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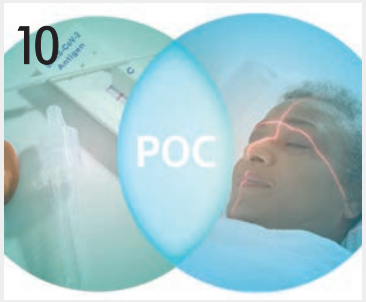

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Hurricane Wit

Rick Dana Barlow
Senior Editor

Historians and observers alike remain flummoxed about the origin of a famous but profound saying. They attribute it to a number of folks, but famous and relatively obscure.

Paraphrased, it reads something like this: History doesn't repeat itself, but it rhymes.

Perhaps a more classic interpretation should be: History doesn't repeat itself but it's rife with synonyms.

After Hurricanes Fiona and Ian ripped through the Caribbean and Southeast (mainly Florida) and their sibling Julia was whipping herself up across Central America at press time, it may be high tide and time for the annual hurricane season to be taken more seriously. Exacerbating the impact on the supply chain? Two years and still counting of a pandemic that crippled labor levels, supply flow and transportation routes.

Some might call these last two years the "perfect storm" creating a massive clot in need of a serious four-way bypass.

If anything, this brief two-year era of accountability should serve as a wake-up call – strategically and tactically – that business and financial operations may be nearing, if not at, wit's end.

Certainly, planning and prepping for disasters shouldn't be a shocking surprise to the healthcare community. *Healthcare Purchasing News* has been covering it for decades – from natural disasters to terrorist attacks to weather-related environmental trauma.

The crux of the matter continues to be how providers and suppliers react to the aftermath of each encounter. Arguably, such reactions should be business-as-usual or standard operating procedures by now. Why? Because the concentration should focus on "proaction" – how to prep for and prevent problems.

During the last two years as just-in-time and stockless distribution models faltered, a passionate movement emerged to pursue domestic sourcing. Clamoring for manufacturers and distributors to relocate plants and warehouses deep inside the confines of the United States may be unrealistic in the short term as so much would need to be untangled, but not necessarily unreasonable in the long term.

Going forward, rather than issuing price hikes as a knee-jerk but now nominal reaction to climate-damaged facilities, clogged transportation arteries or convenient and routine access to raw materials and other resources, it may make sense to use a portion of the profits earned in past years to fortify production and distribution footprints into formidable fortresses that can withstand what nature's and nurture's furies foists upon them.

During and following major crises, the last thing a citizenry and an economy need are price hikes stemming from dubious motivations. At this point, disasters should come as no surprise because we've seen just about every conceivable example and model short of an alien invasion or asteroids pummeling the surface.

No, this doesn't mean companies create fortified secret lairs worthy of a James Bond archnemesis or villain or move production off-world to a space facility subjected to errant orbiting junk and operational satellites – including Elon Musk's floating Tesla Roadster (since February 2018).

Whether off-shore or on-shore, product manufacturers and distributors should use the collection of crises in the 21st century so far – arguably a notable increase in frequency from the prior centuries – to craft and develop improvements that prepare us for a progressive future.

There's no time like the present.

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FAST STATS

The growing demand for endoscopy

There can be no surprise to the undeniable facts behind the booming endoscopy market. The increasing demand for endoscopic procedures correlates not only with the aging population, but the rising prevalence of gastrointestinal disorders and other chronic conditions around the world. These minimally invasive procedures will continue to increase in terms of innovation and application.

- As per the reports from the Administration of Community Living (ACL), the number of people of age 65 and older were **54.1 million** in 2019 and is projected to grow around **94.7 million** by 2060 in the U.S.;
- As per the recent reports from the American Cancer Society, there are over **26,380** new cases of stomach cancer observed in 2022, accounting for **1.5%** of all cancers diagnosed;
- As per the epidemiology study cited in the NCBI, gastric cancer is deemed as 5th most common forms of cancers with high mortality and caused over **783,000** deaths in 2018.
- Global market for endoscopy was valued at over **US$33.48 billion** in 2021 and is estimated to register a **7%** CAGR during the forecast period of 2022-2030.
- Global endoscopy industry revenue from the endoscope product segment surpassed **US$16.81 billion** in 2021 due to the rising incidence of chronic diseases, such as cancer and gastrointestinal disorders.
- Global endoscopy market value from the laparoscopy application segment is expected to cross **US$16.71 billion** by 2030 with the awareness about early detection and treatment of diseases and access to advanced equipment.
- U.S. endoscopy market share is anticipated to surpass **US$23.8 billion** by 2030, with increase in geriatric population, medical device innovations, modern healthcare infrastructure and rising cases of chronic conditions.

https://www.gminsights.com/industry-analysis/endoscopy-market

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NEWSWIRE

Grim report for hospitals predicted to close out 2022

A new analysis prepared by Kaufman, Hall & Associates, LLC and released today by the American Hospital Association shows that hospitals and health systems continue to face intense pressure on staff and resources while also dealing with rising expenses for supplies, drugs and equipment, as well as for the workforce.

Left unaddressed, these financial challenges have the potential to jeopardize access to essential health care services for patients. The trends are expected to continue through 2022, with losses in the billions of dollars for hospitals and health systems, resulting in the most financially difficult year for the field since the beginning of the COVID-19 pandemic in early 2020.

The first half of 2022 has severely tested hospitals and health systems due to the impacts of COVID-19 surges, increased expenses and a lack of COVID-19 relief funding. As a result, even the most optimistic projections for the entirety of 2022 indicate margins will be down 37% compared to pre-pandemic levels, with more than half of hospitals operating in the red. Under a pessimistic scenario for the rest of 2022, margins could be down as much as 133% compared to pre-pandemic levels, with over two-thirds of hospitals operating in the red.

"While federal support and relief has tapered off, the fight against COVID hasn't. Managing the aftermath of the pandemic has placed the vast majority of America's hospitals in serious financial jeopardy as they experience severe workforce shortages, broken supply chains, the Medicare 2% sequester kicking back in and rapid inflation that has increased the cost of caring," said Rick Pollack, AHA president and CEO. "These realities translate into access to services being put in jeopardy. This deserves the immediate attention of policymakers at every level of government to ensure we are able to keep people healthy and maintain essential public services that our communities depend on. America simply can't be strong without its hospitals being strong."

Read on: https://hpnonline.com/21281014

Black boxes landing in operating rooms

For decades, the airline industry has benefited from so-called black boxes, which record flight data and cockpit conversations. The collected information allows airlines to boost safety by predicting and mitigating risks.

Now, similar technology is moving into another high-stakes arena: the operating room. The new technology, called OR Black Box, has been installed in four operating rooms at Stanford Hospital — the first on the West Coast — with plans to expand to several more rooms.

These sophisticated monitoring systems capture everything that goes on in the operating room, from human performance to distractions, patient vital signs to equipment malfunctions — all factors that might affect the outcome of a procedure.

"I was inspired by aviation and what made aviation the safest form of transportation," said Teodor Grantcharov, MD, PhD, the inventor of the OR Black Box, who recently joined Stanford Medicine as a professor of surgery.

"Our patients are not aircraft, but a lot of the methods — the culture, the approach to safety, the never-ending pursuit of 'safer' — is transferable," he said.

The information collected by the monitoring system becomes a rich resource from which new protocol solutions can emerge. When quality, safety and operations teams at Stanford Hospital notice potential problems in efficiency, collaboration or safety, they can turn to the data to pinpoint factors that can be improved.

Read on: https://hpnonline.com/21283211

New study show SARS-CoV-2 infects fat tissue

A study by Stanford Medicine investigators shows that SARS-CoV-2 can infect human fat tissue. This phenomenon was seen in laboratory experiments conducted on fat tissue excised from patients undergoing bariatric and cardiac surgeries, and later infected in a laboratory dish with SARS-CoV-2. It was further confirmed in autopsy samples from deceased COVID-19 patients.

Obesity is an established, independent risk factor for SARS-CoV-2 infection as well as for the patients' progression, once infected, to severe disease and death. Reasons offered for this increased vulnerability range from impaired breathing resulting from the pressure of extra weight to altered immune responsiveness in obese people.

But the new study provides a more direct reason: SARS-CoV-2, the virus that causes COVID-19, can directly infect adipose tissue (which most of us refer to as just plain "fat"). That, in turn, cooks up a cycle of viral replication within resident fat cells, or adipocytes, and causes pronounced inflammation in immune cells that hang out in fat tissue. The inflammation converts even uninfected "bystander" cells within the tissue into an inflammatory state.

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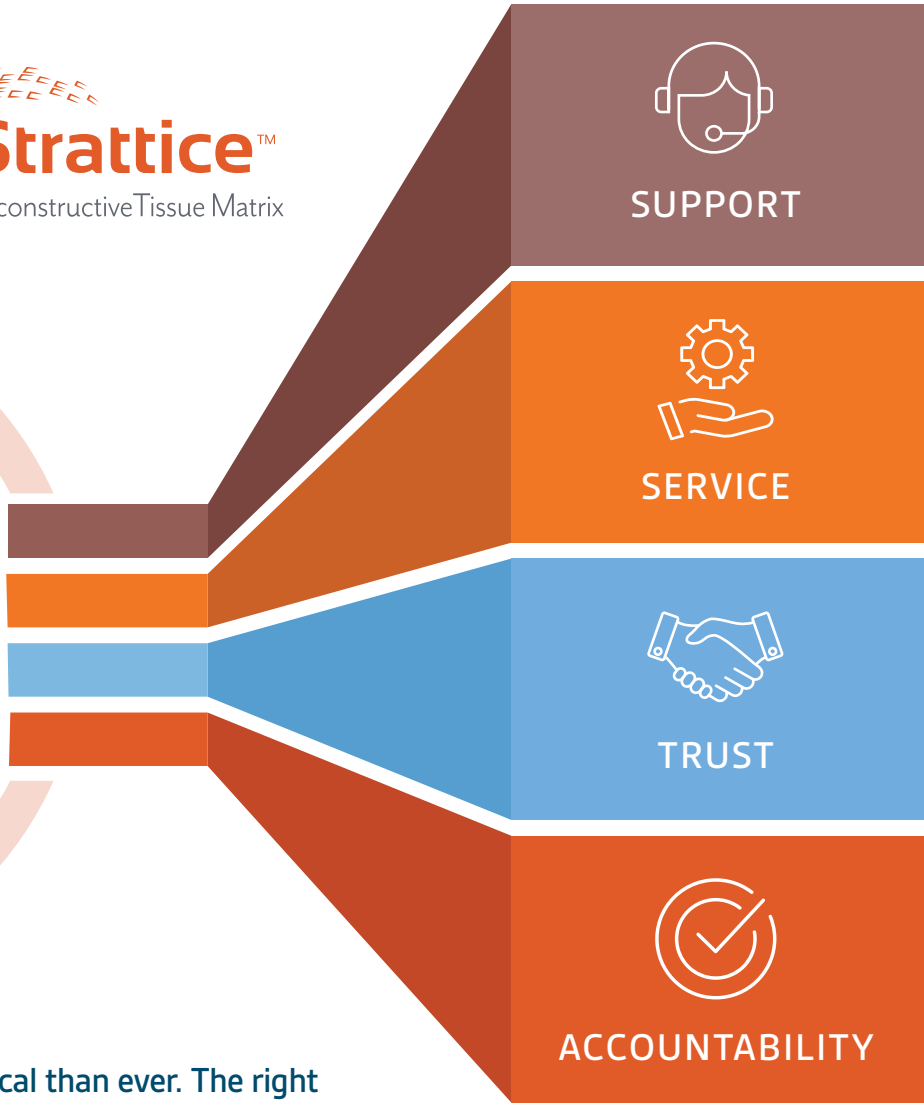

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References: 1. Data on file, Allergan Aesthetics, July 2022; Aesthetic Monthly Tracker. **2.** Data on file, Allergan Aesthetics, July 2022; PRM Customer Summary. **3.** Data on file, Allergan Aesthetics, July 2022; Tissue Contracts. **4.** Data on file, Allergan Aesthetics, July 2022; Supply Chain Attitude and Usage Assessment. **5.** Wainwright DJ. Use of an acellular allograft dermal matrix (AlloDerm) in the management of full-thickness burns. *Burns.* 1995;21(4):243-248.

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"With 2 of every 3 American adults overweight and more than 4 in 10 of them obese, this is a potential cause for concern," said Tracey McLaughlin, MD, professor of endocrinology.
Read on: https://www.hpnonline.com/21282917

FDA updates COVID-19 test policy

The U.S. Food and Drug Administration updated its COVID-19 test policy to ensure continued access to tests while encouraging the transition of these important public health tools to traditional premarket review pathways. The updated policy describes the FDA's intent to review only a small subset of new emergency use authorization (EUA) requests for diagnostic tests and encourages developers of all test types interested in marketing authorization to pursue authorization through the de novo classification or 510(k) clearance pre-market review pathways.

"Testing remains one of the key pillars in combatting the COVID-19 pandemic," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "Taking into account the current status of manufacturing capacity and consumer access given the Administration's important investments in tests, for most new tests, shifting to traditional premarket review would best meet the public health needs at the current stage of the COVID-19 public health emergency. The FDA will continue to offer support and expertise to assist with the development of accurate and reliable tests, and to facilitate continued access to tests for all Americans."

Since the start of the pandemic, the FDA has adapted its regulatory approach to address the public's testing needs and has worked closely with test developers to adjust as those needs have changed. These efforts have helped increase testing capacity and broaden public access to rapid tests, including those purchased over-the-counter (OTC). The U.S. currently has the capacity for authorized manufacturers to produce hundreds of millions of tests per month, although the number of tests available for use at any given time will depend on demand and other factors.

To date, more than 430 distinct COVID-19 tests have been issued EUAs. The available information indicates that these tests are providing sufficient testing capacity for COVID-19 tests throughout the United States. Recognizing the current testing capacity, at this time, the agency believes most future submissions are best suited for traditional premarket review pathways. Therefore, the FDA is revising its policy to update the types of COVID-19 tests for which the agency intends to review EUA requests and discuss the use of the traditional premarket review pathways for COVID-19 tests. Tests for which EUA authorization requests are pending prior to this announcement will remain in the queue.
Read on: https://www.hpnonline.com/21282103

Changes at the top for GHX

Global Healthcare Exchange (GHX) has announced that Bruce Johnson will transition from his role as president and Chief Executive Officer to Executive Chairman of the Board effective January 1, 2023.

The GHX Board has confirmed Tina Vatanka Murphy, division president, Value Based Care, to be appointed as the company's next president and CEO.

Johnson joined GHX when the company was founded in 2000 with a passion for creating something that had never existed in healthcare: an industry-unifying exchange platform led by a group of healthcare providers, suppliers and distributors working together to reduce the cost of delivering care. His successful tenure has resulted in a community of more than 896,000 trading partners including hospitals representing more than 90% of net patient revenue and suppliers representing 85% of medical-surgical spend in the U.S. Under Johnson's leadership, GHX has delivered innovative solutions that have helped the healthcare community save more than $13.7 billion since 2010.

"Serving as president and CEO of GHX for the last 15 years has been the highlight of my career and I am incredibly grateful to have worked alongside a tremendous team of purpose-driven individuals. Together, we have pioneered healthcare's largest cloud-based supply chain network and built a community of tens of thousands of healthcare organizations across the globe," said Johnson. "I've had the pleasure of working alongside Tina for more than two decades and admire her as a trusted advisor, customer champion and a focused and authentic leader with a passion for advancing healthcare's value-based future. Her ability to remain clear-headed and focused in the face of adversity helped steer GHX, and our customers, through the height of the COVID-19 pandemic, and will continue to make a difference in the healthcare community at large."

Vatanka Murphy is a multi-faceted leader with a strong track record of driving global performance improvement, delivering value to customers and fostering an employee culture predicated on equity and inclusivity. Her extensive knowledge of GHX, its broad and still expanding customer community and the complex healthcare industry at large positions her to lead the company into the future.

"I am honored by the Board's decision to entrust me as its next chief executive and I am humbled to carry on Bruce Johnson's strong legacy of leadership," said Tina Vatanka Murphy, incoming president and CEO of GHX.
Read on: https://www.hpnonline.com/21281343

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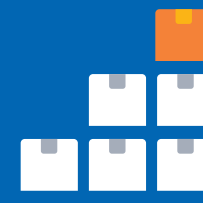

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Ease and excellence intersect at the Point of Care

by Kara Nadeau

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The COVID-19 pandemic has driven tremendous innovation in bringing diagnostics and treatment throughout the care continuum down to patients' homes – and it is not stopping. It is only getting broader in scope and more advanced.

"The evolving healthcare system includes new delivery models in which primary care physicians and nurses are assuming more significant roles, with the patient more involved in decision-making and self-care," states the National Institutes of Health (NIH) regarding its Point-of-Care Technologies Research Network (POCTRN). "These changes require the development of inexpensive and easy-to-use medical devices and information sharing tools that provide timely health status information at the point of care (POC)."[1]

While telehealth applications, home tests for SARS-CoV-2 and remote monitoring of vital signs have become commonplace, new technologies for POC imaging and testing are providing clinicians and patients real-time, in-depth knowledge of various conditions and disease states anytime, anywhere.

POC testing drivers and challenges

A global study of 634 healthcare professionals on the evolution of the POC and rapid testing market published in February 2022 found the following top reasons driving patients to self-administer rapid tests:[2]

- 77% fast to get results
- 67% easy to use
- 65% easy to obtain
- 57% confidentiality of test result
- 54% saves travel time
- 51% affordable
- 47% less scary than hospital setting

Among challenges cited in POC rapid testing:[3]

- 47% specificity/sensitivity of tests
- 33% cost of tests
- 33% complexity of sampling
- 32% lack of awareness in POC rapid test among healthcare professionals
- 29% lack of trust from healthcare professionals in POC testing

Another challenge is bringing supplies needed to the POC and storing them, as Midmark describes in its white paper, "Point of Care Inventory Control: A Place for Everything and Everything in its Place."[4]

UMass Chan Medical School and UMass Lowell researchers surveyed healthcare professionals before and during COVID-19 to explore whether the pandemic altered their perceptions about the usefulness of point-of-care technologies (POCTs). Their findings were published in the July 2022 Humanities & Social Sciences Communications, a Nature Portfolio journal. Key findings include:

- POCTs are not only useful for diagnosing COVID-19, but healthcare professionals also perceive them as increasingly important for diagnosing other diseases, such as cardiovascular, endocrine, respiratory and metabolic diseases.
- Healthcare professionals also viewed POCTs as "facilitating the humanization of epidemiology" through improved disease management and monitoring, and stronger clinician-patient relationships.
- As the accuracy and integration of these technologies into mainstream healthcare delivery improves, hurdles to their adoption dissipate, which encourages healthcare professionals to use them more frequently.

The researchers state their belief that "technological advances made in POCTs during COVID-19, combined with shifting positive perceptions of their utility by healthcare professionals," may better prepare healthcare for the next pandemic.[5]

Examples of where POCT is making a difference

A growing number of U.S. health systems are leveraging POCTs to expand diagnosis and treatment, and in some cases, lowering care costs simultaneously. They are also researching ways to apply POCTs to new patient populations and conditions.

For example, Massachusetts General Hospital (MGH) in Boston performs over 600,000 POCTs annually through blood glucose kits, pregnancy kits, strep tests, and others.[6] The MGH POCT program

team evaluated its testing with regards to regulatory compliance, quality and costs. They found their approach has reduced inspection citations from 3.17 per testing site to 0.27 citations, with a $1.89 average test cost.[7]

The Mayo Clinic has successfully leveraged remote patient monitoring (RPM) to reduce hospitalizations in cancer patients with COVID-19. Use of in-home technology to assess symptoms and physiologic data, with centralized nursing and physician oversight, reduced the hospital admission rate by 78%. As the researchers noted, even when patients in the RPM group were hospitalized, they "experienced a shorter length of stay and fewer prolonged hospitalizations, intensive care unit admissions and deaths."[8]

The Johns Hopkins Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases has been leading development of accurate, acceptable and optimal implementation of POC tests for sexually transmitted diseases (STDs) in diverse care delivery contexts. Researchers from the Johns Hopkins University School of Medicine reviewed the performance and time to result of POC assays for STIs in the last 10 years.

Their research, which was published in the August 2021 Sexually Transmitted Diseases journal, found diagnostic technology for POC assays for STIs has achieved high sensitivity and specificity (>90%) using recent molecular advances in past decade. At the time of the journal article's publication, the FDA had approved three tests for chlamydia and gonorrhea, two for trichomonas and two for syphilis.[9] In 2022, The Johns Hopkins Center offered funds toward the development of POCTs that meet or exceed the current clinically accepted STD POCT assays through its participation in the NIH POCTRN.[10]

Emerging trends and technologies

As the UMass Chan Medical School and UMass Lowell researchers noted in their published article, COVID-19: a gray swan's impact on the adoption of novel medical technologies, "the technological trajectory and potential usefulness of POCTs is still in its infancy."[11] Here is a sampling of advanced technologies that have been developed to satisfy the need and desire for POC diagnostics and treatment.

Ultrasound anywhere

Use of point-of-care ultrasound (POCUS) has expanded significantly in the past two decades, beyond emergency and critical care medicine to many other subspecialties.[12] Recent research has shown its proven success in supporting hospital at home (HAH) programs to "help providers assess, diagnose, and monitor a range of conditions."[13]

GE Healthcare Venue POC ultrasound solutions

"Ultrasound has a large impact helping medical professionals keep up with growing demand, particularly at the point of care," said Dietmar Seifriedsberger, General Manager, Point of Care & Handheld Ultrasound, GE Healthcare. "One of the most exciting trends in POCUS is the power of AI. Given a substantial number of POCUS users are new to ultrasound, AI-based tools help increase exam efficiency and user consistency. These AI tools can help these users learn and adopt ultrasound more quickly.

"Since POCUS can be performed anywhere, from the chaotic trauma bay of a hospital to the side-lines of a football field, it is important that the user select a system that is designed for these settings…easy to move, probes that are easily accessible, and battery power that can last for the duration of several exams," Seifriedsberger added. "It's also very important to select a system that is easy to learn and use. Moreover, these systems should be easy to clean with smooth and seamless surfaces to control infection."

Imaging throughout the care continuum

Computed tomography or CT scanners are critical tools in diagnostics, enabling clinicians to visualize organs, soft tissue, blood vessels, and bones. They can range from fixed scanners positioned in an imaging suite, to mobile scanners that can be moved from room to room.

The next evolution is bringing CT scanning to patients in their communities, which is what Xoran Technologies is in position to do with its TRON mobile, full-body fluoroscopy, CT X-ray system. The company was granted FDA 510(k) clearance for the device in August 2022.

"This compact, mobile, open-bore device is poised to revolutionize global initiatives to democratize access to diagnostic imaging," said Xoran CEO Misha Rakic. "TRON is uniquely suited to provide safe, ultra-high-resolution, low dose imaging in traditional settings such as the operating room, surgery center, and critical care unit where space is limited and hospital budgets are stretched thin."

"TRON's compact size and weight make it truly nimble without any need for bulky motors and batteries," Rakic continued. "Because TRON scans take less than a minute, and the system is easy-to-use, it can be further mobilized by placing it in small vans, lending TRON to low-dose screening brought to patients and not the other way around. This means that Xoran's Vehicle-Based Solutions can be used for community health initiatives and in ambulance and military front-line scenarios."

Xoran CEO Misha Rakic with the TRON mobile, full-body fluoroscopy, CT X-ray system

Remote patient monitoring advancements

According to Kathryn Gray, Sr. Manager, Corporate Strategy & Business Development, McKesson Medical-Surgical, Remote Patient Monitoring (RPM) has experienced a quick rise over the past couple of years because of a variety of factors: it helps reduce emergency room (ER) visits and hospital readmissions; helps support reimbursement for physicians in areas such as remote therapeutic monitoring; provides availability of affordable and easy to use technology; an increase of patients with chronic conditions; and the onset and continuation of the COVID-19 pandemic.

"A couple bigger headwinds are patient access to the internet and provider staffing," Gray commented. "We are starting to see more equipment options that are cellular enabled allowing for transmissions where the patient does not have internet

access. RPM providers, who understand practice workflow recognize the support services required to get patients setup and trained, as well as do some of the monitoring, are keys to success. This is enabling providers to utilize RPM without requiring more time from the staff."

Cancer care is one area where virtual care is supporting improved patient care. Skin cancer is a common type of cancer, and early diagnosis and treatment are key to successful outcomes. The SkinIO HIPAA-compliant, AI-driven, virtual skin cancer screening platform allows anyone, anywhere to perform a skin exam in just 10 minutes using their smartphone. It helps identify which marks matter and compare changes over time. SkinIO images are reviewed remotely by expert dermatologists, users receive their results by email in just a few days, and then they are connected to care if they require in-person follow-up.

Wound management is another area where RPM can improve outcomes, and lower care costs. Complex wounds are a huge physical burden on patients, significantly impacting their health-related quality of life. They are also a sizable expense in the U.S., with complex wound management costing our health system approximately $25 billion annually.[14]

Swift Medical AI-powered, digital wound care platform

Swift Medical provides an AI-powered, digital wound care platform that allows any clinician to easily capture a high precision image of a wound with their mobile phone, autonomously determines wound dimensions and clinical characteristics, enables virtual wound care consultations, and provides real-time, predictive insights to drive enhanced preventive and personalized care. With the company's latest product, Swift Ray 1, providers can detect a wound before it breaks through the skin, allowing for early intervention and significantly reduced healing time.

"This kind of care at home is not a replacement for a doctor visit," cautions Gray. "It allows monitoring between visits so intervention can be provided at the point where it is needed – not next month in an office visit or next week in the ER."

Gray comments on the future of RPM, stating: "Centers for Medicare and Medicaid Services continues to expand reimbursement for remote care. To support this, we expect to see innovation in areas like medication monitoring and chronic pain management over the next couple of years, along with new innovations that don't require patients to perform the measurement." **HPN**

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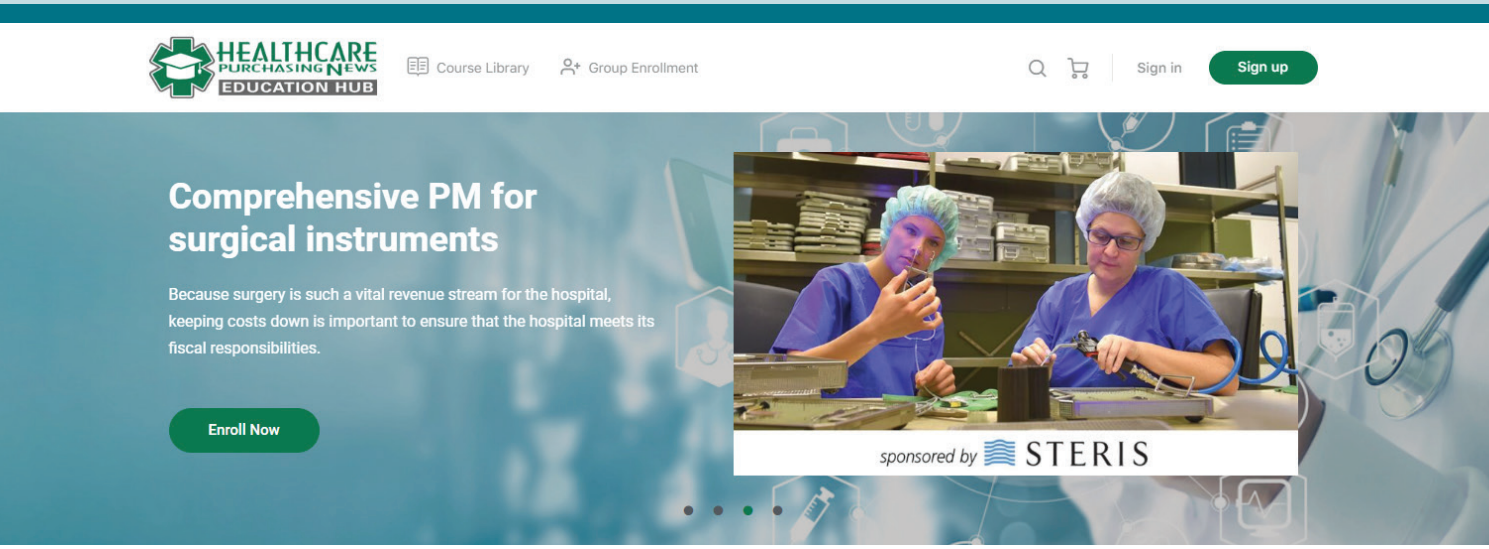

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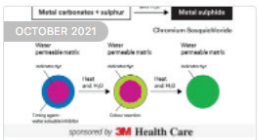

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The dripping, ticking time-bomb of IV shortages

by Kara Nadeau

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It seems like healthcare facilities have been struggling with intravenous (IV) therapy supply shortages forever and there is no end in sight. It was five years ago that Hurricane Maria devastated production of IV bags in Puerto Rico, causing widespread shortages of sodium chloride 0.9% injection bags also known as "saline." Even before that event, IV saline bags "long faced supply issues," as noted by the U.S. Food and Drug Administration (FDA) in a February 2018 press release.[1]

Virtually all hospitalized patients require saline, whether it is part of a medication infusion, hydration, resuscitation, or as an irrigation fluid.[2]

Despite efforts to diversify production and increase capacity, here we are in 2022 facing the same challenges. So how did we get to another place of widespread IV supply shortages, how is it impacting care, and what can healthcare industry stakeholders to do fix it?

How did we get here?

While Hurricane Maria in 2017 was one of the most publicized causes for IV solution shortages in recent years, the problems began long before that storm. As the FDA stated at the time, "Although Hurricane Maria affected Baxter's facilities in Puerto Rico, there have been limited supplies of IV fluids since 2014."[3]

Throughout 2014, the U.S. experienced a nationwide shortage of IV solutions, specifically saline large volume intravenous solution. Manufacturers blamed supply disruptions on plant shutdowns for routine inspection and upgrades.[4] A "worse than average" flu season placed strain on already limited supplies. Hospitals reported a significant jump in price – with bags costing fix or six times more than they had prior to the shortage.

The FDA acts

To help alleviate the 2014 shortage, the FDA announced that it was working with the three U.S. manufacturers, Baxter Healthcare, B. Braun Medical and Hospira, to increase supply.[5] The agency also approved Fresenius Kabi USA to temporarily import its European sodium chloride 0.9% Freeflex Injection Solution for Intravenous Infusion into the U.S. market in late 2014.[6]

Then in May 2015, the FDA approved Baxter's Sabinanigo, Spain facility as a manufacturing site for 0.9% sodium chloride injection, USP, for the U.S. market.[7]

Even with these interventions, the American Society of Health-System Pharmacists (ASHP) reported shortages of 0.9% sodium chloride irrigation and 0.45% sodium chloride injection bags throughout 2016 across multiple manufacturers, including B. Braun, Baxter, Hospira and Pfizer.[8]

Market changes and challenges

In February 2017, ICU Medical announced that it had completed acquisition of Hospira Infusion Systems from Pfizer, including IV pumps, solutions and devices. The marriage of the companies established "ICU Medical [as] one of the world's leading pure-play infusion therapy companies."[9]

But the honeymoon was soon over. In July 2017, ICU announced that it was voluntarily recalling one lot of saline injection that had been manufactured in the U.S. by Hospira on February 1, 2016, and was distributed nationwide to Hospira customers between April 14, 2016, and February 2, 2017. The recall was prompted by, "a confirmed customer complaint of particulate matter identified as stainless steel within a single flexible container."[10]

The following month, August 2017, B. Braun announced a double whammy to the market, with a press release stating: "unplanned production interruptions have resulted in significant decreases in supply of product necessary to meet current demands of our customers" and the company was "planning a plant shutdown to do critical maintenance work at the end of the year," which would further strain its inventory levels.[11]

Then came Hurricane Maria one month later in September 2017, knocking Baxter's IV saline production facilities off the grid.

Offshore supplies to address the shortages

The FDA and manufacturers recognized the domestic challenges and the opportunity

to secure saline products from plants outside of the U.S. In late 2017, the agency announced that it had approved temporary import of products from Baxter facilities in Ireland, Australia, Mexico and Canada, and from B. Braun in Germany.

In addition to temporary imports, the FDA also continued to expedite review of drug applications, including approval of Fresenius Kabi and Laboratorios Grifols saline to help address the shortage.[12]

In January 2018, B. Braun Medical announced that it has received FDA approval for 0.9% sodium chloride injection, USP in its Ecoflac Plus 500 mL container, which it had been temporarily importing to the U.S. from its FDA inspected sterile injectable facility in Melsungen, Germany.[13]

More relief came in April 2018, when Baxter initiated temporary importation of saline products produced by the company's manufacturing facility in Ireland and marketed in Europe.[14]

Then the market took a step back when Fresenius Kabi issued a voluntary nationwide recall of its sodium chloride injection, USP, 0.9% in November 2018, citing product labeling issues.[15]

The calm before the next storm

Things were looking up in early 2019, after the U.S. Justice Department closed an antitrust probe examining possible communication among IV solutions manufacturers during supply shortages that created higher prices.[16]

In May 2019, B. Braun announced *Solutions for Life*, a $1 billion investment in "new and enhanced IV therapy manufacturing facilities including a new state-of-the-art manufacturing facility in Daytona Beach, Fla., and modernizations to existing facilities in Irvine, Calif., and Allentown, Pa."[17]

A sudden drain on sodium chloride from COVID

From the time SARS-CoV-2 hit the U.S. in early 2020, through the waves of variants that have sickened patients for nearly three years, healthcare providers have struggled with saline shortages due to a variety of factors.

The supply has never fully stabilized from the production issues and recalls that have persisted since 2014, despite efforts by the FDA and manufacturers. The pandemic-driven influx of hospitalized patients increased demand for saline used to rehydrate patients, administer IV medications and flush vascular access devices (VAD).

Even COVID-19 vaccines have played a role in saline shortages. Pfizer, a producer of the small vials of saline used to flush drugs infused through intravenous lines, shifted use of these vial to production of its Pfizer-BioNTech COVID-19 vaccine. When healthcare providers turned to large bags of saline to fill flush syringes, this snowballed into shortages of these products as well.

Alongside the pandemic, recalls have continued, including Cardinal Health's August 2021 voluntary recall of select Monoject Flush Prefilled Saline Syringes (0.9% sodium chloride), which are intended for use in flushing compatible intravenous tubing systems and indwelling intravascular access devices.[18] A subsequent recall of Aligned Medical Solutions custom convenience kits, which contained the Monoject syringes, occurred in November 2021.

Where we are now?

The rollercoaster of supplies and shortages has continued into 2022. In January of this year, B. Braun announced that it had received final FDA approval for its new

pharmaceutical manufacturing plant in Daytona Beach, FL. The site will produce 0.9% sodium chloride for injection available in B. Braun's Excel Plus IV Bags in 1,000 mL and 500 mL sizes.[19]

This was followed just two months later in March 2022, by B. Braun's announcement of voluntary recall of five lots of 0.9% sodium chloride for injection USP 250ML in Excel "due to fluid leakage or low fill volume of the respective containers."[20]

At the time this article was written (September 2022), the FDA listed shortages of sodium chloride 0.9% injection bags across 52 different products from six manufacturers (B. Braun Medical, Baxter Healthcare, Fresenius Kabi USA, Hospira, ICU Medical and Laboratorios Grifols) citing reasons including demand increase and manufacturing delays.[21]

Infusion therapy scheduling in the face of supply and staffing shortages

The complex model of scheduling patients for infusion therapy has become even more challenging as infusion centers face both staff and supply shortages, according to Obehi Ukpebor, Director of Customer Success for Infusion Centers, LeanTaaS.

"It is almost impossible for infusion centers to predict demand," said Ukpebor. "Someone is going to walk in tomorrow, get a cancer diagnosis and for the next eight weeks will need treatment. If you don't have the right personnel, with the right equipment, in the right room, at the right time, with the right patient, you can't perform that service at that time."

Ukpebor says today most infusion appointments are made through an open calendar or block-based scheduling where patients are scheduled on a first-come, first-served basis. There is no supply versus demand logic behind it; therefore, centers cannot effectively balance patient needs with clinician and equipment/supply availability.

Complicating the scheduling are factors such as variability in the type and duration of treatment required by patients at each appointment and matching patient needs to clinician skill set so staff members are practicing at the top of their licenses. From a supply perspective, infusion centers must consider the number of pharmacy techs they have available to prepare drugs for infusion, and whether this meets patient demand on any given day.

Ukpebor says LeanTaaS applies machine learning and predictive analytics to help infusion centers achieve the correct balance of patients, services, staffing and supplies. By providing projections of scheduled and predicted volume, centers can better plan resources to meet demand.

His advice to infusion centers:

"Listen to your nurses. They know a lot more about what is happening on the floor and are a lot closer to the patients' needs. Talk to them to make sure the data makes sense."

Medical plastics shortages add more supply pressures

It is not only IV solutions in short supply, but also medical plastics that are key to the production of IV administration products, including IV tubing, catheters, and syringes. These shortages were spurred by the COVID-19 pandemic and further aggravated by a February 2021 winter storm that shut down oil fields and refineries in Texas that produce petrochemical products used in plastic products, including medical products.

Supply costs in general, whether in short supply or not, have skyrocketed for healthcare organizations since the pandemic began. In its Fall 2022 report, The Current State of Hospital Finances, KaufmanHall notes how expenses for supplies are projected to grow by $11 billion in 2022, primarily due to inflationary pressures.[22]

Group purchasing organization (GPO) Premier also predicts that the Russia/Ukraine war will impact the global supply and pricing of plastics due to "disruption to crude oil and natural gas production and flow in Eastern Europe or Russia." In the 2022 Premier Supply Chain Report on Impacts of Russia/Ukraine Conflict, the GPO states," Both natural resources are used in the production of plastics, which in turn, are used to manufacture multiple healthcare products such as trays, syringes, specimen bottles, pill containers, sharps containers, and much more."[23]

What is the path forward?

HPN reached out to IV saline solutions manufacturers to understand the challenges facing healthcare organizations because of shortages and obtain their recommendations on how providers can maintain consistent and effective IV therapy to patients. BD offered its response.

"No industry is immune to current supply chain volatility," said Rian Seger, Vice President and General Manager, Medication Delivery Solutions, U.S. Region at BD. "Hospitals are no exception, and we recognize the critical role BD plays in maintaining supply for products that are needed for undisrupted patient care – like those for IV therapy. We also understand that healthcare organizations are feeling pressures from labor challenges, reimbursement, supply disruptions and inflation, to name a few."

Rian Seger

"BD is committed to helping overcome these challenges – and it's why we continue to invest in innovation, supply continuity and capacity for these essential medical devices," Seger continued. "This includes building redundancies to source raw materials, engaging policymakers to prioritize medical supply production and expanding U.S. manufacturing capacity. In fact, BD has increased supply of these devices to help overcome other challenges in the market, and we will continue to turn on new capacity."

"We have dedicated teams at BD that can provide support on product capacity and innovation, as well as training and education, clinical assessments and more, to help healthcare organizations make the right choices for their patient needs," Seger added.

Resources for healthcare providers

Given continued IV supply disruptions, ongoing spread of COVID-19, and experts predicting a severe flu season for 2022-2023 based on flu levels in the Southern Hemisphere, it is in the best interest of U.S. healthcare providers to keep abreast of shortages and alternatives. Here are a few of the industry resources available online.

Earlier this year, the U.S. Food and Drug Administration (FDA) published a letter to healthcare personnel on its website (www.fda.gov) with prefilled saline flush syringe conservation strategies[24]

The Institute for Safe Medical Practices (ISMP) has guidance on its website (www.ismp.org) for both pharmacy personnel and nurses on managing shortages of 0.9% sodium chloride, sterile water for injection, and EPINEPHrine.[25]

The ASHP Drug Shortages Database, accessible on its website (www.ashp.org), provides an up-to-date list of shortages, reasons for them, and available products.[26]

The National Home Infusion Association (NHIA) has compiled product shortage recommendations to help clinicians manage patient care and conserve prefilled 0.9% sodium chloride syringe supplies,

which is available on its website (https://nhia.org).[27] HPN

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Disinfecting in dangerous times

by Scott Tomko

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The efficient application of disinfectants in hospital settings is integral to both the health of the facility and, likewise, to all of the persons who work or reside therein. Along with the processes of cleaning and sterilization, disinfection is a chief means of ensuring safety from the pathogens that spread sickness, disease, and hospital acquired infections (HAIs).

When healthcare facilities are developing their protocols and policies for carrying out effective methods of disinfection, their chief concern is the consideration of the microorganisms which can be potentially present according to the device and/or environment.

Each and every day, instrument disinfection efforts are undertaken with extreme precision and care by the professionals in the CS/SPD. Considering the broad range of items that require reprocessing, as well as the varieties of disinfectants (and combinations of disinfectants) that are needed to achieve the intended level of disinfection, the processes are highly specialized, with high reliance on time and precision.

The question is how

So, how exactly are disinfectants utilized in healthcare facilities and hospitals today to ensure the safety of both staff and patients? How do we determine which are the best to use according to the specificities of the place and situation? What are some of the factors that need to be taken into consideration?

"Proper cleaning and disinfection of instruments is vital to ensure our patients receive the highest quality care that can be provided," said Janet Pate, JD, MHA, BSN, RN, Nurse Consultant/Educator at The Ruhof Corporation. "Evidence-based guidelines should be followed at all times when processing instruments. If instruments are not cleaned appropriately, biofilm and debris can remain on them, ultimately putting the patient at risk for a healthcare acquired infection which could cause negative outcomes."

Janet Pate

Know your device, follow the rules

Natalie Lind, an Education Director at HSPA, speaks to the importance of understanding how a device will be used when selecting the level of disinfection:

"Not all disinfectants are alike, and the word 'disinfectant' is a general term. Different chemical disinfectants provide different levels of disinfection, so knowing how the device will be used can help determine the level of disinfection required. That information, along with the device's IFU, can provide solid information. I believe that Sterile Processing professionals have always had a good understanding of the importance of the disinfection process. It's what we do!"

Natalie Lind

Determining the right type of disinfectant can often be determined by paying heed to a device's instructions for use (IFU), as all such documentation should provide succinct instructions on cleaning and disinfecting the apparatus. The IFU must be referenced and strictly followed throughout the process (of using said instrument).

"There may be situations where certain disinfectants may not be appropriate for all environments and instruments," Pate commented. "Determine the ease of use and compatibility with the instruments/devices. The duration of exposure and type of microorganisms should be evaluated to ensure the appropriate disinfectant is used. The IFUs for the devices and disinfectants should be followed. Each scenario should be evaluated to ensure the selection of the product is appropriate for the intended use and adjustments are made accordingly."

Classify with Spaulding

HPN asked Randalyn Walters, Clinical Educator/Manager at BeliMed, for her thoughts concerning the selection of appropriate disinfectants depending on the circumstances. She referenced the Spaulding classification system, the disinfectant's safety data sheet (SDS), and the device's IFU as critical tools for decision making.

"When it comes to selecting the right chemistry for your healthcare's reprocessing department there are many factors to consider. First, identify what is the purpose and level of disinfectant you require. Start by utilizing the Spaulding classification to determine this level during the selection process. It is critical for healthcare professionals to understand what pathogenic microorganisms they are working to eliminate. Various forms of disinfectants are available, including solutions with a variety of chemical makeup."

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1. List N: Disinfectants for Use Against SARS-CoV-2. Feb 28, 2022, www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.
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"Personnel should consult the SDS (safety data sheet) and intended IFU to determine what particular chemical is safe to use and what it is comprised of," she added. "Disinfectants have specific approvals from the EPA and contact times, so that should always be a consideration if looking for agents to disinfect surfaces."

When selecting a disinfectant, Walters advises to pay close attention to the following attributes and/or ask related questions:

- Non-abrasive or toxic product, which is safe for your team and patients
- Free rinsing product that can disinfect the inventory in suitable time
- Cost effective and fits into your budget, making sure to consider the dosing amounts and concentration so you can forecast how much your team will utilize or require
- Provides a rapid kill rate, and is approved to eliminate the types of microorganisms you are facing
- Is the product environmentally friendly, or does it require special disposal, or storage conditions? Do you have a safety spill kit for this chemical?
- Does it require specific handling instructions, PPE, and respiratory ventilation?
- Does the chemical provide your department with safe, efficient and effective disinfection or does it require a mixture of other costly tools or neutralizing agents?

Pate notes the importance of aligning the disinfectant to the device and the environment:

"To ensure the appropriate detergents are selected, determine the compatibility with the instruments to be cleaned, the type of microorganisms that potentially may be on the instruments, the exposure time to the organism, and the physical environment where the chemicals/detergents will be used. IFUs for the devices and detergents selected should be followed. Ensure there is compliance with the parameters given for water hardness, pH, and temperature for each disinfectant, and that it is appropriate for use for that particular instrument."

Follow best practice standards

HPN asked Nancy Fellows, MSN MPA RN CNOR Sr. Clinical Education Consultant, at Advanced Sterilization Products (ASP) to comment on some of the main points of disinfection concern. She emphasized adherence to best practice standards.

"Factors that come to mind are safety and knowing best practices to minimize exposure for healthcare workers and patients. Best practices are the safest and most effective means of providing care. Implementing best practice standards and procedures ensures patient and staff safety. Performance characteristics should be considered when selecting an appropriate disinfectant solution for any item, and applied it in the most efficient way."

Fellows proceeded to list the following key questions that should always be answered by the CS/SPD teams in selecting and utilizing a disinfectant:

- What devices are to be high level disinfected?
- Do they adhere to Spaulding Classification for clinical application?
- Are the devices material compatible with the HLD solution being considered?
- What are the air exchanges needed depending on the physical environment where HLD is to be performed?
- Is there manufacturer support for education of staff?
- Is it easy to use?
- Is PPE required?

Close adherence to standards is not only imperative for health of the patients, but the staff as well. Improper use of disinfectants is often inclined to physically damage a device; likewise, the usage of disinfectants without proper ventilation for the staff can have both instantaneous and long-lasting negative side effects."

Best means isn't a clear-cut decision

Damien Berg, BS, BA, CRCST, AAMIF, VP of Strategic Initiatives for the Healthcare Sterile Processing Association (HSPA), was adamant in his statement that the so called 'best means' for choosing an appropriate disinfectant is a difficult question to answer.

Damien Berg

"This question is vast because the variety of product depends on some factors that the end user must take into account." He suggests asking the following questions when evaluating disinfectants:

- What level of disinfection are you wanting/needing to achieve?
- What are the disinfectants and device's IFU and are they compatible with one another?
- What are staff safety considerations with other chemicals in the department?
- Does use of the product work with the flow of the department?
- Is the product approved for use in the healthcare facility?

"All of these are important factors that can determine the appropriate disinfectant and when and how to use it," said Berg.

Mr. Spaulding and the rational approach

A microbiologist by the name of Earle Spaulding devised a rational approach to classify the methodologies for properly disinfecting or sterilizing patient-care items.

The Spaulding classification system divides items and equipment according to their likelihood of spreading infection when in use. Dependent on that likelihood (critical, semi critical, or noncritical), it can thus be determined what level of disinfection is required to remove any potential microorganisms.

The Centers for Disease Control and Prevention (CDC) defines the Spaulding Classification system as a "a strategy for sterilization or disinfection of inanimate objects and surfaces based on the degree of risk involved in their use."

The Spaulding classification system is the main reference material many standard committees as well as device manufacturers utilize when developing new devices.

In accordance with the Spaulding Classification system, three levels of disinfectants have been established to disinfect instruments based on their capabilities for containing and transferring harmful microbes.

Used in response to noncritical patient care items/areas, low level disinfectants are pretty commonplace throughout the hospital setting. These can range from floor cleaning products to surface disinfectants in patient rooms and surgical areas, and also routinely include bedpans, blood pressure cuffs, and crutches.

Intermediate level disinfectants are registered with the Environmental Protection Agency (EPA) with a tuberculocidal claim (unlike low level disinfectants, which, though also registered with EPA, do not carry a tuberculocidal claim). Due to their ability to kill most bacteria and viruses, intermediate level disinfectants are often used on surfaces contaminated with blood (though are often applied on such instruments as respiratory therapy items, and sleep study devices).

Lastly, high level disinfectants are used (in addition to sterilization) for items that are considered critical or semi critical in nature, and thus require the removal of any and all microorganisms. Examples of critical items include surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes; semi critical devices include, among others, anesthesia equipment, some endoscopes, esophageal manometry probes, and cystoscopes.

Limit your options

With all the disinfectant products on the market today, Lind suggests standardizing as much as possible to help drive safe and effective use and minimize the risk for errors:

"If there are disinfectant options and an approved disinfectant is already in use in the SPD, keeping the number of chemicals to choose from to a minimum reduces the chance for confusion and user error. Again, selecting the effective disinfectant that poses the lowest risk of exposure or injury to the staff should always be a consideration."

How COVID raised questions, and the bar on staff education

"Early in the COVID-19 pandemic, there were questions about which disinfectants would kill the virus. Once there was guidance on that, we moved to a business-as-usual mode. SP has always dealt with killing microorganisms; therefore, SP professionals already knew what to do to protect themselves and provide safe devices for patient use," added Lind.

Berg was quick to highlight the impact of the COVID-19 pandemic and the resulting boom in the application of countless disinfectants.

"Working in a frontline hospital before and during the pandemic I saw that the use of disinfectants was really highlighted. It was interesting having conversations with my clinical counterparts, as well as our hospital leaders, purchasing department and infection prevention teams on how to best "kill" COVID-19 — and how to train technicians to use disinfectants and other products appropriately and safely. We did have some shortages of certain types of disinfectants, but overall, we still always had something to use. We did see that the long-term use of disinfectants on surfaces of certain devices (phones, computers, countertops) had a negative effect on the lifespan of that surface or device, depending on the type of disinfectant used and how often. Overall, I feel that many SP professionals 'backed into' education and sought more information and knowledge around terms such as concentration, dwell time, IFU, and compatibility. These words were known before the pandemic, but they really became everyday words as they related to disinfectants."

The most noticeable and troubling impact of COVID-19 was related, of course, to the hindrance and disruption of the supply chain. As the pandemic was an unknown entity with undetermined causes and effects, it required time and effort to effectively determine the types of disinfectants that would kill the virus.

Many organizations stockpiled some of the wider known brands of disinfectants, thereby resulting in other organizations having to alternate from their preferred brands. Likewise, staff had to be trained on these new products to ensure that they worked effectively.

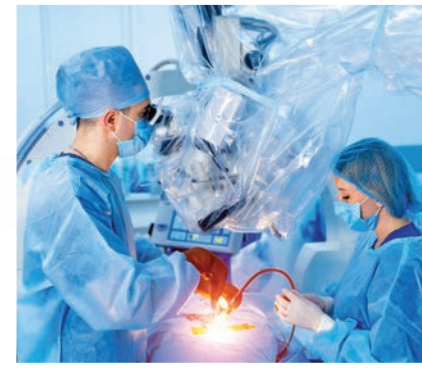
All things considered, the critical factor in determining the efficacy of a disinfectant lies in the 'dwell' time needed for the chemical to stay wet and in contact with the surface, and long enough to eliminate the targeted microorganisms.

Berg went on to stress that there continues to be an increased demand for understanding of disinfectant use in our health facilities today.

"In my working in the hospital and also working on a national and global scale in the world of disinfection and sterilization, I am seeing a positive trend to focus on the basics, which we know work but may not always give the attention needed. I see people in Sterile Processing really wanting to know more about what the right thing is to use and how to use it safely as opposed to the mentality of "spray and pray." **HPN**

Sterile Processing integral to circular healthcare reality

by Rick Dana Barlow



Elsewhere in this month's edition of *Healthcare Purchasing News* sits an editorial exploration of sustainability, one of the key components that makes up what's called the "circular economy."

Similarly, Sterile Processing & Distribution (SPD) – in department and functionality – represents a key component of what could be classified as a "circular healthcare reality." It goes something like this:

- Without SPD, there can be no surgery – including minimally invasive procedures.
- Without surgery, there can be no fixing and healing of patients.
- Without the fixing and healing of patients, people die more quickly.
- Without people propagating, there is no need for healthcare services.
- Without healthcare services, there is no need for surgery.
- Without surgery, there is no need for SPD.

Here's the bottom line that *HPN* has promoted every November, consistently for 18 years that you can dismiss this axiom at your own peril: Sterile Processing (department and function) is essential.

And with surgical techniques and technologies advancing every year – particularly in the area of minimally invasive procedures that rely on rigid and flexible endoscopic equipment and robotics – it's essential for SPD professionals to keep pace with how to care for the delicate, expensive and high-tech tools wielded by surgeons.

From pre-treating to cleaning to disinfecting/sterilizing to aerating/drying to repairing to storing and to repeating the process continuously until replacement is needed, SPD is responsible for some of a healthcare organization's more costly assets that assist in maintaining a patient's most costly asset – life.

Because SPD takes this mission and vision seriously, so has *HPN* for all 45 years of its publishing history and annually for the last 18 years with dedicated, themed content each November. If you need proof, be sure to visit HPN HPN Online (www.hpnonline.com) and use the search term "Endoscope Care."

Continue reading …

ANSI/AAMI changes face, force of sterile processing via ST91 update

When the American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) wanted to improve sterile processing practices and procedures as well as protect patients by updating the ST91 guidelines, the collaborating ANSI Endoscope Reprocessing Working Group and the AAMI Sterilization Standards Committee knew any wholesale changes would instantaneously spur discussion and debate.

And now.

Mission accomplished.

With the release of this comprehensive guideline update, Healthcare Purchasing News wanted to examine how ANSI/AAMI's accomplishment would affect sterile processing practices and operating room procedures, as well as explore how the updated ST91 will improve performance, quality, safety and workflow.

Consequently, *HPN* asked a small group of Sterile Processing & Distribution (SPD) company executives to share their impressions and predictions about the "new world order."

Step in the right direction

"ST91 is another incremental step to refine and improve the safety, quality and efficiency of reprocessing endoscopes, and to a larger extent all small-lumen medical devices. Since hospitals are at varying levels of processing sophistication and process improvement, this new guidance may require both capital equipment upgrades and new staff training for many.

"On the positive side, this guideline update urges us forward in a good direction.

Refining the guidance for each step in the reprocessing of endoscopic devices will help providers to take the next steps toward improving their processes, equipment and training so they can achieve a new level of safety and compliance.

Richard Radford

"Each step in the endoscope reprocessing cycle must undergo ongoing evidence-based improvements to assure optimal outcomes for patients. Cenorin focuses on the reprocessing step of thoroughly drying these devices, in particular

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small-lumen devices including bronchoscopes, cystoscopes and robotic devices. The channels in these important devices provide an unfortunate opportunity for residual organisms and moisture, both of which can reduce the effectiveness of later reprocessing steps or even cause a processing cycle to abort."

Richard Radford, CEO, Cenorin LLC

More costly but necessary

"AAMI ST 91 is going to cost healthcare institutions more money and take more time to process scopes because reprocessed endoscopes require proper handling from point of use, through all cleaning steps, and on to transport for use. This is how we make sure we're doing everything we can to provide properly reprocessed scopes that are safe to use on patients.

"Healthcare personnel understand that reprocessing is not a 100% guarantee that scopes will truly be patient-ready, despite the best efforts of the reprocessing staff. Infections by cross-contamination are rare, but patients are aware they are possible and have begun requesting single-use devices. I believe standardization of the guidance in handling these scopes will have a positive impact on performance, quality and workflow. SPD personnel are already used to working with certain standards and processes, so this standard is an enhancement to what they pretty much already do.

Sharon Ward-Fore

"Some of the important enhancements of AAMI ST91:

- Guidance on transportation of scopes (how to keep the devices from drying during transport).
- Manual disinfection is no longer recommended due to the variability/inconsistency personnel responsible for the process.
- Point-of-use [treatment] (formerly precleaning), cleaning and delayed reprocessing guidance.
- 'Significant revisions' to leak test guidance, including the regular testing of automated leak testers.
- Added a designation of 'high-risk' endoscopes.
- Strengthened wording on which scopes should be sterilized and which can be high-level disinfected.
- Guidance that single-use biopsy port caps and valves should be used when available and reusable ones should undergo sterilization or HDL after use.
- Recommends formal training and competency verification ahead of a technician's first solo reprocessing assignment, as well as certification for all personnel in flexible endoscope processing.
- Requires monitoring HVAC systems and water quality for automated endoscope reprocessors."

Sharon Ward-Fore, MT(ASCP), CIC, FAPIC, Infection Prevention Advisor, Envista

'Wake-up call to action'

"The overall 'call to action' inherent in the new ST91 is purposeful embedding of quality control at multiple steps of processing endoscopes. Significant effort was made to ensure this was a user-focused document, providing guidance on best practices to enable quality processing – and, in turn, protect patients. Clinical investigations and research from recent years guided the recommendations and serve as the sobering 'wake-up call' for why such recommendations are necessary.

"Notable areas of focus in the new standard include:

- Emphasis on certification, training, and competencies
- Management of "high-risk endoscopes"
- Enhanced visual inspection, cleaning verification, borescopic inspection
- Recommendations against manual disinfection
- Active drying post processing
- Appropriate physical space considerations
- Quality control for manual as well as automated processes
- Monitoring water quality
- Multidisciplinary risk assessments

"For those facilities previously lacking such embedded quality control steps, first impressions may be that any additional steps add to turnround time and costs. However, unless we look, we will not know; and unless we measure, we cannot evaluate how we are doing. Those are basic principles behind

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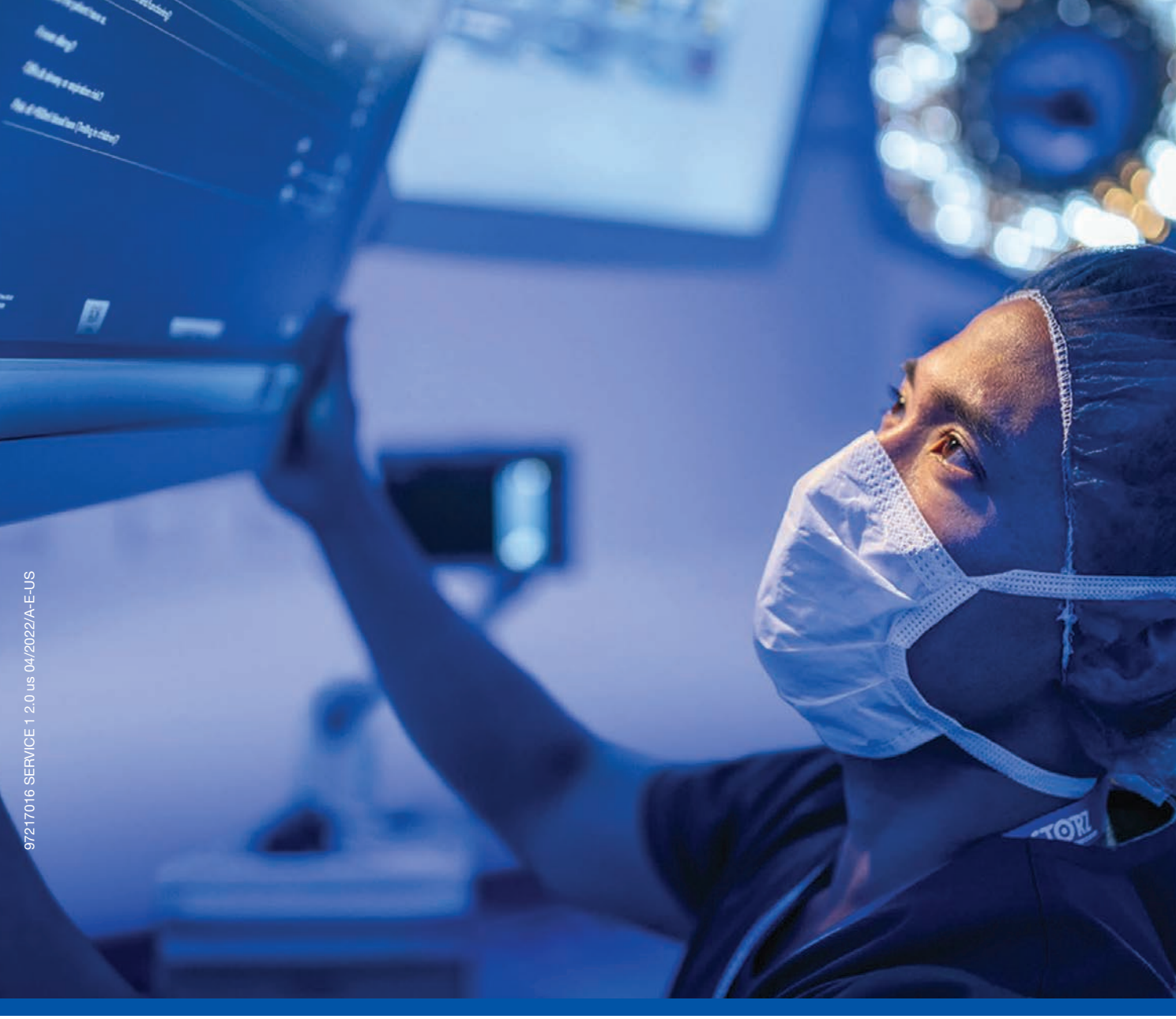

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any successful operation. The focus also always needs to remain on the end result – producing an effectively cleaned and disinfected or sterilized endoscope to the next patient."

John Whelan, Clinical Education Specialist, Healthmark Industries

John Whelan

Gearing up

"For facilities that follow AAMI standards, the ST91 updates may add time to the reprocessing procedure for leak testing, drying time and cleaning verification depending on endoscope risk. CS/SPD departments should make trial reprocessing runs based on the new standards to determine how the updates may impact their specific facilities. There are products on the market that already provide built-in features that address the guideline changes.

"CS/SPD departments will need to determine whether existing equipment and processes are sufficient to meet the new standards. A facility, for instance, may need more drying equipment to incorporate the additional reprocessing time or new equipment to track reprocessing and storage steps. Facilities may need to schedule more time between procedures to account for the longer reprocessing requirements."

Melinda Benedict

Melinda Benedict, Director, Infection Prevention and Control, Olympus Corporation of the Americas

Follow evidence, embrace science

"Adding additional guideline recommendations poses the question: Are the recommendations backed by evidence-based science? The idea that a recommendation can point out an improvement in a best practice is extremely important. However, it is critical that evidence, education, staff training and effective implementation can support the change."

Ron Banach

Ron Banach, Director, Clinical Training, Ruhof Healthcare

Work in progress

"I find that the biggest changes impacting both SPD and endoscope processing areas are the new requirements for cleanliness testing after manual washing and 10-minute drying times. Both requirements impact the reprocessing of flexible endoscopes by adding procedures that take time. Another important change has to do with the requirement to report damage. Section 7.4.8 d) states, 'Report the leak test failure per organizational policy and procedure, including the endoscope product identification and traceability information.'

Gregg Agoston

"ST91 calls for cleanliness testing after each use for 'high-risk' endoscopes and the verification of all other endoscopes on a statistically significant frequency: *'3.31 High-risk endoscopes and/or those that are of complex design (e.g., duodenoscopes, linear ultrasound (EUS) endoscopes, bronchoscopes, endobronchial ultrasound (EBUS) endoscopes, ureteroscopes, cystoscopes and as determined by the facility) shall be monitored with cleaning verification tests after each cleaning. Manual cleaning of flexible endoscopes that are not determined to be high – risk should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (e.g., at a statistically significant frequency based on the number of procedures performed).'*

"I believe that the requirement for cleanliness testing is a move in the right direction. The lumen of a flexible endoscope is very small and even with brushing and flushing bioburden can remain in the channel. The use of a test to detect organic materials will assist in ensuring that the endoscope is clean. My question is shouldn't we test all flexible endoscopes after each use? Doesn't every patient deserve to have a clean and properly processed endoscope? The endoscope must be thoroughly cleaned prior to sterilization or HLD.

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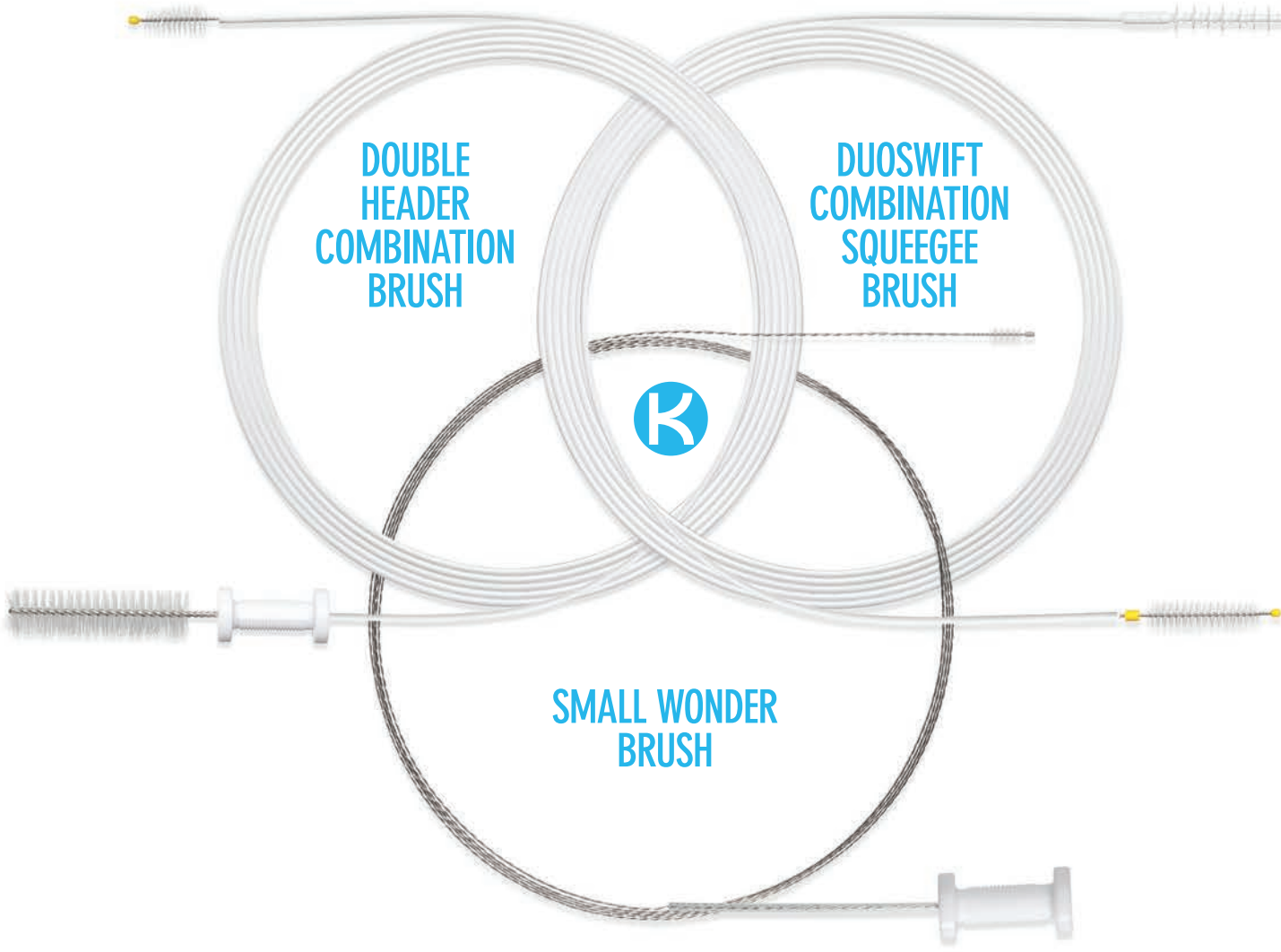

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"Drying the endoscope makes scientific sense. Water is needed for growth of all living organisms. Drying the endoscope as quickly as possible helps prevent bacterial growth. The challenge with the new standard is that first, most facilities do not actively dry the lumens after processing. Most simply hang the endoscope and allow it to drip dry, thus this is a significant change. Second, the requirement for 10 minutes adds significant time to the process and some departments struggle to keep up with the workload without this new requirement. Lastly, drying takes space and the equipment to perform the function. It is not efficient for a technician to use an air gun or similar tool to dry lumens. An automated system that connects to the endoscope is needed to ensure that the process is effectively administered and timed for the appropriate cycle. Facilities will need to purchase flexible endoscope drying cabinets or convert to storage systems that actively dry the endoscope.

"'8.2.5.1 The endoscope and its components should be dried after completion of the cleaning and disinfection process. Flexible endoscopes with channels should be dried for a minimum of 10-minutes with pressure regulated force instrument air or a minimum of HEPA – filtered air.'

"Many processing departments do not have medical air or HEPA-filtered air available, thus this requirement will force those facilities to add this tool. In addition, without automating the process, there is a great chance that staff will not perform this process for the required 10-minute period. In addition, it will be a significant drain on technicians' time if the process is not automated. The extra 10 minutes required for this process, if all manual, could cause delays in reprocessing in busy departments. Or with high-level disinfected endoscopes, most endoscopy suites simply hang the endoscopes after processing them in an AER. An absorbent towel is placed in the bottom of the storage cabinet to absorb any water that drains from the endoscopes. For sterilized endoscopes, the drying process is now performed primarily to prevent sterilization failure as the machines are very sensitive to moisture and in addition moisture interferes with the sterilization process. To be successful, management will need to implement training, provide the appropriate space and tools needed for the air drying and enforce recording drying times. Unless the process is automated, this will be a very challenging task for management.

"It is important to recognize that both changes impact SPD and GI endoscopy processing areas as small diameter flexible endoscopes (e.g., ureteroscopes, cystoscopes, etc.) are impacted by these changes.

"Another change in AAMI ST 91 is for the reporting of leak test failures. Almost every IFU states that the endoscope should not be used on a patient if it leaks. The reason for this is that only the exterior of the endoscope and the interior of the lumens are rendered sterile or HLD through reprocessing. When a leak forms, the interior of the endoscope is exposed, and this space is not clean, and [therefore] cannot be considered sterile or HLD even if it is exposed to sterilant. (Those endoscopes that are sterilized by hydrogen peroxide or ozone gas require a vent port be attached. This vent port allows the sterilant gas to penetrate the interior of the endoscope. The vent cap is used to allow the pressure within the endoscope to equalize during the sterilization process. Without the vent cap, the endoscope cover could tear due to the pressure inside the endoscope. While the sterilant enters the interior of the endoscope, the interior is not considered sterile because it is not an area that is or could be cleaned).

"Leak testing should be performed prior to cleaning. It is also performed in AERs. Both processes occur prior to the use of the endoscope on the patient. Post-case if a leak is detected the endoscope must be immediately taken out of service and sent for repair or replacement. Leaks typically are a result of accessory devices used with the endoscope (biopsy forceps, snares, laser fibers etc.), improper handling (bending, torquing) improper care (sharps, heavy equipment placed on or near the endoscopes and general wear and tear (parts fail due to age condition).

"In most cases the damage occurs during use. Currently, physicians have no way of telling if the endoscope that they are using has a leak. When a leak occurs, the endoscope can no longer be considered sterile or high level disinfected and should not be used on a patient from that point in time when the leak occurred. Notification of a leak post case is not a perfect solution because the patient likely was exposed to a

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non-sterile/ non-high-level disinfected endoscope which is a health risk to the patient. The new standard to report and record leaks could assist a physician in the treatment of their patient and bring heightened awareness of monitoring those patients that were exposed to a non-sterile/non-high-level disinfected endoscope during a procedure.

"Lastly, a much more difficult task for hospitals and endoscopy centers pertains to the need to separate endoscope decontamination from the sterilization process. Many GI endoscopy reprocessing departments perform all functions in one small room. While grandfathered in due to facilities constraints, due to the high risk of cross contamination and the fact that the air flow is incorrect, hospitals and surgery centers should work to correct this critical flaw in the processing of GI endoscopes. This practice would never be allowed for an SPD, and it should not be allowed for GI endoscope reprocessing areas. Both contain biohazardous materials and have the risk of harm to staff and patients. For this reason, there should be no difference in requirements between and SPD and a GI endoscope reprocessing area."

Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare

Responsibility, accountability for pre-treating soiled devices finds a home

ANSI/AAMI houses the procedure at the point of use, in the OR immediately after a procedure

by Rick Dana Barlow

One of the hottest debates fomenting tension between the Operating Room (OR) and Sterile Processing & Distribution (SPD) showed little sign of abating until the American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) demonstrated steadfast and swift parenting skills.

Few, if any, challenge one of the fundamental and logical tenets of reprocessing: Clean first before high-level disinfecting or sterilizing anything because if something isn't thoroughly cleaned first it cannot be high-level disinfected or sterilized and ready for safe use on a patient.

Acknowledging and accepting one of the central tenets of reprocessing, OR and SPD professionals then move next to timing. Where does the process of reprocessing actually begin?

Until the revised ANSI/AAMI ST91:2021 standards were released by ANSI's Endoscope Reprocessing Working Group in conjunction with AAMI's Sterilization Standards Committee, the guidelines for reprocessing flexible and semi-rigid endoscopes left the notion of "pre-cleaning," which ST91 re-labeled as "pre-treating," to circular finger-pointing.

SPD professionals recognize the frustration around pre-treating soiled devices. The longer that biological/organic material remained on soiled devices post-surgery, the faster the material dried, making it harder – and more time-consuming – for SPD techs to clean. This extended the overall reprocessing time in SPD as well as the turnaround time to return devices to the OR.

Logically, to prevent biological/organic material retained on soiled devices post-surgery from drying and hardening, it makes sense to apply some sort of pre-treatment material to the soiled devices earlier than in SPD to keep the biological/organic material soft and therefore easier to remove during the cleaning process. From a timing standpoint, the ANSI/AAMI experts recognized the tenable solution to which Ron Banach, Director, Clinical Training, Ruhof Healthcare, emphasizes matter-of-factly.

"The March 2022 release of the ANSI/AAMI ST91:2021 update has made it very clear: Pre-treating needs to be carried out in the OR," Banach told *Healthcare Purchasing News.*

"The use of enzymatic products should start during the pre-cleaning process at the point of use immediately following procedures," Banach continued. "Enzymatic foams, gels and humectants designed for pre-cleaning aid in loosening soils and keeping instruments moist pending further cleaning until reprocessing begins. This discourages soils from drying and forming biofilms."

Banach cites the direct, codified reference to remove any doubts on page 29 under the heading "7.2 Point of use treatment" and subheading "7.2.1 General considerations.

"*To prevent buildup of bioburden, development of biofilms, and drying of secretions, point of use treatment is performed immediately after completion of use of the device. It is imperative that the written IFU from the endoscope, cleaning equipment, and cleaning solution manufacturers are followed. When labelled for this purpose, commercially available sponges or wipes can be used for point of use treatment. Also new automated sprayer delivery systems can add efficiency, compliance, and effectiveness.*"

Although OR nurses historically have mumbled and grumbled – and in some cases resisted – about their participation in what largely has been SPD's responsibility, ANSI/AAMI threw down the gauntlet and clarified the matter once and for all.

"Noncompliance by the OR staff is unacceptable," Banach said. "When pathogens and micro-organisms are left on the medical device, they begin drying in minutes. It is critical to keep the device moist long enough so the decontamination processing department can do their job effectively." Ruhof makes Prepzyme Forever Wet with Bio-Clean Technology, a multi-tiered enzymatic humectant spray for pre-treating soiled devices in the OR.

Other SPD experts quickly reinforce pre-treating soiled instruments in the OR.

"We believe that pre-treating is crucial at point of use, immediately after a procedure and prior to transport," said David Willoughby, Vice President, Marketing & Business Development, Medtrica Solutions Ltd. "Once instruments leave the procedure room there are too many variables that can and will delay pre-treating, so not using an enzymatic pre-cleaning agent at POU immediately after the procedure can become extremely problematic. Although pre-treating at POU can at times be perceived as an inconvenience in terms of time,

it is still an important and critical first step in the cycle of instrument reprocessing. By pre-treating instruments in surgical theaters with enzymatic pre-treatment solutions, [you] will greatly reduce the occurrence of bio-contaminants adhering to instrument surfaces. And, as simple as applying a POU pre-treatment solution sounds – and is to do – unless this takes place the infection control chain can be broken causing the very outcomes these protocols were established to avoid."

Melinda Benedict, Director, Infection Prevention and Control, Olympus Corporation of the Americas asserts the OR's important role in this necessary process.

"Manufacturers and professional organizations across the healthcare spectrum agree pre-cleaning endoscopes post-procedure is an essential step in safe patient care," Benedict indicated. "Also agreed is the timing of this step: The sooner, the better. Medical device instructions for use generally recommend pre-cleaning be performed at the end of the procedure, immediately after use, while still in the procedure room. Delays in reprocessing may require additional steps in making the device patient ready and safe. In that regard, staff are in the best position to carry out this critical step in reprocessing as they are most aware of the 'procedural stop time.'"

Workflow should – and will – adapt, Benedict insists.

"Wiping and flushing with water or detergent can easily become part of the workflow as a documented standard of care at the bedside," she noted. "The purpose of the wipe or flush is to remove heavy debris from the instrument to avoid drying of residual bioburden. Highlighting the rationale for this activity can increase user knowledge as to why the step is important and facilitate understanding of why pre-cleaning should be carried out by the staff who have immediate access to a device following a procedure at the point of use."

There should be no question when and where pre-treatment should happen if you analyze procedural patterns and workflow models, according to Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare.

"Pre-treatment or pre-cleaning must be done in the OR," he said. "This first step of the cleaning process helps to remove gross soil and keep the instrument moist. Due to the variable workloads in the decontamination department, instruments often have extended wait times one-two hours before the manual cleaning process begins. For flexible endoscopes, per certain IFUs, it is required that before the endoscope is detached from the video processor, that enzymatic solution or water is suctioned through the working channel. It is not feasible for the Decontamination staff to perform this process.

"From my experience, there is significant variability in OR staff performing pre-cleaning," Agoston continued. "The key aspects are to first remove gross debris then apply enzymatic solution or take steps to prevent debris from drying on the instrument, e.g., covering with a moist lint free towel."

John Whelan, Clinical Education Specialist, Healthmark Industries, expresses concern about questioning this logical development.

"Regardless of the product used, the sooner the better for removing microbial load and limiting biofilm formation," he said. "Minutes matter! Point-of-use treatment needs to occur ASAP after the procedure is complete. [A] lack of complete

or effective point-of-use pre-treatment can add to the downstream workload and effectiveness – for manual cleaning, as well as high-level disinfection or sterilization. An endoscope not effectively precleaned can take that much longer to manually clean and/or may inhibit complete manual or automated cleaning/removal of bioburden and biofilm, which in turn affects the success of disinfection/sterilization.

"For certain brands of flexible endoscopes, there are steps that can only occur at the bedside – while the scope is still connected to the processor in the procedure room (e.g., the IFU directed use of the "AW Channel Cleaning Adapter")," Whelan continued. "These steps cannot be reproduced in the processing area."

Olympus' Benedict remains sacrosanct. "Neglecting pre-cleaning immediately following a patient procedure may increase the risk for infection and could increase processing time," she said. "Allowing clinical soil to dry on the endoscope may allow biofilm to form on the device. [Pre-treating] is critical to ensure subsequent reprocessing steps, including high-level disinfection or sterilization, can be effective. When performed correctly and with knowledge as to why the process is critical, [pre-treating] is a cornerstone in high-quality safe patient care. [Pre-treating] requires minimal time to complete and provides the foundation for effective and efficient reprocessing of medical devices."

As some in the OR may question the workflow changes, SpecialtyCare's Agoston raises the specter of workflow changes not requiring pre-treatment in the OR.

"Failure to properly [pre-treat] instruments in the OR sets up a cascade of possible effects in the SPD," he insisted. "Instruments that are not [pre-treated] require more time and effort by the SPD staff to clean them. This can lead to excess force being used on the item or tools that could possibly damage the instrument, e.g., wire brushes. We know that the risk of biofilm formation increases the longer the bioburden remains on the instrument. This increases the risk of ineffective cleaning, increasing the risk of [surgical site infections] to patients. It is extremely important that the OR staff perform complete [pre-treating] prior to returning products to the SPD." HPN

Alternative options to reusable endoscopes simmering

By 2035, healthcare organizations can expect influx of hybrid products

by Rick Dana Barlow

From a reprocessing perspective, Sterile Processing & Distribution (SPD) experts anticipate minimally invasive surgery migration to hybrid rigid and flexible endoscopes by the mid-2030s but the expected shift seems to be simmering to a slow boil.

Generally, healthcare organizations can choose between three types of flexible and rigid endoscopes – those that are completely reusable, those that are completely disposable/single-use only and those that are called "hybrid" for infection control purposes because they are reusable devices with a select number of disposable components that can be discarded after use (e.g., distal covers and adaptors, etc.).

By and large, two primary issues sparked the emergence of disposable and hybrid models as alternatives to the traditional reusable endoscopes that surgeons have operated since the 1980s: The challenges and difficulties in thoroughly cleaning, disinfecting and sterilizing these increasingly intricate and complex devices and the number of healthcare-associated infections attributed to inadequately reprocessed devices, such as bronchoscopes.

Early countermeasures called for more education and training of SPD technicians handling these delicate and expensive instruments, followed by demands for more detailed, but clearly organized and easily understandable instructions for use (IFUs) from the device manufacturers. Within the last decade, however, the third option of changing the devices themselves emerged as a possibility.

Several years ago, *Healthcare Purchasing News* began exploring and reporting on the potential shift that generated buzz and quick momentum with radical predictions of a progressive shift in behaviors and habits, but as time progressed, topped by a global pandemic, the early full-speed-ahead approach seems to have settled into a steady, but surefire gait.

Once again, *HPN* reached out to a small group of executives at manufacturers of endoscope devices and related reprocessing supplies and equipment about their changing forecast of any market shifts through 2035. They were able to choose from among five different potential market scenarios and to share their reasoning.

1. **Fully reusable endoscopes will remain.** Healthcare organizations will continue to rely on fully reusable flexible and rigid endoscopes for the majority of minimally invasive surgical (MIS) procedures
2. **Hybrid models will become a minority segment.** Healthcare organizations will increasingly shift toward using hybrid flexible and rigid endoscopes that incorporate disposable components that can be discarded after use, but the hybrid models WILL NOT surpass the use of fully reusable models
3. **Hybrid models will become the majority.** Healthcare organizations will increasingly shift toward using hybrid flexible and rigid endoscopes that incorporate disposable components that can be discarded after use, and the hybrid models WILL surpass the use of fully reusable models
4. **Disposable/single-use only models will become a minority segment.** Healthcare organizations will increasingly shift toward using fully disposable flexible and rigid endoscopes, but the disposable models WILL NOT surpass the use of fully reusable models
5. **Disposable/single-use only models will become the majority.** Healthcare organizations will increasingly shift toward using fully disposable flexible and rigid endoscopes, and the disposable models WILL surpass the use of fully reusable models

Last year, Nos. 1 and 5 didn't generate support as executives felt remaining with fully reusable models – essentially, the status quo – wasn't an option and neither was complete conversion to disposable/SUDs. This year, opinions and predictions seems to have shifted and tempered a bit, retreating to a wait-and-see area on one hand to a gradual acceptance and adoption of hybrids as part of conventional practice.

Olympus Corporation of the Americas, one of the world's leading manufacturers

SPD endoscope reprocessing quality performance hinges on practice, procedure – not product

When it comes to Sterile Processing & Distribution (SPD) striving for and ensuring high-quality reprocessing performance improvement the strategies and tactics needed to deliver those outcomes remain rather consistent.

Practices and procedures matter much more than product types, which means switching to disposable/single-use devices for all or selected procedures or switching to hybrid devices that contain disposable/single-use components likely won't trump four other overarching concerns, two of which remain consistently at the top as most important for five consecutive years running.

Hence, practice and procedure continue to outweigh product by widening margins.

Even though media coverage of healthcare-associated infections likely linked to substandard reprocessing may be blamed on technique and/or technology, industry experts point to improving technique as a more effective countermeasure than redesigning technology to compensate. As minimally invasive and standard medical/surgical devices become more complex with nooks, lumens and components that can be hard to clean, which then makes them hard to disinfect and sterilize, some may believe that disposing rather than reprocessing those devices make more sense for patient safety even at the expense of the budget.

But not everyone thinks the same way. Instead, others point to education, training and performance tracking as more effective, efficient and relatable options.

For the fifth consecutive year, *Healthcare Purchasing News* surveyed a small group of sterile processing subject matter experts on seven potential – but likely scenarios – that may direct and redirect how SPD navigates the 2020s from a quality standpoint. HPN asked the executives from device manufacturers and reprocessing product companies to rank the seven strategies (1 being the most important or influential; 7 being the least important or influential).

To show the trends year over year, *HPN* publishes the aggregate respondent data from 2021 through 2018, with rather consistent results. In fact, the top two strategies this year echo the top two last year, which had represented a transposition of the top two the year before that. Essentially, the top two strategies – fundamental in their own right – have remained consistent for five consecutive years. Curiously, the third and fourth choices also remain consistent, albeit transposed from last year but widening the gulf between the top four and bottom 3, all of which are technology-related.

1. Thoroughly educating, training, vetting and certifying SPD staffers on proper and effective cleaning techniques

2022 average score: 1.5
2021 average score: 1.7
2020 average score: 2.43
2019 average score: 2.5
2018 average score: 1.5

2. Demanding, receiving and following validated instructions for use (IFUs)

2022 average score: 1.8
2021 average score: 2.6
2020 average score: 2.64
2019 average score: 1.9
2018 average score: 2.5

4. Comprehensively monitoring and tracking all steps in the process with sensors and video technology

2022 average score: 3.2
2021 average score: 4.5
2020 average score: 4.85
2019 average score: 4.7
2018 average score: 3.4

3. Holding staffers accountable/responsible for endoscope cleaning "violations"

2022 average score: 3.7
2021 average score: 4.0
2020 average score: 4.23
2019 average score: 4.8
2018 average score: 2.8

5. Switching to disposable/single-use-only endoscopic devices for selected endoscopic procedures only (e.g., bronchoscopy, etc.)

2022 average score: 5.2
2021 average score: 5.3
2020 average score: 4.46
2019 average score: 4.3
2018 average score: n/a

6. Switching to endoscopes that contain disposable/single-use-only components that can be discarded or swapped out after use

2022 average score: 5.4
2021 average score: 4.8
2020 average score: 3.62
2019 average score: 4.1
2018 average score: n/a

7. Switching to disposable/single-use-only endoscopic devices for all endoscopic procedures

2022 average score: 7.0
2021 average score: 6.6
2020 average score: 4.77
2019 average score: 6.1
2018 average score: 4.8

HPN invited respondents to explain their perspectives and even offer alternatives. Here's what they shared.

Melinda Benedict, Director, Infection Prevention and Control, Olympus Corporation of the Americas, reiterated that, "Single use for certain patients and procedures is recommended by the FDA, whose guidance is of utmost importance."

Meanwhile, Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare, emphasizes staff education, training and even specialization as paramount for mastering this process and not redesigning the products.

"There are many complex instruments in hospitals that the SPD/GI units must be able to properly clean and sterilize/[high-level disinfect]," he noted. "Unless there is a clear advantage, e.g., cost, impact on environment or technology advancement, I do not believe that disposable endoscopes are the correct answer. We only have to look at the increase in medical waste to see the impact of single-use devices. I believe that the key to success is to allow for specialization within the hospital for endoscope reprocessing.

"There should be dedicated staff, who are highly trained and paid commensurate with the skills needed to perform the work, which in the case of GI flexible endoscopes is very high," Agoston continued. "There are over 100 pages of instructions in the IFU on the proper procedures to reprocess a flexible GI endoscope. Each step in the process must be performed correctly to render the endoscopes safe to use on a patient. The staff must be trained, certified with annual or more frequent competency evaluations. Pay must be commensurate with the work and expectation that all IFU processes will be performed on every endoscope.

"The SPD typically rotate staff through each processing area. Given the current challenges in finding qualified SPD staff, the rotation practice results in every technician processing complex instruments," he said. "This results in significant variability due to skill sets and the fact that the technicians do not process the devices on a frequent enough basis to become expert. No manufacturer puts inexperienced technicians on their most technical jobs. Hospitals should not do this either."

of endoscope products and technology embraces the practical approach because none of the options cited adequately addresses what they feel is the issue.

"Reusable flexible endoscopes have been designed to meet clinical challenges where durability, reliability, tactile feedback and stability for manipulating the scope appropriately to ensure proper positioning and usage," said Melinda Benedict, Director, Infection Prevention and Control, Olympus Corporation of the Americas. "Single-use endoscopes may surpass reusable in some specialty areas or locations within a facility, but adoption will be different for different patient populations, different physician preferences and different facilities. We agree with the ACG, ASGE, and SGNA that clinicians will not rush into this without first understanding the new and unintentional risks we may be introducing to our patients such as an increased risk of procedural failure, perforation, or pancreatitis. In addition, the medical waste and cost challenges will need to be addressed."

Others concur that clinicians will favor continued use of reusable scopes for the majority of MIS procedures due in large part to sustainability.

"All hospitals are concerned about sustainability and reducing hospital waste," noted Richard Radford, CEO, Cenorin LLC. "By reducing single patient use medical devices, hospitals will reduce their waste stream and help achieve their sustainability goals."

With a career that spanned service with several original equipment manufacturers, Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare, issues a challenge to OEMs.

"Medical waste disposal is a significant issue and costly," he said. "With 75 million endoscopy procedures performed annually, think of the cost to the environment from this mountain of waste. OEMs should focus their efforts on developing more robust endoscopes, ones that can be fully sterilized by low cost low environmental impact methods."

The switch is on

Others see that the migration – albeit partial and slow – already is underway as hybrid models are being incorporated for select uses, but that ultimately, reusable models will prevail as the preference among the majority.

"I think the increased use of hybrid scopes with disposable components is the realistic expectation within that [13-year] timeframe," said John Whelan, Clinical Education Specialist, Healthmark Industries. "Yes, we can hope for everything disposable tomorrow, but that will not be realistic for all facilities, let alone the environment.

"We need to consider here all the clinical locations where endoscopes are clinically used," Whelan continued. "Generally speaking, a larger health system may be able to afford and support an all-disposable inventory, but less so a standalone endoscopy center or clinic. Technology needs to catch up – beyond what already exists. It is good to have disposable options, but we also look forward to reusable endoscopes that can be routinely more effectively processed. That requires material changes for the endoscopes themselves and/or automated cleaning and disinfection/sterilization options that are currently in R&D stages of development."

Sharon Ward-Fore, MT(ASCP), CIC, FAPIC, Infection Prevention Advisor, Envista, the parent company of Metrex Research, expresses similar hesitancy and trepidation about a meaningful migration.

"Although patients will be looking for healthcare to use more disposable scopes or scopes with more disposable components, I don't think we are there yet with disposable scopes," she asserted. Still, she acknowledges a radical shift could occur "if the quality and cost enable their use.

"Disposable would completely eliminate the possibility of cross-contamination, providing piece of mind for the patient and the healthcare institution," Ward-Fore added.

Dan Gusanders, President, Pure Processing, remains the most optimistic, contending that a shift to hybrid models will surpass the use of reusables in a dramatic market shift.

Dan Gusanders

"The use of more hybrid models seems likely as there continues to be lapses in reprocessing and outbreaks of antibiotic resistant infections related to endoscopes," Gusanders told *HPN*. "I imagine low-volume facilities will continue to use mostly reusable models by 2035, with larger facilities seeing more hybrid models than fully reusable. The demands on reprocessing environments (e.g., decontamination sinks, AERs, storage) will be fascinating to see with the increased of hybrid models." HPN

The return of reusing SUDs may have a prequel in haste to reduce waste

As the discourse about reusing single-use devices continues to simmer even as healthcare professionals verbally spar over economic benefits, product durability, procedure quality and patient safety, a growing movement is emerging outside of healthcare that may render it all moot.

The movement stems from environmental calls for banning the use of single-use plastics to keep these products out of landfills after disposal.

Think of it as a preventive measure to prevent another preventive measure. After all, if device manufacturers don't have access to single-use plastics to make SUDs, then healthcare organizations won't have to worry about deciding whether to re-use SUDs.

Healthcare Purchasing News pondered whether this movement outside of healthcare may develop traction and transition to inside healthcare, asking relevant experts to share their thoughts.

"Plastics are an important and almost irreplaceable material in the manufacture of many medical devices. To eliminate this versatile resource from engineering and manufacturing toolkits would potentially curtail the many wonderful medical solutions and positive clinical outcomes that could evolve from them.

"A far better approach would be to design in extended usefulness or life cycles for plastic devices (i.e., make reusability a design requirement) and a

process for recycling and repurposing the remaining materials. The popular press and scientific literature are full of examples of the repurposing of basic materials. Why not make this a requirement for purchasing medical devices? Healthcare purchasers could influence sustainability beyond the doors of their institutions with such a requirement. The cost savings from 'optimized' reusable plastic devices would certainly pay for the adjustments in purchasing and use that would arise with this new approach."

Richard Radford, CEO, Cenorin LLC

"One of the primary reasons for single-use accessories is patient safety. The amazing advancements in developing plastic accessories was to improve diagnostic and therapeutic abilities and reduce cost. In the cases where reusable devices are utilized, the use of an optimized enzymatic detergent is of the utmost importance. Cleaning with an enzymatic detergent removes organic soils such as blood, mucus, feces or tissue from instrument surfaces, lowering the risk of healthcare-acquired infections not only for patients, but also for healthcare personnel."

Ron Banach, Director, Clinical Training, Ruhof Healthcare

"Environmental impact is something every industry has been grappling with more and more over recent decades; the healthcare industry is certainly no different. Reducing – or even eliminating – the use of single-use devices is a clear, substantial opportunity to lessen the healthcare industry's environmental impact and become more sustainable. The obvious challenge here is ensuring that patient safety remains the top priority – a healthcare facility with great environmental and sustainability policies is terrific, but if they can't ensure the safety of their patients, none of it matters.

"As it relates to achieving a higher degree of environmental conscientiousness via the reduction of single-use devices, the key is to implement methods, processes and solutions that enable proper reprocessing of reusable devices. Tackling concerns around compliance, visual inspection, resource usage, and overall quality of reprocessed devices can help departments ensure patient safety, maintain compliance with IFUs [instructions for use], reduce unnecessary expenditures on resources, hopefully save some money by eliminating what are effectively consumables, and ultimately lessen their environmental impact. In an ideal world (with investments made to help departments achieve these goals), becoming more environmentally friendly should be a win-win-win for the hospital, the environment, and most importantly, the patient."

Dan Gusanders, President, Pure Processing

"Olympus has aggressive goals to design and manage environmentally friendly solutions for single-use endoscopes. We are exploring partnerships and new ways of thinking about and actioning sustainability.

"Simultaneously, Olympus has added carbon neutrality to its goals and is at work enabling a circular economy as an additional ESG (Environment, Social, Governance) initiative. This ESG goal will apply for all Olympus manufacturing and development sites to achieve the global target of Carbon neutrality by 2030."

Melinda Benedict, Director, Infection Prevention and Control, Olympus Corporation of the Americas

"We have a moral obligation to leave the world a better place than we found it. We are blessed in this country with resources. We should do all we can to preserve them. To do this we must understand the cost/benefit of our activities. We have an obligation to investigate the total cost of resources used for both reusable and disposable instruments. I believe that currently, this favors the use of reusable flexible endoscopes. With an estimated 75 million U.S. annual endoscopic procedures performed, imagine resources required to build the endoscopes and the mountains of waste that will be created if all were disposable. Looking at the root causes of the need for disposable flexible endoscopes we find two primary drivers. First, failure to properly clean and process reusable endoscopes; second, in the case of ERCP endoscopes engineering design and lastly, industries need to create new markets to 'sell more products.' With the exception of those endoscopes with design flaws (some ERCP endoscopes), flexible endoscopes can be effectively reprocessed and rendered safe for use if the reprocessing staff is competent and follows the IFU. AAMI's ST91 includes new requirements for cleanliness testing and drying both will help improve outcomes."

"Like any other production system, if the staff is not properly trained, supervised and managed there will be failures in the process. In addition, ST91 calls for detailed event tracking. This is the area that I most often see failure to comply. Many facilities do not track and manage events as they should to improve the system. Often, staff are lax in reporting events, events are not reported with enough details and no one reviews the history to recognize trends. Events tell you where system failure is occurring. Event tracking and monitoring should be the most important task that SPD and Endoscopy managers have. Endoscopes that have design flaws that hamper effective cleaning or sterilization should be and are being corrected. Lastly, there is an incentive for manufactures to create repeat sales. Disposable products do this often at the expense of the environment."

Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare

'Right to Repair' remains steeped in 'caveat emptor, let the buyer beware'

Several industries outside of healthcare but linked to healthcare are grappling with a regulatory solution to a long-time lingering challenge through "right-to-repair" laws that are igniting a flurry of lawsuits.

Essentially, these laws are designed to prevent original equipment manufacturers (OEMs) from refusing to license or sell their components and parts to independent service organizations (ISOs) so that the OEMs retain the maintenance and repair business of their products. Some argue that these measures suppress competition from third-party companies. Providers see ISOs as a less expensive alternative to the OEMs, but the OEMs counter with quality concerns among third-party repair companies that may affect the durability and performance of a device. To protect themselves, OEMs may void product warranties when customers opt for third-party ISOs to control costs.

Two industry experts offered their observations and takes on this controversial issue with reasonings designed to satisfy a single mission, if not reach some kind of middle ground.

"On this issue, Olympus agrees with industry group AdvaMed, which has developed a website outlining its position. The position is presented in high-level form as follows: 'The manufacturing and repair of highly complex medical technologies and devices is rigorously regulated by FDA, the global gold standard for medical device safety and efficacy — and for good reason: patient safety is number one.'" *Editor's Note: You can access AdvaMed's "The 'Right to Repair' is Wrong for Patients" here: https://www.advamed.org/industry-updates/policy-issues/right-to-repair-wrong-for-patients/*

Melinda Benedict, Director, Infection Prevention and Control, Olympus Corporation of the Americas

"This is a very big topic that needs to be focused to help make sense of the situation. After having represented three major OEMs' service offerings (e.g., V. Muller, Karl Storz and Stryker) and an Independent Service Organization (ISO a k a Third-Party Repair) over the past 25 years, looking at the products by classification can be helpful.

"First, let's limit the discussion to surgical instruments. This removes medical equipment such as beds, pumps, monitors etc. For surgical instruments, they can be classified as general and complex. General instruments consist primarily of hand-held stainless-steel instruments, such as graspers, needle drivers, speculums, etc. These are most frequently serviced by ISOs either with or without authorization of the OEM. For these instruments most of the work involves polishing, sharpening and replacing small components such as springs, screws and carbide inserts. ISOs have been repairing and refurbishing general instruments for many years and have access to parts. For general instruments, part acquisition is not an issue as there are many sources available with most of the parts being made in Germany.

"For complex surgical instruments such as endoscopes, cameras, power tools and video equipment, parts for most of the major manufacturers are available either from parts suppliers, reverse engineering and in some cases from the OEM. Many ISOs have reverse-engineered components and make their own parts or they outsource the parts to other third parties. Parts typically are not a significant issue for devices that have been on the market for a few years. Parts for new technology are often an issue as the ISO has not had time or perhaps the technical skills necessary to reverse-engineer (copy) the component. Parts suppliers generally wait for demand before they invest in sourcing or reverse engineering components. The OEMs claim that they want and need to control the components to avoid unauthorized repair activities to their products.

Legal reality, responsibility

"The repair of medical instruments and devices is not regulated by the FDA. The manufacture of medical instruments is heavily regulated. However, when an OEM repairs its products, this is

subject to FDA inspection and regulation. For ISOs, registration with the FDA as a repairer of medical devices is voluntary. Thus, OEMs have an extra burden and cost associated with their repair activities. Virtually anyone with a license to do business in a state can provide medical instrument repair. There are no requirements for quality or ability to repair the device back to the OEM specifications. When an ISO repairs a product, there is no requirement for the ISO to label or mark the product as being repaired by them. The OEM's name and product information remain on the product, thus should failure of the product occur post-ISO repair, the customer likely will associate the product failure to the OEM and not the ISO.

Quality questions

"OEMs regularly find evidence of improper repair and repairs that do not meet their product specifications. In some cases, the improper repair could pose a risk to patient safety. As just one example, upon receiving a complaint from a hospital customer that a resectoscope used in ureteroscopy was failing because the electrode was being crushed when the surgeon tried to advance the electrode, the OEM was being blamed for poor quality. Upon investigation, it was discovered that an ISO had replaced the ceramic beak on the resectoscope. The ISO beak was not to the same specifications as the original OEM part. The ISO repair technician apparently was not aware of the critical nature of the part. Because the ISO beak was oversized, the electrode was catching on it and could not be advanced. The surgeon could not perform the procedure on the patient due to this. The patient was exposed to the OR environment for longer than necessary increasing their risk for [surgical site infection] (American College of Surgeons Risk Factors for SSI 2018).

"I have witnessed power tools (e.g., saws, drills etc.) where because the ISO did not have a control board for a newer model device, they substituted a control board from a previous model that did not provide the same functions to the user. The user hospital was not notified of this change by the ISO. One ISO reversed the cables on a flexible endoscope so that up was down and down was up.

Regulatory recommendations

"I believe that the FDA should classify instruments as general or complex. For complex instruments, the FDA should require full compliance from all companies that provide repair services. General instruments, due to the lower risk of improper repair, do not need to be regulated by the FDA. It should be up to the OEM whether it chooses to authorize and/or sell their components to an ISO. It should be the ISO's sole responsibility to ensure that it meets OEM specifications for a repair, or it should notify the end user of the change they made. OEMs typically charge more for repair services versus an ISO; however, with the OEM the customer is assured of high quality and customer support on each repair. With an ISO, there is no guarantee that the repaired product meets the OEM specifications."

Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare

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18 *Laura Moulton, Audience Development Manager* Date: 9/19/22

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HEALTHCARE PURCHASING NEWS

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Cross out cross contamination in endoscope processing

by Heide Ames and Pam Boulet

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

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LEARNING OBJECTIVES

1. *Discuss the four stages of endoscope processing*
2. *Identify opportunities for cross contamination during the cycle*
3. *List straightforward ways to prevent cross contamination when processing endoscopes*

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Flexible endoscopes are among the most complex and indispensable medical devices used in healthcare. And yet, despite mounting evidence identifying cross contamination opportunities during endoscope processing, many sterile processing and endoscopy departments dedicate little space to the proper cleaning, rinsing, and disinfection or sterilization of these lumened scopes. At the same time, regulatory and guidance organizations are taking a hard look at the details of this process and are updating best-practice recommendations. This is likely to lead to changes in processes, equipment and workflow space to enable compliant flexible endoscope processing.

Contamination level related to the stage of processing

Endoscope processing roughly divides into five stages. The first stage consists of receipt, cleaning, and rinsing. Processing staff move soiled endoscopes from the decontamination holding area to the cleaning area. At this point in the cleaning process, the endoscope has its highest level of contamination. The endoscope is leak tested and submerged in cleaning solution as it is brushed and flushed. Once cleaned, the endoscope moves to a rinsing sink. Once again, the endoscope is submerged, and its channels are flushed per the manufacturer's instructions to help ensure complete removal of cleaning solution and soils.

Rinsed endoscopes move to the second stage, the inspection. Despite cleaning and rinsing, pathogenic microorganisms are still on the endoscope. The endoscope is placed on an absorbent pad and is dried using a non-linting cloth. Lighted magnification is used to examine the external surfaces, and a borescope may be used to view some of the internal channel surfaces that run through the endoscope.

Once inspection is completed, the endoscope is moved to the high-level disinfection or liquid chemical sterilization area, which is the third stage. High-level disinfection and sterilization start with an endoscope with a low level of contamination and end with an endoscope virtually free of living pathogenic microorganisms. Both of these processes can be manual or automated. In a manual process, the endoscope is placed in high-level disinfectant or sterilant solution for a specified amount of time at a specified temperature. Once the time has passed, the endoscope is removed and rinsed several times to remove the solution from the endoscope. For automated processes, the endoscope is placed within an automated reprocessor. The adaptors are connected to ensure flow of the solution though all channels of the endoscope. The automated reprocessor performs both the disinfection/sterilization and rinsing steps.

The fourth and final stage of activities is drying and storage. At this stage, the endoscope has no pathogenic microorganisms and must be kept this way until used on a patient. Once at the drying area, a clean non-linting cloth is used to dry the external surface. All channels are purged with instrument quality or HEPA-filtered air for 10 minutes or longer, until all channels are dry. Once dry, the endoscope is transported to the storage cabinet where instrument quality or HEPA-filtered air keeps the cabinet at a positive pressure as compared to the room environment.

During this processing cycle, endoscopes follow a path from highest to lowest contamination. Cross contamination frequently happens when an endoscope is exposed to contamination from an earlier stage.

Identifying sources of cross contamination

The first well-publicized source of cross contamination is inadequate cleaning and disinfection. Residual soils left by inadequate cleaning protect microorganisms from subsequent high-level disinfection or liquid chemical sterilization processes. In addition, endoscope damage that goes undetected during inspection can harbor residual soils and biofilms that also shield microorganisms. And when a properly

cleaned and rinsed endoscope undergoes improper or inadequate high-level disinfection or liquid chemical sterilization processes, microorganisms can survive and transfer to the next patient, creating an opportunity for infection.

Properly processed endoscopes may be exposed to contaminated surfaces or fluids before they are used. During leak testing and cleaning, sink fluids become contaminated by the endoscope. Brushing and flushing during cleaning create opportunities for splashes, spills and aerosolization of the contaminated fluids, which can reach as far as six feet from the sink. Moving or storing endoscopes within this space exposes them to contaminated fluids, creating an opportunity for cross contamination.

Another commonly forgotten source of contamination is personnel protective equipment (PPE). While PPE protects staff from splashes, spills, and aerosolized contaminants, the PPE materials and surfaces become contaminated. Gloves are the most likely equipment to create cross contamination opportunities. When PPE is not changed between highly contaminated tasks, like cleaning, and tasks with less contamination, such as removing endoscopes from automated reprocessors, cross contamination can occur. It is commonly believed that changing gloves (and not the fluid-resistant gown) prevents contamination. However, one touch of a cleaned endoscope to a contaminated gown can recontaminate the endoscope.

Another source of cross contamination is the air. Room air can become contaminated from aerosolized cleaning fluids, external contaminants coming in with the heating and cooling system air, and lint or dust carried by lint-generating activities, such as unpacking items from corrugated shipping boxes. Airborne contaminants can settle on drying or stored endoscopes.

Pseudomonas aeruginosa and Klebsiella legionella are two microorganisms often found in small numbers within facility water. When these microorganisms colonize a water system, large colonies can form, creating biofilms. Biofilms can release microorganisms into the water that could contaminate endoscopes during rinsing. Normally, this would not be a concern. However, when the conditions are right, these microorganisms can create a mature biofilm within endoscopes, which is extremely difficult to remove and kill.

Biofilms can form anywhere moisture pools or items remain damp for long periods of time. Residual soils, holes in endoscope coverings, and damaged seals are perfect locations for biofilm formation. Endoscopes stored wet can give rise to biofilms in the residual moisture. Sink drains, wet floors, and absorbent towels retain moisture for long periods of time and contributes to biofilm formation and the opportunity of cross contamination.

Simple ways to prevent cross contamination

Preventing cross contamination requires a multi-pronged approach involving education, physical barriers, and mechanical controls to stop the spread of microorganisms. The process begins with best practice. Several agencies provide guidance for processing flexible endoscopes. The Society of Gastroenterology Nurses and Associates (SGNA), the Association of Professionals in Infection Control and Epidemiology (APIC), the Association for the Advancement of Medical Instrumentation (AAMI), and the Association of peri-Operative Registered Nurses (AORN) publish guidelines and standards for processing flexible endoscopes. Of these organizations, AAMI and AORN have issued the most recent guidelines, both released in 2022.

Follow all equipment instructions

Policies, procedures, and work instructions should strictly follow the endoscope's instructions for use and the instructions of all items used to process the endoscope. Additionally, departments should implement a documented and rigorous training program that tests the competency of staff members processing endoscopes, and this competence should be regularly reviewed. Some organizations recommend certifying staff members who process flexible endoscopes. Several trade organizations, colleges and universities offer programs specific to the processing and management of endoscopes. Facilities should consider implementing programs that encourage certification in flexible endoscope processing.

Separate dirty and clean

Most organizations agree that processing should be divided into two rooms. The first room, decontamination, receives soiled endoscopes, leak tests, cleans, rinses, and inspects. In the second room, or clean room, technicians high level disinfect or liquid chemically sterilize the endoscopes and dry them. Endoscopes should always travel unidirectionally from areas of high to low contamination.

The decontamination room should be at a negative pressure as compared to the adjacent hallways and rooms. This ensures that air flows into the room from the adjacent areas, keeping microorganisms that may be in the air, from escaping to adjacent areas causing cross contamination. The heating and cooling system should exchange the room air with fresh air to reduce the total airborne contamination within the room. ANSI/ASHRAE/ASHE Standard 170 Ventilation of Health Care Facilities specifies the relative negative pressure, room air exchange rate, and air management for potentially contaminated air. Endoscopy processing supervisors should work with facilities to ensure compliance to the standard's revision that applies to the specific model of ventilation system in their facility.

Keep sinks away from inspections

Within the decontamination space, splashes, spills, drips and aerosolization of contaminated cleaning solution and rinse water carry microorganisms to surfaces, counters, walls, floors, and equipment around them. One study showed that splashes could reach as far as six feet from the sink. For this reason, it is necessary to physically separate sinks from endoscopes undergoing inspection. AAMI recommends a minimal distance of four feet. If this is not possible, a physical barrier extending four feet from the sink's rim towards the ceiling should separate the sink from inspection space.

Clean sinks and surfaces

To prevent potential cross contamination between endoscopes, sinks should be drained, cleaned, and disinfected after each endoscope. Clean spills, sprays, and drips immediately. Regularly clean and disinfectant surfaces that may become contaminated during decontamination of endoscopes. Faucet handles, cleaning solution dispensers, leak testing equipment, flushing tubing and connectors, counters, and floors are a few items to consider. Ensure regular cleaning and disinfection of high contact points like door handles, cabinet pulls, and equipment contact points within the room. Always follow manufacturer instruction for use to ensure proper use of cleaning solutions, disinfectants, and disinfection methods for equipment.

Clean inspection equipment

During inspection, drips, aerosolization from blowing channels clear of fluid, and

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

missed residual soils on or in endoscopes are potential sources of contamination. Use a fresh clean towel to dry each endoscope. Change absorbent pads regularly to prevent potential biofilm formation and cross contamination between endoscopes. Lighted magnification used to inspect endoscopes can become contaminated as staff manipulate the magnifier. Borescopes used to visualize the internal channels and ports can become contaminated as it touches the contaminated scopes. This is especially true when finding residual soil in an endoscope channel. Policies and procedures are needed for cleaning and disinfecting inspection equipment and surfaces.

Transfer endoscopes that are ready for high level disinfection or liquid chemical sterilization through a pass-through window to the clean side. Avoid using doors between the decontamination and clean sides, as they make it difficult to maintain positive pressure within the room and allow contaminated air to cross into the clean side. Also, segregate cleaned endoscopes from high level disinfected or liquid chemically sterilized endoscopes. Placing a disinfected endoscope on a surface that held a cleaned (but not disinfected or chemically sterilized) endoscope could transfer contamination from one scope to another.

Change PPE

Be sure to change PPE between the decontamination and clean processing areas. PPE, such as gloves, become contaminated when handling clean but unprocessed endoscopes. Touching processing equipment or removing processed endoscopes with those contaminated gloves is an opportunity for cross contamination.

Replace manual disinfection/sterilization

Manual high-level disinfection and liquid chemical sterilization is discouraged by many organizations. Manual processing increases the chance of staff exposure to disinfectants and sterilants, and manual processes are more likely to create spills, splashes, and aerosols. As in the case of cleaning sinks, consider physical barriers between processing and drying areas.

Many standards indicate that automated high level disinfection or liquid chemical sterilization systems are best practice. These systems do not have the same splash, spill and aerosolization cross contamination opportunities as a manual process. Pass-through automated systems allow loading of the cleaned endoscopes into the unit on the decontamination side of the wall and unloading of processed endoscope on the clean side of the wall. This unidirectional flow significantly reduces the possibility of cross contamination by offering an efficient and complete separation of dirty and clean. It also helps support the negative and positive pressures of the rooms by allowing only one door of the reprocessor to be open at a time.

Endoscopes must be dried prior to storage or terminal sterilization. Clean non-linting cloths dry surfaces and forced instrument or HEPA-filtered air dries internal channels. Dry endoscopes are critical since any moisture that stays in the endoscope can become a breeding place for biofilm. Drying cabinets can help to dry surfaces, channels, or both. Using pass-through drying cabinets between decontamination and clean sides can help prevent contamination. Be sure to assess the drying cabinet's ability to dry surfaces and channels completely.

The clean room should be kept at a positive pressure as compared to the decontamination room, adjacent hallways, and other adjacent rooms. This ensures that air flows out of the room to the adjacent areas and keeps microorganisms from entering and contaminating the processed endoscopes. As discussed, ANSI/ASHRAE/ASHE Standard 170 Ventilation of Health Care Facilities provides guidance.

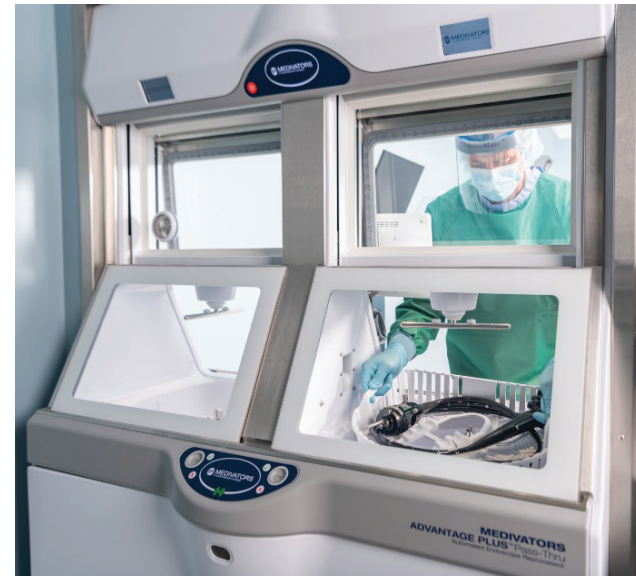

Figure 1 Pass thru automated systems give separation between loading of the cleaned endoscopes in decontamination and unloading of processed endoscopes on the clean side of the wall.

Attention to detail protects patients

Guidance for many healthcare processes is based on evidence and designed to offer practices that help reduce avoidable patient infections. The physical separation of dirty and clean processing environments is a globally recognized infection prevention best practice. Add to that some simple department practices that focus on the cleanliness of surfaces, PPE and processing equipment will help reduce the risk of recontamination and help to ensure patient-ready endoscopes for every procedure. HPN

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CONTINUING EDUCATION TEST • NOVEMBER 2022

Cross out cross contamination in endoscope processing

Circle the one correct answer:

1. **At which stage is the endoscope most contaminated?**
   a. Cleaning
   b. Inspection
   c. High level disinfection
   d. Drying
2. **Manual high level disinfection is preferred by all organizations**
   a. True
   b. False
3. **Why is drying prior to storage important?**
   a. It identifies leaks
   b. It prevents soils from touching the endoscope
   c. It helps kill microorganisms
   d. It prevents the formation of biofilms
4. **In which direction should endoscopes travel through processing?**
   a. From low to high contamination
   b. From high to low contamination
   c. From cleaning to leak testing
   d. From sterilization to cleaning
5. **What is connected to the endoscope when using an automated endoscope reprocessor?**
   a. Adapters
   b. Air / water valves
   c. Leak tester
   d. Syringe
6. **Which personal protective equipment can contaminate an endoscope?**
   a. Gloves
   b. Gown
   c. Face shield
   d. a and b
7. **What biofilm agent can be found in tap water?**
   a. Calcium
   b. Water
   c. Pseudomonas aeruginosa
   d. Staph. Aureus
8. **What can cause contamination in room air?**
   a. Lint
   b. Rinse water aerosolization
   c. External air
   d. All of the above
9. **What is the best way to prevent contamination between clean and dirty activities?**
   a. Putting distance between the activities
   b. Cleaning and disinfecting between activities
   c. Placing a barrier between activities
   d. Separating the activities in two buildings
10. **How do pass-through endoscope reprocessors prevent contamination?**
    a. Prevents staff from touching the endoscope
    b. Prevents staff exposure to disinfectants
    c. Separate loading of clean from unloading of disinfected endoscopes
    d. Separates drying from storage

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SUBMIT YOUR QUESTIONS:
editor@hpnonline.com

General peel pouch questions

by Stephen Kovach

Q "Why do you and other companies suggest in your in-services to use one- to 1- ½ inches of spacing within a peel pouch? I have been told it has to be at least two inches. What is the correct spacing?

A While the present ANSI/AAMI ST79 does not give a specific distance, critical thinking is important when placing any device in a peel pouch. This revolves around selection of the pouch for the device to be sterilized. You need to ask the following questions.

Q "What size and type the medical device is and what form of sterilization does this device need?"

A There are various types and size of peel pouches on the market today.

- Pouch Types:
- Paper /plastic (steam and EtO)
- Tyvek (low-temperature sterilization).
- Sizes /Kinds:
- Heat sealable
- Self-seal
- Roll stock (may be cut to size)
- Gusseted (mostly for large items).

Choosing the correct size and application of the pouch is important. When placing a medical device inside a peel pouch, we need to make sure it is not:

- *Too tight*: the seal may not hold.
- *Too loose*: the item will move too much, which could also stress the seals to the point of rupturing.

Thus, when placing the medical device inside the peel pouch, it will need to allow for adequate air removal, penetration of the sterilant, and drying.

You must remember the peel pouch expands and contracts with any sterilization process, so spacing inside the peel pouch is vital to have delivering a sterile device inside that peel pouch.

As with any product, manufacturers give instructions for use (IFU) and other supporting documents. To use their products properly, you must have training. I will use the example from one of the many manufacturers of peel pouches. I find support in their IFU for the general statement concerning distance; thus, in their IFU/other documents, they suggest to, "Leave enough space beyond the seal for the opener to easily grasp (usually ½-inch to two [2] inches)."[1] "As a general guideline, it is recommended filling a pouch up to a maximum of 3/4 of its packing volume to allow the package to conform to air evacuation processing during sterilization…."[2]

Various technical training manuals for medical device reprocessing technicians make these statements concerning distance within a peel pouch.

"A paper-plastic pouch of appropriate size should be chosen. … The pouch must be large enough to allow at least one inch (2.5 cm) of space between the item and the edges of the pouch."[3]

"To allow space for packaging contraction and proper circulation, leave about one inch (¼" per side of package) of space between the items in the pouch and the sealed edges."[4]

I understand that many departments do not have a complete selection of pouches to adequately place devices inside pouches. Because departments do not order enough peel pouches and the proper sizes, staff must adjust and use the products they have. Ideally, staff would have many sizes, but that is not the case.

Based on my years of experience, I have taken the approach that each department is different. There are many different medical devices and staff need to use critical thinking, and what CPD really stands for ("Creative People Downstairs"), in applying how to use proper peel pouching technique with what they have available. Thus, giving guidance of one- to 1- ½ inches is not out of line per the information supplied by the manufacturer(s) and my experience and research.

Photo credit: wip-studio | stock.adobe.com

I hope this helps answer your question

My suggestion, regardless of who you buy your pouches from, is to apply critical thinking skills—starting with reviewing the companies you use for peel pouches, their IFUs, and other documents. Next, look at reference manuals (e.g., professional societies) and articles to make a Standard Operating Procedure (SOP) for the department you work at. This way, you base it on the products you have available to supply a sterile medical device.

Oh, and do not forget to have proper training with a repeat demonstration in how to pick a) the proper peel pouch, b) place the medical device inside, c) seal and label it, d) load it in the sterilizer, and e) store and retrieve it properly to deliver it to your customer. **HPN**

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Stephen M Kovach, BS, CFER, started in the medical field in 1975 as a sterilization orderly and has worked in many positions within the Healthcare Industry. He presently is Clinical Educator Emeritus at Healthmark Industries.

Pushing back on bullying in Sterile Processing

by Tony Thurmond, CRCST, CIS, CHL, FCS

Recently, I was invited as a member of the perioperative leadership team to discuss the findings from a survey sent to all members of our perioperative team, which includes more than 200 staff members, to identify areas for improvement and determine whether bullying and incivility were issues they faced in the workplace. Respondents provided detailed responses to the questions and revealed an alarming statistic: nearly 60 percent of the perioperative team admitted that they experienced bullying and incivility on the job.

Our organization certainly is not alone. In fact, the Harvard Business Review surveyed more than 800 managers and employees across 17 different industries and found that after experiencing incivility or bullying:

- 48% of employees intentionally decreased their work efforts;
- 38% of employees intentionally decreased their quality of work;
- 80% of employees lost work time worrying about the incident;
- 63% of employees lost work time avoiding the offender;
- 66% of employees indicated that their work performance suffered;
- 78% of employees said their commitment to the organization declined; and
- 12% of employees left their job.

Incivility in the workplace can rear its head as harsh or inappropriate words, nonverbal behavior, facial expressions or body language. Bullying, on the other hand, is a type of incivility that often entails repeated examples of malicious behavior, including deliberate threats, demeaning comments or profanity, and overbearing criticism and supervision. Exhibiting even a one such type of behavior can qualify as workplace bullying, and the outcome can be detrimental to the entire department.

Many SP departments (SPDs) experience employees who miss work, which then translates to diminished productivity and employee loyalty, and even depression, anxiety and a willingness to look for employment elsewhere—all of which can affect customer service, interdisciplinary relationships and, above all, patient outcomes. SP professionals play an essential role in safe, high-quality patient care and their daily responsibilities require full attention, focus and cooperation, and we must do better for ourselves, our teammates, and those we serve.

A notable outcome from of our organization's town hall discussion to discuss the survey findings was the discovery that some employees noted that uncivil or negative comments occurred during important teaching moments. More specifically, some employees perceived the problem stemmed from a hard-lined, "learn this or move on" teaching approach that made some personnel to feel pressured and intimidated. Leaders must realize the importance of establishing realistic performance goals and expectations that build employees' knowledge and skillsets in a positive way that is rooted in support, patience and positive teamwork.

Kick the bad behavior

All healthcare leaders, including those in the SPD, should aim to be visible, approachable, empathetic and supportive, and they must strive to understand their employees' challenges. This may translate to lending assistance when possible and advising team members who are struggling how to access the employee assistance program and intervening whenever incivility or bullying is experienced.

Every SP leader should spend more quality time among the department's staff members to witness firsthand employee interactions and staff members' day-to-day challenges. If harmful communication and negative interactions are seen (or anytime an employee expresses concern about bullying or incivility among SP teammates or healthcare customers), the leader must take action to explore the situation and identify unruly or disrespectful behavior that can cripple morale and deplete employee satisfaction. Above all, it's about teaching and regularly reminding all members of the team demonstrating that incivility and bullying of any kind will never be tolerated. If an employee experiences bullying or incivility from a leader, they should take the issue to the next highest person in command (if a supervisor behaves in a bullying way, for example, the employee should share that with the departmental manager or director; if a manager or director bullies or is uncivil, the employee should take the issue to Human Resources).

Supervisors and managers should also routinely ask employees what's on their mind and encourage them to speak up when a challenging issue with a co-worker or interdisciplinary customer arises. Of course, good leaders also keep a finger on the pulse of their departmental practices and workflow to ensure that employees have what they need to function effectively, safely, consistently and positively in the workplace. Most organization have a harassment and bullying policy, and all employees should receive a copy of the policy upon hiring—and departmental leaders should also speak with all employees, so they understand that any incidents of bullying or incivility could spur disciplinary action, including termination.

Conclusion

Incivility and bullying have no place in the SPD or any other healthcare department or setting. Any SP professional who personally witnesses bullying or uncivil acts or see it directed toward another employee should promptly address or report it. Allowing any individual, regardless of title or tenure, to continue their poor behavior only lends more power for them to continue.

Additionally, SP leaders must ensure that positive communication is experienced daily. If bullying, incivility or other damaging behaviors are identified, all SP leaders and staff members must work to eradicate it. This involves advocating for oneself and one's co-workers, their collective departments, and their patients. When respect, dignity and support are shown, the department, its customers and the entire organization reaps the rewards. HPN

Tony Thurmond, CRCST, CIS, CHL, FCS, serves as Central Service Manager at Dayton Children's Hospital. He is an HSPA Past-President and currently serves on the HSPA Board of Directors.

How might healthcare supply chain stake claim on sustainability?

Attitudes, motivations may matter more than experiences, skills

by Rick Dana Barlow

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Outside of healthcare, in the food service, manufacturing and retail industries, Supply Chain *owns* sustainability as both a cause and an operation, encouraged by corporate brass because it promotes cultural/social responsibility as well as environmental responsibility, and this stewardship reflects well on the balance sheet and within boardrooms.

Supply Chain responsibility makes sense as well because who else assesses, evaluates and contracts for products and services, manages packaging and transport resources and tracks fiscal and operational results (known largely as "outcomes" in healthcare)?

Those who do it right and well resonate as heroes within their companies and communities; those who have yet to do it covet as much success as possible.

Healthcare, meanwhile, has miles to go before it sleeps, often garnering a frosty reception when proposing eco-friendly, environmental and sustainable anything to the C-suite.

So how do healthcare providers and suppliers reach for and grab that brass ring to make it golden for their organizations and industry?

Recommendations by corporate executives involved in sustainability run deep, far and wide.

Rely on what and who you know, encourages Mary Starr, Chief Operating Officer, Greenhealth Exchange. Before joining GX, Starr served as a supply chain leader in hospital, nonacute care and group purchasing organization (GPO) settings.

Mary Starr

"Supply chain leaders should leverage the experience they've gained through collaboration with clinical initiatives to become involved in sustainability work at their organization," Starr indicated. "Working with other champions in the organization to develop priorities, ascertain requirements, set goals, identify alternatives and measure results are strengths and tools supply chain professionals use routinely to implement improvements. These same steps can be applied to sustainability focused projects.

"Gaining C-suite support can be done using methods employed for other supply chain projects: Outline the benefits including components such as cost-savings, improved clinical outcomes, improved community or employee health, supporting the organization's mission, improving resiliency, community stewardship, etc.," she added.

Sustainability leadership

Supply Chain serves as a logical choice for sustainability leadership, according to Evelyn Miller, Senior Manager, Environmental, Social and Governance (ESG), Medline Industries.

"A majority of a health system's environmental footprints come from Scope 3 emissions, which are the result of activities from assets not owned or controlled by the reporting organization (EPA.gov)," Miller indicated. "This includes elements of the supply chain. When you consider where health systems can make the greatest impact, oftentimes it's through the help of their suppliers. This gives supply chain professionals all the more reason to be leading the charge on environmental sustainability efforts internally.

Evelyn Miller

"Of course, it's always helpful to demonstrate the business case for environmental

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sustainability," she continued. "To help start, consider switching some of your more cost-effective products to a sustainable alternative. Enrolling in a reprocessing program is another relatively quick win that can help demonstrate strong business and environmental results."

Eileen Buckley, Vice President, Corporate Responsibility, Stryker, sees sustainability as an opportunity for Supply Chain leaders and professionals to advance and improve, particularly against the backdrop of the pandemic.

Eileen Buckley

"Business has changed rapidly in recent years," she noted. "It is important to upskill supply chain professionals so they're aware of the rapidly changing expectations, including regulations around sustainability requirements. Organizations should also revisit their supplier and employee codes of conduct to ensure they meet shifting stakeholder expectations and regulations. And finally, collaborate with industry groups and across the value chain to bring consistency to sustainability priorities and expectations of suppliers, which will encourage confidence in the investments required to scale sustainability impact."

Buckley shares three key tips for Supply Chain approaching the C-suite for the green light.

"First, establish robust governance practices and engage stakeholders, including through exercises that result in internal and external stakeholder feedback," she said. "Also, create a reporting plan that has a maturation curve and includes goalsetting alongside thoughtful disclosures that build trust and create accountability. Finally, it is good practice to embed prioritized sustainability requirements into [requests for proposals] and tender processes. Ensure there is transparency in the weighting of this criteria and that each question has a purpose aligned with the healthcare system's sustainability strategy."

Paul Murphy, Vice President, Major Accounts & Vertical Markets, Canon Solutions America Inc., acknowledges that sustainability may not be high on C-suite priority lists but expects its position to be changing and elevating.

Paul Murphy

"Sustainability efforts are not necessarily at the forefront of every healthcare organization's day-to-day activities, but as more healthcare organizations realize that population health is intrinsically connected to ESG initiatives, incorporating sustainability into the decision-making process becomes a natural extension of care delivery," he indicated. "Most healthcare organizations have mission and vision statements that highlight their commitment to serving their communities and for the long term, but these statements rarely articulate a measurable action.

"Supply chain professionals need to work within the institution's framework to identify sustainability champions both inside and outside the healthcare environment," Murphy continued. "Asking the right questions to determine what suppliers can offer is a key part of this process. More often than not, sustainability efforts end up supporting the enhancement of healthcare services by establishing measurable goals, creating efficiencies and reducing waste. Supply Chain can improve its external reputation by becoming the lead in these initiatives and a resource for external practices."

Introspection for interjection

If anything, healthcare organizations should look inward at their own operations to make outward manifestations of sustainability, according to Mikhail Davis, Director of Technical Sustainability, Interface.

To wit, the Centers for Disease Control and Prevention and the World Health Organization both cite climate change as the No. 1 threat to public health in this century, even after a global pandemic, Davis notes.

"For Supply Chain to make the case for sustainability efforts, they need to start with what their organization already believes is important," he continued. "Maybe it's public health in general, maybe it's specific health conditions that are a concern in your community. For any of these issues, there is always a sustainability link when analyzing solutions. And once you begin to understand the sustainability and health impacts of the materials and products you purchase, it becomes clear that to make strides towards reaching sustainability goals, supply chain and procurement must be top of mind.

Mikhail Davis

"In fact, a healthcare organization's biggest source of emissions that contribute to climate change is from the materials used to keep it running," Davis noted. "Every product can and does contribute to climate change – this emissions type is referred to as embodied carbon.

"Embodied carbon emissions just from building material production make up at least 11% of humanity's global greenhouse gas emissions," he continued. "And it is estimated that for a new building constructed in 2020, 72% of its impact on climate change between now and 2030 will be from embodied carbon. Engaging with your supply chain and partnering with vendors to purchase low embodied carbon products, starting with building products, is an essential part of contributing to a stable and healthy climate for all of us."

Andrew Knox, Manager, Environmentally Preferred Products, Premier, concurs about introspection as a starting point.

"This really depends on the state of sustainability efforts within each individual organization," he noted. "For example, if a health system is early in its sustainability journey, sometimes coming forward and volunteering can be all that is required. There may be efforts already underway that are looking for allies/champions, and the supply chain plays a key role – either in leading the charge or lending important support. It may not be a case of gaining ownership as much as it is forming networks to achieve common aims. Overall, the most successful sustainability efforts include a cross-functional and enterprise-wide team inclusive of C-suite, clinicians as well as supply chain and operations leaders and teams.

"Broadly, making the connections between sustainability and the overall mission to enhance health can help engender internal support," he added. "Further, talking about sustainability publicly and highlighting your efforts can create a groundswell of support as well as enhance your organization's reputation."

While the pandemic may have changed thinking priorities, strategies and tactics in business, the sustainability issue remains consistent, according to Rob Chase, Founder & CEO, NewGen Surgical Inc.

"We live in a different world now than even just 24 months ago," he said. "In the past Supply Chain has been focused on cost and finding the products at the best price. Now it has become clear that acquisition cost is not the only deciding factor but also how a product is made, where it is made, and the materials used are increasingly important to understand.

Rob Chase

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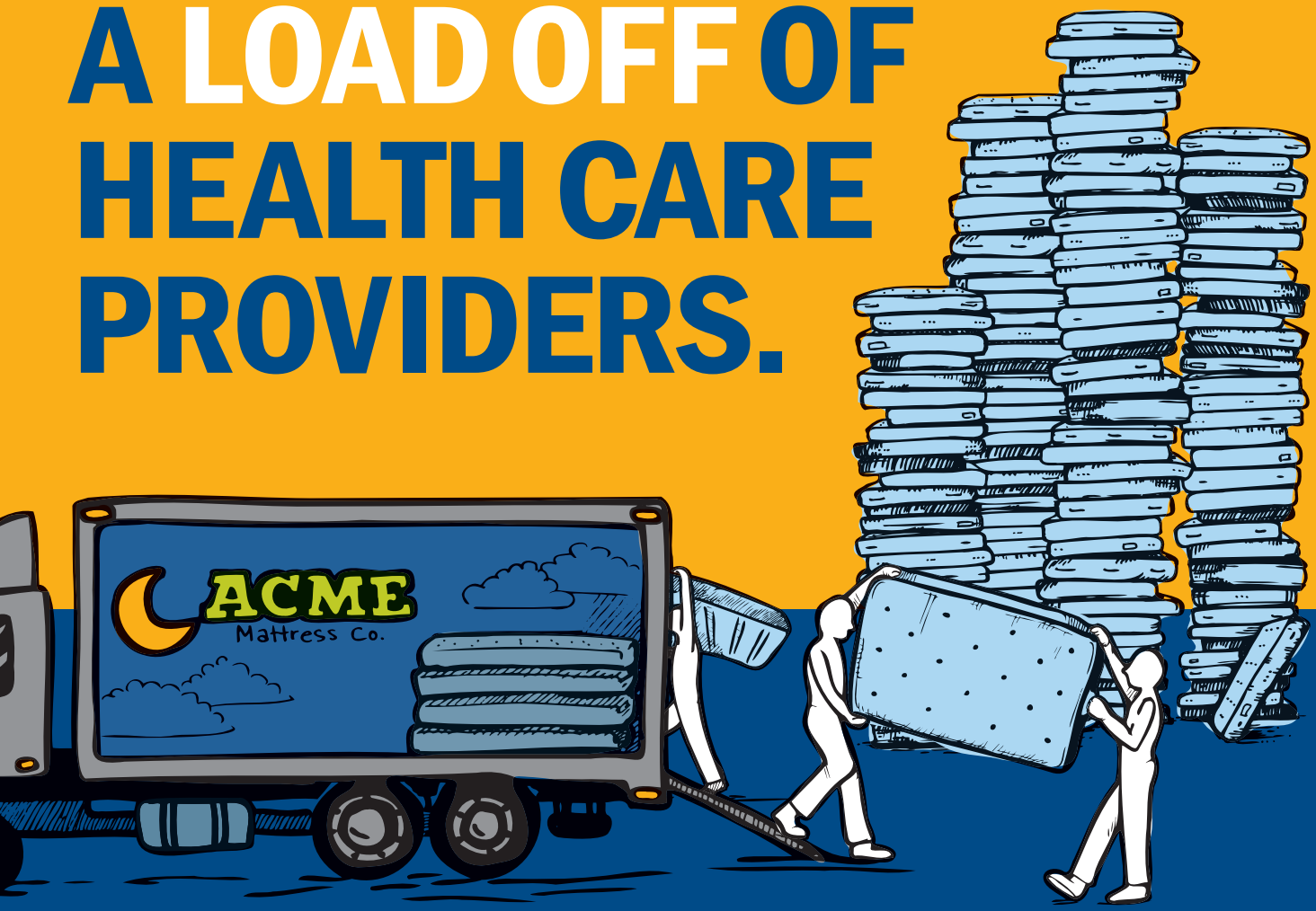

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Healthcare contributes 10% of the total U.S. CO_2 emissions.

"The United Nations has developed the 'Sustainable Development Goals,' which are a roadmap for society to become more sustainable," Chase continued. "These goals can be a roadmap for healthcare as well [with] SDG 12 responsible consumption and production. Bring the C-suite into these conversations and discuss how your healthcare facility can be part of the solution to climate change, just through your purchasing decisions and integration of environmentally preferable products. Small changes in what you buy can have a huge cumulative impact in lowering your facility's environmental footprint, and also stimulate demand in the market for suppliers to create more sustainable product solutions. In terms of ownership, we all need to take ownership in solving our industries and society's problems. However, given the influential role of supply chain leaders, they are in a great position to create a positive impact and make a difference for us now and for future generations."

Sweat the small stuff

A comprehensive, but granular perspective may be necessary for Supply Chain to make its case for sustainability leadership.

"Ownership and responsibility for managing sustainability must begin with a clear understanding of the choices and protocols that promote the best outcomes, encourage stewardship and assure sustainable use of medical devices and supplies," said Richard Radford, CEO, Cenorin LLC. "The supply chain in healthcare is an immensely complex system that is influenced by many cost sources, market forces, inventory management methods, product types and by how products are used. Financial accounting should include the associated book-end costs related to inbound freight and waste disposal. Unfortunately, typical hospital cost analysis fails to include all direct, indirect and external costs related to utilizing a product for its natural life and then disposing of it correctly. Workflow processes and transit times that an individual product type may encounter are another under-recognized variable cost associated with its use.

Richard Radford

"The most effective way to make a successful argument is to present the facts as they exist in the organization, which may not necessarily be apparent to those focused on solving a higher-level problem," he continued. "In our experience, supply chain and inventory management accounting does not include all related costs in the analysis. In many cases these costs are siloed in different parts of the data collection or are not accounted for at all. It would seem to me that professionals in supply chain management could come together and develop a comprehensive list of cost sources that would lead to a more accurate and thorough understanding of absolute/total costs."

Categorizing devices and products may offer significant benefits for sustainability efforts, according to Radford.

"It may also be useful to review medical devices by product type, material construction or professional classification, and to recommend processing techniques that might optimize full life use and minimize costs," he advised. "For example, the costs associated with single-patient-use (SPU) and disposable devices is an extraordinary financial burden for healthcare providers. Twenty years ago, this was the basis for the FDA approving the use of third-party reprocessors. Their success has been remarkable in lowering hospital costs for many device types."

But Radford acknowledges that third-party reprocessors are not the sole solution.

"Hospitals need to know that they can significantly reduce SPU device costs by applying new approaches that directly address specific medical devices with reprocessable component materials and appropriate reprocessing products and protocols. The cost-saving opportunity may be in the billions nationwide. Moreover, product and process solutions to address this opportunity are currently approved and available. These approaches are systematic and include a tried-and-true, integrated process to clean, high-level disinfect, and thoroughly dry the devices, along with electronic documentation for the entire process by individual device."

Dan McGown, Northeast Coordinator, Mattress Recycling Council, indicates the C-suite concentrates on one key area.

"The C-suite is primarily focused on cost analysis," he said. "If the sustainable alternative isn't specifically a lower upfront cost, the Mattress Recycling Council would provide your facilities or housekeeping manager or your sustainability officer with information on how your institution can save money by recycling your old mattress. If you are located in California, Connecticut or Rhode Island there will be no disposal fee to get rid of your old mattresses. There is no cost to your institution. Put simply, its free."

Healthcare needs to recognize its own footprint and impact on the environment, surmises Andy Marshall, CEO, Sterilis Solutions.

"Healthcare in the United States produces more than 5.9 million tons of biohazardous medical waste each year," he said. "In addition to the tremendous amount of waste that healthcare spaces and laboratories produce, they also use 10 times more energy and four times more water than typical office spaces.

"Since Sterilis Solutions deals directly with hazardous medical waste disposal, we have some unique insights into the relationship between waste disposal and the environment," Marshall continued. "Today, regulated medical waste is disposed of by medical waste hauling services that move the waste from the point of creation to designated disposal sites. There are clear operational benefits that come from ushering in sustainability efforts, as well as environmentally friendly outcomes."

Sterilis works on a number of initiatives with My Green Lab. [Editor's Note: See Sustainability project examples - https://hpnonline.com/21283854] Marshall cites from a My Green Lab study how segments of the healthcare industry contribute to the carbon footprint.

"The study finds that the global biotechnology and pharmaceutical industry alone has a carbon footprint larger than the semiconductor industry, the forestry and paper industry, and equal to nearly half the annual emissions of the United Kingdom," he indicated. "A critical part of the solution will require companies to carefully quantify their emissions up and down their respective supply chains and leverage their purchasing power to motivate their suppliers and customers to reduce their own impacts.

"Building a culture of sustainability in healthcare will transform the industry for the better and help organizations carry out their lifesaving missions without damaging the environment," Marshall continued. "It's important to remember that the supply chain in healthcare organizations is usually at the forefront of the action and that their action, or inaction, can have a lasting impact on the industry."

Environmental stewardship

Lars Thording, Vice President, Marketing & Public Affairs, Innovative Health, stresses

the concept and importance of environmental stewardship that could emanate from Supply Chain.


Lars Thording

"The role of the 'environmental steward' in U.S. hospitals is often parenthetical and somewhat isolated from the core operations of the hospital," he said. "However, 71% of hospital emissions are Scope 3 emissions (emissions stemming from the supply chain), and the issue therefore should be a primary responsibility of the supply chain. Moreover, making the supply chain function responsible for environmental initiatives brings the topic right into the middle of the hospital's core operations, and enforces a focus on accountability and results." He cites a 2019 report from Health Care Without Harm found here: https://noharm-global.org/sites/default/files/documents-files/5961/HealthCaresClimateFootprint_092319.pdf.

"To gain support for this, I would recommend pointing out what the numbers say and reminding executive leadership that the environmental responsibility topic has become inescapable from a political, governmental and public opinion perspective," Thording continued. "Hospitals that don't make the environment a core initiative will have some explaining to do."

Thording outlines a blueprint of action.

"Supply chain professionals should start by mapping out the environmental impact opportunities space specifically in terms of purchasing, demand environmental scorecards from vendors, set specific goals (packaging, reuse, preferential purchasing, etc.)," he said. "Engaging physicians and staff is a ripe opportunity for energizing this effort. A recent study published by the European Society of Cardiology found that physicians are highly motivated to reduce environmental impact. A total of 278 physicians from 42 hospitals were polled and 62% were motivated to work towards more sustainable solutions." *[Editor's Note: Find the study here: https://academic.oup.com/europace/article/24/Supplement_1/euac053.592/6589249.]*

Still, Thording recognizes that healthcare organizations are trying to improve in this area, but that it may not be enough.

Most U.S. hospitals today are moving towards very dedicated sustainability strategies," he acknowledged. "A common frustration is that only a fraction of the sustainability effort is about hospital operations – most pollution, waste, and environmentally harmful production are inherited from the suppler. In other words, a hospital can be 100% committed to sustainable practices, yet still end up a doing a lot of harm to the environment – because of what their vendors do. The problem here is that vendor evaluation and strategy is traditionally about price exclusively, and this needs to change. Our best partners are asking us to report on cost, resilience and sustainability. My recommendation is that environmental sustainability metrics are made part of not just the RFP process, but also value analysis assessments, preferred vendor programs, and periodical business reviews."


Cristina Indiveri

Cristina Indiveri, Associate Vice President, Strategic Programs and Contract Services, Vizient, relays the vast media coverage and publicity surrounding sustainability and climate change topics as motivation that they surpass COVID-19 and monkeypox as public health threats long-term if not addressed right away.

"That is because the impacts to human health from climate change are vast," she emphasized. "From increased cardiovascular and respiratory diseases caused by air pollution to water and food insecurity creating malnutrition, healthcare providers, suppliers and group purchasing organizations need to work together to solve the climate equation. After all, the healthcare industry works to ensure we're not only healing patients but that we're also contributing to the improvement of our communities' health and ensuring the safety of future generations.

"A healthcare organization's supply chain can take ownership of sustainability because it is the products and devices an organization purchases that bring in chemicals of concern and emit carbon from their transportation," Indiveri continued. "Research demonstrates that 90% of healthcare organizations' greenhouse gas emissions are generated in the upstream and downstream value chain, better known as the supply chain." She cites from an EPA report found here: https://www.epa.gov/climateleadership/supply-chain-guidance.

"Supply chain must have a seat at the table of organizations focused on fighting the climate crisis," she insisted. "But supply chain staff are not the only interested parties. Whether they are clinicians who conduct research in this area or analysts who evaluate the front- and back-end costs of climate change, find your champions. Sustainability can be overwhelming because it touches everything from anesthetic gases in the operating room to patient food. Start with small wins that encourage improvements in people, planet and prosperity, such as removing toxic mercury from the supply chain or modifying printer settings to reduce waste and save money. Recognizing and celebrating wins that are necessary for human health, the environment and the bottom line are essential to building momentum and continuing this work to ensure healthy and safe communities." **HPN**

Options, starting points for relevant, useful sustainability projects, programs

Just like companies in other industries, healthcare organizations face a plethora of choices when deciding how to embrace and implement sustainability projects and programs, including which to do first and before others.

To gauge the possibilities and potential opportunities, *Healthcare Purchasing News* surveyed more than a dozen company executives in the sustainability space, offering them 13 designated sustainability strategies and tactics from which to choose as targets to be implemented at healthcare provider organizations or for healthcare provider organizations to require of their product and service suppliers via the contracting process. *HPN* also included an "Other" option for executives to specify something generally not included in the list of choices.

HPN lists below the options in order of their acceptance and importance as indicated by responding executives.

HPN then asked participating executives to select their top three choices to recommend providers implement first, along with proffering reasons why. Those insights follow the overall list of options.

1. Conserving/reducing energy and resource consumption, including (but not limited to) electricity, fuels and water
2. Reducing material waste, including the disposal of new and unused but expired products and the disposal of soiled/used products
3. Reprocessing/reusing products when and where appropriate via approved/regulated procedures for safety and security (and legality)
4. Contracting for/investing in sustainably designed and/or manufactured products
5. Reducing chemicals of concern in the products themselves as well as the manufacturing process (e.g., PVC, DEHP, etc.) – or at least contracting with those suppliers/vendors who do this
6. Calling for more detailed information on product labeling that identifies components and raw materials to facilitate more sustainable sourcing decisions
7. Recycling appropriate/relevant consumable materials, including certain plastics, paper, corrugated cardboard, etc.
8. Recycling (versus disposing) of equipment, furniture, mattresses, etc.
9. Incorporating climate/environmental awareness in all building/construction/renovation projects
10. Reducing the variety of packaging materials used in freight/shipping containers of all sizes
11. Developing a database that tracks and traces sustainability efforts vs. achievements and records standardized progress
12. Relying more on local/regional suppliers/vendors for products and services, which will reduce cross-country/cross-ocean transportation emissions globally
13. Farming and growing your own food and nutritional resources
14. "Other" relevant suggested options include:
    - Establishing standardized "total cost of use" models to better inform the industry and healthcare providers of opportunities to reduce waste and costs
    - Reducing excess supplies by transferring, selling, or donating products
    - Understanding the climate impacts and embodied carbon emissions of all purchased goods/prioritizing low embodied carbon products/purchasing.
    - Setting science-based energy reduction targets
    - Requesting and tracking carbon emissions of your organization and your suppliers to manage your carbon emissions including the majority of where emissions come from per scope 3 terms

Priorities to pursue

From the list above, responding sustainability experts give top priority to the following options.

1. Reprocessing/reusing products when and where appropriate via approved/regulated procedures for safety and security (and legality) to reduce the volume of single-patient-use devices and related disposal requirements and costs
2. Establish standard 'total cost of use' models to better inform the industry and providers and to push positive change forward
3. Recycling (versus disposing) of equipment, furniture, mattresses, etc. to reduce waste streams and encourage the industry to innovate production using recycled materials

Richard Radford, CEO, Cenorin LLC

1. Eliminate Chemicals of Concern
2. Implement changes that reduce negative impacts on climate
3. Projects that improve community health and resiliency

Mary Starr, Chief Operating Officer, Greenhealth Exchange

1. Reprocessing/reusing products: "Reprocessing is arguably the most impactful environmental initiative in hospitals. Some hospitals reduce their carbon footprint by 2,000+ pounds CO_2 equivalent per year only by reprocessing cardiology devices."
2. Contracting for/investing in sustainably designed and/or manufactured products: "Manufacturers do not feel pressure today to invest in sustainable design. Hospitals should put more pressure on them."
3. Reducing chemicals of concern in the products themselves: "The manufacture of most medical devices and instruments take an enormous toll on the environment in terms of carbon emissions."

Lars Thording, Vice President, Marketing & Public Affairs, Innovative Health

1. Understanding the climate impacts and embodied carbon emissions of all purchased goods and prioritizing low embodied carbon products/purchasing: "Much of the carbon footprint associated with the built environment is embodied carbon. We can begin to decarbonize healthcare facilities through low-carbon material procurement. As a healthcare organization, if you are serious about promoting the health and wellness of those in your community, you must prioritize sustainable purchasing for human and climate health."
2. Incorporate climate/environmental awareness in all building/construction/renovation projects: "The building industry is responsible for nearly 40% of energy-related global greenhouse gas emissions, with the healthcare industry responsible for 4.4% of global carbon emissions. Climate change caused by human emissions has led to increased health problems worldwide, including cardiovascular problems, respiratory problems and insect-borne disease. As stewards of public health, the industry must reduce its environmental impact to reduce harm to human health. To do this, healthcare organizations can partner with vendors that prioritize sustainability in their supply chain and procurement

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efforts. By asking a vendor what their most aggressive sustainability goal is, you can start to identify which companies are taking these issues seriously and may be able to help you achieve your sustainability and public health goals."

3. Contracting for/investing in sustainably designed and/or manufactured products: "Given that purchasing is such an important part of sustainability, using contracts to lock in better pricing for products that support your organization's mission and goals should be a high priority."

Mikhail Davis, Director of Technical Sustainability, Interface

1. Reprocessing/reusing products when and where appropriate: "[This] oftentimes reduces cost, helping to enhance the business care for environmental sustainability, and is a relatively quick win compared to other sustainability initiatives, still resulting in a big payoff."
2. Contracting for/investing in sustainably designed and/or manufactured products: "Medical suppliers are increasingly developing environmentally friendly products that better serve the environment without compromising patient care. I recommend putting the onus on your suppliers and inquire about their sustainable product offerings to discover items in their portfolio that can serve as a substitute for products currently being purchased that do not have sustainable characteristics. The more health systems can collaborate with their suppliers on their sustainability journey, the more innovation we'll see in the space – ultimately helping healthcare sustainability professionals achieve their goals."

Evelyn Miller, Senior Manager, Environmental, Social and Governance (ESG), Medline Industries

1. Recycling (versus disposing) of equipment, furniture, mattresses: "Recycling your institution's old mattress is relatively easy compared to some other recycling program. The Mattress Recycling Council will pick up your old mattress and transport them at no cost to you to a recycling facility. You will not pay a disposal fee nor any transportation costs. You may view it as low-hanging fruit or no-brainer recycling.
2. Conserving/reducing energy and resource consumption: "The Mattress Recycling Council recycles about 75% of all the components within a mattress. In the last six years, MRC has diverted more than 380 million pounds of steel, foam, fiber and wood from landfills and recycled these materials into new products."

Joy Broussard, California Program and Logistics Coordinator, Mattress Recycling Council

1. Contracting for/investing in sustainably designed and or manufactured products
2. Calling for more detailed information on product labeling that identifies components and raw materials to facilitate more sustainable sourcing decisions
3. Reducing chemicals of concern in the products

Rob Chase, Founder & CEO, NewGen Surgical Inc.

1. Conserving/reducing energy and resource consumption, including (but not limited to) electricity, fuels and water: "Conservation of energy and resources must hold a preeminent place in our planning. Cutting our consumption directly reduces our impact on the environment and lessens the need for further mitigation. Energy conservation also directly addresses a health system's scope 1 and 2 emissions. Finally, efforts to reduce electricity usage at a particular facility can potentially avoid the need for expensive infrastructure upgrades as further draw is added to the facility's footprint due to future electrification, e.g., vehicle charging, gas-to-electrical switching, etc."
2. Incorporate climate/environmental awareness in all building/construction/renovation projects: "Environmental awareness during building/renovation, etc., goes hand-in-hand with energy and resource conservation. Health systems, guided by supply chain, should be setting ambitious energy and performance targets for new builds and renovations. Making this a priority right from the start will yield buildings that perform better and more cost effectively over their entire lifespan. Complying with today's codes may not be enough, we need to build in a way that is future proofed against the rapid changes that we should expect over the next few years."
3. Reducing chemicals of concern in the products themselves as well as the manufacturing process (e.g., PVC, DEHP, etc.) – or at least contracting with those suppliers/vendors who do this: "Elimination of toxics is always a priority. This protects not only our patients but also everyone that touches the product throughout its lifecycle, from production to disposal."

Andrew Knox, Manager, Environmentally Preferred Products, Premier

1. Contracting for/investing in sustainably designed and/or manufactured products
2. Reducing material waste, including the disposal of new and unused but expired products and the disposal of soiled/used products
3. Conserving/reducing energy and resource consumption, including (but not limited to) electricity, fuels

Andy Marshall, CEO, Sterilis Solutions

1. Conserving/reducing energy and resource consumption: "Advancing a journey to carbon neutrality and ultimately net zero through energy reduction via energy efficiency projects, renewable procurement and renewable power purchase agreements, among other pathways, is critical to reduce a company's carbon footprint. It is a priority for Stryker as we have set a goal to make all Stryker facilities carbon neutral (scopes 1 and 2) by 2030."
2. Reducing material waste: "Waste reduction is an area in which the industry will need to continue to create innovative solutions, including in the manufacturing of products. Stryker has invested heavily in additive (or 3-D) manufacturing, which has shown to create less waste."
3. Contracting for/investing in sustainably designed and/or manufactured products: "Packaging that considers recyclability, responsible materials and weight will become increasingly important, not only for long-term environmental sustainability but also for cost savings. It is also important to develop a system that tracks and traces sustainability efforts vs. achievements and records standardized progress: Implementation of this tracker for Environmentally Preferred Purchasing (EPP) programs and transparency with suppliers of the results will drive more accountability and engagement on the sustainable procurement journey."

Eileen Buckley, Vice President, Corporate Responsibility, Stryker

1. Calling for more detailed information on product labeling that identifies components and raw materials to facilitate more sustainable sourcing decisions
2. Develop a database that tracks and traces sustainability efforts vs. achievements and records standardized progress.
3. Contracting for/investing in sustainably designed and/or manufactured products

"Any of the above sustainability initiatives are important to further improvements in human and environmental health. The key targets depend on organizational goals that may include: waste reduction, utilization of safer chemicals, carbon neutrality, transparency and more.

"Product transparency and visibility into product components is essential for purchasers. Purchasers should know what is included within the products being used for patient care. Many healthcare providers are prioritizing products that have a low carbon footprint, reduce or eliminate waste, or are made without harmful chemicals of concern, such as flame retardants and bisphenols which adversely affect human health. By prioritizing transparency into components, purchasers can select the products that further improvements in multiple areas, from safer chemicals to decreased carbon emissions. These selections, safer products purchased at increased rates, will signal to manufacturers to focus on sustainable criteria for the future.

"The lack of standardization is a top concern within sustainable procurement. Currently, many purchasers struggle to determine which products are more sustainable than others due to rampant greenwashing, wherein an organization makes untrue claims about the positive impact of its product or service on the environment, while suppliers may hesitate with sustainable product re-design efforts due to lack of clarity. Tracking which products, contracts and suppliers are environmentally preferred within a database improves efforts to manage sustainable procurement, benchmark against peers and partner with suppliers to battle climate change together. Sustainability in healthcare requires that providers, suppliers and group purchasers be at the table to move the needle towards a safer future. Data visibility and transparency should be a priority for all.

"Contracting for sustainably designed products is critical to signal purchasing priorities to supplier partners. This will ensure your supply partners know up front what your organizational priorities are and also showcase a heightened level of awareness by holding suppliers accountable to purchasing standards. A standardized contract template, which includes sustainable product and service criteria ensures various departments within an organization will all receive the safest and cleanest products for their patients, family members and providers."

Cristina Indiveri, Associate Vice President, Strategic Programs and Contract Services, Vizient

1. Conserving/reducing energy and resource consumption
2. Reducing chemicals of concern
3. Reprocessing/reusing products

Paul Murphy, Vice President, Major Accounts & Vertical Markets, Canon Solutions America Inc.

Why not simply do nothing about sustainability in healthcare?

by Rick Dana Barlow

The United States of America may have sustained the existence of the "Know-Nothing Party" in the mid-1850s, but here in the early 21st century apprehension, cynicism, indifference, procrastination and skepticism are among the culprits of a "Do-Nothing Party" when it comes to implementing sustainability projects and programs within healthcare organizations.

While plenty of hospitals and nonacute care facilities have implemented sustainability efforts through the years, plenty more have yet to do it with the naysayers typically using budgets, economics and priorities as motivation for their eco-friendly malaise.

Still, by and large, the healthcare industry seems to lumber along at a glacial, if not snail's, pace and remains in operation for millions upon millions of patients. So what if much of the industry did nothing about the environment and just maintained the status quo on sustainability?

After posing that question you'd think you lit the fuse of a powder keg, albeit a fuse made from sustainable organic hemp, of course.

Small part of bigger picture

"This work is part of an organization's continuous improvement efforts," said Mary Starr, Chief Operating Officer, Greenhealth Exchange. "Maintaining the status quo would be like saying the clinical products we use are adequate so there is no need to look at any new technology. Healthcare organizations' missions typically focus on health, and sustainability plays a significant role in the health of patients, employees and the community, so it must be constantly evaluated for improvements."

Maybe it's even larger

"The link between human health and planetary health is clear. Health systems exist to keep people healthy; healthy people are harder to come by in an increasingly unhealthy world," observed Evelyn Miller, Senior Manager, Environmental, Social and Governance (ESG), Medline Industries. "Just like many health systems are stepping up to address social determinants of health in their community to advance health equity, they must also consider their own impact as it relates to climate change. If you're not working to address climate change, are you really working toward greater health and well-being?"

Cause, effect tops symptoms

"In the healthcare industry, organizations have already mastered the ability to manage symptoms for the illnesses their patients present," indicated Mikhail Davis, Director of Technical Sustainability, Interface . "But if we want to improve the overall health of our communities, we must look at underlying causes. With climate change as the No. 1 public health concern for our society and purchasing being the No. 1 impact of businesses on climate change, if your organization does not have a plan to confront climate change through prioritizing low carbon purchasing, you are not doing everything that you can to promote public health."

What a dangerous idea

"Doing nothing is just not an option, and hospitals who ignore the call to make the environment a supply chain issue will do so at their peril," noted Lars Thording, Vice President, Marketing & Public Affairs, Innovative Health. "Consumers have made purchasing choices based on the environment for decades, and this is coming to healthcare rapidly today. In addition, political pressure to adopt environmentally friendly policies mandatory are likely to arrive at the hospital doorstep soon."

You're kidding, right?

"This is not an option," detonated Paul Murphy, Vice President, Major Accounts & Vertical Markets, Canon Solutions America Inc.

Simply a poor decision

"It would be the advice of the Mattress Recycling Council that to do nothing but to continue to trash your old mattresses is a poor decision," noted Joy Broussard, California Program and Logistics Coordinator, Mattress Recycling Council. "It is a poor decision financially because your institution will pay ever growing disposal fees and transportation costs. If a mattress is not recycled, then it is landfilled. Many states or communities are banning mattresses from landfills because a mattress takes up too much space. Your trash disposal firm will need to drive further and further to find somewhere to bury your old mattresses and at ever increasing tip fees. Those costs are always passed directly onto you.

"As an institution trying to improve its environmental reputation, doing nothing is a poor environmental decision. The longer travel distances to ship your old mattresses add to greenhouse gas emissions. The valuable materials within the mattresses that are buried are lost forever. Just imagine, for example, how many times those steel springs that you buried with that old mattress could continue to be re-shaped into future steel products time and time again."

'Code Red' moral responsibility

"We must change course, move the healthcare industry and supply chain onto a more sustainable path," said Rob Chase, Founder & CEO, NewGen Surgical Inc. "As the United Nations said recently about climate change, 'It's Code Red for humanity.' Doing nothing is not an option! We have a moral responsibility to our families and to future generations that we must do better and take action against the threat posed by climate change. As a country we have a goal to reduce carbon emissions by 50% by 2030. Just because healthcare supplies life-saving medicines and surgical care does not mean we get a hall pass to do nothing. There are many areas where we as an industry can make a meaningful difference and the companies that manufacture and supply products and services need to step up and lean into these challenges that we all face. Those in supply chain can help ease this needed transition to low carbon patient care by seeking out and purchasing environmentally preferrable products. Production follows consumption, so making even small changes in what you purchase can have a meaningful and lasting impact."

Healthcare must lead

"I don't believe doing nothing is an option, and even the status quo is unlikely to be good enough," said Andrew Knox, Manager, Environmentally Preferred Products, Premier. We are increasingly witnessing the effects of climate change and pollution on the people we as healthcare professionals serve, as well as on the environment. Pressure for change is only going to increase, whether from patients, stakeholders, or regulators. Healthcare cannot stand by and leave it to other industries to limit environmental impacts. We must show leadership."

Amounts to a critical duty

"Although healthcare industries continue to operate and even grow, we cannot maintain the status quo because without drastic change, there will be an irreversible negative impact on the environment," warned Andy Marshall, CEO, Sterilis Solutions. "Since the 2016 Paris Agreement to limit global warming, businesses have been putting plans in place to reduce carbon dioxide emissions. Despite these advances, progress on climate action has been limited. This lack of progress is partly attributed to supply chains since the bulk of carbon dioxide emissions happen here. A company's sustainability efforts reside mainly in the supply chain, giving light to the fact that a company is no more sustainable than its supply chain.

"Health operations are fundamental to maintaining the health and welfare of our society, as well as individual health, and have lasting impacts on the development and economic growth of the world. By developing and implementing environmentally conscious, forward-thinking solutions within our supply chains, we can further progress the health and general well-being of current and future generations.

"Implementing sustainability solutions now is critical to mitigating future consequences for generations to come. Sustainability should be at the forefront of most, if not all, healthcare organizations' priorities. By seeking out products, organizations and solutions that position environmentally friendly initiatives at the helm, we greatly strengthen our health systems and the health of the environment."

Too much is at stake

"The healthcare industry needs to do its part for people and the planet, which are inextricably linked. The health of the planet affects human health, and with 5% of the global carbon emissions and 14,000 tons of waste per day from U.S. healthcare facilities, we have a responsibility to act," argued Eileen Buckley, Vice President, Corporate Responsibility, Stryker. "We see incorporating responsible, sustainable practices across Stryker as a way to support our customers, help protect the planet, drive business value and growth and attract and retain talent. We take a business-minded approach to our corporate responsibility and sustainability investments, which also yield a positive social and environmental impact. The average time to payback on our energy investments is about 4.5 years. The risks of inaction could be far greater, including loss of market share, being in violation of country laws and regulations, missing opportunities on operational efficiencies and cost savings, including across our value chain, business interruption due to climate risks, losing out on top talent and more."

Doing nothing is … unhealthy

"When it comes to sustainability, the healthcare industry is not fine, and it hasn't been," observed Cristina Indiveri, Associate Vice President, Strategic Programs and Contract Services, Vizient. "It is contributing to a significant amount of carbon emissions, creating waste and exposing patients to potentially dangerous chemicals. COVID, which highlighted multiple weaknesses in healthcare, is the perfect example of why we must act now to course correct. Instead of letting lack of sustainability continue to balloon, impacting human and environmental health, shouldn't we collaborate to deflate the crisis that it will surely bring if nothing is done?

"Doing nothing is not an option. My children's lives and the lives of countless other individuals are at stake. Extreme heat, severe weather, air pollution and other symptoms of climate change are significantly increasing heat-related deaths, injuries and diseases across the globe. Harmful chemicals, once introduced into the supply chain, are not easily, if at all, extracted, except through attrition. [See https://newsroom.vizientinc.com/improving-human-and-environmental-health-call-for-environmentally-preferred-health-care-sourcing.htm?blog/supplychain.]

"Simply put, healthy people cannot exist on a sick planet. I refuse to be a bystander while the 'greatest global threat to public health' negatively impacts the health and wellbeing of our current generation and the generations to come." HPN

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VALUE. DELIVERED.

Leaders honoring leaders

by Karen Conway, Vice President, Healthcare Value, GHX

During my second term on the AHRMM board, I had the pleasure of working with then chair Brent Petty, whose theme for his term was "Leaders Leading Leaders." That sentiment was alive and well at this year's Bellwether League Foundation Induction and Recognition Event (BLFIRE). It was a night to celebrate, for multiple reasons. Not only was it the first time since 2019 that we were able to gather in person to honor individuals who have made meaningful contributions to the healthcare supply chain profession, it was also the 15th anniversary of the event. Third, and most notable for me was how this year's class demonstrated the true value of collaborative and collective leadership.

Case in point: Among those inducted into the Hall of Fame for Healthcare Supply Chain Leadership was Teresa Dail, who also served as a chair of AHRMM. As the chief supply chain officer for Vanderbilt University Medical Center (VUMC), Teresa was recognized for her entrepreneurial spirit, which has positioned her as the president of three wholly owned, for profit LLCs affiliated with VUMC. In her acceptance speech, Dail noted how another one of this year's Bellwether inductees, Rosaline Parson, was in fact her mentor when they both served at Orlando Health.

Both Dail and Parson were trained as nurses and paved the path toward the clinically integrated supply chain. Rosaline specifically was credited with being one of the first healthcare leaders to pioneer "the concept of linking value analysis to self-contracting and self-distribution." A prior Bellwether inductee, Barbara Strain, also noted as she introduced another honoree that Rosaline had also been one of her mentors, no doubt laying the seeds that led Barbara and others to form the Association of Healthcare Value Analysis Professionals.

In another testament to the level of respect for those recognized as Bellwethers, Jake Groenewald, who was inducted in 2021, jokingly explained how he had pulled rank over one of his directors to be able to introduce another one of this year's honorees. Jake and Tom Lubotsky worked together at Premier as leaders in the field and in solutions consulting respectively and have remained both professional colleagues and close friends ever since. In his opening remarks, Jake noted Tom's commitment to achieving positive results, for his organization, colleagues and patients. In his acceptance speech, Tom shared a very personal story about losing his twin brother to cancer at an early age, and how that propelled him to a career in healthcare.

Two other Bellwether honorees also shared a common connection. Dave Myers with Owens & Minor, who was recognized for his "customer first" philosophy, is no stranger to industry recognition. In 2019, he received the John F. Sasen award from the Health Industry Distributors Association (HIDA), which is bestowed upon those who demonstrate exceptional leadership, commitment, and service to the healthcare products distribution industry and HIDA. Bellwether Hall of Fame status was also bestowed posthumously to John F. Sasen, Sr., the first recipient of the award that was later named in his honor. The former chief marketing officer for McKesson was credited with his ability to transition confrontational relationships between buyers and sellers into true collaborations.

Three other healthcare supply chain leaders were also inducted into the Hall of Fame:

Ed Hisscock, senior vice president, supply chain for Trinity Health, was recognized for his ability to bring together diverse groups of stakeholders to find solutions to some of heatlhcare's most challenging problems. In the process, many of those who have had the opportunity to work for Ed, regardless of where they started, are now leaders in their own rights, serving as vice presidents in supply chain organizations across the country. As his nomination form stated, "Ed instills and inspires authenticity, a strong moral compass, balanced by a compassionate mindset in every interaction and decision that comes his way."

Named by Harvard as one of the world's top chief executives, former McKesson CEO John Hammergren was recognized for his strong leadership during times of crisis, his dramatic turnaround capabilities and most importantly his ability to instill a spirit of accountability and customer service among his employees and his personal commitment to openness and honesty with customers, regulators and the media.

Last but certainly not least, the Bellwether League honored healthcare consultant Sue Tyk whose distinguished nursing background has advanced supply chain operations wherever and for whomever she has worked. Friends and colleagues, and even Sue herself, says her experience as a nurse (who often nagged supply chain for products) gave her an appreciation for the importance of clinical and supply chain collaboration. As Sue noted in a magazine interview, "I realized you don't have to be a clinician to help people."

Finally, four emerging supply chain leaders received designation as Future Famers, an award given to those who have made significant contributions to their organizations and the profession in the first decade or so of their careers. This year's Future Famers are:

- Ryan Burke, vice president, strategic sourcing, Pandion Optimization Alliance
- René Gurdían, assistant vice president, Supply Chain Finance and Strategy, Ochsner Health
- Caroline Marion, manager, Supply Chain Clinical Engagement and Implementation, Novant Health
- Allison Tidd, assistant vice president, Contracts, Atrium Health/Atrium Health Supply Chain Alliance

I have long recognized the importance of learning from history, to avoid repeating the same mistakes made in the past. But what the Bellwether League Foundation has taught me, most notably at this year's 15th anniversary event, is it is even more important to learn from our leaders who go beyond being great at their jobs to make sure they are leading the next generation of leaders. HPN

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