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**Then, please complete the back of this page in order to register your interest for invitation**

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**BACKGROUND:** The volume of product recalls has been dramatically increasing. Class l recalls, those that can lead to serious patient injury and death, are now at a very high level. Facilities and their patients are affected now more than ever before.

**National Recall Alert Center's mandate, as a 49-year-old, federally-approved, non-profit organization, is to mitigate this critical situation.**

National Recall Alert Center has been awarded this funding in order to meet its mission. The value of each full grant can be as much as $18,000 per year and covers the cost of the entire, real-time, 24/7/365 closed-loop system.

**The entire system will also substantially reduce your personnel costs as well as streamline your recall safety, reporting and compliance requirements.**

*(Completing this does NOT commit or obligate either party.)*

Please complete to ONLY REGISTER your interest and determine qualifications
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Or Complete the questions online at:
www.recallalertgrant.org

*Please Call for any additional information: 1-888-537-8376*

Date you are completing this form: _____

Name of facility: _____

City and State of facility: _____

## Please Answer the Following 5 Questions

1. **How many hospitals are in your system (if more than 1) and what is your approximate number of licensed beds?** _____

2. **Does your facility use a paper system for recall alerts and management?**
   **YES** _____ **NO** _____

3. **Does your facility CURRENTLY receive recall alerts from a private/outsourced recall alerting service? YES** _____ **NO** _____

4. **If your answer above is 'YES', what is the name of the service or services?** (Note: if you receive an invitation and already have a contract with another service, a reservation to earmark the grant for future use may be possible.)

   _____

5. **What is the name, title and email and office phone of the individual completing this form?**

   **Name: (Print)** _____ **Title:** _____

   **Cellphone (optional) (  )**_____**Office Phone: (  )**_____

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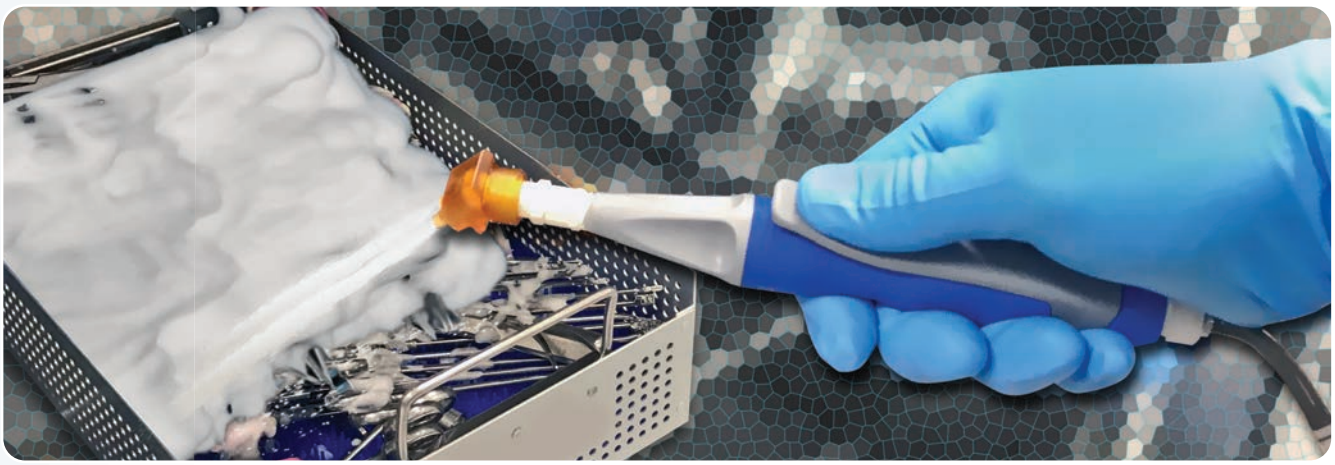

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# BASTION

# Remembering

While the scintillating topics that could be covered and explored here to cap off the year are numerous, one takes precedence for respect alone.

The year 2020 may best be canonized by the COVID-19 pandemic, but the last year at best for the healthcare supply chain represents one of tremendous loss – of experience, knowledge, intelligence and talent. From January 2021 until now we've lost what surely must be an unprecedented number of experienced healthcare supply chain leaders.

Five to be exact during the first four months of this year. There may be more that we missed in the ensuing months, and we hope you will share those names with us so that we may share this with you in a future update. Send an email to rickdanabarlow@wingfootmedia.buz and cc editor@hpnonline.com.

Before we turn the page on a duo of difficult years – and before you turn the page here within this December 2021 edition of Healthcare Purchasing News – we'd like to remember and salute one last time five we lost this year

What follows are the notable and noteworthy departures from this plane in 2021.

**Thomas W. Hughes, 75 – January 26,** is well-known and highly regarded from Strategic Marketplace Initiative (SMI), BD Healthcare Consulting & Services, Concepts in Healthcare, Tufts New England Medical Center, Boston; Waterbury (CT) Hospital and Beth Israel Hospital, Boston.

**Henry Berling, 78 – February 9,** is well-known and highly regarded from Owens & Minor, Custom Healthcare Systems and A & J Hospital Supply.

**Edmond D. Hardin Jr., 54 – February 10,** is well-known and highly regarded from Froedtert Health, Milwaukee; Healthcare Purchasing News' 2016 Supply Chain Department of the Year CHRISTUS Health, Irving, TX; Resource Optimization & Innovation (ROi), St. Louis; Alvarez & Marsal, BearingPoint and Computer Sciences Corp.

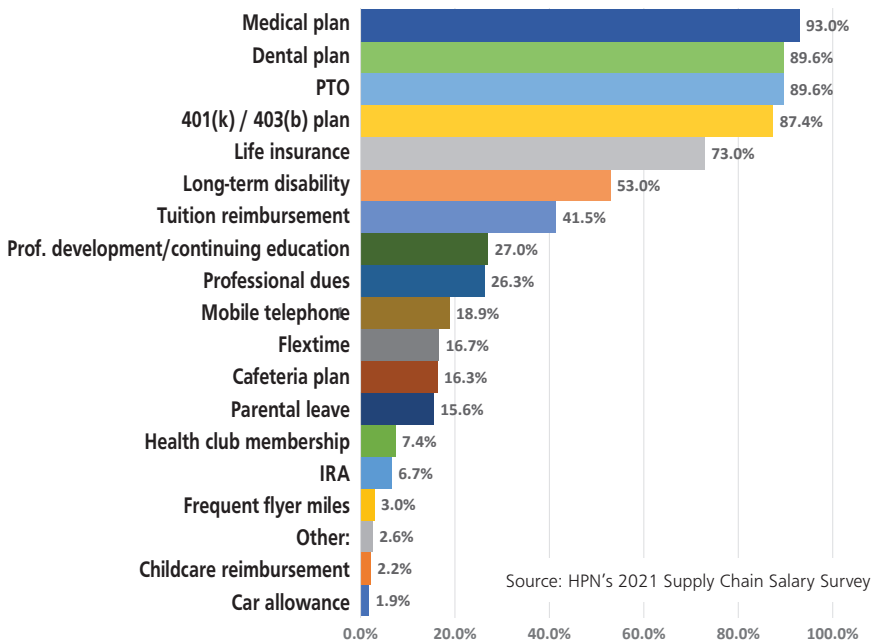
**James W. Burns, 71 – February 10** is well-known and highly regarded from two northeastern regional group purchasing organizations, Hospital Central Services (HCSC), Allentown, PA; and Hospital Purchasing Services (HPS), Philadelphia; after a career in the food service industry.

**James F. Dickow, 78 – April 18** is well-known and highly regarded from Dickow Consulting Group, Lerch Bates, Kowalski-Dickow Associates, R & J Medical, Gentec Healthcare, Will Ross (division of G.D. Searle), Drake Sheahan-Stewart Dougal, Delco Electronics, McDonnell-Douglas, CPC International.

Good night and rest in peace, gentlemen.

# DATA BANK

## What is included in your benefits package?




Source: HPN's 2021 Supply Chain Salary Survey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# FAST STATS

**The KFF Covid-19 Vaccine Monitor, an ongoing research project by the Kaiser Family Foundation, tracks the public's attitudes and experiences with Covid-19 vaccinations. The surveys were conducted October 14 - 24, 2021.**

## 38%

**of adults surveyed said they believe the government is exaggerating the number of Covid-19 deaths**

## 18%

**of adults surveyed said they believe that deaths resulting from Covid-19 vaccines are being intentionally hidden by the government.**

## 14%

**of adults surveyed said they believe you can get Covid-19 from the vaccine.**

## 42%

**of unvaccinated U.S. adults are age 30-49. This represents the largest block of unvaccinated U.S. adults during the survey period.**

## 1 IN 5

**adults who were either vaccine hesitant or resistant in June 2021 had received at least one dose of a Covid-19 vaccination by September 22, 2021.**

## 1 IN 3

**adults who received a first Covid-19 vaccine dose between June 1 and Sept. 22, 2021 said that knowing someone who got seriously ill or died from the disease was a major reason they decided to get vaccinated.**

## 39%

**of adults who received a first Covid-19 vaccine dose between June 1 and Sept. 22, 2021 said the Delta variant was a major reason they decided to get vaccinated.**

## 19%

**of adults who received a first Covid-19 vaccine dose between June 1 and Sept. 22, 2021 said that social pressure from family and friends was a major reason they decided to get vaccinated.**

https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor-dashboard/

Photo credit: Alekss | stock.adobe.com

# NEWSWIRE

## Where are America's most cost-efficient hospitals?

A new analysis identifies the most cost-efficient hospitals in America and highlights how potentially billions of dollars could be saved in the nation's Medicare program.

The analysis from the Lown Institute, a healthcare think tank, uncovered big differences in the cost of care between hospitals, even those within the same city.

The study analyzed data from more than 3,000 hospitals, looking at how much Medicare was billed and comparing that to how many patients died, both 30 and 90 days from admission.

Among hospitals with average 30-day mortality rates, according to a Lown Institute press release, costs ranged from $9,000 to $27,000 per patient. The study shows that if all hospitals matched the performance of the country's most cost-efficient hospitals, there would be $8 billion in Medicare savings each year.

10 most cost-efficient hospitals in America:

- Pinnacle Hospital (Crown Point, IN)
- Saint Mary's Regional Medical Center (Reno, NV)
- Mercy Medical Center Dubuque (Dubuque, IA)
- Encino Hospital Medical Center (Encino, CA)
- Park Ridge Health (Hendersonville, NC)
- Oroville Hospital (Oroville, CA)
- Saint Michael's Medical Center (Newark, NJ)
- UnityPoint Health - Meriter (Madison, WI)
- East Liverpool City Hospital (East Liverpool, OH)
- Maple Grove Hospital (Maple Grove, MN)

The Institute tracked Medicare patients hospitalized from 2016-2018 using claims data and adjusted both mortality rates and cost based on patient risk. Total Medicare cost included claims from inpatient hospitalizations and post-discharge claims (hospice, skilled nursing facilities, etc). Hospitals with the lowest mortality rates and lowest costs received the best scores on cost efficiency.

The study is part of the 2021 Lown Hospitals Index. A full methodology for the cost efficiency rankings is available.

## IAHCSMM adds federal lobbyist to help secure hazard pay for SPD professionals

The International Association of Healthcare Central Service Materiel Management (IAHCSMM) has joined forces with the Association of Surgical Technologists in hiring a federal lobbying firm, McAllister & Quinn, to help enact hazard pay for sterile processors, surgical technologists and surgical assistants for their work during COVID-19 in 2020 and 2021.

Currently, the federal legislation does not include sterile processors. The lobbying firm will work to add sterile processors to the legislation along with trying to secure passage of the legislation.

Sterile processors are important members of the healthcare team and have played an increasingly critical role during the COVID-19 pandemic. Not only are Sterile Processing technicians responsible for ensuring that equipment and instruments used during surgical procedures are properly decontaminated, cleaned, inspected, and sterilized prior to patient use, the pandemic has led a growing number of technicians to also become responsible for sterilizing certain types of personal protective equipment under U.S. Food and Drug Administration's emergency use authorization.

Sterile processors are high-risk healthcare workers and should be included in this legislation, said Josephine M. Colacci, Esq., Director of Government Affairs for IAHCSMM. "These professionals have been responsible for sterilizing some types of personal protective equipment, including N95 respirators; therefore, there should be no doubt that sterile processors deserve hazard pay for their efforts during the COVID-19 pandemic. This is a great team effort by IAHCSMM and the Association of Surgical Technologists to hire federal lobbying support."

## Rankings announced for the Gartner Healthcare Supply Chain Top 25 for 2021

Gartner, Inc. has released its 13th annual Gartner Healthcare Supply Chain Top 25 ranking. To reflect growing maturity across the healthcare and life sciences supply chain, the ranking now solely focuses on U.S. health systems.

"We're making the move to an all-healthcare-provider ranking because we recognize that the healthcare supply chain has made significant progress in size, scope and capabilities compared to when we started the ranking in 2009," said Eric O'Daffer, vice president analyst with the Gartner Supply Chain practice. "This shift in methodology allows for more healthcare providers to be featured in the ranking and for a better distinction from our Supply Chain Top 25 ranking, which is global and covers all industries."

In this revamped ranking, Cleveland Clinic takes the top spot with the highest overall peer and analyst opinion scores.

Banner Health, Ochsner Health Systems, Baylor Scott & White Health and Mercy complete the Top 5. As a result of the new methodology, eight healthcare providers make their debut.

"Cleveland Clinic is a prime example of sustained leadership," O'Daffer said. "They excelled in optimizing the clinical supply chain across products and services, including new construction, pharmaceuticals and purchased services. RFID-based point-of-use technology now spans across most procedural areas, increasing patient safety, capturing revenue, and reducing loss and expiration."

In its fourth year, the Healthcare Supply Chain Top 25 Masters recognizes sustained supply chain leadership in healthcare. To be included, those health systems must have attained top 5 composite scores in any seven of the last 10 years.

"Mayo Clinic and Intermountain Health Care sustained their standing as Masters for yet another year. Even with the pandemic still disrupting healthcare, they expanded their operations, piloted new home care programs and continuously improved their capabilities," O'Daffer said.

Three major themes stand out when looking at the leading health systems:

- **Increased Risk and Resilience Capabilities**

The COVID-19 pandemic with its ups and downs forced health system supply chains to deal with all kinds of disruptions and shortages, from personal protective equipment (PPE) availability to talent shortages. While this was a challenging situation for supply chain leaders in healthcare, they took on the challenge and are now witnessing the results of their efforts.

- **Expanded ESG Efforts**

Supply chain leaders are also thinking about the environmental, social and governance (ESG) aspects that the C-suite and other stakeholders may be demanding of the supply chain. This means, for example, expanding diversity, equity and inclusion (DEI) initiatives and forming partnerships to mitigate health equity issues.

- **Focus on Collaboration**

The pandemic showed how important collaboration is in the case of PPE and the manufacturing of capital equipment like ventilators. Many organizations, including manufacturers, realized that they can't fulfill their mission without more collaboration with the health systems. In turn, the health systems recognized that they need an efficient supply chain that has the right product at the right place and at the right time, and that they need the resources of the manufacturers of clinical equipment to better serve their patients.

## A tribute to Anne Cofiell

Anne Cofiell passed away peacefully in her sleep on Friday November 5, 2021. Her passion for sterile processing has moved our industry to a better place. Anne was 90 years old and helped advance the Sterile Processing Profession in so many ways. She was very active in AAMI and believed in the process of education and standards.

Truly, the SPD profession and industry is better off today thanks to the efforts and achievements of advocates like Anne. Healthmark set up an award in her name years ago because of her passion to the profession and her focus on the importance of cleaning, the Decontaminator of the Year Award, named in Honor of Anne Cofiell.

Anne told *Healthcare Purchasing News* in July of 2002 in an interview, "In my own experience of 20 years as an assistant director of materials management responsible for supply, sterile processing and distribution, I faced many of the same problems that are prevalent today – budget cutbacks, inadequate staffing, outdated equipment and constant pressure to do more with less," she said. "Research and my experience as a consultant have convinced me that our patients and customers may not be getting the best we can produce, the best that could be achieved by implementing a quality system."

It still rings true. HPN

*Supply Chain Operations Worth Watching*

# Supply Chain makes a difference through thick, thin and thistle

*by Rick Dana Barlow*

Photo credit: Yarkee | stock.adobe.com

For many hospitals and healthcare facilities, the last two years can be classified as nothing short of a thrilling but perilous roller coaster ride, complete with corkscrew twists and turns interspersed with steep and slow climbs, followed by deep and touch-and-go dives, courtesy of the COVID-19 global pandemic.

Some have told *Healthcare Purchasing News* that for this reason alone, every hospital and healthcare organization should qualify for its annual "Supply Chain Operations Worth Watching" recognition, now celebrating its 10th year.

To a degree, *HPN* agrees. Certainly, all healthcare organizations have earned and deserve a hearty salute as they have bobbed and weaved through patient care demands and supply chain demands against a growing tide of product backorders, clogs and shortages. Some argue that that's their job anyway. No argument there. But the immense pressure placed on them to perform as if every day were a critical calamity is nothing short of extraordinary – both the Herculean and occasionally Sisyphean efforts, and the outlandish circumstances in which they were placed.

Not surprisingly, the pandemic shaped much of this list for the second consecutive year.

In that regard, *HPN* extends a heartfelt pat on the back and shoulder on which to rest for a spell with hopes that these last two years will prove a corrective, eye-opening, encouraging and resetting anomaly for the next century.

But for the sake of this decade-old feature culminating this month, *HPN* would like to shine a spotlight on 10, bringing the overall total of watch-worthy organizations to 120 since 2011.

Please note that once an organization's Supply Chain department/team "makes the list" it remains "worth watching" unless it's absorbed via merger or acquisition, in which case it's possible for the "new" crew to make the list (if nominated, of course) under the "new" name because they may be accomplishing more "new" things. *For the running list of 120 Supply Chain Operations Worth Watching, visit HPN Online.*

Here's a glimpse at *HPN*'s latest Supply Chain "Elite" lists, in alphabetical order by name, for highlights on what they're doing and why they matter. What's noteworthy among this group is the business creativity and decision-making during the pandemic that expanded the traditional boundaries of healthcare supply chain.

## Supply Chain Elite

### Bayhealth, Dover, DE

**www.bayhealth.org**

The ideal within information technology circles centers on total integration and interoperability within an enterprise. Bayhealth's Supply Chain team has applied that approach to operations and the relationship between Supply Chain, Sterile Processing and Surgical Services. In short, the process linking this trio of departments is built on mutual respect and trust generating from a complete and comprehensive reengineering project that resulted in elevated service levels and performance improvement. With a blueprint and charter rooted in customer service, data management, education and training and workflow improvement, Supply Chain succeeded in breaking down most, if not all, barriers among the three departments to the point that the Sterile Processing team earned a national award in recognition of its performance that was supported by the OR all the way up to the C-suite. If anything, the success here demonstrates the next-generation Supply Chain team as the process facilitators they seem destined to become as standard fare.

### CentraCare Health, St. Cloud, MN

**www.centracare.com**

CentraCare Health may represent an integrated delivery network (IDN) that operates eight hospitals serving the rural communities in central, west central and southwest Minnesota but it performs as keenly as a well-oiled suburban system. CentraCare's facilities, spread throughout a sprawling area, recognized early on the value centralizing supply chain operations among its systemization strategy of evolving as a single, cohesive enterprise. Within that "common culture," CentraCare emphasizes "consistent collaboration" between its supply chain sectional duopoly with Contracting & Procurement (negotiating, selecting, sourcing, procuring and data management) working parallel with Logistics (perpetual inventory management, unit-level supply chain management, receiving and couriering), aligned by contract categories in a model that makes sense for the organization type. They centralized their enterprise resource planning (ERP) system to Oracle, which has fueled growth in electronic ordering, replenishment and workflow management, but also retained bar-coded two-bin Kanban PAR locations. They are specializing in purchased services, which they call "strategic services," and are widely regarded as the system's "contracting experts" from the C-suite on down. They even actively participate in provider recruitment, working with physician candidates from the beginning on supply chain protocols.

## Cone Health, Greensboro, NC

**www.conehealth.com**

The Supply Chain team – specifically Clinical Value Analysis and Strategic Sourcing – at Cone Health didn't wait for the pandemic in early 2020 to develop a system-wide quality improvement process. They implemented it three years earlier, using Hurricane Maria hitting Puerto Rico in 2017 and disrupting supply lines, to reinforce that business as usual going forward would be most unusual. Working with clinicians and administrators they developed the "Product Disruption Tracker" whereby Supply Chain, pharmacists, physicians and nurses worked together to identify and locate product alternatives when crises or disasters threatened access for their hospitals and outpatient clinics. They set up a color-coded product-related warning methodology as a communication mechanism and established a "Product Availability Alert" system they would during the next several years to deal with product shortages due to manufacturing issues (including raw materials access, sterilization challenges) and also to source personal protective equipment (PPE) and assist in purchasing decisions and staff education during the pandemic. The Product Disruption Decision Committee developed a vendor vetting process to ensure that products are certified and verifiable from alternative, non-traditional supplier pools. To infuse the process with some levity, they would hold PPE fashion shows to test and demonstrate PPE comfort levels of new products.

## Ochsner Lafayette (LA) General Medical Center

**ochsnerlg.org**

Ochsner Lafayette not only had to contend with the pandemic aftershocks, but also an "incredibly active" hurricane season and "record-breaking" freezes to ensure its facilities maintain access to needed products and a flexible supply chain. Ochsner Lafayette also served as a COVID-19 vaccine storage and distribution hub for the region as well as a vaccination center for a community of tens of thousands overseen in part by Supply Chain and Pharmacy leadership. This involved detailed planning for vaccine receipts and adequate storage, including the requisite freezers. The facility also forged supply chain partnerships with three oil and gas suppliers in the region to piggyback on commodity ordering to fill supplemental gaps for PPE products and other essential supplies. Supply Chain relied on its infection prevention specialists to help determine the quality of products brought in from alternative suppliers to meet demand spikes. Through it all, they were able to expand and open additional community clinics to serve patients.

## Penn State Health, Hershey, PA

**www.pennstatehealth.org**

As the pandemic caused raw fill rates to plunge to 70% to 90%, Penn State worked out a sweet deal to house all of the additional product Supply Chain would have to procure. Penn State partnered with nearby Hershey Foods, which donated 22,000 square feet of new warehouse space, along with six full-time employees who worked at the Chocolate World warehouse. Thanks to this infusion of space and talent, Penn State's Supply Chain team was able to get the new warehouse operation up and running within nine days to store such essential items as disinfectant wipes, hand sanitizer and PPE. This also enabled Supply Chain to concentrate on sourcing products and maintaining safety stock for physician practices and critical items for the hospitals and clinics. This included a 30-day safety stock and a 90-day pandemic stock to provide some slack should backorders and shortages tighten supply lines. They also were able to support an additional 245 long-term care and extended care facilities in south central Pennsylvania with their supply chain needs.

## Sentara Healthcare, Norfolk, VA

**www.sentara.com**

Through a series of provider partnerships, collaborating with physicians and surgical staff to clinically integrate supply chain with demonstrated outcome measures, and using group purchasing contracts, Sentara is booking more than $31 million in supply chain and pharmacy savings in 2021. Working with two other provider systems they have built a process that concentrates on specific commodities and service lines to drive greater contractual savings. They also are improving purchased services sourcing and contracting to enable more efficient regionalized support and service metrics throughout the enterprise. Sentara has implemented a more progressive supply chain platform, starting with a dedicated Supplier Diversity Executive Council chaired by the system's Supply Chain leader. They are targeting $6 million in spending to go to qualified smaller, minority-owned and managed and veteran-owned and managed suppliers. They also are providing quarterly educational sessions for smaller suppliers to help them operate more effectively and efficiently with requests for proposals and other supply chain-related transactions, tactics and strategies.

## South Broward (FL) Hospital District d/b/a Memorial Healthcare System

**www.mhs.net**

If a "Worst Timing Ever" award were given for trying to engineer wholescale organizational and process improvements at the onset of a pandemic, hurricane prep and a massive product recall, Memorial Healthcare System might be a finalist. Being led by a seasoned data-specializing supply chain executive who arrived from an HPN Supply Chain Department of the Year winner, however, certainly emboldened this team to bob and weave through one crisis after another successfully, like that pivotal "flying cow" scene in the 1996 film, "Twister." Facing a surgical gown recall as the pandemic hit didn't help the process of centralizing operational functions to eliminate the supply chain's historical fragmentation with "shadow" operations in many areas, including the Operating Room. But they navigated through alternative suppliers, non-palletized trailers, large shipments and space constraints to reorganize their storage and warehouse footprint. The kicker? The warehouse team consisted almost entirely of physical therapists, rehabilitation therapists, fitness instructors and coaches within the system who had little to no experience in supply chain and had to learn on the job and during a crisis. MHS also was tapped by the state to serve as one of five healthcare systems to serve as a cold storage and distribution hub for COVID-19 vaccines, which meant gearing up with hard-to-find ultralow-temperature freezers, and as a "Vaccine Village" by converting a conference center into a Vaccination Center administering 1,000 doses daily without hiccups.

## Spectrum Health, Grand Rapids, MI

**www.spectrumhealth.org**

This long-standing Michigan IDN, itself a fusion of two prominent heritage healthcare systems, simply wasn't satisfied with the status quo and has been punching through annual savings targets for several years now with 2021 potentially reaching their highest level yet. Systemwide Supply Chain has migrated its influence into a growing number of areas that previously had been outside its purview, such as facilities and purchased services, and has infused its ranks with leaders and staffers from outside healthcare to introduce new perspectives on internal operations. They're also making headway with the clinical community, linking their Workday supply management software with the Spectrum's Epic clinical management software, implementing risk management agreements with selected clinical device suppliers (including Medtronic) and enabling the Value Analysis teams to represent Spectrum clinician interests as well as coach current and prospective suppliers on how to work with Spectrum in sharing risk and reward. Spectrum's Supply Chain team also has been working with the Healthcare Industry Resilience Collaborative on advanced fulfilment and delivery processes against the backdrop of crises and disasters, including event model monitoring, supply chain mapping and resiliency scorecards between providers and suppliers. They've hired their first demand planner with three dedicated inventory buyers within their distribution center that leverages Workday's software capabilities with data and operational consulting expertise from Tecsys.

## Stanford Health Care

**stanfordhealthcare.org**

While some healthcare organizations may have used the pandemic to scramble to develop or reset crisis/disaster plans, Stanford's Supply Chain team used it as a divining rod to assess status quo vendor performance, legacy contracts, negotiating standards and outmoded operational practices with the notion of retooling, if not utterly transforming just about everything. Searching for incremental improvements simply wasn't enough. Stanford reached back to the global suppliers of raw materials through its manufacturer-produced and distributor-delivered products contracted through its group purchasing organization Vizient. In short, everything was on the table for discussion and fair game for observation and renewal. They didn't just think outside of the box either. In fact, they tossed the box. They physically relocated their Assistant Director of Category Management in Asia for him to develop and secure entirely new and sustainable product pipelines. They retained an import agent to deal with customs, shippers and airfreight carriers. Stanford now sources products from five of the globe's seven continents to minimize regional supply disruptions. They synchronized supply chain relationships between clinical customers and the contracted suppliers via elevated fill-rate expectations with rewards and penalties, risk-sharing arrangements and stratified sourcing streams in a way that elevates non-labor expense management to an art form fueled by science. To offset product shortages, Stanford worked closely with internal and external resources. They partnered with Carbon3D and Resolution Medical to design and 3D-print needed products, such as sampling swabs, and worked with on-campus imaging and 3D engineers to scan and manufacture hundreds of repair parts for essential devices. They worked with Lockheed Martin to design and manufacture isolation gowns and leveraged the talent of Stanford's internal reference laboratory scientists to self-manufacture test media for COVID-19 tests.

## Virginia Hospital Center, Arlington, VA

**www.virginiahospitalcenter.com**

Amid the COVID-19 pandemic, Virginia Hospital Center strove for what they called an "audacious goal." They were weary of being on the "wrong side of the power balance" and wanted to "reclaim the balance of power." Part of their efforts included sourcing products from alternative means, including out-of-state warehouses, a fast casual restaurant and a garbage bag factory in El Salvador, which was retooled and workers retrained to make gowns. Internally, they reorganized the contracting function to centralize supplier options (with Medline as their primary distributor) and improve data management for physician preference products via Kermit expense management software that generated nearly $4.3 million in savings. They also used BlueBin inventory management software to implement a Kanban system to eliminate ordering and stocking variance. HPN

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# Maintaining air, steam, water quality simply elemental

*by Kara Nadeau*

Photo credit: nikkytok | stock.adobe.com

By air, steam or water, microbes and contaminants can spread throughout healthcare facilities, including those areas that play a key role in patient care and safety. This includes the Central Service/ Sterile Processing & Distribution (CS/SPD) department, where instruments are reprocessed, and the operating room (OR) and other procedural areas where patient care is delivered.

Because it is often difficult – if not impossible - to monitor effectively air circulating in a room and the water and steam used for cleaning and sterilizing instruments with the naked eye, the quality of these elements can sometimes be overlooked. Poor air, steam or water quality in a healthcare environment can endanger staff members and patients, and damage infrastructure, equipment and instruments.

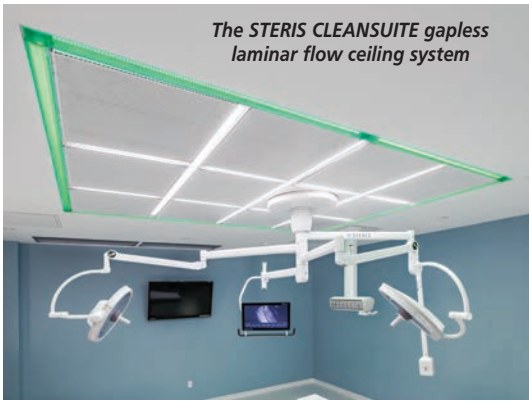
Manufacturers of systems for air, steam and water quality management, mitigation and treatment in healthcare environments offer their insights into the challenges faced in this area, the impact of poor quality, and best practices for measuring and monitoring these critical elements.

## Quality in the air

Air quality is quickly becoming the next frontier in infection prevention, explains Jim Dacek, Senior Product Manager, Surgical Solutions, STERIS.

"In recent years, healthcare has addressed room surfaces, hand hygiene, gowning, etc., in the OR, but there hasn't been much emphasis placed on air as a primary source of contamination. Hospital staff members need to be aware of potential risks associated with air quality that is out of spec (temperature, humidity, particle counts, differential pressure, etc.) per American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 170-2017, Ventilation of Health Care Facilities."

In the OR and other procedural areas, James Marsden, Ph.D., Executive Director of Science and Technology, RGF Environmental, notes how air-borne or particle-borne pathogens including bacteria, virus and mold, can result in nosocomial infections and reinfection rates. He points to a recent case where a hospital's failed efforts to contain Aspergillus mold led to a one-month-old baby's heart infection following open heart surgery, and the family's subsequent lawsuit.[1]



*The STERIS CLEANSUITE gapless laminar flow ceiling system*

"Poor air quality presents considerable risk to patients and staff through nosocomial infections," said Marsden. "Airborne viruses like SARS-CoV-2 and influenza can cause patient and staff issues, as can air and surface born bacteria like MRSA, strep, *C-diff*, as well as mold and yeast issues in HVAC and air-conditioned spaces."

Karen Hoffmann, RN, MS, CIC, FAPIC, FSHEA, an infection preventionist consultant for the Vidashield UV24 from Nuvo Surgical, echoes the risks.

"Contaminated air in CS/SPD has been a factor in surgical site infection outbreaks primarily involving mold and fungi (e.g., *Curvularia*)," said Hoffmann.

"CS/SPD staff, who must work in close contact with disinfectants and sterilant products, can also suffer from breathing respiratory irritants for prolonged periods."

Specific to the CS/SPD, Oyvind Birkenes, CEO of Airthings, points to how harmful contaminants, such as airborne pollutants, particulate matter, bacteria and more, can undermine sterilization efforts if they are not removed from the air in the department.

"There's a reason we refer to air quality contaminants as 'the invisible enemy' – cracks in the building's foundation, outdated or poorly functioning HVAC systems, and windows that are not properly sealed (or conversely, left open for too long) can all carry air pollutants into an environment and make achieving sterilization difficult," Birkenes explained.

"The goal of a hospital CS/SPD is to provide the right items to the user at the right time and under the right conditions," Hoffmann added. "Providing a sterile item in the right condition to the end user's area requires not only good work practices, but also good environmental conditions. The challenge for CS/SPD is to ensure that environmental monitoring systems are used routinely (according to the established standards) for proper quality assurance to ensure good environmental conditions."

As Birkenes indicates, the impacts of poor air quality can also have a major impact on health and well-being of CS/SPD staff members. He references the risks of "Sick Building Syndrome," which the Environmental Protection Agency (EPA) defines as:

"A set of symptoms that affect some number of building occupants during the time they spend in the building and diminish or go away during periods when they leave the building. Cannot be traced to specific pollutants or sources within the building."[2]

"Poor air quality, caused by a broad range of factors like CO2, airborne pollutants, particulate matter and more, can lead to a number of detrimental outcomes ranging from triggering asthma and allergies all the way to radon-induced lung cancer and the transmission of airborne viruses," said Birkenes. "Mold or mildew spores can also irritate the respiratory system."

Birkenes says another contributing factor to poor air quality in the hospital environment is the heavy use of chemical cleaners, coupled with "notoriously dry air" that increases the risk for chemical exposure and virus transmission due to lower-than-recommended humidity levels.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"Bottom line, if you don't know what's lurking in your air, you're likely making it harder to achieve a sterilized environment," Birkenes added.

*Airthings for Business continuous air quality monitor*

**Monitoring and measuring air quality**

With an estimated 1 in 25 hospital patients suffering at least one healthcare-associated infection (HAI) each year, according to the Centers for Disease Control and Prevention (CDC),[3] hospitals and other healthcare facilities have good reason to identify and address the factors increasing infection risk, including the quality of air in the OR.

"Air quality can have a big impact on preventing HAIs, so it is critical that patients are provided the best possible indoor air quality (IAQ), especially in the OR," said Dan Diehl, CEO of Aircuity. "Key parameters to healthy air in the OR include Total Volatile Organic Compounds (TVOC), particles and dewpoint."

Diehl explains that if dewpoint/humidity levels get too high, it can affect equipment performance by damaging circuit boards or other components which were not designed for those levels of humidity exposure. This in turn directly impacts the level of patient care a hospital provides.

To ensure CS/SPD departments have the right air quality ventilation measures and monitoring in place, NUVO Surgical's Hoffmann suggests hospitals following indoor air quality standards, including ASHRAE guidelines 62.1 and 170 and ISO 14644. These specify that the clean air must be particle free, and the air-filter pore size should range between 0.05 µm and a maximum of ≤10 µm. She adds that tests for differential air pressure (minimum, 2.5 Pascals), air velocity (minimum, 2,500 cfm), air exchange rate (≥10 per hour) and air microbiology (measuring bacterial and fungal colony counts) are required to minimize air impurities in the sterile zone.

"The entire CS/SPD decontamination processes (from cleaning to sterilization) can only be safe if the surrounding environment is clean and controlled," she said. "Air should always move from the sterile zone to the dirty zone to avoid cross contamination. Purified and moisture-free air is essential for preparing sterile materials and preserving them for a long time. An environmental quality monitoring system can reduce unnecessary sterilization cost and increase the shelf life of medical devices."

Marsden recommends hospitals employ negative or positive pressure monitoring in isolation rooms, per CDC guidance; ATP (adenosine triphosphate) testing to show evidence of microbial activity for verification of cleanliness for critical equipment and areas; HVAC equipment monitoring operational and maintenance status; and general monitoring of indoor air quality (e.g., temp, humidity, particle counts and evidence of microbial activity).

Birkenes says healthcare facilities can leverage technology solutions for continuous monitoring of CO2, radon, PM 2.5 and 1, airborne chemicals, virus risk, mold risk, and many more factors that can lead to contamination.

"By monitoring for these factors constantly, CS/SPD departments can achieve an informed and data-rich knowledge base of what needs to be addressed specifically and where the issue may be stemming from," Birkenes said. "Once that's determined, they can take more aggressive action, such as using air sterilization techniques like Ultraviolet Germicidal Irradiation (UVGI) – but before that can happen, it all starts with diagnosing the problem."

Diehl recommends facility managers look at both small and large particles, along with dewpoint in each OR suite. Leveraging ventilation system readings, they can determine how a particular issue was handled to justify temperature and humidity readings if a regulatory body had any questions during their visit.

"Facility engineers can extract the data and present graphical reports during their monthly meeting with infection control," said Diehl. "When a question about the condition of a particular space arises, data can also be brought to doctors, nurses and infection control teams to determine whether air quality had any influence. Staff can then focus on the clinical side, getting to the root of the problem."

*Aircuity's centralized, multi-parameter demand control ventilation system*

*The Nuvo Surgical Vidashield UV24 adjunct air purification system*

**Using UV to disinfect the air**

As the U.S. Food and Drug Administration (FDA) states, ultraviolet (UV) radiation has effectively been used for decades to reduce the spread of bacteria and may also be effective in inactivating the SARS-CoV-2 virus.[4] Healthcare facilities have been implementing a variety of hospital-grade UV technologies to disinfect the air and surfaces.

When updating its handbook, ASHRAE convened Technical Committee, 2.9, Ultraviolet Air and Surface Treatment to clear up misconceptions regarding UV technologies, with the Committee members expressing the hope that the "pandemic has left no doubt that the 254 nm germicidal wavelength (UVC light) can inactivate the genetic material in the SARS-CoV-2 virus."[5]

American Ultraviolet offers a wide range of UVC solutions, including mobile UVC, fixed mounted surface and air disinfection units, and upper room UVC for occupied spaces including all HVAC applications, all made in America in the company's main factory in Lebanon, Indiana.

"Our Fixed Mounted UVC packages have been very popular in healthcare," said Katja Auer, Clinical Director of Healthcare Solutions at American Ultraviolet. "These packages are unique in that they provide effective and fast cycle times, are easy to use, offer daily automated cycle times, and do not require additional FTEs. They are found in operating rooms, surgical suites and any areas that benefit from adjunct UVC cleaning in-between patients or procedures and/or after terminal cleaning in an operating suite took place."

Since the COVID-19 pandemic began, American Ultraviolet has been working with multiple robotics companies to develop "truly autonomous UVC robots" for use in healthcare, where they have worked with clients to design and build mobile N95 mask disinfection solutions, and several government agencies to provide effective solutions for air and surface disinfection.

"What makes American Ultraviolet so unique is simply the people working for the

company," Auer added. "The last two years have really been a push trying to help and provide as many solutions for as many people/environments as possible and we asked a lot of our team, the admin or 'front of the house', engineering, production, sales, and all continuously work hard to deliver solutions. They put in the extra time knowing how important their work is, to help to keep people safe."

R-Zero is a biosafety technology company that provides smart, sustainable disinfection to improve productivity, reduce sick days and enable better health through "clinically clean" shared spaces. As Natalie Quinn, Director of Brand and Content describes, R-Zero is devoted to enabling better outcomes for patients and providers:

"R-Zero takes a holistic approach to indoor environmental health by understanding the risk factors of a given hospital or health system's spaces and then identifying how our technology can mitigate that risk while improving indoor air quality (IAQ) and eliminating pathogenic threats. We believe clinically clean shared spaces are achievable with less waste and less use of harmful chemicals, and we are deeply committed to enabling a new normal where elevated indoor health is the status quo."

R-Zero's Arc UV system enables hospital-grade efficacy while emitting 109% more light at a lower cost than competitors. With Arc's powerful lighting array and overall design, the device can disinfect the air and surfaces in a 1,000 square foot room in just seven minutes. Arc also has LTE-M connectivity to R-Zero Connect, the company's dashboard that allows users to track disinfection cycles, thereby making the traditionally unseen disinfection process visible and auditable.

*R-Zero's Arc UV system*

"Simply put, we kill COVID - and a host of other common microbial threats," Quinn commented. "R-Zero's disinfection ecosystem enables safer indoor environments by destroying 99.99% of pathogens (including coronavirus, E. coli, the common cold, and the flu). As our products disinfect spaces in mere minutes, they eliminate the need to use harmful chemicals - all while creating a clear record of disinfection activity via our software dashboard. Implementing R-Zero's suite of solutions will enable you to fight COVID today and HAIs or any other emergent threats tomorrow."

## Quality in water and steam

The Joint Commission has made water quality a priority, as evidenced by its New Water Management Requirements issued March 19, 2021. Under the new requirements, a hospital must have a water management program that addresses Legionella and other waterborne pathogens, and an individual or team responsible for the oversight and implementation of the program, including but not limited to, development, management and maintenance activities.[6]

Water quality is a key consideration for the CS/SPD department in the processing of instruments for re-use, from water used in decontamination sinks for pre-cleaning and rinsing, to the water used to generate steam for sterilization.

"When maintaining purity of water for CS/SPD departments, most of the challenges center around particles, minerals, bacteria and endotoxin," said Marissa Khoukaz, Medical Prefiltration Product Manager, Pall. "These contaminants can impact the lifespan of equipment or the sterilizing cycles themselves. Bacteria and endotoxin are of particular concern since infection and inflammation can result when levels are too high. If the water purity is not well maintained, there is a greater risk of equipment downtime and a greater patient infection risk."

Steven Autiello, Regional Manager, Barclay Water Management, explains how the maintenance of water treatment equipment and monitoring of water quality presents several challenges to healthcare organizations and their CS/SPD departments.

"Rinse water used in sterile processing should be pre-treated with a de-ionized (DI) or reverse osmosis (RO) treatment system to remove organics and inorganics from reaching instruments. Normally SPD departments handle the operation of this equipment, or it is done by a third party. Steam purity is typically at the mercy of the hospital's central steam system, which would originate from a central steam plant in the hospital over which SPD has no control."

## Monitoring and measuring water and steam quality

"Checking bacteria and endotoxin levels are the best way to measure and monitor to understand the water quality," said Khoukaz. "Other measurements to consider are pH, conductivity and water hardness. The first step for water purity concerns would be to assemble a team and do swab and water testing to establish current levels. If levels of water contaminants are higher than acceptable levels, various types of filtration can be used to address different problems."

*Pall Kleenpak capsule filters for small-batch sterile filtration of aqueous pharmaceutical solutions*

To overcome the challenges of water treatment and steam generation performed outside of the CS/SPD department, Autiello has seen hospitals install dedicated equipment for the pre-treatment of rinse water and steam generators specifically for sterilization within the sterile processing area.

"Properly maintained air, water and steam is nothing new to the industry so there are no silver bullets, though diligence in maintaining the installed pretreatment equipment is crucial," said Autiello. "Try to identify the issue (air, water or steam) based on evidence or perceived issue. Work with facilities to correct or third-party vendor, if applicable." HPN

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## Solutions/tools for better air, water and steam quality

With greater recognition for the impacts of air, water and steam quality on patient/staff safety, infection prevention and effective instrument sterilization, manufacturers have developed solutions for proactive treatment, monitoring and contamination remediation in healthcare environments.

**Aircuity**: Aircuity's centralized, multi-parameter demand control ventilation system continuously measures and adjusts ventilation rates using science-based IAQ parameters, so ventilation levels are based on current conditions. This can be used not only in OR suites, but also in medical research buildings, vivariums and other variable population areas, such as a lobby or waiting room. Users can monitor analytics on ventilation rates using the solution's dashboard, helping facilitate compliance with external regulatory reporting.

In the OR, a solution called Clean Standby Mode continually measures dry bulb temperature, dewpoint/humidity and optimizes unoccupied ventilation for energy savings during times when the OR suite is not in use. When any IAQ "event" is detected and when the OR is in use, ventilation rates run at full occupied flow. This solution provides clean air while helping to address hospital sustainability goals and utility budgets.

**Airthings**: The Airthings for Business solution provides healthcare organizations the ability to continuously monitor a very wide range of air quality levels in as many rooms, buildings or campuses as they desire, including procedural areas and the CS/SPD. Armed with detailed air quality information, facility managers can optimize HVAC settings and ensure optimum air quality conditions. The Airthings Dashboard allows facility managers remote access to live air quality data across all monitored locations at once.

Through Airthings API, a healthcare facility can also integrate with building management systems to automatically trigger HVAC systems to turn on/off based on actual air quality data, ensuring that people are kept in a healthy environment while also reducing energy usage in buildings.

**American Ultraviolet (AUV):** AUV's Fixed Mounted UVC packages deliver disinfection energy from multiple points on the ceiling, which limits or eliminates shadowed areas. The system is always available at the "push of a button", offers fast cycle times and eliminates having to track down and move a mobile UVC robot. The daily auto-disinfection cycle can be scheduled to run when needed, such as one hour before treatment/surgical suites are opened, or on a prescheduled 30-, 45-, or 60-minute cycle. All disinfection cycles and operational data reports can easily be downloaded and shared with staff on a daily, weekly or monthly basis.

**Barclay Water Management:** As a water treatment company, rinse water and steam treatment is one area of Barclay Water Management's expertise using pretreatment equipment and chemicals as its tools to provide solutions. Other services/solutions include:

- Chemical treatment programs for cooling towers, boilers, closed loops, specialty systems and wastewater
- Water management plans and consulting
- Water hygiene products and services for minimizing the risk associated with Legionella bacteria, the bacterium responsible for Legionnaires' disease, in building potable water systems with an emphasis in healthcare
- Environmental cleaning services such as cleaning services for cooling tower, ice machines, hot and cold water storage tanks, decorative fountains and air handlers
- SAFE system storage and feed systems designed to eliminate operator handling of water treatment formulations, eliminating problems associated with handling and dispensing of treatment chemicals and the disposal of empty water treatment containers
- Service Tracking and Reporting Program (STAR) Internet-based application through which customers can access water test results and state-of-the-art software packages for data logging and remote communication with water treatment feed and control equipment

**Nuvo Surgical:** The Nuvo Surgical Vidashield UV24 adjunct air purification system uses ultraviolet germicidal irradiation (UVGI) to deactivate airborne bacteria and other organic pollutants, like mold and certain viruses. The Vidashield UV24 system can be incorporated seamlessly into existing overhead lighting or new construction and operates automatically by individual control decreasing the many issues with free standing floor units. The system pulls contaminated air directionally up to the ceiling as opposed to wall or floor HEPA /UV portable units that pull contaminated air across the room potentially exposing individuals in the pathway.

Improved ventilation using an adjunct UVGI system, like the Vidashield UV24, has demonstrated other benefits for healthcare workers, including improving the overall smell in the area and decreasing respiratory irritants and allergens that come from patient care procedures and enclosed environments.[7]

**Pall:** Pall Kleenpak capsule filters with intrinsically hydrophilic positive zeta potential Posidyne membrane are rugged, self-contained sanitary filters designed for small-batch sterile filtration of aqueous pharmaceutical solutions. With a net positive charge in most aqueous solutions from pH 3 to 10, Kleenpak Capsules with Posidyne Membrane Assemblies can be effective in removing contaminants, such as cell debris and endotoxin smaller than the filter rating.

**RGF:** RGF offers a variety of tools for air quality monitoring and management, including:

- Rapid Recovery Unit air purification and odor control system for non-occupied spaces
- Lucidium CUV system for HVAC coil sanitation and germicidal UV-C air purification (eliminates mold and yeast on coils, bacteria and viruses in the air)
- Lucidium Polaris upper room UV system, in accordance with CDC COVID-19 guidance
- Proprietary PHI-Cell in-duct whole building air purifiers for continuous, no-touch air treatment with low level, airborne gaseous hydrogen peroxide
- U.S. Food and Drug Administration (FDA) 510(k) approved medical devices Microcon MAP and ExC7 units for airborne pathogen control and creation of negative or positive isolation rooms (pair with Accustat room pressure monitors)

**R-Zero:** The R-Zero Arc UV system enables hospital-grade efficacy while emitting 109% more light at a lower cost than competitors. Due to Arc's powerful lighting array and overall design, the device can disinfect the air and surfaces in a 1,000 square foot room in just 7 minutes. Arc also has LTE-M connectivity to R-Zero Connect, our dashboard that allows users to track disinfection cycles, thereby making the traditionally unseen disinfection process visible and auditable.

**STERIS:** The STERIS CLEANSUITE ceiling system helps mitigate the risk of airborne particles and prevents gaps within the room air unlike traditional laminar airflow systems. It is a true gapless laminar flow ceiling system, designed to minimize turbulence and gently guide particles away from the surgical site, bathing the patient and staff in ultra-clean air. At 100 particles per cubic foot, it delivers air quality aligned with the ISO Class 5 Cleanroom specification, surpassing the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) 170 standard for patient safety.

The flexible, modular design of the CLEANSUITE Ceiling System integrates structure, air delivery and room lighting. Internal and external truss systems allow for seamless mounting of surgical lights, booms, monitors, and c-arms. Prefabricated structural steel frame installs six times faster than traditional site-built ceilings to help maximize OR uptime. According to recent data provided by a national design and construction firm, CLEANSUITE is up to 40% less expensive than a traditional site-built ceiling.

### General healthcare environments:

- American Society for Health Care Engineering (ASHE): https://www.ashe.org
- Centers for Disease Control and Prevention (CDC): https://www.cdc.gov
- Environmental Protection Agency (EPA): https://www.epa.gov
- The Joint Commission: https://www.jointcommission.org

### CS/SPD department specific:

- Association for the Advancement of Medical Instrumentation (AAMI): https://www.aami.org
- International Association of Healthcare Central Service Materiel Management (IAHCSMM) https://www.iahcsmm.org

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# PPE, top to bottom

## *Shortages mask supply chain resiliance*

*by Nancy Pasternack*

Photo credit: Alessandro Biascioli | stock.adobe.com

In late March, 2020, the Association for Professionals in Infection Control and Epidemiology (APIC) set out to provide a picture of how supplies of personal protective equipment (PPE) were meeting demand in the nation's hospitals. To that end, they conducted a survey.

Though the onslaught of SARS-CoV-2 cases was barely underway in the U.S., infection prevention specialists reported that their facilities were battling dire shortages.

"Nearly half of U.S. healthcare facilities surveyed are already out of, or almost out of respirators to use in caring for a patient with COVID-19," reads an APIC March 27 press release. "Lack of N-95s, masks, face shields threaten health workers in facilities in every state, in every size facility."

Pleas went out for Emergency Use Authorizations to be granted for use of non-traditional PPE sources, and for the reuse of masks and other PPE.

"Like so many companies, we struggled to get product from previously reliable suppliers," said Ralph J. Basile, Vice President of Marketing for Healthmark Industries Company Inc. "Where we could, we altered our supply chain, including utilizing domestic sources of product – and we began manufacturing more in-house in order to better control supply and meet the increase in demand."

Healthmark wasn't the only company struggling to keep up.

"During COVID-19, the PPE industry has faced unprecedented surges in demand, port delays, raw material shortages, capacity constraints, labor shortages and manufacturing shutdowns," said Asilinn La Brie, RN, BSN, MBA, Senior Consultant in Business and Clinical Optimization at Cardinal Health.

Cardinal had to remain flexible in its supply chain and sourcing approach, La Brie said, "but we were committed to only sourcing direct from reputable manufacturers and our own manufacturing network."

Heather Mallinckrodt, Associate Vice President of Contract and Program Services at Vizient said the shortage was an equal-opportunity challenge.

"The magnitude of the pandemic – I don't think anyone was fully prepared for that," she said "The entire U.S. was struggling to get product."

Unprecedented times, however, "require unprecedented speed and results." The company demonstrated an ability to respond rapidly to provider needs, Mallinckrodt said.

"The broken supply chain is our most frustrating challenge," said Melanie Miller, Vice President and Chief Strategy Officer for Silver Lining Apparel, which makes reusable isolation gowns. But, she said, "we became nimble and flexible and learned along the way to ensure that our product met care practice needs and exceeded expectations."

As the even-more virulent Delta variant surged and eventually waned, many on the front lines of the pandemic have been able to imagine light at the end of the tunnel. But work at the companies that make, sell, buy and deliver infection protection products is only beginning. Strategic plans designed today, after all, may be heading into against a dramatically changed supply chain landscape.

In the meantime, executives say, they must prepare for the next supply chain curveball.

### Adjusting one's stance

When reflecting on 20 -plus months of supply uncertainty – and lessons to take away moving forward – the themes expressed across the industry are similar: More diversity must be built into a company's lineup of PPE manufacturers, with an emphasis on production closer to home; More visibility and transparency must be built into the system so that clients and other stakeholders can track product and share information. And in order to be successful in the supply chain

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of tomorrow, a company will need to maintain flexibility and be able to shift gears quickly.

Domestic production, said Anika Sutter, a Vizient Portfolio Executive, "has become more of a focus. Members are interested in being more localized," she said. Expectations have grown, she said, for more specific product information, Sutter said. For instance, they are more concerned than ever about each product's pedigree – where the components were sourced.

When the first wave of COVID-19 started its assault on the U.S. healthcare system, elective surgeries nearly everywhere were put on hold. Demand for surgery-related products was put on hold too, said Lionel Bonte, Vice President of Medical Business, Ahlstrom-Munksjo.

Leadership at the Finnish company moved its focus away from the sterilization wraps that had been a reliable part of their lineup, and doubled down on production of PPE items most needed during the pandemic.

"As a result of the material scarcity driven by the shortage, our mix (of products) has shifted toward higher demand in the face mask and the drapes and gowns category," Bonte said.

"We went to great lengths of operational agility to increase capacity, restart dormant assets and restaff existing assets," he said. " We were also very successful in adapting our portfolio to meet the growing demand of face mask and isolation gowns by developing and validating new products."

## War room

One of Vizient's first moves in response to COVID-19 and supply chain concerns was to open channels of communication between manufacturers, suppliers and end users.

"As shortages grew, we had to ensure provider needs were met," said Mallinckrodt. "We set up what we call 'the War Room' to field provider questions, validate new products and provide near real-time information to members as well as clinical support in cross-referencing and substitutions during the shortfall."

Mallinckrodt said Vizient already had been working to create a system of transparency, and to develop a broader network of suppliers.

"COVID pushed those initiatives forward faster," she said.

Allison Pearsall, Honeywell Senior Product Management Leader, Healthcare PPE, said her company also wasted no time making adjustments.

"Honeywell quickly invested in the rapid addition of multiple production lines in the U.S. and North America to produce NIOSH (National Institute for Occupational Safety & Health) -approved N95 respirators and surgical N95 respirators to help fill the significant gap in the market supply," she said. "Honeywell is now one of the leading brands of N95s for the healthcare segment."

For Cardinal Health, the advantages of having manufacturing and supply channels close to home were evident even before COVID-19 came ashore in the U.S. But the arrival of the virus added a real sense of urgency.

"We were pursuing moving production of key items of our infection control apparel and facial protection portfolios," La Brie said. "The pandemic underscored this need for a strict quality control process and resilient supply chain in North America."

Today, the company is launching more than 20 new PPE items, La Brie said, "all manufactured in North America."

## New approaches, new products

Tai Edmund, Vice President Healthcare, Tronex International, said his company, which supplies disposable isolation and protective gowns, exam-grade gloves and face masks, managed to weather the storm by diversifying locations for manufacturing.

"Tronex Healthcare's longstanding supply resiliency strategy of optimizing production diversification, maintaining deep and continually expanding manufacturing capacity and capabilities, and maintaining US-based program supply buffers across multiple national warehouses," Edmund said, "proved essential to assuring our program (provides) customers robust supply."

In addition to new lines of PPE products and new services -- introduced during some very difficult months of the pandemic -- a new team at a familiar B2B company made its debut.

Alibaba.com Select uses the Chinese company's global online marketplace model to source PPE and get those products to where they're most needed.

"We are seeing that there are issues across many product categories," said Josh Price, Head of Strategy & Operations

at Alibaba.com Select, North America. "Businesses face challenges identifying supply, shipping their orders due to container shortages, gaining access to vessel space and port shutdowns and congestion."

Alibaba.com's U.S.- based team, "facilitates global B2B ecommerce trade at scale," Price said.

"We work with a network of suppliers that offers a variety of products, including surgical masks, isolation gowns, face shields, goggles, nitrile gloves, vinyl gloves and much more," Price said. The company, "has the supply chain insights and capabilities to assist customers with getting their orders to where they need them by connecting with a variety of qualified logistics services."

At the height of the pandemic, Healthmark Industries added two new products to its portfolio of PPE accessories. Both products are designed to be worn in decontamination areas.

The wrap-around decontamination gown, designed for use in device reprocessing areas, eliminates the need for a plastic apron, according to a website description.

It features a middle section, "manufactured of a liquid impervious zone, including preventing strikethrough of detergent cleaning solutions even when physically leaning against sinks or other cleaning baths."

Healthmark's face shield with drape is meant to be worn, "where added protection from splashing is recommended."

The drape, according to the description, "adds a 12-inch fluid barrier that extends below the standard face shield and tucks inside a protective garment, providing additional protection in the area under the shield from splashing."

Honeywell also added to its product line during the COVID-19 pandemic.

The new Soft Comfort Nitrile Exam Glove, is designed, Pearsall said, "for low-fluid exposure situations."

The gloves offer "easy donning and high tactile sensitivity," she said, and represent the newest option among the company's portfolio of exam gloves.

Bonte said that Ahlstrom-Munksjo has seen demand for masks -- both medical and civilian grow at an unprecedented pace.since the start of the pandemic.

In response, "the company decided to use its sustainable product offering and momentum to develop its face mask materials further," Bonte said. Ahlstrom-Munksjo's new TenderGuard product portfolio, "offers a full suite of fabrics for medical and civil use face masks."

"The product is biodegradale and compostable under controlled conditions (by European standards)," bonte said. The masks, "are protective, hypoallergenic and environmentally friendly."

"As the latest wave of COVID-19 recedes, cancer patients have started returning to chemo treatment centers, and physical protection for staff at those facilities is as important as ever.

The Cardinal Health ChemoPlus gowns and sleeves, produced in North America, limit exposure risks for those who handle chemotherapy drugs. The new, comprehensive PPE line, according to a company description, "provide AAMI Level3 fluid protection, are USP-800 compliant, and are tested for use with 16 types of chemotherapy drugs, from preparation and handling to administration and disposal."

## Building reassurance

In the summer of 2020, just a few months after the first wave of COVID-19 had peaked, Vizient embarked on a new series of expansion partnerships.

An agreement with Encompass Group LLC in August 2020 provides access to a much greater supply of PPE. It also allows Encompass to begin manufacturing in the U.S., which it will likely do in early 2022. The company currently uses manufacturing lines created in Mexico with Vizient.

The move, according to a press release from August, 2020, "is part of Vizient's larger strategy to outmaneuver uncertainty by creating a more resilient supply chain built on transparency and trust between manufacturers and providers."

The strategy, "includes increased visibility of raw materials and product origin, expanded domestic capacity and additional onshore inventory for member hospitals," according to the Vizient press release.

And Vizient isn't the only organization looking for new partnerships in the wake of COVID-19.

Honeywell recently announced a collaboration with Premier Inc. to expand U.S. production of nitrile exam gloves and increase the domestic production capacity for those products.

The themes are increasingly familiar: More transparency is necessary throughout the industry. Resilience and flexibility must be baked in. And eggs should not all be placed in one basket.

"The manufacturing competitive landscape will become a lot more aggressive than it has ever been," Bonte of Ahlstrom-Munksjo predicts. "The traditional manufacturer landscape might look differently in two years from now, only making room for the most agile." **HPN**

*Visit https://hpnonline.com/21246088 for the sidebar, "Tips for selecting the right PPE."*

## Featured PPE

*Cardinal Health gown project*

*Healthmark Decontam gown*

*Silver Lining reusable isolation gown*

*Healthmark face shield with drape*

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| 6 | $1,141 | $545 | $596 |
| 7 | $1,331 | $636 | $695 |
| 8 | $1,521 | $727 | $795 |
| 9 | $1,711 | $818 | $894 |
| 10 | $1,902 | $908 | $993 |
| *16 | $3,042 | $1,453 | $1,589 |
| 50 | $9,508 | $4,542 | $4,966 |
| *62 | 11,789 | $5,631 | $6,158 |
| 99 | $18,825 | $8,992 | $9,832 |
| 100 | $19,015 | $9,083 | $9,932 |
| 101 | $19,205 | $9,174 | $10,031 |
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HEALTHCARE PURCHASING NEWS

SELF-STUDY SERIES

# Chemical Indicators for monitoring sterilization processes: Part two

*by Brian Kirk*


## December 2021

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


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## LEARNING OBJECTIVES

1. *To understand the International and National standards and guidance for chemical indicators*
2. *To understand how chemical indicators are tested*
3. *To understand how standards of practice prescribe the use of chemical indicators*

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In this second article covering chemical indicators, we will examine the international standards for chemical indicators, how they are categorized, how they are tested and how practice standards describe they should be used.

## National and international standards and guidance

International Standards, termed ISOs, are developed by expert committees working within the International Standards Organization (ISO). The committees are made up of individuals who represent their country's standards organization and are experts in the field drawn from academia, industry, and professional organizations. National standards and guidance are created by country-based committees made up of experts coming from within the country.

Once completed, international standards are often published as local country standards possibly with minor modification. Thus, some of the chemical indicator series ISO 11140 are published in the US and under such circumstances the standard will be labelled with an ANSI/AAMI ISO number e.g., ANSI/AAMI ISO 11140-1.[1] This indicates that the international standard has been adopted and published as a national standard by, in this case, the American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI). International standards are sometimes developed in cooperation with the European standards organization, CEN (Committee European de Normalization or European Committee for Standardization). Under such circumstances, a standard will then be published for use in Europe and have an EN ISO notation which, when published by a European country's standards body, will appear as a local standard. For example, the United Kingdom will publish these jointly developed standards as British Standards with the notation BS EN ISO such as BS EN ISO 11140-1 and these will in principle be the same as those published in the US.[1]

## Standards for chemical indicators

The requirements for chemical indicators are described in the series of international standards numbered 11140 and some of these are published in the US as AAMI/ANSI standards as discussed above.[1] There are six parts in the series. The first part covers general requirements, as well as requirements for the majority of indicators printed on a substrate or designed as a moving front indicator for use with sterile medical device packs, such as surgical instrument sets. Part 2 is unused. Parts 3, 4 and 5 cover special test chemical indicators used for the daily Bowie-Dick test. Part 6, which is in development, is an international replacement for European Standard EN 867-5, which specifically covers indicators for testing small steam sterilizers and covers the helix device often used by practitioners.

Part 1 of the 11140-1 series describes six types of indicators.[1] These are shown in table 2. Each type has specific requirements that are associated with it. Part 1 of the standard also describes the require-

*Table 2: The six types of CI described in EN ISO 11140-1:2014*

| CI Type | Title | Description |
|---|---|---|
| 1 | Process Indicator | For use with every pack to distinguish processed from unprocessed load items |
| 2 | Special Test Indicator | Intended for use in specific tests defined in relevant sterilizer/sterilization standards (e.g. Bowie- Dick Test [9] described in EN ISO 17665) |
| 3 | Single Variable Indicator | Reacts to one of the process variables of the sterilization process |
| 4 | Multi Variable Indicator | Reacts to two or more of the process variables of the sterilization process |
| 5 | Integrating Indicator | Reacts to all of the process variables of the sterilization process that mimic the response of a biological indicator |
| 6 | Emulating Indicator | Reacts to all of the process variables of the sterilization process giving a result related to the standard exposure conditions specified in a sterilization standard e.g., 132 for 4 minutes [4] |

ments for CIs used in different sterilization processes including steam (often termed moist heat sterilization), dry heat, ethylene oxide, radiation, low temperature steam and formaldehyde and vaporized hydrogen peroxide sterilization processes. (Table 2, previous page.)

## Terminology: endpoint and stated values

Each type of CI will have a specific function and requirement associated with it. Before considering each of the types of CI, it is imperative that the reader understands two fundamental terms associated with the performance of CI's. The first is the term "endpoint" and the second is the term "stated value" and both are interrelated. The "endpoint" of a CI is the point at which a pass color change result is indicated after exposure to the conditions specified by the manufacturer or the standard, ANSI/AAMI ISO 11140-1.[1] The exposure conditions which give rise to the pass color change or endpoint are called the "stated values", and there may be one or multiple stated values for each of the process variables the CI responds to depending on which type of indicator is in use. Figure 4 illustrates the endpoint and stated values for a type 5 CI.

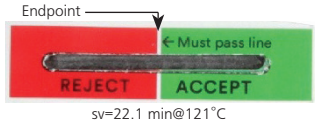


***Figure 4:*** *Showing the endpoint on a moving front CI (the reject/accept line) and the stated values (sv) which give rise to the endpoint being reached.*

## The six types of CI

Table 2 describes the six types of CI described in ANSI/AAMI/ISO 11140-1.[1]

**Type 1 CIs** are designed for placement on the outside of individual packs of sterile medical devices including surgical instrument sets. These indicators may be in the form of an indicator tape which is used to secure instrument sets wrapped in flexible tray wrap. They may be in the form of an adhesive label which contains information about the pack contents. In some cases, a bar code for use within a track and trace systems and an indicator imprint which changes color with exposure to the sterilization process. They may also be in the form of some other device which has a specific function. For example, some tamper evident sealing systems used with sterilization containers may have a CI printed on them which changes color when exposed to the sterilization process. The indicator may also be printed directly onto packaging materials such as paper bags or paper/film pouches. Type 1 chemical indicators provide a very important function because they help ensure non-processed instrument sets are not released into use. Before sets are released from the SPD, operators should be trained to examine every pack to make sure the CI has changed color. Similarly, operating room practitioners must also be trained to do the same. Sadly, reports still appear in the press which recount the use of non-sterilized sets by surgeons.[2] It is important to understand that type 1 CIs are not intended to provide evidence of sterility and should not be regarded as sterility indicators.

**Type 2 CIs** are used in special tests usually related to making sure the sterilizer is performing correctly before it is used for processing loads. A prime example of this type of indicator is the Bowie-Dick type indicators used daily to ensure that a steam sterilizer is achieving adequate air removal and steam penetration when tested using a standardized test load (3, 4). Parts 3, 4, 5 and in the future 6 of ISO 11140 describe the requirements for such indicators. The Bowie-Dick test will be discussed in more detail in part 3.

**Type 3 CIs** are single variable indicators which are designed to respond to just one process variable of the sterilization process. A good example of these types of indicators are the Diack tubes which contain a pellet of wax material sealed inside a glass tube that melts when exposed to the correct sterilization temperature.[5] Clearly these types of indicators have limited utility because in order to know that a sterilization process has been effective, we need evidence that all of the process variables (i.e., those contributing to microbial kill), have been present at a sufficient level during the process.

**Type 4 CIs** are multi-variable indicators, which are designed to respond to two or more process variables. For a steam sterilization process whose process variables are time and temperature in the presence of moisture, a type 4 CI must react to at least two of these variables. It is important to note that the practitioner must make careful choices when using such indicators since in a steam sterilization process, the presence of moisture is vital in ensuring efficacy of the process. So, a type 4 CI, which only responds to time and temperature, may give rise to misleading conclusions because such an indicator would also respond to identical dry heat conditions. The manufacturer of a type 4 indicator is required to specify the stated values for each of the process variables the indicator responds to however, there is no requirement for the manufacturer to choose a stated value with a relationship to the sterilization process in which the indicator might be used (see type 6). Practitioners should be aware of this and ensure that if they are using a Type 4 indicator, the stated values are of relevance to the sterilization process they are using. For example, a Type 4 may have stated values of 1 minute at 132 °C in moist heat, which clearly has little relevance to a sterilization process that is being operated at 132 °C for 4 minutes.

**Type 5 CIs** are integrating indicators and are designed to respond to all of the variables of a sterilization process. Thus, in a steam sterilization process they must respond to time, temperature, *and* the presence of moisture (typically in saturated steam; see later section). Conversely, they must not give a 'pass' result when exposed to the same time and temperature of exposure in the absence of moisture (i.e., dry heat) and they are tested to make sure they do not. Similarly, in an EO process they must respond to the process variables of time, temperature, ethylene oxide concentration and humidity, and for vaporized hydrogen peroxide, time, temperature, and hydrogen peroxide vapor concentration. They must not give a pass result if EO gas or humidity are at inadequate levels.

Type 5 integrating indicators have a special characteristic in that they provide a result that is similar to one that would be expected from a biological indicator - effectively mimicking the response of a biological indicator.[6] With this in mind, the manufacturer of a steam type 5 indicator must provide at least three stated values. The first should be at an exposure temperature of 121 °C and must be not less than 16.5 minutes. The second value must be at 135 °C and should not be less than 1.2 minutes, and at least a third must be declared at an equidistant intermediate time and temperature of exposure. The temperature coefficient (theoretical z value) of the color change reaction must then fall between 10 and 27°C. All of these requirements mirror the minimum values that are given for a biological indicator for steam sterilization in ISO 11138.[6]

**Type 6 CIs** are emulating indicators and are designed to provide a pass result which has a direct relationship to a time/temperature combination which may be cited in a standard, local guidance, national regulation or a pharmacopoeia. As an example, a type 6 steam CI might have stated values of 132 °C and 4 minutes, which means it will give a pass result after exposure to moist heat at 132 °C for 4 minutes -- a commonly used time/temperature combination used in the US. In theory, a type 6 CI should only have one set of stated values related to a particular sterilization process. However, it is common practice for manufacturers to

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

specify a range of stated values covering a range of sterilization temperatures used by practitioners around the world. For example, 121, 132 and 134 °C are common exposure temperatures used in various parts of the world and a CI may have stated values for each of these temperatures with appropriate exposure time stated values.

## Testing chemical indicators

All chemical indicators have to be tested before they are released into use, and this includes every batch produced by a manufacturer. Type 1, 3, 4, 5 and 6 CIs are tested in a special type of "exposure apparatus" called a Chemical Indicator Evaluating Resistometer (CIER) vessel or Resistometer. CIER vessels are designed for accurate control of the exposure conditions occurring within what is usually a very small chamber - typically 10 to 20l in volume.

International standard ISO 18472 [7] is the standard that describes the requirements for CIER vessels. The CIER vessel is also designed to ensure that the required exposure conditions (e.g., 132°C for 4 minutes) are reached very quickly and that the chamber is vented equally quickly at the end of the exposure period. For example, a typical test carried out within a steam CIER vessel would involve mounting the samples on a sample holder, (which should not influence the outcome of the results) and placing the samples in the chamber, closing the door, and then drawing a vacuum to 45 mB absolute pressure (1.33 inches of mercury). Steam is then admitted to the chamber to the required exposure temperature and pressure within 10 seconds. The exposure temperature is then held within a tolerance of +/- 0.5 °C for the required exposure time (the stated value for the indicator or as prescribed in the standard); at which point the chamber is evacuated to 10mB (3 inches of mercury) within 60 seconds. By using such a test cycle, the indicator is exposed to carefully controlled, constant conditions that are often termed 'square wave' conditions. This is in contrast to the conditions that would be encountered in a production sterilizer where multiple pulses of vacuum and steam injection would be employed to remove the air trapped within the chamber and load prior to exposure to the sterilization phase where temperature and pressure are maintained relatively constant. These multiple pulses can give rise to some color change in CIs prior to exposure to the sterilization phase which is unavoidable and quite normal.

## Testing chemical indicators: pass and fail

As described above, type 3, 4, 5 and 6 CIs will have stated values associated with them that are defined by the manufacturer of the product. When the p-roduct is exposed to these stated values in a CIER vessel, a pass result (called its endpoint) should be observed. Clearly CIs will also show a fail response under certain exposure conditions and ANSI/AAMI ISO 11140-1[1] prescribes test conditions under which such a failure response should be observed in the CI. Thus, the CI will be tested for both a pass and a failure response. Generally, the exposure conditions which should be used for testing for a failure response are related to the stated values for the indicator. The failure exposure test condition is usually a percentage reduction in the CI's stated value for exposure time (and concentration) and a defined reduction in the CI's stated value for temperature. The test requirements for type 1 CI's are an exception to this approach in that the standard specifies which test conditions should be used for a pass and fail exposure condition .

To illustrate this further, table 3 shows the test conditions for type 1, 3, 4, 5 and 6 steam sterilization CIs.(Table 3)

*Table 3: The exposure conditions in a steam CIER vessel allowing establishment of the performance to ANSI/AAMI/ISO 11140-1 of various types of a chemical indicator for monitoring steam sterilization*

| CI Type | Pass Exposure Conditions | | Fail Exposure Conditions | |
|---|---|---|---|---|
| | Temperatures (°C) | Time (min) | Temperatures (°C) | Time (min) |
| 1 | 121 | 10 | 121 | 2 |
| | 134 | 2 | 134 | 0.3 |
| 3 | SV | SV | SV-2 | SV-25% |
| 4 | SV | SV | SV-2 | SV-25% |
| 5 | 121 | SV >16.5 | SV-1 | SV-15% |
| | 135 | SV >1.2 | SV-1 | SV-15% |
| | T[a] | SV | SV-1 | SV-15% |
| 6 | SV | SV | SV-1 | SV-6% |

Type 2 are special test indicators for which separate parts of ISO 11140 exist. The manufacturer of a type 5 CI declares SV's at 121 and 135 °C and at one other temperature

Sv = manufacturers stated value

## Standards for using Chemical Indicators

Chemical indicators are used in various applications as discussed above.

There are a number of standards and local guidance documents which provide information on how and when they should be used. International standards for various sterilization processes and local guidance documents require the use of a system for differentiating processed from non-processed items.[4] Whilst a carefully controlled segregation system might be used in an industrial manufacturing setting, the most obvious and secure means of complying with this requirement in a healthcare facility is to use a type 1 process indicator which should be attached to every pack. This provides evidence to the SPD operators that each and every pack has been processed and to the end user it signals that that particular pack has similarly been processed.

Internal pack indicators are vital for indicating that sterilant has penetrated into the pack and that sterilizing conditions have been achieved at the point of placement. An internal pack indicator of type 5 or 6 showing a pass result will provide some evidence that the correct conditions have been met, because the performance of these types of indicators are linked to the response of a biological indicator or relate to a recognized sterilization time temperature relationship. Conversely a CI that shows a fail result should sound immediate alarm bells that something has gone wrong during the sterilization cycle, or incorrect packaging materials or accessory items have adversely affected the process.

The requirements for the use of internal pack indicators are described in a number of national guidance documents. Thus ANSI/AAMI ST 79[4] requires the placement of a CI in every pack which is to be steam sterilized. The use of such indicators is primarily aimed at the healthcare professionals who will eventually use the packs during patient therapy. The Operating Room (OR) teams will normally carry out a series of checks on instrument sets prior to use. This will include checks to ensure the sterile barrier system is intact with no signs of perforation or staining. If sterilization container systems are used, they will check the tamper evident seal and once opened, the filter systems or valve assemblies to make sure they appear operational. The lid seals will also be checked for integrity. One of the most important checks that will be carried out is on the process indicator attached to the instrument set to make sure it has changed color. In addition, the OR teams will also check the color change of any internal CI included with the instruments. It is vital that such indicators have a very clear endpoint, and that full instructional material is available to the end user to enable correct interpretation of the CI. Any changes in supplier should also be notified to the end users so that appropriate training and instructional material can be made available to those who will interpret CI results.

All of these checks are described in the World Health Organization's Surgical

Safety Checklist [8] which describes CIs as "sterility indicators" which is technically incorrect, but in common use by medical and nursing practitioners. The checklist is designed to prevent accidental harm arising due to unforeseen circumstances and has been shown to be highly effective when implemented in practice. Clearly the use of non-sterile instruments during an OR procedure could be catastrophic for the patient, leading to infection or morbidity.[2] Examination of the internal and external CIs provides one of the vital pieces of evidence ensuring sets are safe to use.

## Conclusions

Chemical Indicators are one of three basic types of technology that can be used to routinely monitor the efficacy of sterilization processes used in industry and the hospital SPD. They can be used to identify unprocessed from processed surgical instrument sets when adhered to the outside of packs, thereby avoiding non sterilized packs being sent to the OR department. They can be used to indicate that sterilizing agent has penetrated through the sterile barrier system packaging and stated exposure conditions have been met, thereby avoiding inadequately or incorrectly processed loads being used.

Chemical Indicators are therefore an extremely useful and practical tool for ensuring SPD processes are functioning correctly. There are six types of Chemical Indicators and the test requirements for each is specified in standards. Several standards used by medical personnel describe the use of CIs to help OR teams determine if a surgical instruments set is sterile. HPN

*This article is part of a three-article series. Part three will be in our February issue.*

References online at: https://hpnonline.com/21246339

## CONTINUING EDUCATION TEST • DECEMBER 2021

# Chemical Indicators for monitoring sterilization processes: Part two

### Circle the one correct answer:

1. **Process indicators can identify processed from unprocessed load items (from Table 2)**
   A. True B. False
2. **Type 4 chemical indicators can effectively monitor all critical variables in any sterilization cycle**
   A. True B. False
3. **Type 5 chemical indicators or integrators can detect all the critical variables on steam sterilization cycles.**
   A. True B. False
4. **Type 6 chemical indicators or emulators can be used in every modern steam sterilization cycle.**
   A. True B. False
5. **Testing chemical indicator can be conducted in any steam sterilization equipment.**
   A. True B. False
6. **The use of chemical indicators is part of the tools SPD's professionals can use to detect potential cycle failure.**
   A. True B. False
7. **The use of internal chemical indicator in every pack or containers is required on ANSI/AAMI ST 79:2017.**
   A. True B. False
8. **Internal Chemical Indicators must be checked at the OR prior to the use of the instruments.**
   A. True B. False
9. **Chemical indicators can be used only following its manufacturers instruction for use.**
   A. True B. False
10. **Containers do not need to be assessed with external chemical indicators**
    A. True B. False

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# Surveyors probe ultrasound device HLD practices

*by Julie E. Williamson, Director of Communications and Editor-in-Chief, International Association of Healthcare Central Service Materiel Management*

Surveyors from the Joint Commission (TJC) are dialing up their focus on reprocessing of medical devices, including ultrasound probes, to ensure accountability and compliance with infection control standard IC.02.02.01. The standard requires Joint Commission-accredited facilities to reduce the risk of infections associated with medical equipment, devices and supplies. This heightened focus began in 2014 when TJC released a safety alert warning that high-level disinfection or sterilization (HLD) was not being properly carried out. When noncompliance increased between 2009 and 2016, TJC reissued the safety alert in May 2017.

"TJC has zeroed in on this because they said that 74% of all immediate threats of life were from improperly sterilized or high-level disinfection of devices. That's very concerning," said Emily Smith, BS, RDMS, VT, Clinical Marketing Specialist, CIVCO Medical Solutions, during her IAHCSMM Virtual Conference session, "A Joint Commission Survey: What You Need to Know Regarding High-Level Disinfection."

## Collaboration, documentation, training crucial

TJC recommends strong collaboration between Infection Control/Infection Prevention departments and all departmental areas responsible for high-level disinfection (HLD) and sterilization processes, said Smith. Proper disposal of those devices, and storage of the equipment after sterilization and HLD, are also being more closely eyed by TJC surveyors in recent years. She noted that important infection prevention and control information should be available to staff, standard- and transmission-based precautions and instructions for use (IFU) should be readily available and consistently followed, processes should be carefully documented, and any infection outbreaks should be properly investigated TJC surveyors will want to ensure facilities are following evidence-based guidelines and standards, as well as manufacturers' instructions for use (IFU), per IC.01.05.01. Multiple guidelines, standards and best practices are available, including ANSI/AAMI ST58:2014/(R) 2018, *Chemical sterilization and HLD in health care facilities*; the Centers for Disease Control and Prevention' Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (updated Feb. 15, 2017); the Association of periOperative Registered Nurses' 2016 Perioperative Standards and Recommended Practices for Sterilization; the American Institute of Ultrasound in Medicine's (AIUM's) Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers Between Patients, Safe Handling, and Use of Ultrasound Coupling Gel; and the Society of Diagnostic Medical Sonography's Guidelines for Infection Prevention and Control in Sonography: Reprocessing the Ultrasound Transducer.

Although TJC surveyors are not concerned about which evidence-based guidelines a facility uses, they will look to ensure the facility sticks with the one it has chosen. "They may request a copy of this, so make sure you keep a copy close in the department—and they will expect you to show how you're following those guidelines as well. They may ask questions about IFU for your HLD disinfectant, and they may also ask for your IFU or manual for your automated HLD system, as well as the IFU from the ultrasound manufacturers themselves."

If there is conflicting information between the guidelines a facility uses and manufacturers' IFU, Smith said the facility must resolve those differences by contacting the equipment and product manufacturers and also the society/group responsible for the evidence-based guidelines.

Inadequate monitoring or documentation of HLD or sterilization processes can also contribute to survey noncompliance. "Proper data logging is an essential part of the HLD process because it allows for the tracking of instruments, disinfectants, etc. for outbreak investigations," said Smith.

For ultrasound probes, the following should be logged for each use:

- Instrument being processed, including serial number or some other unique identifier
- Name of person reprocessing the items
- Date/time disinfection process occurred
- Type of HLD chemical and lot number, and expiration date for the HLD
- Temperature of the HLD at the time of reprocessing
- MRC test results (know the type, lot # and expiration date of test strips)
- HLD submersion time and documentation of the rinse cycles (how long probes are submersed in the chemical)
- Proper storage

Lack of employee knowledge and training on proper sterilization or HLD processes also contributes to noncompliance. Training should be required and provided any time a new employee is hired and whenever new equipment is introduced (to ensure all employees know how to clean it properly). Annual competencies should be assessed for all employees, and all must be carefully documented.

Noncompliance results when processes for sterilization or HLD are not followed properly, or when shortcuts are taken. "Know the steps that are outlined in your particular evidence-based guidelines, follow them consistently and document that you did [follow them]," said Smith, noting that this should include every step, from pre-cleaning, minimum recommended concentration (MEC) testing and HLD to rinsing, data logging and proper storage.

Surveyors will also ensure that dedicated staff members are overseeing proper processes, and they will examine reprocessing areas to ensure that probes follow a "dirty to clean to storage and use," flow. Proper ventilation or air filtration and personal protective equipment will also likely be assessed, along with eye wash station availability.

TJC surveys are not always black and white and are often subjective, said Smith. But even when noncompliance is discovered, she said, the organization or facility will have an opportunity to resolve it. "[Surveyors] are looking for long-term compliance, so if you follow your evidence-based guidelines and IFU, you'll do fine." HPN

# Simplifying the Semantics

*by Stephen Kovach*

**Q "I was just told by a sales representative that I must use their product, and I must test my cleaning equipment each day that it is used, with their product only. Is this really a requirement?"**

**A** In general, the terms "must", "shall", "should", "can", and "may" (within the standards) are not clearly understood, because they are defined in the introduction, and people tend not to read that section.

In the standards (i.e., AAMI and ANSI), there are five terms used that have universal meaning. Here's how they are used in writing [*not in any particular order*]:

1. **Shall:** Indicates requirements strictly to be followed to conform to the recommended practice.
2. **Should:** Among several possibilities, one is recommended as particularly suitable:
   a. Without mentioning or excluding others
   b. A certain course of action is preferred but not necessarily required
   c. (In the negative form), a certain possibility or course of action should be avoided, but is not prohibited.
3. **May:** Indicates that a course of action is permissible within the limits of the recommended practice.
4. **Can:** As a statement of possibility and capability
5. **Must**: *Only* used to describe "unavoidable" situations—including those mandated by government regulation.

Therefore, to answer your questions about a salesperson saying you "must use their test," and you "must test at a certain frequency," here is how I look at your question. In this specific concern, the standards (as they pertain to the United States market) are clear—the term "should" is to be used, not "must" (ANSI/AAMI ST 79 -13.2)—when it comes to testing and monitoring your cleaning equipment.

Concerning the statement, you "must use their [test]," to me, that is a gray area. I would think you would use a clinically relevant and evidence-based test to challenge your equipment. A department has the right to use the product they feel is best for their process based on all available information. It would not have to be *that company's test*, unless they had all the information you requested to make the best choice.

An example for a sterilizer, many people make biological and chemical indicators, but they are not always from the same company as the sterilizer manufacturer. However, they are still used because the department feels it is the best product for their practice. The same should be true for cleaning equipment verification. Again, use the best product that is clinically relevant, and evidence based.

**Q "Can you help me understand the difference between regulations, standards, and guidelines?"**

**A**

- **Regulations**:
  - A rule or directive made and maintained by an authority.
  - Mandatory (must).
  - Think OSHA, CMS.
- **Standards**:
  - Requirements and specifications to ensure consistency and fit for purpose.
  - Voluntary, but can become mandatory.
  - Think ANSI/AAMI Documents.
- **Guidelines, Recommended Practices, Technical Information Reports**:
  - Technical guidance, information, or preferred procedures about a given topic.
  - Voluntary, but with interpretation.
  - Think AORN, SGNA, AST.

In today's world, many of the documents mentioned above are in Portable Digital Format (PDF), which means they are easy to search/find information and store on a computer. My recommendation is to get these documents in PDF format when purchasing. HPN

Reference

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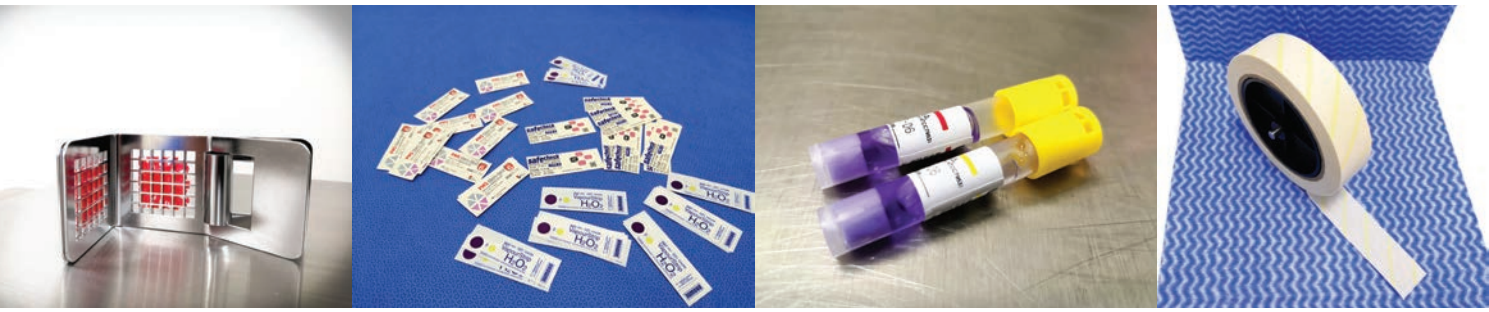

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# All key indicators point to change

*The moving target of sterilization best practices for quality outcomes*

*by Kara Nadeau*

2021 has been a significant year in the field of Central Service/Sterile Processing & Distribution (CS/SPD), with several guidance changes impacting the processing of instruments and devices, and changes in terminology and language that redefine the CS/SPD profession.

The International Association of Healthcare Central Service Materiel Management (IAHCSMM) Board of Directors voted to change the name of the organization to the "Healthcare Sterile Processing Association (HSPA)," effective January 1, 2022, which the the board states "better reflects the role of the professionals we represent."[1]

Also in 2021, The Joint Commission issued New Water Management Requirements, requiring hospitals to have a water management program that addresses Legionella and other waterborne pathogens.[2] With the effectiveness of CS/SPD operations reliant on the quality of water and steam used in the decontamination, cleaning and sterilization processes, this change is likely to impact hospital CS/SPD departments.

Perhaps one of the most impactful changes to sterile processing workflow this year is the Association for Advancement of Medical Instrumentation's (AAMI) amendments to ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities, "offering users new clarity and fresh guidance to stay in compliance with accrediting bodies."[3] Amendment 3 and 4 change recommendations on the frequency of sterilizer cleaning and the put into place requirements for the recording of biological indicator (BI) lot numbers in sterilizer records.

*Jamie Zarembinski*

"While they are small updates, they stress the importance of staying up to date on industry changes and how it is critical to the sterile processing departments' efficiency," said Jamie Zarembinski, CRCST, CER, CCSVP, Clinical Educator, SPD, Key Surgical.

In light of these and other changes impacting the field, industry experts offer their insights on the current state of sterility and quality assurance in the CS/SPD department, including advice on how to improve compliance with industry guidelines and manufacturer' instructions for use (IFU).

## Decontaminate, test, disinfect

A clean and safe patient procedure starts with a clean and safe CS/SPD, explains Sharon Greene-Golden, BA, CRCST, CER, SME, FCS, Central Sterile Processing Manager, Adventist HealthCare Shady Grove Medical Center, Rockville, Md., Past President IAHCSMM, and Co-Author of the books *SPEAKING MY TRUTH* and *WILD (What I Learned During the Pandemic)*.

*Sharon Greene-Golden*

"If you go into an SPD and the team isn't following the rules and regulations, I guarantee the rest of the hospital isn't either," commented Greene-Golden. "I remind my team members that if they were the patient in the operating room (OR), they would want everything cleaned to the highest standards; therefore, they should work to ensure they do that for everyone."

Given the critical importance of cleaning and disinfection to instrument quality and safety, some CS/SPD leaders took the time to evaluate their processes and make improvements aligned to industry standards during COVID-driven surgical case slowdowns. They are reaping the benefits today as case volumes grow closer to pre-pandemic levels.

"Healthcare organizations must clean and disinfect to maximize patient safety and to reduce the risk of transmission of antibiotic-resistant pathogens," commented Christine Hilbert, Ph.D., MBA, Marketing Technical Writer, Hygiena. "Recently, the COVID-19 pandemic has raised public awareness of the need to control the spread of infectious diseases, making it even more important that

healthcare professionals monitor the effectiveness of both cleaning and disinfection/sterilization procedures."

The CS/SPD team at NorthShore University HealthSystem based out of Evanstan, Ill. was one of these proactive organizations, designing standard decontamination workflows and cleaning pathways based on ANSI/AAMI ST79 and the Association of periOperative Registered Nurses (AORN) Guideline for care and cleaning of surgical instruments. The leaders of the initiative, Courtney Mace Davis, MBA, CMQ/OE, CHL, CRCST and Joan M. Spear, MBA, RN, CNOR, CRCST, published a summary of their work in the August 2021 AORN Journal.

To confirm that the proposed standard decontamination workflows and cleaning pathways were effective, the CS/SPD team performed cleanliness verification tests on sets that contained complex instruments, including a laparoscopic gynecology set and a sinoscopy set following extended time between point of use (POU) and decontamination steps. After set decontamination in compliance with the proposed standardized workflow, the sterile processing manager performed cleanliness testing on instruments from each of the test instrument sets. Of the nine instruments tested, all passed the test. Periodic cleanliness testing followed implementation of the new workflows as a part of the Quality Systems in place.[4]

Mace Davis comments on their work, stating:

"Most of us in sterile processing departments understand the importance of following instrument IFUs in decontamination. However, this can be challenging to do and the IFU review must be based on each department's own medical devices/instruments, equipment, cleaning agents, and POU process. Additionally, the workflow expectations of frontline SPD staff can be varied and complex. As leaders our job is to make steps easy to follow so our technicians can follow the processes each and every time. Using data obtained from cleaning verification tests, such as borescope inspection and residual protein detection, give us confidence we are following our processes and that the devices/instruments are clean."

**Two separate but vital tasks**

As Hilbert explains, cleaning and disinfection are two separate tasks, and it is during the cleaning process that CS/SPD team members must do the hard work of removing organic material (aka bioburden) from surfaces. She states:

"Disinfectants are not designed to remove organic material, whether bacterial, viral or other debris. Instead, disinfectants are made to ensure that clean surfaces stay microbe-free. Disinfectant application needs to follow a good cleaning of the surfaces with enough force to thoroughly remove most of the unwanted material. Even after cleaning, surfaces can have gaps that might harbor potential pathogens. Therefore, it is critical to not only clean but also to disinfect and test areas to confirm they are free of contaminants."

Hilbert says visual inspection is not enough to determine if a surface is clean and microbial tests (swabbing surfaces and then testing for growth in a lab)

take days for results. She comments on how facilities have increasingly turned to new technologies that can quickly provide objective and reliable measurements of cleanliness.

"A rapid, reliable, easy-to-use solution is adenosine triphosphate monitoring (ATP testing)," explained Hilbert. "ATP is an indicator of biological residue, including bacteria, yeast and mold, so it is an excellent measure of cleanliness. In addition, ATP testing provides results in seconds and is sensitive, quantitative, effective and straightforward. General protein tests (i.e., Pro-Clean) can also be usefully in making sure residual proteins have been removed."

## Sterilization best practices

The world of CS/SPD is not static, rather as instruments and IFUs change, and industry associations and regulatory bodies change their stance on practices, sterile processing teams must adapt to remain effective, safe and compliant. And as practices evolve, CS/SPD departments can benefit from validity testing at each step of their process.

*Hudson Garrett Jr.*

"First and foremost, the device manufacturer's IFU should be rigorously followed, and secondly, healthcare facilities should carefully follow current evidence-based practices dictated by organizations such as AAMI, CDC, and AORN," said Dr. Hudson Garrett Jr, Adjunct Assistant Professor of Medicine, Division of Infectious Diseases, University of Louisville School of Medicine. "Additionally, the use of a variety of verification practices is the most prudent in ensuring the safety of surgical instruments."

Janet Tull, VP, Clinical Operations, Moab Healthcare, a Sterile Processing Staffing, Interim Management & Consulting firm, recommends that CS/SPD teams conduct random quality assurance audits to drive sterilization efficacy and safety.

*Janet Tull*

"These audits should include proper placement of chemical indicators, tray weight evenly distributed, using correct wrapper size and strength or correct rigid container, and choosing the correct sterilization cycle," explained Tull.

### Sterilizer operation

There are numerous factors that can impact whether instruments are properly sterilized. Seth Hendee, CRCST, CIS, CHL, CER, CSPDT, CFER, IAHCSMM Approved Instructor, Clinical Education Coordinator, SPD, Healthmark Industries, points to proper loading as one practice that greatly affects sterilizer efficacy.

*Seth Hendee*

"An overfull sterilizer cart reduces steam penetration and circulation," he commented. "When sets are not appropriately orientated on the cart, it can impede steam but may also trap water and create wet loads. Guidance on properly loading of sterilizers can be found in the sterilizer and packaging IFUs and in guidance documents like ANSI/AAMI ST79."

"Trays should be loaded flat on the sterilizer cart and not placed on their sides unless they are non-perforated (e.g., basins and mayo trays)," Malinda Elammari, ST, CSPM, CSPDT, CFER, CSIS, CRCST, CIS, CHL, CER, CLSSGB, Clinical Education Specialist, Healthmark Industries added. "Keeping trays flat ensures the metal mass stays evenly distributed. Additionally, rigid trays should never be stacked unless validated by the container IFU. Heavier trays are always positioned below lighter trays and wrapped trays above rigid containers in mixed loads. Peel pouches are placed on the top shelf, standing on their edge, facing in the same direction."

### Sterilizer cleaning

One of the 2021 amendments to ANSI/AAMI ST79 has a direct impact on sterilizer cleaning practices. Amendments 3 eliminates previously stated recommendations on daily cleaning of sterilizers, instead urging CS/SPD teams to follow the sterilizer manufacturer's IFU when cleaning this equipment.

Hendee commended on these amendments during an episode of the company's Ask the Educator podcast, stating:

"Instead of AAMI taking a stance that might have been contradictory to an IFU, they said we are going to pull that back and say your IFU should tell you what to look for and if abnormalities are found (e.g., staining, debris), also follow your IFU. That will most likely prescribe cleaning but again; that is up to the sterilizer manufacturer. It is their product and they should give us the guidance."

### Testing and monitoring

There are a variety of tests that CS/SPD team can employ to assess sterility assurance. Biological indicators (BI) contain microorganisms to test the effectiveness of steam, hydrogen peroxide gas, ethylene oxide and other sterilization methods.

Common chemical indicators employed include Type 1 chemical indicators to help differentiate between processed and unprocessed loads, Type 2 chemical indicators, such as Bowie-Dick tests, to monitor steam sterilizers for air removal efficiency and steam penetration, and Type 5 chemical indicators to test the parameters of time, temperature and steam.

Amendment 4 of the ANSI/AAMI ST79 guidelines is around the recording of BI lot numbers. As Hendee explained in the recent podcast episode, CS/SPD teams must now not only record the BI that was run, but also the BI control lot number as well.

"For those CS/SPD departments with electronic systems that already attach their control results and lot number to each load, it should be very easy to comply," said Hendee. "But those with manual systems where things are written down, they will have to figure out a system to make it work."

With regards to Bowie-Dick tests used for routine monitoring of sterilizer air leaks and inadequate air removal, and Type 5 chemical indicators to test time, temperature and pressure, it is important to follow instructions to ensure the tests are correctly performed, explains John Sullivan, Director, Crosstex International, part of the Hu-Friedy Group a Steris Company.

"There have been more than a few times that a facility will call us and say our Bowie Dick or Type 5 tests are not working. After further research and investigation at the facility we find that our products are working and doing exactly what they are designed to do and that is identify issues. Facilities want to make sure that the product they are using are performing, they also want to be able to see a Type 5 in the container when they open it and that they are priced fairly."

**Selecting an indicator**

When evaluating potential indicator technology, Dr. Garrett recommends CS/SPD professionals ensure the indicator product has the necessary regulatory body approvals (e.g., FDA), meets the intended use of the product within the clinical setting, and has extensive clinical testing data to demonstrate its efficacy.

"Finally, the indicator should be cost effective and easy to implement within one's health system," Dr. Garrett added.

With regards to ease of use, the U.S. Food and Drug Administration (FDA) has raised the issue of CS/SPD team members misinterpreting indicator results because there is no standard indicator color to indicate a sterilized device. The agency has urged departments to "enhance staff training on the indicators for all sterilization systems employed in the facility."[5]

"Each manufacturer has developed its own color scheme to validate the sterilization process, and the colors vary among manufacturers even though many are validated for the same cycle conditions," explained Zarembinski. "The FDA is collaborating with manufacturers of sterilization systems to improve product labeling and explore standardization for colors used to indicate sterilization. It's important to always address the sterilization indicator's IFU on how to interpret the indicator results."

Hendee stresses the importance of indicator compatibility, noting how many indicators on the market are not designed for extended cycles, which are becoming more common in the CS/SPD. He states:

"These cycles may be appropriate per the instrument IFU but are they appropriate per the indicator IFU? Most type 5 chemical indicators and biological indicators are designed to monitor a four-minute sterilization cycle. Because of this, you need to ask yourself, are they appropriate for a longer sterilization time? For example, type 5 indicators react to all critical variables within a cycle. When the critical variable of time changes, shouldn't the type 5 indicator change as well."

## Education and training

As with most aspects of sterile processing, sterility and quality assurance goes back to effective staff education and training. Key Surgical Clinical Educator Michelle Lemmons comments on this point, stressing how important it is for CS/SPD staff members to be able to confidently and independently evaluate effectiveness and have a working knowledge of how to troubleshoot issues that they encounter.

"It is critical to educate staff on how the equipment works, new products, who to contact if they have questions and WHY each step is needed," said Lemmons. "Also, providing opportunities for education and certification advances the sterile processing profession, allows for personal and professional growth of the individual, and increases the visibility of sterile processing's incredible value to the facility."

"Best practices for ensuring effective sterilization include a well-trained staff, documenting your processes to verify the requirements are being performed for the task at hand, and auditing your process to see if there are any areas of improvement," Zarembinski added. "Most standards and industry guidelines lay out the baseline expectation for best practices, implementing these into a facility policy along with specific requirements established by the healthcare facility will maximize effective sterilization."

Elammari says she has seen two positive impacts on CS/SPD quality assurance recently: the addition of educators and the implementation of huddle boards at shift huddles, stating:

"The addition of educators specific to SPD has positively impacted the facilities that have implemented this role. They provide staff with resources for additional education and professional growth. Another impact is the use of huddle boards during shift huddles. When used correctly, they help close communication gaps, allow staff to speak up and encourage them to take ownership for issues they bring forth. It also allows for discussion concerning essential factors they will face for the day."

Tull points to increased requests from surgeons for vendor trays as a challenge to CS/SPD staff competency, noting how greater in-servicing and training can help boost quality when processing these items.

"With the increased use in vendor trays, there is an increased need to have a strong QA process in sterile processing," Tull commented. "There are so many different companies and systems that staff must be in-serviced so that when performing QA checks knowledge of critical instruments are a must."

## Looking to the future

Looking to the future of CS/SPD, Hendee sees a trend towards centralized instrument processing. He acknowledges that while this is not a new concept, it is being utilized in more situations than ever before.

"SPDs have been processing (cleaning and sterilizing) instruments for clinics and nursing floors within the facility for decades, but now processing departments are being asked to push this service well beyond those walls," said Hendee. "While this may help in standardizing processes across the organization, it adds challenges as well. Ensuring quality in a centralized structure will require careful planning, especially around the external transport of these instruments."

Dr. Garrett has seen an increased interest in system-wide sterilization and sterile processing, referencing continued focus by the FDA and infection prevention departments on the CS/SPD. In his opinion, greater adoption of automation and monitoring technologies is key to overcoming current challenges in quality and safety. He states:

"Given the high rate of personnel turnover and the growing complexity of reprocessing and sterilization processes for each device, there is a high potential for human error that exists in the equation. This can lead to cross-contamination of surgical instruments and subsequent potential infection risks to the patient. Innovative automation and monitoring technologies are rapidly entering the medical market and show tremendous promise in optimizing clinical workflow, but also in reducing infection risks to patients when all steps in the reprocessing or sterilization process for a device are properly and consistently adhered to." HPN

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# 10 headline integral, pivotal products needed, used in healthcare delivery

*by Rick Dana Barlow*

If the United States of America indeed represents the highest-quality healthcare provider in the world with the most advanced products, techniques and technologies then its healthcare practitioners and citizens are spoiled.

Clinicians are conditioned to grab a readily available device or tool when a patient describes some kind of ailment or malady. Generally, the exam requires the collection of various vital signs, made easier by these tools.

But what if they didn't have these tools? Some go back less than 100 years. Others for centuries. Clearly, it can be easy to take them for granted.

This is part of the reason why *Healthcare Purchasing News* launched its Healthcare Product Hall of Fame and Healthcare Product All-Stars features last year. Without these devices, products and tools – from the most basic and rudimentary to the most advanced and scientifically challenging – we likely would be experiencing much higher mortality rates, much lower population growth and perhaps less resource consumption and wastage.

For this follow-up feature, the themes seemed to center on accessibility and convenience with an emphasis on personal healthcare through vital signs tracking and visualization as well as supply tracking and visualization, and ways to support operations through crises and disasters.

Without further delay, here are the 10 members of *HPN*'s Healthcare Product Hall of Fame Class of 2021.

## Blood pressure cuff

**KEY SUPPLIERS:** ABN, Accoson, ADC, Advocate, AMG Medical, Amydi-Med, Aspel, W.A. Baum Co. Inc., Berry, BioMedical Technologies, Bionics, Bosch + Sohn, BPLab, B.Well, DDM, Diagnosis, Easy@Home, ERKA, FDK, GBUK Group, GE Healthcare, Hartmann, iHealth, Kenz, LifeSource, Luxamed, MDF, Med Accessories, Medke, MedLinket, Microlife, MIPM, Nihon Kohden, Omron, Orantech, Pedia Pals, Proact, ProMed, Pronk Technologies, Riester, SECA, SinMed, Solaris, SunTech Medical, Technicuff, Unimed, UpnMed, Withings, ZellaMed Instrumente

**WHY IT MATTERS:** When you walk into your doctor's office for a routine health checkup you can expect the nurse to take your temperature, check your height and weight and one more necessary vital sign before the physician ever walks into the exam room – your blood pressure. Equipped with all of this data, the physician then can dive a bit deeper into your physiology. Taking your blood pressure, however, can alert the doctor about a variety of issues, including whether you're suffering from internal pain and/or stress or may have arterial and blood vessel blockages hampering blood flow to the heart, which can cause serious damage to the aorta. Readings also can assist in determining whether medications might be needed or whether current medications being taken actually are working as they should.

With the pandemic motivating heightened interest in telemedicine, you have more opportunity than ever before to invest in your own blood pressure cuff via local retail outlet or online exchange.

## Hearing aid

**KEY SUPPLIERS:** Audio Controle, Audious, Bernafon, Coselgi, Demant (includes Oticon), Eargo, Electone, Elkon, Entific, General Hearing Instruments, GN ReSound (includes Beltone), Hansaton, HueHearing, Interton, Lyric, Magnatone, Micro-Tech, Miracle-Ear, Puretone, Rexton, Rion, Signia, Sivantos (includes Siemens), SONIC Innovations, Sonova (includes Phonak), Sonovation, Starkey Laboratories, United Hearing Systems, Unitron Hearing, Widex, WonderEar

**WHY IT MATTERS:** Battery-powered or electronic hearing aids, by and large, come in four types, according to Johns Hopkins Medicine. The first type is called "In-the-ear (ITE) hearing aids. They come in cases that fit in the outer ear and generally are used for mild to severe hearing loss." The second type is called "Behind-the-ear (BTE) hearing aids. Worn behind the ear, they also come in a case that connects to a plastic ear mold inside the outer ear. They also generally are used for mild-to-severe hearing loss." The third type, as noted by Johns Hopkins Medicine, is called "Canal aids. They fit directly in the ear and come in two sizes – in-the-canal (ITC) aid and completely-in-canal (CIC) aid. They are customized to fit the size and shape of a person's ear canal and generally are used for mild-to-moderate hearing loss." The fourth type, according to Johns Hopkins Medicine, is called "Body aids. They generally are reserved for profound hearing loss that other types will not accommodate and are attached to a belt or pocket, connected to the ear with a wire." All are designed to convert sound waves to electrical signals.

## Artificial heart

**KEY SUPPLIERS:** BiVACOR, CARMAT, SynCardia Systems LLC, but if you loosen the definition to include Ventricular-Assist Devices (VAD), you can add CarWave, Medtronic, Tandem Life, Thoratec

**WHY IT MATTERS:** Depending on what's wrong with your heart, if defibrillation, drugs or stenting don't solve the underlying problem, all that's left is an organ transplant. Access to donor organs – particularly the heart – can be difficult and potentially a long wait. While doctors try to prolong a person's life as much as possible through medications as he or she awaits a replacement heart, they were provided another option that can be traced in part back to the 1930s and 1940s: An artificial (mechanical) heart. The first to receive a patent for a human artificial heart were Paul Winchell and Henry Heimlich (he of the famous maneuver conceived in the mid-1970s used to prevent choking). Others would research and develop their own versions, the most famous of which was designed by a team headlined by Robert Jarvik that was implanted in a patient in 1982. This mechanical device originally

wasn't designed to be a permanent replacement for a faulty organic one (even though the concept is touted regularly in science fiction). Instead, it serves as a temporary implantable prosthesis to serve as a bridge until a donor organ could be located and implanted.

## Thermometer

**KEY SUPPLIERS:** Angelus, Aoss Medical Supply, BV Medical, Dealmed, DWK Life Sciences, LCR Hallcrest, Mediaid, Medical Indicators, Pyromation, SP Bel-Art, Thermco, ThermoWorks, VWR International, Waitz

**WHY IT MATTERS:** You can trace the concept of a thermometer back some 500 years when inventors – including Galileo – developed what became known as "thermoscopes" that used glass tubes of trapped air submerged in water. The way it worked went like this: If the tube was placed in hot water, the trapped air would expand and cause the water level to rise; if the tube was placed in cold water, the trapped air would contract and show the water level as falling. By the early 1600s, an Italian inventor added a numerical scale to the thermoscope and voila! The first thermometer was born. From there, inventors experimented with alternatives, such as switching to alcohol-filled glass tubes. In the early 1700s, however, a German physicist named Daniel Fahrenheit would use liquid mercury within the glass tubing and a standardized scale that became the standard bearer of a universal technology relied on for centuries until the advent of contact and no-contact external thermometers (2020 All-Stars).

## MRI scanner

**KEY SUPPLIERS:** Alltech Medical Systems, Aurora MRI, Canon, Esaote, GE Healthcare, Hitachi, Laifu, Medonica, MinFound, Philips Healthcare, **Siemens Healthineers**, Shimadzu, SternMed, Synaptive, Time Medical Systems, WDM, XBO, XGY.

**WHY IT MATTERS:** Last year, *HPN* inducted the proverbial Three Musketeers (Athos, Porthos and Aramis) of Diagnostic Imaging: X-ray, ultrasound and computed tomography. This year, just like in the fictional tale, the dashing, younger D'Artagnan joined the trio.

Magnetic resonance (MR) can trace its imaging roots to the early 1970s as an outgrowth of nuclear magnetic resonance studies dating back to the 1940s, according to Wesley Gilson, Ph.D., Senior Director, Business Development, MR, Siemens Healthineers. Healthcare started seeing commercial MRI units emerge in the 1980s. MR represents the "youngest" of the leading four diagnostic imaging modalities that include ultrasound, X-ray and CT with positron emission tomography (PET) added to the group since the 1950s. "All of these work together and build on one another, effectively defining the field of radiology," Gilson told *HPN*.

Where MR makes a difference involves its interior reach and speed, and connection to surgery.

"All of us recognize certain clinical indications where MR is the preferred imaging modality," Gilson noted. "I'm thinking of all musculoskeletal issues and traumas, including brain injury (e.g., CTE in football). MR also is helpful in diagnosing brain disorders, neurodegenerative diseases like ALS and dementia and is effective in detecting lesions for MS and other chronic diseases. MR represents a tool to prevent the need to go inside a body and to help plan and guide necessary surgical intervention."

Technological development has facilitated visual acuity and efficient data transmission, according to Gilson.

"The progression of computerization and super-conducting magnets has enabled more clarity in the images taken and the digitization of those images for reading, diagnosis, storage and transmission," he noted. "The image quality produced now has come a long way from the early analog days of the modality. The other development involves the speed of acquiring data for the images. In the past it took hours to acquire and process the images.

"Routine imaging exams are now being completed in 20- to 30-minute scan slots," Gilson noted. "Innovative acceleration techniques and faster computing power have reduced individual image set acquisitions down to only a few minutes or less."

## Bar coding in healthcare

**KEY SUPPLIERS:** Datalogic, **GS1 US Healthcare**, IOS, **Jump Technologies**, **Toshiba**, **Zebra**

**WHY IT MATTERS:** Back in the early 1970s, the grocery industry sought for a way to increase speed at checkout lanes but also drive efficiency in tracking inventory and sales. So in 1973, the major grocery retailers agreed to adopt and implement the Universal Product Code (UPC), a bar code symbol that included transactional data within a series of printed vertical stripes on a label that could be scanned and sent to a computer for tracking and record keeping. The concept of bar coding wouldn't emerge in healthcare for another two years when an enterprising hospital supply chain executive in North Dakota developed a system internally to accomplish something similar. From 1975 onward, bar coding established a beachhead in healthcare, albeit slow growing, under the intention of efficiency and safety at the point of care.

"The foundation of care delivery is patient safety," said Rikki Jennings, Chief Nursing Informatics Officer (CNIO) at Zebra Technologies. "The development of automated data capture has transformed clinic practice at the point of care. Bar-code scanning has become the underpinning of efficiency for patient identification workflows such as medication administration and specimen collection. Scanning technologies ensure consistency and validation that the correct patient receives the designated treatment at the right time, reducing error and vastly improving patient safety."

Jessica Bernardo, Senior Product Marketing Manager, Barcode and Label Print Solutions, Toshiba America Business Solutions, offers even higher praise.

"Thermal bar-code printers are the unsung heroes of smooth logistics and healthcare practice excellence," Bernardo said. "No doubt, patients attribute successful medical outcomes to clinicians, facilities and thorough aftercare. Working behind the scenes for each of these are essential technology components that are often invisible but extremely critical in determining successful outcomes.

"This is true for thermal barcode printers," she continued. "These systems allow clinicians to track medical supplies and medications, ensuring administrative accuracy of medicines while securing and maintaining the privacy of patient data in an effective, efficient and affordable manner. Thermal bar-code printing is an integral and dependable element of healthcare delivery with oftentimes nary a thought to its existence. Printers perform in small spaces with minimal maintenance and low cost. Devices can easily accommodate various size labels or even patient wristbands and require little knowledge to print multiple labels at one time. From patient admissions to the pharmacy and more, thermal bar-code printers are the workhorses behind successful patient care."

Angela Fernandez, Vice President Community Engagement, GS1 US, recalls the bar code's early 1970s roots "to support price lookup at point of sale in retail to expedite the checkout process," but adds that it has grown beyond that original mission.

"Since [then], bar codes have evolved to become an essential data carrier to provide track and traceability for products as they move through supply chains," Fernandez said. "Today, bar codes can hold product identification and essential information such as lot and batch numbers, expiration dates and other pertinent details to assist in tracking the product's entire life cycle. This data is essential to healthcare in an increasingly complex supply chain and patient care system, helping prevent errors and assure availability of medical products when and where they are needed."

Fernandez acknowledges the slower pace of bar code progress in healthcare versus grocery and retail.

"The healthcare industry did not begin broadly adopting bar codes until the early 2000s," she noted. "Recognizing the need for better, more reliable and more robust data to help manage pharmaceutical and medical device supplies, healthcare stakeholders are now widely using global standards and barcodes in their daily operations. Today, even the patients are identified by bar codes on the bracelets they wear in a hospital – helping to increase safety, ensure they receive the right medication or product, and to populate health records with details about the products that are used in their care."

In fact, the bar code has been much more widely applied across healthcare to improve operational efficiencies, accuracy and patient safety, according to Fernandez, in that It is used to carry data that uniquely identifies pharmaceutical products and medical devices and to provide additional details about them. "The bar codes can be scanned throughout the supply chain to enhance track and traceability, simplify and expedite recalls where necessary, help identify expired product for removal and more," she continued. "When the bar codes are also scanned into patients' electronic health records, follow-up monitoring can be extended to offer better tracking of outcomes, side effects and other information that helps providers understand their efficacy and make more informed purchasing decisions for the future."

Government regulations, such as the FDA's Drug Supply Chain Security Act, or DSCSA and Unique Device Identification Rule, or UDI, are driving momentum because they now require standardized bar codes on packaging for prescription medications and medical devices, respectively, she added.

The emergence, adoption and implementation of global data standards for unique identification of products, locations and services underpin bar coding's growth, according to Fernandez. Globally recognized standards ensure information contained in a bar code can be scanned, captured and incorporated into diverse data systems utilized by supply chain stakeholders, and understood by all as a common language for organizations to communicate vital information about the products they manufacture, distribute, and use, she added.

"Using these standards, the captured data can be shared between organizations throughout the supply chain to help ensure the right product (medication or device) reaches the right patient, at the right time, in the right location and in the right dose or use. We refer to these crucial parameters as the 5 Patient Rights," Fernandez said. "The use of GS1 Standards continues to increase in healthcare partly to support legislative requirements, and overall, to help improve the entire healthcare system's ability to continually provide the best possible patient care and safety.

## Radiofrequency identification (RFID) in healthcare

**KEY SUPPLIERS:** CenTrak, GE Healthcare, **IDENTI Medical**, IOS, Jump Technologies, Stanley Healthcare, TeleTracking, T**erso Solutions**, **Toshiba**, Versus, **VUEMED**

**WHY IT MATTERS:** Bar coding may have emerged in healthcare in the mid-1970s, but its "more advanced" younger sibling RFID needed at least another 15 years to place its flag in the sand alongside bar coding among the most forward-thinking of hospital supply chain leaders.

"Bar-code scanning and/or RFID serves as the foundation of any modern point-of-use technology," observed Mike Ferrazzo, Product Manager, Jump Technologies. "It has allowed for a fast, simple and accurate means of recording supply consumption in a hospital. It also has helped improve patient care and safety by reducing the time clinicians have hands on keyboards, while providing more accurate identification of staff, patients, equipment, medications and implants used in a procedure."

Joe Pleshek, President and CEO, Terso Solutions, envisions a bright future for RFID in healthcare.

"RFID has been and will continue to be rapidly adopted in the healthcare market to improve inventory visibility across the supply chain," Pleshek said. "Enhanced visibility to critical supplies enables each stakeholder to be more efficient, lower costs and ensure patient safety. Traditionally, the management of inventory has been very manual, requiring clinicians to take stock counts, check expiration dates and update software systems as products are being consumed throughout a procedure.

"I believe life for clinicians and patient care already looks a lot different on the other side of RFID inventory management systems," he continued. "With this technology, the management of inventory is automated, allowing clinicians to spend their time on providing patient care instead of searching for inventory."

Today, automation such as RFID are helping to relieve workplace pressure as hospitals deal with labor shortages across the country, according to Pleshek.

"From a patient safety perspective, RFID is ensuring product integrity and chain-of-custody," he indicated. "Many therapies, specialty pharmaceuticals, and biologics need to be consistently stored at a certain temperature. Terso Solutions' RFID enabled freezers, refrigerators and cabinets automatically track when a product or pharmaceutical has been removed from the device, who removed it and if the temperature of the product has been compromised in any way. We are just scratching the surface of the value RFID can bring to our healthcare system."

Regardless of automated tracking modality, adoption and implementation remains a long slow climb.

"Hospitals always seem to us an advanced place – it's true when it comes to clinical innovation," said Or Lomnitz, Head of Marketing and Strategic Partnerships, IDENTI Medical (formerly LogiTag). "But when it comes to operational processes today there are still administrative tasks that are done manually or with outdated technics that consume time away from patient care and fail to give a full business view to the hospital management.

"One of the most prominent areas is the management and documentation of medical implants and consumables in operating and procedural rooms," Lomnitz continued. "Today's solutions do not provide a satisfactory solution to those unique and stressful environments. As a result, the hospital is exposed to risks of patient safety, waste and burnout of the nurses. The core reason is that hospitals find it difficult to capture inventory utilization and trace stock at point of use.

"It leads to uncertainty in inventory available on core areas` shelves," she said. "For example, it has often happened that expired products have found themselves transplanted into a patient. Or a case of a recalled product that because no digital tracking was done, it was not possible to

locate those transplanted people. This is the reason why data-capture regulations as the FDA's UDI rule is being forced in the past 10 years. Today hospitals management realize they must invest in data integrity in point of care."

Lomnitz promotes that IDENTI Medical "cracked the system" and developed an easy-to-use platform that provides complete visibility in operating and procedural rooms.

"While the other solutions concentrate on resolving the symptoms, the IDENTI platform addresses the problem itself. By combining UHF-RFID Smart Cabinet with Snap & Go image-based charge-capture, we deliver a clear and safe view of the current stock and usage. When all items and costs are documented, accurate management is made possible."

Arnold Chazal, CEO, VUEMED, identifies and outlines seven ways RFID makes a difference in the healthcare supply chain, spanning accuracy of documentation and item tracking, reliable data to guide decision-making, increased productivity and substantial savings and revenue generation. For Chazal, RFID enables the following:

1. Makes the monitoring, documenting, and accounting of items efficient, accurate and easy – it's hands free, cabinet free and virtually error-proof;
2. Provides an item's location and chain of custody in the hospital at any moment, and can track assets, patients and personnel with equal agility using the same light, inexpensive overhead infrastructure;
3. Enables UDI regulatory compliance by embedding the item's unique ID and all pedigree data like lot/serial number and expiration date on its tags;
4. Reports in real time on product availability and low par levels, automates replenishment, and optimizes inventory size and composition by providing the data visibility needed to be proactive and take action;
5. Increases billed revenue and patient record accuracy through automated, accurate clinical documentation at the point of care;
6. Reduces waste by automating expiration tracking so that items no longer expire on the shelves, and protects patients by preventing expired and recalled items from reaching them;
7. Guarantees swift and easy recall management by being able to report instantly on usage of recalled products in completed patient procedures, which saves time for clinicians and identifies the concerned patients for proper follow-up care.

"When used in combination with smart key performance indicators (KPIs), optimization software and Cloud analytics, RFID technology can lead to dramatic improvements," Chazal continued. "In one of our case studies involving a large academic medical center in California, expired items have been maintained at less than 0.5% of total inventory value; unused inventory and inventory above recommended PAR levels have been reduced by more than 60%; and billing accuracy is now more than 90%, just to name a few key results."

VUEMED uses RAIN RFID technology to power its clinical inventory management and supply chain optimization solutions in hospitals – a type of advanced RFID distinguished by its use of the GS1 UHF Gen2 protocol, according to Chazal.

"RAIN RFID isn't new," he noted. "The adoption of RAIN RFID is broad and deep, spreading across many industries around the globe. It is new to healthcare, however, and we are seeing a growing level of interest in this set of capabilities as providers are looking for ways to gain more visibility and control over their operations in a world where they are continuously under pressure to control costs and juggle labor shortages, while simultaneously delivering high quality patient care.

"With RFID, we now have the Internet of Things (IoT) for medical devices and supplies. From application of the tag to their use at the point of care, each individual item is recorded in the Cloud, as well as every event and location associated with it," he continued. "Providers can now identify the exact location and usage of all medical supplies and products at all times, thereby dramatically improving clinical documentation, integration of key supply data into other systems, and ultimately patient outcomes."

Todd Stewart, Vice President, Enterprise Workflow Solutions at CenTrak, emphasizes the necessary productivity gains that automated location technologies provide healthcare organizations.

"The demand for care has increased exponentially over the past decade, and there is no sign of it slowing down," he said. "Powered by CenTrak RTLS (real-time location systems), RFID tags are crucial resources for healthcare facilities, patients and staff. Health systems need operational workflow automation to help them work smarter, not harder. This approach improves outcomes while simultaneously reducing the operational cost of care delivery in a scalable, repeatable manner."

## Mobile clinical/medical/reprocessing facilities

**KEY SUPPLIERS:** Extreme Canopy, Mastertent, **MMIC Medical Systems**, Sprung Structures, **STERIS**, TentCraft

**WHY IT MATTERS:** Whether dealing with over-capacity service demands or the aftermath of some crisis or disaster, hospitals and other healthcare facilities have appreciated and relied on mobile units to provide a variety of services, including diagnostic imaging, laboratory testing, sterile processing, standard medical care and during the last year or two, COVID-19 testing and vaccine distribution and injection.

But these facilities extend far beyond "pop-up" service providers. They can amplify or reinforce existing service, particularly during construction and renovations.

"Sterile Processing Services (SPS) have been notoriously ignored until recent problems, traced to a lack of understanding [of] properly sterilized instruments used for surgery," said Janet Lumbra, Director of Business Development, MMIC Medical Systems, which manufactures and markets temporary facilities to ensure business/service continuity. "These problems awakened hospitals to the importance of the SPS role in reducing the risks associated with hospital acquired infections (HAIs). As a result, many hospitals are upgrading, updating, and totally overhauling outdated SPS departments to be effective in their role as the first line of defense against HAIs. These renovations receive top priority with facilities as their implementation maintains a good reputation of the facility well into the future."

To facilitate a code-compliant on-site solution for hospitals to use during renovations is one of the primary reasons MMIC Medical Systems designed its Mobile Sterile Processing System, according to Lumbra. "Now clinicians have a solution that retains staff, ensures proper processing protocols are preserved during the renovation while also providing the assurance of code compliance, perhaps even to a greater degree than the space they are renovating," she noted.

STERIS Corp. offers its STERIS Mobile Sterile Processing Unit as a one to three expandable semitruck platform that "allows for a turnkey solution and process to continually support the SPD and Surgical department delivered to the hospital site to support clinicians without disruption during hospital construction, renovation, or emergency situation," said Nicholas Shelton, Director of Mobile Solutions.

"Turnkey Mobile SPD solutions enable hospitals to maintain 100% surgical volume and a high level of infection control during construction renovations and emergent situations," Shelton indicated. "A Mobile Sterile Processing Unit is a fully integrated, Mobile SPD that allows for a turnkey process to continually support the OR without disruption during times of construction, renovation, or emergent situations. The Mobile SPD solution creates value for hospitals by decreasing down-time, lowering costs, and creating an environment for continual effective sterilization."

STERIS maintains a large fleet of mobile SPD units that has responded to facility renovations that have lasted months to years, surgical capacity demand increases and emergencies, including floods from hurricanes and rivers, fires, sewage backups, HVAC issues and compliance issues, according to Shelton.

"The STERIS Mobile SPD has supported hundreds of projects over the years and continues to allow clinicians, SPD and Surgical departments to maintain a high level of care for patient populations and is truly an innovative product and solution that is unique in the marketplace," he added.

## Capsule endoscopy, a.k.a. pill camera

**KEY SUPPLIERS:** Capsovision, Chongqing Jinshan Science and Technology, Medtronic (via acquisition of Covidien, which acquired Given Imaging Ltd.), **Olympus**, IntroMedic

**WHY IT MATTERS:** By using a small wireless camera that can be swallowed by the patient a doctor can see inside that patient's digestive tract, including the esophogas and small intestine. This enables doctors to diagnose cancer, gastrointestinal ailments and bleeding as well as see polyps more quickly. Capsule endoscopy provides faster access to internal visualization without the need for invasive surgery. Where the diagnostic imaging modalities provide views inside the body from outside the body, capsule endoscopy provides views inside the body from inside the body.

Philip Doyle, Executive Director of Marketing for Endoscopy at Olympus Corporation of the Americas, traces the roots of this technology to the early 1950s when the first gastrocamera was developed to allow doctors to see all parts of the gastrointestinal (GI) tract. But there were limits.

"As technologies evolved through the end of the 20th century, the endoscope allowed doctors to reach to the end of the colon and into the stomach," Doyle said. "But most of the small intestine remained off limits to endoscopic technology due to its tortuous anatomy that includes 20 feet of loops and turns and a very compact lumen."

Not all parts of the GI tract were able to be seen without surgery until the advent of the capsule endoscope, which means that diagnosis and treatment of digestive diseases and disorders, such as Crohn's disease, GI bleeding and small bowel tumors were very challenging, according to Doyle. Doctors were able to see inside the small bowel, courtesy of the capsule endoscope in 2001.

"With this pill-sized, wireless capsule endoscope, the small intestine is fully scanned while the patient is at home, and physicians can process and access imagery without the need for lengthy hospital procedures," Doyle noted. "Patients wear an antenna belt and a recorder. The pill takes about 8 hours to travel through the digestive tract, and once it's done, the patient gives the equipment back to the physician, who downloads the exam into processing software and reads the exam. There are risks associated with this type of procedure, including potential interference with implanted electronic devices and possible retention of the capsule endoscope, which may require open surgery."

Endoscopic technologies continued to advance enough to allow physicians access to the small bowel for non-surgical treatment, according to Doyle. "With the introduction of balloon-assisted enteroscopy, physicians were able to move the endoscope deep within the small bowel, and now it is possible to perform many minimally invasive treatments of the small bowel, such as removing polyps, opening blockages, sampling tissue, and stopping bleeding, without the need for surgery." [1,2]

**WHAT IF IT DIDN'T EXIST TODAY:** Without Given Imaging pioneering the field of capsule endoscopy two decades ago, physicians either would have to rely on the diagnostic imaging modalities such as MR that allow views of organs and soft tissue or at the very least more invasive surgical techniques.

## Surgical staple

**KEY SUPPLIERS:** Johnson & Johnson's Ethicon division, Medtronic (via acquisition of Covidien, the former U.S. Surgical)

**WHY IT MATTERS:** Questions might be raised about why the surgical staple makes it into the Hall of Fame earlier than its predecessor, the suture. Fair question. The challenge for the suture is that, by and large, it's nothing more than "medical/surgical-grade thread" that is part of a much-larger family of products that include rope, string, twine, etc., and is used in multiple industries and markets. But then some might counter with the fact that staples are used in packaging (think corrugated cardboard boxes and containers) and form/paper groupings as well as serving as the brand name for a famous office supply store. Again, fair enough. But surgical staples represent a noteworthy advancement and alternative to suture in how they function within the anatomy and affect the healing process.

The surgical staple, by and large, offer a number of benefits that differ from traditional suture, which is why it tends to be the tissue closure of choice for minimally invasive surgical procedures. Benefits include convenience and portability in that the surgical stapler can be inserted into the body cavity quickly and activated to connect tissue after an organ has been removed (resection) or sealed (transection). Until absorbable staples were manufactured (like absorbable suture), the surgeon could remove them rather easily and quickly compared to suture. This also meant that the patient spent less time in surgery and under anesthesia, compared to when suture was used. Finally, because of their durability and strength, surgical staples tend to be used on the skin to close skin "under high tension," such as the scalp for cranial and neurosurgery.

During the last decade, the U.S. Food and Drug Administration has received reports of problems and data involving device malfunctions that led to several major product recalls. The FDA also held public meetings that led to a final guidance on labeling as well as reclassifying surgical staplers for internal use as a Class II (moderate risk) medical device from a Class I (low risk) medical device.

**WHAT IF IT DIDN'T EXIST TODAY:** Doctors and surgeons still would have access to suture and thread, but that would be the extent of it. One wonders also that if staples weren't conceived, developed and used as an upgrade to suture would the industry innovate to the point of developing surgical glue, which has been an All-Star nominee for two years? HPN

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# The Critical Role of Sterile Supply Management During COVID

By John Jorge, CSD/SPD Director at St. Francis Hospital and Medical Center

It is no secret that hospitals around the world are under extreme pressure to maintain a safe and sterile environment while managing a rapid influx of patients during the COVID-19 pandemic. These efforts have put pressure on both hospital staff and supplies. Many hospitals are facing significant backlogs as they scrambled to provide treatment to COVID patients as efficiently as possible while also ensuring that they address the needs of other patients.

For many hospital managers, this unprecedented scenario highlights areas where hospital operations are often at risk – including workflows and procedures related to sterilization. As these challenges continue, there is growing evidence that hospitals that took steps to integrate a sterile reprocessing management solution before the pandemic are better positioned to maintain top-level patient care.

### Staying safe and organized with T-DOC by Getinge

When the pandemic hit, hospitals were thrown into a world of chaos as we worked to treat patients and keep staff members safe. I heard many stories from colleagues at other hospitals who quickly ran out of sterilized products that resulted in procedure delays and significant disruptions in workflows. Hospital teams often had to scramble to find the products they needed. Thanks to our asset tracking system called T-DOC 2000, St. Francis Hospital and Medical Center was able to stay ahead during these challenging times.

Installed in 2001, T-DOC 2000 provides access to full traceability of instruments and other goods the operating room needs. The system also documents all the sterile processing steps necessary to ensure regulatory compliance and quality assurance. The T-DOC solution seamlessly integrates into our existing scheduling, materials management and finance systems. With this capability in place, when the pandemic hit, the automatic prioritization feature made it possible to identify and triage the instruments that need to be processed to prevent scheduling and operating room delays. T-DOC also integrates with our materials management system, which helps reduce the risk of backorders and replenish instruments that are needed for upcoming procedures. Our T-DOC system continues to manage these needs even as we see rapid exponential growth in patient admissions.

T-DOC 2000 ensures full traceability of instruments and other surgical assets.

### Addressing problems before they happen

Keeping washers and sterilizers running at optimal levels is imperative during regular times and even more so during times of crisis. A second resource called Getinge Online provides digital support to manage workflows and address problems before they arise. Through this online platform we can access extensive real-time information on our Getinge washers and sterilizers, 24/7 from any location. The system also sends an alert text message if there is an equipment error or when an important process is complete. If there is an issue, I can go back through the last 30 printouts to confirm and address the problem. I am also able to communicate with members of the Getinge service team and stop or start any instrument sterilization procedure, all from my phone. The service also provides detailed analytics that help assess the performance of Getinge equipment as well as related throughput, productivity, and ensure compliance and regulatory requirements.

### Sterilization in a post-pandemic world

As we begin to recover from the pandemic, the importance of efficient workflows and high-level sterilization remains top of mind for physicians and hospital decision makers. Systems like T-DOC that allow for integrated use and real-time monitoring can help ensure departments have the tools they need to better support patients by reducing surgery delays while ensuring patient and physician safety. Without these solutions, we would not be able to provide patients with the care they need.

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*2021 Healthcare Product All-Stars*

# Six products represent year of personalization

If there's an underlying common denominator among the 2021 All-Stars it's size, portability and convenience to the end user/patient. In general, this year's All-Stars are easily accessible and stored or even … wearable, which has blossomed in popularity within the last two years or so, due in part to pandemic-related restrictions.

## Wearable fitness/health trackers

**KEY SUPPLIERS:** Amazon, Apple, DarioHealth, Fitbit, FitsWatch, Google, Masimo, Omron, Oura

**FIELD PERFORMANCE:** You'd be hard-pressed to miss all of the media attention and hoopla surrounding the emergence of a growing number of personal health trackers. Last year, *Healthcare Purchasing News* recognized the hand-held external temperature scanner and the wearable glucose monitor. This year adds in the smartwatches tied to smartphone apps as well as the smartphone apps themselves, necklaces, pins and even a finger ring that enables the wearer to check, record and transmit various vital signs and sleep habits to clinicians for populating the electronic health record. Such data production, collection, storage and transmission can augment – but not replace or supplant – the live, in-person exam with a clinician.

**IF BENCHED:** You eliminate the convenient access to basic vital signs, which means reverting to making live, in-person appointments with physicians and/or physician assistants and nurses at retail clinical outlets.

## HeartLogic remote heart failure diagnostic/monitor

**KEY SUPPLIER: Boston Scientific**

**FIELD PERFORMANCE:** This is a "personalized, remote heart failure diagnostic and monitoring" device that uses "multiple physiologic sensors with high sensitivity and low-alert burden," according to manufacturer Boston Scientific. Basically, it's designed and validated to provide "weeks of advance notice for detecting early signs of worsening heart failure," citing a MultiSENSE study in a clinical journal.

**IF BENCHED:** Little to no warning of a potential cardiac event.

## At-Home OTC COVID-19 test

**KEY SUPPLIERS: Quidel (QuickVue brand)**

**FIELD PERFORMANCE:** This non-prescription product is available at many prominent and well-known retail outlets and online and promises to provide rapid results in 10 minutes. Imagine if this were available in mid-2020 as the lines formed in remote testing stations around the country.

**IF BENCHED:** Long lines at remote testing stations throughout 2021 and in testing queues in places of business until vaccinations become mandated on federal, state and local levels with severe financial, legal and occupational penalties for non-compliance.

## HeartGuide wearable blood pressure monitor

**KEY SUPPLIERS: Omron**

**FIELD PERFORMANCE:** While this technically can be included in the wearables category, what makes this product worth singling out is its clinical accuracy and FDA clearance to provide blood pressure and pulse rates and sleep patterns.

**IF BENCHED:** More frequent visits to the doctor or retail clinic, if necessary, or more effort and time in using your own 2021 Hall of Famer blood pressure cuff.

## Cerebrotech Visor for stroke detection

**KEY SUPPLIERS:** Cerebrotech Medical Systems

**FIELD PERFORMANCE:** This portable, wearable neurotechnology device is a non-invasive technology designed to assist in the "assessment of fluid volume asymmetry between the cerebral hemispheres" in adult patients under neurological care. It provides real-time assessment of brain fluid distribution in about 30 seconds, facilitating earlier intervention to prevent further brain damage, according to the manufacturer.

**IF BENCHED:** Interest in and pursuit of early stroke detection has grown during the last few years as a way to prevent serious debilitation and mortality. In a sense, for patients and clinicians to be forewarned translates to being forearmed.

## Vidashield UV24 Air Purifier

**KEY SUPPLIERS:** Nuvo Surgical

**FIELD PERFORMANCE:** To environmentalists, LED lights may be all the rage, but during the pandemic of the last two years for clinicians and infection preventionists alike, the growing popular choice is ultraviolet (UV) light as a way to kill microorganisms, including COVID-19, on surfaces and in the air. Although numerous manufacturers and distributors of this technology have emerged and reached out to *HPN*'s audience, the VidaShield UV24 garnered a considerable number of readership votes during the September and October online campaign to warrant its own spotlight.

**IF BENCHED:** Sure, there may exist a variety of choices and options on the market, but if UV technology as an infection prevention device were unavailable then healthcare professionals would rely on other means of disinfecting, sanitizing and sterilizing surfaces and the air. This might be more time consuming and require more effort than an automated system of filtering light. How that translates to extending the duration of the pandemic is left to clinicians and scientists to discuss and validate. HPN

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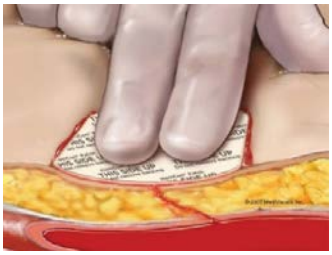
## TRICOL BIOMEDICAL

**HemCon OneStop Vascular**



Tricol's hemostatic device for vascular closure rapidly controls bleeding even for anticoagulation therapy patients. OneStop Vascular leverages chitosan technology working independently of the body's clotting cascade, forming a strong, adhesive seal when contacting blood. OneStop provides an antibacterial barrier and is clinically proven to reduce hold times. Distributed through Medline.

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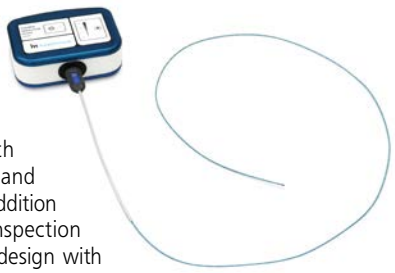
## HEALTHMARK



The **FIS-007 borescope** is designed to visually inspect internal channels of potentially soiled or damaged items with enhanced light, vision, and magnification. This new addition to the ProSys Optical Inspection line features a modular design with interchangeable flexible inspection scope attachments available in multiple diameters. These scopes have a working length of 110cm and attach to a control box which allows for light level adjustments, image capture, and video recording.

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## DALE MEDICAL

**Post-Surgical Bra**

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## R-ZERO

**R-Zero's Arc UV-C** air and surface disinfection device resets the pathogen risk in any unoccupied space to zero. Arc delivers the best performance on the market with shorter cycles and higher efficacy. Arc can disinfect the air and surfaces in a 1,000 square foot room in 7 minutes.

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# Addressing supply shortages with standard identifiers

*by Karen Conway, Vice President, Healthcare Value, GHX*

Using standard device identifiers can deliver multiple benefits, from touchless orders to more accurate clinical supply documentation. But what about addressing the supply shortages that continue to plague hospitals? Standard identifiers, in combination with classification codes and descriptions, can help healthcare delivery organizations find acceptable alternatives in the event of shortages, while more widespread use across healthcare can also help ensure products are where they are needed most. In this month's column, we will explore what is possible if a single health system, or even the entire country, used standard product identifiers like GS1 Global Trade Item Numbers (GTINs) to identify products.

The GTIN is one of the codes compliant with the U.S. FDA's UDI rule, which requires manufacturers to assign a unique device identifier (UDI-DI) to their products at each packaging level. For example, the same product packaged in a box of 12 would have one UDI-DI, while the same product packaged in a case of 6 boxes of 12 each would have a different UDI-DI (illustrated in Figure 1 as the different last digit in the device identifier column and in the UOM column).

## How creating a cross-reference table supports addressing vendor backorders

Figure 1 is a cross-reference table (simplified for demonstration purposes) that shows how a hospital could find alternative vendors or products using GTINs as the UDI-DI.

Let's say your hospital normally buys a mask manufactured by Acme Medical from Smith Distribution. If Smith Distribution is not able to supply the mask, you could use the GTIN in the first column to determine that another vendor, All Products Distribution, sells the exact same mask, packaged either as a box of 12 each, or as a case of 6 boxes of 12 each. The similar numbers in red represent a company prefix associated with the manufacturer in the GS1 system.

But what if Acme Medical cannot supply the masks to either distributor? In this case, your hospital could use the combination of the UNSPSC classification code (grouping similar products) and the description to find a suitable substitute, this time made by a different manufacturer but sold by your usual vendor, Smith Distribution. The different company prefix represents the different manufacturer.

Now, let's consider what happens when you are not able to procure a product, this time a respirator, directly from the manufacturer. By looking at the last two rows in Figure 1, your hospital determines that the same product (but at a different packaging level) is sold via distribution from All Products. Note the device identifier has the same company prefix but a different last digit in the device identifier column and the different UOM.

## Using standard identifiers to address widespread shortages

Figure 2 depicts the potential value to a single, multi-hospital system, as well to the nation as a whole, in the event of widespread shortages like we experienced with personal protective equipment (PPE) early in the pandemic. During those shortages, every hospital system reported their PPE inventory levels and burn rates. If a health system uses UDI-DIs across hospitals, it could see the respective inventory and consumption levels, both for the same product and ones that it has deemed acceptable substitutes, and as such, could move product to where the need is greatest.

Now consider if all hospitals not only used UDI-DIs in those reports, but also all of healthcare, including the Strategic National Stockpile (SNS) and both PPE manufacturers and distributors. In this case, we would have had a much better understanding of where the need was greatest as the pandemic hit different parts of the country harder at different times. Further, with use of the Global Medical Device Nomenclature (GMDN), a code based on regulatory approval based on use and available in the FDA's Global UDI Database, the SNS could determine functional equivalency in emergency situations. As such, we would have had much better data with which to prioritize deliveries to support needs-based allocation.

**FIGURE 1: Sample Cross Reference List**

| Device Identifier | Manufacturer | Vendor | Noun | Type | Description | UOM | UNSPSC | Commodity |
|---|---|---|---|---|---|---|---|---|
| 012345XXXXX221 | Acme Medical | Smith Distribution | Mask | Face | MASK FACE ACME EARLOOP | Box of 12 each | 42131713 | Surgical isolation or surgical masks |
| 012345XXXXX221 | Acme Medical | All Product Distribution | Mask | Face | MASK FACE ACME EARLOOP | Box of 12 each | 42131713 | Surgical isolation or surgical masks |
| 012345XXXXX222 | Acme Medical | All Product Distribution | Mask | Face | MASK FACE ACME EARLOOP | Case of 6 boxes of 12 each | 42131713 | Surgical isolation or surgical masks |
| 054321XXXXX331 | Jones Medical | Smith Distribution | Mask | Face | MASK FACE TIE LATEX FREE BLUE | Box of 24 each | 42131713 | Surgical isolation or surgical masks |
| 054321XXXXX441 | Jones Medical | Jones Medical | Mask | Respirator | MASK RESPIRATOR CONE LATEX FREE MIST | Box of 18 each | 46182002 | Respirators |
| 054321XXXXX442 | Jones Medical | All Product Distribution | Mask | Respirator | MASK RESPIRATOR CONE LATEX FREE MIST | Package of 48 each | 46182002 | Respirators |

## RUHOF

The **ScopeValet TipGuard** is an endoscopic distal tip protector which provides a simple, safe, and highly effective method of protecting the delicate optics of an endoscope, while allowing the tip to aerate, decreasing the likelihood of microbiological growth. This product fits onto a wide variety of scopes (diameters ranging from 2.5mm to 14mm), is individually packaged for one-time-use, and ensures guideline compliance.

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## RUHOF


**Elementum AW** is a multi-tiered enzymatic detergent that has been optimized for the automatic, ultrasonic, and manual cleaning of surgical instruments. Elementum AW is synergistically blended to produce the most powerful detergent for use on clinically used medical devices. This best-in-class solution has superior soil penetration and suspension, rapidly breaks down tough-to-clean medical soils, including the multi-layers of bioburden, and prevents redeposition.

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## NUVO

**UVGI Air-disinfecting Ceiling Light**

The CDC recommends the use of UVGI within indoor spaces to help inactivate SARS-CoV-2. The Vidashield UV24 is simple non-invasive upper room air disinfection solution that utilizes UV-C. Vidashield UV24 uses a UV bulb operating at 253.7 nm in an enclosed chamber to neutralize viruses, bacteria, and fungi.

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## ADVERTISER'S INDEX





**FIGURE 2: Inventory Management and Reporting (2-Hospital System)**

| Product | Hospital | Inventory on Hand | Burn Rate | Days on Hand | GMDN** |
|---|---|---|---|---|---|
| 012345XXXXXX1 | St. Mary's | 24 boxes of 12 each | 144/day | 2 | 11111 |
| 012345XXXXXX1 | St. Joseph's | 36 boxes of 12 each | 72/day | 6 | 11111 |
| 054321XXXXXX2* | St. Joseph's | 5 boxes of 24 each | 24/day | 5 | 22222 |

*The health system has deemed this product an acceptable subsitute for 012345XXXXXX1

** Numbers for demonstration purposes only (not actual codes)

While both of these illustrations are focused on emergency situations, the examples also support healthcare's long desire to implement demand planning at scale. *See the September 2021 issue of Standard Practices.* In the spirit of never let a good crisis go to waste, now is the time to leverage the UDI rule, which has made UDI-DIs available on most medical products for emergency planning, but also to support our ongoing need for better supply and demand matching to support healthcare delivery. HPN

| Class | Family | Segment |
|---|---|---|
| Surgical textiles | Medical apparel and textiles | Medical Equipment and Accessories and Supplies |
| Surgical textiles | Medical apparel and textiles | Medical Equipment and Accessories and Supplies |
| Surgical textiles | Medical apparel and textiles | Medical Equipment and Accessories and Supplies |
| Surgical textiles | Medical apparel and textiles | Medical Equipment and Accessories and Supplies |
| Respiratory protection | Personal safety and protection | Defense and Law Enforcement and Security and Safety Equipment and Supplies |
| Respiratory protection | Personal safety and protection | Defense and Law Enforcement and Security and Safety Equipment and Supplies |

# Healthcare providers shouldn't be green about going green

*by Jimmy Chung, M.D., MBA, FACS, FABQAURP, CMRP*

Most of us on this planet might consider 2020 and 2021 as the years when everything changed. Even as we struggled with the pandemic, climate change manifested itself in some of the most dramatic ways imaginable, such as record-setting temperatures, apocalyptic wildfires and unprecedented drought. Every industry is refocusing on reducing environmental harm, and healthcare is no exception.

Of the nearly $1 trillion wasted annually by the U.S. healthcare system, a significant portion is attributable to unnecessary variability and lack of standardization.[1] For example, one study showed that the average neurosurgical case wasted nearly $1,000 of unused products due to variability.[2] The average hospital could reduce supply expenses by 18% through standardization without sacrificing quality.[3] Two very tangible and high-yield opportunities can help operating rooms achieve this: reduction of GHG effect from anesthesia gases and optimized use of reprocessed products (RPs).

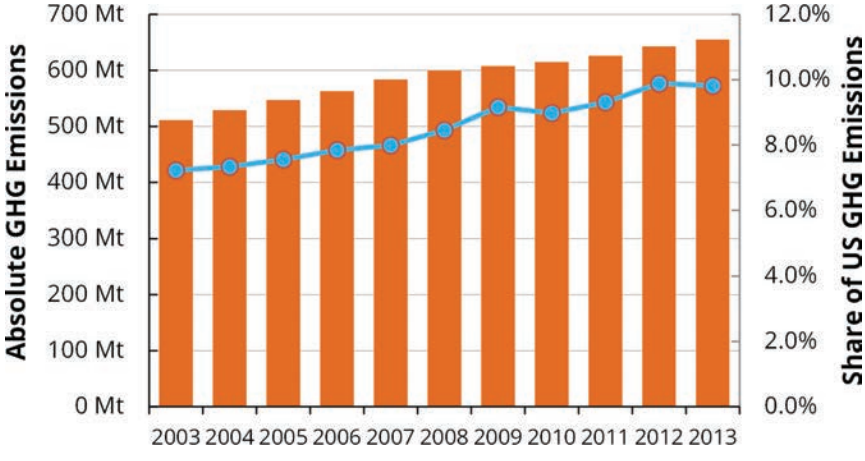
Healthcare contributes about 10% of the total greenhouse gases (GHG) emitted in the United States. Hospitals produce about 40% of this, of which about half come from operating rooms, mostly through anesthesia gases, energy use and surgical supplies.[4,5] Anesthesia gases may account for between 5% and 65% of the GHGs emitted by operating rooms, depending on the facility.[6] The wide range suggests variability that could be standardized to best practice, but most hospitals do not measure how much anesthetic gas is actually used or wasted into the atmosphere. In addition, among the commonly used anesthetic gases, there is as much as a 20-fold variance in their potency as a GHG.[7] While this is a controversial topic in the clinical community, no specific anesthesia gas has been shown to result in significant differences in any patient outcomes.[8] By changing practice, hospitals can reduce both cost and GHG emissions without affecting quality of care.

Reprocessing of "single-use" surgical devices is a solution that could reduce cost and the amount of solid waste. However, this seemingly straightforward solution is not without challenges. One major challenge is the stigma of the "reprocessed" label that incorrectly implies inferior quality, like "used" or "refurbished" products in other industries, such as cars or personal electronics. In reality, the method of "reprocessing" is often much more than simply cleaning and repackaging a used item; many reprocessed products (RPs) are technically "remanufactured," utilizing used items as raw materials.

Communicating the quality and reliability of RPs and dispelling myths about the reprocessing process to end users is critical to the success of initiatives to optimize the use of RPs. A 2015 study that compared reprocessed diathermy devices to identical original equipment manufacturer (OEM) controls found fewer defects in the reprocessed devices.[9] One explanation for this may be that RPs are individually checked and tested prior to being packaged for sale, whereas mass-produced OEM products are usually checked for quality through random selection.

Optimal use of RPs must also include a thorough analysis of their true "end-to-end" environmental impact compared to OEM products. While use of RPs should decrease the amount of solid waste (and also the demand for OEM device production), factors unique to reprocessing should also be considered, such as the energy required to collect and ship used products, the water and energy used for reprocessing and potential impact of any cleaning chemicals.

The concern for climate change and the role of supply chain cannot be overstated. Global efforts to use resources responsibly and reduce environmental harm must be sustainable and uniformly adopted by all industries. In healthcare, improving the use of anesthesia gases and increasing the adoption of RPs are just two of these opportunities that can be implemented without delay as part of a broad and holistic strategy toward stewardship and sustainability. Supply chain professionals are uniquely positioned to lead these discussions and bring together the right multidisciplinary stakeholders through education and data analytics. HPN




**Matthew J. Eckelman , Jodi Sherman, Environmental Impacts of the U.S. Health Care System and Effects on Public Health**
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0157014

*Visit https://hpnonline.com/21245954 for references.*

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