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HEALTHCARE PURCHASING NEWS®

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Green Cash Flow Offer

Q: How does the $100 upgrade credit work?

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

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

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

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

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

Q: What does a 1 year payback mean?

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

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

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

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

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

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

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

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

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

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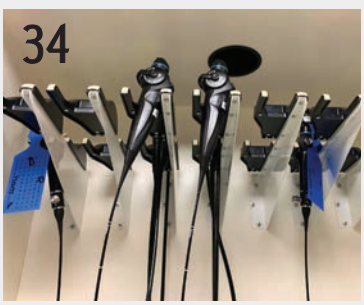

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* According to ECRI data from May 2020 to June 2021.

BOUNDLESS
Supply drain

If only the cure for the current global pandemic-afflicted supply chain woes were something as simple as ordering more stuff and then storing more stuff.

Overlook the fact that doing both tactics likely will bloat budgets as you'll be paying more to purchase more product, paying more to have more product delivered and then paying more to store more product – including ensuring the storage facility is safe and sterile when needed and workflow-efficient.

Some may embrace the inspirational words of Mick Jagger who was quoted as saying, "Too much … is nehvuh … enough!" That may not represent sheer joy for hoarders, but it can spark a twinkle in the eye of the "safety stockers" and those clever enough to finagle consignment deals for backup caches.

If the pandemic effects on supply chain taught us anything it's that we've fully rebounded from the just-in-time/stockless era with the urge to purge to the just-in-case/just-enough stockpiling era with the urge to surge.

Still, no matter what the majority may say, the supply chain technically isn't broken. It seems to be surrendering to its own sense of fragility as bent, perhaps a bit misshapen, but still malleable enough to relocate its way after a nearly two-year derailing.

So why isn't it enough just to buy more stuff? Manufacturing isn't the sole problem. It's not even the biggest problem. What's bigger? The multifaceted, multi-sourced, multitasking logistics morass.

Among the challenges? Stuff leaves factories from across either pond on the west and the east. Ships then arrive at domestic ports but remain stalled there (as opposed to being mired in the Suez Canal). Why? Considerable labor shortages on the docks. Factor in the escalating costs of fuel for ships as well as airplanes, the tariffs designed to prop up and protect economies, followed by the high cost of gas for trucking and the labor shortages in domestic transportation … insert overdramatic exasperated sigh here … and you should be able to deduce that we're facing less of a "make" problem, and more of a "get" problem.

Thank goodness all of those dark brown and slate blue-with-a-light-blue-smile delivery vans are making such a difference on a daily basis – sometimes more frequently than daily! Let's go domestic! Let's go local! That's the answer!

Yet without effective use of reliable automation, electronics, accurate data and supply data standards to facilitate authentic demand planning and consumption pattern identification, the organizational comfort food of chicken pot pie becomes more like Cajun crawdad gumbo.

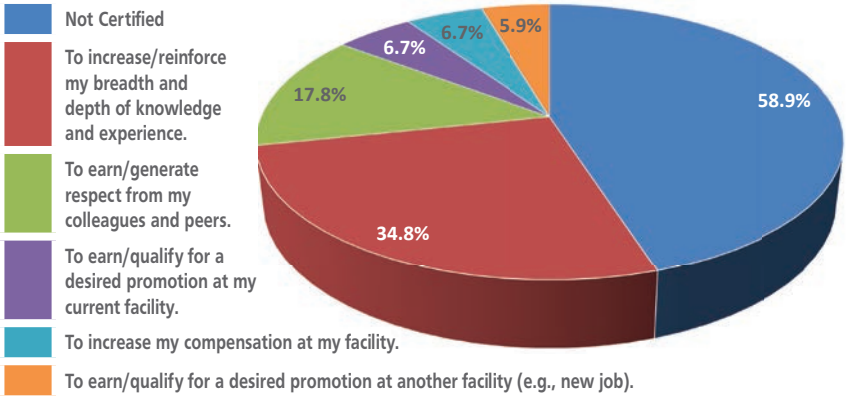
We've endured decades of seemingly endless debates and discussions about how to improve the "get." But somehow a global pandemic distracts us to focus for a spell on the "make."

The supply chain can't afford that. It's high time to refocus on the process. There's still so much work to do. To borrow a phrase from TV's Dr. Phil McGraw, it's time to "get" real.

DATA BANK

From the 2021 Supply Chain Salary Survey:

What motivated you to earn your certification(s)?



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It's time to evolve to a Möre efficient way of working

With 85% of nurses experiencing a lifetime prevalence of musculoskeletal disorders[1], it's time for bold solutions. The new Mölnlycke **S.A.F.E.™** Injury Prevention Program that gives you the tools and support to:

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In 2015 overexertion injuries in the healthcare industry were estimated to be **$1.7 billion**[2]. Our clinical team are dedicated to helping you develop and implement protocols that will reduce staff injuries, compensation claims and improve overall patient handling and efficiency.

For further information on how our S.A.F.E.™ Injury Prevention Program can reduce hazards, injuries and claims, contact us at info.us@Molnlycke.com

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References:
1. Power, Jan. Two Methods for Turning and Positioning and the Effect on Pressure Ulcer Development A Comparison Cohort Study. J Wound Ostomy Continence Nurs. 2016;43(1):46-50.
2. https://www.cdc.gov/nora/councils/hcsa/pdfs/17-Zheng-508.pdf

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FAST STATS

One U.S. child loses a parent or caregiver for every four COVID-19 deaths, a new modeling study published in* Pediatrics *reveals as reported by the National Institutes of Health. The findings illustrate orphanhood as a hidden and ongoing secondary tragedy caused by the COVID-19 pandemic and emphasizes that identifying and caring for these children throughout their development is a necessary and urgent part of the pandemic response – for as long as the pandemic continues, as well as in the post-pandemic era.

142,637

or one in 500 children in the United States is estimated to have experienced the death of at least one parent, custodial, or co-residing grandparent caregiver due to COVID-19.

120,630

is the number of children in the U.S. who lost their primary caregiver due to COVID-19.

1.5 MILLION

Children around the world lost a primary or secondary caregiver during the first 14 months of the COVID-19 pandemic.

20%

of U.S. children had been living in single-parent homes, pre-pandemic; 10% had a grandparent as their primary caregiver, pre-pandemic.

65%

of U.S. children orphaned by COVID-19-related deaths were children of racial and ethnic minorities.

4.5

Ethnic and minority children were 4.5 times more likely to lose a parent to COVID-19 than a white child.

168

One of 168 American Indian/ Alaska Native children experienced the death of a caregiver due to COVID-19, while one of every 753 white children in the U.S. has been orphaned by COVID-19-associated deaths.

The study was a collaboration between the CDC, Imperial College London, Harvard University, Oxford University, and the University of Cape Town, South Africa.

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NEWSWIRE

Report analyzes the current state of PPE costs and the future

Data from PINC AI, a technology platform, show that over the course of the pandemic, hospitals nationwide spent more than $3B to source personal protective equipment (PPE) for worker and patient safety. However, since the high point of spending in the second quarter of 2020, PPE costs have steadily declined. The report was released by Premier.

During a pre-pandemic baseline period (2Q-3Q 2019), hospitals typically spent a little over $7 per patient, per day on PPE, a figure that skyrocketed to $20.40 during the spring of 2020, driven by increased consumption, as well as off-contract buying and PPE bidding wars that occurred as health systems had to compete with federal and state governments and other providers to source limited supplies. Since that point in time, pricing has fallen to $12.45 per patient, per day – or about half of what was paid during the height of the pandemic.

In addition, PINC AI data show that for some PPE categories, such as eye protection, surgical gowns and face masks, pricing is very near pre-pandemic levels, while demand remains strong.

While costs are on the decline demand for and consumption of PPE remains strong given the delta variant caseload surges this summer and fall. For instance, providers are still using 1,300 percent more N95 respirators than they were at the pre-pandemic baseline. However, Premier members are better positioned than others in the market because of best-in-class contracting, sourcing innovations and technology-enabled purchased services solutions.

Premier's S2S direct sourcing subsidiary can source supplies globally on a supplemental basis. On average, S2S has been able to avoid many pricing increases and/or reduce overall costs for commodity items by 10-15 percent – cutting about $40M in costs from across the participants. S2S can provide an extensive array of PPE items from its global network, including all the categories discussed in this analysis.

To create competitive domestic alternatives to overseas overreliance, Premier has worked with our members to make investments in and/or long-term purchasing commitments with U.S. manufacturers, including Prestige Ameritech for N95 respirators and face masks, DeRoyal Industries for surgical gowns, Honeywell for nitrile exam gloves and Exela Pharma Sciences for pharmaceuticals.

Through these investments and long-term purchasing commitments, members can diversify their supply sources at a price point competitive with overseas manufacturing– effectively avoiding price increases that foreign suppliers have forced others to accept during the pandemic. In addition, these suppliers have increased their production to protect members from shortages that continue to plague the market.

To conduct the analysis, PINC AI compared PPE spending trends across quarters beginning from September 2019 through September of 2021, leveraging a database representing 30 percent of U.S. hospitals across all geographic regions and hospital types. PPE items included in the analysis included eye protection, surgical gowns, N95 respirators, face masks, exam gloves and swabs. Total costs were calculated by measuring quantities used per patient, per day, multiplied by the percent change in pricing for that quarter.

Innovative NIH research awards to address health disparities and health equity

The National Institutes of Health has announced they are funding bold, new research ideas that focus on interventions to address health disparities and advance health equity.

Eleven grants were awarded to support the work of exceptionally creative researchers across the United States through the NIH Common Fund's Transformative Research to Address Health Disparities and Advance Health Equity initiative totaling $58 million over five years, pending availability of funds. The grants are innovative because the applications focused on the significance of the research problem, the novelty of the idea or approach, and the magnitude of the potential impact rather than on preliminary data or experimental details.

A health disparity is a negative health outcome that affects disadvantaged populations like racial and ethnic minority populations, socioeconomic disadvantaged groups, underserved rural populations, and sexual and gender minorities.

For example, racial and ethnic minority populations in the U.S. face a disproportionate burden of disease, such as diabetes, heart and respiratory diseases, HIV, and obesity. More recently, the racial and ethnic differences in COVID-19 incidences and deaths illuminated health disparities and inequities that affect minority populations.

Each of the awards includes an innovative intervention component and focuses on one or more NIH-designated populations that experience health disparities in the U.S., including the following examples:

- Community-based research collaborations will develop and test financial

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interventions that address structural racism in neighborhoods predominantly populated by African American residents and examine spiritual healing and stress reduction interventions for youth from racial and ethnic minority communities to prevent chronic disease outcomes.

- Telehealth-driven or technology-assisted interventions have surged in the wake of COVID-19 and will be integrated into several of the community-based interventions for physical and mental health.
- Technology-enhanced approaches will be designed to advance cancer health equity among diverse deaf, deafblind, and hard-of-hearing populations.
- Researchers will also develop and evaluate a new model of school-based, telehealth-driven preventive care to prevent health disparities in underserved rural and socioeconomically disadvantaged children.

Additionally, the initiative expects to expand the research base for health disparities research at minority serving institutions (MSIs). A dedicated funding opportunity was specifically designed for MSIs, which the NIH Common Fund plans to reissue in fiscal year 2022 to support additional projects. Through the transformative health disparities research and the commitment to MSIs, this Common Fund initiative supports NIH's broader commitment to end structural racism and racial inequities throughout the biomedical research enterprise and the goals of the NIH UNITE initiative.

Health systems launch member-led company to transform digital healthcare

Graphite Health, a new member-led company focused on transforming digital healthcare to improve patient outcomes and lower costs, launched and announced its first three organizing members, SSM Health, Presbyterian Healthcare Services, and Intermountain Healthcare. Modeled on Civica Rx, a health utility company, Graphite Health will focus on healthcare interoperability challenges according to their press release.

Building on a common data language, Graphite Health is creating a standardized, interoperable data platform that enables a secure and open marketplace to streamline the distribution of digital health solutions for both health systems and entrepreneurs. For entrepreneurs, the common data language addresses inefficiencies in data translation and supports the development of plug-and-play digital applications. In turn, health system members can implement trusted digital tools as easily as anyone can download an app from an app store to a smartphone. These improvements will lead to more convenience, better quality care, lower costs, and overall efficiency.

There are numerous digital solutions on the market, but it's currently difficult for healthcare systems to adopt them. Health systems spendup to two years on average implementing new apps; negotiating the contracts and evaluating the security protocols alone can take more than six months. This impractical process means systems have to fully commit to the adoption of a new digital tool long before they can make meaningful use of it.

Graphite Health will overcome these challenges through the collective power, scale, knowledge, and commitment of its health system members.Graphite Health anticipates bringing additional healthcare systems and philanthropies into their coalition in the coming months, and partnering with leading technology innovators.

HHS updates rules on surprise billing

On September 30, 2021, the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (collectively, the Departments), along with the Office of Personnel Management (OPM), released an interim final rule with comment period, entitled "Requirements Related to Surprise Billing; Part II."

This rule is related to Title I (the No Surprises Act) of Division BB of the Consolidated Appropriations Act, 2021, and establishes new protections from surprise billing and excessive cost sharing for consumers receiving healthcare items/services. It implements additional protections against surprise medical bills under the No Surprises Act, including provisions related to the independent dispute resolution process, good faith estimates for uninsured (or self-pay) individuals, the patient-provider dispute resolution process, and expanded rights to external review.

In conjunction with the release of this interim final rule, the Departments and OPM launched a website focused primarily on providing general information about No Surprises Act provisions. It will include a federal portal for organizations to apply to become certified independent dispute resolution entities and for providers and payers to participate in the federal independent dispute resolution process:

The Departments and OPM intend to post additional information over the next several months, including information about how to initiate an independent dispute resolution process in the federal portal, and plan to highlight different provisions as they become more relevant to different stakeholders and audiences.

On July 13, 2021, the Departments and OPM issued "Requirements Related to Surprise Billing; Part I,"a rule that will restrict excessive out-of-pocket costs to consumers resulting from surprise billing and balance billing. This rule goes into effect for healthcare providers and facilities, and providers of air ambulance services on January 1, 2022, and for plan, policy, or contract years starting on or after January 1, 2022, for group health plans, health insurance issuers, and Federal Employees Health Benefits (FEHB) program carriers. The rule:

- Bans balance billing for emergency services. Cost-sharing for emergency services must be determined on an in-network basis.
- Requires that patient cost-sharing, such as copayments, co-insurance, or a deductible, for emergency services and certain non-emergency services provided at an in-network facility cannot be higher than if such services were provided by an in-network provider, and any cost-sharing obligation must be based on in-network provider rates.
- Prohibits OON charges for items or services provided by an OON provider at an in-network facility, unless certain notice and consent is given. Providers and facilities must provide patients with a plain-language consumer notice explaining that patient consent is required to receive care on an OON basis before that provider can bill the patient more than in-network cost-sharing rates.
- To protect patients from surprise bills and remove them from payment disputes between providers, facilities, or providers of air ambulance services and plans or issuers, the July 13, 2021 rule established that, for emergency services and certain non-emergency services furnished by OON providers at certain in-network facilities, the patient pays a cost-sharing rate similar to that imposed in-network. The rate for this cost sharing is calculated based on a state All-Payer Model Agreement, specified state law, or, if neither of these apply, the qualifying payment amount (QPA).

To ensure transparency in the independent dispute resolution process, the rule establishes monthly reporting requirements for certified independent dispute resolution entities to inform quarterly public reports on payment determinations.

The Departments will certify independent dispute resolution entities on a rolling basis. Entities that would like to be certified by January 1, 2022, should submit their application by November 1, 2021. HPN

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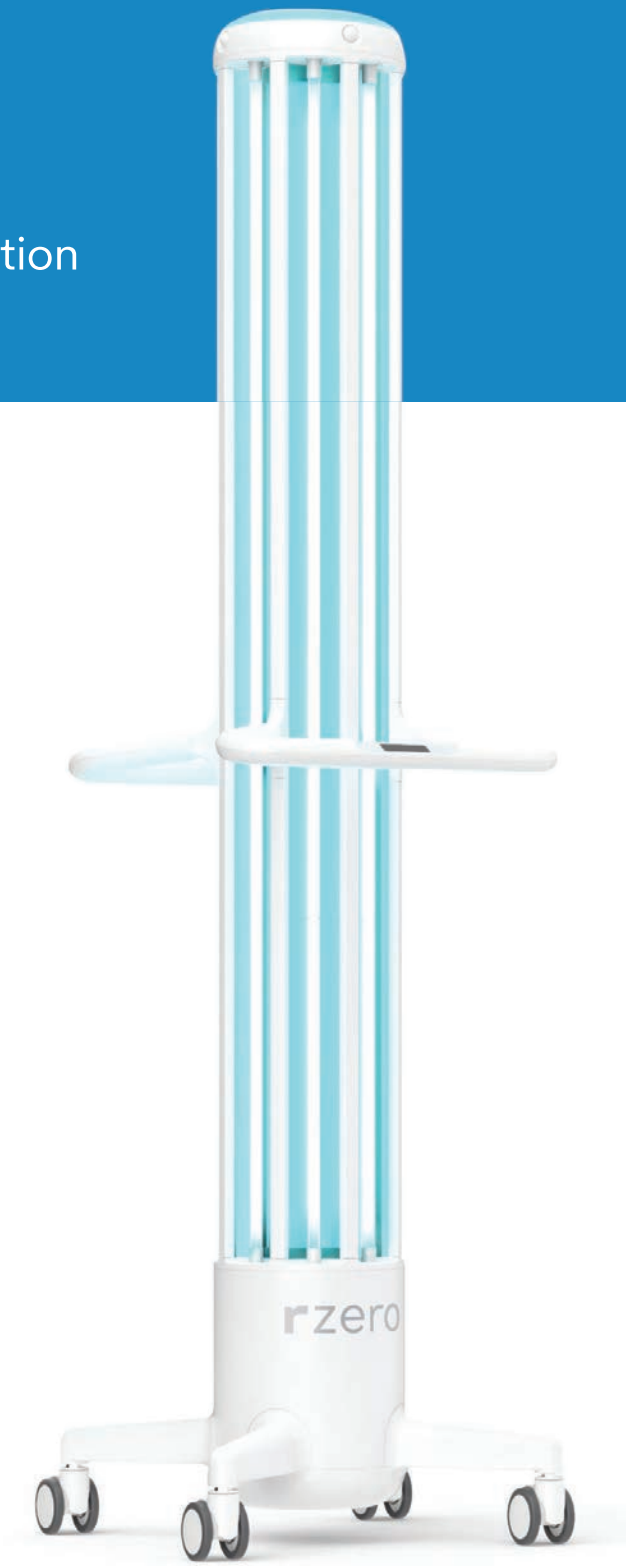

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Competing priorities, multiple perspectives slow sustainability progress

by Rick Dana Barlow

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On the surface, sustainability as an issue seems simple enough. Many within the healthcare industry acknowledge, recognize and understand the ideas behind conservation, eco-friendly, environmentally responsible and safe or even "green."

Further, sustainability as a functional strategy and tactic generally can be organized into four key categories:

- Conserving/reducing energy and resource consumption (including air, electricity and water)
- Reducing material waste (e.g., disposal of unused new products or pre-consumer waste and used products or post-consumer waste, etc.)
- Reducing chemicals/elements/materials of concern in the manufacturing process (e.g., carbon, PVC, DEHP, etc.)
- Contracting for/investing in sustainably designed and manufactured products – essentially the next step after the previous three.

Two major factors appear to pose challenges to sustainability's progress toward acceptance, adoption and implementation by even a slight majority of healthcare organizations.

1. Sustainability subject matter experts (SMEs) who are corporate executives at some of the leading companies in the healthcare industry have yet to agree on the priority of sustainability initiatives worth promoting and pursuing
2. And these same experts offer a diversity of reasons for why healthcare organizations have been slow to respond to a set of changes widely regarded as "the right thing to do."

Although none of the interviewed corporate executives agree on which sustainability projects to make higher priority or why senior healthcare leaders hesitate to support it, none essentially is wrong in his or her perceptions and understanding of human behavior.

Healthcare Purchasing News conducted a brief survey of six prominent sustainability SMEs from manufacturers, distributors and group purchasing organizations (GPOs). Each responded to four questions. In two of the questions, all six varied their responses across the board. In one, the majority coalesced around a central premise. In the last, they were split down the middle.

HPN asked the sustainability experts to rank the four categories in terms of priority for Supply Chain or any department or individual to address.

Five of the six selected different leading priorities and one changed the definitions of the categories, regrouping three under one category and introducing several others as meaningful to the organization and its customers.

Mike Lewis

For Mike Lewis, Vice President, Benko Medical, reducing material waste should be top priority as he cites research from such organizations as Practice Greenhealth and WWF Australia.

"The American healthcare system is a huge contributor of environmental waste, with recent estimates exceeding 10 billion pounds per year, or 29 pounds of waste per bed per day, according to PracticeGreenhealth.org," Lewis said. "Much of this waste comes from single-use items made of plastic and polymer materials and ends up in our landfills. The half-life on this type of material ranges from 40 years to 500 years, depending on many production and sourcing variables, according to WWF Australia. This current status quo model of heavy disposable, single-use products advocated by healthcare executives, supply chain managers, GPOs and suppliers is unsustainable and irresponsible. There are better, less damaging options available, particularly in the protective equipment sector. Reusable protective equipment has been proven to be more effective, safer, easier to use and significantly less costly. In addition, it reduces the disposal of rate of medical waste by [around] 700%."

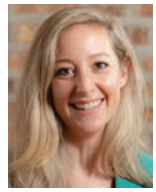
Lewis points next to contracting for and investing in sustainably designed and manufactured products. He attributes the reliance on single-use products to ignorance and simple economics.

"They just don't know any better because this is the way it has always been done or at least the way it has been done since the advent of cheap, readily available plastic/polymer materials," he observed. "The availability of these materials contributed to the shift of manufacturing to overseas, which compounded the problems and included little oversight available from U.S. companies. Cost became the main reason to purchase."

Reducing chemicals, elements and materials of concern in the manufacturing process leads the way for Francesca Olivier, Senior Director of Social Responsibility, Medline Industries.

"All four areas are important and each one contributes to a significant stride in achieving

a sustainable operation," Olivier contended. "As a healthcare manufacturer and distributor, Medline is committed to leveraging our healthcare sustainability expertise to help customers contract for sustainably designed and manufactured products."


Francesca Olivier

Olivier acknowledges, however, that from a healthcare provider's perspective, reducing material waste and conserving energy and resource consumption are "where supply chain departments often see more immediate cost savings," she added.

Kim Chase, Co-founder, Vice President, Marketing & Business Development, NewGen Surgical, agrees that contracting for and investing in sustainably designed and manufactured products should lead the way, followed by reducing chemicals/elements/materials of concern in the manufacturing process (e.g., carbon, PVC, DEHP, etc.)


Kim Chase

"These are all critical and should be included in any serious look at sustainable initiatives," Chase admitted. "The importance ranking is listed by ease, as the latest UN IPCC (Intergovernmental Panel on Climate Change) report has accelerated the dates for long-term meaningful action. And that action needs to start today! Each initiative has a timeline and cost, as well as long-term meaningful impact investment. But the key is to start today, and with what is available to us. There are companies like ours that accomplish [the first three] with in our product design."

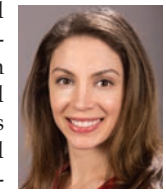
Conserving and reducing energy and resource consumption tops the list for Andrew Knox, Manager, Environmentally Preferred Products, Premier Inc.

"It's difficult to produce a ranking of sustainability priorities today as the urgency of the moment in which we're living truly cries out for an 'all of the above' strategy," he noted. "However, with the net-zero clock ticking ever louder, any action that reduces the production of greenhouse gasses might be considered highest priority.

"Reducing electricity and natural gas consumption has direct, meaningful and quantifiable benefits," Knox continued. "This holds equally true for water conservation, particularly in water stressed regions of the country. Both waste material reduction and contracting for sustainably designed materials in healthcare promote environmental stewardship and sustainability in the sector overall, while eliminating chemicals of concern is at the heart of healthcare's healing mission."


Andrew Knox

Cristina Indiveri, Senior Director, Program Services, Vizient Inc., concentrates on what some consider the end game. She favors contracting for and investing in sustainably designed and manufactured products as the top priority, followed by reducing chemicals, elements and materials of concern in manufacturing.


Cristina Indiveri

"Contracting for and investing in environmentally preferred products is the most important priority among the four as it ensures the purchase of the safest products for the environment and for human health," Indivieri insisted. "Products with a reduced environmental footprint have been manufactured with consideration for all stages of a product's life cycle. A sustainably designed product encompasses all the above priorities and then some: Its raw materials are renewable, recycled and responsibly sourced; it does not contain chemicals of concern that can cause risk to patients; it can be used longer than alternatives and can be reprocessed and diverted from the landfill; and it is locally or regionally made, consuming fewer resources while being less dependent on fossil fuels for transportation. All of these sustainable procurement tenets ensure patients' healing with no adverse health effects transpiring."

Indivieri homes in on N95 masks in high demand during the global pandemic for their infection prevention properties as a noteworthy example.

"Unfortunately, the lifecycle of disposable N95 masks is far from sustainable," she indicated.

Indivieri cites five reasons why N95 masks can be challenging sustainably.

- **Raw materials:** "Plastics for N95 masks are made from fossil fuels that can be mixed with chemicals of concern," she said.
- **Manufacturing:** "N95 masks that are made overseas may include heating plastic fibers that release toxic fumes."
- **Transportation:** "This form of PPE can be transported across the world by various forms of shipping and ground transportation, adding fossil fuels into the environmental equation."
- **Use:** "A single N95 mask is used once per each care episode."
- **Disposal:** "They're disposed of in the landfill and take hundreds of years to degrade."

Supply chains cause most greenhouse gas emissions, 80% across the world to be exact, and human health suffers because of it, according to Indivieri. She cites research from *Health Affairs* that states in 2013, negative health impacts produced from healthcare pollution were comparable to deaths from preventable medical errors. "Scope 3 greenhouse gas emissions, defined by the EPA as those that are the result of activities from assets not owned or controlled by the reporting organization, such as product transport, employee travel and commuting, account for approximately four-fifths of the total greenhouse gas emissions from the healthcare sector in the United States," she said.

Greenhealth Exchange, a group purchasing organization specializing in sustainable products and services, segments sustainability into three pillars, according to Mary Starr, Vice President, Member Services. They are social, economic and environmental, which include three of the non-contractual categories listed earlier.


Mary Starr

Consequently, setting priorities for sustainable projects can be based on numerous factors, including:

- Geography and environmental challenges associated with a facility's location
- Community socio-economic factors
- Community/culture
- State/local regulatory requirements
- Organizational budgetary goals
- Environmental/health concerns

"Ranking depends on the purchasing organization's priorities/goals and on the type of product under consideration," Starr said. "For example, if a healthcare organization has a goal to reduce greenhouse gas emissions, they may prioritize the first one. If they are buying a product that has patient contact, such as IV bags and tubes, they may prioritize chemicals of concern. The social criteria focus on people, and if you are buying a product where forced labor has been a persistent issue, this criterion may weigh more."

Determining social and economic sustainability issues may fall outside of Supply Chain's traditional purview, but that doesn't make the two pillars any less important, according to Starr.

"For our organizations, social is focused on health and well-being of people and ensuring the basic human rights in their employment, such as equal opportunity, fair wages, using diverse suppliers, and safe working conditions," she said. "One might need to [recognize] 'social determinants of health' to be fully understood.

"Economic is focused on using economic power for the good of all society, such as buying local, cost savings, looking at the total cost of ownership," Starr continued. "This approach can make the work seem daunting, but the key is to establish a plan, priorities

and start the work. The more complex issues can be tackled with progress and experience with success."

Must a healthcare organization have someone on staff researching social criteria to ferret out forced labor? Not necessarily, Starr notes.

"At Health Care Without Harm, Practice Greenhealth and Greenhealth Excchange (GX) there is a strong emphasis on the issues that can impact climate change, which covers a host of areas for focus, but also significantly affect human health," she said. As for how to determine if forced labor is an issue, Supply Chain professionals should stay informed on the supply categories that have a pattern of using forced labor, such as gloves and textiles, but also just being aware of where products are made can help narrow the areas of risk. There are non-profits such as HCWH that are researching and addressing these issues and government agencies that report information on forced labor. Like with any other market change, the customers' collective voice can impact this issue."

Sensible starts

If Supply Chain were asked to choose one of the four key categories that make the most sense to start sustainability projects, four of the six sustainability experts agree on one area: Contracting for and investing in sustainably designed and manufactured products.

"Although we firmly believe that reducing material waste is the single most important item to address, it is essentially an outcome or a result. It is not an action item," Benko Medical's Lewis noted.

"The most effective way to accomplish reducing material waste is by contracting and Investing in sustainably designed and manufactured products," he agreed. "This requires a paradigm shift in thinking. It will disrupt the status quo. There are companies out there, like Benko Medical, who are seeking solutions for healthcare and are ready to deliver on a larger scale to American hospitals and facilities."

Contracting contains a framework, according to Medline's Olivier.

"Many of these areas require the sustainability team within an organization to embark on their own adventure and create a strategy, but there's already criteria in place to help health systems contract for sustainably designed products," she said. "Organizations such as Practice Greenhealth offer environmental purchasing specifications and guides to help health systems ask suppliers the right environmental questions about products, explanations of environmental issues around products and referrals to product lists."

Contracting for and investing in sustainable products is where healthcare can make the most difference and lead the way, argued NewGen Surgical's Chase.

"The timeline for global decarbonization mandates that developed countries achieve 45% reduction in CO_2 by 2030," she noted. "As a major contributor to global carbon emissions and global economies, and as the industry dedicated to human wellbeing, the healthcare sector should lead by example and solutions. The industry must rapidly endorse science-based targets and adopt low-carbon products, processes and services. The clinical device market is rich with opportunities to reduce carbon emissions and align products with the goals of healthcare.

Chase cites data from Health Care Without Harm's Global Roadmap to Decarbonization on how implementing circular healthcare and sustainable waste management can reduce a cumulative 4.8 Gt of CO2e by 2050. "The circular economy [comprises] two unique cycles that maximize the utility of each product input along its entire lifecycle," Chase said. "The technical cycle maintains products made from extractive inputs such as metals and plastics through maintenance, reuse, refurbishment and then recycling. Complementary to the technical cycle is the biological cycle, which metabolizes biological materials as product inputs, natural energy sources, biochemical extracts and then soil nutrients. The World Economic Forum recommends redesign as a leading sustainable idea. Products can address reducing plastic, chemicals of concern and carbon using circular design principles," she added.

Vizient's Indivieri acknowledges the vastness of sustainability's reach.

"Sustainability can be overwhelming," she admitted. "It touches everything in a healthcare organization – from anesthesia given to patients, to food that provides healing nutrition, to care givers and family members who spend time in the healthcare setting. Rather than focus on one theme, all should be taken into account when contracting for sustainably designed products.

Indivieri advocates for an organization-wide environmentally preferred purchasing policy that outlines key priorities as a smart place to start. It's simple economics or business.

"Environmentally preferred purchasing criteria can be used to signal to suppliers that environmentally preferred products and services are a priority and will therefore earn more business," she insisted. "In short, going green equates to making green for vendors and distributors. Everyone wants to do the right thing, but revenue and profit will absolutely motivate businesses to move swiftly."

But she spots demand shifts already.

"Many GPOs in the healthcare industry are requesting environmentally preferred information from suppliers and are sharing it with their members to ensure transparent purchasing," she said. "What's needed is to go a step beyond and implement environmentally preferred contract language for medical/surgical and physician preference items. GPOs must ask suppliers to provide safer alternatives when environmentally preferred product attributes are not met and request that suppliers provide a plan to eliminate chemicals of concern or hazardous waste. Instead of simply encouraging sustainable procurement, GPOs should partner with their suppliers to ensure the health care market makes lasting changes to encourage human health and combat the negative effects of carbon emissions."

Premier's Knox still favors reducing energy and resource consumption.

"Reducing energy and resource consumption is a logical place to start because it has the potential to generate both quantifiable and meaningful cash and carbon savings," he said. "Many organizations use this data as a foundation upon which to launch other, perhaps more challenging, sustainability initiatives. Reducing material waste by reprocessing medical devices, and ensuring supplies do not expire before utilization, can also generate similar data. Starting with these types of initiatives to generate excitement and momentum for a broader sustainability program can be a useful approach, especially early on."

Finding direction depends on an organization's goals, according to GX's Starr.

"Generally, sustainability looks at ensuring patient and environmental health," she observed. "The important thing is to do the planning work so that the priorities selected reflect the organization's larger goals and strategies. This will aid efforts as the work moves forward."

Rather than ignore the issue of modern-day slavery, human trafficking and forced labor, healthcare organizations should pay attention to it because of risk, Starr insists.

"There is risk organizationally, legally, reputational, etc., if an organization has been buying goods produced by child or forced labor," she said. "One health system is training physicians and clinicians to be aware of patients who might be subject to these conditions and opportunities they have to recognize and address. This also addresses basic human rights of people and healthy working conditions."

Booking ROI

Half of the corporate sustainability executives surveyed anticipate the healthiest potential return on investment in one area:

Contracting and investing in sustainably designed and manufactured products.

For Benko's Lewis, it begins at the top.

"Everything starts with the decision makers, the executives, the shareholders, etc.," Lewis insisted. "If there is no push to decrease waste from the top, very little can be accomplished from below, no matter the level of passion that is put behind it. Independent of high-level approval, a great idea will most likely die with the idealist. Healthcare organization leaders must lead the charge of reducing their impact. By contracting with, and investing in American producers of reusable items, they will act as advocates for a cleaner environment, and people will follow."

The contracting aspect represents working smarter, not harder because all the responsible elements already are in place at that point, according to Vizient's Indivieri.

"Sustainably designed products utilize renewable resources, are made from recycled content and are responsibly sourced," she said. "These products are safer for our patients, their family members and our care givers because they do not contain chemicals of concern. They are free of bisphenols that are endocrine disruptors, reproductive toxins, developmental toxins and heavy metals, which are carcinogens. Their product life is longer than usual because they can be cleaned, maintained and repaired. They can be reprocessed and diverted from landfills because they are reusable, recyclable, do not generate hazardous waste and do not generate waste when delivered. They are locally sourced, meaning that they reduce transport miles, contribute to a sustainable economy and support local job creation. They consume fewer resources because they are resource efficient. Last, but certainly not least, they curb carbon emissions because they are less dependent on fossil fuels."

NewGen Surgical's Chase concurs.

"Climate-smart design in products addresses all sustainable goals and are immediately available for measurable, meaningful environmental results in the supply chain," she added.

Others aren't quite so deliberate as decisions and outcomes will vary by organization.

"The starting point will depend on the organization's current environmental impact and their priorities moving forward," said Medline's Olivier. "For example, a pediatric department may have more concern over reducing chemicals of concern in the manufacturing process because it can impact the health of children from a young age. A laundry department may prioritize conserving energy because they use a lot of electricity, making energy conservation an element of sustainability where it can have the greatest impact."

Much depends entirely on a health system's individual aims and aspirations, according to Premier's Knox.

"The first two options (conserving/reducing energy and resources and reducing material waste) have the potential to produce measurable and meaningful results more immediately, while the other two options (reducing chemicals/elements/materials of concern and contracting/investing) are currently more difficult to quantify," he said. "Eliminating chemicals of concern, for instance, is a worthy objective, but it can be very difficult for an individual hospital system to quantify the impacts of those measures."

Participation in sustainability projects and achieving measurable results with "low-hanging fruit" initiatives can drive interest, according to GX's Starr.

"If you've done no work in waste, then there are areas for recycling and using reusable products," she said. "In energy, if nothing has been done, just look for 'Energy Star' electronics. If chemicals, look at plastics with toxic chemicals used in the NICU [with the] most vulnerable patients." HPN

From IV drips to container ships

Products made; lessons learned in the time of COVID

by *Nancy Pasternack*

Photo credit: Sherry Young | stock.adobe.com

During the earliest months of COVID-19's incursion into the U.S., a dramatic shortage of both clinician time and personal protective equipment (PPE) created a new hospital practice: Moving intravenous infusion pumps out of patient rooms and into hallways.

The hallway move allowed nurses to check patients' solution levels, medication dosing, and to change IV bags without donning and doffing new PPE sets each time. And, of course, reducing in-person patient checks minimized clinicians' risk of exposure to the virus.

But making the change from bedside to hallway required a key fix.

"They needed longer tubing; they needed an extension line," said Steve Weber, Director of Marketing Vascular Access & IV Systems at B. Braun Medical.

Creating a new – albeit fairly simple -- product that B. Braun hadn't made before would normally take six to eight weeks from conception to market, Weber said. But company leaders, in an effort to quickly fill a critical void in hospital systems, took an all-departments-on-deck approach. B. Braun's engineering, regulatory, operations, manufacturing, marketing and sales departments became part of the expedited process.

"All those players had to come together," Weber said. "It required us to challenge some of our own internal systems, but we got it to inventory in just two weeks."

B. Braun was able to help alleviate a shortage and create a new product for itself in one move, in spite of COVID-related challenges.

To manufacture the product, worker masking had to be instituted, and barriers had to be erected to make sure operators could maintain a proper distance from one another. Producing just about anything during a pandemic, after all, requires a lot of new considerations.

B. Braun's reach, which includes operations on every continent but Antarctica, helped make the project possible.

"We have good access to supply (of materials) and we have good supply chain relationships," Weber said. It didn't hurt either that the company has manufacturing plants in the U.S., and that they are strategically spread out: Allentown, PA, Irvine, CA and Daytona Beach, Fl.

Michael Schiller, Senior Director of Supply Chain for the Association for Health Care Resource & Materials Management (AHRMM) would like to see this kind of flexibility from manufacturers, vendors, buyers and everyone else on the supply chain. He and other industry leaders have studied fundamental issues laid bare by COVID, and are making recommendations for industry-wide change.

"We have a geographic concentration of manufacturers – no doubt about it," he said, pointing to one key source of trouble for the industry. "How do we best diversify? Bringing all manufacturing to the U.S. is unrealistic and not possible." Right now, interests lie almost entirely in Asia. "But how do you build an infrastructure in other places to manufacture these products? It's very complex."

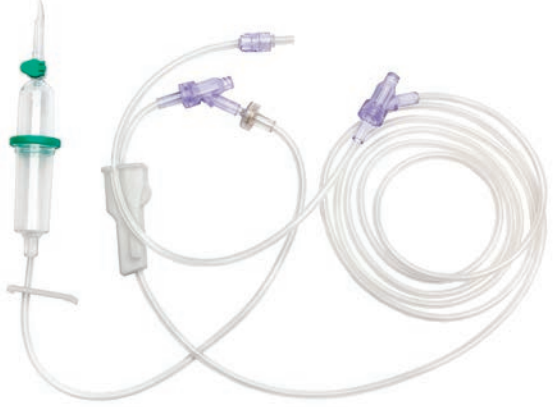
Now, as the Delta variant is waning and operating rooms are scheduling patients once again, the after-action review has begun. Schiller and other supply chain leaders have observations, studies and takeaway messages to share about the industry's responses to COVID-19. They have identified and deconstructed some of the root causes for medical supply shortages, tallied the exorbitant human and financial costs that have resulted, and built a series of recommendations for the healthcare supply chain moving forward.

"When you peel those layers of the onion back, there's a lot to this," he said.

Surviving and thriving

Thus far, individual businesses have been working with the hand that COVID has dealt them. Each has had to make decisions based on individual strengths, resources, immediate circumstances, and both short and long-term predictions.

"Surgery centers were down for most of 2020, so we focused our priorities differently," B. Braun's Steve Weber said. "We weren't going to build every product that we usually do." This allowed the company to invest resources elsewhere.



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B. Braun recently debuted its CARESAFE IV Administration Set. The system includes a unique, optional AirStop feature. A version of the product has already been successful in Europe.

When an IV bag is empty, "air can eventually get into the IV tubing line if the clinician doesn't stop the infusion," Weber said. "It's all a timing game." The clinician must take time to remove the air so it doesn't get into the patient. "They're constantly checking and then having to get the air out if it gets into the IV line."

The product is designed to remove risks to the patient.

"The AirStop prevents air from getting into the IV line," Weber said, "so it helps streamline the workflow for nurses and helps keep patients safe." And employing the device, he said, "helps stressed clinicians so they can stop worrying about the IV and focus on value-added care."

At ivWatch, a smaller and very different kind of enterprise, Jaclyn Lautz, Ph.D., Chief Operating Officer, said her company made an unexpected move in response to the marketplace effects of COVID. Like Weber, she said her company was spared many of the woes visited upon the industry due to the fact that it manufactures products here in the U.S.

"This mitigated most of the supply chain and manufacturing issues hitting the market hard during this time," Lautz said.

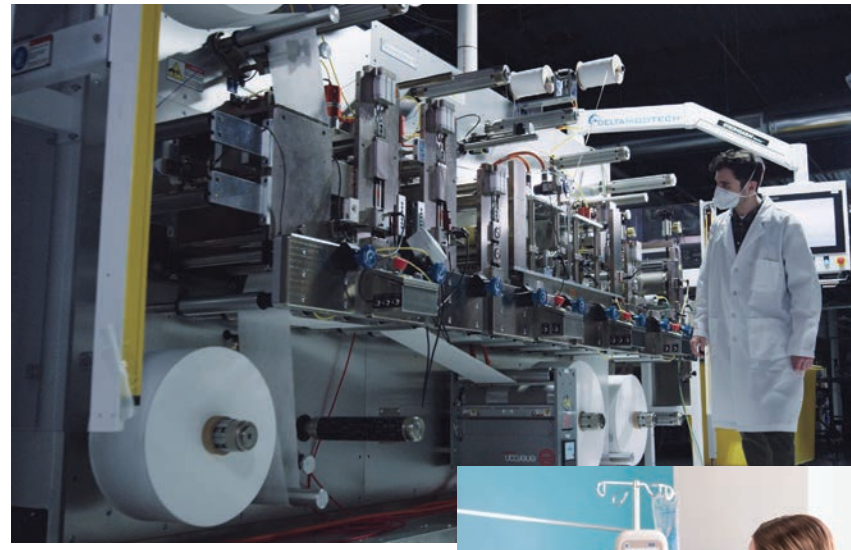
The unique product for which her company is named uses technology to monitor a patient's IV site, "to catch infiltration and extravasation events early," she said.

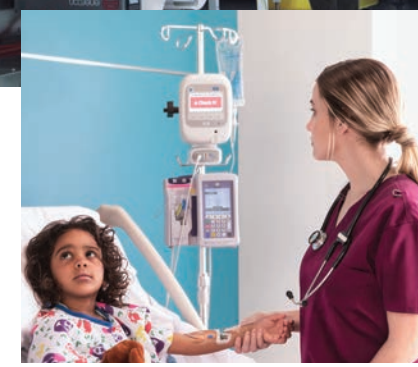
According to a description of the product, ivWatch employs, "a miniaturized biosensor that uses visible and near-infrared light to measure changes in the optical properties of tissue near the IV insertion site."

The sensor is placed near the IV site on the patient's wrist, where it continuously measures volume changes to the tissue fluid. When it detects changes indicating that IV fluid is leaking and pooling in the tissue, it prompts an alarm that can be both heard and seen.

"Getting an IV is still one of the most common procedures performed in a hospital, and even the most perfectly placed IV can fail," Lautz said. "With the current workload for clinicians, they need all the support they can get with things like technology that will help improve patient outcomes."

But like many businesses whose operations slowed due to COVID-19, ivWatch has used some of its manufacturing capabilities to produce something for which the pandemic has generated high demand: respirator masks.





ivWatch manufacturing plant (above) and patient example (right)

"Overseas, counterfeit N95s were flooding the marketplace. We knew we could leverage our supply chain connections and internal expertise to make a difference," Lautz said.

The company converted some of its machinery at the company's Newport News, VA facility to this new crisis-born enterprise.

"We are currently in the final stages of our NIOSH application and certification," Lautz said. The product was third-party tested, she said, by Nelson Labs and Pacific Biolabs.

Sharing smart

At yet another point along the supply chain, Charlotte Perkins, Vice President of Supplier and Portfolio Management at Owens & Minor, said her company has had its own view of the landscape.

"Demand for IV catheters is increasing slightly at a time where there are minor shortages," she said. "We anticipate this being a short-term challenge and have been working with our customers to offer alternate products if needed."

"We have only recently seen minor supply chain challenges with IV solutions," she said, "compared to some other categories that were more directly affected due to COVID-19."

Perkins said that what sets Owens & Minor apart from other companies grappling with COVID-19's financial effects is tight control and visibility over their supply chain. They have been able to supply customers with PPE, she said, "because we already have vertical integration of our supply chain for these critical products through our Americas-owned and operated manufacturing facilities."

Owens & Minor has a product that Perkins said speaks to the company's focus on communication and transparency. Her clients can subscribe to alerts, via the SMART Card (Supplier Metrics & Accountability Report Tracker).

"By subscribing to these alerts, healthcare facilities and systems gain access to weekly supplier snapshots and updates," she said. The updates, "keep them aware of supplier constraints or disruptions."

"We have a unique viewpoint regarding the state of the market, demand trends and the issues healthcare facilities may be experiencing related to outside factors, like COVID-19," Perkins said.

Cause and effect

A "perfect storm" created by COVID, according to Schiller, actually began with some storm clouds that formed months earlier, thousands of miles away.

Annual Chinese New Year celebrations shut down business in that country for two weeks, and 2020 was no exception. Manufacturing there all but ceased.

"Then you began to see COVID spike there -- in the very same places where PPE products were manufactured, thereby reducing manufacturing output further," Schiller said. Meanwhile, COVID was beginning its destructive journey around

the world, ramping up demand for PPE everywhere. The same was true for many other medical products that are manufactured, or partly manufactured, in other Asian countries.

Weber said that even with B. Braun's many global resources, not everything was smooth sailing when looking to produce IV tubing.

Storms that left Texas in a deep freeze back in February and tore up its coastline during hurricane season put Tyvek, the polyethylene product made by DuPont, in short supply. The material is used in making everything from HAZMAT suits to packaging materials. Tyvek could no longer be made in Texas, so that all-important resource became tough to access.

"So now, even the availability of packaging materials is strained," Weber said, "not because of the pandemic but because of natural disasters."

"That impacts what you produce, and the ripple effects go all the way to end users," he said.

Some of the results can be seen in long lines of hulking container ships waiting outside of U.S. ports. The bullwhip effect, as supply tries in vain to catch up to demand, is not a pretty sight to anyone in the industry. A computer chip shortage, stemming partly from shortages of raw material, caused downstream shortages in many products that require the use of that chip, including medical devices like IV pumps.

All those product shortages have links to manpower shortages.

"Products might be sitting on a boat in San Francisco or San Diego, but there's not enough people to unload them," Weber said.

When they do manage to offload containers, "then you're waiting for trucks to move the products because there's a shortage of drivers." Schiller said.

To mitigate the effects of the next pandemic, or cascade of disasters like those of the past two years, healthcare and supply chain leaders will need to embrace change in a number of areas. he said. A national, clinically acceptable products list should be developed, and a more open system that uses existing supply and distribution infrastructures. That way, resources can be allocated and shared when necessary.

"We need to improve transparency, but once the system is transparent, how do you manage human behavior?" he asked. For instance, when production and PPE inventories finally improved after devastating shortages, "Some hospitals spent tens of millions building PPE inventory so they wouldn't run out again, Schiller said. Stockpiling can create shortages all over again.

Other changes Schiller urges for the system's future health:

Hospitals will need to examine their purchasing habits. ...Single source contracts for a particular product may result in some cost savings, but might not be best in the long run.

"Let's move away from where we're ordering just in time so we're all lean and mean," he said. "If I'm looking to build redundancy and reduce risk in the supply chain, I'll need more than one vendor, or a list of clinically acceptable substitutes."

But there are always caveats.

"All these decisions and changes will come at a cost," Schiller said. And the point person – the supply chain leader – will have a role that's far more complex than it had been, pre-COVID.

"I need to have more visibility upstream – see what's going on with manufacturers," he said. "What's going on logistically? What's going on politically? I have to have a global picture now. I need to be much more strategic."

In the meantime, Schiller's keeping his eye on the future. "When the next spike occurs," he said, "it starts all over again." HPN

Solutions for sanitizing

How to choose what you use

by Kara Nadeau

Photo credit: Audrey Durose | stock.adobe.com

The world of disinfectants for healthcare facilities – from those to disinfect surgical instruments and devices in Central Service/Sterile Processing & Distribution (CS/SPD) departments, to those used by environmental services (EVS) staff members to reduce microbes in rooms and on equipment – has changed in many ways throughout the COVID-19 pandemic.

CS/SPD and EVS teams, presented with a wide variety of products with some now labeled effective against the SARS-CoV-2 virus, have to ask more questions and seek more answers to ensure they are selecting the right solution for the job at hand.

Conversely, some elements of disinfection never change, including effectiveness, safety, compatibility with equipment and surfaces, and proper use in alignment with safety data sheets and instructions for use (IFU).

To clear up some questions, address misconceptions and help CS/SPD and EVS teams evaluate the variety of disinfectants available today, manufacturers and users of these products offer their insights on product selection and use.

Safety risks from improper disinfectant use

While chemical disinfectants can be used by staff members to safely reprocess instruments and maintain clean spaces, when misused these products can cause harm to users and those around them, including patients.

According to the Occupational Safety and Health Administration (OSHA), common unsafe work practices include mixing of cleaning products that contain bleach and ammonia; incorrect dilution of cleaning solutions, lack of proper PPE and inadequate ventilation.[1]

And it is not just EVS and CS/SPD staff who are at risk. A study published in *JAMA Network Open* found regular use of chemical disinfectants among female nurses to be a risk factor for the development of Chronic Obstructive Pulmonary Disease (COPD).

Among the 73,262 nurses in the study, 22.9% reported weekly use of disinfectants to clean surfaces and 19% to clean medical instruments. The study authors noted how the nurses were affected by high-level exposure to several disinfectants, such as glutaraldehyde, bleach, hydrogen peroxide, alcohol and quaternary ammonium compounds, "all exhibited significant associations with COPD incidence."[2]

The CDC urges healthcare facilities to ensure staff members understand, "all potential health hazards and using all recommended protective measures, including barriers to prevent contact with body parts and respiratory protection. And for staff to follow 'manufacturers' instructions and product label directions for safe, effective use."[3]

"Staff and patient safety are both factors to consider when using disinfectants," explains Seth Hendee, CRCST, CIS, CHL, CER, CSPDT, CFER, IAHCSMM Approved Instructor, Clinical Education Coordinator, SPD, Healthmark Industries. "Providing appropriate PPE, adequate ventilation, staff and area monitoring may be required to ensure staff members are not adversely affected when using disinfectant chemistries."

Hendee says many CS/SPD departments have transitioned away from disinfectants like glutaraldehyde because they require a protective hood system and staff exposure monitoring, stating:

"The patient safety factor is twofold. Ensuring the instrument is exposed to the disinfectant is the first, but the second is just as important. Thoroughly rinsing these stringent chemicals off the device is just as important and can cause adverse effects if they are not."

Seth Hendee

Following the manufacturer's IFU and labels also means leaving the disinfectant on the surface or equipment long enough to be effective. Inadequate dwell time presents its own safety risks, explains Chris Farrell, Enterprise Business Manager for Contec Professional. He states:

"COVID-19 has increased the demand for disinfectants, but it's important that people pay careful attention to the dwell times for any product they use. If the chemical isn't left on the surface long enough, the disinfectant's efficacy is greatly diminished."

Risks for equipment damage

Improper use of disinfectants can also damage medical equipment, instruments and care area surfaces. In a September 2021 memorandum, Alberta Health Services describes how improper cleaning and disinfection techniques can increase the risk for equipment damage and malfunctions, "leading to patient safety risks and increased costs."[4]

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2. Refer to device manufacturer's instructions for use.

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"The COVID-19 pandemic has opened the eyes of patients and healthcare professionals even wider to the need for proper sanitation," said Emily Lorcheim, Brand Manager for ClorDiSys Solutions. "Many healthcare associations are using increasing amounts of chemical methods of cleaning to not only combat viral transmission. However, these methods are often times not effective, or are damaging to surfaces. Many common chemical cleaners corrode surfaces, and even if not initially visible, there will be ever growing amounts of wear and pitting on these surfaces.

"As with any product used on reusable medical devices, ensuring those devices are not damaged/degraded by the product is essential," added Hendee. "Disinfectant chemistries, especially sodium hypochlorite, can have adverse effects on metals and plastics."

"Any amount of damage invites bacteria to enter even the slightest pitted or worn areas and begin biofilm formation," Lorcheim added, citing a study on the subject.[5] "Electronics are another item that are extremely tricky to clean because of the complexity and risk of damaging both the surface and internal components by use of chemicals."

One example of equipment that must be disinfected with care is ultrasound probes, explains Ken Shaw, President of the Americas, Nanosonics, stating:

"SPDs should ensure high level disinfectants are compatible with the ultrasound probes being reprocessed. Compatibility is essential to avoid probe damage. Damaged probes must be taken out of circulation, as they may have compromised image quality or could become reservoirs for pathogen growth, placing patient safety at risk. Probe manufacturers can void warranties if incompatible disinfectants are used so it's essential to consult both the probe and disinfectant manufacturer's IFU to ensure compatibility endorsement. If there are discrepancies, reach out to the manufacturers before implementing new products or processes."

Todd Campbell, President of TBJ, says while his company has not come across any issues with its customers using disinfectants that are damaging to their stainless steel sinks, ultrasonic cleaners, tables and cabinets during the COVID-19 pandemic, there has always been an issue with customers using bleach as a disinfectant and not following IFUs for dilution.

"Improperly diluted bleach solution has been an issue even before the pandemic," explains Campbell. "Bleach (sodium hypochlorite) should typically be diluted to a 10% solution (9 parts water, 1 part bleach). Bleach solution is corrosive to stainless steel; therefore, thorough rinsing must follow its use. Improperly diluted bleach or full-strength bleach will corrode and pit stainless steel very quickly. Customers then mistakenly think that the stainless steel is 'rusting.'"

Photo Courtesy: TBJ

Undiluted bleach exposure to type 304 stainless steel sink

How to select the right disinfectant

In its Hazard Communication for Disinfectants Used Against Viruses, the Centers for Disease Control and Prevention (CDC) notes how staff members must, "select the appropriate disinfectant based on the type of surface to be disinfected (e.g., hard surface, soft surface, electronics, fabric, etc.)."[3]

"The use of disinfectants in SPD must align with critical factors that play a role in the function and effectiveness of the products," said Malinda Elammari, Clinical Education Specialist, Healthmark Industries. "Factors such as dwell time dictate how long the product must remain wet on a surface to be effective."

"Other factors to consider are compatibility with the surface material, location and application of the disinfectant," Elammari continued. "For example, when disinfecting the surfaces of a nursery, one should never use a phenolic-based disinfectant. An additional factor that SPD must take into account is the safety measures related to each specific product."

"Comparing the materials compatibility stated in the device and the disinfectant manufacturer's IFUs will be important to avoid unwanted damage or corrosion," Hendee added. "If selecting a disinfectant wipe, consider how staff will meet the required contact time. Complying with a 5-minute wet dwell time will likely require an item to be wiped multiple times."

During the COVID-19 pandemic, CS/SPD and EVS professionals have faced a new enemy in terms of disinfection - SARS-CoV-2 – requiring new weapons in their arsenals, or confirmation that existing disinfectant solutions are effective against the virus.

In March 2020, Ruhof Corporation announced that its Biocide Detergent Disinfectant Pump Spray proved effective against COVID-19, and in September 2021, that the product effectively kills all SARS-CoV-2 variants, including the Delta variant.

"As our country continues to battle SARS-CoV-2-2 we are seeing additional variants of concern emerge, such as the Delta variant," said Noreen Costelloe, Director of Marketing Ruhof Corporation. "We take our responsibility to support our customers very seriously and have followed up with the U.S. Environmental Protection Agency (EPA which regulates claims on disinfectant product labels."

When asked for tips to evaluate the variety of products available today to disinfect instruments, Hendee states:

"My tip: Do your research ahead of time. Before purchasing a new device or the specific disinfectant recommended for it, use critical thinking. Ask yourself, is the facility already set up with everything needed to use it correctly? If the answer is yes, then that decision is more straightforward. If the answer is no, ask yourself, is there another device the facility is ready to use? The same applies to the disinfectant. If it requires specific tools or workflows to utilize properly, is the facility prepared for it. These details are important to know well ahead of the actual purchase."

Non-chemical alternatives

While chemical disinfectants have long been used in the healthcare environment, new technologies have emerged that effectively disinfect without the risks associated with harsh chemicals.

Lorcheim explains how the use of ultraviolet light is shown to be gentler on surfaces and more effective (compared with chemical disinfectants). She points to a study on smartphone sanitation, which found "UV-C sanitization methods are potentially superior to disinfection with bleach, ethanol or quaternary ammonium solutions…Because of the risks of smartphone damage with exposure to liquid disinfectants." This study also showed that UV-C was also the only sanitation mode that resulted in a complete kill of organisms as compared to chemical forms tested such as quaternary ammonium and bleach.[6]

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Nanosonics trophon2 ultrasound probe high-level disinfection (HLD)

Corporation Biocide Detergent Disinfectant Pump Spray

"UV-C has the ability to provide kill to wherever the light is shining, without the use of chemicals and often times these are areas not reached by human personnel," said Lorcheim. "It is a quick method of disinfection allowing for quick room turnover times. Plus, there is a reduction on excessive expenditures on consumables such as wipes. UV-C bulbs often have a lifetime of 16,000 hours, providing users a long return on investment."

Automated HLD

Automated high-level disinfection (HLD) is another advancement that can help support both patient and SPD staff safety, while increasing efficiency in the SPD, explains Shaw. He states:

"Automation mitigates staff chemical exposure risk compared to manual bulk liquid high-level disinfection methods. Automated methods are also validated, ensuring expected microbiological performance outcomes are consistently achieved without dependence on human factors. This is essential to guarantee reproducible disinfection for every patient, consistently mitigating infection risk."

"Automated processes also offer digitized traceability capabilities," Shaw continued. "Digitization supports traceability standardization by minimizing manual administrative burden and associated risk of incomplete record keeping, when compared to paper-based methods."

Cleaning one of the most contaminated spaces

While the CS/SPD department's goal is to deliver clean and sterilized instruments into the hands of clinicians, the first step is for technicians in decontamination to remove bodily fluids, tissue, hair and other contaminants left over on instruments from prior patient use.

How do environmental services (EVS) professionals effectively clean and decontaminate CS/SPD departments experiencing a constant flow of dirty instruments arriving from clinical areas? It's not easy.

Melissa G. Morgan, MSN, RN, CIC, CSPDT, FAPIC, Senior Systemwide Director for Infection Prevention & Sterile Processing for Moses H. Cone Health in North Carolina, recognized there were gaps in terminal cleaning for the health system's six sterile processing departments. She sought out room disinfection technology that was both effective and safe.

"We want to ensure that one of the most contaminated spaces in the hospital is as clean as possible," Morgan said.

Morgan and Cynthia Lee, Assistant Director for Moses H. Cone's Sterile Processing Department, chose to implement a pilot program with the Tru-D SmartUVC technology. The robot uses UVC wavelengths at 254 nanometers to inactivate microorganisms, such as bacteria, viruses and protozoa. It offers an effective, environmentally friendly and chemical-free way to

prevent microorganisms from replicating in an environment.

The Tru-D Sensor360 technology calculates the time needed to react to room variables, such as size, geometry, surface reflectivity and the amount and location of equipment in the room. The robot then effectively delivers the precise UVC dose needed during a single cycle from a single, central location in the room.

Tru-D and Moses H. Cone Health collaborated on a one-month trial to evaluate the system's effectiveness in the CS/SPD. At the trial conclusion, Morgan presented the business case to the health system's executive leadership, who approved the funds to purchase the device.

The Moses H. Cone Health EVS team has taken ownership of the UVC disinfection program, which Morgan believes has driven its success. Because the robot is activated by a remote control outside of a room, operators are free to complete other tasks, maximizing workflow and productivity.

"The staff loves having ownership of the Tru-D program, and they feel the organization values them for investing in this tool," commented Morgan.

"Our team at Tru-D worked hand-in-hand with Moses Cone to ensure a successful

trial," said Bob Taylor, Senior Regional Sales Manager for Tru-D. "We look forward to a long-lasting partnership." **HPN**

References

1. Protecting Workers Who Use Cleaning Chemicals, OSHA, NIOSH, https://www.osha.gov/sites/default/files/publications/OSHA3512.pdf

2. Exposure to Disinfectants, Cleaning Products Linked to COPD Risk Among Female Nurses, AJMC, October 29, 2019, https://www.ajmc.com/view/assessing-potential-biomarkers-in-copd-to-reduce-corticosteroid-antibiotic-intake

3. Hazard Communication for Disinfectants Used Against Viruses, CDC, https://www.cdc.gov/niosh/topics/disinfectant/default.html

4. UPDATE: Equipment damage due to improper cleaning and disinfection, Alberta Health Services, September 10, 2021, https://www.albertahealthservices.ca/assets/healthinfo/ipc/hi-ipc-memo-clean-critical-device-risk.pdf

5. Otter JA, Vickery K, Walker JT. Surface-attached cells, biofilms and biocide susceptibility: implications for hospital cleaning and disinfection. J Hosp Infect 2015;89:16-27

6. Lieberman, Mia T et al. "Evaluation of 6 Methods for Aerobic Bacterial Sanitization of Smartphones." *Journal of the American Association for Laboratory Animal Science : JAALAS* vol. 57,1 (2018): 24-29.

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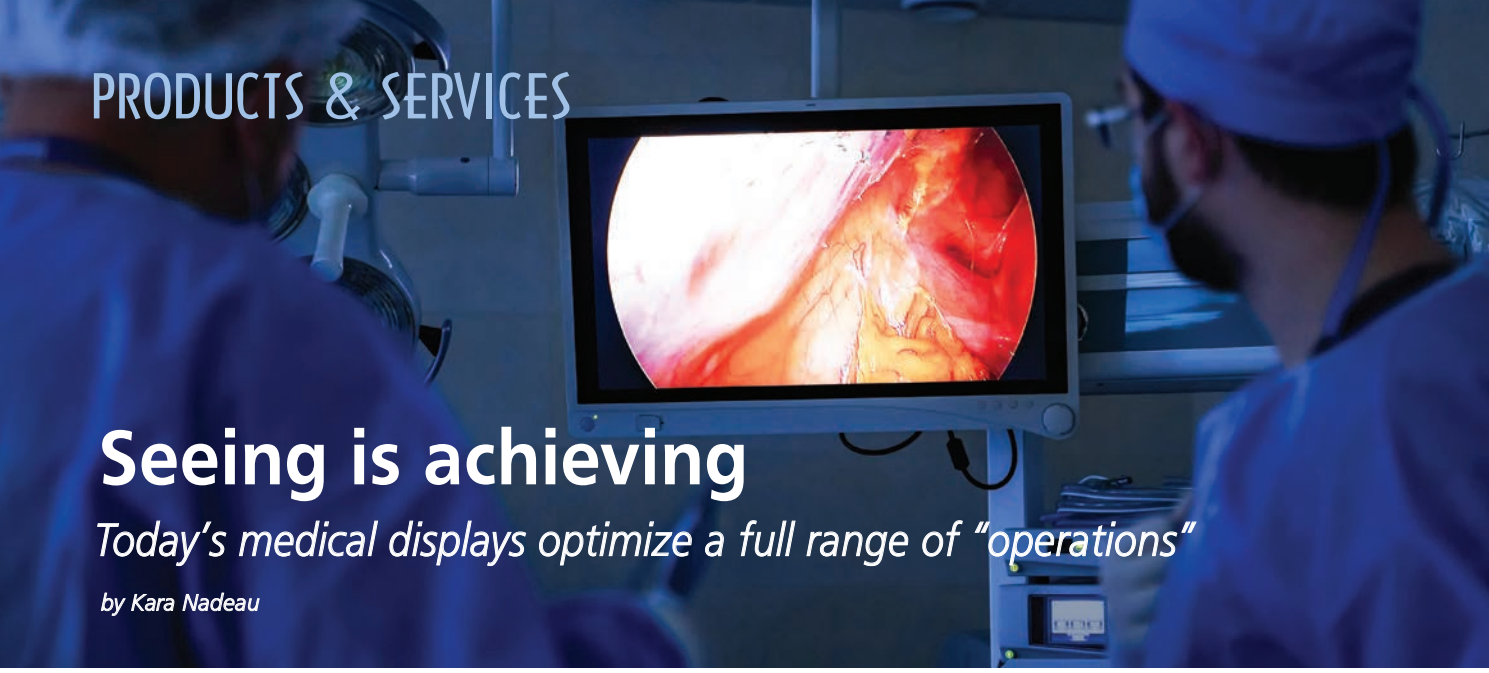


Seeing is achieving

Today's medical displays optimize a full range of "operations"

by Kara Nadeau

Photo credit: Vadim | stock.adobe.com

The desire for clinicians to see clearly inside the human body has driven the proliferation and advancement of instruments and devices for this purpose, including extremely high-resolution medical grade displays. It is big business. The global medical displays market is expected to reach $2.45B by 2025, driven by the growth in diagnostic imaging centers and hybrid operating rooms (OR).[1]

Manufacturers of medical displays and monitors continue to stretch the bounds of what can be made visible to the human eye to improve procedural precision and patient outcomes. At the same time, they are developing larger screens that can take the place of multiple, smaller monitors to improve procedural area workflows by reducing complexity and clutter.

Clinical training is another key consideration when it comes to medical display and monitor selection. With the shift to remote learning that has taken place during the COVID-19 pandemic, high-resolution displays can bring medical students into a surgery from anywhere when paired with supporting technologies.

And with safety always critical to successful patient procedures, medical display and monitor manufacturers are designing new products with infection control/prevention in mind.

The visualization evolution

According to Sony's Marketing Manager, Anne Bondulich, many of the trends in medial grade displays and monitors are tied to the pursuit of better visualization during surgery and post-procedure. She points to 4K, 3D and High Dynamic Range (HDR) as some of the latest technology innovations in this area, stating:

"4K offers four times the resolution of standard HD and virtually no pixelation. This is helpful for medical professionals because the enhanced level of detail, clarity and in turn, more information, provides a better view of a procedure."

Bondulich says Sony's 4K medical displays can also provide upscaling of HD video content. Additionally, medical teams using Sony's 4K display technologies have the capability to see a "quad-split" view of four full HD signals (1920x1080) on one display, helping them view four full HD sources at one time.

"3D offers depth of field that helps to increase immersion," Bondulich explains. "In addition, HDR delivers better contrast with more realistic peaks of brightness, shadow detail and deeper blacks, which are important when identifying and working with blood, blood vessels, nerves and other critical structures. All of these technologies help provide more engaging and realistic training and education."

"In addition, having access to the most advanced tools and technologies helps surgeons see more, be more efficient and helps promote accuracy," she added. "Having enhanced access and visualization can result in the potential for improved patient outcomes."

LMD-X3200MD, 32-inch 4K 2D LCD medical monitor from Sony

Larger displays maximize visibility, reduce OR footprint

The continued growth in the types and number of minimally invasive surgical procedures performed on patients has driven the need for improved surgical imaging. Between 2016 and 2020, minimally invasive surgery demand grew 4% and this demand is expected to continue in the years ahead driven by the benefits over open surgeries (e.g., less trauma, reduced complication risk, faster recovery times, etc.).[2]

Hilary Dilsaver, Product Manager, 4K Imaging, Surgical Endoscopy, Olympus America, has seen an increase in Big Screen end-to-end 4K monitor (often 55") usage for laparoscopy in the OR, which enables surgical teams see four times the resolution of HD imaging for help in visualizing details in difficult procedures, stating:

"The larger, natural color gamut helps in delineation of tissue boundaries, visualization of blood vessels and lesions. The larger monitors also may provide the OR staff a more immersive experience. All eyes can be on the Big Screen monitor regardless of an OR team member's position in the room."

Dilsaver explains how 4K systems deliver four times the pixels, higher resolution, better light and a wider color gamut than High-Definition (HD) displays for a Big Screen Surgery experience in the OR.

While the vast array of equipment for surgeries is growing, in most cases the square footage of ORs is not. Surgical staff members struggle to care for the patient surrounded by machines, monitors, cords and other related items. Dilsaver says Big Screen monitors help OR teams overcome this challenge:

"By using a larger screen, hospitals are replacing the clutter of smaller monitors in the room as well as decreasing the footprint in the OR."

55" 4K UHD Monitor in Operating Room, by Olympus America

Displays designed for infection prevention

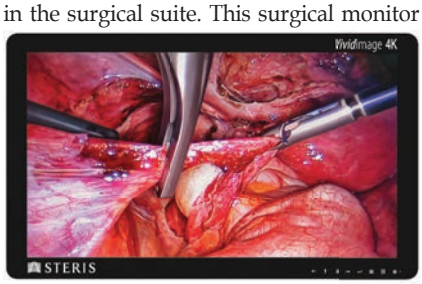
Hospital-acquired infections (HAI), including surgical site infections (SSI), endanger patient lives and add billions of dollars in healthcare costs each year. Research has shown that in "open clean surgery, risk of SSI is strongly correlated with the amount of airborne bacteria being present in the operating room and the surgical field."[3]

Medical display and monitor manufacturers are designing new technologies with features that reduce the risk for contamination of the sterile field from airborne microbes, as Matt Bottino, Director of Marketing, Surgical Solutions, STERIS, describes:

"STERIS Surgical Displays are designed for use within the sterile field or any clean environment. Unlike other displays, STERIS Surgical Grade displays are sealed, ventless and fanless so they don't collect or blow contaminants into the environment. They can also be disinfected quickly without worry that the cleaning agent will get inside the display."

The STERIS Vividimage 4K Surgical Display delivers accurate, true-to-life surgical video in the OR. With four times the detail of HD video, surgeons experience greater visual depth and a wider range of colors allowing them to visualize fine details in tissues and structures.

With a sealed, fanless and durable design, the Vividimage 4K Surgical Display is silent, easy to clean and highly resistant to impact in the surgical suite. This surgical monitor is also designed for staff comfort and safety, offering a black bezel to reduce eye strain and a white back for visibility in a dimly lit OR.



STERIS Vividimage 4K 31.1" Ultra High-Definition Surgical Display

Streamlined education and training

The consolidation of monitors and displays can help with staff education as clinicians can train on fewer pieces of equipment, explains Katie Szyman, Corporate Vice President, Critical Care, Edwards Lifesciences.

"Our latest monitor, HemoSphere advanced monitor, is the only monitoring platform on the market that offers compatibility with noninvasive finger cuffs, sensors and catheters," said Szyman. "We believe the all-in-one solution is an important advancement, and one that could help clinicians and hospitals on many fronts." This full-range compatibility enables individualized patient management across a diversity of patient profiles and across care settings and can help simplify the variety of different monitors a hospital needs to purchase.

HemoSphere advanced monitor from Edwards Lifesciences.

Beyond sensor and catheter compatibility, HemoSphere monitor has a mobile application that enables clinicians to view patient data from their smartphones so they can closely track and manage multiple patients in different rooms at one time. The mobile application will be available later this year.

The HemoSphere monitor also supports more efficient and effective clinician workflows through its software. Szyman says it is the only monitor on the market that is compatible with software that predicts the likelihood of intraoperative hypotension, Acumen Hypotension Prediction Index software.

"Intraoperative hypotension is common and associated with risks such as acute kidney injury and myocardial injury," Szyman explained. "Using the HemoSphere monitor along with a noninvasive cuff or an arterial line sensor, clinicians can access this software and get an alert if a patient is trending towards a hypotensive event. The clinician can also get insights on the root cause and inform a potential course of action."

In support of remote learning

The COVID-19 pandemic has presented significant challenges to medical education and training. An international team of clinicians from the U.S., UK and Europe published a review article in 2020 on the subject, stating:

"The shutdown of academic institutions, alongside the novel challenge imposed on healthcare systems worldwide, have taken an immense toll on the quantity and quality of medical education. Medical students and junior doctors are thus faced with the oxymoron of not receiving adequate education but being required to potentially serve in the frontlines. How can medical students and residents bridge the gaps created in their training, and ensure that they will continue to receive the knowledge and skills required to progress as competent and safe clinicians?"[4]

The Association of American Medical Colleges (AACM) describes how medical educators shifted their approach as "Webcams captured hospital rounds, 3D images replaced cadavers, and Zoom classes had students raising virtual hands to debate diagnoses."[5]

Bondulich comments on the trend toward virtual learning for medical students and describes how medical displays have supported this new approach:

"The pandemic forever altered how medical students are trained on surgical procedures. The benefits of having fewer people in an operating room to minimize the spread of disease rapidly came into focus. Having tools like a large, state-of-the-art display helps everyone inside or outside of the OR to have the same view as the primary surgeon – whether it's members of the care team or students."

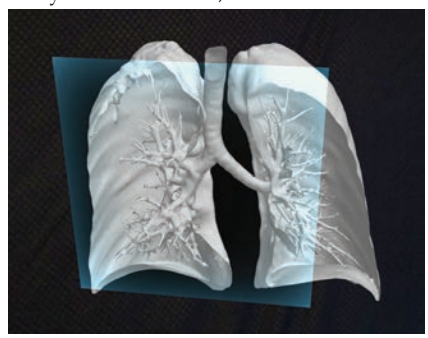
"What's also beneficial is that Sony's displays can easily be integrated with remote monitoring solutions including PTZ cameras and the Sony NUCLeUS video-over-IP system to enable a live surgery to be viewed remotely, from virtually any location in the hospital, including conference rooms or lecture halls," Bondulich added.

The future of surgical imaging and visualization

Innovation never stops, especially in the medical field. Manufacturers are constantly working to develop new technologies that will enhance visualization during surgery and the surgeon experience. Here are two new products recently announced by

manufacturers that leverage digital capabilities, such as artificial intelligence (AI), machine learning (ML), extended reality (XR), robotics and computer vision (CV).

Cloud-enabled, 3D modeling:
DICOM Director's Intravision XR is a cloud-based, 3D model medical software tool that automates the process of creating fully formed 3D models from any DICOM dataset, such as CT and MRI scans. Models contain complete anatomical detail, including spatial relationships between organs and their internal structure. Pending FDA approval.



Dicom Director's Intravision XR hologram

"The potential of INTRAVISION XR technology extends not only to patient education and surgical planning but will also push the barriers of actual real-time surgical guidance," said DICOM Director's CEO David B. Pearlstone, MD, MBA. "With object placement and registration we will have the capability to create 'virtual x-ray vision' in the OR."

AI-enhanced laser visualization;
Certes by Perfusio allows surgeons to see the actual dynamic physiology of blood flow distribution in tissue, using a proprietary combination of multi-spectral imaging and AI-enhanced laser speckle contrast analytics with immediate real-time display of quantified tissue perfusion.

Perfusio Certes multi-spectral physiologic visualization (MSPV) surgical imaging technology

"The uncomfortable truth is that annually in the U.S. there are over 400,000 preventable surgical adverse events at a cost of over $29B," said Perfusio CEO Monte B. Tucker. "A major contributor to these events is sub-optimal blood flow in critical tissues that is unable to be recognized by the surgeon using visible light."

Perfusio's Certes resolves this dilemma by providing new knowledge utilizing multiple wavelength illumination and AI-enhanced analytics based on laser speckle contrast imaging to display in immediate real-time multi-spectral physiologic visualization (MSPV) of the actual dynamic physiology of blood flow distribution in tissues.

MSPV does not require patient contact, dyes or ionizing radiation. It is safe for patients and providers, even when used multiple times during an operative procedure to enhance surgeon judgment and decision-making. MSPV immediately identifies which tissues have normal perfusion, and which tissues do not, giving the surgeon the opportunity to identify and correct perfusion problems at the time of the initial procedure.

"Our purpose at Perfusio is to implement solutions that improve patient lives and to create significant overall savings to the healthcare system by developing a new standard of care with AI-enhanced visualization and new knowledge," Tucker added.

Google Maps for the body[6]

Proprio, based in Seattle, is developing an advanced surgical imaging platform that leverages CV and ML to improve surgical navigation. By synthesizing views from multiple sensors, the platform enables users to navigate surgical environments in 3D.

"Proprio is developing a revolutionary medical technology that combines XR, AI, robotics and computer vision to empower surgeons to perform surgery more efficiently," said Gabriel Jones, Proprio Co-founder and CEO. "Today, surgeons use navigation to improve accuracy but have to accept that it takes more time and reduces efficiency. At Proprio, we recognize there is an unprecedented opportunity to optimize surgical performance by connecting technology with surgical ability. Our goal is to transform the operating room by creating the new way of seeing." HPN

Propio advanced surgical imaging platform leveraging XR, AI, robotics and computer vision

References

1. Global Medical Display Market, Size, Outlook, Trends and Forecast (2021-2026), Envision Intelligence, June 30, 2021, https://www.envisioninteligence.com/industry-report/global-medical-display-market/

2. Minimally Invasive Surgery Market to Surge 1.6x, back by Preference for Robotic Surgery: Fact.MR Study, Fact.MR, September 27, 2021, https://www.factmr.com/media-release/2368/global-minimally-invasive-surgery-trends

3. Persson M. Airborne contamination and surgical site infection: Could a thirty-year-old idea help solve the problem? Med Hypotheses. 2019 Nov;132:109351. doi: 10.1016/j.mehy.2019.109351. Epub 2019 Jul 31. PMID: 31421424.

4. Medical and Surgical Education Challenges and Innovations in the COVID-19 Era: A Systematic Review, In Vivo, May/June 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8378024/

5. No classrooms, no clinics: Medical education during a pandemic, AAMC, April 15, 2020, https://www.aamc.org/news-insights/no-classrooms-no-clinics-medical-education-during-pandemic

6. "Google Maps for the human body" – AI's rise in surgical tech, June 9, 2021, https://www.propriovision.com/news/google-maps-for-the-human-body-ais-rise-in-surgical-tech

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LEARNING OBJECTIVES

1. *Explain the importance of a quality PM program*
2. *Recognize adverse events related to non-functioning, broken, or contaminated instruments*
3. *Discuss the elements of a successful PM program.*

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SELF-STUDY SERIES

Comprehensive PM for surgical instruments

by Malene McLain

Surgical services are a central function in most hospitals. They typically account for 40% of a hospital's operating expenses and generate about 70% of its revenue.[1] Because surgery is such a vital revenue stream for the hospital, keeping costs down is important to ensure that the hospital meets its fiscal responsibilites. A significant portion of an operating room (OR) budget is allocated to cleaning, maintaining, and repairing surgical instruments. To keep ORs running efficiently, it's important to have a plan for ensuring that all surgical instrumentation is functioning safely and effectively and is procedure-ready. A comprehensive preventive maintenance (PM) program helps ensure that instruments are well cared for, free of bioburden, and functioning properly.

Just as routine maintenance of a car can lengthen its lifespan, prevent significant performance changes, and help avoid expensive repairs, surgical instruments can benefit from a PM program. PM and repairs help avert costly damage and extend the lifespan of hospital instrument inventories, both of which save a facility money.

There are also indirect costs associated with using non-functioning, broken, or improperly cleaned instruments, such as avoidable surgical site infections and other adverse patient events. To get an accurate accounting, hospitals cannot just look at the direct cost to repair and maintain instruments; they also need to look at the consequential costs of injuries associated with instruments that are not effectively maintained. Patient safety is a priority and removing these risks and costs must also be a primary goal.

This self-study article discusses the importance of a PM and repair program, the risks associated with poorly maintained instrumentation, and considerations for a successful PM program.

The value of a quality PM program

A large hospital in the Midwest found that it had reoccurring deep-tissue infections that were traced back to one specific surgeon. This surgeon was using Kerrison rongeurs for the majority of his surgeries. When these rongeurs were inspected, technicians discovered they had retained bioburden inside the instruments. It turned out that these older rongeurs could not be taken apart and cleaned properly in the sterile processing department (SPD).

A senior manager from this facility called an instrument repair company, asking if they could come in and teach their staff how to disassemble, reassemble, and clean the rongeurs properly. After much discussion, the hospital realized that the risk they would be assuming by using existing staff to disassemble and reassemble the instruments for cleaning and inspection was too great. Management decided that the instrument repair company would take on that task. Since the doctor operated on Mondays and Wednesdays, the repair company came in on Tuesdays and Thursdays, at a cost of $3,000 per day, to disassemble, clean, and adjust the devices. After approximately 24 weeks

Figure 1: Kerrison Rongeur

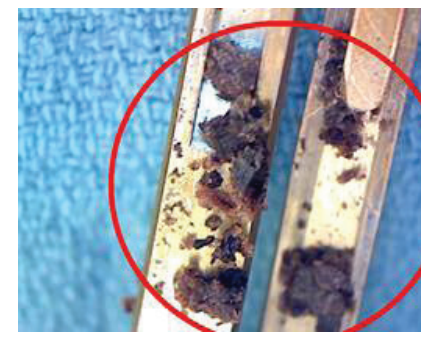

Figure 2: Bioburden inside Kerrison Rongeur

and $144,000 spent, the cleaning regimen was successful and stopped the deep tissue infections. However, the hospital realized that the most cost-effective long-term solution was to purchase the newer, disassemblable Kerrison rongeurs, which would enable their staff to properly clean the instruments. This eliminated costly weekly visits from the instrument repair company and saved the hospital several thousand dollars in the long run. This example shows the importance of having a PM program that can identify instrument issues before they affect patient care and outcomes.

A quality PM program may not result in immediate cost savings, but the long-term savings can be significant. "Hospitals that had proactive maintenance programs were able to address budgeting issues more quickly and the severity of damage to instruments was reduced when customers embraced education as part of their PM programs."[2]

Adverse events are costly

The quality and functionality of surgical instruments is a critical factor in ensuring the highest standards and best patient outcomes. When instruments fail or break during a surgical procedure, the consequences to the patient can be catastrophic. An article presented by the National Center for Biotechnology Information stated, "There may be as many as 1,500 incidents a year of poor-quality surgical instruments causing harm."[3] In 2008, the U.S. Food and Drug Administration (FDA) published an alert that stated, "Nearly 1,000 incidents of retained pieces of broken instruments (unretrieved device fragments) occur each year, leading to a range of problems including local tissue reactions, infections, disability, and even death."[3] The graph shows a percentage breakdown of seven common unretrieved fragment sources.

The high costs associated with this type of preventable harm affect the hospital and its patients and increase overall healthcare costs for the general public. In 2008, it was estimated that preventable harm in the United States costs as much as $19.5 billion.[4] Not all this cost is associated with instrument failures or retained bioburden, but it is considered to be a part of the problem.

According to a January 2021 report by The Joint Commission, the highest number of sentinel events (events that result in death, permanent harm, or severe temporary harm) for surgical or invasive procedures was unintended retention of a foreign object. Between 2018 and 2020, there were 362 reported events of retained foreign objects. Even though the FDA mandates that any serious injury or death caused by surgical equipment must be reported, there is no mandate to report it to the Joint Commission.[5,6]

By establishing a comprehensive, thorough PM program, a hospital can mitigate much of the risk of adverse events related to broken devices or retained bioburden. SPD follow the original equipment manufacturer's instructions for reprocessing and repair, but it can be expensive to return instruments to the manufacturer for repair. In 2014, the U.S. Centers for Medicare and Medicaid Services (CMS) updated their 42 CFR 482.41(c)(2) standard concerning the equipment maintenance requirements for hospitals. The standard now allows hospitals to seek alternative methods for inspection and repair of surgical instrumentation that may be less expensive, but these methods must still ensure that instruments are safe for use and fully functional.[7]

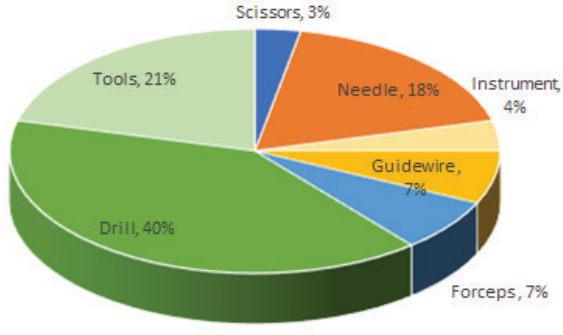

Figure 3: Distribution of broken instruments in reported patient safety incidents between August 2004 and December 2010 (Dominguez E, Rocos B., June 10, 2019). Patient Safety Incidents Caused by Poor Quality Surgical Instruments. Cureus 11(6): e4877. doi:10.7759/cureus.4877)

Alternative Equipment Maintenance (AEM) programs

The Code of Federal Regulations CFR 482.41 (c)(2) states that "Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and equipment." It also states that all equipment must be tested before initial use and after repairs or upgrades to ensure that it is functioning properly and is safe to use on patients. As noted by CMS, an AEM program allows a healthcare facility to "adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment from what is recommended by the manufacturer, based on a risk-based assessment by qualified personnel."

AEM programs are strictly regulated to minimize risk to patients and other people in the hospital. The maintenance must adhere to specific guidelines for documenting how the instruments are inspected and repaired. Once an SPD decides to adhere to AEM activities, it needs to determine what type of maintenance strategy it will employ. The types of maintenance strategies include *PM* (time-based), *predictive maintenance* (condition-based), *reactive maintenance* (corrective, breakdown or run-to-failure), or *reliability-centered maintenance*.

A PM program may not seem to be cost-effective at the beginning. However, in the long run it can save a hospital thousands of dollars every year because it's designed to identify small problems before they become major issues. According to the Centers for Medicare and Medicaid Services, a PM program is "a strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance."[8] Regardless of whether a hospital follows the original equipment manufacturer's maintenance instructions or an AEM program, all maintenance must be accurately documented to provide a record of maintenance activity.

Considerations for a successful PM program

Avoid disruption

Surgical instruments need to be ready whenever they are needed for a case. Therefore, SPD managers need to develop PM programs that will ensure as little disruption to their hospitals' surgery schedules as possible. For example, they need to determine which trays are the most frequently used, and then make sure scissors are sharpened, needle holder jaws are inspected for wear, and osteotomes, rongeurs, and other cutting devices are tested for sharpness on a regular schedule that works around the surgical schedule. A PM plan will include a schedule for all instrument sets to be routinely inspected for serviceability when they can easily be pulled out of use.

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

Maintain communication

In addition, thorough and timely communication is a must between the SPD and the surgical services department to mitigate any problems with unavailable trays or instruments. Because surgical volumes can change, there needs to be precise communication as to when the instruments or sets will be down for inspection, maintenance, or repair and when they are expected to be back in inventory.

Plan for the unplanned

The SPD also needs to make sure there are enough sets/instruments available for high-volume case days. A maintenance and repair program should never interrupt surgery schedules to the point of needing to cancel cases. Responsive communication with the repair company is another important factor in managing instrument inventories to ensure that the hospital is prepared to handle surges and emergent cases.

Assess repair companies

There are many companies that offer instrument/equipment repairs, but not all offer the same quality of service. Hospitals should research what each company offers in terms of service, frequency, cost, experience of repair technicians, guarantees, and accountability. Furthermore, what works for one hospital may not work for another hospital. Factors such as surgical volume, the number of instrument sets in inventory, the number of personnel, the instrument maintenance budget, and the availability of extra instruments all play a role in determining the type of PM program that will be best for a specific hospital.

Assess your issues

In order to develop a successful PM plan, both the hospital and the repair company need to have a thorough understanding of the extent of the problem. Specifically, they need to assess how many instruments are failing, the number of times an instrument or set has been serviced in a specific amount of time, how often surgeries have been delayed or canceled due to instruments that are broken or unavailable, and what these issues have cost in the past. This will give the hospital a basis from which to negotiate a contract with a repair company, and it will help the repair company understand the level of involvement that will be required.

Establish and implement the plan

Between the hospital and repair company, a plan is then negotiated that will allow continuity of service to the operating room while also making sets available to be inspected. Often the plan will include a negotiated number of trays to be serviced per visit/year. This then correlates to the number of trays that the repair teams and the hospital staff can handle in a given service visit, which then correlates to the number of visits needed per week/month/year. Once a plan is established, it needs to be implemented and documented to ensure sets are being serviced as contracted.

Repair companies can work onsite within the hospital to repair and inspect surgical instruments and devices. More often, however, they either arrive with a truck in which they perform the work, or for more complex repairs they have the instruments shipped to their facilities. Typically, work is done onsite if repairs are not too extensive.

Protect instruments, patients and budgets

The cost of healthcare has skyrocketed in the past 10 years. That cost is increased by each surgical case that has an adverse outcome because of a broken, non-functioning, or dirty instrument. Hospitals have a duty to ensure patient safety and prevent avoidable adverse events, but they also need to find ways to contain healthcare costs.

When sterile processing leaders invest in robust, comprehensive PM programs, they also help keep instrument purchasing costs down. Instead of being discarded, the majority of poorly functioning instruments can be repaired and effectively maintained. And since it is less expensive to repair an instrument than to buy a new one, performing PM on a hospital's instrument inventory will help reduce the long-term cost of surgical asset management. Improving patient safety while also reducing instrument management costs creates a win-win situation for hospitals. **HPN**

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Figure 4: Inside a lab

Figure 5: Instrument sharpening

References:

1. Open Anesthesia. OR Costs: Labor vs Materials, Open Anesthesia. https://www.openanesthesia.org/or_costs_labor_vs_materials/ Accessed September 7, 2021.

2. Costello, R. (January/February 2013) PM saves money in the long run, Vendor Vantage, IAHCSMM Communique', pg. 76-77.

3. Dominguez E, Rocos B Patient safety incidents caused by poor quality surgical instruments. *Cureus* 2019 11(6): e4877. doi:10.7759/cureus.4877 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6687421/ Accessed October 1, 2021.

4. Bernazzani, S. Tallying the high cost of preventable harm. Costs of Care. 2015 https://costsofcare.org/tallying-the-high-cost-of-preventable-harm/ Accessed October 1, 2021.

5. The Joint Commission. Definition of sentinel event. https://www.jointcommission.org/resources/patient-safety-topics/sentinel-event/ Accessed July 14, 2021.

6. The Joint Commission. Summary data of Sentinel Events reviewed by The Joint Commission January 27, 2021 summary SE report 2020.pdf

7. Center for Medicare and Medicaid Services Manual System, Department of Health & Human Services Centers for Medicare & Medicaid Services 42 CFR 482.41(c)(2) State Operations Manual Rev. 103, Issued 02-21-14.

8. Center for Medicare & Medicaid Services (CMS) (2013) CMS memorandum to state survey agengy directors: Hospital equipment maintenance requirements. Issued 12/20/2013 https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-07.pdf Accessed October 1, 2021.

9. Dietshe, E. How much will adverse patient safety events cost the healthcare system? MedCity news 2018 https://medcitynews.com/2018/02/much-will-adverse-patient-safety-events-cost-healthcare-system/ Accessed October 1, 2021.

10. Hospital equipment maintenance requirements Survey & Certification Letter. S&C:14-07-Hospital. 2013. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-07.pdf Accessed July 14, 2021.

11. Keluskar, S. (2017, September 15) FDA seeks to lay down guidelines for surgical instrument repair, Persistence Market Research https://www.persistencemarketresearch.com/news/2017/september/fda-seeks-to-lay-down-guidelines-for-surgical-instrument-repair Accessed October 1, 2021.

12. Shultz, R. (May/June 2019) Instrument repair secrets that can help deliver better outcomes, greater value, pg. 76-78, www.iahcsmm.org May.June-2019-Instrument-Whisperer-Final.pdf. Accessed October 1, 2021.

CONTINUING EDUCATION TEST • NOVEMBER 2021

Comprehensive PM for surgical instruments

Circle the one correct answer:

1. **What is the typical percentage of a hospital's revenue attributed to surgical services?**
   a. 50%
   b. 20%
   c. 40%
   d. 70%

2. **Non-functioning, broken, or improperly cleaned instruments can cause surgical site infections.**
   a. True
   b. False

3. **There may be as many as _____ incidents a year of poor-quality surgical instruments causing harm.**
   a. 1,200
   b. 1,000
   c. 1,500
   d. 500

4. **A comprehensive and thorough PM program will _____.**
   a. Mitigate the risk of adverse events
   b. Cost millions of dollars per year
   c. Only be effective if they repair 500 instruments a year
   d. Help a hospital pass The Joint Commission audit

5. **The _____ allows hospitals to seek alternative methods for equipment maintenance and repairs.**
   a. FDA
   b. OEM
   c. CMS
   d. DHHS

6. **_____ is a strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance.**
   a. Predictive Maintenance
   b. Reactive Maintenance
   c. Reliability-Centered Maintenance
   d. Preventive Maintenance

7. **When assessing a repair company, a hospital needs to look at cost, frequency of service, and _____.**
   a. Accountability
   b. Experience of repair technicians
   c. Guarantees
   d. All the above

8. **A PM program helps assure that instruments are _____.**
   a. Repaired every week
   b. Procedure-ready
   c. Replaced every 6th use
   d. Steam sterilized

9. **The biggest percentage of unretrieved device fragments was from:**
   a. Needles
   b. Drills
   c. Forceps
   d. Guidewires

10. **Investing in a robust, comprehensive PM program ... _____.**
    a. Helps keep instrument costs lower in the long run
    b. Costs millions of dollars to implement
    c. Helps with employee satisfaction
    d. Makes surgeons angry

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The approval number for this lesson is **STERIS-HPN 210410** .

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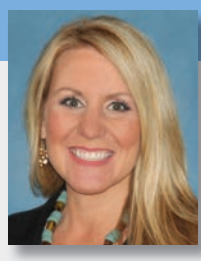

IAHCSMM VIEWPOINT

IAHCSMM Fellowship

Take next big step in professional journey

by Julie E. Williamson

Sterile Processing (SP) professionals can take numerous steps in their career journey—from becoming certified, serving as a mentor, scaling the rungs of the professional ladder to embrace leadership opportunities, and committing to continuing education and other approaches that can help set them apart within the discipline. Attaining Fellowship (FCS) status through the International Association of Healthcare Central Service Materiel Management (IAHCSMM) is another worthy pursuit, and it's an honorable distinction being earned by a growing number of professionals in recent years.

Many disciplines have Fellowship programs. For each, earning Fellowship status conveys one's commitment to excellence and professional development. IAHCSMM Fellowship helps demonstrate one's knowledge, dedication and professional advancement in the SP discipline by fulfilling a series of Fellowship requirements that includes an initial application and reference process and the submission of an original research paper topic and proposed outline; the completion of a detailed, well-researched paper on a topic pertinent to the profession; and (following the acceptance of the research paper) an interview with Fellowship committee members.

"The Fellowship process is, by design, challenging but it's also very rewarding. When a person becomes an IAHCSMM Fellow, they have done the hard work necessary to achieve this elevated and honorable status," explains Natalie Lind, CRCST, CHL, FCS, IAHCSMM's Education Director and Fellowship Committee member. "Fellowship isn't for everyone, and it is not something that all applicants will achieve, but that's precisely what makes attaining Fellowship status so special and worth the work."

Prior to 2021, there were only 25 IAHCSMM Fellows, but that number recently grew by four, (and more candidates are currently in various stages of the Fellowship process). This year's four new Fellows submitted excellent research papers, each covering unique and timely topics that underscored the authors' personal experiences and perspectives through thoughtful content and hard data. The research papers will be posted online in their entirety in early 2022 at https://www.iahcsmm.org/education/fellowship.html#CurrentFellows. Abbreviated versions of each paper will also be published in IAHCSMM's *PROCESS* magazine throughout 2022, beginning with the January/February issue. HPN

IAHCSMM would like to introduce and congratulate the following four new Fellows:

Delores O'Connell, LPN, BA, AGTS, ASQ-CQIA, CRCST, CIS, CHL, CER, CSPDT, FCS

Senior Clinical Education Specialist
STERIS Corporation

Research paper topic: Aligning the Reprocessing of Dental Instrumentation with ANSI/AAMI ST79:2017

Brenda Jan Prudent, CRCST, CIS, CHL, CER, CFER, FCS

Sterile Processing Manager
Eastern Idaho Regional Medical Center

Research paper topic: Raising the Bar by Centralizing the High-Level Disinfection Processes

Cheron Rojo, BS, CRCST, CIS, CER, CFER, CHL, FCS

Clinical Educator Coordinator-SPD
Healthmark Industries

Research paper topic: Inspection and Integrity Testing of Insulated Instruments—Concerns for Failure and New Guidelines for Testing

Tony Thurmond, CRCST, CIS, CHL

Central Service Manager
Dayton Children's Hospital

Research paper topic: Developing an In-House Instrument Repair Department

What Is IAHCSMM Fellowship?

IAHCSMM's Fellowship Program was developed to recognize the competency of its members and provide a measure of achievement that will be meaningful even to those outside the organization.

Fellowship status is among the highest honors professional organizations can bestow upon their members. As such, IAHCSMM Fellowship is an honorable distinction that must be earned through hard work, a commitment to professional excellence, and a desire to raise the bar as both an IAHCSMM member and as a contributor to the Sterile Processing profession.

Ready to learn more and take the next steps toward IAHCSMM Fellowship attainment? Visit https://www.iahcsmm.org/education/fellowship.html.

Basic IAHCSMM Fellowship Requirements

1. Must be an active IAHCSMM member in good standing for at least five years and hold the Certified Registered Central Service Technician (CRCST) designation;
2. Must have responsibility for the direction of a Sterile Processing department or have an interest by virtue of practice; and
3. Must complete the Fellowship application (www.iahcsmm.org/images/Education/Fellowship-Application.pdf) and submit a Curriculum Vitae, two professional letters of recommendation, and a research paper and detailed outline. Upon approval of the application/submissions, applicants must then write and submit a well-researched and well-written paper on their approved topic. Once the paper has been accepted by the Committee, the applicant will sit for an interview with the Fellowship Committee to demonstrate knowledge of the information presented in the research paper.

4 examples of Julian dating for SPD tracking; label symbol question

by Stephen Kovach

Q I just moved to a different medical facility, and they use Julian dating. This is different than what I have used before. I thought there is only one form of Julian dating. Are there more?

A The Julian date is the continuous count of days since the beginning of the Julian period and is used primarily by astronomers, military and in software for easily calculating elapsed days between two events (e.g., food production date and sell by date). It starts January 1 as 001.

Many departments use Julian dates to show when the sterilization of their items occurred, and I have seen Julian dating used in many formats over the years. It is important to read the policy at your specific facility. Here are some examples of Julian dating and a translation of how it is used.

Example 1
Julian Date 12032 (YYDDD)
= 2012, February 1

Julian Dates	Correlation
12032 (YYDDD)	February 1, 2012
12 (YY)	Year 2012
032 (DDD)	Day 32 = Feb 1

The first two digits (YY) represent the year the item was sterilized. The last three digits (DDD) represent the day of the year starting with January 1 as 001 and continuing with each day of the year in sequence.

Example 2
Julian Date 03212 (DDDYY)
= February 1, 2012

Julian Dates	Correlation
03212 (DDDYY)	February 1, 2012
032 (DDD)	Day 32 = Feb 1
12 (YY)	Year 2012

In Example 2, the digits invert. The first three digits (DDD) represent the day and the last two (YY) represent the year the item was sterilized.

Example 3
Using Julian dating for Date-only (DDD)
Julian Date 028 = January 28

In Example 3, notice the year is not part of the Julian date. It uses the first three digits (DDD) to represent the month/day only. At many medical facilities for which I have worked, they just use the Julian date on Biological Indicators and wrapped items.

Example 4
026210105 (DDD | YY | SS | LL)

Example 4 combines the Julian date and sterilization information to make nine-digit segments.

- The first three digits *026* equal the date January 26.
- The fourth and fifth digits *21* in this example represent the year 2021.
- The sixth and seventh digits *01* is the sterilizer number, thus, sterilizer 01 was used to sterilize this item.
- The eighth and ninth digits *05* represent the load, which was the fifth load of the day.

Digit Segments	Correlation
026	January 26 (DDD)
21	Year: 2021 (YY)
01	Sterilizer number (SS)
05	Load of the day (LL)

All packages intended for use as a sterile product should be labeled with the lot control identification. The "sterilization label" or "load sticker" should include: (a) the sterilizer identification number/code, (b) the date of sterilization, and (c) the cycle number. This is necessary if a sterilization recall is required, and items must be retrieved. Julian dating, in my view, makes it easy for tracking items sterilized because the Julian day, or Julian day number (JDN), is the number of days that have elapsed since January 1.

Here is an example of a label gun and labels you can use.

As you can see, there are many ways to track sterile supplies that are sterilized in-house using the Julian date system. This dating system allows a facility to meet the requirements in the various standards a medical device reprocessing department must abide by for "Best Practice."

Q Can you tell me what this symbol means? (See Figure 1). I saw it for the first time on one of my peel pouches.

Figure 1

A Medical device manufacturers have various standards they need to follow. Symbols are one way to communicate a universal message.

When it comes to labeling, two of the many standards manufacturers follow are ISO 15223 and ISO 20417. The symbol you asked about means, "Do not use if the sterile barrier system is damaged." HPN

References

Association of Surgical Technologies (AST). (2009) *AST Standards of Practice for Packaging Material and Preparing Items for Sterilization*. https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard_Packaging_Materials_Preparing_Items.pdf.

IAHCSMM: Instrumental to Patient Care®. (2016) *IAHCSMM CCSVP Vendor Education Program Module 4 Sterilization*. https://www.iahcsmm.org/images/Education/CCSVP_Modules/CCSVP_Module_4_July_2016.pdf.

n.a. (1976; 2010). Infection Control/Central Service: Sterilization Quality Assurance Procedure. *Hospital Topics, 54*(4), 1-44. DOI: https://doi.org/10.1080/00185868.1976.9950346. https://www.tandfonline.com/doi/abs/10.1080/00185868.1976.9950346?needAccess=true&journalCode=vhos20.

University of Toledo Medical Center Sterile Processing Department (UTMCSPD). (2006; 2020). Subject: Operation of Steam Sterilizers in SPD. https://www.utoledo.edu/policies/utmc/sterile_processing/pdfs/SP3-3-operation-of-steam-sterilizers-in-spd.pdf.

Quora. (2020). *Why does the military use the Julian date system?* Quora, Inc. https://www.quora.com/Why-does-the-military-use-the-Julian-date-system.

Sterile Processing *matters*, there's just no operating without it

by Rick Dana Barlow

The following refrain bears repeating … frequently: Sterile Processing is the engine of a hospital and ambulatory/outpatient surgery center, among other healthcare facilities.

How is that possible? Simple. What happens to a cruise ship or even the Starship Enterprise without crew members manning the engine room? That cruise ship becomes stranded in the Gulf of Mexico or the U.S.S. Enterprise in the outskirts of the Alpha Quadrant in space.

Without the engineering crew enabling these vessels to operate, they go nowhere. Floating land barges in the water; stationary but rotating space station in the final frontier.

Now imagine a healthcare facility – inpatient or outpatient – without the sterile processing crew. Before the relatively recent advent of disposable endoscopic devices, for example, surgeons relied exclusively on reusable models that require extensive cleaning (including pre-treating at the point of use, the new phrasing for the former "pre-cleaning" concept), disinfection – high-level or otherwise – and sterilization. After each use on each patient.

Without the Sterile Processing engine crew, who brings these expensive surgical tools back for acceptable and proper use on patients? The surgeons? The nurses?

Will complete adoption of disposable or single-use endoscopic devices solve the problem and even reduce the need for Sterile Processing's capable crew? Not really. You'll read why a few pages from here.

So how does Sterile Processing & Distribution (SPD) navigate through the lingering pandemic while prepping for future crises and remain relevant?

For Jean Sargent, veteran Supply Chain and SPD leader-turned-consultant who has served on the editorial advisory board of *Healthcare Purchasing News* faithfully for nearly 25 years, it requires three central tenets:

1. Support from senior leadership: "Through the pandemic, many sterile processing departments came into view at a higher level than their direct management," said Sargent, Principal, Sargent Healthcare Strategies. "It is time to take advantage of the newfound recognition by educating leadership, physicians and staff on the function of SPD, its importance, the guidelines that must be followed – walk a day in the shoes of an SPD tech."
2. Appropriate pay: "Now that the senior leaders have seen the functioning of the department, the knowledge required, and the certification(s) required – pay the staff at an appropriate level. Kudos to those who have met that need," she continued.
3. Recognition: "Recognize the department for their important contributions to patient care, patient safety and supporting the clinicians," she urged. "Bring physicians into the department and allow them to visualize the time and care taken to process each and every item/tray."

Sterile Processing matters. That's why *HPN* extensively has covered the profession and function since the 1970s. In fact, this Endoscope Care section represents the 17th consecutive year it has shared insights and prose from the pros on proper procedures within *HPN*'s 44 years in print.

In fact, last year, *HPN* editorially dissected the multistep process of reprocessing endoscopic devices in one of the most extensive education and training handbooks on the matter worth keeping. You can revisit that story, "Endoscope Care in 2020 and beyond" here: https://www.hpnonline.com/sterile-processing/article/21157237/endoscope-care-in-2020-and-beyond. You also can find additional useful information at *HPN* Online (www.hpnonline.com). Just use the search term "Endoscope Care."

Continue reading …

Whether in print, online or digital, HPN has SPD covered.

Photo courtesy: Healthmark Industries

Pre-treatment at point-of-use 'whodunit'

Follow expert clues to determine whether it's in OR or SPD

by Rick Dana Barlow

Ask any Sterile Processing & Distribution (SPD) technician, supervisor, manager, director or clinical educator about the most important first step in what they do for the operating room (OR) and if they don't recite from memory the refrain, "Cleaning, because if it's not clean, it cannot be disinfected or sterilized," then they might be from an alternate/parallel dimension.

But SPD professionals have long recognized how difficult and strenuous it is to clean post-procedure used devices and instruments – complex endoscopic models or otherwise – coming from the OR … particularly if those products have been enjoying a good soaking and instead are left in the open air for bioburden and organic material to gelatinize or harden into crusty scabs of tissue left behind.

Pre-treating at the point-of-use (formerly known as "pre-cleaning") begs the following questions whose responses should be standard operating procedure industry wide.

Who's responsible for pre-treating used devices and instruments and where? Circulating or surgical nurses in the OR? SPD techs?

How soon after a surgical procedure is completed before the used devices and instruments should undergo pre-treatment in a soak?

What materials should be used in this pre-treatment process?

Finally, who should take responsibility when these steps are not carried out?

Timing is everything

While this issue remains a sensitive one that has simmered seemingly for ages, SPD experts and leaders acknowledge that something should be done to promote safe and efficient practices and even see some headway being made.

"This is an age-old question," Shaun Sweeney, Vice President, Cygnus Medical, told *Healthcare Purchasing News*. "Logic dictates that it should be done immediately following the procedure for several reasons. Mainly the efficacy of the overall process but also for preventing stainless steel pitting caused by extended contact with blood. However, the OR turnover time often takes precedence. Seeing case carts lined up in the hallway untouched is a common sight.

"Many hospitals have SPD personnel working within the OR to take over these responsibilities," he continued. "This is a good step towards improving the process. Rinsing blood and other contaminants from the instrument as soon as possible is always the best option but is not always practical. Preventing pockets of biofilm from forming in cracks and crevices is a time-sensitive topic. It is more in the realm of minutes and hours than in days. The use of pretreating instruments with detergents is an option, but if the gel or detergent is left to dry it may create a soap film that can harbor microbes. This is an even worse outcome.

"Maintaining moisture in or around the instrument will keep the blood in a more rinsible state but water is also the one element biofilm needs to colonize. Not to mention the negative effects of stainless steel pitting and rusting still remain. In a perfect world rinsing and drying instruments after the procedure offers the greatest overall benefits," Sweeney added.

J. Hudson Garrett Jr., PhD, MSN, MPH, MBA, FNP-BC, CPHQ, PLNC, AS-BC, IP-BC, VA-BC, CFER, CPPS, CDONA, DICO-C, GDCN, NREMT, NCEE, FACDONA, TR-C, FAAPM, FNAP, FSHEA, Adjunct Assistant Professor, Division of Infectious Diseases, Department of Medicine, Center for Education and Training in Infection Prevention, University of Louisville School of Medicine, and an advocate for disposable/single-use only options, adds some context and depth to the discussion.

"First and foremost, the device should be handled and cleaned according to the manufacturer's instructions for use (IFU)," Garrett advised. "These instructions for use may dictate the timeframe for which the [pre-treatment] should take place. These instructions for use are part of the validated cleaning processes submitted by the device manufacturer to the Food and Drug Administration. Generally speaking, the sooner that [pre-treatment] and the removal of gross, organic soil can take place, the less likely the device is to form a dangerous biofilm, which can lead to patient contamination. As such, [pre-treating] at the bedside would typically be most prudent prior to transporting the device to another department."

J. Hudson Garrett Jr.

The paramount issue is timing, according to Ron Banach, Director of Clinical Education, Ruhof Inc.

"'Time is of the essence' is a critical requirement for point-of-use [pre-treating] whether Operating Room or SPD staff are assigned to the task," Banach insisted.

"Science has proven in laboratory studies that bioburden (e.g., blood, protein, fats, carbohydrates and starches) immediately starts to dry and create a biofilm shell made of polysaccharides over the micro-organisms left on the medical device," he noted. "In order to effectively perform the chemical treatment, it must be applied immediately after the procedure so it can solubilize the polysaccharide shell to allow the HLD or sterilization process to kill the micro-organisms."

David Willoughby, Vice President, Marketing & Business Development, Medtrica, stresses the criticality of timing.

David Willoughby

"We believe that [pre-treating] is critical at the point of use (POU) immediately after a procedure and prior to transport." Willoughy told *HPN*. "Once instruments leave the procedure room there are too many variables that can and will delay [pre-treating] so by not using an enzymatic based [pre-treating] agent at POU immediately after a procedure is, in our view, extremely problematic.

"Although POU [pre-treating] can at times be perceived as an inconvenience in terms of time, it is still an important and a critical first step in the cycle of instrument reprocessing," he noted. "By using [pre-treating] solutions in surgical theatres or other clinical areas conducting patient procedures, will greatly reduce the occurrence of bio-contaminants adhering to instrument surfaces. And, as simple as applying a POU [pre-treating] solution sounds – and is to do – unless this takes place at the POU the infection control chain can be broken causing the very outcomes [healthcare-associated infection] prevention polices were established to avoid and prevent."

Michelle Lemmons RN, PHN, CNOR, CCSVP: Clinical Educator – Operating Room, Key Surgical, a STERIS company, pinpoints the precise location for pre-treating used devices and instruments. And it's not in SPD or even the hallway outside the OR.

Michelle Lemmons

"Without any hesitation, the [pre-treating] step should be completed in the procedure room," she said. "It is well known that scopes can be a challenge to clean. In fact, in 2008 the HICPAC Guidelines for disinfection and sterilization in healthcare facilities states that 'contaminated endoscopes have been linked to more healthcare-associated infections than any other medical device.' Not starting the cleaning process at the point of use can make it more difficult to effectively clean/sterilize instruments. Shortening the time from use to cleaning will decrease the risk of biofilm formation and increase the ease of reprocessing."

Note the 'golden hour'

Lemmons' colleague, Jamie Zarembinski CCSVP, CER: Clinical Educator – Sterile Processing, Key Surgical, a STERIS company, offers the SPD perspective with some gilding.

"The goal is to reprocess the scope within the 'golden hour,'" she said. "Most often, this means that cleaning needs to begin at the bedside. To minimize the growth of microorganisms, the length of time between patient use and delivery to decontamination needs to be as short as possible, and this time varies between facilities. In addition to reducing the time between use and cleaning, facilities should standardize their [pre-treating] process. Standardizing the workflow can reduce endoscope turnover time, improve communication and training processes between OR and SPD, and can minimize the opportunity for errors."

Melinda Benedict

Melinda "Mindy" Benedict, MS, CIC, CFER, Global Senior Manager, Infection Prevention, Olympus Corporation of the Americas, affirms that pre-treating surgical devices and the timing of this step – the sooner the better – is widely accepted by professional

organizations, healthcare providers and suppliers alike.

"Medical device instructions for use (IFU) generally recommend pre-cleaning be performed at the end of the procedure, immediately after use, while still in the OR," she said. "Delays in reprocessing may require additional steps in making the device patient ready and safe. In that regard, OR staff are in the best position to carry out this critical step in reprocessing as they are most aware of the 'procedural stop time.'"

Benedict recommends this step as a standard inclusion of workflow.

"Wiping and flushing with water or detergent can easily become part of the workflow as a documented standard of care at the bedside," she said. "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 OR staff who have immediate access to a device following a procedure."

Melissa Kubach, Clinical Education and Training Manager, National Solutions Team, Agiliti, understands the conundrum between OR clinicians or SPD techs handling pre-treatment.


Melissa Kubach

"Unfortunately, there is no simple answer to this question," she indicated. "There are pros and cons for both scenarios, but the smart move is to follow the option posing the least risk. [Pre-treating] should be completed every time at the point of use – as soon as possible – and should involve [those] already in the room since timeliness is important. Delaying [pre-treatment] or waiting for a courier before transporting to Sterile Processing invites potential delays and other logistical questions. How many case carts are in line to be cleaned? Which ones contain endoscopes? How many Sterile Processing departments have available staff to send post-case to the Operating Room? Sterile Processing departments across the country are already struggling with personnel shortages."

The type of device also can complicate the process for SPD, according to Kubach.

"Large diameter gastrointestinal models require cleaning steps unable to be completed without their processor/light source, bottle, tubing set-ups, valves and active suction," she noted. "It is doubtful that a secondary tower and accessories would be housed in Sterile Processing due to cost alone."

Kubach acknowledges that Operating Rooms have long struggled with flexible endoscope [pre-treating] requirements and compliance.

"Critical steps are often partially completed or skipped entirely. While there are many reasons for this lack of compliance, the reality is that there are many natural barriers and competing priorities that lead to ineffective [pre-treating] in the Operating Room," she continued. "For example, a controlled sterile environment is not conducive to utilizing non-sterile liquids and detergents, especially while the patient is present. OR staff are naturally relucent to introduce the potential of a messy, contaminated process. Patient care and recovery rightfully must take priority after the procedure and post-case turnover activities may be rushed. These challenges are not easily solved for and should not be dismissed."

But she sees room for improvement and suggests some "quick-wins" through engaging and comprehensive education.

"OR staff rarely receive formal model- or manufacturer-specific training, and most have never seen or read [pre-treating] requirements in the endoscope manufacturer's IFU," she said. "The greater the number of personnel involved proportionately decreases the likelihood of effective 'hands-on' training, especially for models with [pre-treating] procedures that are quite complex. Additional underlying factors also contribute, such as a perception that cleaning should only take place in a reprocessing area or that [pre-treating] is not important since SPD will just be cleaning it again anyway."

POU POV

Jean Sargent, Principal, Sargent Healthcare Strategies, has extensive experience as a hospital Supply Chain and SPD leader and remains sacrosanct.


Jean Sargent

"This is a point of use function," she said. "The scopes are delicate, intricate and expensive. The scopes generally require a quick turnaround time. Delaying the start of the cleaning process by 15 minutes allows the bioburden to begin to harden. This extends the overall cleaning time, therefore turnaround-times, and can cause possible damage to the scope to the point of taking it out of service. All delays in patient care."

Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare, concurs with the location of pre-treatment and even specifies who should be responsible for doing it.

"[Pre-treatment] of surgical instruments should always be done in the OR," he asserted. "During the procedure, when instruments – including endoscopes – are traded off by the surgeon, the scrub nurse/tech should remove any gross debris. After the surgery, for rigid endoscopes, the scrub should carefully wipe off all gross debris using a clean towel or sponge soaked in water."


Gregg Agoston

For all endoscopes, the distal end should receive particular attention, according to Agoston.

"The distal end contains the optic window and light window and in the case of some flexible endoscopes channel openings and air water nozzles," he said. "It is very easy to run a sponge up and down the shaft of a rigid endoscope or the insertion tube of a flexible endoscope, however, the distal end is the most challenging to clean due to its small size and cervices formed by the juncture of the windows/channels."

Agoston insists that saline solution should never be used because the salt can cause harm to components.

"For flexible endoscopes it is essential for the scrub/surgeon to follow the manufacturer's IFU and suction water or enzymatic solution in sufficient quantities through the endoscope, and in addition, wipe down the insertion tube with water or enzymatic solution," he continued. "One of the key concepts is that the quantity of water/enzymatic solution must be sufficient per the IFU. Often, we see clients use smaller quantities of water/enzymatic solutions (e.g., 250ml for an adult colonoscope when 500ml should be used on this device) when a greater volume is required for thorough [pre-treating]."

Accessory instruments, such as cameras, light guides and instruments, should also be wiped off with a moist towel or sponge to remove gross debris, Agoston advises.

After pre-treating in the OR, the instruments must be transported to SPD.

"To prevent drying, a towel moistened with water can be placed over the instruments and/or the instruments can be sprayed with enzymatic solution/foam designed for [pre-treating]," Agoston recommended. "As a prerequisite to using a sprayed enzymatic solution/foam, the instrument should be cleaned of all gross debris. In addition, it is very important that the enzymatic solution/foam cover the entire instrument and lumens if indicated.

Agoston urges that transport and cleaning of the instruments should occur as quickly as possible following the surgical procedure for a very logical reason:

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"Certain instruments require an extended processing cycle if too much time passes between the procedure and the start of the cleaning process. IFUs should always be followed," he warned.

"In cases where it is known that processing will be delayed, there are foam products that are designed for extended hold times," he said. "These products are specifically designed to encapsulate the flexible endoscope, keeping it moist and working to prevent the formation of biofilms for extended periods of time. When using these products, it is extremely important to follow the IFU regarding filling all channels with the product. Covering only the exterior of the endoscope is not sufficient to prevent biofilm formation in the channels." HPN

Editor's Note: Due to a recent industry lexicon change, all references to "pre-cleaning" have been changed to "pre-treating" or "pre-treatment."

Pre-treating short cuts, task shifts can breed danger for patients

by Rick Dana Barlow

Delaying or even skipping out on the pre-treatment of used surgical devices and instruments – endoscopic or otherwise – creates serious problems for Sterile Processing & Distribution professionals and can lead to dangerous problems for patient outcomes.

"When pre-cleaning is not performed, the likelihood for biofilm formation increases due to the prolonged time afforded for bacteria to adhere to the device itself," said J. Hudson Garrett Jr., PhD, MSN, MPH, MBA, FNP-BC, CPHQ, PLNC, AS-BC, IP-BC, VA-BC, CFER, CPPS, CDONA, DICO-C, GDCN, NREMT, NCEE, FACDONA, TR-C, FAAPM, FNAP, FSHEA, Adjunct Assistant Professor, Division of Infectious Diseases, Department of Medicine, Center for Education and Training in Infection Prevention, University of Louisville School of Medicine. "Skipping this step altogether can tremendously endanger the overall efficacy of high-level disinfection of the device."

Ron Banach, Director of Clinical Education, Ruhof Inc., is more direct: "Once the biofilm process has started, the ability to attain high-level disinfection or sterilization will fail."

If there are any questions about pre-treatment or the delay or lack thereof, Jamie Zarembinski CCSVP, CER, Clinical Educator – Sterile Processing, Key Surgical, a STERIS company, synopsizes the inevitable outcome. "Patient harm. There is no way around it. An improperly reprocessed scope is a hazard for the patient," she warned. "Taking shortcuts, skipping steps in the reprocessing cycle, and not following the instructions for use (IFU) ultimately leads to patient harm. There is significant pressure in this role to get things done quickly. This pressure is often coupled with inadequate training and insufficient continuing education opportunities. Endoscopes are incredibly complex and should be reprocessed with great care and attention to detail. These devices are required to come with detailed IFUs for the manufacturer to obtain 510(k) clearance. The IFU must contain reprocessing instructions. By referencing the IFU for each device, providing adequate training and continuing education, and keeping IFUs accessible, facilities can reduce errors and the risk of patient harm related to neglecting steps in the reprocessing cycle."

Zarembinski's colleague on the OR side agrees wholeheartedly.

"It is vital to remember that the patient on the operating room table is all our patient, and we are dealing with their life," indicated Michelle Lemmons RN, PHN, CNOR, CCSVP, Clinical Educator – Operating Room, Key Surgical, a STERIS company. "There is no shortcut that is worth putting a person's well-being and life at risk. The 'do more, with less, in less time' cycle can be challenging to overcome. However, keeping the patient front of mind is the solution to breaking this cycle. As Jamie stated, endoscope reprocessing is complex and attention to detail is imperative. The scope reprocessing role should be considered as specialty, and the training and preparation for this role should reflect that. Remember that the 2008 HICPAC Guidelines stated, "contaminated endoscopes have been linked to more healthcare-associated infections than any other medical device." Prioritizing this specialty through training and education is a great investment for any facility."

Cornerstone of quality

[Pre-treating] is critical to ensure subsequent reprocessing steps, including high-level disinfection or sterilization, can be effective, according to Melinda "Mindy" Benedict, MS, CIC, CFER, Global Senior Manager, Infection Prevention, Olympus Corporation of the Americas.

"When performed correctly and with knowledge as to why the process is critical, [pre-treating] is a cornerstone in high quality safe patient care," she noted. "[Pre-treating] requires minimal time to complete and provides the foundation for effective and efficient reprocessing of medical devices."

The absence of pre-treatment at the point of use, interrupts the linear progression of the entire process, according to David Willoughby, Vice President, Marketing & Business Development, Medtrica.

"Simply put, failure to conduct [pre-treating] on post-procedure instruments can significantly complicate the manual cleaning/decontamination process, which in turn increases the risk of patient morbidity and patient cross-contamination," Willoughby said. "It is well understood that the longer bio-contaminants are left on instruments the harder they are to remove. Microbes can easily damage instruments if they remain on instrumentation surfaces (internal and external) for prolonged periods of time, making the removal of these encrustations and biofilms extremely challenging, if not impossible, to address through standard cleaning procedures. This in turn creates a cascade of problems and circumvents the very procedures so rigidly adhered to by SPD.

"So, in essence, POU [pre-treating] really comes down to effectively adhering to and applying pre-transport protocols with the most effective enzymatic and detergent-based [pre-treating] and wetting agents (formulations) available in order to not only prevent instrument damage and or malfunction but also (and more importantly) to mitigate the risk of surgical site infection," he added.

John Whelan, RN, Clinical Education Specialist, Healthmark Industries, cautions that OR and SPD professionals should not short-change pre-treatment but also should recognize additional necessary steps in that early process. This includes disconnecting accessories, preparing handoff communication, and preparation for soiled transport, he added.

Where and when this occurs matters for six key reasons, according to Whelan.

- "It's in endoscope manufacturer's IFUs to perform point-of-use treatment as soon as the procedure is complete. IFUs always need to be followed.

- "It's consistently found in national standards and guidelines – endoscopes need to undergo [pre-treating] at point of use. Standards and guidelines direct best practices.
- "For certain brand, generation and type of endoscopes, there are steps that can only occur at the point of use – while the scope is still hooked up to the processor. For example, certain GI endoscopes require flushing the air water channel with the air water channel cleaning adapter. This can only happen while the scope is connected to the airflow regulator in the procedure room – so it can't be done in the reprocessing room.
- "The rationale here is critical to understand the significance. The sooner the better to remove residual bioburden and limit biofilm development. It only takes minutes for biofilm to form and proliferate.
- "Each step of processing done correctly and completely allows the steps that follow to be more successful.
- "Each step performed correctly and completely serves to limit chances for patient injury/infection."

Simple math

OR and SPD professionals merely need to equate the pre-treatment process as a mathematical equation, according to Melissa Kubach, Clinical Education and Training Manager, National Solutions Team, Agiliti.

"Each flexible endoscope cleaning step serves a purpose necessary for achieving the desired outcome – a patient-safe device," Kubach said. "[Pre-treating] is the first step in an extensive line of steps. Skipping any one step places all subsequent cleaning actions at a disadvantage.

"Mathematically speaking, each stage of cleaning equates to reducing bacteria," she continued. "Every stage, from [pre-treating] to scrubbing to flushing to rinsing, is only able to achieve a certain level of logarithmic bacteria reduction. Even with repetitious cleaning, there will be a point for which no additional benefit will be realized. This is even more concerning when employing high-level disinfection; a method that does not remove or kill all living microorganisms.

"Delayed cleaning allows bacteria to multiply at exponential rates. Consequently, as bioburden is allowed to increase, the proportionate ability to produce a thoroughly clean final product has decreased. Additionally, biofilms can form as bacteria adhere to internal channels, making removal increasingly difficult or even impossible - and which places patients at even greater risk of infection," Kubach noted.

Shaun Sweeney, Vice President, Cygnus Medical, encourages the OR and SPD to set priorities.

"Unfortunately, unlike with flexible endoscopes many ORs have not prioritized [pre-treating] as a critical step," he observed. "The more intricate the instrument the more chances of gross contamination drying in crevices and not being properly removed in the wash cycle. Like eggs on a plate, they are easily removed with water immediately after the case. With added time they are proportionately harder to remove. The quality of patient care for the next patient and the overall condition of the instrument inventory are at risk."

Because flexible endoscopes represent some of the most complex instruments to clean, processing errors have resulted in serious patient harm and death, which has been well-document in media reports and professional studies, according to Gregg Agoston, M.B.A., Vice President, Business Development, SPD Transformation Services, SpecialtyCare.

"The American College of Surgeons identified two risk factors for [surgical site infections] that specifically pertain to Sterile Processing," Agoston said. "First, the longer a patient is exposed to the OR the greater the risk of SSI. Second, the instruments must be sterile or high-level disinfected. The level of processing is dependent upon the IFU/Spalding Classification. Instrument processors can impact the length of OR exposure if the instrument is not available or if an instrument is delivered to the OR that is not in good working condition. In addition, if an instrument is not clean it cannot be considered sterile and could lead to an SSI. While there are many risk factors that contribute to an SSI – some intrinsic to the patient (e.g., smoking, diabetes, etc.) and other extrinsic (e.g., patient preps, sterile technique, use of antibiotics etc.), instrument processing does play a significant role in the prevention of SSI by ensuring that products they are responsible for do not extend patient exposure in the OR and by ensuring that instruments are in fact sterile or high-level disinfected."

Jean Sargent, Principal, Sargent Healthcare Strategies, has extensive experience as a hospital Supply Chain and SPD leader, and highlights the butterfly effect.

"The delay in completing the complex cleaning process of over 100 steps will likely create delays in turnaround-times, and possibly cause damage, further delaying the time to have the scope ready for the next patient. Delay in patient treatment or cancellation of treatment is an issue in the satisfaction scores," she said. **HPN**

Editor's Note: Due to a recent industry lexicon change, all references to "pre-cleaning" have been changed to "pre-treating" or "pre-treatment."

What does SPD need for endoscope reprocessing quality performance?

As much of the Sterile Processing & Distribution profession buzz swirls around the emergence of disposable/single-use-only endoscopic devices, SPD leaders want to ensure those on the front lines remain grounded in the fundamentals.

They quickly point out that the media coverage surrounding healthcare-associated infections likely stemming from improper reprocessing may not be blamed totally on the devices and technological complexity, even as they acknowledge that endoscopes include numerous nooks, crannies and areas that can be hard to clean, which makes them hard to disinfect and sterilize.

But the disposable/single-use-only endoscopes don't represent the silver bullet that some might hope will solve the quality issues bedeviling SPD operations. In short, this represents less of a device issue and more of a communication, education and training issue that must be checked and solved regardless of the device or technology being upgraded or redesigned. It's akin to the old adage, if a device isn't clean, it can't be sterilized.

For the fourth 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 2020, 2019 and 2018 as well. What's noteworthy is that the results seem consistent. In fact, the top two strategies this year are the same as 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 three consecutive years. Curiously, the proverbial Bullwhip moves up a notch to No. 3 and Big Brother jumps three spots to No. 4 – both of them above the relatively new disposable/single-use tech breakouts.

1. **Thoroughly educating, training, vetting and certifying SPD staffers on proper and effective cleaning techniques**
   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)**
   2021 average score: 2.6
   2020 average score: 2.64
   2019 average score: 1.9
   2018 average score: 2.5
3. **Holding staffers accountable/responsible for endoscope cleaning "violations"**
   2021 average score: 4.0
   2020 average score: 4.23
   2019 average score: 4.8
   2018 average score: 2.8
4. **Comprehensively monitoring and tracking all steps in the process with sensors and video technology**
   2021 average score: 4.5
   2020 average score: 4.85
   2019 average score: 4.7
   2018 average score: 3.4
5. **Switching to endoscopes that contain disposable/single-use-only components that can be discarded or swapped out after use**
   2021 average score: 4.8
   2020 average score: 3.62
   2019 average score: 4.1
   2018 average score: n/a
6. **Switching to disposable/single-use-only endoscopic devices for selected endoscopic procedures only (e.g., bronchoscopy, etc.)**
   2021 average score: 5.3
   2020 average score: 4.46
   2019 average score: 4.3
   2018 average score: n/a
7. **Switching to disposable/single-use-only endoscopic devices for all endoscopic procedures**
   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.

Shaun Sweeney, Vice President, Cygnus Medical, emphasizes that "thoroughly educating, training, vetting and certifying endoscopy staffers on proper and effective cleaning techniques" is essential. "Bedside cleaning still falls within the realm of the endoscopy unit and is the most important step in the process," he added.

Although she ranked No. 6 a little higher, Melinda "Mindy" Benedict, CIC, CFER, Global Senior Manager, Infection Prevention, Olympus Corporation of the Americas, qualifies the option from a regulatory perspective. "Single use for certain patients and procedures is recommended by the FDA, whose guidance is of utmost importance," she said.

Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare, remains squarely in the camp of the top 4 rankings (with the bottom two in that group transposed). He points to staff quality as paramount.

"For the processing of flexible endoscopes used in a GI clinic, most hospitals and clinics have dedicated staff whose only job is to assist with the endoscopes and process them," Agoston noted. "Having a dedicated team, who are highly trained to follow all steps outlined in the [instructions for use] is critical to the successful cleaning and processing of the devices. For flexible endoscopes used in the OR, many hospitals

process these in SPD often with much lower rates of confidence that all processes in the IFU have been followed. This is partially due to the competency of the technician who performed the cleaning. It is also due to the common practice in most SPDs where everyone takes a turn at all functions (including decontamination, assembly, sterilization, case carts etc.).

"By not designating qualified staff to the important function of cleaning flexible endoscopes, significant variation is created in quality," Agoston continued. "With some flexible endoscopes IFUs containing over 100 pages of instruction for processing, if the hospital does not designate highly trained specialists to clean flexible endoscopes there is a significant chance that the instruments will not be properly prepared for sterilization or high-level disinfection."

Agoston points to cross-training and multitasking as the culprit even though some feel it's more efficient.

"When we look at the root cause of processing failure, it usually boils down to not having qualified staff perform the processes, lack of proper equipment/supplies for the process and the lack of standard work developed as the process," he indicated. "Allowing everyone to take a turn in decontamination to clean complex instruments results in significant errors."

Switching fully to disposable/single-use devices poses its own challenges, according to Agoston.

With over 50 million GI procedures and another 25 million surgical procedures performed with flexible endoscopes (e.g., ureteroscopy, cystoscopy, ENT, etc.), if we switched to disposable flexible endoscopes, the mountains of surgical waste would be enormous," he said. "In addition, while flexible endoscopes are complex instruments, they certainly are not the only complex instrument that we ask SPD to process. If we are calling for disposable or 'semi-reusable' flexible endoscopes because we are not confident in SPD to process them, then we should be calling for disposables for Da Vinci instruments, and most of the other complex instruments used in minimally invasive orthopedic, spine, ENT, etc."

Agoston traces the roots to quality concerns in SPD to roughly 80 years ago.

"The cause of all of this is found in the origin of SPD back in the 1940s when the American College of Surgeons called for a centralization of the sterilization process," he recalled. "At the time the instruments were very simple by today's standards, but the sterilization process was complex due to not having automation for the sterilization process or record keeping of the sterilization parameters. At the time, you could move staff over from dietary or [environmental services] and with good supervision, [they could] clean and sterilize the stainless steel instruments used in open surgical procedures that were being done at that time.

"Fast forward to the advent of [minimally invasive surgery] and advanced surgical procedures where the majority of the devices are complex," he continued. "Thinking that you can bring in 'lay-people' and expect them to know every IFU, work process, piece of equipment in the department, how to disassemble, clean, reassemble, test, package and sterilize for every instrument in a hospital is not attainable, particularly given the very high rate of turnover in SPD staff.

"The solution is in allowing for specialization in SPD where there [are] staff who are more highly trained to process complex instruments," he recommended. "We do this in orthopedics with the help of the vendor reps, and we do it in GI endoscopy clinics. For the vast amount of other complex instruments for MIS, everyone in SPD takes a turn. Recall that there are many small diameter flexible endoscopes that are processed by SPD. This variation in staff competency results in significant variation in quality."

Automation plays a key role, too, according to Agoston.

"Automation of processes is very important because no matter what is done, humans will vary in their processes," he noted. "Machines do not unless they are malfunctioning. With machines we get consistent times, chemical exposure, rinsing and disinfection. Most rigid endoscopes can be processed through automated washers if they have the proper container, but most hospitals do not do this, resulting in variation in cleanliness. All facilities processing flexible endoscopes should have the latest equipment for cleaning and processing the devices. This can also be said for DaVinci instruments where we see hospitals that do not have the appropriate ultrasonic equipment to clean the devices. The list goes on.

Supervision also must be addressed. "Without a knowledgeable supervisor and documented competency, process variation again will enter," he said. "Variation is the enemy of quality." **HPN**

All hail to the hybrids by the mid-2030s

New model excitement eventually will settle into balance in motion

by Rick Dana Barlow

As the billowing smoke clears from the roiling emergence of disposable/single-use-only endoscopes, Sterile Processing & Distribution executives and leaders are beginning to see some clarity on endoscopic product market shifts as the future comes into focus.

From an armchair investor standpoint, their advice seems to line up this way:

1. Don't invest in reusable endoscope growth, but don't totally dump all your stock in it.
2. Don't bet your entire fortune on disposable/single-use-only domination just yet, but certainly bolster your portfolio.
3. Look for the future to be somewhere in between the previous two extremes as the market and SDP behaviors will find balance between moving back and forth rather slowly.

Healthcare Purchasing News continues to explore the emergence of disposable/single-use-only endoscopic devices that currently are making some headway in terms of generating interest and gaining customers. Just a few years ago, the Surgical Services and SPD market segments had disposable/single-use endoscopic devices on their wish lists as the products remained in development. They're here now.

And rather than keeping these new products at arm's length, SPD executives and leaders fully acknowledge they're here to stay, but SPD likely shouldn't be concerned that their future in reprocessing reusable devices is in jeopardy.

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 during the next 10 to 14 years 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

Move to the middle

Experts remain steadfast and unmovable in their opinions that the two "fringe" elements – Nos. 1 and 5 – likely will not happen. They believe the market will not sustain the use of only reusable endoscopes for surgical procedures. At the same time, they also argue the market will not shift totally to disposable/single-use models either, nor will these models surpass or overwhelm the use of reusables.

Several, however, anticipate a growing shift toward use of disposable/single-use endoscopes for an increasing number of surgical procedures but they will not surpass the use of fully reusable models.

"Continuing outbreaks associated with all flexible and rigid endoscopes dictate that there is a device-related contamination issue that transcends medical disciplines," concluded J. Hudson Garrett Jr. PhD, MSN, MPH, MBA, FNP-BC, CPHQ, PLNC, AS-BC, IP-BC, VA-BC, CFER, CPPS, CDONA, DICO-C, GDCN, NREMT, NCEE, FACDONA, TR-C, FAAPM, FNAP, FSHEA, Adjunct Assistant Professor, Division of Infectious Diseases, Department of Medicine, Center for Education and Training in Infection Prevention, University of Louisville School of Medicine. "As such, there must be a shift from using the exact devices that the data shows cause infection outbreaks and move to a more suitable platform of sterile, single-use endoscopes that completely eliminate the need for reprocessing. Eliminating

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this risky process is the highest possible level of infection control intervention."

Melinda "Mindy" Benedict, CIC, CFER, Global Senior Manager, Infection Prevention, Olympus Corporation of the Americas, concurs to an extent and with caveats.

"Single-use endoscopes will surpass reusables in some specialty areas, but adoption will be different for different patient populations, different physician preferences and different facilities," she said. "The medical waste and cost challenges will need to be addressed."

Hybrids stake shallow claim

The majority of sterile processing subject matter experts remain solidly behind so-called hybrid model endoscopes, which are reusable devices that incorporate disposable/single-use components that can be discarded after use. And while this group foresees hybrids gaining in popularity, they are split right down the middle on whether they will overtake the use of fully reusable devices.

"I do not see disposable rigid endoscopes taking over their reusable counterparts," said Melissa Kubach, Clinical Education and Training Manager, National Solutions Team, Agiliti. "Disposable rigids have been tried in the past, but adoption was minimal due to problems with image and lighting quality, and those devices ended up being cost prohibitive. Without addressing those issues, I believe the industry will stay with the current rigid equipment.

"Incorporation of hybrid flexible endoscopes with disposable components will increase," she observed, "especially for procedures with elevated risk. This is further supported by the current [Centers for Disease Control and Prevention] recommendations."

Kubach predicts fully disposable models to be reserved for specialized functions.

"Employing fully disposable flexible endoscopes has and will continue to increase for certain procedures and specialties such as airway management, including some bronchoscopy," she noted. "Currently, this has been highly based on emergency use or convenience, such as after-hour or weekend use, when cleaning staff are not readily available. Disposable 'back-up' inventories have also increased for high-volume Anesthesia departments. Another area benefiting from disposable-use based on need is Urology. Fast-paced patient turnover and the delicate nature specific to small diameter flexible ureteroscopes has created a niche."

Kubach sees certain endoscope types not yet fully ready for disposable prime time.

"Standard large diameter flexible endoscopes will be slow to jump the disposable threshold," she indicated. "Reimbursement, or the lack thereof, is key. Further speedbumps are related to current reusable high-definition image quality and the 'feel' of the endoscope itself. Physicians will be slow to relinquish high resolution and technological features such as anatomical positioning and enhancements from narrow band lighting, spectral imaging or blue and white light features."

Weighing the pros and cons of using primarily reusable models indicates that the rise of hybrid models seems inevitable, according to Shaun Sweeney, Vice President, Cygnus Medical.

"The current reusable scope image quality and construction clearly offer the doctor greater control, which leads to greater patient care," Sweeney said. "The industry is constantly improving cleaning techniques at each of the cleaning stages, but there are some challenges that remain. Focusing on the problem areas, such as using disposable components of ERCP elevator mechanisms, has already begun. Disposable valves have been very successful in making this transition.

"The infection control benefits of a 100% disposable scope does not outweigh the benefits of the performance quality of current reusable scopes," he continued. "Having had an 8-track player in my first car, I have come to realize how hard it is to see how dramatically things can change overnight. Likely, 20 years from now, there will be an exponential technology shift that has not even raised its head in today's market. I think the best strategy today is to constantly be looking for incremental improvements until that time comes."

John Whelan, RN, Clinical Education Specialist, Healthmark Industries, casts his impressions in context of the previously unforeseen circumstances from the COVID-19 pandemic.

"Who could have foreseen the global semiconductor shortage that has crippled availability for new vehicles?" he asked. "Also using the automobile analogy, the cost of hybrid and fully alternative (for endoscopes, read as fully disposable) technology is prohibitive for many facilities to consider. I believe even 15 to 20 years out, purchase/lease decisions [for] flexible endoscopes will still be considerably influenced by purchase/supply costs, and less so by sustainability (i.e., recycling) considerations."

Because healthcare institutions are layered organizations, change happens slowly, according to Whelan. "Until or unless governmental direction is even more prescriptive, and/or full facility reimbursement for single-use endoscopes is guaranteed across-the-board, reusable endoscopes will still be in use," he said. "What I do believe will change more over the next several years is technological advances in the automated cleaning, disinfection and sterilization for reusable devices – including flexible endoscopes. Research and development continue underway to bring such changes to the market, and with a goal of affordable implementation."

Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare, expects the market will shift to help solve current problems.

"To this end, hybrid products will play a role and to the end that the product changes provide economic and safety benefits that outweigh current products, they will be accepted," Agoston indicated. "Often with flexible endoscopes, they are the singular product used in the procedure, thus it is relatively easy to identify the endoscope as the cause of an infection when this occurs.

"In the majority of other [surgical site infections] it is not so easy," he continued. "Was it the rigid endoscope, the shaver, the [minimally invasive surgery] hand instrument, the failure of the nurse to properly prep the patient, or the patient intrinsic factors that lead to the infection? My point being that if we are moving to more costly or waste-producing products because we are fearful that the SPD staff cannot properly clean them, then we should do this for all surgical procedures that use complex instruments because all can cause infection.

"We know that the SSI rates as of the last report were the only category of [healthcare-associated infections] that did not show a decrease," he said. "We also know that SSI are only tracked for a certain few procedure types, thus the true number of SSI is much higher than reported. At a recent meeting for OR business managers I asked the audience how many had had or had a close relative or friend acquire an SSI and three-fourths of the audience raised their hand. The solution should be focused on product improvements to make them easier to process, process improvements to automate as much as possible and staffing improvements recognizing the importance of a well-trained, stable staff of professionals whose role it is to process complex instruments."

Hybrids go deep

Some may not believe hybrids will progress so far as to be used by the majority, but others certainly do.

"The most important things that will be considered are budget, Infection rates, and material quality," said Jamie Zarembinski CCSVP, CER, Clinical Educator – Sterile Processing, Key Surgical, a STERIS company. "If the cost of a hybrid or disposable scope is comparable to the cost of reprocessing a reusable scope, it will increase their use. Further, if hybrid/disposables decrease infection risk, the industry trend will undoubtedly support the transition to hybrid/disposables. Finally, the material quality and complex video components in each type of scope will influence choice.

"One of the current hot topics causing hesitation to transition to hybrid/disposable scopes is image quality," she said. "If surgeons are unable to properly visualize, diagnose and treat related to scope image issues, the industry is going to stick with reusables. There is a lot of pressure on manufacturers of all types of scopes to optimize outcomes in all three of these areas – budget, infection rate reduction, and quality, but this pressure will ultimately lead to greater patient outcomes."

For Ron Banach, Director of Clinical Education, Ruhof Inc., economics and image quality will drive migration.

"The cost of the disposables will limit the full integration of disposable flexible and rigid endoscopes unless the insurance companies adjust their procedure reimbursement rates to include the additional cost for the disposables devices, and the manufacturers can equal or exceed the physicians demands for diagnostic quality," he said.

Sterile Processing technicians have had to endure the cleaning challenges with complex reusable medical devices like flexible, semi-rigid, and rigid endoscopes, according to Cheron Rojo, CHL, CIS, CER, CFER, CRCST, Clinical Education Specialist, Healthmark Industries.

"With the implementation in recent years of a disposable tip for some of the vendors of duodenoscopes the change has made a positive difference for sterile processing professionals regarding cleaning, but there is still room to expand without altering the feel or function of the medical device for the surgeon or proceduralist," Rojo said.

"Hybrid [models] with both reusable and disposable sections save money and the environment instead of a full disposable medical device that can be costly to the patient and add to the landfill, especially in states with clean initiatives like California, Hawaii, etc.," he said. 'Further development still needs to take place to think outside the box to provide hybrids in semi-rigid and rigid endoscopes that meet surgeon, sterile processing and healthcare facility's needs; and most of all, provide a functional, clean, and safe medical device for patients."

Jean Sargent, Principal, Sargent Healthcare Strategies, and a former Supply Chain and SPD director, offers a curious perspective that hearkens to the bottom line.

"For me personally, I am hoping hybrid models will be a back up to reusables," she said. "However, in dealing with requests from physicians for disposable or hybrid scopes for convenience, we are overlooking the root cause. Is the root cause staffing? Proximity to processing facilities? Not enough reusable scopes? Once a root cause analysis is completed, determine what needs to be done to address the need. It may be reusable/hybrids or it may be staff or updated processes. Each and every organization is different and should look at the need from all three viewpoints when determining a strategic direction for these products." HPN

ENDOSCOPE CARE 2021

Dawn of the disposables domination

Or maybe that dream is single-use only vs. sustainable?

Sterile Processing & Distribution (SPD) executives and leaders with special expertise in endoscopic devices may envision a future flush with hybrid products that represent the optimal answer to the reusable vs. disposable debate.

But do they *ever* anticipate disposable/single-use rigid and/or flexible endoscopes emerging as the preference used by the majority of surgeons and healthcare organizations? Maybe. Maybe not.

"In the long term, I think this is very much a possible reality to reduce the risk to patients and to improve clinical through-put of clinical procedures. There are two critical determining factors that will likely drive this transition: Clinical device performance and functionality and price. The single-use devices must perform the same or better as reusable devices and the single-use devices must be economically priced to encourage use. In addition, additional single-use device reimbursement will help healthcare facilities in making the transition away from reusable devices."

J. Hudson Garrett Jr., University of Louisville School of Medicine

"At this point, I do not see fully disposable endoscopes gaining an overall 100% acceptance rate. Widespread, fully disposable rigid use will remain minimal. Small diameter flexible disposables use will continue to grow in areas of non-therapeutic procedural need. Duodenoscopes used for ERCP procedures will continue to move towards partially or fully disposable aspects. The remaining reusable flexible models will continue to be the norm until issues such as image quality, features, cost-effectiveness and waste concerns are sufficiently addressed."

Melissa Kubach, Agiliti

"It depends on the facility's focus on sustainability, cost and staffing levels. The impact on the environment to manufacture disposables must be taken into consideration. The cost of disposables could possibly pay for another staff member. What happens to all the scopes that are in good working condition? I liken this to disposable laryngoscope blades and handles – so much waste and stacks of reusables in drawers. That is not caring for the environment."

Jean Sargent, Sargent Healthcare Strategies

"Single-use endoscopes are going to be a great option depending on facilities' volume of cases and their infection rate. For a low-volume, high infection rate facility, it's a clear choice: Go single-use. Similar to instruments in the operating

room, surgeon preference and case-mix are going to be drivers in making these decisions. According to the American Gastroenterological Association, gastroenterologists suffer from overuse injuries such as pain in their fingers, wrists, forearms and back. It would be great to see the considerations between single-use and reusable create some positive ergonomic changes to scope design and further optimize the user experience in addition to improving safety and quality of these devices."

Michelle Lemmons, Key Surgical, a STERIS company

"Clinics where there are specialized staff dedicated to the processing of flexible endoscopes, given that they have the proper training, supervision, equipment specifically designed and automated as much as possible, should not need to rely on single-use endoscopes.

"Hospitals where they require the SPD to process GI scopes and small diameter flexible endoscopes, often without proper training, supervision, and equipment specifically designed for these devices, run the serious risk of the instruments not being properly processed. This concept applies not only to flexible endoscopes but also to all complex instruments. I believe that the answer is in solving the root cause of the problem, which in some cases is the design of the endoscopes, but in most cases is in providing a dedicated highly trained staff that is properly incented to perform high quality work, and [with] the tools to do so – these being supervision, automated equipment, proper supplies and standard work through documented processes and procedures."

Gregg Agoston, SpecialtyCare

Don't let hang-time become a hang-up

Aeration, drying and storage represent integral finishing steps for patient safety

Photo courtesy: Healthmark Industries

From pre-treatment at the point of use to visual inspections and leak testing to cleaning to high-level disinfection and rinsing to sterilization, the process to reprocess endoscope devices and instruments can be as complex as the products themselves.

But the final step in the reprocessing process – aeration, drying and storage – before handling/transportation to the point of use and ongoing maintenance and repair – represents the last and perhaps most important quality checkpoint before those endoscopic devices and instruments exit Sterile Processing & Distribution (SPD) on the route back to Surgical Services.

Because that closing step remains so essential for patient safety, *Healthcare Purchasing News* recruited a small group of SPD experts to share useful tips and tricks to ensure ready-to-use endoscopic devices and instruments. Here's what they recommend.

Melinda "Mindy" Benedict, MS, CIC, CFER, Global Senior Manager, Infection Prevention, Olympus Corporation of the Americas, emphasizes that endoscope drying and storage play a key role in endoscope reprocessing as it is important to stress that preventing the introduction of contaminants after disinfection is pivotal to patient safety. Benedict's tips on drying and storing reprocessed endoscopic devices:

1. "The quality of compressed air used to dry endoscopes is important. Inadequately filtered air could introduce contaminants to a clean endoscope. Societies are moving toward the use of instrument-quality air. The AORN guidelines state, "The exterior surfaces of the endoscope should be dried with a soft, lint-free cloth or sponge and all channels purged with instrument air."[1] GNA indicates that step No. 8 in endoscope reprocessing is drying, "which requires an alcohol flush, followed by forced-air drying with instrument-quality compressed air."[2]
2. "Heathcare facilities may want to consider avoiding the use of oil-based compressors for drying endoscopes.
3. "When drying endoscope channels, be sure the maximum air pressure introduced does not exceed manufacturer IFU requirements. The latest Multisociety Guidelines recommend, "Endoscopes should be completely dried after reprocessing and before use."[3]
4. "Whenever possible, store the endoscope in a drying cabinet. If a drying cabinet is not available, dry the endoscope (exterior and lumens) and hang it in a well-ventilated HEPA cabinet that provides positive pressure.
5. "Once disinfected, endoscopes should be dried and stored in a way that will protect them from external contaminants. Hang the endoscope in a vertical position

to enable drying and maintain scope integrity. Remove caps, valves, and other detachable parts per IFU instructions."

Ron Banach, Director of Clinical Education, Ruhof Inc., urges SPD pros to look intricately for moist and dark lumens.

"Once the endoscope [high-level disinfection] process has been completed, studies have reported that bacteria growth can occur in a moist and dark lumen. There are scope drying devices or endoscope storage cabinets with a HEPA-filtered air flow pump that use connector tubing attached to the endoscopes lumens/channels while it hangs in the storage cabinet."

Melissa Kubach, Clinical Education and Training Manager, National Solutions Team, Agiliti recommends following the proper order of things.

"Proper drying of flexible endoscopes has taken priority over hangtime. Fully dried endoscopes are essential for discouraging conditions that facilitate bacterial growth. There are many methods and products currently available for completing effective drying.

"Drying principals are simple, but often misunderstood. The air must be HEPA-filtered at minimum to avoid blowing contaminants and particulates into the channels. It is necessary to control temperature and humidity conditions, as well as utilize multiple filters, including ULPA and oil filtration, when employing traditional mechanical air compressors. Storage areas and cabinet conditions should be monitored for humidity and temperature as well.

"Many users associate drying with air pressure (PSI), which is not the correct correlation for highly effective drying. Instead, the emphasis should be on airflow, which facilitates thorough and timely drying through air circulating over the drying surface, which is measured in cubic feet per minute (CFM).

"Drying time should be ample to address the hard-to-dry internal channels. Keep in mind, lengthy small diameter channels are the most difficult to dry, especially without automated drying. If drying takes place prior to storage, then cabinet conditions should encourage maintaining the 'dry' status. This may include circulated or positive air pressure and/or continuous air feed within the channels."

Shaun Sweeney, Vice President, Cygnus Medical, cautions that gravity doesn't solve everything.

"The past five years have introduced several eye-opening studies that have shown the amount of water remaining in the channels after [high-level disinfection] reprocessing. For years the common practice and assumptions, were that by hanging a scope long enough gravity would remove any droplets from the channel. A good portion of the water is removed this way. However, trails of tiny micro droplets are left behind in the process, and sometimes large droplets. At their level of atomic mass, the surface tension of water is stronger than the forces of gravity leaving the droplets there indefinitely. With no natural air exchange there is no mechanism for evaporation, so the droplets remain.

"Also in question is the role of an IPA alcohol purge. We have found in our studies that although there is a benefit the effect and results have been grossly overstated. The most effective process is evaporation through a continuous air flow. We have found the same results whether scopes are dried vertically or horizontally and with or without an alcohol purge."

John Whelan, RN, Clinical Education Specialist, Healthmark Industries, suggests surpassing well beyond the urge to purge.

"The drying that occurs in an automated endoscope reprocessor (AER) is a purge, not an intentional drying cycle. Anyone who has removed an endoscope from an AER knows it is still wet on the outside, and water drips from the channels. Scopes need to be purposely dried at the end of processing, even when an AER is used. Clinical investigations and research have shown that fluid remains in endoscope channels for days after placed in storage. This provides an ideal environment for microbial contamination and biofilm growth.

"Current expectations from standards and guidelines call for:

- Active HEPA-filtered forced air drying prior to storage, or the use of HEPA-filtered forced air-drying cabinets (where endoscope channels are connected to continuous airflow); and
- Active drying post-processing – regardless of whether the scope is headed to another procedure or into storage.

"The good news is that multiple options for drying are already on the market, and more are coming. These include drying cabinets as well as table-top dryers. As with any automated process though, it will be important to periodically perform quality control testing. This is where drying verification tests come in. These are very easy and quick ways to corroborate channel drying adequacy.

"Reprocessed items post high-level disinfection are not packaged like sterilized items that are in peel pouches or trays, so you can't tell just by looking at the device that it's been through processing. A scope after processing can look the same as a scope pre-AER. This calls for visual cues on the individual endoscope – before leaving the processing area. This means a label or tag attached to the scope that includes:

- the processing date
- the name(s) of the person(s) who performed the processing
- expiration ('hang time') date, based on the facility's established risk assessment.

"Multiple options exist for endoscope tags and labels, including various colors, blank or pre-printed, hang tag and zip tie options."

David Willoughby, Vice President, Marketing & Business Development, Medtrica, stresses keeping each device separated and secure.

- "Hang in containers or cabinets with unrestricted clean airflow so that gravity and clean air movement can effectively help with aeration and drying.
- "Do not allow instruments to make contact with another instrument or itself during storage.
- "Use a disposable and breathable cover to act as a physical barrier between the instrument itself, other instruments and the environment during both storage and pre-procedural transport
- "Use a disposable and breathable paper-based cover on the insertion tube during storage to wick away any remaining moisture after reprocessing.
- "Use a sterile cover to protect the distal end of an instrument during storage and transport, one that is not only disposable and breathable, but also one that is constructed with non-porous/non-absorbent materials."

Gregg Agoston, M.B.A., Vice President, Business Development, SPD Transformation Services, SpecialtyCare, reminds SPD pros not to proceed to the aeration/drying/storage step if prior steps have not been satisfied.

"If a flexible scope fails leak testing upon the return of the instrument to the processing area, this failure means that the instrument technically was not sterile or high-level disinfected during the procedure unless it can be documented that the cause of the leak test failure happened post-case. No one would ever allow a flexible endoscope to be used in a procedure if it was known to have a leak." HPN

References

1 Association of periOperative Registered Nurses. Guideline for Processing Flexible Endoscopes. Revised February 2016 for publication in Guidelines for Perioperative Practice, 2016 edition

2 Society of Gastroenterology Nurses and Associates. Standard of Infection Prevention in the Gastroenterology Setting. 2016.

3 Multisociety Task Force Article. Guideline on reprocessing flexible GI endoscopes and accessories. 2021.

ENDOSCOPE PRODUCT SPOTLIGHTS

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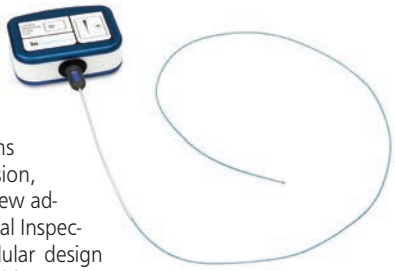

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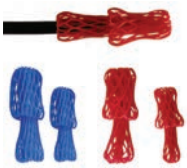

Endoscope Lens Tip Protectors: Expandable mesh protects lens from front and side impact. Allows moisture to escape, eliminating potential bacteria growth that occurs with most foam or solid protectors. Sterile/Non-Sterile.

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From patients to the planet:

A holistic approach to healthcare's most wicked problems

by Karen Conway, Vice President, Healthcare Value, GHX

Hospital and healthcare system leaders face numerous challenges: workforce burnout, staffing and supply shortages, increasing health disparities, and a continuing trend toward lower reimbursement and higher costs, to name just a few. And now, the esteemed National Academies of Medicine (NAM) wants to add another wicked problem to the list: addressing climate change through decarbonization of the health sector. To some, this will just be one more thing to add to what they consider an already seemingly insurmountable list. But if you consider each of these issues from a systems perspective, it becomes clear that they are interrelated, and adding the health of the planet to the mix may create a galvanizing platform to help find solutions to multiple problems. And once again, supply chain is front and center as a contributor to both the problem and the potential solutions.

In late September, NAM held the public launch for the Action Collaborative on Decarbonizing the U.S. Health Sector, an initiative being led by leaders from the various parts of the healthcare ecosystem, including manufacturers, distributors, hospitals, physicians, nurses, payors and the federal government, among others. The goal of the initiative is to reduce the health sector's negative environmental impacts while strengthening its sustainability and resilience. In other words, the action collaborative seeks to tackle several of healthcare's biggest challenges simultaneously. As steering committee member and former Cardinal Health CEO George Barrett noted, "We must address these challenges concurrently; we don't have time to do them sequentially."

Globally, the health sector is responsible for 4.5 percent of the world's total carbon emissions; but in the U.S, the percentage is nearly twice as high, with healthcare accounting for 8.5 percent of the nation's total carbon footprint. Those carbon emissions contribute to global warming, which in turn creates more extreme weather and a disproportionate negative impact on our most vulnerable populations. When carbon in the form of carbon dioxide is released into the air, it traps the heat and warms the planet. Higher temperatures, in turn, contribute to longer wildfire seasons, more intense heat waves and higher concentrations of water vapor in the atmosphere that can result in heavier rain and snow storms. When moister and warmer air is located over the oceans, it can strengthen hurricanes and cause deadly flooding like we experienced with Hurricane Ida.

Individuals with chronic disease often suffer more from climate change compared to the population as a whole. As we saw firsthand with the pandemic, chronic disease is more prevalent in low-income populations and communities of color. This is often due to the lack of gainful employment, nutritious food, safe housing, and transportation, among other social determinants of health. During the pandemic, these underlying health conditions led to higher rates of hospitalization and death from Covid-19. Researchers expect the impact of climate change to have a similar if not more severe impact on those same populations. Climate change and carbonization also contribute to higher deaths from extreme heat, and increased prevalence of respiratory and infectious diseases from air pollution and unsanitary living conditions made worse by severe weather events, respectively. Those same at-risk populations are further challenged by their limited ability to take protective action when faced with extreme weather occurrences.

For these reasons, the Biden Administration recently opened the Office of Climate Change and Health Equity, which Assistant Health and Human Services Secretary Rachel L. Levine, MD (another steering committee member) says is the first of its kind to address the intersection between the health of the planet and the health of vulnerable populations. At the public launch, the collaborative's leaders referenced the contribution of the healthcare supply chain to the sector's overall environmental impact. More than 82 percent of the U.S. healthcare system's total carbon footprint is tied to the production, transport, use and disposal of goods and services. The supply chain is the focus of one of four collaborative work groups (the others being Healthcare Delivery, Professional Education and Communication, and Policy, Financing and Metrics).

The Supply Chain and Infrastructure Working Group has an ambitious agenda, although it is primarily focused on the supply chain upstream from the delivery of care. The workgroup's "opportunities for action" list currently includes developing and promoting lower carbon and more sustainable innovations in products and services and creating shared sustainability metrics for manufacturers and distributors. At the launch, working group co-lead Michelle McMurray-Heath, MD, with the Biotechnology Innovation Organization (BIO), referenced a number of exciting innovations, including the use of CRISPR to create synthetic alternatives to carbon and less carbon-intensive plastics.

While exciting, I believe there are more things the collaborative can do to reduce supply chain's impact, including taking a lesson from the National Health Service in the U.K. Through its effort to be carbon neutral by 2050, the UK determined that one of the largest contributors to its carbon footprint was the National Health Service (NHS) and two-thirds of the NHS's carbon emissions could be traced to the supply chain. But rather than simply finding alternatives to current carbon-based products, the UK is considering how the delivery of unnecessary or duplicative care contributes to the overall carbon footprint. By using evidence to eliminate care that does not deliver value to patients, the NHS believes it can reduce the environmental impact associated with the delivery of that care, as well as the upstream impacts of manufacturing and transporting the products used in that care. Approaches

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such as this have the potential to reduce the total cost of healthcare delivery; in 2014, the Institute of Medicine estimated that unnecessary healthcare services contributed to about 10% of the nation's total healthcare expenditures, or nearly $300 billion a year. Beyond reducing unnecessary expenditures, better data on what works and what doesn't for specific patient populations can help us direct finite resources to the patient populations that need them most.

The supply chain can be a great source of data to support this real-world evidence generation. For example, supply chain can support the processes and back-end data management that enable accurate and complete documentation on what products were used in what kinds of care on which kinds of patients. By tying that data to the clinical outcomes achieved, we can build a robust repository of real-world data that guides evidence-based care redesign. As supply chain plays more of a role in the delivery of necessary social care interventions, it can also help document the effectiveness of various social care interventions, such as helping Type II Diabetes patients control their blood glucose levels with diet vs. just pharmaceuticals. In the end, it's all about understanding what works for which patients, and helping them get the kind of care (social and clinical) they need to optimize their health, while minimizing the negative impacts on the planet. HPN

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Quality sterile processing starts with IFUs at point of use

by James Schneiter

Protecting patients from the risk of infection is the chief responsibility of those involved in the sterile processing of reusable medical devices. The stakes are high; returning a contaminated instrument to surgery could be catastrophic.

The work begins with pre-cleaning a device at the point-of-use and involves all personnel involved in decontamination, cleaning and sterilization processes. The manufacturer of a device has an equal responsibility in protecting patients from harm. Validating the cleaning and sterilization Instructions for Use (IFU) promises that only clean, sterile, moisture-free devices will result from every processing cycle.

Unfortunately, many people mistakenly believe that if a device has been sterilized, even though it remains contaminated with organic debris after cleaning, it is safe to use on a patient. Nothing could be further from the truth. Any device that remains contaminated with residual organic debris is not safe to use, even after complete and thorough sterilization.

1 The first step in quality sterile processing begins with treating the device at the point of use.

The process starts by placing the contaminated device into sterile water or an approved enzymatic detergent. This initial step in the cleaning process is vital because if soiled organic materials dry or bake onto the device, the removal process becomes much more difficult. Even worse, it can render the disinfection or sterilization process less effective, or even ineffective.[2] Reusable medical devices must be presoaked or rinsed in neutral pH water or in a detergent solution immediately after use to prevent blood from drying. A spray detergent may be used in place of water or a detergent solution to keep the devices moist during transport. Once the devices have been treated at the point of use they are ready for transport to the decontamination area.

The Association of periOperative Registered Nurses (AORN) also recommends pre-cleaning at point of use.[3] Finally, point-of-use treatment is recommended and covered in sections 6.3 thru 6.4 in AAMI ST79 (2017).

2 The next step in quality sterile processing involves the decontamination and cleaning of the device. Manual cleaning is required in those areas that do not have mechanical cleaning units (e.g., ultrasonic cleaners or washer disinfectors). Manual cleaning is also required for fragile or difficult-to-clean instruments (e.g., Kerrison Rongeurs, laparoscopic instruments, etc.).

The most common types of mechanical or automatic cleaners are ultrasonic cleaners, washer decontaminators, washer-disinfectors and washer-sterilizers. The use of a washer-disinfector requires additional care when loading surgical instruments into the unit. All modular/take-apart instruments should be disassembled as per the manufacturer's IFU.[4]

Sterile Processing can ensure that devices are completely clean after processing and prior to the sterilization cycle. Conduct a verification test to help ensure that the device is clean and ready for further processing. These tests include protein tests, adenosine triphosphate (ATP) bioluminescence tests, both of which test for residual soils. Other options include reagent tests that test for protein and hemoglobin, and another 3-in-1 test for lumen devices that test for blood, protein and carbohydrates, all at the same time.[5]

Also consider using devices that have had their cleaning and sterilization IFUs validated by an independent testing laboratory using "worst case" cleaning validation protocols as established by the Association for the Advancement of Medical Instrumentation (AAMI) and the Food and Drug Administration (FDA). Without a validated IFU, sterile processing personnel can be doing everything right, according to the manufacturer's non-validated IFU, and still not have the assurance of sending clean, sterile, moisture-free devices back to surgery.

In order to ensure quality sterile processing in your facility — and the patient safety that lies at the heart of these efforts -- you must demand that device manufacturers provide a copy of their validated IFU. When asking a device manufacturer for a copy of the validated IFU, you need to be sure the manufacturer understands you are asking for more than just cleaning and sterilization instructions. The manufacturer must provide you with the independent laboratory validation test report that proves their IFUs actually work for cleaning and sterilizing the device. If a device manufacturer can't – or won't – provide you with cleaning and sterilization IFUs that have been independently validated using AAMI and FDA testing protocols, then you need to look for another device manufacturer who can and will.

If you would like to learn more about this subject, please visit #IFUcan via social media. The online resource was created by a small group of independent veteran healthcare executives, advocates and specialists in the subjects of sterile processing and distribution (SPD). The site explores the use of validated IFUs to improve sterile processing quality and reduce the risk of patient harm. Visit https://www.linkedin.com/showcase/68681202/admin/ for more details. HPN

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References

1. https://www.cdc.gov/infectioncontrol/guidelines/disinfection/cleaning.html
2. Ibid, "CDC"
3. https://aornguidelines.org/tool/content?gbosid=396870
4. Ibid, "CDC"
5. Ibid, "CDC"

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

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