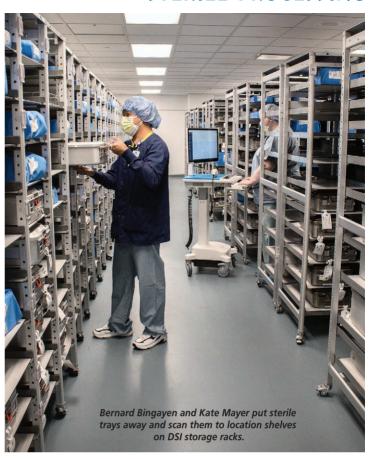
SPD's expansion and modernization project included a thorough capacity analysis based on actual cycle times and volumes because the typical capacity for a piece of equipment may actually be less than expected with larger, more complex orthopedic trays, according to Mace Davis.

SPD focused on staff safety when purchasing ergonomic sinks, flushing systems and workstations. They emphasized patient safety as they established one directional flow (to clearly separate dirty, non-sterile and sterile trays) with pass-through equipment including sterilizers (steam and low-temperature models). They installed quality stations for borescope inspections, and staff were trained on what to look for and how to document issues. SPD also initiated a partnership with a local vendor – Phigenics – to monitor water quality by collecting and testing samples and reporting results to NorthShore's Water Management Committee, which promptly invited SPD to join as a member.

Mace Davis stresses SPD's water works.

"I recommend this for all SPDs," she said. "As an industry, we have learned so much in recent years about the importance of water quality and we've appreciated the dependability of this vendor partner." HPN

NorthShore University HealthSystem's award-winning Sterile Processing team roster can be found at https://hpnonline.com/21259839





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NorthShore upends SPD status quo

System invests in criticality, development, essentialness

by Rick Dana Barlow

istorically, Sterile Processing as a department and function tends to be given short shrift when it comes to organizational respect. At best, SPD is viewed transparently; at worst, SPD is blamed when something goes awry.

"Many people don't understand how technical our jobs are and how many different things we are responsible for managing – people, water quality, workflow, quality, cost savings, regulations/ standards, supplies, etc. This goes back to the importance of telling our story, leading and developing teams, and building trust," noted Courtney Mace Davis, Director, Sterile Processing, NorthShore University HealthSystem.

But Mace Davis acknowledges that trust takes time to build, so the SPD team achieved it by leading collaborative teams toward improved workflow, compliance, and cost-savings. She shares three examples – one representing each improvement.

"Workflow was improved at [NorthShore's] Skokie hospital as part of the renovation project. While the new space was needed to support volumes, it also required a need to improve our workflows. For instance, case carts that previously were delivered to decontamination right next to the sink now needed an indicator to signal that case carts were ready to be unloaded. This was due to the new distance between the elevator and the sinks. We now have blind spots to account for and a need to prioritize the workflow. We had an elevator light installed in the ceiling to indicate a case cart's arrival and a receiving person in decontamination prioritizes the work by pushing case carts to the appropriate sinks.

"Compliance was enhanced as we improved our robotic reprocessing through the purchase of STERIS washer racks with flushing adapters, lighted magnifying glasses, timers and soaking buckets with racks. The result was fewer quality events reported by the OR.

"We hired an instrument coordinator at one of our hospitals who is working with other hospitals in the system to identify extra instruments and check with each other before purchasing new. This system-based approach to instrument management is new to us in the past six months but has already saved our department more than \$100,000 in new instrument costs."

SPD's essential nature to the operating room and to patient care needed to be promoted, according to Mace Davis.

"The critical role of the Sterile Processing department (SPD) to a high-functioning operating room (OR) is often underappreciated and misunderstood," she observed. "They are often recognized when there was a system breakdown and left to their own work when things were 'going fine.' This cycle of transactional interaction and underinvestment needed to be broken first by elevating the SPD team to the table as a member of the OR management team on equal footing with any other stakeholder."

And that's precisely what NorthShore University HealthSystem did with its SPD team.

The road to respectability started with a new leader over the OR who saw with his own eyes just how SPD operated once the OR finished a case.

"As the Vice President of Perioperative Services, I would round with clinical leaders and also spend time asking direct care givers for an understanding of what is working and where we have opportunities to improve," said Gus Granchalek, Vice President, Perioperative Services & Anesthesia. "In my early days in the role, I recall being in the sterile core between cases as the rooms turned over and watching as the nurses, techs and team leaders prepped for the next case. Invariably, they would wheel a case cart into a room, inventory their trays and supplies and realize they were missing something. The feeling of anxiousness that washes over that team, now scrambling to find their missing tray or supply, is incredibly powerful and served as a call to action for all of us. In the beginning, the motivation

for this journey was to ensure that every case started in a coordinated fashion and the team could keep their focus 100% on the patient."

NorthShore also added Matt Belanger as Director, Clinical Operations, who was new to SPD, but ready to learn fast. What they found motivated them to pursue transformational change and sustained improvements using their internal assets and resources rather than outsourcing to a third party.

"Hiring consultants was a consideration as we embarked on our improvement journey," Granchalek noted. "From the vantage point of the VP, the key to transformation is leadership and sustainability, which we hired for with the Director of Sterile Processing. She and the Director of Clinical Operations were a formidable pair. Together, they had profound understanding of the organization's culture, deep industry expertise and an ability to form and lead teams that would build a culture of excellence. Simply, they believed in what was possible and that was infectious. Building this culture has been the foundation for success throughout our journey. Organizational leadership felt it important to empower and challenge the director and managers to lead these important efforts and create sustainable change."

With a seat at the multidisciplinary table, SPD often leads discussions and outcomes; hosts daily huddles and routine management review meetings, monthly multi-disciplinary "Connections" meetings and quarterly quality and productivity meetings; and cross-trains staff so that they can fill in when and where needed but also specialize in selected areas.

SPD helps managers learn and then lead projects with such methodologies as 6S, Plan-Do-Study-Act (PDSA) and Define-Monitor-Analyze-Improve-Control (DMAIC), according to Mace Davis. One of the managers, working with OR peers, created a poster about the power of teamwork that was displayed at a national OR conference.

NorthShore SPD team salutes supplier partners as instrumental in success

Who supports an award-winning organization? Evanston, IL-based NorthShore University HealthSystem's Sterile Processing team appreciates the product and service companies that have helped them develop and improve their operations and performance during the last several years. The team shines a spotlight on 11 below that were critical to their success.

Agiliti worked with us to develop temporary tray transportation solution (heat and humidity monitored) to help decompress operations during construction at Skokie Hospital. They were flexible and easy to work with, and also provided free education (CEs) to SPD.

Ascendco Health partnered with us to implement a new instrument tracking system that resulted in improved quality of trays to the OR, point-of-use care of instruments, and compliance related to staff certification and competencies. They spent countless hours with our team to understand our needs and collaborated with us to implement new solutions.

Casechek helped with loaner tray tracking, metrics and display. They initiated vendor feedback meetings by providing data to drive improvement of on-time delivery and tray check-in compliance.

DePuy Synthes assisted with organizing implants to make it easier for SPD staff to locate. This resulted in saved SPD labor time and more accurate ordering of implants.

Phigenics worked with our team to implement a water quality management system that's easy to sustain with actionable results. This was especially important during intermittent operations related to construction and COVID-19.

Pure Processing LLC elevated the level of staff satisfaction working in decontamination with ergonomic sinks and flushing devices, enhanced sink organization, better lighting and added magnification. They were invested in our success and provided education for staff as needed.

SIPS Consults provided temporary educators to help train new sterile processing program graduates. Onboarding new technicians with a desire to work in SPD has been one of the most rewarding and long-term investments we made last year, and the SIPS team was a big part in our ability to do this. They were personable and understood the importance of a positive first experience for anyone working in sterile processing.

STERIS provided equipment that was a solution for workflow and compliance challenges. This automated pass-through technology promotes one directional flow and in some cases helps with pressure differentials between work zones.

STERIS IMS helped us establish and sustain an instrument preventive maintenance schedule in conjunction with our instrument tracking system. They also contributed to creating a quality station with borescope inspection.

Stryker and **Zimmer Biomet** helped us keep backup instruments organized and put trays together through construction to assist our SPD staff. These suppliers were very good about asking what they could do for us and how they could help. This level of support continues to be invaluable to our perioperative team.



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NorthShore SPD weathers pandemic pressure

Like all healthcare organizations during the last two years, the Sterile Processing department at NorthShore University HealthSystem faced a number of pandemic-related challenges.

"Instead of dwelling on the negative we turned our attention to opportunities and found ways to seize the moment to drive change," said Courtney Mace Davis, Director, Sterile Processing. "This started with posting and reinforcing our department's strategic plan. With NorthShore's mission, vision and service values as our guide, our team identified additional values that were important to us as an SPD department. Using ANSI/AAMI ST90 as guidance, we collectively defined our quality policy, quality objectives and core values."

SPD uses this strategy to recruit and interview for new staff, Mace Davis continues, because they want candidates to know what SPD is looking for in its team members and what they can expect once they join the team.

"With the patient at the center, clinical excellence is key to our health system's culture," said Gus Granchalek, Vice President, Perioperative Services & Anesthesia. "With this guiding our way, we have been able to build upon our expertise and talent to provide differentiated care to our patients and communities by continuously asking ourselves how we can be incrementally better.

"We want to hire the best fit," Granchalek continued. "Like any good team, we are a compilation of different talents and perspectives that leads us to more diverse and innovative solutions to the challenges we face. As we hire, we emphasize transparency, our commitment to excellence and how our team plays a vital role in actualizing that. Our pace of innovation and accountability makes NorthShore a rewarding place to work for many. We receive comments about how professional and solution-oriented our teams are when working alongside our colleagues in the ORs and other areas."

NorthShore and SPD leaders stress that patient and staff safety are non-negotiables. Data form the basis of conversations and decision-making designed for continuous improvement, according to Mace Davis.

"What makes our strategic outlook different than others is our focus not on *what* we want to do, but *how* we're going to do it," she said. "We strive for excellence every day by considering the possibilities of how tomorrow can look better than today. We focus on corrective action (prevention) instead of only correction (fixing the problem at hand). This is difficult when volumes are high and staff are stretched thin, but we understand that if we don't invest that time today no improvement will be sustained."

One of the primary pandemic-related challenges involved staffing.

"Yes, we definitely experienced this," Mace Davis acknowledged. "By initiating daily supervisor calls between our hospitals, we were able to assess daily volumes and staffing levels and send staff to help at other locations as needed. This was a reactive approach to managing staff shortages but allowed us to successfully leverage our strength as a system."

But SPD didn't stop there.

"Additionally, I personally met with most of the staff that were still committed to our NorthShore team," she continued. "Exit interviews can provide helpful information, but I felt it was important to have those conversations before someone decided to

leave the organization. These were in person, face-to-face conversations

outside of the work area. Gathering this feedback in a relaxed, open forum and addressing concerns went a long way in showing our commitment to staff retention.

"When we have bad days or there are challenging times like many departments faced during the pandemic, we know we can rely on each other for support and emotional safety," Mace Davis added. "Candor with compassion is emphasized as we know that's the only way to improve, even when it leads to uncomfortable conversations."

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"Incorporating problem solving tools puts some structure to our ideas and solutions and reminds us of the importance of monitoring to sustain," she said. "Putting things in poster form is a great way to build pride and communicate wins. It also gives our team a chance to showcase their work both internally and externally."

Still, SPD saw a number of staff members leave for various reasons, including personal and pandemic-related challenges around mid-year last year, Mace Davis notes. SPD turned to recruiting new graduates from local college sterile processing programs that allowed them hands-on training. Thankfully, SPD were able to obtain funding to invest in temporary educators to fill more than 60% of those open staff lines with dedicated preceptors who don't take away from the full-time staff supporting daily operations. In fact, at one point, 25% of staff was new and in orientation, she adds.

"Once we had the SIPS Educators in place, we were able to better partner with local SPD programs and brought new grads in at a rate of 10 new hires a month," she said. "This was very exciting, but also impacted our daily operations. In order to maximize our training resources, we put all new hires in one location. While this was the best way to train so many people at one time, it was also challenging to support in terms of available locker space, workstations/ computers, and break room space - especially when capacity was diminished due to pandemic-related social distancing requirements."

With 85% of SPD staff certified, Mace Davis is making a concerted effort to increase that number as well as promote re-certification through monthly focused continuing education opportunities during work time. SPD also developed career opportunities within the department across the entire system through budget restructuring to fortify SPD's enduring bench strength, she adds.

Mace Davis credits the diversity of SPD's management team's experience as contributing to departmental success.

"SPD is a rapidly changing field and none of us has all the answers," she indicated. "However, having hired from diverse backgrounds there is likely someone on our team who has the answer we are looking for. Finally, we have developed a culture in which, in the absence of an answer, we can openly discuss, disagree and find consensus." HPN

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SPD should be a quality hub within healthcare organization

NorthShore's SPD leader emphasizes patient care hinges on SPD performance

ourtney Mace Davis sees no viable reason why healthcare organizations should not take sterile processing seriously. Nor does she understand why this even is an issue if quality-motivated executives simply connect the dots between what happens to patients in the Operating Room, which relies on Sterile Processing and Distribution (SPD) service, and what happens to those patients post-discharge – as in outcomes.

With an extensive background in quality management systems, Mace Davis should know. She shares with *Healthcare Purchasing News* Senior Editor Rick Dana Barlow the critical nature of what her award-winning team does and why it matters.

HPN: Let's start at the beginning of the process. How does your team access manufacturer instructions for use IFUs? What is your biggest challenge with IFUs? Access? Content details? Something else? Why?

MACE DAVIS: We use OneSource to access IFUs and also request them from the original equipment manufacturers. The biggest challenges with IFUs are the lack and inconsistency of information - especially when it comes to cleaning devices. Manufacturers have an opportunity to ensure these documents align with the actual workflows in SPD. This is a high-pressure environment, and our technicians need IFUs with simple, easy-to-follow instructions. Years ago, I was part of a team that performed an analysis of five trays, which resulted in 153 IFUs with unique workflows. It's not realistic to manage that many workflows, and this was only for five trays! Additionally, in some cases the content is outdated and not based on current technology or standards. This is slowly improving as more end-users become involved in AAMI work groups and standards development.

What makes SPD in a university healthcare system different from SPD in a secular system – investor-owned, non/not-for-profit or government and why?

At first glance, the emphasis on teaching, learning, and innovation in a university healthcare system may seem like a difference, but I believe once that mindset is cultivated those attributes can be promoted in any setting.

Of SPD's ongoing strategic goals, which do you foresee as the most challenging for your SPD team and why? How about the least challenging and why?

The most challenging isn't any particular goal, but rather the pace we maintain to achieve the goal. This goes back to the theme of not what we have to do, but rather how we do it. Working in SPD is a marathon and something we need to manage intentionally and proactively every day. But many of the SPD challenges coupled with the effects of the pandemic (both personally and professionally) have turned this marathon into a sprint. There's often a sense of urgency to pivot as we are faced with new and often unexpected challenges (staffing, variable case volumes, construction) on a daily basis, and this pace can sometimes feel unmanageable and overwhelming. As a whole, our healthcare team's well-being is very important to NorthShore, and we need to lead by example. That means taking time to slow down and separate from work. This can be challenging when there's so much to do, but it is important and expected.

The least challenging strategic goal for our SPD team will be doing the right things every day. I believe we have built a culture in which we do the right thing every day every time, whether someone is looking or not. It is incredibly powerful to have this level of confidence in ourselves and our teams

Returning to the pandemic, what were some of the key challenges that SPD faced in 2020-2021 that they overcame and excelled?

For us one of the key challenges was taking care of our people and ourselves during a time of great uncertainty and loss. Our SPD leaders are aligned in our management philosophy of helping each other succeed, but the pandemic affected us all in different ways. The support needed isn't the same for everyone. It's a different level of leadership when we personally get to know our team members and what we need to do to

support them through a crisis like we've experienced the past couple of years.

I believe our team has built resilience and compassion during the pandemic and we are better leaders because of it. We are humble and appreciative of others; we've listened more and worked together to help each other – these are all ways we excelled as people and leaders over the past couple of years.

Courtney, your background is in quality improvement and process management, and it includes the University of Iowa Hospitals and Clinics (UIHC was a finalist for the 2016 SPD Department of the Year Award), as well as CIVCO and Celestica, where you concentrated on quality and business process improvement and lean management engineering. What elements and experiences from that background have you brought to NorthShore and implemented in SPD because you deemed them valuable contributions and why?

We were finalists at Iowa under my leadership in 2016 and 2017. Third time is the charm!

I've been fortunate to work in a variety of positions in my career. At Motorola (referring to Motorola instead of Celestica since there was an acquisition) I learned about the power of Six Sigma and reducing process variation, Lean and the power of workflow management including the elimination of waste, and the value of engaging the front-line staff in process improvements. As a Corporate Quality & Business Process Improvement Manager for CIVCO Medical Solutions, I learned about medical device quality systems, product validations and how to manage teams across multiple locations. And at UIHC, I spent several years working with an amazing team in operations excellence where we focused on ways to facilitate improvements in many healthcare departments.

I have brought all of these valuable experiences with me to NorthShore. As much as we share our stories as an industry, SPD is still a misunderstood department. In particular, the mindset of continuous improvement and strong people-focused leadership are a couple of things I prioritize

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with my team. With this approach anything is possible!

If any other facilities reading about you wanted to emulate NorthShore's SPD success by implementing any or as many of your organization's processes as possible, how would you advise them to start? Which areas should they tackle first and why?

Hire the right people – and then support them! The complexities in managing high-performing SPD departments are increasing rapidly. Technology and standards are changing, and we have budgets to adhere to. SPD leadership is not for the timid. We are protectors of our teams, our organizations and our patients. Doing the right thing every time isn't always easy, but leaders can make difficult decisions easier with a safety net built on both personal and professional relationships. If our teams feel supported, they will be more willing to step out of their comfort zones and lead some

of these process improvements that have traditionally been out of scope for SPD.

After the right people are in place, a gap analysis and risk assessment should be done. This collaborative approach to priorities will promote needed buy-in. What you actually tackle first will be dependent on things like risk, ease and speed of implementation, stakeholders, resource availability and skillset. This can't be prescriptive and will depend on the organization. HPN

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LEARNING OBJECTIVES

- 1. Review the principles of sterilization quality control.
- 2. Discuss the basic requirements of validation.
- 3. Examine the requirements and application of routine monitoring.

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SELF-STUDY SERIES

Sterilization quality control

Validation, routine monitoring go hand in hand

Craig Wallace, President, Wallace Sterilization Consulting, LLC

roper sterilization of medical and surgical instruments is a critical piece of any infection prevention program. The very best aseptic technique will not be able to compensate for contaminated instruments. The equipment and processes used in the sterile processing department are complex, and the success or failure of a sterilization process is not easily determined. The sterile processing team must rely on a comprehensive quality system approach to ensure that instruments are safe and ready for use on patients.

Introduction to sterilization quality control

You can't see sterility. A sterile instrument looks identical to a nonsterile instrument. Thus, the decision on whether processed instruments are safe for patient use must be based upon other information. A sterilization quality control (QC) system must be in place to provide a process testing framework that will provide this necessary information. A QC system can be loosely defined as a system that maintains the quality of a product (in this case, the product is safe surgical instruments) by testing the product against a set of specifications. In this context, sterilization QC systems

do not test the instruments themselves because instrument sterility testing is not practical in a hospital setting. Instead, the sterilization process conditions are tested using an array of different types of tests that provide a comprehensive picture of the quality of the sterilization process.

The OC system should cover every aspect of instrument reprocessing (e.g., cleaning, inspection), with tests designed to provide information specific to each step in the process. This article will focus on the sterilizer and the sterilization process, and the QC approach that supports the final decision on whether to release the instrument load for use on patients. In addition, the focus will be on steam sterilization, as this process is used for the majority of surgical instruments. However, the principles discussed can be applied to low temperature sterilization processes as well.

Approaches to quality control

There are two different approaches to quality control for sterilization processes (also called sterility assurance). The first approach is called process validation, the second approach is called verification. In some situations, the validation approach can enable the use of parametric release for

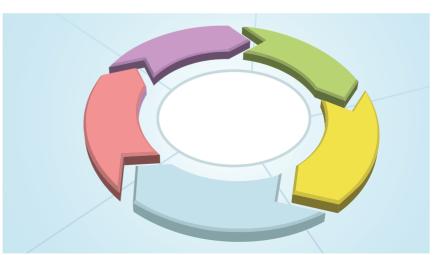


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the final load release decision. Verification relies on individual process testing and is often called routine monitoring. In this approach the load release decision will be based on the results of an array of tests on that specific sterilization process and load. The validation and routine monitoring approaches are quite different, however, there are ways they can be compatible. We'll start with a detailed review of each approach.

Validation

The term validation is defined as a "confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled"1. The "provision of objective evidence" refers to testing that produces data on the performance of a process, in this case, a sterilization process. This data is analyzed to determine if "the requirements . . . have been fulfilled," in other words, if the sterilization process met its expected performance parameters. For steam sterilizers used in healthcare, validation is typically performed by the sterilizer manufacturer to define and control the selected cycle. To really understand the details of the validation approach we can look at how validation is used by medical device and pharmaceutical manufacturers. The larger scale of their sterilization processes and required compliance with healthcare regulations makes validation the preferred sterility assurance approach for these companies. Substantial technical and financial resources are required to support the validation programs. Let's take a closer look.

The validation approach starts with testing and documentation that verifies that the equipment is installed and operating correctly. Process development begins with physical testing to confirm the critical variables of the process, and also determine the process parameters of the process. Critical variables are process variables such as exposure time or temperature that have a direct effect on the efficacy, or killing power, of the sterilization process. A process parameter is the actual numerical setting for a variable. For example, temperature is considered a critical variable for steam sterilization. A specific setting of 132°C would be the process parameter for the temperature variable. In the healthcare setting the sterile processing team will "choose" process parameters by selecting from pre-programmed cycles on the sterilizer. For an industrial setting that is using the validation approach the parameters must be established by testing. This testing can be quite extensive and complex. This process development testing will include establishing the limits of the process, that is, how much the parameters can be varied and still provide the required process lethality. Sometimes called "worst case" testing, these process tests will include physical measurements from multiple cycles using complex instrumentation that is placed in several locations inside the chamber and load. Process efficacy is typically evaluated through microbial inoculation of the most difficult to sterilize locations within the most challenging surgical devices, followed by culturing in a microbiological laboratory.

Once the required sterilization process parameters are established, the rest of the validation approach is focused on ensuring that those parameters are controlled and achieved on every single cycle. The core of the validation approach is the data-driven establishment of the process parameters followed by active control of the process and parameters to ensure that the process achieves it's expected efficacy. Active control means taking steps to ensure that the equipment is always capable of delivering the required process parameters. This will include rigorous on-going calibration of all testing equipment and sensors, and strict adherence to preventative maintenance procedures for the sterilizer and any ancillary equipment. A major challenge for steam sterilization is assurance that the steam quality does not vary from cycle to cycle. Steam quality is a critical process variable, as problems with steam quality (e.g., too wet, too dry, superheated, contaminated with non-condensable gasses) will adversely affect the efficacy of the process. Variations in steam quality can be difficult to detect and require significant investment to control. Validated steam sterilization processes typically require dedicated steam generation equipment, strict control of feedwater quality, and a rigorously maintained delivery system. The steam quality is carefully monitored to ensure it continually meets the requirements established in the process development and validation testing.

Another general requirement of the validation approach is change control. Again, the overall philosophy of the validation

approach is establishment of the conditions necessary to achieve a successful sterilization process, then active control of those conditions for all routine sterilization processes. Change control requires an assessment of the possible effects of any change from the original validated conditions, with subsequent revalidation of the process to accommodate the change, if needed. Changes can include intended changes to process parameters as well as any changes in cleaning processes, process or testing equipment, packaging or containers, instruments in the load, and even changes in load size or configuration. Sterility assurance by validation requires complete documentation of all materials processed, all process conditions, and the results of all change control assessments. Periodic re-validation of the process is required even if there are no substantive

A final aspect of the validation approach is possibility of the use of parametric release. Parametric release is defined as "declaration that product is sterile, based on records demonstrating that the process parameters were delivered within specified tolerances."1 In this system the decision to release a load of instruments for use on patients is based on assessment of the critical process parameters for that load, to see if all of the parameters were within the ranges established during the validation work. While this sounds straightforward, in reality it is quite complex. The parameter measurements require sophisticated instrumentation. A typical sterilizer cycle printout generated by a single sensor in the sterilizer chamber would not meet this requirement. In addition, the use of parametric release assumes the full critical parameter control system is in place for this cycle, and for all cycles. Parametric release is an efficient tool and well suited for industrial applications that are capable of the high level of process control and documentation required to utilize it.

Verification and routine monitoring

The term verification is defined as "confirmation, through the provision of objective evidence, that specified requirements have been fulfilled". The definition is similar to that of validation, but verification is a bit narrower. It is not defined as a process and focuses on "specified requirements" instead of the broader "intended use." For

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

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sterility assurance, a practical way to look at verification is routine monitoring, where the specified requirements would be the expected results of physical, chemical, and biological testing of a process. For steam sterilizers used in healthcare, verification is performed by the sterilize processing department personnel on each cycle.

The fundamental assumption behind the routine monitoring approach to sterility assurance is that total control over all process parameters coupled with a rigid system that does not allow variation is not possible in many situations. Healthcare facilities are typically not staffed, equipped, or funded to be able to implement the full validation process. The size, weight, and composition of healthcare sterilization loads are known to vary widely based on the cases scheduled in the operating room.3 The validation approach operates under the assumption that, through rigorous engineering and controls, every sterilization cycle and load is identical. The routine monitoring approach operates under the assumption that variability is inherent in the system and, for load release, treats each sterilization cycle as a distinct, independent event. In this system each sterilization cycle is tested with independent monitors, and the load release decision is based on the test results for that specific cycle.

The testing tools used for routine testing load release are physical monitors, chemical indicators, and biological indicators. Physical monitoring is accomplished by sensors in the steam sterilizer chamber that measure temperature and pressure and record the readings on the cycle printout. Physical monitoring helps ensure that the intended cycle was selected and provides a printed record of the cycle. Chemical indicators placed on the outside of packages are used to provide visual confirmation of exposure to the process, while chemical indicators placed inside of packaged items will provide information on the physical process parameters occurring inside of the load. Biological indicators, typically placed inside of process challenge devices, challenge the sterilization process with a large number of highly resistant bacterial spores. Biological indicators provide the only direct measurement of process lethality because they measure the process' ability to kill microorganisms rather than evaluating physical parameters.² The results of all tests are considered for the final load release decision.

While the routine monitoring approach considers each sterilization cycle as a unique event regarding load release, there is still a need for a broader QC program. Documented standard operating procedures should be in place that define the requirements for all processing steps. An example of a broader QC program for steam sterilization is provided in AAMI ST79:2017 (Comprehensive guide to steam sterilization and sterility assurance in health care facilities) 4. This standard defines different types of tests for the sterilizer and sterilization process that go beyond load release testing and provide a much broader picture of the overall quality of the sterilization process. In addition to Routine Load Release, AAMI ST79 recommends Routine Sterilizer Efficacy Monitoring (routine monitoring of the process with process challenge devices), Sterilizer Qualification Testing (a special testing regime to be used to return a sterilizer to service), and Periodic Product Quality Assurance Testing (to verify instrument manufacturer's Instructions for Use). This matrix of quality control tests provides a breadth of information about the sterilization process while accommodating the realities of the flexibility required in health care sterilization.

Routine monitoring with validation

The validation and routine monitoring approaches to sterility assurance are quite different, and at first glance would seem to have little or no overlap. The validation approach seems to be best suited for industrial sterilization or sterilizer manufacturers, and not really applicable to the health care environment. However, while a fullblown validation system is typically not suited to healthcare, there are elements of the validation approach that can complement and strengthen a routine monitoring program. From a higher level, a general philosophy of more control and consistency in all processes can help reduce variability and improve quality. Careful attention to sterilizer sensor calibration and sterilizer preventative maintenance of testing and process equipment can also reduce variability. Some healthcare facilities already do quarterly or annual testing of sterilizer process parameters and such things as varied load configurations as part of their quality program. Though

sometimes called validation, this type of testing should not be confused with a full validation program that requires on-going control of all process parameters, a full change control system, etc. In a general sense, any additional quality control steps taken beyond normal routine monitoring are helpful and can improve the quality of the overall process. In this way validation and routine monitoring can go hand in hand.

Summary

Sterility assurance programs are required to ensure that processed instruments are safe and ready for patient use. The full validation approach is effective but requires significant resources and is typically only used in industrial settings. The routine monitoring approach accommodates variability and the flexibility required in health care settings. Elements of the validation approach can augment and strengthen the routine monitoring approach in healthcare facilities. HPN

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3M Health Care sponsored this article.

Craig Wallace, president of Wallace Sterilization

Consulting, LLC, has over 28 years of experience in the field of medical device disinfection and sterilization. Craig is the Convenor of the ISO TC198 Working Group 4, the ISO committee responsible for international biologi-



cal indicator performance standards, as well as a U.S Technical Expert for Chemical Indicators (ISO WG 6). He is also the Co-Chair of the United States (AAMI) Biological Indicator Working Group, and an active member of several other AAMI working groups including chemical indicators and vaporized hydrogen peroxide sterilization.

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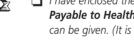
Validation, routine monitoring go hand in hand

Circle the one correct answer:

1.	Since you can't determine if an instrument is sterile just by looking at it, you need to rely on other information to decide if a load of instruments is safe for patient use. A. True B. False	6.	The validation approach assumes each sterilization cycle is the same as the previous cycle. A. True B. False
2.	The process validation approach to sterility assurance is primarily used by medical device and pharmaceutical manufacturers. A. True B. False	7.	Routine monitoring relies on the results of physical, chemical, and biological indicators. A. True B. False
3.	A process variable is a specific value of a process parameter. A. True B. False	8.	For load release, routine monitoring treats each sterilization cycle as a unique event. A. True B. False
4.	Validation and routine monitoring are two approaches to sterility assurance. A. True B. False	9.	The routine monitoring approach to sterility assurance is the typical approach used in health care facilities. A. True B. False
5.	Parametric release relies on the results of physical, chemical, and biological indicators. A. True B. False	10	Elements of the validation approach can be used to strengthen the routine monitoring approach. A True B False







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I want to see clearly

by Stephen Kovach

"We have an eyewash station in my department. What are the standards that we should be following to make sure they are safe to use any time? In fact, the eye cover is off the eye shower, and the tag attached is not filled out. What should I do?"

A When it comes to emergency eyewash stations, there are plumbed and non-plumbed types (Fig. 1). This article will focus upon plumbed emergency eyewash stations. In my view, the type that should be in a medical device reprocessing department is a plumbed emergency eyewash station, because it allows the person to use it hands-free once actuated.

When it comes to ensuring staff safety for using plumbed emergency eyewash stations, ANSI/ISEA Z358.1-2014 standard is what is referenced worldwide.

"This globally accepted standard continues to be the authoritative document that specifies minimum performance criteria for flow rates, temperature and drenching patterns," said Imants Stiebris, chairman of the ISEA Emergency Eyewash and Shower Group and Safety Products Business Leader of Speakman Company. "These are important characteristics for a user to receive adequate emergency treatment of the eyes and body when exposed to injurious materials."

Within the United States, it is a combination of documents a) OSHA ², b) ANSI/ISEA Z358.1-2014, and c) ANSI/AAMI ST79 (and ST90) that govern eye wash stations. The latter of which takes its reference from OSHA for its standard.

"The decontamination area must have an emergency eyewash/shower station...eyewash stations should not be in a location that requires flushing of the eyes in a decontamination sink."^{3,4}

Medical facilities with departments that reprocess medical devices utilize chemicals that employees can be exposed to; thus, they need to provide plumbed emergency eye stations in case the employee gets any chemical(s) in their eyes, and they must flush their eyes.

"If eye contact with a chemical or contaminant occurs, the eyes should be immediately flushed with large amounts of water according to the SDS."⁵

To ensure that a plumbed emergency eyewash station is performing properly, ANSI/ISEA Z358.1-2014 outlines what needs to be tested weekly; this helps to ensure safety of the staff and that these pieces of safety equipment are working when needed.

- Verify flushing fluid supply at the delivery head of the device.
- Clear supply line of any sediment buildup potentially preventing fluid delivery.









Figure 1: Eyewash with no covers on

• Minimize microbial contamination because of standing water. Document the a) date, b) person testing, c) location of the plumbed emergency eyewash station, and d) the temperature, according to your facility's policy on record retention.

"Properly maintained eyewash facilities"6

The presence of emergency equipment is not meaningful if the equipment is not maintained in working condition. Thus, for the plumbed emergency eyewash station a Quality Management System approach is needed to ensure it is working properly (IQ, OQ, PQ).

The plumbed emergency eyewash station must be designed so that the valves remain open without the use of the operator's hands until intentionally closed (i.e., hands free and its actuation system works correctly once engaged, whether by hand or foot). (Fig. 2).

ANSI/ISEA Z358.1-2014 requires eye and eye/face nozzles to be protected from airborne contaminants and full bowl dust covers provide additional protection from debris/trash accumulating within the eyewash bowl. This should be noted upon actuation the eye covers operate properly.

Based upon medical recommendations and various physiological studies, the ANSI/ISEA Z358.1-2014 standard requires that tepid (temperature range is 60- to 100 °F [16- to 38 °C]) flushing fluid be delivered. This temperature should be kept for at least one-minute after actuation of the eyewash station.

The information presented in the article is taken from ANSI/ISEA Z358.1-2014, which covers all types of emergency showers, eyewashes, eye/face washes, and combination units. The standard is intended to provide uniform, minimum guidelines for their performance, use, installation, test procedures, maintenance, and training.

Once again, the information here has focused on the plumbed emergency eyewash station because this is the recommended type of emergency eyewash station (most used) for staff who work within a medical device reprocessing department.^{7,8}

Broken eyewash cover

Concerning your statement on the broken eyewash cover; according to the standard, the eyewash cover should get replaced as soon as possible. Who knows what will fall onto the spray shower itself? (Fig. 3). That "stuff" could get into somebody's eye by mistake, causing more damage.

In my view, regardless of who is responsible for checking the plumbed emergency eyewash station, it is still the management of your department that is always accountable for the station being in working condition. That is why I always suggest the department should own the testing process. HPN

Visit https://hpnonline.com/21259860 for references

HSPA VIEWPOINT

HSPA's 2022 Annual Conference

Your Ticket to In-Person Education, Networking

by Julie E. Williamson



he Healthcare Sterile Processing Association's (HSPA's) Annual Conference is taking place April 23–27, 2022, at the San Antonio, Texas, Convention Center and will be *the* in-person sterile processing educational and networking event of the year.

After so many in-person events were canceled over the past two years due to the pandemic, attendees, industry experts and HSPA staff members are eager to meet again in person and participate in a wide range of educational offerings that will advance technical and leadership knowledge for the Sterile Processing department (SPD), provide updates to standards and regulations, develop and sharpen critical soft skills, and allow attendees to learn about the latest products and services impacting the profession. Attendees arriv-

ing early to San Antonio can kickstart their learning by participating in preconference labs and workshops (HSPA is offering assorted complimentary labs and workshops for registered attendees on a spaceallowed basis; additional workshops, including the "Getting the Most from Your Instrument System" and "Hot Topics in SP Management" tracks and the "Educators Forum" are paid events that require pre-registration and additional payment).

"This year's conference will bring us all together again for industry-leading education and valuable networking," said HSPA's Education Director Natalie Lind, CRCST, CHL, FCS. "There is nothing like the power of learning alongside professional peers and having an opportunity to meet with some of the industry's leading experts. The positive energy and informa-

tion sharing experienced at our in-person conference is something we are all eagerly anticipating once again, and our session and event lineup will not disappoint."

The general conference schedule (Sunday, April 24–Wednesday, April 27) will provide 16 available continuing education (CE) credits, and additional CEs may be obtained by participating in preconference events and in-booth education offered in the Expo. The Expo, be held Monday and Tuesday, April 25–26, will feature more than 100 vendors and provide a perfect opportunity for attendees to ask questions and get up close and personal with the newest SP-related products and services.

What follows is an abbreviated schedule at a glance. To register or learn more about the 2022 HSPA Annual Conference, visit https://myhspa.org/conference-information.HPN

Saturday, April 23

8–11:30 a.m.: Getting the Most From Your Instrument System (additional paid workshop)

8–11:30 a.m.: Hot Topics in SP Management (additional paid workshop) **8:30 a.m.-5 p.m.:** Assorted Complimentary Labs/Workshops (free to registered conference attendees; limited space available—first come basis) **12:30—5 p.m.:** Educator's Forum (additional paid workshop)

Sunday, April 24

8-9 a.m.: Opening Remarks

9-10 a.m.: Opening Keynote (Ben Nemtin)

10:15–11:15 a.m. (General Session): Quality and Safety for Every Patient and Every Worker, Every Time

1—2 p.m.: Advocacy Update

2:30–3:30 p.m. (Concurrent Sessions): Dental Instrumentation and ANSI/AAMI; How to Evaluate Stains After Steam Sterilization; Managing Water Quality

3:45–4:45 p.m. (Concurrent Sessions): Inspecting and Integrity Testing of Insulated Instruments; Developing a Comprehensive Disinfection Sterilization System; No Unicorns in the OR

5 p.m.: HSPA Membership Meeting

7 p.m.: Opening Reception

Monday, April 25

7–8 a.m. (Concurrent Sessions): Surgical Tray Optimization; Strategies to Construct and Maintain Container Compliance

8:30–9:30 a.m. (Concurrent Sessions): Time Is Running Out: The Importance of Time and Environmental Conditions on Contaminated

Instrumentation; Supply Chain and COVID-19: Behind the Scenes; Steam Sterilization Cycle Load Optimization

11 a.m.–12 p.m. (Concurrent Sessions): Challenges for Processing Robotic-Assisted Surgery; Sterilization Standards and Standard Development; Cost Analysis: Where Is Your Money Going?

1-5 p.m.: Expo Opens

Tuesday, April 26

7–8 a.m. (Concurrent Sessions): Man, All I Want to Do Is Clean; Best Practices in Sterile Processing

8 a.m.-12 p.m.: Expo Open

1:30-2:30 p.m. (General Session): AAMI ST91 Updates

2:45–3:45 p.m. (Concurrent Sessions): Leadership: Who Wants to Follow You; External Transportation; Bring It On! Test Your Knowledge in the Gamification of Vaporized Hydrogen Peroxide

4–5 p.m. (Concurrent Sessions): Professional Development for Frontline Staff; Can You Handle It? Medical Device Manufacturer Learning; Managing the Sterile Processing Department's Different Leadership Styles

Wednesday, April 27

8:30–9:30 a.m. (General Session): Navigating Multiple Instructions

9:45-10:45 a.m. (General Session): Sorry, It's Not a Career Elevator

11-11:30 a.m.: Closing Remarks

11:30 a.m.-12:30 p.m.: Closing Keynote (Shola Richards)





upply storage, management and tracking from receipt through use has long been a challenge for U.S. hospitals given the sheer volume of medical/surgical and drug supplies, the many stakeholders who handle them, and various logistical factors (e.g., limited storage space, outdated inventory management systems, etc.).

Faced with crippling cost pressures, supply shortages, and the need to maximize resources, hospital supply chain leaders are continuously seeking ways to solve supply issues, and companies are responding with new solutions aimed at taming complexity and boosting accuracy and efficiency.

Ceasing the mad supply scramble

"What happens in your kitchen when you are in the middle of cooking your Thanksgiving meal and you cannot find an ingredient, utensil or cooking pan and you need to finish the meal before it gets cold? A mad scramble for a solution takes place. Do you make a run for it? Do you panic? How much time searching before you make phone call to neighbor? It's not a position anyone likes to be in whether at home or at work. This is comparable to what happens throughout a hospital's supply chain on a daily basis," said Ian Loper, Vice President of DSI.

Loper points to the challenges caused by old storage methods and disorganized supply rooms, including expired, misplaced or damaged supplies. Hospital staffs can't manage what they can't see; therefore, he advocates for ways to improve supply visibility in storage areas.

"Visual indicators down each row, at the top of each section, better/bigger labeling for each item being stored for each compartment, and color coding by service line are all simple ways to enhance the efficiencies and employee morale in the workplace," said Loper.

He says DSI Direct has elevated its labeling product offering to include a variety of

different ways to enhance visual indicators and labeling to help reduce the time it takes to identify and retrieve the supplies.

"When doing so, it makes it easier and quicker for the staff to look for, find and deliver the supplies to the patient, surgeon or colleague in need of the item," Loper added.

Gaining visibility to supply storage everywhere

"Hospitals typically have visibility of their onsite perpetual inventories in central supply or central sterile, however, that does not account for all of the inventory available to a hospital," said Zach Malingowski,







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Senior Director, Medline Supply Chain Optimization. "Best-in-class inventory visibility includes hospital-owned inventory stored throughout the entire supply chain network, including inventory stored in nursing supply areas, offsite warehouses, and with a third-party logistics provider."

When evaluating hospital storage areas, Malingowski says he often finds supply rooms underutilized. He recommends maximizing existing storage space by using wider and deeper wire racks/shelving, and designing a mix of location sizes into spaces, while always including open storage space for growth.

"Inventory demand is not static; a hospital must be able to increase/decrease an item's on-hand quantity while storing it in the most optimal location size," said Malingowski. "The space for growth is needed so new items and higher on-hand quantities can quickly be added to support new patient services and increases in census."



Medline electronic shelf label

Malingowski has seen greater use of electronic shelf labels in hospital storage areas, which can be integrated with the hospital's enterprise resource planning (ERP) system for instantaneous updates.

"Not only can you change the SKU number and PAR quantities, but the label can also display nurse-friendly descriptions, reflect a temporary substitute SKU number, and alert end users of a manufacturer back order or product recall," he said. "There are a handful of vendors out there that sell electronic shelf labels, including Medline."

Achieving just in case without the clutter

As David Phillips, Marketing Manager, Hänel Storage Systems, explains, many hospitals have reconsidered 'just-in-time' inventory management methods because of pandemic related supply shortages. He states:



"A 'just-in-case' method is more proactive and dictates a healthy stockpile to avoid running out of inventory. The trick is to find a proper balance between the two. A consequence of a poor inventory management strategy is that supplies could be prematurely exhausted or unavailable for medical procedures, which in turn can compromise patient care."

According to Phillips, most hospital shelves are only populated with supplies from about knee to shoulder height because staff members find it too difficult to access items from the top and bottom shelves.

"The next time you're in a hospital, look up. Vertical space overhead is often the most vacant. This area can potentially store lots of inventory, minimizing the need to expand through walls to acquire more space. It's also far less expensive to grow vertically through a ceiling than it is to increase a footprint horizontally."

To make vertical supply shortage space accessible and usable, Hänel Storage Systems offers the Rotomat Automated Vertical Carousel, which stores inventory in unused overhead space, densely packed for a truly efficient use of space. Onboard software integrates with the hospital's ERP and tells users exactly the inventory quantities on hand. It also brings all stored items to the same waist-high level upon request, eliminating the need to repetitively bend, reach or search for items

Applying Lean manufacturing principals for greater efficiency

"Nurses need fast and accurate access to potentially life-saving supplies to provide

good patient care," said David Jacobson, Marketing Manager, Akro-Mils. "When hospital storage rooms aren't effectively managed the result can include wasted time searching for the correct supply, potential for over- and under-stocking supplies, expired product used, and additional labor time to address emergency stockouts."

Jacobson recommends hospitals incorporate Lean manufacturing principles, such as 5S (everything has a place and everything in its place) and Kanban systems (employs visual indicators to avoid stock outs), to improve supply management productivity.

He notes that bins are used in multiple ways to manage inventory. Some hospitals use a 2-Bin Kanban system that consists of two stocked bins with one bin holding the primary stock and the second bin (usually located behind the primary



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bin) holding the backup stock. When the primary stock is depleted, the first bin is sent for replenishment and the backup bin becomes the primary stock. He says another approach is using bins attached to electronic scales that are connected to an inventory system. When stock gets low, central storage is notified electronically to refill the bin.

"Akro-Mils products include our AkroBin and Shelf Bins, which are widely used in hospital storage rooms and can be adapted to integrate into many types of inventory control systems," Jacobson added. "Both bins come in multiple colors that can represent the types of products contained in the bins—or translucent to see the contents—and spaces for labeling."

Boosting clinician confidence in supply management

The practice of hoarding supplies wreaks havoc on inventory management, according to Dave Salus, Market Manager, Healthcare Division, InterMetro Industries Corporation. A nurse putting aside products for emergency use can lead to other nurses not having what they need and creating their own supply stashes, and it snowballs from there.

"Now, the supply tech is noticing the increase in 'consumption,' so replenishment amounts are increased to keep up with the 'increased demand,' said Salus. "You can see how this can quickly spin out of control by expanding this to all SKUs in all the stocking locations that are used by countless people. This inevitably leads to excess inventory, and worse, it leads to inventory that is no longer controlled. It all comes down to trust, trust in that what is needed will be there, when its needed."

There are a lot of solutions out there to help manage inventory, but without trust



none will succeed. Communication is the foundation to establishing that trust, and supply chain and clinical stakeholders must come together to pinpoint problem areas and identify solutions aimed at the challenges they need to overcome.

InterMetro Industries Corporation offers a variety of supply storage and organization options to support inventory management solutions. These can be open or enclosed and deliver high density storage or high visibility and access. They include moveable aisle track solutions, cantilevered baskets, adjustable wire shelves, slanting shelves, as well as totes and bins.

Safeguarding drug supplies

Given the numerous associated costs and risks, security and safety issues around hospital drug supplies are always a concern in healthcare facilities. Phillip Van Gorp, President, USA Belintra Med IT and Storage Solutions, cites growing threats of theft and malpractice from pharmacy to bedside when medication management processes are not controlled and documented properly.

"Individual medication distribution at patient level is in great need of higher security," said Van Gorp. "Making sure the right medication is administered by the nurse holding the required authorizations at the right moment, and to the right patient is a challenge. Bedside scanning of patient, nurse and medication is the only way to guarantee a safe closed loop."

Belintra's medication distribution carts allow hospitals to control, track



and trace access to specific drawers by a USB controlled single sign on technologies. Medication distribution is based on unit dose, allowing for greater efficiency and cost saving. The advanced computer on wheels (COW) controller facilitates individual battery management, with DC over AC power that gives a 20 hour battery life.

"As every hospital has its own way of working, we are offering various locking alternatives on our trolleys, as well as different capacities in respect of which volumes of medication is being distributed or administered," Van Gorp added.

Automating drug distribution

In addition to risks for drug loss, expiry and diversion, Len Hom, Director, Point of Care Marketing, Omnicell, says poor management of medication inventory can lead to clinician frustration and delayed patient therapy as caregivers are forced to search for drugs when they need them.

"Technology is the great equalizer when it comes to improving operational efficiency," said Hom. "Cloud-based software solutions, connected to pharmacy automation solutions, can provide realtime inventory visibility and predictive and prescriptive analytics that remove manual steps in inventory management, saving time and money. Especially with today's labor shortage, you can maximize



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pharmacy tech time by assigning them tasks in-app, and once the tasks are completed, the pharmacy admin can see the completion in real time. This saves time from having to make phone calls or manually tracking restocking, destocking, par level adjustment activities."

Omnicell One is a technology-enabled service that provides visibility, insights and workflows to optimize medication inventory management. Integrated Intelligence with the XT Automated Dispensing System allows hospitals to leverage predictive and prescriptive analytics to aggregate and analyze data, delivering the visibility, insights and workflow tools to elevate pharmacy performance. Operational dashboards make it easy to quickly locate a medication across a health system, track COVID-19 medication use trends, and identify compliance issues that may indicate drug diversion.

Tecsys Elite Healthcare Data Capture Technologies

Expanding options in medical/surgical supply management

In recent years, BD has made major investments in new supply chain automation solutions for the point of care (POC) with its Pyxis Supply Portfolio to meet the changing needs of its hospital customers. The company also offers flexible leasing options on all POC solutions through which customers can modify their "footprints" in terms of automation technology to meet changing needs.

"We want to partner with our customers to make sure they can not only meet cost, quality and outcomes (CQO) goals today, but also with whatever challenges they face in the future," said Theo Stephens, Associate Director U.S. Region, Pyxis Supply at BD. "Using our assessment tools we can go into a hospital, understand their supply challenges and quickly come back with an automation strategy customized to address their specific pain points."

BD Pyxis offers two open solutions through which a hospital can use existing supply storage infrastructure for management and replenishment of medical/surgical supplies. One is ParActive where each item in a par location is assigned two RFID cards. A clinician places a card into an RFID-enabled "mailbox" to alert materials management of 50% inventory depletion, and the other card to communicate a stockout. The second solution is StockStation, a barcode scanning inventory



management system for POC product capture of chargeable items in the operating room (OR).

For secure management of chargeable supplies, BD Pyxis offers RFID enabled cabinets, that, along with their other solutions, are integrated with the hospital's electronic health record (EHR) and financial systems to automate supply documentation, charge capture/billing and process reorders. The company's open and secure POC solutions are integrated with one another to deliver data and insights all in one place.

A single approach to medical/surgical, drug supply chains

Historically, hospitals have managed their medical/surgical and pharmaceutical supply chains separately, using individual IT systems and workflows. This is changing as health systems and hospitals seek to standardize supply chain systems and processes for clear and immediate visibility into all supply spend and utilization.

"For most hospitals, there's a thornbush of best-of-breed bolt-on systems to manage medical and drug supplies, but when you pan out to a hospital or health system level, that creates a mixed bag of data and visibility, and you miss out on that command center view — being able to see what's going on in 'all' areas," said Cory Turner, CMRP, Senior Director, Healthcare Strategy, Tecsys.

"A lack of visibility translates into ordering challenges, unexpected stock-outs, expiration and recall management issues, and ultimately not having the right products at the right time; all of these things, on top of being supply chain issues, are clinical distractions that erode patient care," Turner added. "At a time where nursing labor shortages are rampant, using clinical resources to shore up an ineffective supply chain practice should be out of bounds, especially when the right supply chain processes and technologies can avoid that burden on nursing."

Furthermore, without a holistic, in-hospital inventory management strategy, supply closets tend to become "catch-alls" overwhelmed with linens, housekeeping, scrubs and more, encroaching on space for valuable clinical items.

"It harkens back to the importance of visibility and control, and how an end-to-end supply chain management strategy focuses on building a whole that truly is greater than the sum of its parts," stated Turner. HPN

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"Past the pandemic" priorities: What they mean for supply chain

by Karen Conway, Vice President, Healthcare Value, GHX

have been asked a lot of late: "What are the priorities for hospitals and health systems as we move beyond, if not past, the pandemic?" In this month's column, I explore some of those priorities, including the implications for supply chain.

Financial recovery

The financial pathway forward starts on ground sown rough by the pandemic. Front and center are ongoing labor and supply shortages that increase expenses, while creating capacity constraints that limit higher revenue generating elective procedures. For some hospitals, labor costs now represent 45 to 50 percent of revenue; drug costs were 40 percent higher in September 2021 than the year prior, with supply costs up 14 percent. To address an unsustainable financial scenario, healthcare financial executives are actively exploring partners and technology to reduce manual work, while improving the work experience, especially for clinicians. For many, the use of robotic process automation (RPA) is being used for a variety of repetitive administrative functions, from revenue cycle to patient intake and scheduling.

From the Supply Chain Perspective: RPA holds promise for automating supply chain tasks, from managing contracts to auto-ordering items that reach low par levels. The pursuit of the perfect order has also experienced renewed interest, as supply chain departments work to minimize the need for manual intervention by reducing discrepancies. Hospitals are also investing in technology to automate clinical documentation and alert clinicians when products are expired or recalled, thereby minimizing the time nurses must spend on supply chain activities and increasing patient safety. Healthcare management company Kaufman Hall recommends health systems unable to invest in their own capabilities consider use of more third-party operational solutions, something the vast majority of hospital executives say they intend to do.1

The great patient migration

Before the pandemic, we had begun to witness a slow, but relatively steady, migration of care from the acute care hospital to settings from ambulatory surgery centers (ASCs) to the home. Enter COVID-19, and the move to virtual (especially telemedicine) grew exponentially. As the pandemic begins to release its monopolistic grip on hospital operations, patients who delayed care during the pandemic are starting to return to hospitals, while others are staying home. Thanks to advances in remote patient monitoring technology, more discerning patients looking for comfort, convenience and cost savings are choosing virtual and/or hospital-at-home (HaH) care. According to recent research:

- 40 percent of the amount of virtual care provided during the pandemic is expected to continue, even in the absence of the virus².
- 28 percent of hospitals say they have fully or partially implemented a HaH program, while another 42 percent say they are planning their programs³.
- As a result, outpatient volume is expected to grow by 19% by the end of the decade, compared to just one percent for inpatients. Ambulatory surgery center volume alone is on track to grow by 25 percent⁴.

From the supply chain perspective: Suppliers, such as Stryker, Baxter, Cardinal and Owens & Minor, have acquired companies with capabilities to support the transition of care beyond the hospital and into the home. Baxter and Cardinal joined Mayo and Kaiser Permanente in investing in Medically Home, which enlisted long time group purchasing association veteran Mark Scagliarini to run its supply chain operations, which include the movement of both products and people to patients' homes. Supply chain professionals will increasingly be called upon to determine how to most efficiently and effectively serve a far more distributed footprint for healthcare delivery.

In pursuit of preparedness

The pandemic intensified the focus on emergency preparedness and resiliency, with healthcare leaders from both the public and private sectors vowing not to be caught in the future unable to secure critical products. Both providers and suppliers are exploring how to gain better upstream visibility into potential or pending shortages. Strategies range from an increased use of third-party supplier risk management companies to the creation of the industry-driven Health Industry Resilience Collaborative (HIRC). With better upstream monitoring, manufacturers can determine when raw materials, components or products are or will be in short supply and take corrective action and/or communicate possible or pending shortages to customers and regulators. Providers, meanwhile, are augmenting a near relentless pursuit of product/vendor standardization with proactive identification of clinically acceptable alternatives. Recognizing there will still be times when even the alternatives are in short supply, providers are also pursuing a number of other strategies. Some are fairly traditional responses, such as investing in more inventory on hand and working with 3PL companies for inventory management and storage. On the other hand, some strategies will change the role of and relationships between various healthcare organizations. For example, Ochsner entered into a joint venture under which it is has become a manufacturer of personal protective equipment. Other healthcare institutions are investing in more enterprise-level inventory visibility to support moving product to where it is most needed, while others are exploring how they might collaborate with peer institutions to increase preparedness by managing and sharing critical products and resources as during emergencies.

From the supply chain perspective: The supply chain is core to emergency preparedness, a realization that only gained broad recognition with the pandemic. Beyond the creative operational responses

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mentioned above, the real game changer will come when providers and suppliers are able and, most importantly, willing to share data. Data on product levels and utilization is key to collaborative work at any level, whether across facilities within the same organization, among peer health systems, or between providers and suppliers. The pursuit of better preparedness will drive new capabilities that support inventory visibility across trading partners and demand planning. New data sharing opportunities will also present themselves as hospital and health system boards of trustees prioritize equity and the environment. Providers are already asking their individual suppliers to share how they are addressing both social issues, from minimizing the carbon footprint of their products to the use of diverse suppliers for their supply chain needs.

The pandemic has left its scars on nearly every aspect of society, but with adversity

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also comes creativity. When that creativity becomes a collaborative effort, real transformational change can occur. Perhaps nowhere is that spirit of co-creation more alive than in the healthcare supply chain, and working together, we are saving lives. HPN

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HAVING MY SAY



Have 'modular' instruments lowered surgical infection rates?

First of a two-part series

by James Schneiter

ata from the Centers for Disease Control and Prevention (CDC) indicate that surgical infections cause more than 8,000 patient deaths annually.¹ A significant number of these infections are caused by surgical instruments that are difficult, if not impossible, to thoroughly decontaminate, clean and sterilize. Contaminated surgical instruments have always been and continue to be a significant cause of surgical infections.

To reduce the risk of a surgical infection caused by a difficult- to-clean surgical instrument, a number of surgical instrument companies began to introduce "modular" instruments that could be disassembled for cleaning internal surfaces during processing. Two of the more common modular instruments are laparoscopic instruments that were introduced more than 25 years ago and modular Kerrison Rongeurs that were introduced more than 10 years ago.

According to the manufacturers' claims of modular instruments that can be disassembled to help decontaminate and clean, their major benefit is that once they've been disassembled, you can "visualize" the bioburden and debris inside of the instrument and manually remove it. Regretfully, the human eye is NOT capable of seeing microscopic bacteria and biofilm on the surface of a surgical instrument.

During a recent discussion with a surgeon about modular instruments, he made a very interesting observation. His comment was that "Modular instruments were supposed to be easier to clean, which in turn would reduce the rate of surgical infections. Where are all of the studies and clinicals that prove that modular instruments have reduced surgical infections over the last decade? If they really did reduce the number of contaminated instruments being returned to the O.R. after reprocessing, the manufacturers would have the studies plastered on the walls in every surgeons lounge in the country."

The simple answer to the surgeon's question is that modular instruments have not reduced the frequency, nor the rate of surgical infections caused by contaminated

instruments. Being able to 'visualize' the inside of a modular instrument does NOT ensure a clean, sterile, moisture-free instrument (assuming that the processing personnel know how, or even remember to take the time to disassemble, thoroughly clean it and then properly reassemble the instrument).

"A major limitation of many manufacturers' IFUs is that they require a CS/SPD professional to visually inspect an instrument after cleaning for bioburden and/or biofilm prior to sterilization. For some complex instruments that means disassembling them to both clean and inspect. But the dirty little secret is that this residue is invisible to the naked eye — making the task physically impossible." ²

Logic dictates that if modular instruments were truly effective in reducing surgical infections, we would have seen a reduction in surgical infections. However, according to the CDC, "Advances in infection control practices include improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis. Despite these activities, surgical infections remain a substantial cause of morbidity and mortality among hospitalized patients."³

The only way to ensure clean surgical instruments on every reprocessing cycle is to use instruments whose cleaning and sterilization IFUs have been validated. Such validation must be done in accordance with U.S. Food and Drug Administration (FDA)-mandated validation testing protocols described in 21 CFR 820.3(k) "Validation of Reprocessing Methods in Accordance with the Quality System Regulation."

Unlike reusable surgical instruments whose cleaning IFUs may have been validated by independent laboratory testing, no brand, make or style of modular instruments have ever had their cleaning IFUs validated. In fact, no manufacturer of modular instruments has ever even attempted to validate the cleaning IFUs on their modular instruments because no two people can or will clean an instrument the same way on every reprocessing cycle.

Key point: There is simply no way to ensure "repeatability" of cleaning results with a reusable surgical instrument that relies on manual disassembly and cleaning to remove bioburden, especially microscopic bioburden and biofilm that is NOT visible to the human eye. Conversely, even the most inexperienced processing person can consistently flush a "flushable" reusable surgical instrument whose cleaning IFUs have been validated with a syringe in less than 10 seconds and be assured of a clean, sterile, moisture-free instrument on every processing cycle.

So how does the lack of validation of cleaning IFUs for modular surgical instruments impact you, your healthcare facility and most importantly, your patients? Unless a surgical instrument manufacturer has validated that its cleaning process removes the bioload from the instrument, you have no assurance that you are sending a clean, sterile and safe instrument back to the OR. You and your healthcare facility have an ethical, moral, financial and legal responsibility to demand validated IFUs from all your surgical instrument and reusable medical device suppliers. HPN

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Prior to his retirement in December 2018, James Schneiter had been the founder, owner and president of America's MedSource Inc., which designed, developed, licensed and marketed a variety of implantable vascular devices, laparoscopic devices and neurosurgical instruments. Schneiter has nearly five decades of experience in medical device design and production, is a recognized expert in instructions for use (IFU) and independent laboratory IFU validation studies and is a co-founder of #IFUcan, an online community that examines and explores the world of manufacturer IFUs. Schneiter can be reached at jas.schneiter@talloaks2014.com.



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