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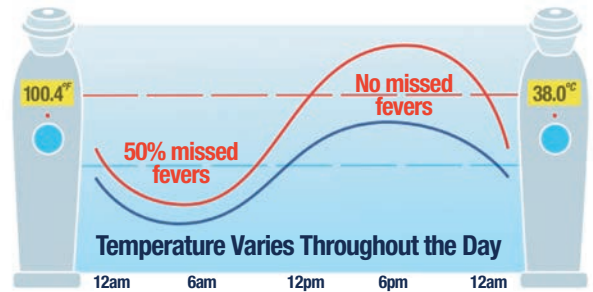
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In these times of COVID-19, checking for fever in the morning is not the most accurate time to detect a fever. Our daily circadian rhythm regulates our body temperature, which is lowest in the morning, and highest in the evening. New research shows this happens with fevers as well.

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Q&A's on Temperature Screening

Q: What are the recommendations for back-to-school and back-to work temperature screenings?

A: Back to school and back to work recommendations from authorities direct temperature screenings to be done at home.

- American Academy of Pediatrics Interim Guidance for School Re-entry
- Centers for Disease Control and Prevention (CDC)
- Occupational Safety and Health Administration (OSHA)

Q: How do circadian rhythms impact temperatures and assessments of temperatures?

A: Our internal biological clocks produce circadian cycles that vary throughout the 24 hours of each day. This causes body temperature to vary about 1.6°F (0.9°C) between lowest temperatures in the morning and highest temperatures in the evening. With fever, the circadian variation still occurs, but at higher temperatures. Accordingly, temperature assessments in the morning are low and will miss about half of the fevers. Temperature assessments in the evening are high and will detect all the fevers.



Q: When should temperatures be taken?

A: Twice Daily. Before leaving for school or work in the morning, and at dinner time in the evening. If a fever is detected at either time, a medical care professional should be contacted immediately. Even if school or work is done on-line, it is important to check temperature twice daily for the health of the family.

Q: What makes thermometers accurate? What should we know about thermometer accuracy? How about No Touch Thermometers?

A: Published peer-reviewed clinical studies. Without such studies by medical professionals, there is no assurance of accuracy on children and adults in all settings. No Touch thermometers are well known to be inaccurate, with unavoidable errors of +/- 4 deg F. They have no published peer-reviewed clinical studies supporting their accuracy.

Q: What types of thermometers are recommended for use in schools and workplaces? For use by families?

A: Only those thermometers that are clinically accurate as demonstrated by published peer-reviewed clinical studies.

Q: Can you explain how a thermometer margin of error might guide the choice for a cut-off of fever?

A: Some attempts to use a lower cut-off for Covid-19 screening have been made due to the low readings of the no touch thermometers from their inaccuracies. These attempts have been unsuccessful in "improving" the no touch devices' accuracies. A thermometer with accuracy backed by more than 80 published peer reviewed studies requires no adjustment to the medical standard cut-off for fevers.

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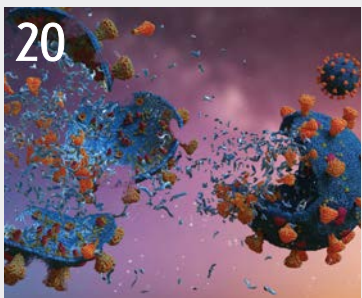


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1. European Heart Journal, Volume 34, Issue 37, 1 October 2013, Pages 2862–2872,
<https://academic.oup.com/eurheartj/article/34/37/2862/503604>.

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Greetings, my fellow Americans (and all of you devoted readers across the borders and seas).

Citizens of the United States of America head to the polls on November 3 to vote for a variety of incumbents and challengers, but perhaps the most popular contest by far this leap year is whether to extend the term of the 45th president or elect the 46th president.

Whatever the outcome of this 21st century election, you might be surprised to know the supply chain connections to several 19th and 20th century presidents.

In my private life I'm working on a presidential trivia book set against the backdrop of notable and noteworthy historical events, decisions and crises. As of this writing in early October, I've surpassed 900 questions through the Ronald Reagan administration of the 1980s. By the time you may be reading this, I should have cleared more than a 1,000 questions through 2020.

You might ask ... pffft! Why?

Well, you can learn a lot by "looking backward." (Yes, that's a favorable nod to Edward Bellamy's superb 1888 sci-fi novel.) The personalities. The platforms. The politics. How they mingle and mix - especially those behind-the-scenes deals and previously unknown negotiations between candidates, and the comradeship between past presidents and their contributions to current decisions and trends.

Out of 45 presidents to date, five (or 11 percent) recorded some hands-on roots in supply chain operations, be that in military service or in civilian service as part of, or in the aftermath of, war.

Four of the five served distinctly as military branch quartermasters - three in the Army and one in the Navy.

No. 18, Hiram U. Grant (you probably know him better as Ulysses S. Grant) (1869-1877) served as an Army quartermaster during the Mexican War (1846-1848).

No. 21, Chester A. Arthur (1881-1885) served as an Army state quartermaster (first assistant general and then general quartermaster) during the Civil War (1861-1862).

No. 25, William McKinley Jr. (1897-1901) served as a quartermaster sergeant during the Civil War, achieving heroic status for driving a supply wagon through Confederate fire in Antietam to outfit isolated Union troop units. Additional war-time feats earned him several more promotions - one even from future president Rutherford B. Hayes. McKinley ended as brevet major.

No. 31, Herbert C. Hoover (1929-1933), an engineer by training with a specialty in mining, initially orchestrated and oversaw massive humanitarian aid and relief programs in Europe during World War I, which led to President Woodrow Wilson asking him to lead the American Food Administration through the war and then the American Relief Administration after the war. As Commerce Secretary for Presidents Warren G. Harding and Calvin C. Coolidge, he worked to standardize a variety of industrial commodities to streamline operations and supply chains nationwide. President Harry Truman also recruited Hoover to help reorganize government bureaucracy following World War II as the Marshall Plan fortified war-torn Europe.

No. 37, Richard Nixon (1969-1974) worked with supplies as part of the Navy in the South Pacific in 1943 during World War II.

A number of the early presidents counted farming in their background. Many were lawyers and diplomats and quite a few served as state governors, which granted them management experience.

Not surprisingly, diplomacy, law, management and production/provision (farming and operations) represent key areas that strengthen Supply Chain Management.

So the next time you hear someone berate Supply Chain as part of the "Basement Brigade," be sure to enlighten them about their links to history and greatness.

Epilogue: No. 20, James A. Garfield (March-September 1881) may be recorded as the second president assassinated by a bullet, but he actually died from an infection that was traced to his physician's unclean hands and the use of unsterilized instruments. The caveat? Remember to wash your hands and thank your sterile processing professional colleagues.

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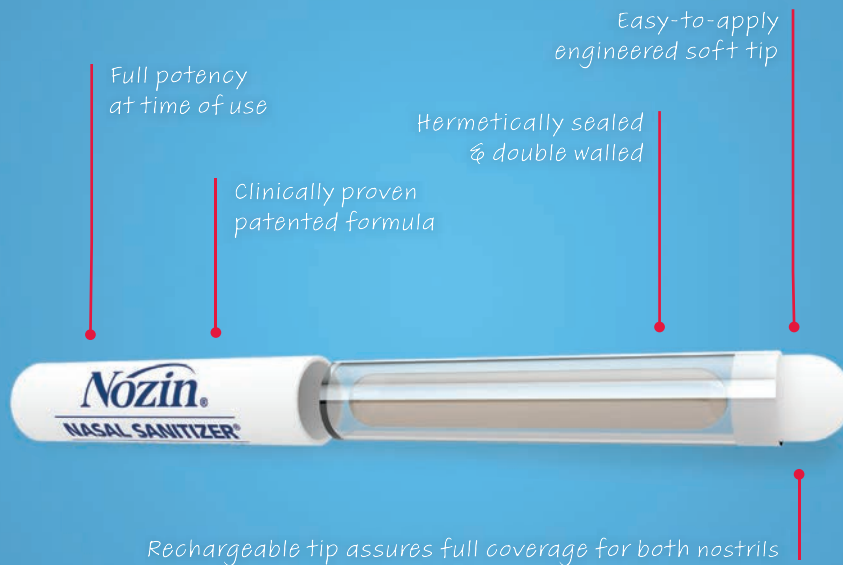
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FAST STATS

2.8 MILLION+

antibiotic-resistant infections occur each year in the United States, resulting in the deaths of more than 35,000 Americans, according to the CDC's updated estimates in 2019.

\$4.8 BILLION+

in medical costs were caused by a subset of resistant infections in 2017, estimated the CDC.

38%

decline occurred between 2015 and 2018 in medically important antibiotics sold for use in food-producing animals, reported the FDA in 2019.

18%

decrease occurred in the overall number of U.S. deaths from antibiotic-resistant infections from 2012 to 2017.

30%

decrease occurred in the number of U.S. deaths from resistant infections in hospitals as a result of efforts to prevent infections and control their spread.

20%

decrease in healthcare-associated antibiotic-resistant infections by 2025 is an objective for the CDC.

10%

decrease in community-acquired antibiotic-resistant infections by 2025 is an objective for the CDC.

10

new antibiotic resistance-related diagnostics projects across the U.S. Government by 2021, through funding or scientific or technical support, are an objective for ASPR/BARDA, CDC, FDA, NIH, ARS, and DoD.

100

new projects (e.g., grants, contracts, CARB-X awards) awards aimed at therapeutic discovery or development by 2024 are an objective for ASPR/BARDA.

Citation: NATIONAL ACTION PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA 2020-2025, October 2020, From the Federal Task Force on Combating Antibiotic-Resistant Bacteria, <https://www.hhs.gov/sites/default/files/carb-national-action-plan-2020-2025.pdf>

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NEWSWIRE

SMI announces Jane Pleasants as new Executive Director

SMI, a non-profit, member-driven community of healthcare supply chain thought-leaders has announced that effective February 1, 2021, Tom Hughes will begin serving as SMI Executive Director, Emeritus and Jane Pleasants will assume the leadership role of SMI Executive Director.

Pleasant will start her new position on February 1, following her retirement after



Jane Pleasants



Tom Hughes

many years as the vice president of supply chain at Duke Health. Her supply chain career has spanned more than 3 decades and in addition to her many accomplishments at Duke, she has led supply chain teams at both Vanderbilt University and University of Rochester. As an SMI founder, long-serving member on the Board of Directors, Board Chair-Elect and current Chairman of the Board she is a highly visible member of the SMI community and also was inducted into the Bellwether League Hall of Fame for Healthcare Supply Chain Leadership in 2015. She brings extensive knowledge, experience, and purpose to lead the next chapter of SMI.

Hughes has held the position of executive director of SMI for 16 years after a long-standing career in healthcare. Under his leadership, vision, and dedication, SMI has grown to more than 130 member organizations, which represent the nation's top providers, suppliers, manufacturers, distributors and innovators, like Johnson & Johnson, 3M, Abbott, Kaiser Permanente, Ascension and Amazon. He began on the front lines of hospital administration before founding Concepts in Healthcare, a healthcare supply chain consultancy, and after the sale of this company to BD, he ultimately became the vice president of BD Healthcare & Consulting Services. He is recognized for pioneering new approaches for provider-supplier relationships and has been a respected mentor, innovator, advisor, and leader to many in the healthcare supply chain industry. Hughes is the recipient of AHRMM's George R. Gossett Leadership Award and was inducted into the Bellwether League Hall of Fame for Healthcare Supply Chain Leadership in 2021.

Steve Gundersen, Vice President and General Manager of BD, a founding member of SMI and Chair-Elect said, "I've had the pleasure of knowing Jane and Tom for many years. Both are visionaries who have had a profound impact improving supply chain processes for clinicians and patients. Tom's countless contributions will be felt throughout the healthcare supply chain industry for years to come. Jane's willingness to listen, connect and contribute make her uniquely qualified to be the next leader of SMI. It has been an honor to know them both as colleagues and dear friends. I am excited for this next new chapter for Jane, Tom and SMI."

National action plan for combating antibiotic-resistant bacteria updated for 2020-2025

The National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), 2020-2025, presents coordinated, strategic actions that the United States Government will take in the next five years to improve the health and wellbeing of all Americans by changing the course of antibiotic resistance.

This plan is based on the U.S. Government's 2014 National Strategy for CARB, and builds on the first National Action Plan released in 2015 by expanding evidence-based activities that have already been shown to reduce antibiotic resistance, such as optimizing the use of antibiotics in human and animal health settings.

This plan continues to prioritize infection prevention and control to slow the spread of resistant infections and reduce the need for antibiotic use. To ensure that patients receive the right antibiotic care, the Plan supports innovative approaches to developing and deploying diagnostic tests and treatment strategies.

A One Health approach, which recognizes the relationships between the health of humans, animals, plants, and the environment, is integrated throughout the Plan, with an expanded effort to understand antibiotic resistance in the environment. The Plan also focuses on collecting and using data to better understand where resistance is occurring, support the development of new diagnostics and treatment options, and advance international coordination.

To address the growing threat of antibiotic resistance, the U.S. Government released the National Strategy for CARB in September 2014, which outlined five inter-related goals to guide Federal action. At the same time, Executive Order 13676 established the Federal Task Force for CARB to identify actions to implement the National Strategy. In March 2015, the Task Force released the first National Action

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Plan for CARB, aimed at moving the nation toward the goals of the National Strategy through specific objectives, strategies, and milestones to be achieved within one, three, and five years.

The new National Action Plan for 2020-2025 maintains the original five goals of the National Strategy and includes new objectives and targets aimed at achieving those goals.

Efforts to reduce the effects of antibiotic resistance are working: from 2012 to 2017, the overall number of U.S. deaths from antibiotic-resistant infections fell by 18 percent, and the number of U.S. deaths from resistant infections in hospitals fell by nearly 30 percent as a result of efforts to prevent infections and control their spread. However, antibiotic resistance continues to harm too many Americans, and worrisome trends are emerging, including the discovery of new resistant pathogens, such as *Candida auris*, and an increase in resistant *Neisseria gonorrhoeae* infections.

Other drug-resistant, community-acquired bacterial infections from group A *Streptococcus* and ESBL-producing *Enterobacteriaceae*, for example, are also increasing. The U.S. government is therefore committed to sustained and enhanced work to combat antibiotic resistance. In September 2018, the CARB Task Force began developing an updated National Action Plan for CARB, which would cover activities in the years 2020 through 2025. The Task Force reviewed prior efforts and anticipated future challenges and opportunities. The PACCARB solicited and reported on public input, which the Task Force considered alongside perspectives from Federal experts. The result is a set of coordinated, strategic actions aimed at changing the trajectory of antibiotic resistance and improving the health and wellbeing of all Americans, as well as the health of animals, plants, and the environment.

Many of the actions build on and expand evidence-based activities initiated under the 2015-2020 National Action Plan for CARB that have already shown impact, such as the appropriate use of antibiotics in human health, animal health, and in the environment. The Task Force continues to consider infection prevention and control, especially within healthcare facilities, to be high priorities, to both slow the spread of antibiotic-resistant infections and to reduce the need for antibiotic use. Many actions focus on collecting data and turning it into information that can be used to better understand where resistance is occurring, to support the development of new diagnostics and treatment options, and to advance international coordination.

The 2020 Plan maintains the original five goals of the 2014 National Strategy but establishes a new set of objectives to move the country toward those goals. Where possible, the 2020 Plan has established targets to be achieved by 2021, with some targets set for longer timeframes. Each annual report on this Plan will provide updated or added targets as relevant along with rationale for these changes. For example, the first annual report might note that a 2021 target has been achieved and establish a new 2022 target for that objective. HHS has the full report at, www.hhs.gov/sites/default/files/carb-national-action-plan-2020-2025.pdf

Vizient launches Environmentally Preferred Advisory Services

With the growing interest of hospitals to improve their environmental footprint, Vizient, Inc. announced the launch of its Environmentally Preferred Advisory Services, a supply chain solution designed to integrate sustainability to drive environmental solutions and positive health impacts. The new service expands on Vizient's environmentally preferred sourcing work, which includes the nation's largest portfolio of environmentally preferred hospital furniture.

Environmentally Preferred Advisory Services pairs Vizient member hospitals with sustainability experts who provide assessment and strategy services to elevate environmental initiatives. Such services may include gathering greenhouse gas data, an analysis of environmentally preferred purchasing volume, identification of opportunities for cost reductions and a forecast of energy reductions. The new service also provides a strategy that includes goal setting, metrics and key performance indicators as well as best practices for achieving a defined vision. Finally, the service includes policy development, workshops, educational materials and other stakeholder engagement tools as well as integration with existing processes through its comprehensive implementation services.

CDC updates "How COVID is Spread" webpage to include airborne spread

The Centers for Disease Control and Prevention (CDC) has issued updated guidance to its How COVID-19 Spreads website, which includes information about the potential for airborne spread of the virus that causes COVID-19.

CDC continues to believe, based on current science, that people are more likely to become infected the longer and closer they are to a person with COVID-19. The

update acknowledges the existence of some published reports showing limited, uncommon circumstances where people with COVID-19 infected others who were more than six feet away or shortly after the COVID-19-positive person left an area. In these instances, transmission occurred in poorly ventilated and enclosed spaces that often involved activities that caused heavier breathing, like singing or exercise. Such environments and activities may contribute to the buildup of virus-carrying particles. The guidance includes:

- How easily a virus spreads from person to person can vary. The virus that causes COVID-19 appears to spread more efficiently than influenza but not as efficiently as measles, which is among the most contagious viruses known to affect people.
- Some infections can be spread by exposure to a virus in small droplets and particles that can linger in the air for minutes to hours. These viruses may be able to infect people who are further than six feet away from the person who is infected or after that person has left the space.
- This kind of spread is referred to as airborne transmission and is an important way that infections, like tuberculosis, measles, and chicken pox, are spread.
- There is evidence that under certain conditions, people with COVID-19 seem to have infected others who were more than six feet away. These transmissions occurred within enclosed spaces that had inadequate ventilation. Sometimes the infected person was breathing heavily, for example while singing or exercising.
- Under these circumstances, scientists believe that the amount of infectious smaller droplets and particles produced by the people with COVID-19 became concentrated enough to spread the virus to other people. The people who were infected were in the same space during the same time or shortly after the person with COVID-19 had left.
- Available data indicate that it is much more common for the virus that causes COVID-19 to spread through close contact with a person who has COVID-19 than through airborne transmission.
- COVID-19 spreads less commonly through contact with contaminated surfaces. Respiratory droplets can also land on surfaces and objects. It is possible that a person could get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or eyes.

CDC has the report at www.cdc.gov/media/releases/2020/s1005-how-spread-covid.html **HPN**

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Sustainability strives for attention, priority in pandemic-stricken world

But some link sustainability to resilience

by Rick Dana Barlow



Historically, it should be no secret that sustainability as an aim, issue and management priority has struggled to gain a solid foothold among the key tentpoles of business operations.

This year, against the backdrop of a global pandemic that has shaken the very foundation of supply chain performance, is no exception even as the clinical, financial, operational, administrative and supply chain responses to COVID-19 shuffles sustainability lower down the priority list.

Sustainability supporters and promoters, however, remain dedicated, devoted, passionate, resilient, resolute and undaunted.

Sustainability matters

Zoë Beck, Manager, Sustainability, HealthTrust, acknowledges the challenges the pandemic has wrought but assures that the commitment to sustainability remains steadfast.



Zoë Beck

“Realistically, most hospitals have not been able to focus on sustainability due to pressing issues to keep hospitals open, functioning and safe for patients and staff,” Beck told *Healthcare Purchasing News*. “However, what hospitals have been doing as a result of the pandemic can be lessons moving forward for what is important for future resiliency. Sustainability plays a huge role in this.

Beck points to value lessons learned.

“While the healthcare industry has dealt with huge issues in terms of supply availability, facilities have been able to be innovative in the ways they conserve, obtain and stock supplies,” she said. “These lessons can be useful for the future as hospitals look at ways to ensure they have a robust supply chain. They have learned ways in which they can use fewer products, reprocess products that have not traditionally been reprocessed, monitor use of products and possibly move purchasing to more local manufacturers.

“While sustainability has most definitely not been the focus, the lessons learned from

COVID can help health systems to be more sustainable and resilient in the future,” she concluded.

The pandemic offers up a wealth of teachable moments for everyone, according to Rob Chase, Founder and President, NewGen Surgical.

“The pandemic has caused everyone, in healthcare and in society, to change what they are doing and to adjust priorities,” Chase noted. “However, the pandemic



Rob Chase

has also ignited a renewed focus on how healthcare can recover as more resilient and sustainable. You saw not only the real challenges to a supply chain that was not ready, but the actual plastic pollution of the PPE in front of us on the streets and in the water. The pandemic has forced us all to reflect on the interconnectedness of humans, the environment and our health. There is an increased awareness of the need to take action in support of sustainable initiatives to protect the foundation of all health – a healthy environment.”

Although the pandemic has disrupted many facets of life, according to Cristina Indiveri, Senior Director, Strategic Programs, Vizient, healthcare organizations are seeking environmentally preferred purchasing strategies based on consumption behaviors and patterns.



Cristina Indiveri

“Prior to the pandemic, it was routine for healthcare organizations to utilize disposable products, especially PPE,” she observed. “Now, healthcare organizations have found ways to safely reuse what would normally be considered single-use items like N95 respirators. In addition, hospitals are also integrating other reusable items such as gowns, bouffant caps, skull caps, fabric masks and shoe covers. Utilizing reusable products also reduces

their environmental footprint by minimizing waste.”

By “going green,” Indiveri added, healthcare organizations are finding that using reusable items can lower costs in the long term “by factoring in the return on investment instead of upfront costs.”

Andrew Knox, Manager, Environmentally Preferred Products, Premier, understands the dilemmas that clinicians, administrators and supply chain professionals have been facing for the last nine months at least, particularly as COVID-19 challenged sustainability efforts.

“It has been all hands on deck for healthcare providers as they work tirelessly to care for patients and ensure they have the critical products and supplies they need to do so,” Knox noted. “In this environment, anything that is not an immediate priority has had to wait its turn.”

But the pandemic should serve as an impetus to act and not an excuse to postpone and wait.

“Sustainability is central to the mission of the healthcare industry,” Knox insisted, “and the pandemic only reinforces its importance. For example, several recent studies have suggested a link between the severity of COVID-19 infections and local levels of air pollution, and the stress on supply chains for disposable materials has certainly highlighted the dangers of relying too heavily on single-use items.”

The pandemic reinforces heightened awareness, Knox emphasizes.

“Healthcare is beginning to truly understand its environmental footprint – and with an increasing awareness of the need to set aside competitive boundaries and work together to promote and encourage participation in green initiatives,” he said. “Practice Greenhealth, a non-profit that helps embed sustainability into healthcare operations, and the Healthcare Anchor Network (HAN), which focuses on local impacts of large healthcare institutions, have been essential in fostering meaningful collaboration.”

Seeing green

Executives at Greenhealth Exchange have witnessed the butterfly effect the pandemic has wrought on healthcare facilities and on sustainability projects, in particular.

Lingering supply chain challenges remain evident, according to Rachel Franklin, Senior Director, Contracting & Supplier Relations, Greenhealth Exchange.

“The decrease in elective procedures, and subsequently revenue, has put increased pressure on Supply Chain to take cost out of the system,” Franklin noted. “As a result, Supply Chain staff [are] focused on the lowest invoice price and not necessarily with other attributes, such as those aligned to sustainability.”

Further, “Supply Chain staff are overwhelmed just trying to manage day-to-day product shortages and patient volume spikes, which cuts into the time needed for sustainability-related improvements,” she acknowledged.

Yet among those challenges, opportunities abound, according to Thresa Pattee, Director of Sustainability, Greenhealth Exchange.

“One specific example is the dependence and high-volume use of disposable products,” Pattee indicated. “Soaring prices, extreme stocking challenges and dramatic increases in waste have opened the door to consider reusable products and sourcing of domestic products and services where they would never have been evaluated previously.”



Thresa Pattee

The pandemic also provides the industry and the world with a panoramic view of a potential future that can be fixed – even down to the local level, Gary Cohen, President and Founder, Health Care Without Harm, states.

“The COVID-19 pandemic is exposing all the cracks in our safety net system – all the economic, racial and social inequities,” he said. “We need to build more localized systems that don’t depend entirely on global supply chains. Healthcare needs to partner with other actors – like regional food systems, distributed energy systems and local social services – to build more resilient communities.”



Gary Cohen

“More broadly, COVID-19 gives us a glimpse into a future where society is fundamentally threatened by ecological forces that know no borders and impact everyone in the world,” Cohen continued. “We have arrived at this future sooner than we thought. Our presence and our responses to this pandemic will provide us with crucial lessons for how we can address the broader climate crisis that is also fast approaching.”

Supply Chain probably should consider focusing on a back-to-basics approach, urges Stacey Winston, Vice President, Program Management, Intalere.



Stacey Winston

“With the pandemic, much of the focus has shifted to the fundamental aspect of supply chain – assurance of supply,” Winston said. “With this, many organizations have in some cases reduced or eliminated sustainability goals in their evaluation of potential suppliers. Over the long term, however, it will be important to reinforce these standards. A sustainable supply chain is a resilient supply chain and having a dialogue with suppliers about their initiatives on sustainability indicates that the relationship has moved well beyond traditional, transactional relationships.”

Medline Industries, meanwhile, sees the pandemic less as a roadblock to progress and more as a springboard to innovation in terms of dedication to sustainability and service to customers.

“Our responsibility as a healthcare company will always be ensuring the health and safety of those that we serve,” said Hannah Anderson, Sustainability Specialist, Medline Industries. “Part of ensuring health and safety is continually addressing climate change-related issues in all that we do. Throughout the pandemic, the general atmospheric sense of urgency extends to our sustainability work. We’ve been doubling down on our commitments to combat climate change and zeroing in on programs and initiatives that have the largest positive effect on our planet for the greatest number of individuals. For many of us in the healthcare space, the pandemic has brought home the importance of climate change action.”



Hannah Anderson

So Medline executives and professionals have doubled down on a new initiative.

“With packaging waste and plastic use top of mind for many of our customers and across the industry, we set out to create a program to pave the way for large-scale change,” Anderson continued. “This September, we launched our Sustainable Packaging Lab – a cross-functional team of Medline R&D, Operations, Engineers and Sustainability team members providing solutions to packaging challenges. The lab will address issues core to climate change and global warming; cutting down on use of fossil fuels, virgin material use and scaling up sustainable material substitutions for plastic and cardboard packaging.” **HPN**

Keeping sustainability front of mind on the front line and back office internally

But also acknowledging and emphasizing its importance with supplier partners externally

As the world struggles to survive and surmount a global pandemic, healthcare organization executives and professionals in the administrative, clinical, financial, operational and supply chain realms bob and weave, pivot and pursue sustainability initiatives among competing priorities.

Healthcare Purchasing News reached out to more than a dozen experts in sustainability initiatives, projects and strategies for tips and techniques to maintain and grow environmentally based efforts within their organizations as well as externally with their suppliers and third-party service companies. Here’s what they shared.

Provider-based internal focus

Thresa Pattee, Director, Sustainability, Greenhealth Exchange

“On an organization level: Sustainability Policy embeds sustainability criteria, unifies the work and adds consistency for the organization.

- Identify priority sustainability issues to focus/educate on
- Establish goals based on above, communicate them widely and track progress
- Embed sustainability focus into job descriptions, reports, etc., to communicate the importance of this work within the organization

- Include sustainability criteria in RFP/RFI
 - Utilize existing tools from GPO and also inform GPO that sustainability is a priority
 - When moving to more sustainable products, use the opportunity to educate on the benefits of the new criteria and why it is important, what it achieves towards goals, etc.
- “On a personnel level: Be a champion within your own organization.
- Participate in the “Green team” where they exist so that product specifications, etc. can be communicated and effectively implemented
 - Identify other champions (whenever possible, clinicians) with whom to work within the organization

SPECIAL FOCUS

- Partner with outside organizations that provide education and sharing opportunities in sustainability, network with other supply chain professionals doing this work and get educated on sustainability issues/work."

Zoë Beck, Manager, Sustainability, HealthTrust

"In the current environment, supply chain has been focused on ensuring patients and staff are supported appropriately to manage COVID-19. While their efforts have been focused on COVID-19, some very important sustainability efforts have continued.

- **Reprocessing.** These efforts have expanded to non-traditional products and though most have done this out of necessity, it has helped to ease supply availability and save hospitals money. This is an effort that has been maintained and will continue to support the resiliency of our hospitals.
- **Reduce waste.** Hospitals have generally worked to reduce waste over time and have continued these efforts recently. Most efforts toward reducing waste save money and help to keep waste out of landfills. These efforts will also continue to support resiliency in our hospitals.
- **Reduce chemicals of concern.** These efforts have definitely fallen in priority recently as hospitals have raced to focus on keeping supplies available for patient and caregiver safety. However, as hospitals look to the future, consumers are leery about returning to hospitals in general. As hospitals look to reopen and perform more elective procedures, consumers (especially those in younger generations) are looking to feel safe in hospitals. By working to reduce/eliminate chemicals of concern, they will be better positioned to make patients feel safe in the hospital environment. This includes both medical products and those found in the interior of the hospital (the built environment)."

Rob Chase, Founder and President, NewGen Surgical

"Start integrating low-carbon sustainable products in areas that are non-procedure critical. That way you are making meaningful progress without changing anything procedurally on the Operating Room. For example: Eliminating polystyrene packaging trays that are the foundation for many of the custom surgical kits used in the OR. By substituting these with plant-based, recyclable alternatives, supply chain can make an easy change with the OR and eliminate tons of plastics waste and corresponding CO₂ emissions.

"With 35 percent of all hospital waste being generated in the OR, this is a good place to focus. There are two ways to reduce waste coming from the OR.

1. Keep single use items destined for landfill in circulation longer (reprocessing)
2. Move off of single-use plastic products over to reusable or renewable plant-based alternatives and achieving a source reduction of single-use

plastic production, use and disposal. Plant-based renewable products can be easy to integrate and offer a low-carbon, bio-degradable, sustainable alternative to petroleum-based plastic.

"Supporting companies and purchasing products that have a better climate footprint is something that needs to happen across all industries, and in healthcare it supports healthy communities for today and tomorrow. When companies innovate and create sustainable products, supply chain needs to consider and support [by] purchasing these products, assuming they meet the clinical requirements, and support the transition to responsible production and consumption. So really, responsible production and consumption will affect 'Goal 3: Good Health and Well-Being,' 'Goal 14: Life Below Water,' 'Goal 9: Industry Innovation and Infrastructure,' 'Goal 15: Life on Land' and 'Goal 17: Partnerships for the Goals.' [Editor's Note: These are part of the 'The Global Goals For Sustainable Development' initiative.] That is key – working together and collaboratively to make these changes happen." [Editor's Note: For more information, visit <https://www.globalgoals.org/>.]

Elise Bexley, Manager, Strategic Accounts, WestCMR

"Incorporate recycling/zero-landfill initiatives.

"Develop a [first-in-first-out] FIFO system and perform routine no-move reports for inventory with a finite shelf life. Facilities should properly track their inventory, allowing them to identify excess or slow-moving items. Prior to expiration, facilities should attempt to return, transfer, or liquidate products for which they have no use. If items are unable to be returned or transferred, utilize companies offering a sustainable alternative for excess inventory, like WestCMR."

Nicole Misener, Marketing Strategist, WestCMR

"Utilize outlets like WestCMR that offer sustainable solutions for your facility. WestCMR was developed to offer an alternative for when healthcare facilities encounter surplus or obsolete inventory, ultimately reducing material waste."

Andrew Knox, Manager, Environmentally Preferred Products, Premier

"Today, sustainability is an absolute requirement for every company and organization. As the consequences of our current practices become clearer – climate change, habitat loss, plastic pollution and more – a greater number of organizations and people are making their voices heard, using sustainability as a lens

through which to make economic choices and cutting back on waste.

"To support these goals, Supply Chain can help enable sustainable practices in three key ways:

- **Supply Chain must ask questions.** It's critical [that] suppliers know and understand that sustainability is an issue of great importance to their customers, and suppliers must have the ability to accurately respond to questions about what's in their product, how it's packaged and other environmental attributes. Premier requests for information (RFIs) include questions on environmentally preferable policies and practices given an organization's sustainability efforts rely on strong data collection.
- **Make the data available.** Supply Chain is in a unique position to obtain vital sustainability-related information from suppliers and pass it on to decision makers within their organizations. It's also important that Supply Chain has the ability to separate meaningful environmental claims and data from 'greenwashing.'
- **Provide feedback to suppliers.** Alongside an organization's commitment to purchase environmentally preferable products, it's also imperative to let suppliers know that these products were purchased because of their reduced impact. This feedback helps reinforce to suppliers that the sustainable efforts and environmental improvements they undertake provide value and ROI to their purchasers and the market at large."

Cristina Indiveri, Senior Director, Strategic Programs, Vizient

"Supply chain leaders can help their organization grow in the area of environmentally preferred sourcing through education, setting goals and tracking performance. Education of supply chain staff starts with providing an understanding of environmentally preferred attributes and the significance of those in meeting organizational goals. Educating clinical and non-clinical staff will be important for the adoption of environmentally preferred products when changes occur. They need to understand 'the what' and 'the why' when product changes occur. In addition, they need to understand how they can provide feedback when product changes occur so concerns can be efficiently addressed. Lastly, the supply chain needs to set goals for the adoption of environmentally preferred products and then ensure there will be data and analytics to support the work and measure performance."

Hannah Anderson, Sustainability Specialist, Medline Industries

"Sustainable supply chain encourages organizations to consider lateral, deep programs in scale that have the power to affect meaningful change. The most common approaches are recycling, reusability and reducing supply chain waste. Some tips to help maintain efforts:



- Look at what your organization could close the loop on to increase circularity – removing the ‘dispose’ element from the pervasive ‘take, make, dispose’ model much of our economy operates within today. As one example, question the way you transport goods. Could those containers be substituted with a non-virgin material, choosing from options like renewable or recycled content, and reused throughout the supply chain?
- For items that require virgin material, look at local facility recycling capabilities in the areas where you operate.
- Finally, look at surplus products. Is there a better outlet for these items than the landfill and opportunity to reduce waste?”

Stacey Winston, Vice President, Program Management, Intalere

“Supply Chain can help organizations achieve and maintain sustainability goals in a number of ways. Not only can they assist internal initiatives in supporting operations and facility management and achieving energy conservation, waste elimination, etc., by identifying opportunities within different categories of spend and being diligent themselves as employees, but Supply Chain teams can also extend the sustainability initiatives into their Tier 1 and Tier 2 supply base to expand the impact across the integrated supply chain.”

Supplier-based external focus

The key strategy and tactic for this effort is to incorporate sustainability into contract language and negotiations upfront, experts advise.

Thresa Pattee, Director, Sustainability, Greenhealth Exchange

“Develop contracts for sustainable products that:

- Include criteria and reporting requirements in RFI/RFP/RFQ.
- Include sustainability data submission requirements as part of the terms and conditions.
- Encourage GPOs to include criteria and reporting requirements in RFI/RFP/RFQ and require data submission requirements as part of the terms and conditions.
- Encourage GPOs to expand informational data around sustainability criteria
- Encourage GPOs to highlight sustainable products in their product catalogs and contract launch documents.

“Contract Management for sustainability-focused agreements [should]:

- Communicate to suppliers that the submission of sustainability data to GPOs and on your RFP/RFI is important and may be factored into vendor performance measurements.
- Include sustainability components in [quarterly business reviews] and track progress against previous quarter.

- Encourage your GPO to require submission of supplier sustainability data and include it in their [quarterly business reviews].
- Communicate with suppliers on what the organizational sustainability priorities are so that suppliers can respond with opportunities and prepare with product development.

“Contract Renewals [should include]:

- Evaluation of progress towards goals at the health system and GPO level.
- Review of roadblocks at the health system and GPO level.
- Review of goals to determine success at the health system and GPO level.
- Evaluation of market evolution/movement to determine if new (improved) goals are feasible at the health system and GPO level.
- Communication of new goals to suppliers at the health system and GPO level.”

Zoë Beck, Manager, Sustainability, HealthTrust

“Continue to ask the standard questions about medical products. Continue to present the answers to these questions in the sourcing process to encourage discussion around environmental health attributes of products. By continuing to ask the questions and present them in the sourcing process, the conversation continues and we continue to encourage suppliers and health systems to consider sustainability in their purchasing decisions.

“Incorporate questions about the supplier’s internal efforts on sustainability to better understand the companies with whom we do business. This will also help health systems and hospitals to report out on environmental, social and governance factors. This is currently a decision factor for many in choosing with whom they do business and from whom they consume goods or services.

“Educate supply chain professionals on the environmental factors that you are considering in contracting. Many are not aware of these factors and how they affect patients, clinicians, staff and the surrounding communities. When supply chain teams are more educated, they will be more equipped to take environmental health factors into account when contracting.”

Rob Chase, Founder and President, NewGen Surgical

“Include in new supply agreements language that allows for the flexibility to purchase sustainable products. If a new vendor brings to market a sustainable product, you want to be able to evaluate and potentially integrate that product into your surgical suites without being negatively penalized for doing the right thing and supporting a healthy planet. Call it the ‘Sustainability Clause.’ Like a new technology clause in many contracts, this is an area where hospitals should support innovation, especially when it addresses climate change and or plastic pollution.

“Healthcare contributes 10 percent of all CO₂ emissions in the U.S. Recent studies (Health Care Without Harm) suggest that up to 71 percent of healthcare’s CO₂ emissions are ‘Scope 3’ and associated with the products and services used in the delivery of care. The healthcare industry can reduce its emissions with what we call climate smart procurement and products, but it’s going to need the support of distributors. Hospitals that have carbon reduction goals are going to need to engage supply chain and communicate to vendors the importance of understanding and measuring their own product emissions. [They must be] able to measure the embedded energy and emissions associated with the production of each product, which will be essential to greening the supply chain. [They must] discuss sustainability and possibly require submissions of product environmental metrics by the vendors. Every product has a footprint. If you have a product that performs as good as or better, and is better for the environment, aren’t we compelled to use it?

“Require vendors to measure and report on Chemical of Concerns in their products through the use of an environmental scorecard. We also have a program Small Change Big Impact – where we worked with Dr. Ann Blake to scientifically and methodically measure our environmental impacts – plastic reduction and Scope 3 GHG. So many companies make claims, but you have to measure and have them based in science. While we pass all environmental scorecards, there is an excellent article by Dr. Jodi Sherman of the Yale University School of Medicine and Public Health and Dr. Cassandra Thiel, PhD, ‘Reducing Plastic Pollution from the Health Care Industry.’ that really outlines the need for a central widely adopted measurement that is clinical and science-based. I believe once one of these certifications and guidelines becomes the standard, it will be easier to know you are making the most impactful and measurable decisions on sustainability initiatives you can.” [Editor’s Note: For more information, visit <https://ghgprotocol.org/standards/scope-3-standard> and <https://www.carbontrust.com/>.]

Elise Bexley, Manager, Strategic Accounts, WestCMR

“Supply Chains may seek out partnerships with healthcare consulting companies or explore joining a collaborative. These types of organizations are committed to providing their facilities with resources that offer sustainable solutions.”

Andrew Knox, Manager, Environmentally Preferred Products, Premier

“On a fundamental level, Supply Chain must incorporate sustainability-related questions into the RFI/RFP process and documentation. Meaningful action starts with asking strong questions. In addition, Supply Chain should work with suppliers and service companies to make

SPECIAL FOCUS

sure sustainability-related information and data is readily available at the point where purchasing decisions are made.

"Supply Chain can help sustainably minded suppliers make the case as to why one product may be preferable to another. A great example of this is the decision to buy reusable versus disposable products. Reusable items can sometimes bring a bigger price tag, but they are often economically favorable over their lifetime as compared to buying and disposing of a new item for each use. Supply Chain can be critical in helping educate purchasers and enable environmentally conscious decision making.

"Supply Chain should work collaboratively with healthcare systems' subject matter experts. Premier maintains an Environmentally Preferred Purchasing Advisory Council made up of specialists in this area from a cross-section of our membership. The Council's input is vital to ensuring that our sustainability efforts reflect their goals and that the documentation sent to suppliers is fit for purpose."

Cristina Indiveri, Senior Director, Strategic Programs, Vizient

"We believe that a critical step toward incorporating sustainability into their contracting work is adopting a set of environmentally preferred attributes and requesting that this information

be included in all requests for proposals (RFPs). They can also incentivize suppliers to submit environmentally preferred information by offering additional points within the RFP process. We also encourage supply chains to directly communicate their organization's preference and use of environmentally preferred items via public reports and public, organizational mission statements.

"Vizient took this step in 2017 and we now have 81 percent compliance from suppliers, and it has resulted in increased engagement and adoption of environmentally preferred products in our contact portfolio."

Hannah Anderson, Sustainability Specialist, Medline Industries

"When working with a supplier, I think the top priority is to create a roadmap for sustainability efforts and have a conversation with suppliers and service companies so they understand the organization's goals/priorities. This will help them guide your contracting efforts and most importantly, help determine if that supplier is a right fit. To help guide success, I recommend that healthcare providers work with suppliers who are operationally energy efficient and consider certifications like LEED, BCI, ISO14001 and more. A few other things to consider:

- Be clear about the chemicals your organization allows and the chemicals of concern the organization is trying to eliminate. Some of the chemicals we've heard that customers are trying to eliminate include formaldehyde, flame retardants, and polyvinyl chloride. I suggest that healthcare organizations develop a standards document that they can have as a reference to share with suppliers.
- Incorporate a recycled content standard for your packaging. Determine a threshold, based on your product offering that makes sense for your organization, and include those percentages in your documentation. At Medline, we reference the EPA's procurement guidelines, the Federal Trade Commission's Green Guides, and industry leadership for direction on best practice."

Stacey Winston, Vice President, Program Management, Intalere

"It's important to ensure that you have visibility to your entire supply chain and that you map it out from the context of sustainability, understanding social, economic and environmental challenges they face and how they are addressing. You can then better understand potential opportunities for those suppliers to respond to those challenges and improve their sustainability footprint.

"In addition, as an organization adopts sustainability goals internally, it's critical that those very same goals, metrics, and KPIs are extended to supplier partners so they can better align to those enterprise goals. In addition, these should be included in RFPs to ensure that any new or prospective suppliers are evaluated in the context of how they will assist the enterprise in achieving these goals. A supplier is much more likely to adopt those goals and standards in order to win the business as opposed to simply maintaining existing business.

"Finally, it's important that sustainability goals are captured in a contractual document, either explicitly or as part of a supplier performance management program. This could also include sustainability goals for the supplier to implement with their supply base. On an agreed upon frequency, at least annually, the supply chain team and the supplier should meet to discuss mutual actions and performance on sustainability initiatives."

Editor's Note: For additional tips and techniques, be sure to visit "Environmental Sustainability: More process than progress?" November 2019 HPN, <https://www.hpnonline.com/21114109> and "Embarking on environmental sustainability," November 2019 HPN, <https://www.hpnonline.com/21114251>.

Visit <https://hpnonline.com/21158595> for the sidebar: Placing sustainability projects in proper order

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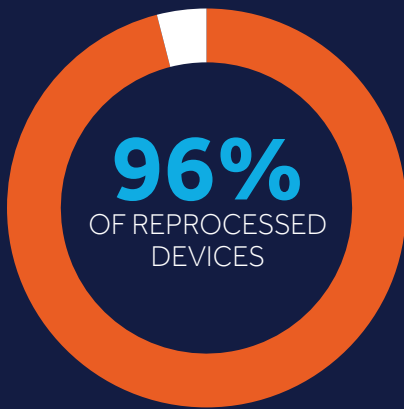
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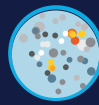
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Study published in *Surgical Endoscopy* raises questions about the ability to effectively clean and sterilize with reprocessed vessel-sealing devices¹



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OF 4 DIFFERENT TESTS**
THAT CHECKED FOR
ORGANIC MATERIAL^{1,‡}

1 OUT OF 165
REPROCESSED DEVICES
**GREW
BACTERIA
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AND THE LEVEL WAS
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[†]Sterility assurance level of 10⁻⁶ accepted by the FDA as laid out in the Association for the Advancement of Medical Instrumentation (AAMI) standards ST67 and TIR 12 for devices contacting normally sterile tissue.

[‡]The combination of failed tests included visual inspection, optical and scanning electron microscopy, hemoglobin detection, and sterility testing.

[§]Medtronic will not perform complaint investigations on competitive devices.

[¶]Optional risk-sharing and indemnification programs include the LigaSure™ Technology Performance Pledge and Project Zero collections programs.

1. Chivukula, S.R., Lammers, S. & Wagner, J. Assessing organic material on single-use vessel sealing devices: a comparative study of reprocessed and new LigaSure™ devices. *Surg Endosc* (2020). <https://doi.org/10.1007/s00464-020-07969-8>.

OPERATING ROOM

IV systems strive for access, fluidity

Maintaining steady flow of equipment, supplies and safety during continuing healthcare crisis

by Ebony Smith

In recent history, intravenous (IV) systems, medications and other necessary devices and items for patient care have undergone shortages. Phenomena, like these, consequently, were the ripple effects of devastating public health and environmental crises.

As *Healthcare Purchasing News* reported in an article last year, “A series of unfortunate IV events, Crisis = Recalls + Seasonal Virus + Supplier Exit + Natural Disaster,” “Within the last decade, healthcare providers and suppliers have experienced at least two notable shortages of IV and pharma solutions.”

“The first emerged in the 2013-2014 timeframe, following a Food and Drug Administration recall, coupled with an aggressive flu strain season and the exit of the No. 2 supplier,” *HPN* reported. “The second emerged in the 2016-2017 timeframe, following a hurricane that damaged the Puerto Rican manufacturing plant of the No. 1 supplier, but also cut out power by damaging the electrical grid on the island nation it hit, which further hampered production.”¹

Pandemic-drawn direction for resources

COVID-19, of course, is the newest and most catastrophic public health emergency disrupting the healthcare landscape and lives around the world today. This time, however, the high demand for inventory in hospital and critical care spanned from medical, testing, and personal protective resources.

“As organizations that represent or collaborate with individuals and institutions at the forefront of delivering health care in the midst of the COVID-19 pandemic, we are vitally concerned with the shortages of masks, face shields and other personal protective equipment (PPE), ventilators, swab kits, and testing capacity that are critically needed by frontline caregivers and patients,” emphasized several healthcare

associations in a March statement released by the American Hospital Association.²

The associations expressed, “We strongly support emergency efforts at the federal level to dramatically increase the production and distribution of PPE and other necessary medical equipment and supplies. We also support the availability of telehealth services during this time to use less PPE while preventing the spread of infection.”

As far as IV systems go, national policies and recommendations were issued to ensure availability for any care needed. This guidance included:

- **FDA – In April, as the number of cases magnified, the U.S. Food and Drug Administration (FDA) released new guidance on the manufacture and availability of infusion pump systems.**

“FDA is issuing this guidance to provide a policy to help expand the availability and remote capabilities of infusion pumps and their accessories for health care professionals during the COVID-19 pandemic,”³ stated the FDA in a guidance document.

While an enforcement policy from the FDA outlined the specific scope of devices needed for care.

“FDA believes it is important to help facilitate availability of the devices, which includes large volume parenteral (LVP) infusion pumps, syringe infusion pumps, PCA infusion pumps, and ambulatory infusion pump devices, and their accessories, in order to support patients who require sustained infusion therapy in the context of the COVID-19 public health emergency,”⁴ the FDA addressed.

The agency noted, “Patients infected with COVID-19 may require continuous infusion of medications, nutrition, and/or other fluids. As such, FDA recognizes the need to help increase access to an adequate supply of devices to treat patients who need these therapies and to help foster technologies that maintain a safer physical

distance between the health care provider and patient affected by COVID-19.”

The policy went on to describe measures manufacturers may take to adequately produce and supply needed equipment.

“Wherever possible, health care facilities should use FDA-cleared infusion pumps and accessories to provide infusion therapy, or a device authorized by an Emergency Use Authorization (EUA),” they explained.

Additionally, they indicated, “More specifically, this policy will create more flexibility for manufacturers that make device modifications to address manufacturing limitations or supply shortages related to the public health emergency.”

- **ASA – In June, as the crisis surged on, the American Society of Anesthesiologists (ASA) made recommendations on the availability and preservation of IV drugs.**

“Because of the COVID-19 pandemic, many institutions throughout the country are anticipating or currently experiencing shortages of vital anesthetic drugs that are also commonly used in intensive care units (ICUs),”⁵ set forth the ASA in a press release.

The society specified, “When institutions approach capacity status in their ICUs and have concerns regarding the availability of sedating and paralytic drugs, anesthesiologists should strive to conserve vital drugs for use in ICUs. Shortages of particular concern include propofol, dexmedetomidine, midazolam, and neuromuscular blocking agents.”

Further, they directed on specific protocols for use of IV anesthetics and agents in surgical care.

“Surgeries that are performed in the operating room should avoid use of total intravenous anesthetics (TIVA) whenever possible to preserve the supply of intravenous agents,” the society stated.

They continued, “Efforts should be made to employ the use of regional anes-

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

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



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

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

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thetic techniques wherever suitable. In the event that intravenous sedation agents are unavailable, inhalational anesthetics have the potential to be used for sedation when anesthesia machines are being used for prolonged periods as ICU ventilators. Use of these agents mandates the continuous presence of a trained anesthesia professional on a 24/7 basis in order to facilitate their use."

• FDA again – By September, the FDA reversed an Emergency Use Authorization (EUA) they issued in May for infusion pump systems.

The FDA wrote in a letter to manufacturers, "This letter is to notify you of the revocation of the Emergency Use Authorization (EUA) issued May 13, 2020, for emergency use of infusion pumps and infusion pump accessories for use by healthcare providers (HCPs) to treat conditions caused by the Coronavirus Disease 2019 (COVID-19) with the controlled infusion of medications, total parenteral nutrition (TPN), and/or other fluids."⁶

The agency went on, "FDA has determined that circumstances make revocation of this EUA appropriate to protect the public health or safety. Based on information and experience since issuance of the umbrella EUA, FDA has determined that circumstances support revocation of the umbrella EUA. Instead, FDA may issue individual EUAs for infusion pumps and infusion pump accessories that meet the requisite EUA statutory criteria."

Focus on system performance, safety and education

Today, manufacturers of IV systems and related technology forge ahead with design, function and safety. Several organizations, as well, provide educational resources and training for staff.

With regard to monitoring infusion during MRI imaging, B. Braun Medical Inc. announced in a press release that they have "received 510(k) clearance from the US Food and Drug Administration for the SpaceStation MRI to allow Space infusion pumps to continuously deliver medications to patients within the MRI suite."⁷

Additionally, they explained, "The SpaceStation MRI is designed to shield Space infusion pumps against 1.5-T and 3.0-T magnetic fields to protect the MR scanner and provide interference-free images. Long infusion lines are no longer needed and hospital-wide Space infusion pumps are now able to safely transition patients into the imaging suite with the SpaceStation MRI."

Concentrated on monitoring blood culture,

reported in a press release that they were "selected as the Innovative Technology Supplier of the Year by Vizient Inc. The award was presented in a virtual Awards Ceremony as part of the 2020 Vizient Connections Education Summit."⁸

Criteria for the award included, "the supplier whose technology has advanced patient care, advanced patient safety and health care worker safety, and/or delivered solutions that drive incremental improvement to an organization's care or business model," they noted.

About their technology, they added, "The patented Steripath Gen2 ISDD product portfolio, including both direct-to-media and syringe configurations, is the only FDA 510(k)-cleared device platform indicated to reduce blood culture contamination. This indication was cleared by the FDA based on peer-reviewed published controlled clinical studies demonstrating Steripath's ability to reduce blood culture contamination by 83% and 88%. Steripath has been clinically proven for use with blood cultures drawn via both venipuncture and peripheral IV starts."



**Steripath Gen2 ISDD
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Focusing on IV education and skill building for staff, the Association for Vascular Access (AVA) announced in a press release that they and B. Braun Medical Inc. have entered, "a long-term collaboration to improve training on the placement of peripheral intravenous catheters (PIVCs). Together the organizations will develop and provide a new series of online courses free of charge to medical, nursing, respiratory therapist, and other allied healthcare schools – the first of which is being piloted at several leading nursing schools."⁹

Further, they stressed, "Vascular access is the most common invasive procedure performed in healthcare, with more than 380 million PIVCs placed in patients annually in the United States. However,



between 33-69% of PIVCs fail before the completion of treatment and more than 50% of adults describe insertion as moderately painful or worse. Collectively, this can lead to serious implications for patients, including increased costs and length of treatment."

Additionally, they noted that they will work together to "create a certificate program for students who complete the courses that will attest to their foundational knowledge in PIVC placements with future employers. The eLearning module will feature interactive graphics and hi-definition videos in addition to the necessary text critical to enhancing the PIVC education in healthcare. It will focus on key aspects like proper device placement, assessment, and insertion to instill confidence in students of all skill levels."

Committed to safety in care in today's crisis and beyond, the Institute for Safe Medication Practices (ISMP) reported in a press release that they and ECRI have launched "a joint Patient Safety Organization (PSO), an important step in making medication, medical devices, and healthcare practices safer for patients across all care settings, now during the COVID-19 pandemic, and into the future. The nonprofit organizations had each been federally designated PSOs since the program began in 2008."¹⁰

Specifically, they indicated, "In an effort to reduce nursing exposure, conserve PPE in short supply, and quickly respond to pump alarms, hospitals overrun with COVID-19 patients moved bedside IV infusion pumps and administration sets into hallways outside patient rooms. The risks and challenges from this innovative process included potential shortage of extension tubing sets, more frequent alarms at high flow rates, and other technology challenges. ISMP medication safety experts and ECRI's clinical engineering team worked together to provide real-time guidance to ensure safety for this technology work-around." **HPN**

Visit <https://hpnonline.com/21158203> for references.



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Viral vigilance requires diligence

Disinfectant efficacy calls for use of the right product on the right surface

by Kara Nadeau

While healthcare organizations have always been focused on reducing the risk of contamination and infections, whether it is dangerous microbes spread by high-touch surfaces, reuse of instruments that have not been properly cleaned/sterilized or other vectors, the COVID-19 pandemic highlighted the importance of safe and effective disinfecting practices. On top of usual efforts to keep patient care areas and equipment free from infectious organisms, stakeholders throughout healthcare are now tasked with additional protocols to stem the spread of SARS-CoV-2, the virus that causes COVID-19.

What follows are some useful tips from industry experts on evaluating the effectiveness of the variety of products used for disinfection of healthcare environments, as well as some of the latest product innovations in this area.

COVID-19: What works?

The COVID-19 pandemic has spurred the development of a wide range of products designed to help combat the virus. Healthcare providers are challenged with differentiating those solutions truly effective against SARS-CoV-2, versus those that are purely hype.

"With COVID-19 continuing to spread and with healthcare workers facing unprecedented challenges, one question inevitably being asked by healthcare professionals is 'What disinfectants can I use against this virus?'" said Richard Lowe, Ph.D., MPH, Associate Research Fellow, Clorox Healthcare. "Fortunately, regulatory and public health agencies in the U.S. provide clear guidance on what products may be used against SARS-CoV-2."

As Lowe explains, the top resource for identifying products that have been tested and shown to be effective against SARS-CoV-2 is the United States Environmental Protection Agency's (EPA)'s List N: Disinfectants for Use Against SARS-CoV-2



Ruhof's Biocide DETERGENT DISINFECTANT PUMP SPRAY



Richard Lowe

(COVID-19). All of the products on the EPA's List N meet the agency's criteria for use against SARS-CoV-2, as well as products that meet other criteria, such as having demonstrated efficacy against viruses similar to or more difficult to kill than SARS-CoV-2.

"It's always useful to contact the manufacturer or check its website for disinfectants that the manufacturer lists as having EPA-approved kill claims against SARS-CoV-2," Lowe added. "Additionally, healthcare professionals should always check the manufacturer's website or product label for proper usage instructions."

Ruhof's Biocide DETERGENT DISINFECTANT PUMP SPRAY has received U.S. EPA approval to kill SARS-CoV-2 when used on hard, non-porous surfaces. The product has been tested and found to kill the virus after one minute.

"As the coronavirus outbreak (COVID-19) continues to develop around the world we take our responsibility to support customers during crisis situations very seriously," said Noreen Costelloe, Director of Marketing, Ruhof Corporation.

Types of disinfectants

There is a wide range of disinfectant methods used in hospitals today. In its Guideline for Disinfection and Sterilization in Healthcare Facilities (2008), the U.S. Centers for Disease Control and Prevention (CDC) lists common chemical disinfectants (e.g. alcohol, chlorine and chlorine compounds, formaldehyde, glutaraldehyde, hydrogen peroxide, peracetic acid, etc.), as well as other inactivating agents (e.g. ultraviolet radiation, pasteurization).

Effectiveness

While COVID-19 is front of mind for healthcare workers, they struggle every day to protect patients against a broad range of dangerous microorganisms; therefore, it is important to select a disinfectant with a broad spectrum of kill.

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

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“Prior to February 2020, when the first COVID-19 infections were diagnosed, the primary, although not the only concern, were *C. diff* infections across all types of healthcare facilities,” said George Clarke, CEO of UMF Corporation. “The prior 10 to 12 months also had infection preventionists discussing and debating the role of biofilm. IC/IP and EVS should ensure that the disinfectant they use, whether it be chemical, UVC or electrostatic sprayer, or a combination of these technologies, be effective against *C. diff* endospores, Norovirus, MRSA, and any other organism of concern and also biofilm.”

Clarke points to the benefits of Klorkleen2, which is found on both the EPA’s N: List (COVID-19) and K: List (*C. diff* spores). He notes how Klorkleen2 is proven effective against a wide range of organisms, including bacterial spores, and is the only disinfectant with an EPA registered biofilm claim.

“The product comes in an effervescent tablet form registered with the EPA under the master label brand Klorkleen2 and available under a number of private label brands, including our own Klorese,” said Clarke. “The product has a long shelf life (in tablet form) and can be used throughout a facility, significantly reduces the storage footprint enabling hospitals and resellers to maintain significant inventory levels – for the next pandemic – in a fraction of the space required for most disinfectants. Additional cost benefits include reduced plastic waste and reduced shipping costs.”

Contact time

Time is of the essence in healthcare, with staff members challenged with caring for multiple patients and having to quickly and safely turnaround rooms and equipment. Therefore, selecting a disinfectant that can kill microbes quickly is a key consideration.

Page 24 ▶

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"People are searching for ways to save time in operations, such as reducing patient room turn times as patient loads have been so high," said Rayne Guest, founder and CEO of R-Water. "One solution is to use products that have a shortened contact time and kill a wider range of germs so that facilities can

move from two-step cleaning processes to a one-step process."

"Infection Control will want to take into account contact time, the amount of time a product has to remain wet on a surface to be effective," Guest added. "Liquid disinfectants generally have a 3-10-minute

contact time. However, if the equipment is not water resistant, wipes should be used. Wipes generally have a contact time of 2-3 minutes. Many wipes may be needed to keep the surface wet for this duration. Otherwise germs will not be eliminated."

Tami Heacock, MBA, CRCST, CHL, CNIM, ST, oneSOURCE Consultant and Manager at Wake Forest Baptist Medical Center, Winston Salem, notes how contact time is also an important consideration in the Central Sterile/Sterile Processing Department (CS/SPD), where staff members are challenged with reprocessing instruments quickly but safely.

"The CS/SPD area requires fast turnover times; a disinfectant with an extended dwell time will hinder a technician's ability to serve his/her customers," she said. "They should also follow the necessary instructions for use (IFU) to ensure every proper step is being taken to decontaminate and sterilize the instruments. I always recommend a platform like oneSOURCE to access the most updated and accurate IFUs because they are all housed in one central hub so you never miss anything."

Creating the right mix

Beyond finding an effective and safe disinfectant to fight against SARS-CoV-2 or some other harmful microbe, healthcare professionals must also determine at what dilution it is effective for the intended purpose and mix the correct concentration.

"In a healthcare setting, disinfectants require a minimum of a 6-log kill rate or 99.9999 percent reduction in pathogens to further remove and mitigate exposure to harmful microorganisms including viruses

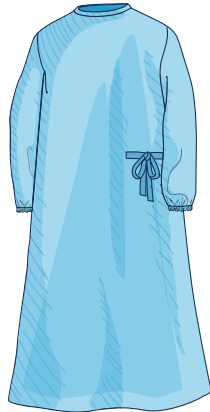
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INFECTION PREVENTION

like COVID-19,” said Ben Oberle, Healthcare & Education Marketing Manager at 3M. “While a common misunderstanding, using more chemical does not equate to a better clean. Instead, using the appropriate amount of chemical with the proper dilution as well as marrying it with a sound protocol is key.”

“Many products degrade surfaces, ruin computer screens, and/or leave residue behind on equipment,” said Guest. “If products leave residues, the need to rinse is an extra burdensome labor step.”

Oberle recommends healthcare teams consider using a chemical management solution, such as a 3M Chemical Management System, “to take the guesswork out of mix-



3M Chemical Management System

ing chemicals and help properly and easily dilute chemical concentrates every time.”

“In achieving accurate dilution, teams can save on chemical costs, while also mitigating labor costs associated with re-cleaning,” Oberle commented. “In addition to ensuring you are using the right type and amount of product, pre-cleaning and abiding by dwell times are also critical steps to more efficient and effective disinfection practices.”

Supply chain challenges

Disruptions in the global supply chain and the sharp and sudden demand for disinfectants during the COVID-19 pandemic have resulted in supply shortages, explains Clarke.

“The current COVID-19 pandemic caught most, if not all, hospitals unprepared as supplies of personal protective equipment (PPE), disinfectants and wipes quickly evaporated, and inventories were depleted with unpredictable lead times for replenishment,” he stated.

Heacock says the supply chain roadblocks caused by COVID-19 have made it even more challenging for healthcare facilities to procure disinfectants that are effective against a wide range of microorganisms,

not only SARS-CoV-2, but other dangerous viruses, bacteria and other microbes commonly found in healthcare environments.

“Since the COVID-19 pandemic hit, obtaining disinfectants effective against a wide range of microorganisms, including the coronavirus, has become increasingly difficult,” she said. “Many hospitals have been forced to revert to manufacturing solutions themselves. Many of these solutions contain respiratory irritants that may cause discomfort to team members. The pandemic has also made it challenging to obtain the PPE necessary to mix and use the solutions needed to disinfect surgical instruments.”

Guest points out how nurses and infection prevention/control personnel have resorted to mixing their own disinfectants on-site using bleach concentrate, which is “unsafe for the workers and everyone involved,” as stated by Guest. Studies have shown that bleach exposure can raise the risk for chronic obstructive pulmonary disease and other respiratory issues.

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"Because COVID-19 is a respiratory illness, using disinfectants that don't exasperate respiratory irritation is crucial," said Guest. "In addition, a lot of people have sustainability goals in healthcare, so when you can produce products onsite, it helps achieve these goals by eliminating unnecessary deliveries and the disposal of cardboard and hazardous plastic waste. Producing disinfectant onsite also eliminates the need to procure, receive and store products, thus alleviating time-consuming tasks in materials management and other departments."



R-Water TK60 Healthcare-Grade Disinfectant

Application options

Proper application of disinfectants is key to their effectiveness, and there are a variety of options on the market beyond the standard "spray and wipe" method. David St. Clair, Chairman and CFO, Halosil International, comments on a few of the available solutions.

"Certain solutions, such as spray and wipe products, require manual application, which increases risks for cleaning staff and introduces the potential of missing pathogens in hard-to-reach areas," said St. Clair. "Electrostatic guns require a human attendant to operate, increasing



The Halo Disinfection System from Halosil International

the risk of exposure for EVS personnel to both pathogens and chemicals as well as introducing a greater risk of human error in disinfectant application. In addition, they require surfaces to become wet, which can damage electronics and leave a sticky residue."

"Other solutions, such as dry foggers, are dry by their very nature and can operate entirely in touchless mode, reaching all the nooks and crannies of an environment without leaving a sticky or wet residue," St. Clair added. "This limits labor costs and exposure of cleaning staff all while mitigating concerns that disinfectants will damage costly equipment."

With regard to UV disinfectants, Dr. Ashish Mathur, Ph.D., Vice President of Innovation and Technology, Ultraviolet Devices (UVDI), says, like manual disinfectants, the effectiveness in use can be evaluated by multiple techniques, including before-and-after environmental contamination studies, culturing and surveillance. However, given the lack of consistent industry standards for UV device efficiency, it is important for healthcare personnel to conduct UV device-specific due diligence of effectiveness prior to adoption and use. He offers four

criteria for healthcare facilities when evaluating and selecting a proven UV device.

"First, is claimed device efficacy validated by independent, third party laboratory testing? Second, are the claims for whole room disinfection supported by testing at real-world distances that correlate to whole room disinfection? Third, has the device's effectiveness been proven in peer-reviewed published clinical studies? Last, does the manufacturer have a proven methodology to confirm that a germicidal dose has reached a target surface? Addressing these four simple questions can help healthcare professionals understand if a UV device is truly effective."

Synexis has developed a biodefense system that uses patented technology to create the gas form of hydrogen peroxide, called Dry Hydrogen Peroxide or DHP. Kari L. Love, RN, MS, CIC, FAPIC, Program Director Infection Prevention, Office of Quality,



Ashish Mathur



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Emory Healthcare, which uses the system, explains how the solution can reach even the most hard-to-reach spaces in a healthcare facility because it is a gas and can go wherever the air goes.

“Additionally, its technology is continuous and automatic, flowing around the clock, while requiring maintenance only once per quarter,” said Love. “And almost as importantly, it’s been proven to reduce viruses, bacteria, odors, mold and insects, but without needing to clear the room of people, so they can go about their normal activities.”

When asked for her advice to other facilities evaluating disinfectant modalities, Love stated: “When considering effective ways to battle common pathogens, healthcare facilities should consider holistic solutions that help reduce the bioburden in the air and on surfaces, but also in places other cleaning methods may not reach. It should be a flexible option that offers minimal labor and training needs.” **HPN**

Reference:

1. Regularly using bleach linked to higher risk of fatal lung disease, University of Washington School of Public Health, September 18, 2017, <https://osha.washington.edu/news/regularly-using-bleach-linked-higher-risk-fatal-lung-disease>

Attacking microbes through the air

According to the U.S. Environmental Protection Agency (EPA), there is growing evidence that SARS-CoV-2, the virus that causes COVID-19, can remain airborne for longer times and further distances than originally thought.¹ The pandemic has heightened concerns around air quality in hospitals and other healthcare facilities, prompting them to implement technologies designed to combat microbes in the air.



One such solution is the UV Angel Clean Air Automated Continuous UV-C Air Treatment System, which uses patented UV-C light air purification technology to reduce levels of viruses, bacteria and fungi. Air is quietly drawn into a sealed UV-C air chamber with a series of fans and filters where it is treated with an enclosed high intensity UV-C light to inactivate bacteria, fungus and viruses in the air. The treated air is then returned to the room creating a cleaner environment.

“Infection Control Professionals, especially in the COVID-19 environment, should be cognizant for the need for air purification at room level,” said Jay Comeaux, President, EDM Facilities. “The coronavirus can remain airborne for a surprisingly length of time. Our UV Angel Clean Air is proven to significantly improve air quality. It is the safe use of UV-C technology in occupied spaces with simple retrofit in 2 x 4 ceiling grids.”

Reference:

1. Indoor Air and Coronavirus (COVID-19), U.S. Environmental Protection Agency (EPA), <https://www.epa.gov/coronavirus/indoor-air-and-coronavirus-covid-19>



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Endoscope Care 2020

In a pandemic world, endoscope care should be at or near center stage

by Rick Dana Barlow

Never forget: Even during a global pandemic, the Sterile Processing & Distribution (SPD) function, practiced by dedicated departments under a variety of names, represents one of the most important procedures in a healthcare organization.

If you deign to question or smirk at that factual and realistic observation, then try this: Send all SPD professionals home for two days on a brief paid sabbatical as an educational lesson for you. See what happens. If you're in the C-suite, you can expect a flurry of calls from outraged doctors and nurses. If that doesn't electrify your malaise, wait until you see the corporate attorney's line show up on your call list.

SPD matters.

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"CS Manager of the Year." Next month we start saluting "SPD Operations Worth Watching." And we've dedicated space annually in the November edition on the topic of "Endoscope Care" for the last 16 of *HPN's* 43 years in print.

Because *HPN* values SPD.

Historically, *HPN's* annual Endoscope Care coverage explores a wide range of topics spanning the fundamental and foundational to the advanced and esoteric (for the specialized).

HPN reaches out to a wide range of subject matter experts to provide and share what you've come to expect to read – keen and useful insights and opinions about how to do what you do even better. This year is no exception.

On this page and on pages that follow you'll be able to educate yourself and enjoy several stories on selected topics.

But you also can find a wealth of useful information at *HPN Online* (www.hpnonline.com). This includes a detailed feature on the key areas for continued improvement in each of the six steps in endoscope processing that

HPN identifies – with the added background context of the pandemic. Visit this link: <https://hpnonline.com/21157237>. Further, be sure to check out *HPN's* extensive coverage last year that features as an online exclusive, "The full scope of reprocessing endoscopes," by clicking here: <https://www.hpnonline.com/21110528>.

Continue reading ...

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

Gird yourself for endoscope product design shifts by 2030

Newer models will be more of a ripple than a tidal wave, experts predict

by Rick Dana Barlow



Photo courtesy: Healthmark Industries

What's emerging in the endoscopic technology realm is not unlike what's been transpiring in the automotive industry.

When it comes to automobiles, consumers can choose between three types of automobiles to drive – cars that run on gasoline, cars that run on a hybrid system of electricity and gas and cars that run on electricity. In the U.S. marketplace, surveys show, by and large, that gas-powered cars represent the largest percentage, followed by hybrids and then electric-powered models.

Similarly, healthcare organizations increasingly are being given the opportunity to choose between three types of flexible and rigid endoscopes – those that are completely reusable, those that are completely disposable and those that could be called “hybrid” for infection control purposes because they are reusable devices with a select number of disposable components that can be discarded after use (e.g., distal covers and adaptors, etc.).

With the advent and emergence of minimally invasive surgical techniques back in the 1980s, surgeons routinely used reusable endoscopes in the operating room. But given the growing number of reports of cleaning, disinfection and sterilization challenges that have contributed to patient infections – some of which prove fatal in time – healthcare providers have been searching for something different.

While reinforcing education, training and certification of sterile processing professionals, switching the reporting of Sterile Processing & Distribution (SPD) to the OR, reassigning sterile processing responsibilities to dedicated Endoscopy departments, or changing the types of high-level disinfection or sterilization procedures – including technologies – may be making a difference for a variety of healthcare organizations, more are looking at the devices themselves and turning to the device manufacturers to offer solutions.

Enter alternatives to reusable models that either fully embrace the single-use concept or merely incorporate disposable compo-

nents that can be swapped out even as the reusable framework remains.

Healthcare Purchasing News has been exploring the concept and emergence of single-use technology in endoscopy for several years now, locating startup companies looking to take the market by storm, but also gauging reactions of current endoscope manufacturers about this influx and potential demand shift.

Not surprisingly, endoscope manufacturers lean toward their “party line” in terms of product offerings, with the single-use product companies anticipating a complete market shift to disposables while those companies that manufacture reusable models temper their expectations, acknowledging that a minority of healthcare providers will embrace fully disposable models or reusable models with disposable components.

Further, they admit that the majority certainly are aware of and interested in the possibilities and prospects of altering their inventory mix.

HPN reached out to more than a dozen executives at manufacturers of endoscope devices and related reprocessing supplies and equipment about their forecast of any market shift during the next 10 years. 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

Bad transport and waiting examples



Photos courtesy: Healthmark Industries

Looking ahead at endoscope reprocessing quality performance

The coming decade, initiated by a global pandemic, promises to bring considerable changes to the sterile processing profession and how the Sterile Processing & Distribution (SPD) department services its customers, the Operating Room (OR).

For the third consecutive year, *Healthcare Purchasing News* surveyed more than a dozen sterile processing subject matter experts on seven potential – but likely scenarios – that may direct and redirect how SPD navigates the 2020s. *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 2019 and 2018 as well.

One noteworthy result is that the top two strategies this year represent a transposition of the same two last year. And while Big Brother continues to languish at the bottom, the Bullwhip curiously moves up two notches above major device shifts.

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

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)

2020 average score: 2.64
2019 average score: 1.9
2018 average score: 2.5

3. Switching to endoscopes that contain disposable/single-use-only components that can be swapped out (if available)

2020 average score: 3.62
2019 average score: 4.1
2018 average score: n/a

4. Holding staffers accountable/responsible for endoscope cleaning “violations”

2020 average score: 4.23
2019 average score: 4.8
2018 average score: 2.8

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

2020 average score: 4.46
2019 average score: 4.3
2018 average score: n/a

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

2020 average score: 4.77
2019 average score: 6.1
2018 average score: 4.8

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

2020 average score: 4.85
2019 average score: 4.7
2018 average score: 3.4

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

“Endoscopes are difficult to clean and therefore to reprocess,” said Betty McGinty, RN, CGRN, CER, Fellow, Clinical Education Services, Boston Scientific Corp. “From an infection prevention standpoint, the single-use application for endoscopes and accessories is favorable to take the medical devices out of the equation for contributing to cross-contamination due to ineffective reprocessing. This can’t happen overnight, and therefore, prioritization for use for such high-risk procedures as endoscopic retrograde cholangiopancreatography and bronchoscopy, allows an opportunity to move in the direction of the single-use concept.”

“A second factor to consider in the prioritization involves consideration of the patient’s comorbidities,” McGinty continued. “A third factor to consider is for the high-risk procedures performed ‘after hours’ to eliminate the need for reprocessing by staff who may have less opportunity to prove competency. In the meantime, high-quality reprocessing requires education, competency, attention to reprocessing steps (validated by tracking), possession of and following of validated, ‘doable’ instructions for use, and certainly accountability by the staff performing the processes.”

Seth Hendee, CRCST, CIS, CHL, CER, CSPDT, CFER, Clinical Education Coordinator, SPD, Healthmark Industries Co., encourages SPDs to apply a resource management mindset to the process.

“Setting and adhering to a realistic expectation for the number of procedures that are able to be performed in a day/shift [is key, as well as] factoring in the number of endoscopes and the actual time it takes to follow all processing steps correctly,” he said.

What do you think about any of these findings and opinions? Drop us a line at editor@hponline.com or share your opinions at HPN Online (www.hponline.com).

WILL surpass the use of fully reusable models.

Yes, SPD, there is a future

Starting with observations from more of the fringe elements, none of the executives believe that healthcare providers will continue using reusable models exclusively.

But that doesn’t mean the sterile processing function is doomed – at least for endoscopy. Why? Because reactions are mixed as to how much the use of disposable/single-use models or components will overtake the use of reusables. In fact, half the executive respondents feel hybrids are the answer while the other half supports disposable/single-use models.

This translates into the notion that reprocessing won’t be dead after all, but also that it has not quite reached the “Houston, we have a problem” stage either.

Make sway for the hybrids

More than a third (35.7 percent) feel that hybrid models – reusable endoscopes that contain disposable/single-use components – will occupy a minority segment of the market.

Marcia Frieze, CEO, Case Medical, keeps her fingers on the pulse of the market, particularly among SPD departments, anticipating a reserved shift.

“Two factors limit the broad adoption of partially or fully disposable endoscopes: Psychology and economics,” Frieze explained. “Endoscope manufacturers and others are in early stages of developing disposable components, and clinicians are even earlier in the awareness and acceptance of these new options. Understandably, new product adoption can be slow in the perioperative sphere due to risk aversion. Moreover, in this case, clinicians weren’t seeking these changes; rather, they are being forced upon them by circumstances and fallout from disease outbreaks tied to flexible endoscopes.”

But Frieze observes an inherent economics issue lingers, particularly exacerbated by the pandemic.

“The economic challenge is twofold: Disposables and single-use devices are an added cost, and hospitals have been dealing with narrow margins for years, even before the disruption of the COVID-19 pandemic,” she continued. “For many decision makers, any program that adds cost (or uncertainty) will be put on the backburner considering the immediacy of managing through this public health emergency.”



Marcia Frieze



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*Muthusamy VR, Bruno MJ, Kozarek RA, Petersen BT, Pleskow DK, Sejpal DV, Slivka A, Peetermans JA, Rousseau MJ, Tirrell GP, Ross AS. Clinical evaluation of a single-use duodenoscope for endoscopic retrograde cholangiopancreatography. *Clin Gastroenterol Hepatol.* 2020; 18:2108-2117.

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MIS procedure types may experience a product shift, acknowledges Carolyn Klimas, Executive Director, Specialty Products Marketing, Olympus America Inc.

“While fully disposable scopes will find certain niches where their use is clinically and economically acceptable, fully reusable scopes – and hybrid designs that retain key characteristics of the fully reusable scopes while add-



Carolyn Klimas

ing disposable components in key locations – will continue to be preferred for many important and high-volume procedures where the best clinical performance and strong economic value are crucial,” Klimas told *HPN*. “An example is the Olympus TJF-Q190V duodenoscope with a disposable distal endcap, which offers improved handling and imaging at a low cost per use, along with greater access and visualization of the distal end around the elevator, thus meeting the FDA’s most recent guidance on duodenoscopes.”

Ron Banach, Director, Clinical Training, Ruhof Corp., points to device quality as the reason that hybrids likely won’t overtake reusables completely.



Ron Banach

“Performance of the reusable endoscope will be superior,” he predicted.

Economics and sustainability remain litmus tests for any device migration, according to Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare.

“Cost [and] environmental waste are significant issues that will limit the conversion to disposable flexible endoscopes,” he said. “I believe that there will be a shift to hybrid endoscope technology. We already have disposable valves, etc. I do not believe that disposable or ‘semi-reusable’ flexible endoscopes are the answer as these will create significant amounts of waste every year, and most likely will be cost-prohibitive. We have to ask ourselves why we would consider disposable products versus reusable. If the answer is that we are concerned about the ability of our technicians to effectively clean and sterilize [or] HLD the endoscopes, we have uncovered the root cause of the problem.”



Gregg Agoston

Agoston stresses that “flexible endoscopes are not the only complex instruments that are reprocessed in a hospital. There are robotic instruments and countless other complex instruments with multiple parts lumens and electronics. If we cannot reprocess flexible endoscopes then we should be questioning if we can reprocess any of these other complex instruments. Should we move to disposable for all of these instruments as well?”

Agoston refers to history – more than seven decades ago specifically – as a key discussion point.

“The current symptoms of flexible endoscopes that are not properly cleaned and prepared for surgery stem from a common root founded in the original SPD organizational model that was created in the 1940s and unfortunately has not changed to meet today’s demanding surgical instrument needs,” he indicated. “In the 1940s a movement began led by W.B. Underwood, John J. Perkins and the American College of Surgeons (ref. IAHCSSM Central Service Technical Manual) to remove instrument processing from the perioperative area to a centralized location, ‘Central Sterile Department.’ This change helped to standardize



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instrument processing, and it removed the responsibility of instrument processing from the nurses, allowing them more time with their patients."

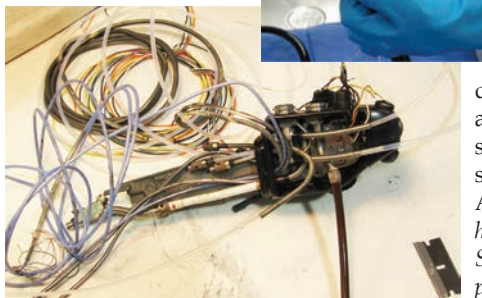
Back then, surgical instruments largely would be considered "non-complex" by today's standards, Agoston continued. They consisted primarily of stainless steel devices used for cutting, grasping, dissecting, etc., along with basins and glassware.

"The staff for the newly created Central Sterile Processing Department often were promoted from dietary services since the functions of cleaning were seen as similar," Agoston recalled. "Pay was a step up from dietary pay. Lost in this transition was the knowledge that the nursing staff had of how the instruments were used and their relative importance to the successful surgical procedure. SPD staff were expected to have the capability to clean, inspect, assemble and sterilize all items that came through the department. This model worked primarily because of the simplicity of the instruments and relatively few instrument sets the department was responsible for."

Advanced surgical procedures began to emerge and grow, Agoston posits, and pressurized the 1940s SPD model.

"Fast forward to today's advanced surgical procedures that require complex instruments - endoscopes, cameras, power tools, robotic instruments, Orthopedic/Neuro/Spine, etc.," he continued. "These procedures could only be dreamed about in 1940. The associated skills needed for cleaning, inspection and sterilization of these complex instruments is much higher compared to the

Disassembled scope reveals cleaning difficulties



Photos courtesy: Healthmark Industries

skills needed for non-complex instruments. Instructions for Use (IFU) went from one page of cleaning instructions to 37-plus pages for a robotic instrument, and over 100 pages for a flexible endoscope.

"With hundreds of hospital- and vendor-owned instruments/sets being processed daily, the importance of a highly productive and effective SPD is just as important to the success of the surgical procedure as are the surgeons, anesthesiologists and nurses," Agoston insisted. [Editor's Note: Agoston shares his vision of a solution in the sidebar, *Advance SPD to include higher-paid specialist teams on page 40*]

Others foresee a more pervasive embrace of hybrid devices. In fact, a smaller segment (14.3 percent) argues that hybrids will be used by the majority.

"Endoscopes are becoming widely known as one of the most difficult medical devices to process," said Seth Hendee, CRCST, CIS, CHL, CER, CSPDT, CFER, Clinical Education Coordinator, SPD, Healthmark Industries Co. "Add to this, our increasing awareness that they are a proven source of hospital-acquired infections (HAIs) makes me believe change is needed and inevitable. An endoscope's complex nature of design factors must be considered, and if the design of the device is a problem, then a redesign is a logical solution."

But Hendee stops short of recommending full conversion to disposable/single-use devices.



Seth Hendee

Page 36 ▶



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"This might lead you to think I would prefer a fully disposable endoscope, but I do not," Hende clarified. "Solving processing issues would be a great leap forward for these devices but could cause others. Adding multiple disposable endoscopes each day to a facility's waste stream is a cost and environmental concern. On the other hand, if only certain components were disposed of, processing outcomes could be improved, and other impacts could be minimized. I believe this win will drive Hybrid endoscopes to eclipse fully reusable models."

Jahan Azizi, Special Projects Manager, Healthmark Industries Co., calls for a device redesign to compensate for the challenges.



Jahan Azizi

"The scope should be redesigned to have disposable section that comes into contact with patient (insertion section)," Azizi asserted. "The electronic and control can remain reusable and sterilizable. This will be the safest for patient, the most cost-effective and environmentally friendly approach."

SUDs make waves

More than one-fifth (21.4 percent) predict fully disposable/single-use devices will be added to a provider's inventory stream, but not dominate what surgeons use.

Betty McGinty, RN, CGRN, CER, Fellow, Clinical Education Services, Boston Scientific Corp., frames her measured perspective across the 10-year span.



Betty McGinty

"The move will be evident, and a contributing driver [will] be reported endoscope-related infections," McGinty predicted. "Identification and tracking of infections to endoscopes is inconsistent, however. Industry will continue to develop single-use models that will 'make sense' to infection prevention-minded consumers to replace their reusable inventory."

Natalie Reece, Endoscopy Clinical Educator, Key Surgical, casts doubt on the cost argument.



Natalie Reece

"Disposable endoscopes and endoscopic devices are the easiest way to decrease the incidence of patient transmission and infection due to contamination," Reece indicated. "Patient safety is of the utmost priority, followed closely by the financial cost of reprocessing and procedures. We are seeing an increase in understanding that disposable scopes are not necessarily more expensive than reusable.

"For example, a study from last year titled, 'Reusable Flexible Ureterorenoscopes are more cost-effective than single-use scopes: results of a systemic review from PETRA uro-group' by Talso, et Al., found that, depending on the number of uses per repair (which varied between 8-29 procedures per repair), the cost per procedure for a scope was anywhere between \$120 and \$1,200 per procedure," she explained. "They say, 'A significant trend was observed between the decreasing cost of repair with the number of usages,' meaning the more usages you got before you needed to send out for repair, the cheaper overall that reusable scope would be for your procedures. They compare this with a couple other disposable ureterorenoscopes that cost \$700, \$1,500 or even \$2,000 dollars a pop."

Reece refers to an Ofstead & Associates research study published three years ago that examined 20 different scopes at three different sites, finding that all endoscopes had visible irregularities.

"What this tells us is that we're currently not sending out our scopes for repair enough," Reece argued. "The cost of repair

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per procedure should be so much higher, meaning that reusable scopes are not necessarily cheaper than disposable.” She cites another Ofstead study that investigated all of the variables involved in reprocessing, including the water, chemicals, PPE, salaries, time and other resources.

“For these reasons, I think most facilities will find that not only are disposable scopes just as good as reusable [scopes] during a procedure, but the quick set-up and low cost (compared to the actual true cost of reprocessing) will make them a no brainer,” she added.

But Reece remains realistic about progress.

“This is healthcare, however, and making changes is often like moving mountains,” she said. “The change is slow and takes time. Oftentimes the silos between decision makers prevent the necessary dot connecting that is needed in order to make

the systemic change toward disposable scopes. Overtime, those who pay out for treating HAIs will incorporate their cost into the mix, and we’ll see that disposable scopes are a no brainer. Lastly, I believe that as these become more prevalent, vendors will be encouraged – or maybe even required; a girl can dream! – to design scopes that have recyclable components and have a smaller footprint on our landfills, though the likelihood of this happening in 10 years is slim.”

Mobile Instrument Service & Repair’s Clinical Education and Training Manager Melissa Kubach, homes in on performance quality perceptions.

“We have yet to see widespread adoption of disposable scopes largely because they do not match the performance of reusable scopes at a price point that allows for substitution,” Kubach noted. “As quality and user experience improve, disposables

will capture market share, provided the cost compares favorably to reusable scopes. Comparable image, performance and maneuverability are important. Loss of technology, such as near focus, specialty light wave applications and endoscope position monitoring may play a role as well. Reimbursement is key, especially when you are requesting insurance companies to cover cost for which they were not historically responsible.

“Considerations of a known safe reusable alternative method may be appealing for higher-risk duodenoscopes but other common models may not make the cut,” she concluded.

Yet others anticipate the tide turning more dramatically.

Christian Escobar, Director of Marketing – Visualization, Ambu, contends disposable/single-use endoscopes actually will be a boon both for SPD, which can concentrate on reprocessing and stocking the vast array of other devices and instruments needed to deliver patient care.



Christian Escobar

“Where possible, single-use endoscopes will continue to offer significant productivity and cost-management benefits for hospitals – much the way that other areas in the hospital have long since moved from reusable equipment to fully disposable to enable greater efficiencies and patient safety,” Escobar indicated. “This shift will alleviate the potential for device cross-contamination and ensure that each patient has a sterile device used on their procedure. This is highly advantageous to healthcare leaders, such as infection preventionists and healthcare risk managers. Not only will it free SPD to focus energies and investments in reprocessing devices that cannot be disposable, it will also enable hospitals to reduce the extensive investment in purchasing and maintaining reusable endoscopes. These devices require an incredible amount of resources to ensure they are ready in a timely manner and adequately prepared for safe use on the next patient.”

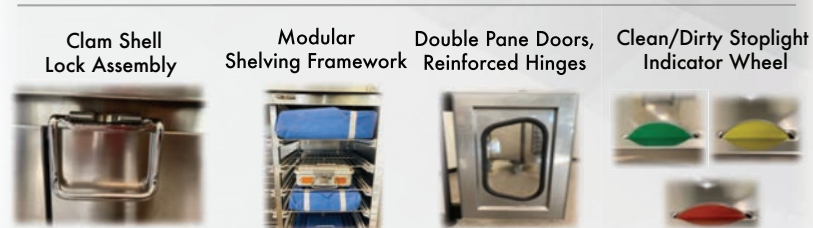
By Integrated Endoscopy’s measure, the gate has been opened.

“The conversion to single-use is already upon us, which started with flexible endoscopy and now is moving into rigid,” said Rob Cripe, Chief Commercial Officer, Integrated Endoscopy. “We believe that this conversion will be 100 per-



Rob Cripe

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cent in the next 10 years. Historically, the reasons reusable products have converted to disposable are generally the same – lost clinician time, high costs of repair and processing, risk of disease transfer and degrading performance over time. Once a single-use option becomes available that can provide the same performance at a low enough cost, the marketplace conversion is typically 100 percent.”

Cripe cites as examples single-use shaver blades in arthroscopy, single-use pressure transducers in cardiac medicine and even syringes, depending on how far back one traces. “The costs associated with repair, processing, sterilization and OR down-

time are some of the key drivers to the rigid endoscopy conversion as well as the performance degradation over time, which is the direct result of processing and sterilization,” he added.

For Bryan Lord, CEO, Pristine Surgical, the panoramic view forward is quite distinctive.

“In the near term, we see synergies and complementarity between reusable and single-use devices,” Lord noted. “But in the medium and longer term, we believe the market will consistently migrate fully to single-use



Bryan Lord

devices. When you can combine high-definition visualization without the headaches, expense or risk of reusable endoscopic platforms, once you experience the benefits, there’s really no reason to go back. Is anyone today begging to go back to 35mm film cameras when we have our high-quality iPhone cameras in our pocket?”

Lord extols additional benefits single-use models can bring. “Complicated vendor contracts put the risk of obsolescence on the customer,” he indicated. “Pristine Surgical’s high-definition digital platform is scalable and extendable, eliminating the risk of obsolescence – and the software and hardware can be seamlessly upgraded without further capital expenditure.”

Alison Sonstelie, CHL, CRCST, oneSOURCE consultant and Sterile Processing Coordinator at Sanford Health, Fargo, ND, advocates complete conversion for several reasons.



Alison Sonstelie

“First, as disposable products continue to be developed, the cost will become more competitive,” she surmised. “This will impact the price barrier that many facilities have and make the product more appealing. Another issue with disposables is picture quality. I think disposable products will continue to evolve and have better picture quality, or have a range of picture quality options with different price points. Another issue to be considered with any disposable item is the environmental impact. Many companies offer recycling programs for various products. If this is feasible with disposable scopes, it would be an enticing option to reduce the environmental impact and decrease prices.”

Sonstelie acknowledges that hybrid models, equipped with disposable components for critical areas of the endoscope, such as distal tips and elevator mechanisms, may offer an alternative to continue operating in the current state. But she classifies it as more of a transitional role.

“There are too many infections and risks to patient safety with some current reusable models,” she insisted. “Additionally, we know that some scopes cannot be cleaned effectively, even when following the IFU. If we convert these critical components to disposables, there are still parts of the scope that remain difficult to clean and inspect. For example, the channels can be damaged and harbor bioburden, creating a patient safety risk. I think having disposable components for the most critical areas of the endoscope is only a partial or temporary solution.” **HPN**

Advance SPD to include higher-paid specialist teams

Amid the developing and growing debate about the adoption and implementation of disposable/single-use endoscopes – and just how pervasive the transformation needs to be, Gregg Agoston believes he has a more fundamental solution that must be implemented first.

Agoston, who serves as Vice President, Business Development, SPD Transformation Services, SpecialtyCare, argues that Sterile Processing & Distribution (SPD) professionals haven’t progressed enough from the proverbial Stone – or perhaps Stainless Steel – Age of the 1940s in the context of 21st century technology and related techniques.

“The bottom line is that the 1940s model for SPD does not work in today’s advanced surgery environment,” Agoston argued. “The model for SPD must be upgraded to allow for highly trained specialists to reprocess complex instruments. Nurses and surgeons specialize in one or two service lines, [but] SPD must be the master of all. Is this a realistic expectation without some form of specialization? Consider orthopedic instruments used for arthroplasty. The majority of these of these instruments are complex. These instruments can be processed effectively primarily because the manufacturer of the instruments/implants provides their representatives who inspect and assemble the instruments prior to the SPD staff wrapping and sterilizing them. If the representatives were not providing these services, there would be tenfold times the errors.

“This model of having a highly trained technician (vendor rep) perform the critical functions in conjunction with less skilled staff who clean and sterilize the set, works,” he continued. “Companies such as ours offer Specialists for Minimally Invasive Surgery, Orthopedics and flexible endoscopes. Specialization works because of the laser focus

of the Specialist on the assigned complex instruments. Removing the responsibility for complex instruments makes it easier for the hospital to hire and train technicians for the non-complex instruments, effectively making them non-complex instrument specialists.”

Agoston scoffs at hospital claims that it cannot afford specialization in SPD.

“They do not realize that they are paying a lot more to staff the department than they realize,” he indicated. “The costs associated with high staff turnover, training, errors, delays, disposable instruments, repairs/replacements, surgeon and staff frustration and the potential for [surgical site infections] all need to be calculated. Single-use or limited-use flexible endoscopes (disposables) will not solve the intrinsic problem of non-qualified technicians reprocessing complex instruments. Complex instruments require a higher level of skills for the technician to be successful.”

Agoston swipes at the compensation levels offered to SPD management and staff as not reflecting the complexities and intensities of the job.

“Most SPDs experience high levels of turnover (20 percent-plus) due to low pay and the demanding work,” he observed. “Typical starting pay for a non-certified SPD technician is around \$12 per hour. Most technicians max out at around \$22 per hour. We find that most SPD departments average between 30 percent to 50 percent of their staff having less than one year of experience. This revolving door for staff and management exacerbates the issues. The symptoms of a poor performing SPD are OR delays, missing/broken/contaminated instruments, demand for single use instruments, high replacement/repair costs, surgeon/nursing frustration, high turnover/vacant positions/agency staffing, etc. These symptoms result in real cost to the hospital.”

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Clearing the air on scope hang times

Whether you're involved in an athletic competition, business project, charitable event, clinical procedure, financial exercise or operational task, including sterile processing, supply chain or surgical workflow, the mantra remains the same: Start fresh; work accurately, effectively and efficiently; and of course, finish strong.

In the reprocessing of endoscopes and other endoscopic equipment, crossing the finish line typically translates to aerating, drying and storing sterile devices so they're ready for use in the surgical suite.

Because these last steps before transporting the sterile devices to the operating room remains so important, *Healthcare Purchasing News* asked more than a dozen sterile processing subject matter experts for useful tips on completing these last tasks properly. Here's what they shared.

Christian Escobar, Ambu

"Ensuring the staff and facility have adequate storage and reprocessing space is critical. Hospitals can invest in large-scale, specially designed storage areas. Additionally, hospitals can evaluate using sterile, single-use endoscopes for procedures - freeing up or reducing demand for space in SPD or point-of-care to store excessive volumes of flexible endoscopes. One benefit of the single-use endoscope is the ability to reclaim crowded, valuable hospital space for more efficient use. Single-use devices also eliminate the potential for cross-contamination when properly utilized."

Betty McGinty, Boston Scientific Corp.

- "Use external drying devices post-endoscope removal from the AER.
- "Drying cabinets offer a drying option for endoscopes both externally and internally.
- "Existing conventional cabinets may be retrofitted with cabinet filters as well as channel drying hook-ups."

Minerva Loran, Clinical Choice LLC

"Effective aeration of an endoscope is best achieved by a system that connects to the Air/Water, Suction and Auxiliary Channels. Endoscopes can be aerated prior to or during storage. Check with your aeration or endoscope cabinet company as to their recommended aeration times.

"Look for endoscope storage cabinets that meet current and future society guidelines. Cabinets with significant 24/7 HEPA-filtered air flow, removable drip trays and abilities to upgrade the cradles

and drying system will protect your endoscopes and your capital investment."

Seth Hendee, Healthmark Industries Co.

- "Allow and take time for thorough and proper drying. The drying cycle of many AERs and simple alcohol flushes do not produce completely dry endoscopes for use or for storage.
- "Invest in air. Whether that is adjustable instrument air at a workstation or filtered forced-air drying cabinets. Both will produce far better results than syringe flushing or hang drying. Both of which have been proven far less effective than their forced air alternatives.
- "Understand drying's importance to the process. The wet environment inside of an improperly dried endoscope is the perfect breeding ground for water-loving bacteria. Thoroughly drying endoscopes between uses and before storage will remove that risk from the process."

Bad scope hanging vs. good



Photos courtesy: Healthmark Industries

Natalie Reece, Key Surgical

"Store endoscopes in an automated drying cabinet. Research has shown that storage using an automated drying cabinet, which allows each channel to be connected to a constant flow of filtered, compressed air along with circulating air to enhance surface drying, is the best for eradicating moisture. (Perumpail et al. "Endoscope reprocessing: Comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet." AJIC 2019)

"Dry endoscopes for a minimum of 10 minutes using forced, HEPA-filtered air. If your facility does not have access to automated drying cabinets, and you use vertical hanging to store, manually drying your scope for about 10 minutes before hanging is the mini-

imum required for eradicating potentially dangerous residual moisture. (Barakat, et Al., "Comparison of automated and manual drying in the elimination of residual endoscope working channel fluid after reprocessing" *Gastrointest Endosc* 2019)

"Conduct a risk assessment at your facility to determine a safe/proper storage time between reprocessing. Assuming that high-level disinfection/sterilization has occurred according to the manufacturer's instructions for use (IFU), and that the scopes are stored in a closed environment with all of the valves and accessories removed, we see a mix of recommendations for how long until the scopes need to be reprocessed again. The Association for Professionals in Infection Control and Epidemiology (APIC) suggests a hang time of seven days, and after that seventh day the scope should be reprocessed. The multi-society guideline published in 2016 suggests that reprocessing within 21 days is safe. SGNA supports a seven-day

storage window as well. AORN and AAMI both agree, but give a vague recommendation that each facility perform a risk assessment to determine proper storage time.

"If you have an automated drying cabinet that forces a constant flow of air through your scope, you may be able to extend the time up to 30 days or however long the IFU calls for. The lack of clarity between the standards is a huge concern because if you are hanging your scopes, there will absolutely be residual moisture left over. Gather up your facility's key players (clinicians who

perform endoscopy, reprocessing personnel, infection preventionists, quality/risk management team and administration). Test how many of your 'patient-ready' scopes have microbial contamination. Test for residual moisture in your scopes. Evaluate the real cost of resources and personnel it takes to adequately manually dry and endoscope, or the real cost of constant reprocessing due to short hang times."

Melissa Kubach, Mobile Instrument Service & Repair

"If the facility does not have internal channel drying capabilities within their cabinet, they could utilize a drying box unit to facilitate drying prior to storage.

"Cabinet upgrade retrofits are available for multiple manufacturers' existing cabinets to add aeration and drying capabilities.

“Cabinets need to be maintained for cleanliness and inspected for chips or damage. There are numerous choices of available cabinets with built-in positive pressure or filtered circulated air. There is one cautionary note when choosing one of these options. Historically, drying has not been heavy with oversight. Many of the cabinet options contain tubing with permanent metal end fittings that do not have clear cleaning instructions. Some [companies] may say wipe down with use, then high-level disinfect weekly. All trends lead to restricting shared connections between endoscopes once cleaned without the attachments being, at minimum, high-level disinfected. Currently, these reusable cabinet hook-ups are not validated to be run in any AER. It would be unfortunate to find out down the line that the reusable tubing and connectors need to be processed with each use as well. Only time will tell.

In a nutshell, drying of endoscopes externally and internally is necessary, and it should involve at minimum safe filtered air sources, clean connections and storage cabinets that either facilitate internal drying or promote the sustaining conditions for endoscopes dried prior to storage.”

Carolyn Klimas, Olympus America Inc.

- “Storage cabinets should be located in a designated room when possible, or at minimum in low-traffic areas. Endoscope storage cabinets should not be located in procedure rooms.
- “Preferred storage for endoscopes is a drying cabinet that dries both the outside of the endoscope as well as endoscope channels. Recommended channel air options for drying cabinets include nitrogen, instrument air, medical air or at minimum, HEPA-filtered air.
- “If a drying cabinet is not available, a ventilated storage cabinet may be used that features HEPA-filtered air, a built-in fan and positive pressure inside the cabinet.
- “All cabinets should include doors that can be closed and secured, hangers to safely hold the endoscope, and adequate space to ensure scopes hang freely without contacting other scopes or any surface of the cabinet (top, sides or bottom).
- “Vertical storage is preferred to enable endoscope channels to drain and maintain the shape integrity of the scope.”

Alison Sonsteli, oneSOURCE & Sanford Health, Fargo, ND

“First, you should consult the endoscope manufacturer’s IFU. Using a platform like oneSOURCE makes it incredibly easy to access the most updated IFUs and preventive maintenance documents needed to effectively decontaminate and sterilize. It

Ergonomics in endoscopy reprocessing requires rigid flexibility

When you have to clean, disinfect, sterilize, store and handle very delicate, sensitive and complex devices like endoscopes, it can be easy to overlook some of the obvious issues in the process.

That’s because the intricate process of reprocessing endoscopes and other endoscopic devices involves disassembling the devices to a degree, as well as conducting detailed inspections of products along the way.

Performing these tasks can be stressful on Sterile Processing and Distribution (SPD) technicians, particularly in the physical areas of gait between stations, posture at workstations and standing for long periods of time.

As a result, ergonomics should be considered a serious factor.

“Ergonomics play a distinct role in the reprocessing arena,” insisted Betty McGinty, RN, CGRN, CER, Fellow, Clinical Education Services, Boston Scientific Corp., who cited the Society of Gastroenterology Nurses and Associates’ “Ergonomics in the Gastroenterology Setting,” a 2020 Position Statement. “Potential injury opportunities include repetitive motions as well as sustained awkward positions. Supportive corrective responses include education about, as well as adherence to, proper body mechanics, rest and use of assistive devices. Reprocessing room design that includes attention to sink depth and counter height (adjustable if possible) as well as use of anti-fatigue mats in the front of the sink (to increase lower extremity blood flow) are ergonomic suggestions. Assistive devices include channel flushing aids.”

Much depends on the departmental footprint and workspace design, according to Melissa Kubach, Clinical Education and Training Manager, Mobile Instrument Service & Repair.

“People do jobs well when they are well trained, practice the process regularly and have the resources to make the job easy to do,” she noted. “Installing sinks and working counter space that can adjust to accommodate the reprocessing technicians’ height is a big help. Also, cleaning is improved with the use of automated flushing devices to limit repetitive motion.”

SPD technicians who reprocess endoscopes handle a variety of devices that require certain equipment, according to Jahan Azizi, Special Projects Manager, Healthmark Industries Co.

“The long scopes require large, deep sinks that the height needs to be adjusted to accommodate a wide range of individuals,” Azizi indicated. “The high-demand, fast-paced department could [and] will cause additional stress.”

Azizi specified the need for height-adjustable sinks and tables, an “assembly line approach” to reprocessing for high-demand departments and

“a quality control person to verify 100 percent enhanced visual inspection after cleaning.”

Proper tools of the trade can make a monumental difference, according to Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare.

“Newer cleaning equipment and aids, such as trough-type sinks that allow the flexible endoscope to be stretched out versus coiled and flush/suction devices like Scope Buddy Plus, greatly assist the technician handling and processing of flexible endoscopes,” Agoston said. “Pass-through AERs that allow for separation between the dirty and clean area are a great help as well as the Medivators horizontal storage cabinets that automate the tracking of the endoscopes [and] extend hang time to 30 days are a great benefit. Advances like these greatly enhance the likelihood that endoscope reprocessing will be done correctly.”

But Ron Banach, Director, Clinical Training, Ruhof Corp., calls for deeper efforts earlier.

“The device manufacturers must work with end users to design products that meet all the necessary guidelines to allow for cleaning and safe use,” he said. “Unfortunately, it comes down to the analysis of costs versus the quality of the outcome.”

Several manufacturers contend they already are working with end users by designing and delivering a different kind of product that doesn’t involve such detailed and intricate cleaning.

“For the last 20 years, hospitals have been trying to meet increasing patient procedure demand – and the corresponding increase in reprocessing protocols – with more people, time and financial investment in reusable equipment,” said Christian Escobar, Director, Marketing – Visualization, Ambu. “Reusable endoscope ergonomics and design may improve incrementally to address a contamination challenge, but the overall ergonomics (size, length, etc.) are not expected to dramatically change. Utilizing more single-use endoscopes is a way to alleviate the overall volume of reusable scopes that require reprocessing, storage, transport and handling.”

Rob Cripe, Chief Commercial Officer, Integrated Endoscopy, concurs.

“As a manufacturer of single-use rigid scopes, we put a lot of energy into ergonomics relative to the user,” Cripe said. “Many times these ‘human factors’ are the most important in driving adoption and can be a significant challenge to incorporate the right combination of function and form. As it relates to cleaning/sterilization, this obviously is not considered since all single-use products are sterilized during the manufacturing process.”

may have instructions for how to perform these tasks.

"Next, you should consult current standards/guidelines from AAMI, AORN and SGNA. For example, a controversial topic for endoscopes has been 'hang time,' which is the amount of time a scope can be stored before it should be reprocessed. Depending on the standard or guideline, you may get different guidance for hang time. Then you should discuss the proposed process and/or gaps with Infection Prevention and possibly the department(s) where the scopes will be

stored. You may find the storage requirements cannot be met in certain areas, due to space, resources, etc.

Next, you should perform a risk assessment that incorporates and documents all the requirements, decisions and outcomes.

Last, update policies, training materials and competencies to ensure that the process is followed correctly."

Gregg Agoston, SpecialtyCare

"Be sure that all flexible endoscopes are hung in a vertical position only without any bends

in the insertion tube or umbilical cable. Traps create areas for water to remain and could allow bacteria to grow.

"New horizontal drying cabinets are a great way to store flexible endoscopes for up to 30 days. These cabinets include aeration to keep the endoscopes clean and dry.

"Be sure that no matter what type of storage cabinet you use for high-level disinfection (HLD) flexible endoscopes that you have, gloves available for the handling of the devices. Flexible endoscopes should never be 'bare handed' when transporting them." **HPN**

Sterilization indicators need their true colors shining through

Earlier this year, the U.S. Food and Drug Administration (FDA) reported a risk of healthcare professionals who reprocess medical devices to misinterpret the chemical indicator tags used to validate the effectiveness of hydrogen peroxide gas plasma sterilization of medical devices.

Essentially, two manufacturers market FDA-cleared chemical indicator products for use. The challenge? Simply put, either product uses a different color to showcase the results.

Within hospitals and other healthcare facilities, the question among Sterile Processing & Distribution (SPD) departments is what they can do about it? [Editor's Note: For a discussion of potential solutions, turn to *Periscope* on p. 60.]

Healthcare Purchasing News posed this question to more than a dozen sterile processing subject matter experts who participated in its annual Endoscope Care coverage. Respondents were asked to choose between four potential solutions or suggest their own solutions and explain. None involve FDA regulations mandating the use of a single, standardized universally accepted color scheme.

The four choices:

1. Increase education and training of SPD professionals to follow their sterilization equipment's instructions-for-use – regardless of different methods or types of equipment used.
2. Demand that color standards for sterilization indicators be established, adopted and implemented – regardless of manufacturer or brand – to facilitate the process.
3. Switch to a different type of sterilization process.
4. Outsource the sterilization process to a third-party company.

Half of the executives leaned toward education indicated in No. 1.

"Education and training are key here," insisted Melissa Kubach, Clinical Education and Training Manager, Mobile Instrument Service & Repair. "Different indicator brands have conflicting colors for identifying processed versus unprocessed. Until the industry requires a standard exposure color, the only viable option is to reinforce training with posted visual examples within Sterile Processing and the Operating Room."

Marcia Frieze, CEO, Case Medical, emphasizes practicality.

"There will always be product and process variations from facility to facility," Frieze told *HPN*. "SPD professionals need adequate and frequent training and support to properly use all the tools associated with their responsibilities at the facility where they work. Management and educators can employ varied training methods and work aids to help assure that everyone is able to perform their duties, and that quality is consistent from employee to employee and shift to shift."

Frieze also recommends a workflow tracking system as a valuable work support tool.

"Processing steps and quality checks are documented, so technicians do not have to rely on memory," she said. "For endoscope processing, these detailed instructions reduce the risk of missing steps in the lengthy and complex process. For quality checks like chemical indicators, the

proper end point color for a passing result can be checked against a guide on the tracking system display. The CaseTrak360 system provides 360-degree end-to-end process tracking, including an Endoscopy Module. The software supports tracking, tracing and best practices and helps eliminate errors as the software guides and monitors the process."

One-third tilted toward No. 2 in demanding the adoption and implementation of color standards.

"A standardization of indicators would be ideal, but these things take time, and the need for understanding is immediate," indicated Natalie Reece, Endoscopy Clinical Educator, Key Surgical. "SPD professionals should receive regular training on their equipment and indicators because each facility is different, and there is high turnover." _

Alison Sonsteli, CHL, CRCST, oneSOURCE consultant and Sterile Processing Coordinator at Sanford Health, Fargo, ND, concurs.

"Ideally, we should have consistent indicators, she noted. "This is not only for sterile processing technicians, but for the end users. If that cannot be accomplished, training, competencies, and visuals need to be adopted to ensure sterile processing technicians and end users are able to correctly interpret the indicator."

Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare, expresses concern when an indicator or integrator may fail to function as expected.

"I recently experienced [an] issue at a hospital where we manage and staff the SPD," Agoston recalled. "The problem was that the integrator changed color but the change was slight on some loads. The OR noticed this and questioned if the device was properly sterilized. A sterilization integrator reading should be a pass/fail choice with little to no room for interpretation."

Only one favored No. 4 in outsourcing sterilization.

No one recommended No. 3, which involved moving away from hydrogen peroxide sterilization altogether.

For some, the choice is rather obvious.

"In an area of healthcare with increasing demands and equipment variance, standardizing on indicators would appear to be a way to reduce confusion in the marketplace," urged Christian Escobar, Ambu's Director of Marketing – Visualization.

But Rob Cripe, Chief Commercial Officer, Integrated Endoscopy, recommends something a bit more fundamental.

"Switch to a single-use devices whenever possible [as they] are guaranteed to be packaged terminally sterile," he said. His company manufactures single-use endoscopes.

"This eliminates guesswork, misinterpretation, mistakes and reduces the burden on staff and ultimately is safer for patient and healthcare professionals," Cripe continued. "When single-use is not an option, outsourcing may be the best alternative as this is a dedicated service that can/should deliver results that are potentially more reliable and reduces the burden on internal resources."

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Want to improve quality, partnerships? Walk in each other's shoes

by David Taylor III, MSN, RN, CNOR

Keeping Sterile Processing departments (SPDs) performing optimally and ensuring interdisciplinary relationships remain strong and productive is often challenging, even for the most knowledgeable and experienced SPD leader. One way SPD leaders can improve outcomes, foster better interdisciplinary partnerships and broaden SPD technicians' experience is to have SPD professionals spend quality time in the various departments they serve. This approach is, of course, in addition to the training, cross training and competency validations SPD leaders already routinely provide in their roles. Such an approach gives SPD employees a clearer view of the big picture when it comes to successful interventional, procedural and surgical departments – and how their products and services directly impact their interdisciplinary customers, and patients.

In my professional career, I've personally seen how rotating staff through different departments for up to two weeks at a time gives them a better perspective of what happens behind the scenes. Interventional, procedural and surgical departments are complicated and have many needs and "moving parts." When high-pressure situations arise in procedural areas and the risks associated with them are mitigated due to prompt, high quality service and attention to detail from SPD professionals, those in the SPD can take pride in knowing their hard work helped prevent a negative outcome – and a new level of trust and respect can start developing between the departments.

Understanding builds collaboration

The more professionals from one department understand about another department's roles, needs and challenges (and how each department's roles interact and intersect with one another), the easier it is to bridge gaps and improve safety and positive outcomes through collaboration. SPD professionals who directly observe procedures gain new perspective about the instrumentation and equipment they process and provide, as well as the need to have sets that are clean, sterile, well-functioning, error-free, and available on time. They will also gain a better understanding of the frustration a surgeon experiences when an instrument is missing or doesn't perform properly in the middle of a high-stress procedure. When SPD professionals take time to thoroughly check the quality and functionality of instruments, the end user will experience less frustration. And when SPD professionals are able to see instruments in action, they realize the impact they have on every patient.

Conversely, the actions of interventional, procedural or surgical staff can have a big impact on SPD professionals' ability to process instruments effectively, efficiently and safely. All staff members in those departments should spend ample time in the SPD, keenly observing all that takes place in each of the critical areas of the department. One day spent in decontamination will convince anyone that properly caring for instrumentation during and after a procedure truly matters. Understanding that the cleaning process actually begins at the point of use rather than in the SPD's decontamination areas is essential, as is being knowledgeable about how to apply appropriate enzymatic solutions to the instruments prior to returning those case carts to the SPD.

Additionally, when procedural staff are able to see firsthand how difficult it can be for their SPD colleagues to manage process quality and follow standards, guidelines, best practices and instructions for use – all while under time pressures – they will have a far better perspective and appreciation of the work being accomplished every day, seven days a week. When all parties understand the issues each other's department routinely faces, the greater likelihood the departments will work together toward a better solution.

Conclusion

Instruments that are improperly cared for during or after a procedure or are misplaced or malfunctioning can result in frustration for the end user and negative outcomes for the patient, facility and all departments involved. When departments work together to build better interdisciplinary relationships and a broader understanding of what takes place within one another's walls, quality and communication will improve, service will be delivered more effectively and efficiently, and positive outcomes will typically result.

SPD leaders (and leaders from the departments they serve) who consistently strive to create a work environment that puts people first and promotes interdisciplinary collaboration will foster greater reliability, safety and accountability. They also help create a team-based environment that can more proactively address challenges and obstacles, mitigate risks and optimize processes and practices – all of which will improve the delivery of safe, effective care and service. **HPN**

David L. Taylor III, MSN, RN, CNOR, is the principal of Resolute Advisory Group, LLC, a healthcare consulting firm in San Antonio, TX. He has written for IAHCSMM since 2019. David@ResoluteAdvisoryGroup.com.



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Disinfecting dropped instruments, Cleaning verification - essential for cannulated medical devices

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



Q We have reached the point of a good, old-fashioned standoff amongst members of our CSSD team when it comes to the issue of an instrument being dropped on the floor in the assembly process and what should be done with it. We have a 50/50 split between sending the instrument back to the decontamination area to be cleaned or wiping it off with a disinfecting wipe. Can you help shed some light on this matter?

A The best practice would be to return the instrument to the decontamination area for complete cleaning and reprocessing. Aside from contamination, an instrument dropped on the floor also could be damaged, and therefore should be carefully inspected for damage and proper functioning. You would not want to wipe the instrument off with a disinfectant wipe for the following reasons:

- The chemical disinfectant may not be compatible with the instrument material or finish and could damage the instrument.
- Cleaning is ALWAYS a prerequisite to disinfecting, so the instrument needs to be thoroughly cleaned with a detergent prior to disinfecting.
- To be effective, disinfectants must remain moist on all surfaces of the item being disinfected for a prescribe period of time according to the manufacturer's instructions for use (IFU), thus the use of disinfectant wipes is not necessarily a faster process.
- Following exposure to a chemical disinfectant, the chemical agent must be rinsed from the instrument.
- If the instrument is urgently needed, you can clean it manually according to the manufacturer's IFU.
- The wipe-off game is a RISKY GAME. Be sure to read the instructions very carefully and follow them precisely.

Q I am the sterile processing quality assurance coordinator for a large healthcare system, which includes a clinical research center. The research center utilizes many unique medical devices, including many prototypes, which require reprocessing and sterilization. A new instrument set that includes several small cannulated devices and specialty needles was recently introduced at the research center. I am concerned about cleaning these items effectively; they are visibly inspected and appear to be clean, and when the channels are flushed the water appears to be clear. However, I am concerned about the possibility of invisible soils that may remain in the channels, presenting a barrier to effective sterilization and posing a risk to patient infection. Can you suggest any additional methods that I could incorporate into our processes to ensure that the items are thoroughly clean and free of any organic soils?

A As you noted, effective cleaning must include the removal of visible as well as invisible soil. Channeled and cannulated medical devices are amongst the most challenging to clean; residual soils remaining in the lumen of these devices can inhibit the sterilization process and indeed result in the transmission of infectious agents from one patient to another. With the widely publicized reports in the media of breaches in cleaning procedures, which have placed thousands of patients at risk, coupled with professional standards and recommendations, cleaning verification has become the standard of practice.

There are various quality assurance tests now commercially available for testing medical devices for cleaning efficacy. There are swab and some flush type tests that can detect either adenosine triphosphate (ATP), protein, or blood. Since you specifically expressed your concern with cannulated and channeled devices, many with very small lumens, I would recommend a flush method test known as ChannelCheck™. This test can detect residual organic soils, including carbohydrates, protein, and hemoglobin. Post cleaning, sterile water is flushed through the channel and collected in a plastic bag. A test strip consisting of three pads, which are sensitive to either carbohydrates, hemoglobin, or protein, is dipped in the test sample. If any pad shows deviation in color, the test is positive for the presence of that soil and must be re-cleaned. (See Figure 1) [HPN](#)



Photo courtesy: Healthmark Industries

Figure 1

Ray Taurasi is Principal, Healthcare CS Solutions. His healthcare career spans over five decades as an Administrator, Educator, Technologist and Consultant. He is a member of AORN, AHA, SGNA, AAMI and a past president of IAHCMM. Taurasi has been a faculty member of numerous colleges teaching in the divisions of business administration, nursing and health sciences.

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LEARNING OBJECTIVES

1. Discuss the evolution of robot-assisted surgeries
2. Identify reprocessing challenges unique to robotic instrumentation
3. List practices and quality control methods to help address reprocessing challenges

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SELF-STUDY SERIES

Managing the reprocessing challenges of robotic instruments

by Tamara Behm and Chasity Seymour

At the conclusion of the 1980 movie “Star Wars: The Empire Strikes Back,” the hero, Luke Skywalker, gets a new hand courtesy of a robotic surgeon. Moviegoers were awed at the thought that someday, in the distant future, a robot would be able to surgically attach a robotic arm to a human being. Amazingly, just five years after the movie was released, the first surgical robots were assisting surgeons in performing biopsies! As we know, this was only the beginning of what robots are helping surgeons do today. Although robotic surgical tools seem like space-age technologies, they are prone to very down-to-earth processing challenges in our sterile processing departments.

The evolution of robot-assisted surgery

When developing advances in surgical technique, innovators have typically set two major clinical goals: to reduce invasiveness (which decreases pain) and to reduce length of stay for patients. Robot-assisted procedures have offered opportunities to provide both these benefits. Patients undergo less invasive procedures that result in less blood loss, and they are discharged sooner than with traditional versions of their surgeries. This is the very definition of surgical advancement.

The first robot-assisted procedure, performed in 1985, was a brain biopsy using the Programmable Universal Manipulation Arm (PUMA) 560 robot. Robot-assisted transurethral resection of the prostate and hip replacement surgeries soon followed, but robotic surgery did not yet enjoy widespread acceptance. In 1995, Intuitive Surgical launched an entirely new type of surgical robot that provided the added benefits of much greater precision and ergonomic support for surgeons.

With success comes competition. In 2006, TransEnterix Surgical launched their

robotic solution for colorectal, gynecological, gallbladder and hernia procedures. Stryker followed in 2013 with a robotic solution for total and partial knee replacement surgeries. In 2018, robot-assisted surgery advanced again with the introduction of a hand-held robot from Human Xtensions and the first flexible endoscopic robot from Medrobotics. Most recently, CMR Surgical obtained FDA clearance for the Versius mobile surgical robot. The number of available robotic systems is expected to continue to grow exponentially.

Today, robots with specially designed instruments can assist in a variety of laparoscopic procedures. Due to their advanced precision, some procedures that were previously unsuitable for laparoscopic methods can be performed with less invasive robot-assisted versions.

The following types of robot-assisted procedures are currently performed around the world:

- Cardiac
- Colorectal
- Gynecological
- Orthopedic
- Thoracic
- Urologic

As with traditional laparoscopic procedures, patients receive the benefits of minimal tissue damage and blood loss from robot-assisted surgeries and diagnostic procedures. In addition, the robotic devices enable a greater degree of surgical accuracy for delicate tasks. In the future, a greater number of traditional laparoscopic and endoscopic procedures are expected to be replaced by robotic versions.

The many advantages of robot-assisted surgery come at a price. The main robotic system itself is about a \$2-million investment, and the surgical arms, staplers and other accessories are limited-use consumables that must be purchased repeatedly. Unlike traditional laparoscopic instrumentation, robotic instruments are designed

for a maximum number of uses based on the number of times the instruments have been energized on the robot. Each robotic instrument can cost between \$600 and \$4,000. These expensive devices must be handled thoughtfully in the surgical suite and in the sterile processing department in order to protect the facility's investment and maximize the number of procedures per instrument.

Processing challenges of robotic instruments

As with other surgical instrumentation, the goal of reprocessing is to remove all debris and bioburden from the instruments so that sterilization of all surfaces can occur. Any failure to sterilize can lead to potential cross-contamination and infections. Removing all bioburden and soils is also important because residual soils can lead to instrument damage and malfunctions, which can cause patient injuries and/or surgical delays.

Robotic instruments, which have complex designs and mechanics, pose unique cleaning challenges that may increase the risk of residual soil. For example, many devices have multiple articulation points controlled by various wires and pulley systems that become contaminated during a procedure. Technicians are challenged to clean around the wires and within the channels in which they lie. Not only is it difficult to reach these points, but technicians are unable to see all areas clearly.

Another unique robotic challenge is char. Char occurs when bioburden on the instrument is exposed to a cauterization arc that burns the bioburden onto the instrument surface and creates a baked-on soil that is especially hard to clean.

Failure to remove bioburden or char in these tight, complex segments of a robotic tool can block sterilant from reaching these areas and impede sterilization. It can also lead to the formation of biofilm, an aggregate of bacteria and soils in a sticky matrix that adheres to surfaces and becomes very difficult to remove.

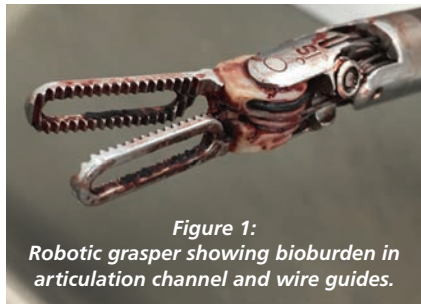


Figure 1:
Robotic grasper showing bioburden in articulation channel and wire guides.

In the OR

To assure thorough cleaning of robotic instruments, every step of their instructions for use must be followed, starting with point-of-use treatment. Operating room staff must remove debris on these instruments between uses and ensure that the device is ready for reuse during the procedure. This can be challenging when robotic instruments remain secured to the robot arms instead of being placed on a surgical stand between uses.

Post-procedure point-of-use processes typically include some disassembly and treatment to maintain moisture on the devices. However, unlike traditional surgical instrumentation, robotic instruments require the priming of channels and other additional steps. Remembering which devices require these extra steps can be challenging for OR staff. Missing a step can be detrimental because bioburden can dry on surfaces and become hard to remove.

In decontamination

The special instructions continue as the instruments move to the decontamination area. Cleaning involves multiple steps and equipment. For example, the Da Vinci Endowrist instruments from Intuitive Surgical require 15 steps for decontamination alone. Reprocessing a single set of robotic instruments according to their instructions can take three hours or more to complete. Decontamination technicians may be tempted to skip steps or shorten soak times as the pressure to turn robotic sets increases. Unfortunately, shortcuts can potentially create opportunities for residual soils and biofilm formation.

Challenges of usage counts

The most restrictive challenge of these instruments is their limited reuse. Each instrument has a defined number of times that it can be used and sterilized. Continued reuse beyond the prescribed processing limits may lead to instrument failure or the formation of biofilm, both of which have the potential to injure patients.

Robotic instruments typically have a manual means to track uses. Technicians manually advance the sterilization count during processing typically by marking the instrument. However, misunderstandings about who does the advancing and when it should occur can lead to problems. Missing a count leads to inadvertent over-processing and overuse. On the other hand, extra counts lead to premature

device disposal and increased cost to the facility.

Addressing the challenges

Robotic instrument reprocessing challenges are not going away, but they can be managed. For example, point-of-use treatment has a big impact on the success of cleaning, so OR staff should be trained and tested on all the required steps and competencies to ensure consistency among all staff members who handle the robotic devices. Consider using placards or cue cards in the OR to remind staff of the proper steps to follow for each instrument.

It's also helpful to include all necessary materials and equipment for point-of-use treatment on each case cart. This may include flushing solution, syringes, adapters and point-of-use treatment products, for example. It can be especially helpful to use tubes that contain cleaning detergents or enzymes on instrument tips. These products perform two functions; they keep the soiled instruments moist, and they begin to loosen bioburden and char from the device.



Figure 2: Enzymatic cleaner within tip tubes begin to breakdown bioburden as shown by the red color in the solution

Precleaning is especially important in the case of robotic instruments since each is limited to a specific number of reprocessing cycles. If residual soil is found after a sterilization cycle, one reuse is wasted because the soiled instrument must now undergo an extra cleaning/sterilization cycle.

As with OR staff, training must be provided for decontamination technicians,

and their ability to properly perform all tasks should be verified. Using competency checklists and spot audits confirms technician performance and captures process changes, both intended and unintended, before they become problems.

Technicians also need easy access to the tools they need to do the job. For example, lighted magnification at the sink allows technicians to see residual soil that may otherwise be missed. Having the correct brushes, syringes and attachment accessories to scrub and flow fluids through robotic channels helps assure thorough cleaning and avoid internal damage.

In addition, ultrasonic cleaners must meet the validated parameters described in each robotic device's instructions for reprocessing. Since robotic instrument channels are too small to be brushed, it's critical that cleaning solution be flushed through them during ultrasonication to remove bioburden. Technicians should be trained on the use of the ultrasonic cleaners and the correct attachments to ensure effective flow.

Thermal disinfection is the last step before the instruments are sent to assembly. When an ultrasonic cleaner is not capable of thermal disinfection, departments use automated washer disinfectors for thermal disinfection. Unfortunately, most of these systems are not designed for use with robotic instruments. Although placing robotic devices loosely in a basket during the automated washer disinfectant cycle may seem like a good idea, it can pose serious risks. Cleaning chemistry can become trapped in the channels during the cleaning cycle. Without a flow mechanism, there is no guarantee that the channel is flushed free of chemistry. The instrument may be thermally treated, but it could harbor residual cleaning chemistries that may harm patients or interfere with sterilization. Only washer disinfectors with racks designed and validated for thermal disinfection of robotic instruments should be used for these devices.

It's important to note that even washer disinfectors that have been designed for robotic instruments may not fully replace required manual cleaning and ultrasonication steps. A thorough reading of the washer's instructions for use will help determine which, if any, of the manual cleaning and ultrasonication steps described in the robotic instrument's reprocessing instructions can be replaced by the washer disinfectant's cycle. In addition, the correct cleaning chemistry must be used.

Assuring quality control

Quality control is an important function that helps to assure that robotic instrument sets are delivered to the OR on time and ready for use. Consistent cleanliness is one of the deliverables needed for every robotic set to be made ready, and quality checks can help capture failures to meet this deliverable before the set gets to the OR.

Proper training and tools contribute to better cleaning quality. For example, both the decontamination technicians performing the cleaning and the assembly technicians preparing sets for sterilization must be aware of the difficult spots to clean and must watch for evidence of physical part failure (fracture lines, cracks, plastic chips, etc.). Both teams should have lighted magnification to perform these intricate jobs. Furthermore, all staff members, including operating room and sterile processing staff, must be trained for their robotics-handling functions and demonstrate competency. Reevaluation of competency should be set per the facility policies and account for any deficiencies found during audits or inspections.

Various types of cleaning tests also help departments manage quality. For example, protein detection tests help detect residual soil on cleaned instruments. Cleaning indicator tests for automated equipment should be conducted daily to assure cycle effectiveness. And all tests should be documented to provide a traceable record of the data.

For robotic tools, accurate sterilization counts are essential for controlling costs and preventing overprocessing. Policies and procedures should identify who is responsible for tracking the instrument sterilization counts and when this will occur. Facilities can also consider using an instrument tracking software to automate the tracking process. If they do, a policy should be in place to resolve discrepancies between the robotic use counter and the tracking system's sterilization counter.

Even if sterilization counts are accurate, premature disposal can still occur. Any time a set is opened to retrieve just one instrument, the remaining instruments must be processed again before the set can be used. Right-sizing the robotic sets can reduce the chances of breaking up a set and wasting a sterilization cycle. Collaborating with surgeons and OR personnel can help determine the minimum requirements for each set. It can also help to use peel pouches for instruments or staplers that may be needed as procedure replacements or for specific cases.

This will not only optimize sterilization processes but will offer versatility when picking case carts.

The future is here

Robot-assisted surgeries are here to stay. They will continue to evolve and advance therapeutic techniques to help improve patient outcomes. With proper planning, training, and quality control measures in place, sterile processing departments will be better able to reduce risk and support the unique processing needs of robotic instruments, staplers, and all the new accessories to come. **HPN**

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Chasity Seymour, BSHM, CST, CRCST,



AGTS, is a clinical education specialist at STERIS Corporation. She began her healthcare career as a surgical technologist and later gained extensive experience as a sterile processing technician, a unit educator and

a regional manager for sterile processing. Chasity has presented lectures, in-services, and webinars at local, regional, and national conferences and has authored and delivered numerous lesson plans. Chasity is a member of AAMI, AORN, AST, IAHCSSM, and SGNA. She currently serves as vice president of the Central Texas IAHCSSM Chapter. She is completing her Bachelor of Science in Healthcare Management from Texas Tech University Health Science Center, Austin, Texas.



Tamara Behm MSN, RN, CIC, FAPIC, CER, CRCST, is a clinical education specialist for STERIS Corporation, with 14 years of clinical nursing leadership and healthcare experience.

She has held various roles as a director of ICU, ICU nurse, infection prevention director, infection prevention consultant, mentor, adjunct professor, presenter, author, and mock surveyor. She is an expert in infection prevention, CMS and other regulatory requirements, and in process improvement. She is a member of APIC, SHEA, AORN, IAHCSSM, SGNA, ASQ, and AAMI.

CONTINUING EDUCATION TEST • NOVEMBER 2020

Managing the reprocessing challenges of robotic instruments

Circle the one correct answer:

1. Which specialties offer robot-assisted surgical procedures today?
 - A. Dental
 - B. Cardiac
 - C. Ophthalmology
2. Which is an advantage of using robot-assisted surgery?
 - A. Patients have less blood loss and shorter length of stay
 - B. Patients recover in the hospital
 - C. The hospital must invest \$2 million
3. Which is true about the design of robotic instruments?
 - A. Instrument char is easy to remove
 - B. All wires and pullies are sealed away from bioburden
 - C. Bioburden can be trapped at the articulation points
4. What can happen if residual soils or char remain on the instruments after cleaning?
 - A. Nothing
 - B. Sterilization can be easier
 - C. Biofilms can form
5. What is a unique requirement for robotic instruments during point-of-use treatment?
 - A. Instruments are kept moist for transport
 - B. Channels are primed
 - C. Instruments are disassembled per the instructions for use
6. How long does the typical decontamination process take for a robotic instrument?
 - A. 30 minutes
 - B. 1 hour
 - C. 3 hours or more
7. Which helps remove soil during transport?
 - A. Tip tubes containing cleaning detergents or enzymes
 - B. Priming the channels
 - C. Point-of-use moisture retention product
8. How does lighted magnification help decontamination technicians at the sink?
 - A. Makes it easier to see inside the channel
 - B. Checks for protein
 - C. Makes seeing residual soil easier
9. When can a washer/disinfector be used to clean and thermally disinfect robotic instruments?
 - A. When the ultrasonic cleaner does not have a thermal disinfection cycle
 - B. When the washer-disinfector is validated for these instruments
 - C. Instruments cannot be put in the washer/disinfector
10. Pouching individual robotic instruments for reprocessing can help facilities optimize the number of uses.
 - A. True
 - B. False



The approval number for this lesson is **STERIS-HPN 200510**.



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Medical displays and monitors move forward with momentum

Focusing on resolution quality, remote and mobile workstations, and data collection

by Ebony Smith

Photo courtesy: Sony Electronics

The world continues to watch the impact of the COVID-19 pandemic on people's health and lives. Hospitals and healthcare facilities channel their efforts and resources around the clock to patient care for COVID-19-related and other medical conditions.

Particular equipment, like medical grade displays and monitors, have become a necessity in critical care during this crisis. Manufacturers press forward to make advancements and ensure availability of these devices for clinicians and staff to use in hospital, non-acute care, post-acute care, and remote work environments.

Resourcefulness and flexibility

In the beginning of COVID-19, LG Business Solutions saw what was coming ahead and planned for the safety of its staff and the demand for its medical monitors, shares Tom Impellizzeri, Senior Account Manager.



Tom Impellizzeri

"We focused on protecting our workers and maintaining business continuity, especially minimizing supply chain disruptions," Impellizzeri explained. "LG leveraged

its global supply chain and prepared in the early stages of the pandemic with dedicated resources to produce enough medical monitors to prepare for the worst to come. LG understood medical monitors are essential to hospitals on the front lines of the pandemic. So, it was vitally important LG could fulfill orders in a timely manner."

Some hospitals rearranged workspaces to accommodate care during the pandemic, observes Anne Bondulich, Marketing Manager, Sony Electronics.

"Over the past few months, the need for critical care rapidly emerged as OR's were quickly turned into ICUs," Bondulich described.

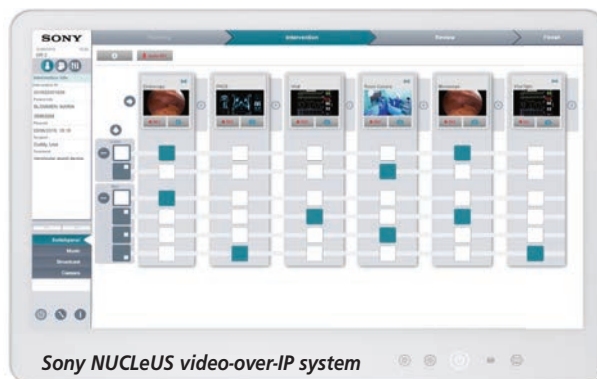
Other facilities that shut down are poised to reopen, notes Brian Schlueter, Senior Marketing Manager, FSN Medical Technologies.

"At the height of the pandemic, the focus of medical facilities was COVID-19-related, and other procedures were given less priority," Schlueter indicated. "As infection rates trend downward, and facilities equip to contain the virus, elective surgery volume will likely increase, including the demand for new capital equipment and upgrades."

Going virtual and remote

Workforces, technology, and work settings modified to support the safest possible care and service.

"Going forward, less contact between staff and patients is a strict requirement to help stop the spread of disease," Bondulich said. "Facilities are focusing on solutions that can quickly help them adapt now and in future crisis situations. One such solution is the Sony NUCLeUS



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* A hypotensive event is defined as MAP <65 mmHg for a duration of at least one minute.

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PRODUCTS & SERVICES

video-over-IP system combined with Sony's PTZ cameras and 4K displays, which allow nurses' workstations to easily and remotely add live view access into any room, whether a surgical suite, ICU or emergency department, to reduce exposure and minimize personnel required in a confined space."

She continued, "Due to distancing measures and infection control, there is a very high demand for advanced telemedicine solutions in hospitals, particularly in the ICU and critical care areas. Now more than ever, Sony's pan tilt zoom cameras are being integrated into leading telemedicine platforms in hospitals to collaborate and communicate virtually."

In some cases, medical staff shifted to remote care and equipment, Impellizeri pointed out.

"During the pandemic, many radiologists have been working more from home," he noted. "Radiologists scrambled to set up their home offices with the same image quality, diagnostic confidence and reliability as they experience in the hospital's reading room. Many turned to us for lightweight, high-performance LG Gram laptops (17Z90N) and DICOM compliant 8MP diagnostic monitors (31.5-inch model 32HL512D-B)."

Edwards Lifesciences adjusted staff schedules and added remote training on products, explains Katie Szyman, Corporate Vice President, Critical Care.

"We increased production of our products, but COVID restrictions reduced our workforce by 25% initially," she stated. "We were able to offset these limitations with increased overtime for the remaining team. In many facilities, our local clinical specialists were able to continue assisting with installation and training on our products. In other facilities, we offered virtual trainings, which were a flexible and efficient option for our customers."

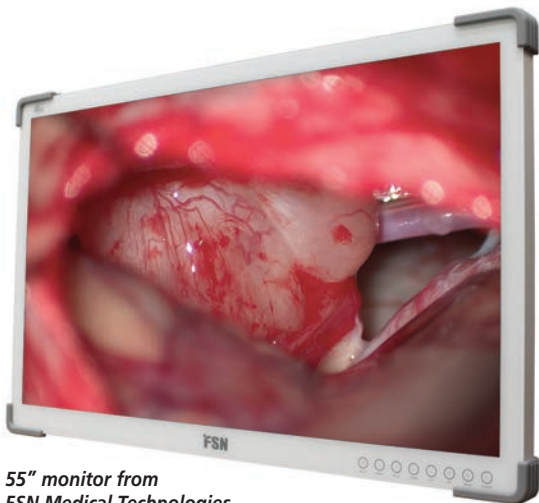


Katie Szyman

Hospital-wide and specialty care

Video imaging is used across various healthcare settings and specialties. Monitors of all sizes and capabilities are needed.

"Primary areas that require display of video images include endoscopy, laparoscopy, arthroscopy, fluoroscopy, surgical microscopes, and ophthalmology," Schlueter addressed. "FSN's family of monitors is designed for use with specialized medical image-generating devices used in those areas. Hybrid ORs and



55" monitor from FSN Medical Technologies

emergency procedure rooms typically use a larger monitor to display multiple images at once for team viewing."

He added, "FSN's 55" and 58" monitors have multiple video signal inputs compatible with a variety of image-capture devices as well as the images produced by monitoring equipment found, for example, in a cath lab. FSN also offers wireless A/V transceivers, recording and archiving equipment, video over IP, multi-viewers for video wall-type needs, signal routing and signal conversion devices, optical fiber cables and other equipment to support infrastructure in the OR."

Patients are monitored in a growing number of environments, expresses Tim O'Malley, President & Chief Growth Officer, EarlySense.

"Historically, higher acuity areas including ICUs, operating rooms and recovery areas have used patient monitoring technology," he indicated. "However, today the use of patient monitoring has expanded to non-acute areas in the hospital, with med-surg and general floors using it as a continuous way to detect changes in patients prone to health complications. Now, beds in general care areas have advanced, robust sensors embedded within them, allowing for most hospital patients to be monitored. Outside of the hospital, there is a rapid adoption of sensor-based monitoring technology in post-acute facilities, and a rapid expansion into the home. With EarlySense's contact-free continuous monitoring technology, a sensor placed under a patient's mattress can accurately transmit real-time data to medical staff outside the patient's room, which is extremely useful in light of the recent coronavirus social-distancing restrictions."



EarlySense's InSight Sensor-based Monitoring Solution

COVID-19, in turn, created a greater need for monitoring high-risk patients, emphasized Szyman.

"The COVID-19 pandemic caused many hospitals to expand ICUs to treat the overwhelming number of cases, which created demand for monitoring technologies," she explained. "Because these patients have a higher risk of developing serious complications, hemodynamic monitoring can help clinicians detect problems quickly, enabling them to make more informed and immediate treatment decisions."

Digital, mobile workstations are playing a vital role in ambulatory care during the crisis, notes Brian Hazelwood, Marketing Manager, Medical Division, Midmark.

"Today's equipment must be designed to provide the flexibility needed to support technology within the exam room, from room to room, when a space-saving solution is needed — or when it's time to expand the point of care beyond the exam space, such as the shift to telehealth resulting from the COVID-19 pandemic," Hazelwood stressed. "Mobile and stationary workstations are designed with technology needs in mind,

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Next-generation models

What will the future of medical displays and monitoring look like? Here are predictions shared.

“We believe that contact-free continuous monitoring is going to be ubiquitous in patient monitoring. With connectivity in a constant state of evolution, we can expect new developments, like monitoring devices being equipped with cloud access capabilities, which would allow for tighter monitoring of patients in almost any location.”

Tim O'Malley, EarlySense

“The future of medical displays will be driven by the advancements of image-generating devices. Next generation 8K video is on the horizon but may not find a stable place in the OR until there are cameras with high enough resolution to make use of it, let alone availability of infrastructure support. Until then, their place likely will be limited to video walls where multiple 4K images are displayed on a single monitor.”

Brian Schlueter, FSN Medical Technologies

“The next step is to route video data from all areas of the hospital and store it for easy retrieval at any time to any location. Hospitals also are looking for solutions employing the ease of a standard IP network connector enabling nurses to prep rooms quickly, without having to reconnect equipment, greatly improving turnover. Furthermore, to enhance the learning experience, smart apps such as telestration and annotation displayed on medical monitors will give much needed guidance to medical students.”

Anne Bondulich, Sony Electronics

“As the industry looks to the future, there is much to consider in facility design, access, comfort, workflow and the caregiver-patient relationship. Connectivity is paramount at the point of care. A fully connected digital ecosystem where point-of-care processes, equipment and caregivers are integrated will help enhance the care delivery experience.”

Brian Hazelwood, Midmark

“The next generation of monitors will not only need more artificial intelligence but also remote monitoring capabilities. Having that data readily accessible, anywhere, maximizes the use of technology to help physicians make proactive treatment decisions.”

Katie Szyman, Edward Lifesciences



6212 mid 3qtr keyboard and mouse from Midmark

whether a desktop, laptop or tablet-based technology component is used. Fully adjustable monitor arms enable monitors to easily be positioned for sitting and standing postures, eliminating neck and eye strain. Dual monitor mounts also are available to support software needs.¹¹

These types of workstations also are essential in surgical settings and procedures. Olympus, for example, announced in a press release, “the introduction of two new products designed to enhance patient care in endoscopy and surgical imaging by improving procedural workflow: the OEP-6 high-definition printer and the WM-NP3 workstation.”



WM-NP3 workstation and OEP-6 high-definition printer by Olympus



The company continued, “The OEP-6 high-definition printer accurately reproduces HDTV images to produce high-definition prints with excellent quality for endoscopist use during patient or colleague consults as well as detailed record keeping. The WM-NP3 workstation has been designed to specially support and add value to current and future imaging systems. It features an increased loading capacity, while taking up less floor space and supporting an expanded range of accessories.”

Trending technology

Medical display and monitoring technology continuously adapts to fulfill the many needs in care.

For example, LG Business Solutions focuses on the growth of its surgical and radiology monitors as well as X-ray imaging, Impellizzeri explained.

“The antimicrobial additive used in LG medical monitors is especially important given the multitude of challenges in achieving and maintaining the adequate cleanliness required of healthcare facilities. In addition to medical monitors, LG also is committed to image acquisition with our Digital X-Ray Detectors.”

Advancements in imaging resolution is another key concentration, Bondulich indicated.

“One of the biggest trends in imaging is the transition from HD to 4K resolution, which has greatly improved visualization for medical professionals during surgery and post-procedure. 4K 3D monitors can be paired with Robotic systems, to offer increased immersivity and depth of field, and High Dynamic Range (HDR), to deliver dramatic contrast with more brightness, accurate shadow detail, and deeper blacks.”

An additional focus is integration of artificial intelligence in monitoring and data collection, Szyman said.

“Artificial Intelligence is a significant development in displays and monitors, enabling the monitor to not only provide information about how the patient is doing now, but also to provide predictive information about how the patient will be doing in the future. For example, we recently introduced our Hypotension Prediction Index that can predict when a patient will have a dangerously low blood pressure event before it happens.” **HPN**

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1. Olympus Introduces the OEP-6 High-Definition Printer and WM-NP3 Workstation, https://www.olympusamerica.com/corporate/corp_presscenter_headline.asp?pressNo=3232

Last in a four-part series

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

The shift from volume to value-based care, with declining reimbursements and penalties for hospital-acquired conditions (HACs) and readmissions, have forced health systems and hospitals to find ways to improve quality of care while reducing costs. Reducing the per capita cost of healthcare¹ is a pillar in the Triple Aim initiative of the Institute for Healthcare Improvement (IHI).

With supplies being the second largest area of expense for hospitals, product procurement is a key consideration. But it is not just about negotiating the lowest price for a product. A critical factor for healthcare organizations to consider is the impact product choices have on patients from admission through discharge and beyond. Furthermore, with labor being the largest expense area for hospitals, product selection must also take into account the impact on staff efficiency and workflows.

While high-volume, low-cost medical supplies and accessories have small price tags, their impact on clinical outcomes and cost can be significant. Since these products (e.g., blood pressure cuffs, breathing circuits/components, ECG leads, temperature probes) come into direct contact with patients, they have significant potential to deliver clinical benefits or compromise safety.

Here are four factors to consider when purchasing medical supplies and accessories to maximize the value of these products, protect patient safety and streamline workflows.

1. Single use for safety

Healthcare-associated infections (HAIs) result in tens of thousands of patient deaths, and billions of dollars in costs annually.² Medical supplies that touch the patient have a higher source of infection risk and human error. For example, one study found even after disinfection, more than 77 percent of ECG leads were contaminated with at least one resistant pathogen.³ To reduce the risk for dangerous and costly

HAIs, hospitals are increasingly adopting single use products to help reduce cross contamination.

2. Minimize waste

Seek out medical supplies with the best durability and performance to reduce waste on products that are unacceptable right out of the packaging or must be replaced before patient discharge. This can also reduce the volume of supplies thrown away because they are ineffective or not tolerated by the patient.

3. Save clinical time and labor

Clinician time is precious – and costly – therefore hospitals must find ways to keep clinicians focused on patient care rather than supply management. Purchase high-quality supplies that hold up to use in the challenging healthcare environment to stop clinical staff from having to frequently track down replacement products and reapply them. Supplies that can be used with a variety of manufacturers' devices when used with appropriate adapters and trunk cables also save money and increase efficiency. The use of kits is another way to simplify supply use for

clinicians. When a manufacturer bundles commonly used products together in a single kit it frees up clinicians to spend more time with patients instead of hunting for supplies.

4. Standardize for savings

When a hospital consolidates spend on supplies and accessories with a single vendor it is in a better negotiating position to secure volume discounts from the contracted vendor. Consolidation also reduces SKUs, improves training and safety, and makes reordering easier. **HPN**

For more information on how high-quality medical supplies and accessories can help your organization reduce the cost of care, read this Frost & Sullivan white paper: *Compromised Safety Can Lead to Reimbursement Penalties and Lower Patient Volumes as a Facility's Reputation for Quality Care Suffers.*

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How COVID-19 can accelerate economic, environmental health

by Karen Conway, Vice President, Healthcare Value, GHX

Over the past few months, I have faced a seemingly classic question of whether to support the economy or the environment (although I hope this column will demonstrate how this does not have to be a zero sum game). My current predicament is: I want to support a local family-owned restaurant, but every time I place a “to go” order, I cringe at the amount of plastic and Styrofoam used to deliver the food safely and how plastic use has grown exponentially in the wake of the pandemic. A recent LA Times article¹ documented “a dramatic increase in the use of plastic,” from hand sanitizer bottles to takeout containers. Even Starbucks temporarily stopped allowing customers to bring reusable mugs for fear that they contribute to the spread of the virus (despite assurances from medical experts that they can safely and routinely be sanitized).

COVID-19 has increased the use of plastics-based products in healthcare, with cities around the world facing dramatic increases in infectious medical waste, including disposable masks, gloves and gowns. Even before the pandemic, healthcare was one of the biggest consumers of plastic.

But there are signs that the pandemic has reinvigorated interest in more sustainable medical products. Faced with shortages of disposable isolation gowns, many hospitals are considering purchasing more reusable gowns. A 2018 peer-reviewed study² looked at the environmental impact of reusable isolation gowns across their lifecycle compared to disposable alternatives. The researchers found that conversion to reusable gowns had significant environmental benefits:

- 28 percent lower natural resource energy consumption
- 30 percent lower greenhouse gas emissions
- 41 percent less total (blue) water consumed
- 93-99 percent lower solid waste generation

Even with such evidence, product conversions are not easy. The director of linen services at the Carilion Clinic recently republished a two-part article³ on how he managed the switch during similar supply shortages caused by the H1N1 pandemic. Eric Frederick gained buy-in from multiple stakeholders, from infection control to nursing, by solving packaging concerns and developing laundry protocols that improved versus reduced repellency of the gowns. UCLA Health also reports saving more than \$1 million dollars and nearly 300 tons of waste since converting to reusable products in November 2015.⁴

As these stories demonstrate, moving to more environmentally sustainable products can also make economic sense. This becomes increasingly significant as we consider how COVID-19 has disproportionately impacted low-income populations and communities of color, which suffer from higher rates of obesity, diabetes and hypertension that can increase the severity of COVID-19 infections.

The critical supply shortages driven in part by a paucity of domestic production combined with the impact of COVID-19 on disadvantaged neighborhoods present some interesting opportunities for community reinvestment. Economists have long spoken

about a multiplier effect when jobs, especially in manufacturing, are created, spurring additional economic benefits for the community where those jobs are located. The 45 plus health systems participating in the Healthcare Anchor Network (HAN) are working with the Democracy Collaborative and Practice Greenhealth to promote more local hospital purchasing from minority- and women-owned local businesses.

Westside United in Chicago did something similar years ago, bringing together unaffiliated health systems to create a shared laundry service staffed by individuals hired from the local community. Such initiatives take on added significance if you consider the potential for increased demand for laundry services with the switch to more reusable personal protective equipment (PPE).

Now, consider how a similar effort might address the need for more domestically produced PPE. What if regional hospitals were to create long-term purchasing commitments that would provide a local manufacturer with the business case necessary to invest in not only production capacity but also take the steps necessary to get U.S. Food and Drug Administration first (FDA) clearance for its products.

During a recent workshop as part of the Association for Healthcare Resource and Materials Management (AHRMM) virtual conference, 40 percent of attendees said they partnered with local businesses to address pandemic-related shortages, with nearly 50 percent planning to work with these companies in the future. The ability of those businesses to continue to supply to hospitals after the FDA’s emergency use authorizations expire will require navigating the ins and outs of FDA clearance. Long-term purchasing agreements can provide those businesses with the assurance that demand for locally produced, quality products will continue beyond the pandemic. Yes, it takes a village to make this level of change happen, but it can also solve multiple problems – from supply continuity to economic development that generates jobs with insurance coverage and the ability for disadvantaged populations to have access to not only healthcare services, but also the social resources, such as good food, housing and transportation, that contribute to better health overall.

As for the challenge of food delivery, I am encouraged by a Singapore start-up that is piloting food delivery using bamboo boxes that can be returned, washed and sanitized before re-use. Of course, to do that in the U.S. would likely require some regulatory changes, but after all, that’s how villages create new standards for economic and environmental health. **HPN**

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Color-coded standard needed for H₂O₂ sterilization indicator strips

Either FDA or manufacturers must step up to the plate

by James Schneider

Earlier this year numerous healthcare facilities alerted the Food and Drug Administration (FDA) of the potential for healthcare personnel to misinterpret colored hydrogen peroxide chemical indicator strips that are used to validate vapor sterilization of medical devices. Misinterpretation creates the potential for patient harm because currently there is no standard indicator color to show if a device has been sterilized and safe for use. This concern led the FDA to issue a letter to healthcare providers on May 7, alerting them to this problem.

According to the FDA's letter, during the COVID-19 pandemic, "Reprocessing staff may be using sterilization systems for the first time or concurrently using sterilization systems from different manufacturers. If staff assumes that all manufacturers use the same color code to validate sterilization, they may mistakenly release contaminated devices for reuse."¹

The FDA's letter also points out that they are currently working with the manufacturers of vapor sterilization indicator strips to improve the products' labeling "and explore standardization for colors used to indicate sterilization."² Currently, manufacturers of indicator strips have been left to come up with their own color schemes to indicate sterility. What is even more confusing is that the manufacturers' various colors have been validated for the same hydrogen peroxide sterilization cycle conditions and approved for use by the FDA.

This lack of a standard color code puts healthcare personnel in the untenable position of not being able to tell immediately whether a device has been sterilized and is safe for use with patients. If a patient infection or fatality can be definitively linked to the incorrect interpretation of an indicator label color by healthcare personnel, the healthcare facility and the label manufacturer potentially will face litigation with a large damage claim.

To eliminate the current risk of patient harm caused by the lack of a standard color-coding scheme, one of three solutions must be adopted and implemented immediately:

1. The FDA issues a requirement for manufacturers of indicator strips to adopt a single, industry-wide color-coding scheme.
2. If the FDA doesn't issue a requirement, then the manufacturers themselves must voluntarily agree to a single, industry-wide color-coding scheme.
3. Unless – and until – one of the first two options are implemented, healthcare facilities can choose to stop using hydrogen peroxide as a sterilization media or, they must follow the recommendations in the FDA's letter:

a. Review the manufacturer's instructions for the particular indicator bar or card being used and know the significance of the indicator colors.

b. Enhance staff training on the indicators for all sterilization systems employed in the facility and reinforce that training with prominently displayed visual reminders.³

Healthcare facilities need to understand that until either of the first two solutions are adopted and implemented, the facility is assuming the legal responsibility for the use of these strips.

Orange is the new check

Over 40 years ago the medical industry solved a similar problem by adopting an industry-wide, color-coding standard for all parenteral (IV) and enteral nutrition delivery devices. As part of that color-coding standardization, it was decided that all enteral nutrition connectors, nasogastric tubes, stomach tubes, P.E.G. tubes, Jejunostomy tubes, enteral feeding bags and pumps would be color-coded orange.

While creating patient discomfort, the infusion of a parenteral drug into a patient's gut through an enteral nutrition device is not a life-threatening event. The accidental infusion of enteral formula into a parenteral delivery device into a patient's vascular system, however, is a life-threatening event. This was why the medical industry went to orange color-coding for all enteral products to protect patients more than 40 years ago.

The present lack of an industry standard for color-coding hydrogen peroxide vapor sterilization indicator strips is a clear, present and ongoing threat to patient safety. The best solution to the problem is the adoption of a standardized color-coding system for these indicator strips. **HPN**

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Prior to his retirement in December 2018, James Schneider had been the founder, owner and president of America's MedSource Inc., which designed, developed, licensed and marketed a variety of implantable vascular devices, laparoscopic devices and neurosurgical instruments. Schneider has nearly five decades of experience in medical device design and production and is a recognized expert in the area of instructions for use (IFU) and independent laboratory IFU validation studies. Schneider can be reached at jas.schneider@talloaks2014.com.

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