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

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Just in place

Certainly you've heard the joke by now that defined much of the pandemic-stricken 2020 for those in supply chain.

It goes like this: What did the materials manager say when he jumped out of the closet? SUPPLIES!

Let the pun-like double entendre sink in for a moment. If you get it, shhh! Don't tell anyone - not a PPE out of you! If you've never heard this one before, don't worry … *I made it up.*

Supply chain leaders and professionals definitely needed to demonstrate their creativity this past year.

A growing number already have as we've profiled throughout the year, including the award-winning *HPN* Hall of Fame team at M Health Fairview led by LeAnn Born; the award-winning *HPN* Hall of Fame team at Dartmouth-Hitchcock led by Curtis Lancaster; his compatriots across the border at University of Vermont Health Network led by Charlie Miceli; and scores of others at HonorHealth, Geisinger, CHRISTUS, Banner, INTEGRIS, St. Luke's and UPMC just to name a few.

One of the key questions emerging from the shortage and backordering of supplies is what the pandemic reactions will do to stockless, modified stockless and just-in-time (JIT) distribution and inventory models. How will they be redefined? Or discontinued? Replaced? With what?

How about just-in-place (JIP) distribution and inventory?

Back in the 1960s, Charles Housley, the healthcare supply chain Hall of Famer (Bellwether Class of 2008) boasted about the benefits of stockless distribution at his hospital. The running joke at the time by critics? His distributor's warehouse resided across the street from his hospital.

Insert the pandemic-motivated laugh track used in empty sports stadia now.

Still, under JIP distribution, this model shouldn't be so far-fetched. In fact, it's nothing more than a hub-and-spoke concept on antiviral steroids.

More than five decades ago, unless a distributor inked a lucrative long-term deal with a hospital it made little financial sense to pepper the landscape with warehouses or even "pop-up" storerooms akin to those retail outlets that sell discounted Halloween costumes from recently vacated buildings.

These days, however, with the proliferation of Amazon and its effects on FedEx and UPS, along with that successful retail Halloween model (e.g., Spirit Halloween, Halloween City) and further development of online commerce as well as the consolidation of distributors, it makes a bit more sense.

With the JIP model, the distributors could become the product and service heroes that providers need when demand far outpaces supply, courtesy of a panic-stricken public and a lack of planning. Further, the distributors politically can reinforce local and regional stockpiles and use information technology to rotate stock around to scores of public and private provider organizations that will reduce obsolescence and waste (think expiry dates).

John Gaida, another healthcare supply chain Hall of Famer (Bellwether Class of 2018), once invested in a vacated department store facility to use for his hospital system as an "off-site" warehouse.

Bottom line? The model's been around for decades. Someone just needs to dust it off, polish the chrome, install a few enhancements and update it for the 21st century. It's doable. And at this point, decidedly needed.

Need a pick-me-up? Start humming a personalized version of R.E.M.'s famous song with a twist … "It's the end of the *year* as we know it … and I feel fiiiiine!"

Then click on SMI's nod to the healthcare supply chain on October 7 by Christine Dean and Nancy Anderson ("Honoring You – Our Healthcare Supply Chain Heroes," https://www.smisupplychain.com/draft-sosc?tmpl=component) as well as what Bellwether League posted back on March 20 ("Hall of Fame for Healthcare Supply Chain Leadership salutes everyone doing their part, making a difference," (http://www.bellwetherleague.org/media.html).

Contrary to critical belief, the supply chain isn't broke. Nor is it a joke. The supply chain merely needs to bend, and supply chain leaders just need to be ahead of the curve.

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FAST STATS

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Kaufmann Hall released "The 2020 State of Healthcare Performance Improvement Report: The Impact of COVID-19," which included responses from hospitals and health systems surveyed in August 2020. For respondents:

41%

said case numbers were climbing in their markets compared to those (23%) that said case numbers were declining.

48%

have encountered significant issues with length of stay or patient throughput and have had to cancel non-emergency procedures.

33%

saw operating margin declines in excess of 100% in year-over-year comparisons of Q2 2020 with Q2 2019.

48%

saw increases in bad debt and uncompensated care.

38%

saw a reduction of commercially insured patients.

22%

saw expense increases of more than 50% for first, personal protective equipment (PPE), and second, nursing staff labor.

73%

had established designated "clean" facilities or units for non-COVID patients.

75%

had increased monitoring and resources to mitigate staff burnout and address issues of mental health.

56%

saw more than 100% growth in the number of telehealth visits that their organization provided.

31%

said that competitive dynamics in their market had been affected as more consumers sought out care from retail-based clinics, such as CVS, Walmart, or Walgreens.

https://www.kaufmanhall.com/sites/default/files/documents/2020-10/2020%20Performance%20Improvement%20Report_KaufmanHall.pdf

NEWSWIRE

Vizient announces the acquisition of Intalere

Vizient, Inc. announced that it has signed an agreement under which it will acquire Intalere from Intermountain Healthcare, enhancing itself as a leader in the healthcare supply chain.

Intermountain Healthcare will now partner with Vizient for supply chain solutions and services, thereby expanding their current relationship with Vizient in clinical and cost analytics.

"This acquisition builds on the strengths of both Vizient and Intalere and furthers our ability to meet the growing needs of the increasingly diverse range of members and customers we serve," said Byron Jobe, Vizient's president and chief executive officer.

The planned acquisition will support and fuel Vizient's mission to strengthen members' delivery of high value care by aligning cost, quality and market performance by:

- Reinforcing our commitment to supply chain as a strategic asset for healthcare providers;
- Expanding our non-acute footprint to create additional opportunities through our Vizient subsidiary, Provista; and
- Increasing our presence in smaller and/or rural acute facilities, helping support these communities with local healthcare services.

"Intermountain Healthcare looks forward to continuing to work together with Vizient in our common goal of providing patients access to high-quality care at the most affordable cost," said Bert Zimmerli, chief financial officer and executive vice president at Intermountain. "This aligns very well with our aspiration of executing a population health strategy by providing value-based care and services to an increased number of patients, families, and communities."

The transaction is anticipated to close during Q1 2021, pending standard regulatory review.

TractManager agrees to be acquired by symplr

symplr, backed by Clearlake Capital Group, L.P., has signed a definitive agreement to acquire TractManager from Arsenal Capital Partners, announced TractManager.

The acquisition enables symplr to deliver the healthcare industry's most complete end-to-end GRC software and services platform. Symplr's SaaS platform will now serve as the single source of truth for provider data management, workforce management, vendor and visitor management, contract lifecycle management, spend management, compliance, quality, and patient safety. The symplr platform addresses the full spectrum of healthcare labor and supply chain regulatory requirements while supporting the delivery of improved quality of care and patient outcomes.

Together with TractManager, symplr will enable healthcare organizations to manage provider and supply chain data, including credentials, authorizations, privileges, quality metrics, staffing, time and attendance, contracts, and spend across employees and third parties. Additionally, customers will benefit from the expanded scale, platform innovation, corporate resources, and service capabilities the combined company will deliver.

Treatments for early COVID-19 infection are a benefit to patients and healthcare systems

COVID-19 treatments for people with early infection are needed urgently, according to a *JAMA Viewpoint* article by National Institute of Allergy and Infectious Diseases (NIAID) Director Anthony S. Fauci, M.D., and colleagues. Treating people early in the course of infection with SARS-CoV-2, the virus that causes COVID-19, would speed their recovery, reduce the likelihood that they develop severe outcomes and reduce demand on the healthcare system, they write.

Despite experiencing only mild symptoms early in infection, many COVID-19 patients progress to severe disease that leads to hospitalization. Some also will experience lengthy recoveries and develop long-lasting fatigue, mental impairment and problems with heart and lung function.

While several treatments, such as remdesivir and dexamethasone, are either available or in development for severe COVID-19, interventions that can be administered early during the course of infection to prevent disease progression and longer-term complications are urgently needed.

Studies are underway to assess whether existing antivirals can be repurposed for early treatment. Scientists also are exploring the effectiveness of early treatment with therapies that specifically target SARS-CoV-2, such as convalescent plasma and monoclonal antibodies. Investigators also are exploring strategies to deliver therapies by alternative routes than by intravenous infusion, such as by inhalation or intramuscular injection.

Continued research is needed to refine current treatment candidates and develop new drugs, and treatments will need to be administered easily and made available widely at low cost, according to the authors. HPN

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Supply Chain & Sterile Processing Operations Worth Watching

Supply Chain, Sterile Processing Elite show why they're the best and brightest

by Rick Dana Barlow

Two of three camps of opinion threatened to undermine the 9th annual "Worth Watching" series by *Healthcare Purchasing News* published each December that celebrates noteworthy supply chain operations.

Using the pandemic as context, one camp believed that because of the intense market pressures this past year – what with seemingly insatiable demand crashing into a rash of backorders and stockouts – every healthcare organization's supply chain team should be saluted for weathering the storm to the best of their abilities.

For realists, it's hard to argue with that assertion.

A rival camp, using the pandemic as context, felt that for the same causes already listed as justification for celebration, those reasons perhaps should prevent anyone from being honored and recognized because the profession and function, by and large, stumbled, if not failed, in their mission and task.

For purists, it's hard to argue with that assertion, too. But it resonates as a harsh assessment of a beleaguered group trapped between crises as they apparently were not as prepared for a virus so dangerously and quickly contagious.

Instead, *HPN* embraced the third camp, which acknowledges that the show must go on, continuity necessary for morale, and because there are quite a few supply chain teams accomplishing great things because of – and in spite of – the pandemic.

But wait, there's more.

This year, *HPN* decided to expand the "Worth Watching" franchise beyond Supply Chain Operations and extend it to Sterile Process Operations, too. After all, Sterile Processing & Distribution (SPD) departments, like Supply Chain, remain as unsung heroes in healthcare provider production, as SPD hunkers in much closer to Surgical Services, a key customer they share with Supply Chain.

The December edition of *HPN* traditionally spotlights "Supply Chain Operations Worth Watching" by soliciting nominations from all sectors of the industry (providers, suppliers, group purchasing organizations and consulting firms) and conducting background research to determine those that emerge at or near the top.

This year, 10 organizations join 100 other ongoing healthcare supply chain superstars profiled by *HPN* since 2011, bringing the grand total to date to 110.

Generally, once an organization's Supply Chain department/team "makes the list" it remains "worth watching" unless its 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 110 Supply Chain Operations Worth Watching, visit HPN Online.*

This year, we add SPD teams to the pantheon with 10 leading the charge of recognized sterile processing superstars.

As always, if your organization – or one you think should qualify – didn't "make either list," be sure to let us know and then plan how to showcase the deserving organization for consideration in the 2021 compilation of Supply Chain Operations and Sterile Processing Operations Worth Watching.

Here's a glimpse at *HPN*'s latest Supply Chain and Sterile Processing Elite lists, in alphabetical order by name, for highlights on what they're doing and why they matter.

★ Supply Chain Elite ★

Dartmouth-Hitchcock Health, Lebanon, NH

www.dartmouth-hitchcock.org

Nothing like a global pandemic to rattle cages and bring out the best in supply chain executives and professionals. But that's all about hindsight. Dartmouth-Hitchcock's award-winning Supply Chain team (they earned *HPN*'s 2020 Supply Chain Department of the Year honors) didn't rely on that so much as foresight, focusing on their people, technology, trade and innovation to keep them ahead of the curve in terms of demand planning. In fact, they were prepping months ahead of the crisis, complete with a dedicated Demand Planning specialist and a technology team of analytics specialists, along with a service provider that fortified sort of a functional "war room" that fused intelligence with strategies and tactics needed to remain operational. Armed with extensive internal strategic planning, they also worked with their colleagues across the state border, UVM Health Network, in promoting supply chain resiliency and supplier communication to prevent disruptions from being … disruptive. By the way, UVM joined the "Worth Watching" list in 2018 and one of its heritage organizations, Fletcher Allen Healthcare, was part of the inaugural class in 2011 – overseen by the same leader.

Dignity Health, San Francisco

www.dignityhealth.org

In the intricate – but oftentimes nebulous – realm of sustainability, little things can add up to a lot, regardless of how complex or simple efforts may be. Perhaps no one knows that better than the team at Dignity Health. Amid the plethora of "green" procurement guides, eco-friendly score cards, special certifications, carbon neutrality, Net Zero and Scope3 rallies and concerns about environmental footprints, Dignity's team started with the fundamentals as foundational – a contract signing, followed by a system-wide conversion process to demonstrate their dedication to sustainable products. Part of

their two-year effort involved working with a custom kit provider to ensure all surgical packs were updated to include sustainable products. The results have been nothing short of eyebrow-raising. Thanks to a small product change to a plant-based needle counter, they were able to eliminate 10 tons of plastic from their operating room supply chain. Making such a change system-wide required considerable negotiations with clinicians, kit packers and suppliers. And for context? Compare the thought of 10 tons with how light and small needle counters are. If they can do so much with so little, think about the replication.

HonorHealth, Phoenix/Scottsdale, AZ

www.honorhealth.com

Under the concept of "alchemy," the supply chain shared services team at HonorHealth embraced structural integrity and clinical integration to morph operations into something "methodical and streamlined" from something that was "reactive and inconsistent." They started at the ground level, concentrating on service lines, PAR levels and a new ordering system. They revamped their staffing levels around four major areas: Support Services, Operations, Innovation and Engagement. They fortified their business intelligence by setting up such processes as business planning, case cost programs, contract cycle to category management, data integrity and dashboards to record and measure key performance indicators, including clinical outcomes, physician relationship engagement and development, expense reduction targets and supplier performance improvement. HonorHealth also strengthened support services by automating technology management, biomedical engineering and facilities management under a unified ServiceNow platform that functions as a user-friendly gateway to clinicians and administrators. If the transformative first five years of HonorHealth's development (following the merger of two health systems) is any indication of future success, the next five should see them turn precocious mettle into precious metal.

Inova Health System, Falls Church, VA

www.inova.org

Four years ago, Inova Health embarked on a rebuild of its own to transform its supply chain from the ground up. As with any rebuilding, the supply chain team began with a system-wide assessment, which identified more than $25 million in potential savings and a significant number of operational improvements across Inova Health's five acute care facilities. Methodically, the team focused on standardizing their inpatient and storeroom supply chain. They relied on a combination of high-tech and low-tech strategies and tactics to do it, leveraging mobile supply chain technology to manage all inventory across the network and implementing a 2-bin Kanban system throughout more than 150 supply rooms. As part of their ongoing journey, Inova Health selected a new prime vendor and group purchasing organization to move them forward. In the current phase they are working to implement a new point-of-use inventory management system and switching their enterprise resource planning (ERP) system, which includes a new contract management system and a content cleansing tool. Once these systems and tools are fully implemented, they will explore centralizing services. Of the more than 40 projects that Inova Health's supply chain team executed during the last four years they have exceeded their original projected savings target from the initial assessment.

Jackson Health System, Miami

www.jacksonhealth.org

Back in March, the supply chain team at Jackson Health recognized Miami as having the earmarks of being a COVID-19 hot zone. As a result, they immediately reached out to their primary distributor and manufacturers, explaining their needs to these key suppliers, using data on the surge in COVID-19 patients to justify their personal protective equipment (PPE) requirements for nearly 13,000 employees treating patients at six hospitals spanning three campuses. These direct appeals strengthened their relationships with suppliers to receive PPE above the allocation parameters to handle the surge. Jackson Health's supply chain team also worked with its GPO to identify additional supply options for bolus orders and obtained commitments up front. Like a growing number of other facilities across the country, Jackson Health identified and credentialed alternative suppliers with long-term sustainability and capacity so they could build redundancy, with a goal to minimize reliance on non-traditional PPE suppliers. The team also kept tabs on raw supply fill rates from manufacturers, comparing that to their supply daily burn rates in reviewing cost optimization and utilization management. They identified and reviewed peaks and short falls, working on PPE conservation plans with infection prevention and nursing leads. Together, they set PPE guidelines and standards for the system, and even established ultraviolet decontamination for N95 respirators as a backup. The result? No stockouts.

M Health Fairview, Minneapolis

www.mhealthfairview.org

M Health Fairview may have earned *HPN*'s 2017 Supply Chain Department of the Year Award (as Fairview Health Services), but three years later the supply chain team continues to impress and innovate, refusing to rest on their laurels. They met with the professors and students at University of Minnesota 's College of Design, College of Science and Engineering (CSE) and the Medical School to examine the pandemic's effects on supply chain product avail-

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ability, researched options, designed plans and met with local manufacturers to facilitate production in a pinch for such PPE as isolation gowns. Early on, they turned to CSE-designed glass-enclosed COVID-19 testing booths and N95 respirator decontamination using ultraviolet light as part of a five-day mask rotation process. One of M Health's pediatric intensive care unit physicians even led efforts to make face shields and ear protection for air purifying respirators. Through this experience, M Health's award-winning supply chain team demonstrated how it can work locally and with the university to fill supply gaps and prevent stockouts.

OhioHealth, Columbus, OH

www.ohiohealth.com

A small but growing number of forward-thinking supply chain teams have been turning to their own ingenuity in developing software to solve problems. OhioHealth is no exception. Through innovation and collaboration, they created a homegrown predictive analytics tool to help them deal with COVID-19-related demands and PPE shortages. They mapped all areas within their organization to determine PPE inventory locations, pinpointing which areas needed reallocation of supply resources right away. Then they used predictive analytics to determine and fulfill demand based on patient volumes. In fact, even at the height of their initial patient surge, the team managed PPE consumption and availability for clinicians to have what they needed to treat patients safely. OhioHealth worked with state, local, public and private sector stakeholders, including nearby health systems, regardless of competitive status, to collaborate and respond collectively to serve their joint communities. One of their cooperative ventures included establishing a 1,000-bed field hospital in two weeks within the Greater Columbus Convention Center for COVID-19 patients. Another involved a novel PPE decontamination system through Battelle that uses concentrated, vapor phase hydrogen peroxide to decontaminate N95 respirators. The idea emerged during a dinner conversation between an OhioHealth nurse and her husband, a Battelle employee. OhioHealth and Battelle then worked together to develop a marketable process from the "proof of concept" to roll out industry wide. OhioHealth also is working with local businesses to support PPE manufacturing and distribution as well as sharing lessons learned with other networks and systems.

St. Luke's University Health Network, Bethlehem, PA

www.slhn.org

Early on as the supply chain team at St. Luke's University Health recognized that the COVID-19 surge was exhausting available PPE, they dispatched a dedicated PPE Purchasing Team to source product with a variety of alternative suppliers. Thankfully, they were able to buy enough to extend inventory to get by for a while longer as demand continued to ramp up. Next, they turned to 3-D printing technology to make N95 masks, PAPR hoods and a variety of other products. They also needed a way to extend the life of their N95 masks so a team effort began between physicians, biomedical engineering techs and sterile processing, along with a Lehigh University professor, to design and fabricate a machine to decontaminate N95 masks with UV-C light. The PPE team recruited local seamstresses to sew fabric masks and circulate them throughout healthcare facilities within the Lehigh Valley community. From this experience, the supply chain team learned how to meet virtually with local university and community leaders to create production lines when a crisis hits.

UPMC, Pittsburgh

www.upmc.com

Although UPMC's supply chain team earned *HPN*'s 2012 Supply Chain Department of the Year Award, it's still pushing out the boundaries of ingenuity and innovation eight years later. With the onset of the COVID-19 pandemic, UPMC needed something to reinforce its perpetual inventory system. As a result, they created a sophisticated supply monitoring tool to capture on-hand inventory quantities among its more than 40 facilities spanning several states. They designed, developed and launched a web-based crisis inventory management platform in partnership with software engineers, pharmacists and project managers. One of the key elements in this system involved a mobile-enabled user interface for use in hospitals and inventory storage rooms without having to access a browser. What's noteworthy is that this product was launched to handle demand for COVID-19-related products, but it's now being configured to cover additional items, too, and released to other health systems needing reporting tools to monitor and manage critical supply counts.

University of Utah Health, Salt Lake City

www.healthcare.utah.edu

The supply chain team at University of Utah Health wanted to reconfigure its inventory system enterprise-wide, standardizing processes in both the inpatient nursing areas in hospitals and non-acute care facilities, such as ambulatory clinics. As a result, they set up an open-bin inventory system with real-time supply quantities wedded to highly sensitive scales integrated to each supply bin that can measure something as light as a single alcohol prep. By using this open system versus a closed cabinet system, they were able to eliminate at least 75 percent of their implementation costs when compared to the closed cabinet system they had. Through this switch, they were able to centralize inventory management functions so that the nursing and respiratory teams could focus on clinical duties. Plus, they eliminated cycle counting and sped up restock times. Data are linked to the materials management information system (MMIS), which in turn, is shared with the distributor.

★ Sterile Processing Elite ★

Albany (NY) Medical Center

www.amc.edu

As part of an academic medical center, the SPD team at Albany Medical Center embraced Lean management to reorganize its departmental footprint to improve workflow. Because its operating room customers practice in a facility that is nearly the size of three football fields, SPD recognized it had to meet the challenges that space and surgical volume created. So it assembled a cross-functional team to design a current-state value-stream map that helped them redesign throughput and improve performance based on desired customer service outcomes. The new layout features standardized prep-and-pack workstations, huddle boards for open communication and task-based evaluations.

Centura Health, Centennial, CO

www.centura.org

The SPD team at Centura implemented its own performance improvement initiative, striving for consistency in quality and service from processing to storage to tray assembly and transportation. They reorganized set storage for improved visibility, streamlined the assembly process and improved instrument cleaning and sterilization. At the center of productivity is a "Lead Priority Pusher" who "ensures the SPD engine is consistent and focused," sort of like a productivity traffic cop. The LPP determines instrument set

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priorities for assembly and adjusts staff assignments based on volume. SPD uses radiofrequency identification (RFID) to automate tray processing and software to assist with forecasting and standardizing of supplies via electronic checklists. They also use this software to help with development, education, training and career advancement.

Children's Hospital of Philadelphia (CHOP)

www.chop.edu

The Central Processing Department at CHOP, which is regarded as the first and oldest children's hospital in the nation, defines performance-based teamwork as driven by training and education, process improvement and quantifiable metrics. It's one of the reasons why this team earned *HPN*'s 2019 SPD Department of the Year Award and debuts on the SPD-centric "Worth Watching" list seven years after its Supply Chain colleagues were so recognized. Unlike many SPD departments that report up through the OR, CHOP's CPD team is one of two on this list that reports up through Supply Chain. CPD has consolidated and centralized sterile processing enterprise-wide for acute and non-acute care facilities, including focusing on pre-cleaning from the OR and tracking instruments through the system. And with an expansion hospital added to the mix, they redesigned their own footprint to handle the additional service requirements. They also created a centralized endoscope center to specialize in those minimally invasive tools.

Geisinger Community Medical Center, Scranton, PA

www.geisinger.org

The Central Sterile Reprocessing team at Geisinger Scranton developed a number of quality projects in the areas of point-of-use pre-cleaning instruments, tray-building accuracy and speed and monitoring productivity and workflow using software for OR scheduling and case tracking. CSR also tackled problems with loaner instrumentation by instituting multiple quality checkpoints and improving communication consistency with the vendors. CSR embraces the philosophy of C.I.Care as the basis for its customer service to user departments. C.I.Care represents an acronym that stands for Connect, Introduce, Communicate, Ask & Anticipate, Respond and End with Excellence.

M Health Fairview, Minneapolis

www.mhealthfairview.org

Believe it or not, the ingenuity and inventiveness of M Health's System Central Sterile Services team can't be traced back to a year, five years or even 10 years. You'd have to look back more than three decades ago when this team first embarked on an enterprise that "insourced" centralized sterile processing services for all of its member facilities. What was novel then may be rather familiar and commonplace now, but M Health Fairview's CSSD developed and progressed, suffering the requisite growing pains to accommodate service expansions but routinely emerging a step or two in front of where they needed to be in the area of centralized processing services for multiple facilities. Not only did M Health Fairview become the first organization to earn both the SPD Department of the Year (2020) and the Supply Chain Department of the Year (2017) awards by *HPN*, but the two also joined *HPN*'s "Worth Watching" lists this year.

Lucille Packard Children's Hospital, Stanford, CA

www.stanfordchildrens.org

Due to the opening of a new fully equipped hospital two years ago that included imaging and surgery integration, the SPD team encountered its own significant renovations to accommodate the clinical service expansion. But despite the assembly line reorganization and shiny new technology installed to improve workflow and throughput, the staffers still had to deliver. While few SPDs are afforded the opportunity of a redesign with the latest technology and tools, Packard Children's SPD team didn't miss a beat, hitting the ground running. They even had a clinical champion in a medical doctor who acted as advocate, educator and sounding board in a professional partnership that's closer than many SPD clinical connections get.

Stony Brook (NY) University Hospital

www.stonybrookmedicine.edu

Years ago, the Central Sterile department at this academic hospital would recruit staff with limited experience and then ramp up education and training into overdrive, developing a crew in which more than 95 percent of technicians are certified. The team created a PAR level system to improve tray assembly quality, reducing the "missing instruments" rate to two percent on more than 100,00 trays per year. The CS team also worked with nurses and surgical techs in the OR to spray all instruments and endoscopes for pre-cleaning. Meanwhile, facility expansion added to their workload, but the C-suite approved fortifying their workspace with the addition of new and more efficient washer/disinfectors and sterilizers.

University of Louisville Health

https://uoflhealth.org

The SPD team at University of Louisville embarked on a rebuilding process to improve its relationship and service to the OR. Among the projects the two areas tackled jointly involved the OR and SPD leaders designing a core for neurosurgery trays that could be tracked by computer scan as they moved through and between departments directly to patients. SPD also reorganized its shelved inventory bins and racks for tray assembly to make it easier for technicians to find what they need. They standardized on one instrument manufacturer and shifted a certain amount of inventory to enclosed cabinets and other devices on vertical pegboards for easier visibility with everything labeled by catalog number for tracking and tracing. Average tray assembly times fell by nearly half. They extended the labeling system with colored luggage tags to sterilization containers to facilitate set and tray matches from one end of reprocessing to the other.

UPMC Horizon & UPMC Jameson, Greenville, Farrell and New Castle, PA

www.upmc.com

Imagine if three hospitals with separate campuses merged operations so that they, by and large, functioned as a single unit. Now imagine how SPD might function through the initial uncertainty. The SPD team at the tri-facility UPMC Horizon & UPMC Jameson campuses knows quite well as they had to coalesce into a regionalized service that involved efficiently maneuvering equipment and operating room supplies among the facilities without interfering with day-to-day operations and production. They also reconstructed SPD's footprint at two of the locations, improving the layout to increase productivity throughout the merged system and standardizing instrumentation. This year, SPD has been pursing automation to track sterilized instruments and trays electronically.

Yale-New Haven (CT) Hospital

www.ynhh.org

The Central Sterile Supply team at Yale-New Haven initiated the four-stage problem-solving model, "Plan-Do-Study-Act" (PDSA), with Infection Prevention, Supply Chain, physicians and vendors to carry out emergent and necessary changes to and development of standard operating procedures complicated by the COVID-19 pandemic. This included reprocessing face shields, N95 respirators and other PPE products. They worked with the Food and Drug Administration's emergency use authorization (EUA) for necessary revisions to reprocessing procedures for Filtering Facepiece Respirators using the Bioquell Hydrogen Peroxide Vapor system to achieve sterilization. The team also relied on PDSA cycles to mediate COVID-related supply distributions. HPN

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A "Commons" and "Standards" approach to strengthen pandemic response

by Karen Conway, Vice President, Healthcare Value, GHX

In November, the distinguished public policy journal *The Milbank Quarterly* published an online version of an article proposing a "commons-based" approach to shoring up access to critical supplies in the event of a national public health emergency, such as we are experiencing with COVID-19. I felt compelled to feature the article in this month's edition of Standard Practices for two reasons. First, the authors, including well-known supply chain professors Gene Schneller and Rob Handfield, provide important insights into a breadth of root causes behind our inability to meet heightened demand for critical supplies during this pandemic, along with recommendations to better prepare for future emergencies by leveraging the respective capabilities of the public and private sector. Second, I wanted to comment on some of the discussions related to the use of standard identifiers and barcode technology to achieve their vision.

The article, entitled "A Commons for a Supply Chain in the Post-COVID-19 Era," responds in part to a legislative mandate in the CARES Act (H.R. 748) that calls for the National Academies of Sciences, Engineering, and Medicine to make recommendations to address "supply chain vulnerabilities or potential disruptions of products that would significantly affect or pose a threat to public health security or national security." The authors conclude that the U.S needs what it calls a "commons-based strategy" that goes beyond a Strategic National Stockpile to include a network of product repositories, active inventory management, and analytics and dashboards to monitor supply and demand.

Drawing upon the seminal work of ecologist Garrett Hardin in "The Tragedy of the Commons," the paper outlines principles for the management of supplies deemed critical to national security in a manner that supports the public good. The authors argue that the federal government, which is charged with protecting public health, should coordinate closely with states and commercial supply chain operators to avoid the unbridled competition among the public and private sector that led to hoarding and price wars, increasing costs for the health system at a time when resources are severely strained and supplies critically needed.

A key recommendation of the paper is for better visibility into available inventory and production capacity across the end-to-end supply chain, from raw materials suppliers to stock held by hospitals and the government, including understanding factors that threaten supply continuity. The paper also calls for strengthening the ability to predict demand and distribute product to where it is needed most. Disaster planning exercises conducted by the public and private sectors are critical to building a shared understanding of the contingency response triggers and the role of the various parties. The authors are emphatic that the public sector should play a governing, not an operational, role, allowing supply chain professionals to do what they do best, run supply chains.

Our nation's experience with COVID-19 has underscored healthcare's lack of investment in the underlying technologies and data management practices needed to provide cross-organizational visibility into supply levels. Many hospitals and health systems across the country scrambled to meet COVID-driven government mandates requiring them to report regularly on current inventory levels, burn rates, and anticipated replenishment and their ability to meet patient and healthcare worker needs.

Where I believe the authors missed the mark is by referencing the use of "common stock keeping unit (SKU) codes" to support data sharing and track the location of supplies. In my opinion, the focus should be on the use of unique device identifiers (UDIs), which the U.S. Food and Drug Administration (FDA) has mandated on the labels of medical devices. The vast majority of products critical in the fight to prevent the spread of COVID-19, e.g., isolation gowns, N95 respirators, etc., are deemed Class II and III products by the U.S. Food and Drug Administration (FDA) and are now required to carry UDIs, which identify the product and include production data, such as lot or serial numbers and expiration dates. Unfortunately, many providers and supplies have still not fully incorporated UDIs into their systems by which they track the purchase and movement of these products.

The paper rightly notes that supply shortages were compounded by "the inability to track where the products were coming from, where they were being sent and who was receiving them," again as a result of a lack of broad adoption of UDIs and barcode scanning technology. The UDI rule requires that UDIs be displayed on labels in machine-readable carriers, such as barcodes, which can convey the UDI "in a form that can be entered into an electronic patient record or other computer system via an automated process." The authors suggest the use of QR codes for this purpose, but many global manufacturers prefer the use of barcodes (linear and increasingly 2D matrix). QR codes are more commonly placed on labels by brand owners to communicate information about their products to consumers. Supply chain leaders from both manufacturer and provider organizations are concerned that because 2D barcodes and QR codes look similar, it could create further confusion for those scanning products using UDIs.

As I mentioned earlier, the paper offers some important considerations as we collectively seek to improve our response to pandemics and other significant public health emergencies. Creation of commons-based stockpiles that can be effectively rotated into use to avoid expiration and waste, along with control tower level visibility and a pre-determined framework for equitable distribution in times of emergencies, are all effective preparedness strategies. The infrastructure and adoption of standard identifiers, barcode scanning, inventory management, data sharing and analytical capabilities all support enhanced supply chain capabilities that – in their absence – contributed to the inability of global supply chains to detect and proactively respond to the pandemic. Better yet, they also enable more effective and efficient supply chain operations in normal times. Beyond common goods, we need a common understanding of how we will respond to future public health emergencies, which requires the use of a common language for identifying and sharing information about the products upon which our health and national security depend. HPN

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INFECTION PREVENTION

De-mist-ifying air, water and steam quality

Healthy environments, energy efficiencies nurture success

by Ebony Smith

Many people have heard the saying, "You are what you eat." If you consume nutritious foods, then you could be a healthier person. Perhaps, like your diet, the same could be said about your environment. In that case, one might argue, "You are what you live in." In that regard, if you are exposed to clean air, water and other natural elements, then you could be a healthier person.

Events occurring in our outdoor or indoor environments impact our health, quality of life and existence. The blazing forest fires in California, hurricanes, air and water pollution, structural erosion, COVID-19 and other airborne, waterborne or surface-spread viruses and diseases, for examples, can endanger our breathing, immune and organ systems, and other vital bodily functions. Medical settings, of course, are not immune to these environmental health hazards.

Spread of pathogens

One imminent danger in medical buildings are the infectious agents passed through the air from person to person, addresses Karen Hoffmann, RN MS CIC FAPIC FSHEA, Infection Preventionist Consultant, Medical Illumination International.

"Healthcare facilities face a challenge in controlling airborne contaminants that come from a variety of reservoirs (soil, water, dust, organic matter) from exposing patients and staff," Hoffmann noted. "Also, several airborne infections in susceptible hosts can result from exposures to clinically significant microorganisms carried by human hosts. Once present in the healthcare facility, these potential pathogens are an ongoing and invisible threat for healthcare-associated infections."

Karen Hoffmann

SARS-CoV-2, the virus that causes COVID-19, poses an extreme opportunity for transference through the air and surfaces.

"Respiratory infections, including the highly infectious SARS-CoV-2, are acquired from exposure to pathogens contained in either droplets or droplet nuclei (bioaerosols)," she added. "Studies show bioaerosols spread around indoor spaces and linger in the air, depending on the number of air exchanges. Primary transmission of COVID-19 occurs via inhalation of infectious droplets and bioaerosols. In addition, when these bioaerosols settle onto surfaces in healthcare settings, they create the potential for fomite transmission via inanimate objects, such as countertops, patient care equipment, or door handles. Once contaminated, the surfaces are a risk transference to medical staff or patients."

All of these health-related issues reinforce the need for clean, sanitized, and safe medical settings.

"The advent of the current pandemic and other events, including SARS, H5N1, MERS and Legionella outbreaks, have had a tremendous effect on the healthcare environment," explained Pat Leach, Business Development Manager, Pure Air, Alfa Laval. "Airborne and waterborne transmission of these pathogens has been documented, requiring measures to protect and isolate critical path airways and waterways."

Pat Leach

Measuring healthcare environment quality and safety

Hospitals and healthcare systems must maintain the highest quality of environmental cleanliness and sanitization in order to deliver safe and effective patient care. Any exposure to bacteria, mold and other infectious organisms within healthcare settings can increase the risk of cross contamination and infections with patients.

Dr. Ashish Mathur, Vice President of Innovation and Technology, UVDI, pointed out, "While the primary transmission modes of pathogens result from poor hand hygiene and surface contamination, airborne and waterborne transmission are equally important for infection control in healthcare facilities. Transmission of pathogens, such as CRE, CRAB, CRPA, through the hospital cooling water towers, plumbing systems and wastewater systems have been documented."

Ashish Mathur

COVID-19, certainly, has shined the light on the significance of environmental assessment and maintenance, expresses Andrew De Vries, Senior Manager, Strategic Sourcing, Valify Solutions Group.

"As there is an increased focus on air, water, and steam quality during the COVID-19 pandemic, hospitals and health systems may be seeking new vendors in these categories or expanding their scope of services with existing vendors," De Vries indicated. "For water quality in particular, an important factor to consider for this often-outsourced purchased services category includes a vendor's ability to provide a field and technical services team to help manage chemical usage, particularly with regard to algaecide, chlorine, chlorine dioxide, and others. A reduction in these agents can support an organization's green initiatives and may also result in additional cost savings."

Bringing on water treatment service specialists also can help raise vital understanding and mitigation of waterborne diseases, such as Legionella, a serious type of pneumonia caused by bacteria that live in water, De Vries emphasized.

"Legionella can make people sick when they inhale contaminated water from building water systems that are not adequately maintained," he noted. "According to the CDC, the number of Legionnaires' cases reported has been on the rise in recent years. Health departments reported nearly 10,000 cases of Legionnaires' disease in the United States in 2018 compared to approximately 3,500 in 2012.[1] All professionals supporting a facility's water management efforts should have specific competencies. These include the abilities to identify control locations and control limits (the range of values that are

acceptable to reduce the risk for bacteria to grow and spread), to identify and take corrective actions if needed, to monitor and document program performance, and to communicate regularly about the program."

Another area of concentration for monitoring is a heating, ventilation and air condition (HVAC) system, which is one of the major reservoirs of microbial contamination in healthcare, addresses Leach.

"The single most impactful challenge facing healthcare is the control and abatement of viable microbial contamination, which commonly is isolated within air, water and steam-based systems in healthcare environments," he stressed. "This problem is becoming more concerning due to the increase of drug-resistant and multidrug-resistant pathogens, especially gram-negative bacteria. And consequently, the largest single source of gram-negative bacteria in hospitals are HVAC systems. Studies have demonstrated the presence of biofilms within the HVAC system harbor and grow many of the pathogens associated with healthcare-acquired infections (HAIs). Left unchecked, this poses the greatest risk to immunocompromised patients, as well as staff and visitors."

One solution that focuses on removing harmful microorganisms that generate within HVAC systems is the Alfa Laval Pure Air system. "Our evidence-based design technology has been proven to eliminate surrogate pathogens associated with HAIs from a moving airstream of 440 fpm (feet per minute) at an efficacy of 99.999 percent in a single air pass," Leach continued.

Like water quality, air quality requires specialized evaluation, measurement and support. How exactly is that handled?

Sarah Callahan, Director Marketing Communications, Aircuity, a smart airside efficiency company, breaks down the process for sensing, sampling and analyzing the quality of air in and outside of healthcare facilities and other environments.

Sarah Callahan

"The biggest challenges that we have seen in terms of indoor air quality is balancing heathy air, which is critical in healthcare settings, and high energy costs," Callahan expressed. "It also is critical that air quality parameters are accurately measured and managed."

More specifically, she added:

- "Airborne Particulates – The novel coronavirus and other viruses attach themselves to particles, and therefore must be minimized in the indoor environment. Even if your building has recently upgraded its filters, you need to be able to quantify the impact. Using the right data, your building can determine the 'effective filtration rate' and whether the healthy small particle levels are being controlled.
- Carbon Dioxide (CO2) – In order to verify that enough dilution air is being brought in, your building should have a reliable system to sense the amount of CO2 in the space and bring more in when needed. Next, your building should use a high-quality analytics platform to look at the CO2 levels of the outside air, supply air and room air. These readings can then be compared against science-based air quality standards to ensure adequate ventilation is controlling CO2 levels.
- Relative Humidity (RH) – When RH is lowered to the 0–40 percent range, respiratory immune defenses are impaired.[2] At these RH levels, airborne droplets containing viruses evaporate and lighten, allowing the droplets to float longer and survive for a longer period of time. Due to these issues, your building should work to provide higher relative humidity levels, ideally in the range of 40–60 percent RH, especially in low humidity and in peak viral season.
- Total Volatile Organic Compounds (TVOCs) – Your building manager should be reviewing TVOC data and ensuring that it's in an acceptable range. This involves a sensor system that identifies any increase in TVOCs from cleaning and sends a signal for more outside air until TVOC levels drop again."

Prior to the COVID-19 crisis, St. Francis Hospital and Medical Center in Connecticut brought in Aircuity for an environmental assessment. "In addition to gathering valuable data about the indoor environmental quality of the operating rooms, Saint Francis was able to implement a 'safe standby' mode in these suites," according to a case study.[3] "When the operating rooms were not in use, airflow could be reduced to save energy with Aircuity monitoring the condition of the space. If issues are detected, airflow is increased to design maximum until containment levels have subsided. Once the air is clean, ventilation levels are lowered again, saving energy."

This process, in turn, enhanced staff satisfaction, building equipment function, and patient care. "The hospital also used the newly available data to provide verification for clinical personnel that air quality was not being sacrificed for energy efficiency. Clinical verification of humidity levels within the OR is another way that Saint Francis is able to deliver superior patient care. Facilities' staff found that circuit boards and other internal components were previously being exposed to higher humidity levels than the manufacturer had intended. With humidity levels now staying constant, equipment performance has increased and spot problems have been eliminated."

Similarly, Airthings for Business, a B2B air quality monitoring solution, helps gauge indoor air quality in long-term care and healthcare settings, which, consequently, has benefited the health and safety of personnel and those they care for, addresses CEO Oyvind Birkenes, Airthings.

"In Norway, our solution already is at work in some local nursing homes and healthcare centers," he shared. "In terms of proven efficacy, one facility was able to report a significant reduction in the sick leave rate of their staff, after addressing issues with high temperatures and low humidity, ventilation, and excess use of hand disinfectants that lead to high airborne chemical exposure throughout the day. In addition to providing personalized indoor air quality data that can identify airborne threats in real time, our products are RESET accredited, meaning they are certified and proven to promote health and sustainability for the built environment."

Even before the COVID-19 pandemic erupted, the demand for indoor air quality monitoring was rising, however, the pandemic further accelerated that growth, indicated Birkenes.

Airthings for Business bundle: Hub Wave, 2 Wave Mini

"Healthcare and medical facilities are under stricter guidelines and more pressure than ever to ensure that they are maintaining a healthy environment for patients, doctors, and medical staff," he emphasized. "Poor indoor air quality in a hospital can be extremely dangerous as it can lead to an increased risk of infection for at-risk patients. Research has proven that low humidity levels impair the body's immune system and allow viruses to survive longer in droplets, making people more vulnerable to airborne viruses. Ventilation and circulation for natural, fresh air is critical in hospital settings."[4]

The quality of the utilities used in processing equipment, additionally, can have implications on the cleaning, disinfection, and sterilization of reusable medical devices, points out Jonathan A. Wilder, Ph.D., Man-

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aging Director, Quality Processing Resource Group, LLC.

"Many healthcare facilities do not follow the recommendations or requirements for steam, water and air in use in sterile processing," Wilder indicated. "These are clearly laid out in AAMI and ASHRAE standards but are only checked when something goes wrong. Proper attention is not generally given to incoming water filtration and treatment. Water quality influences the maintenance schedule of anything that uses it. Steam quality affects sterilizer performance, instrument lifetime and corrosion. If the load is wet due to wet steam, that would require reprocessing any wet item or the entire load. Our audits compare the current situation to the specifications in AAMI ST79 and TIR34. We have helped clients with staining, corrosion, wet loads, failed indicators, and contamination issues, resulting in fewer or no interruptions to the flow of clean, sterile instruments from SPD to point of use."

Natural disasters, especially, can create hazardous conditions with water and other elements, continued Wilder.

"I am concerned about potable water purity in areas where there have been multiple hurricanes and flooding," he said. "The water table in those areas has been flooded, resulting in 'stuff' being dissolved in municipal water that normally isn't. It's the facility's responsibility to provide water of consistent quality since municipal water can show variation. On-site filtration helps with this."

Investing in air disinfection to control spread of infection

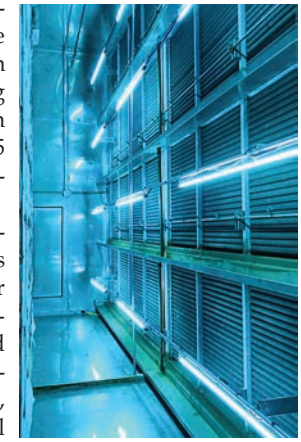
As COVID-19 progresses and air quality remains a priority in healthcare, many medical providers are adopting new cleaning systems for added support, such as UV disinfection.

"The Centers for Disease Control and Prevention (CDC) has confirmed airborne transmission of SARS-CoV-2 does pose a risk," Dr. Mathur noted. "With regard to airborne pathogens, the potential transmission of respiratory viral infections, such as coronavirus, influenza, aspergillus and tuberculosis, has been established in scientific literature. Potential transmission also can occur during aerosol-generating procedures, such as cardiopulmonary resuscitation, bronchoscopy, surgeries, where droplets of infectious particles can be propelled into the air. Many facilities are implementing new protocols – including in-between surgical procedure air disinfection – to help prevent the risk of airborne transmission from aerosol-generating procedures."

UVDI provides a range of UV disinfection products that help control the spread of pathogens from surfaces in rooms as well as from the air filtered through HVAC ducts, adds Dr. Mathur.

"Our UV-C based Indoor Air Quality products are used for air disinfection in leading hospital systems internationally," he shared. "Germicidal UV-C is a proven technology to inactivate high-risk microorganisms and has been recommended by the CDC and ASHRAE as an effective tool to prevent the airborne transmission of the virus. In addition to providing whole room disinfection, the UVDI-360 Room Sanitizer has been confirmed in independent testing to not affect the fit and filtration performance of tested 3M N95 respirators after ten decontamination cycles."

Likewise, Jay Comeaux, President, EDM Facilities, which offers the UV Angel Clean Air UV-C air purification system, sees a growing desire among hospitals and medical settings to enhance environmental disinfection, however, while needing to weigh potential costs.



Fresh-Aire UV commercial installation

"While many facilities would like to initiate new technologies, it has become more difficult due to logistics, budgets, and the time implementation can take," Comeaux emphasized. "Shielded upper room-level UV-C air purification is a proven effective addition to infection control protocols. As a matter of fact, the CDC made mention of this shortly after the COVID outbreak. Through the use of UV Angel Air technology, pathogen levels have been lowered in the air, staff absenteeism has improved, and workflow isn't interrupted since the technology is an engineering control."

The VidaShield continuous UV-C air purification system by NUVO, a division of Medical Illumination International, seamlessly integrates in to existing ceilings, treats the air and helps decrease contaminates and the potential for infections, points out Hoffmann.

"The use of VidaShield provides a noninvasive adjunct to reduce airborne bacteria, viruses, and fungi in the treated air and reduce the settling of bacteria and fungus from treated air on surfaces," she explained. "This is important because untreated air samples on average range from to two to eight times more contaminated than surfaces. In two separate peer reviewed studies, reductions in patient cases of *C difficile*, MRSA, and VRE were reported, as well as total overall infection rates. In addition, the VidaShield combination of UV-C and air filtration has made a notable improvement in healthcare-related odors."

Bottom line, environmental quality can't be overlooked, given its critical impact on patient care, infection prevention, patient and staff safety, financial operations, and communities.

"In the US alone, approximately two million patients suffer from HAIs," indicated Aaron Engel, Vice-President Business Development, Fresh-Aire UV. "HAIs are a significant cause of illness and death, costing the healthcare system tens of billions of dollars annually and resulting in up to 90,000 deaths. Not only are facilities looking to reduce HAIs, but they are also challenged by the current COVID-19 situation and keeping patients and staff safe during a pandemic."

Fresh-Aire UV offers several UV disinfection solutions to help healthcare facilities treat the air and equipment and reduce the risk of cross contamination of pathogens and infections with patients.

"At the on-set of the pandemic, Fresh-Aire UV disinfection systems were being used across Canada and the US to disinfect and extend the life of N95 respirators and other PPE," Engel noted. "Our ceiling mount UV surface disinfection systems were being employed as an adjunct to conventional environmental cleaning practices designed to disinfect high-touch surfaces. Our in-duct- and HVAC- installed UV disinfection systems have been used to complement filtration, disinfecting pathogens in the air handler, drain pan and evaporator coil as well as the duct work, treating the air as it's distributed through the ventilation system. The coronavirus has caused many facilities to re-think how they have been addressing their indoor air quality and what measures they can implement to lessen the chance of surface and airborne transmission." HPN

UV Angel from EDM Facilities

Visit https://hpnonline.com/21162196 for references.

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OPERATING ROOM

Point-of-care patient monitoring

Improving patient, operational outcomes with real-time reporting from anywhere

by Ebony Smith

Patient monitoring broadly falls into many buckets. On one hand, it could involve tracking the volume of patients coming into hospitals and healthcare systems, as well as the supplies and equipment needed to provide care. On the other hand, it may encompass the actual devices, accessories and technology that measure the vital signs and health conditions of patients, whether they are in care on-site, at home, or out in the community.

The COVID-19 crisis unexpectedly hit the healthcare industry as never experienced before. Elective surgeries and other care have declined, resulting in decreased revenue and a sharper focus on managing healthcare inventory and purchasing. In addition, the pandemic and fear of its spread have elevated various methods of care delivery, such as remote patient monitoring, mobile workflows, telehealth, and medical telemetry.

Measuring supplies, equipment, and care

As to the current state of the hospital and healthcare landscape, Clint Pridgen, Senior Director of HealthSight Clinical Solutions, an e-surveillance software monitoring system for BD, points to three levers in administration.

"One of the hallmarks of healthcare is that hospital administrators have three levers to pull from," Pridgen indicated. "You could use time, resources, and tools. Systems that are used to monitor all three have given line of sight into trends to become proactive in their response to the COVID-19 pandemic. We know that surgical procedures, a significant source of funding for hospitals, have substantially decreased since the beginning of March. Insurance reimbursement models have changed, dollars are more scrutinized, and there is more pressure on administrators and providers. They are looking to their patient monitoring systems to help improve efficiency, reduce waste, and improve outcomes."

Clint Pridgen

The expectation of high-quality healthcare experiences requires visibility, integration, proactiveness, and optimization for effective care delivery, expressed Pridgen.

"Now, it's quality-based healthcare," he explained. "How, in real time, can we figure out what patients have and get them appropriate care? What we find is that hospitals have tried to supplement an EMR and tools that aren't connected. We take our charge seriously to help integrate these things together."

The pandemic, consequently, reinforces an even higher level of attention needed with transparency and management of supplies, noted Pridgen.

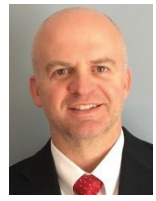
"The challenge we run into, whether we are talking about COVID, antibiotic-resistance or healthcare- associated infections, is we try to put them in a silo," he continued. "You need to have a full picture. How do you make sure you have appropriate staff, meds, and laboratory testing? Today it's COVID, but tomorrow it will be something else. Adaptability and agility in these processes are critical."

Higher costing and single-use medical products also are impacting medical care and spending today, addresses Nora Brennan, Business Development Manager, Cables & Sensors.

"There are ever-increasing costs of supplies and supply chain interruptions," Brennan emphasized. "There is an increased focus on single-use disposable items to lessen the chance of possible infections, which could compromise patients' health and make them more susceptible to COVID-19. Remote monitoring, in particular, has made great progress. Costs of the peripherals used

to perform the monitoring at the remote location need to be considered."

David Karchner, MBA, R.T.(R), ARDMS, RVT, Senior Director of Marketing, North America Operating Room, Patient Monitoring, and Enterprise Services, Dräger, finds facilities making prudent decisions regarding purchasing and operations.



David Karchner

"Patient monitoring purchases typically are a very strategic acquisition, with detailed evaluations, cyber-security discussions, and financial simulations," Karchner expressed. "With COVID-19, many of these projects have been put on hold. COVID-19 is providing a financial strain on our health system that we've never seen in our lifetimes. Healthcare organizations are focused more than ever on improving operational efficiencies. Infinity OneNet, our innovative networking solution that enables life-critical patient data to be sent and received safely and securely over the hospital's existing hospital network, reduces the need to invest in a separate monitoring network."

Achieving connectivity, automated data, and mobility

Patient monitoring systems, however, do pose certain risks with regard to technology connection and protection of patient information, explains Dhaval Kate, Technology Lead, Future Market Insights.

Dhaval Kate

"Despite increasing usage of patient monitoring systems, there are still various challenges and technology-related issues faced by hospitals and healthcare facilities," Kate noted. "Major challenges faced by hospitals while using remote patient monitoring systems are network connectivity, data security, cost and affordability, data manipulation and violation of patient data."

Real-time access of patient health data through automated and mobile devices and work practices can help improve accuracy and quality in patient care, indicates Kylie Gilberg, Marketing Manager, Midmark Corporation.

Kylie Gilberg

"Two of the greatest challenges healthcare facilities can face while capturing vital signs measurements are accurate data and repeatable results," Gilberg said. "Studies show an average 17 percent rate of error during the manual transcription process for vital signs data.[1] Using automated devices can help ensure vital signs are being captured consistently. While the market was already seeing a push toward mobile workflow solutions, the COVID-19 pandemic brought attention to that need in an urgent way. Facilities that already adopted mobile workflows had the appropriate equipment to create pop-up clinics faster than those who lacked mobile equipment."

The Midmark Digital Vital Signs Device provides automated and integrated data for patients. "Our device introduces technology and standardized workflows to help ensure vital sign measurements are being performed consistently, every time a patient is seen," Gilberg shared. "Studies show that automating the vital signs acquisition process can save 69 seconds per patient visit.[2] The device's ability to connect directly with an EMR and automatically transfer the patient's results eliminates the possibility of transcription errors."

While Dräger's Pick and Go monitoring technology offers data at the bedside and in transport, helping to stay with the patient and decrease the risk of pathogen or infection spread. "Our patented Pick and Go focuses on the value for cost savings and operational efficiency, where hospitals could reduce the number of monitors needed across their network," Karchner explained. "What we've found during the COVID-19 pandemic is that our customers also are finding comfort from an infection control standpoint, since a patient can be placed on a monitor at their entry point into the health system, and move from the ER, to OR, to PACU, to ICU, all on that same monitor, helping hospitals reduce the opportunity for cross contamination between patients."

Jake Durgan, Vice President of Marketing, Spacelabs Healthcare, likewise, points to the adaptability of patient monitoring technology and care settings, data reporting and operational efficiencies.

"Remote monitoring and equipment that is quickly configurable for any situation has become critically important," Durgan addressed. "Today, virtually any department in the hospital can be turned into an ICU because our patient monitors can operate like an ICU bed monitor, which allows coronavirus patients to be treated as such, no matter how much the needs of the hospital keep fluctuating. Today's technology allows us to capture more data from more data points than ever before and make that data available on remote and handheld devices. The real challenge is what to do with all that data."

In order to improve the management, efficiency, outcomes, and costs with their telemetry process, Integris Southwest Medical Center implemented Spacelabs Healthcare's cloud-based SafeNSound software, which "leverages digital technology by providing tools that assist with alarm management, ensuring that devices are properly associated to the correct patients, and adding dashboards that facilitate collaboration between caregivers while streamlining communications," he added. "During the first year of use, Integris recognized more than $900,000 in savings."

Advancing remote monitoring, reporting, and telehealth

As patient health data is collected, it must then be shared and applied in order to benefit clinical practice and decisions, emphasized Karchner.

"There is a popular saying in the market right now that '*data is the new gold,*' and we couldn't agree more," he noted. "But

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Dräger Connect Alarm Analytics

data is only valuable if the data can be acquired correctly and presented in a format where health systems can more easily make informed decisions. Research has shown that on average, up to 350 monitoring alarms a day can occur at an intensive care bed. Of these alarms, up to 95 percent are clinically irrelevant and the remaining clinical alarms are only noticed properly by a rate of 50 percent.[3] Dräger is focused on using data analytics to help our customers remove the noise from nuisance alarms, freeing them up to better focus on their patients."

Daniel Kivatinos, Co-founder and COO, DrChrono, envisions remote patient monitoring, as a result of the COVID-19 crisis, will expand in the medical industry and care.

Daniel Kivatinos

"Medicare and Medicaid, as well as other insurance companies, now are receiving reimbursement for remote patient monitoring (RPM)," Kivatinos indicated. "Additionally, Apple Watch and internet-connected scales can be used for RPM. IoT devices also are part of the RPM future, such as IoT glucose meters for diabetic patients, IoT thermometers, and sleep monitoring devices, like the Aura Ring. By adding RPM from providers, such as KeepWell, 100Plus, and MD Revolution, practices can focus on patient care and have access to real-time patient data. With more physicians turning to virtual care, telehealth, and EHRs that manage critical patient data, these are proving to be the lifelines to modern healthcare."

Remote patient monitoring and telehealth will experience continued growth beyond the COVID-19 pandemic, predicts Kate.

"Remote patient monitoring is going to witness exponential growth in the coming years, as it will help people living in inaccessible areas to access healthcare services, improve efficiency, and reduce the inconvenience of stringent medication regimes. In fact, the number of telehealth patient visits has increased around 50-175 times during the pandemic as remote patient monitoring technology keeps patients safe within the home, while reducing stress on hospitals and frontline healthcare workers."

Atrius Health, for example, is using the remote monitoring solution, Glooko, for tracking the health status of patients with diabetes, continued Kate.

"Glooko is a diabetes management system that enables PWDs and their healthcare team to access all their diabetes data in a central location via a mobile and web application," he explained. "Atrius Health uses Glooko to provide optimal care and also to encourage patients to share health and wellness data captured at home, such as diet, activity, blood pressure, etc., with their clinicians so the data can be used to inform treatment decisions."

Mobile workflow, telehealth, and home-based monitoring systems also will be on the rise, forecasts Gilberg.

"We feel there will continue to be a push toward mobile workflow solutions that allow our customers increased flexibility within their clinics," she expressed. "We anticipate there will be more telehealth and at-home vital signs solutions introduced to the market based on feedback gathered during the pandemic. The pandemic has been a driving force to bring the point of care to our homes, and with a better understanding of what's needed to do that, at-home care may be a long-term solution."

Durgan foresees an expansion of wearable trackers and medical telemetry to provide monitoring outside of medical settings and keep patients moving.

"Physiological monitors are no longer just a hospital monitor used to ensure a patient is stable. Today's innovations in lightweight wearable transmitters encourage monitoring early at home, allowing unencumbered ambulation. Getting a patient up and walking—even after something as dramatic as open-heart surgery—is essential. Physical activity is critically important to achieve the fastest, fullest recovery. The future is taking this capability beyond the clinical environment and into the everyday world. Medical telemetry delivers the stringent level of diagnostic quality required to ensure that data collected on the go is as accurate as data collected in the ICU." HPN

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Collaborating to bring back surgeries

by Kara Nadeau

Resiliency is a perfect term to describe the efforts of the healthcare industry during the COVID-19 pandemic, where care providers have confronted unparalleled challenges with courage, strength and an unwavering commitment to their patients. With the halt in elective procedures and subsequent ramp up to perform the countless procedures that had been cancelled or delayed, Central Sterile/Sterile Processing Department (CS/SPD) professionals and Operating Room (OR) teams have shown remarkable resiliency in navigating the many challenges they have faced, and continue to face, in delivering effective and safe patient care.

"One thing we know is that healthcare personnel know how to adapt to any situation. I am proud to be part of this industry as I had to adapt myself," said Mark Duro, CS/SPD Education Consultant, Sterile Processing Direct. "When you look at what happened in the early stages with the shortages in personal protective equipment (PPE), what did we do? We adapted. We did things that would have made your head explode a year ago, such as reprocessing single use disposables."

Mark Duro

While surgical procedures were on hold, CS/SPD and OR teams in health systems and hospitals took the opportunity to examine their processes and make improvements for when cases resumed, not just related to protecting patients against the spread of COVID-19, but also to address long-standing challenges experienced by both departments.

"It has brought us closer together, and really challenged us in thinking outside of the box and coming up with solutions that are still safe and effective," said Garry Bassi, Director, Medical Device Reprocessing, Mount Sinai Hospital, Toronto.

Garry Bassi

Here are some of the ways that CS/SPD and OR teams have worked individually and collaboratively to bring back surgeries in a safe and effective way during this unprecedented time in healthcare delivery.

Stepping up in the CS/SPD

Throughout healthcare facilities, COVID-19 has driven personnel to step up to the challenges presented by the pandemic and take on additional roles and tasks that they would never have considered before the virus emerged. It has also forced greater collaboration and communication among departments, including supply chain, infection control/prevention, CS/SPD and the OR. These strengthened interdepartmental partnerships are more important than ever as facilities resume surgical procedures, particularly the relationship between the CS/SPD and OR.

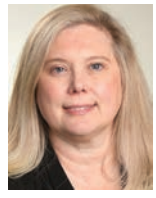
"Communication is the most important aspect of the OR-CS/SPD collaboration," said Robert B. Dybec, BSN, RN, CNOR, Nurse Manager Operating Room, Winthrop-University Hospital, Mineola, NY. "In the many months when elective surgeries were not being performed and ORs were converted into ICUs, thousands of patients were waiting to have their procedures. Now that elective surgeries have reopened, ORs and surgeons are playing catch-up trying to accommodate the huge backlog of previously scheduled surgeries. This means very busy OR schedules and CS/SPD departments that are being hard pressed to keep up with the instrument needs of the OR. Each department must do their part to

Robert Dybec

help the process run smoothly, efficiently and safely for all surgical patients."

Added support to the OR

In order to safely and effectively resume OR procedures, CS/SPD and OR teams have had to engage in collaborative planning on which cases to bring back and when to bring them back based on anticipated case volume and required preparation and supplies (instruments and disposables), says Karen Owens, RN, MSN, CRCST, CIS, CER, CHL, FCS, CQIA, Director of Clinical Education Services, Steris.



Karen Owens

"The OR and CS/SPD must take a proactive versus reactive approach, communicating on staffing and case volumes," said Owens. "This should include needs assessment to determine education, training and competency needs. In addition, there should be cross training between departments - OR learns what SPD does, SPD learns what OR does."

During these challenging times, with reduced on-site access due to pandemic related restrictions, Owens recommends that CS/SPD professionals use online or virtual resources for continuing education and in-servicing that manufacturers often provide.

At Mount Sinai Hospital, Toronto, Bassi and his CS/SPD team have launched many initiatives to support the OR as they resume procedures. For example, they are providing additional support for weekends where extra surgeries and extra rooms are being opened up to catch up on the backlog of surgeries and wait lists. They also prepare additional case carts specifically to contain COVID-19 case instruments that are clearly labeled as being used on a patient with the virus, so that the CS/SPD team is aware of these instruments when they arrive in decontamination.

In addition, Bassi and his team are working with OR to provide alternatives to disposables (e.g. reusable gowns) so the supply chain impact can be lessened, performing stock rotation of their inventory, and helping to refill alcohol hand rub containers using an aseptic process that was developed in-house.

Supporting CS/SPD staff

Disruptions in patient procedures have had a profound impact on CS/SPD workload, with many facilities having to furlough/lay off employees in their departments or drastically cut their hours. As a consultant, Duro has seen healthcare facilities implementing creative staffing plans to keep CS/SPD professionals employed during the pandemic. This includes reassignment of CS/SPD staff to other areas of the healthcare facility to keep them active, especially in areas where existing staff have contracted COVID-19 and cannot work.

"Many have taken the downtime to improve their service and processes by doing extra preventative maintenance on instrumentation and other reprocessing equipment," said Duro. "Others have completed deep cleanings of their processing, decontamination and storage areas. The same has applied to ORs. Although this pandemic has wreaked havoc on healthcare facilities, it has also given them a chance to do things that normally can't be done during the 'norm.' As we open up, many facilities are in a much better position than they were before the pandemic."

Acknowledging how the pandemic has placed added stress on not just the OR but the CS/SPD staff as well, Mount Sinai Hospital, Toronto has taken steps to promote a positive environment within its CS/SPD.

"We offer resilience and change management sessions to keep staff positive, and maintain regular communication to our staff regarding COVID-19 cases, including a COVID-19 update page for all staff and regular town halls; and we provide regular acknowledgement of our staff in various ways to keep the positivity and momentum going," said Bassi.

Collaborating for clean

"Since ORs were permitted to reopen to elective surgeries during the COVID-19 pandemic, there has been an increased awareness of the importance of the OR-CS/SPD collaboration," said Dybec. "The procedures that were working in achieving guaranteed clean and sterile instruments before the pandemic were revisited once again."

According to Dybec, these methods include effective point-of-use cleaning and instrument prep with enzymatic humectant and foam solutions in the OR. He says this process alone has demonstrated increased cleaning effectiveness in the CS/SPD and quicker turn-around of critically needed instruments.

At Mount Sinai Hospital, Toronto, Bassi and his CS/SPD team have minimized hand wash processes as much as possible and are currently washing the majority of their devices through their thermal washer/disinfectors to protect staff who are handing contaminated equipment (e.g. rigid scopes and light cords and anesthetic equipment).

Dybec adds that systems for checking for the cleanliness of instrumentation, such as adenosine triphosphate (ATP) devices, have become profoundly more important during the pandemic. He notes how these devices can also be used to check for cleanliness in many other areas of the hospital and on multiple surfaces.

"The 'new norm' has shown how important it is to clean and disinfect critical areas such as the OR, emergency department, COVID-19 units and intensive care units (ICUs)," said Dybec.

Steps to ensure sterilization

The dangers of COVID-19 infection and the delays in surgical procedures related to the pandemic prompted many healthcare facilities to reevaluate their sterilization processes, supplies and systems.

Biological indicators

Early this year, healthcare facilities notified the U.S. Food and Drug Administration (FDA) of the potential for misinterpreting indicators used to validate the sterilization of medical devices because there is no standard indicator color to indicate a sterilized device. In a letter to healthcare providers, the FDA indicated that the risk for misinterpretation has increased with the COVID-19 pandemic as healthcare facilities "are rapidly adopting conservation practices, including decontaminating disposable compatible N95 and N95-equivalent respirators for single-user reuse."

The letter went on to explain how "reprocessing staff may be using sterilization systems for the first time or concurrently using sterilization systems from different manufacturers," during the pandemic; therefore, "if staff assume that all manufacturers use the same color code to validate sterilization, they may mistakenly release contaminated devices for reuse."[1]

During the time when COVID-19 necessitated a hold on elective surgeries, some healthcare facilities took the opportunity to address the issue of sterilization indicators by upgrading their technology and/or standardizing on one manufacturer's biological indicator (BI) as a way to minimize the risk for misinterpretation of results.

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"Hospitals are struggling to return to pre-pandemic surgical volumes," said Brenda Loguidice, RN, CNOR, CRCST, MBA, Clinical Education Consultant, Advanced Sterilization Products. "The CS and ORs are going the extra mile to thoroughly disinfect work and patient areas, wear PPE and practice social distancing when caring for their patients. The preparation of instruments to ensure they are clean and safe remains at pre-COVID-19 standards."

Brenda Loguidice

According to Loguidice, a biological indicator within a process challenge device (PCD) is the best method used to demonstrate whether the conditions during a sterilization cycle were adequate to achieve a defined level of microbial inactivation. She notes how in recent years biological testing technologies have been perfected to provide results in 30 minutes or less.

"This advancement has made it possible for the CS to discern that surgical instruments and supplies have been processed and sterilized properly before being sent to the OR," said Loguidice.

For those facilities where there is the potential to misinterpret the indicators used to validate the sterilization of medical devices, Loguidice recommends developing an action plan to continually monitor and instruct the staff in the OR and CS/SPD as to how to interpret the indicators. As part of this plan, she suggests the posting of physical charts illustrating what indicators should look like pre- and post-sterilization (including positive and negative results) at the point of use for staff to reference.

She also recommends that healthcare facilities take advantage of resources provided by indicator manufacturers, including educational sessions and training programs they offer to staff members who interpret indicator results.

"Additionally, standardizing and limiting the variety of indicators used can be helpful," Loguidice added. "Clinical input from CS and OR healthcare professionals may provide healthcare facilities important insight when making these decisions."

Bassi says Mount Sinai Hospital, Toronto standardized to one indicator type many years ago as a way to avoid confusion and drive accurate interpretations among staff members.

"This helps with consistency and education around recognition amongst the OR and all other areas in the hospital," said Bassi. "Different departments borrow instrumentation from one another; therefore, having one type of indicator across the board helps with that consistency."

Owens says sterilization indicator manufacturers have designed products that are easier to use and interpret to support accurate and efficient testing, stating:

"One example is a moving front chemical indicator – it allows for easy confirmation that the testing was successful providing confidence in the release and use of instrumentation."

Sterilizers

As Duro points out, because of limited number of surgical procedures performed during the pandemic, CS/SPDs may have used one sterilizer to accommodate instruments from emergency cases, while their other sterilizers sat idle for months. Healthcare facilities have been asking him for advice on how to resume use of these sterilizers now that surgical procedures have resumed. He states:

"I had a customer ask what they should do if they had two of their three sterilizers shut down for the past two-to-three months. What should they do to bring them back online after this work has been done? Depending on the work that has been done (especially after major repairs) and if the unit has been down for extended periods of time (months), we recommend requalifying sterilizers according to Association for the Advancement of Medical Instrumentation (AAMI) recommendations, although in some cases it may not be necessary based on each unique situation. We want to do what is in the best interest of the patient and definitely requalify your units. It's not worth the risk."

Instrument tracking and scheduling systems

As Owens explains, instrument tracking systems are a valuable tool for healthcare facilities as they manage surgical procedures during COVID-19 – and even in a non-pandemic environment - allowing both the OR and CS/SPD to balance instrument availability with procedure volumes.

"Instrument tracking systems provide insight into inventory, including what is being used and what is available, and what are current volume considerations/constraints," said Owens.

According to Duro, during the COVID-19 downtime in the CS/SPD and OR, staff members have taken the opportunities to address tracking and scheduling systems, including making updates, changes, deletions and additions to tighten up databases and ensure their accuracy, performing software updates, and exploring new technologies to ensure they are "providing the best in patient safety."

"Tracking and tracing systems for surgical instrumentation has become a great way to follow the sterilization process from start to finish by barcoding and scanning instrument trays throughout the entire process," said Dybec.

Loguidice points out how biological indicator results can be downloaded into instrument tracking systems, automating the documentation process, and enhancing data management reporting and information on load retrieval.

"The instrument tracking program has become an essential component for every CS and OR," she said.

Looking forward

Throughout the healthcare industry, there is widespread uncertainty around how COVID-19 will impact care in the months ahead. While efforts are underway to develop a vaccine, most agree that healthcare organizations will be providing care in a pandemic environment for quite some time. For example, for HCA Healthcare, one of the nation's leading providers of healthcare services, COVID-19 patients represent about six percent of patient admissions and leadership doesn't believe this volume will be dropping anytime soon.

"We believe we will continue to treat COVID-19 patients through 2021," said HCA's CFO Bill Rutherford. "We believe it is reasonable to estimate about four-to-five percent of 2021 admissions could be related to the virus."[2]

As Duro points out, CS/SPD and OR staff must continue to evolve along with a changing healthcare delivery environment: "Administration in many facilities have been planning even though they are unaware of the future, and who knows, we might have to take steps back again, so CS/SPD and OR always have to be ready to adapt." HPN

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LEARNING OBJECTIVES

- ***Describe device reprocessing steps and its complexity in dental settings.***
- ***Provide recommendations on how to address reprocessing challenges.***
- ***Explain performance of reprocessing equipment to get the best possible outcomes.***

SELF-STUDY SERIES

Removing the mystery from reprocessing

Concepts and first steps for reprocessing in the dental setting

by Nita Mazurat, DDS

Reprocessing is the science and practice of preparing instruments and devices for use and reuse in patient care. To many dental personnel, reprocessing of instruments when they were students was a magical, if not mysterious process, where contaminated devices were exchanged for clean and sterile ones. This mythical component remains for many clinicians since they do not (nor have time to) participate in reprocessing activities in their practices. Fortunately, oral healthcare knowledge of reprocessing, both what to do and how to do it, has advanced through awareness and adoption of established Reprocessing Standards: AAMI ST79:2017 in the United States and Canadian Standards Association (CSA) Z314-18 in Canada. Both standards were developed for use in all healthcare settings with emphasis on the hospital setting; although CSA is planning to develop a standard with a focus on non-hospital or 'community' users.

Reprocessing is a great deal more than a 'sterilizer in a room' and is comprised of many steps.

Steps for reprocessing:

- ✓Cleaning at chairside, also known as 'cleaning at point of care'
- ✓Transport to the central sterilization area
- ✓Pre-cleaning and disassembly of devices (eg mirrors, composite guns, syringes)
- ✓Cleaning, rinsing
- ✓Drying
- ✓Inspection
- ✓Testing for functionality
- ✓Packaging
- ✓Monitoring
- ✓Sterilization (loading and unloading)
- ✓Storage
- ✓Traceability
- • Aseptic presentation

Aseptic presentation is not part of reprocessing, however, because it includes removal of sterile devices from their packaging for patient care. Contamination during operatory set up can negate the careful work of the previous steps.

Manufacturers' instructions for use

During reprocessing, critical decision making is a skill that must be accompanied by strict adherence to instructions from the manufacturer for products and procedures to achieve cleanliness, functionality, and sterility. Let's examine some of these hallmark concepts surrounding manufacturers' instructions for use (IFUs). Please note that these concepts are not in any order and they are all important! All of our activities are driven by the need for patient safety.

- Only instruments and devices, from here forward simply referred to as 'devices,' manufactured with the intent of use and licensed for use in healthcare should be used in healthcare as these have had to be demonstrated to be safe for use during patient care. 'Do no harm' is the overlying umbrella for patient care.
- Devices developed for use in healthcare are 'labeled', meaning that the manufacturer has to provide instructions for their reprocessing.

1. Obtain and follow manufacturers' instructions for use, known as MIFUs in Canada and IFUs in the United States.
Assumptions about how to reprocess may result in devices that are not sterile and therefore, not safe for patient care. Only the manufacturer knows the composition of the device and how it should optimally be reprocessed to prevent premature degradation of the device while providing

instructions to achieve sterility. Manufacturers are required to provide instructions for reprocessing for all classes of instruments, which should include the necessary information required by the FDA (United States) and Health Canada (Canada)[1] from preparation at point of care to storage.

In the excitement of purchasing new devices, it is easy to forget that the first question to ask is 'how will this be reprocessed?' and it will take a team effort to remind each other to develop this change in purchasing practices. Requesting the manufacturers' IFUs prior to purchasing any devices is done to ensure that:

a) The written reprocessing instructions provided by the manufacturer adhere to ISO standards. Preferably these instructions are 'validated'. Validated instructions are instructions that have been shown either by the manufacturer labs or by an independent testing company to verify that when the reprocessing instructions provided by the manufacturer are followed, this will result in a sterile device.[2]

b) Equipment required for reprocessing is available in your office. For example, your hygienists recommend purchasing a new type of highspeed suctioning device that would be more effective during ultrasonic scaling. Upon checking the instructions for reprocessing it was found that the manufacturer had only provided the IFUs of a gravity sterilizer. Even after contacting the company, no instructions were provided for use with a dynamic-air-removal sterilizer. Since your office uses a steam flush pressure pulse (SFPP) sterilizer (a type of dynamic-air-removal sterilization), your office would not be able to sterilize the device because the device has only been tested (validated) in a gravity sterilizer.

Reprocessing is tailored and is not a 'one set of sterilization parameters fits all' process. Until the manufacturer is able to provide instructions for the type of sterilizer that you have in your office, you are not able to reprocess the device, and therefore should not buy it. Only buy what you can clean and sterilize!

One further comment: Often a manufacturer's representative will try to be helpful by providing their assurance that the device can be sterilized using 'a standard cycle.' Unless those assurances are provided by the manufacturer using written instructions, wait for the validated instructions prior to purchase.

2. Devices that do not have IFUs, cannot be reprocessed and are considered single use items.

Some single use items such as burs, may come with IFUs for reprocessing prior to use only. Many disposable cotton products such as gauze, rolls, pellets, and tipped applicators, should not be reprocessed prior to use because they do not have instructions for reprocessing and sterilization only is not 'reprocessing.' This is a practice so commonly performed in healthcare, especially for providing 'sterile' cotton gauze following surgery, that it has become normalized; however, if the office is unable to purchase gauze with validated IFUs and sterile materials are required, then these disposable products need to be purchased sterile.

3. Surfaces must be clean prior to sterilization or disinfection.

Cleaning is the most important step in reprocessing because a soiled instrument cannot be effectively sterilized as the soil shields the bacteria and viruses from the sterilizing agent.

So, this begs the question: what is clean? This question can be addressed by understanding the monitoring tools and methods employed on the cleanliness assessment, which can be described in two groups: qualitative and quantitative.

Qualitative assessment methods are based on observation (which will vary based on the observer, the light conditions, magnification, etc.) or based on devices called markers (e.g. protein or blood); which will react to certain soils by way of color change and therefore providing results.

On que quantitative methods, adenosine triphosphate (ATP) is the most common technology, providing a quantitative result evidencing that organic soil has been sufficiently reduced, enabling devices for future reprocessing steps.

Another important consideration is that devices decontaminated in automatic equipment, often will be disinfected as well, thanks to the higher temperature of the cycles.

4. Cleaning should be directed by the IFUs

All cleaning requires the use of specified cleaning agents; specified water, including temperature and type, especially for the final rinse to remove residual detergent and minerals that are present in tap water; and specific equipment. Water hardness, the concentration of certain minerals, will reduce the efficiency of cleaning agents because the minerals bind with the cleaning agents such as detergents and enzymes. Knowing the water hardness in your facility and receiving guidance when purchasing cleaning agents based on this important variable can be very useful in preventing staining and premature degradation of devices.

a) Manual cleaning

Manual cleaning includes the use of appropriate brushes that are designed and purchased for this purpose. Because brushes, both toothbrushes and denture brushes, are readily available in dental offices, these are convenient and often used. However, these brushes have been carefully designed to be used for oral hygiene, not for cleaning devices. Additionally, since the oral hygiene brushes do not come with IFUs, they may not achieve optimal results for cleaning devices.

Some devices, like lumens, present their own unique challenges. There are open-ended lumens, such as hygiene handpieces that are open at both ends, that require open-ended brushes, and closed-ended lumens for areas such as the lumen in the handle, when mirrors are disassembled (check the instructions for disassembly for mirrors that are not solid state). Brushes used for cleaning lumens need to be large enough to be effective on the inner walls without being difficult to brush back and forth. Open-ended brushes need to be long enough to extrude from the distal end of the lumen. End-cleaning brushes have a 360-degree fan brush at one end for cleaning the resultant solid wall as well as the lumen. Because the cleaning of lumens is a resource-intense step, many offices have switched to disposable items when they are readily available, including air/water syringe tips and high-volume suction tips.

All cleaning and rinsing should be performed in sinks filled with water to allow full immersion of the devices so that they are cleaned and rinsed underwater (not in running water) to avoid producing spatter and aerosols.

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

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b) Ultrasonic cleaning

Ultrasonic cleaning occurs when the bubbles caused by high frequency sound waves in the cleaning solution implode causing cavitation, which draws debris from the surfaces of the devices. Ultrasonic cleaners can be a single tank or multiple tank device and various sizes can be purchased.

If this is the cleaning method of choice in your office, consider the capacity that will be required for efficient cleaning, remembering that ultrasonic cleaning works because all surfaces of the devices are exposed to the solution and overcrowding will reduce the effectiveness of cleaning. Other factors that affect the efficiency of ultrasonic cleaning are:

- Using the correct cleaning agent and maintaining the required level of solution to ensure that devices being cleaned can always be submerged. Follow manufacturers' instructions for the solution specified as these remove debris in the way that the ultrasonic cleaner was designed to work. Know the target soil. Enzymatic assists in removing dried blood and in offices where the majority of procedures performed are surgical, and this would be the preferred cleaning agent. However, in an office that is mostly restorative or orthodontic, a cleaning agent that targets inorganic materials such as luting cements and restorative materials, will be more applicable. Follow the IFUs for correct dilution, correct volume of diluted agent in the ultrasonic tank, and correct water temperature. Cleaning and disinfecting the tank when changing the solution helps to reduce the microscopic bioburden.
- Removing gas bubbles caused largely by trapped air when fresh cleaning agent is placed into the tank. The bubbles need to be expelled by running or 'degassing' the ultrasonic without instruments in the tank for the time specified by the manufacturer, so these gas bubbles do not interfere with further cleaning.
- Placing the devices being cleaned in a tray or basket designed for use in the tank to allow more accessibility to cavitation and prevent the devices from touching the walls and floor of the ultrasonic tank. Stainless steel instruments should not be mixed with aluminum, brass or copper instruments in a sonic cycle as this may cause galvanic reactions that result in corrosion.
- Removing gross debris from the devices prior to ultrasonic cleaning. Clean the devices at point of care and in the reprocessing area by rinsing the devices prior to placing into the tank. When the ultrasonic cleaning solution has less debris, cleaning action is more effective. Rinsing is more effective when devices are immersed using the basket designed to be used in the ultrasonic in water and allowing this to drain prior to placement into the cleaner to remove excess water and gross debris. Lumens should be manually cleaned prior to placement into the ultrasonic washer.
- Following the ultrasonic cleaner instructions for use for loading. A single layer of instruments should only be cleaned at a time so that cavitation can reach every surface. When instruments are stacked, cavitation may be unattainable to every surface. Many dental offices use ultrasonic cleaners that are too small for the volume of instruments and devices that are used in the office, which in turn results in overfilled ultrasonic cleaners with poor cleaning results. Ensure that all items are submerged and that hinged devices are open to allow cleaning.
- Rinsing following cleaning removes residual solution and soil which need to be removed before the next steps in reprocessing. Fully immerse the instruments into the sink used for rinsing using the quality of rinse water required by the manufacturer of the devices.

Ultrasonic cleaners should be run with the lid on to prevent escape of microorganisms into the ambient office air.

Cleaning efficacy or a function test is required at least once weekly, preferably daily, either using a foil test or using a commercial ultrasonic cleaner test.

c) Automated washers

The key here is the word 'automated'. As long as MIFUs exist regarding detergents, water including type of water used and water temperature, and office personnel allow complete cycles to run, there is less human error to intervene in the cleaning process surrounding washers. Just as with ultrasonic cleaners, stainless steel instruments should not be mixed with aluminum, brass or copper instruments during cleaning in a washer or washer/disinfector. As stated earlier, the final level of clean is visual when using a washer, whereas it is microscopically clean using a washer/disinfector. The consequences of this are substantial in how devices are able to be handled in the remaining steps of reprocessing.

Key takeaways:

1. Users should request validated instructions for reprocessing before purchase of devices as well as requesting clarification for instructions for existing devices in the office inventory that are unclear, incomplete, or require parameters of sterilization that vary from the normal expected cycles.
2. Users must assemble and follow the instructions for the entire office inventory of devices.
3. Terms used in this article need to become commonplace when discussing reprocessing in oral healthcare offices. HPN

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Dr. Nita Mazurat is an Educational Consultant to 3M Health Care. *Dr. Mazurat is an Associate Professor, Department of Restorative Dentistry, University of Manitoba, Winnipeg, Manitoba, Canada where she is the clinical dentist for Screening for the undergraduate programs in Dentistry and Dental Hygiene, Director of International Students, and Coordinator of Regulatory Compliance including Infection Prevention and Control. Nita has been a member of OSAP since 2005 and is a proud international editor to ICIP. She is also a member of IPAC (Infection Prevention and Control, Canada), CAMDR (Canadian Association of Medical Device Reprocessing, CSA (Canadian Standards Association) Technical Committee on Sterilization, and SCC (Standards Council of Canada, Canada's accreditation body) and is currently awaiting to hear whether or not she will be selected as an advisor to PHAC (Public Health Agency of Canada) representing oral healthcare professionals. Her passion for Infection Control is matched only by her passion for her family, her husband of 42 years and their three children, and golf.*

CONTINUING EDUCATION TEST • DECEMBER 2020

Removing the mystery from reprocessing

Concepts and first steps for reprocessing in the dental setting

Circle the one correct answer:

1. **Reprocessing of medical devices in the dental setting is done only according to internal facility policies.**
   A. True
   B. False
2. **Decontamination of medical devices is conducted with a multi-step approach, generally known as reprocessing.**
   A. True
   B. False
3. **Devices to be used in healthcare facilities should have instructions for use.**
   A. True
   B. False
4. **One key question to ask when procuring a new device is: How will this device be reprocessed?**
   A. True
   B. False
5. **Cleaning is the most important step in reprocessing.**
   A. True
   B. False
6. **Chairside cleaning includes sterilization and packaging.**
   A. True
   B. False
7. **One type of device that poses an additional reprocessing challenge is a lumened device.**
   A. True
   B. False
8. **Cavitation increase the ability of steam to penetrate the lumens.**
   A. True
   B. False
9. **Degassing (removing gas bubbles) in ultrasonic equipment must be done without instruments in the ultrasonic unit.**
   A. True
   B. False
10. **Automated washers are equipment that completely remove human errors from reprocessing.**
    A. True
    B. False

IAHCSMM
Instrumental to Patient Care

The approval number for this lesson is **3M-HPN 201211**.

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Current, future SP leaders must keep their skills sharp

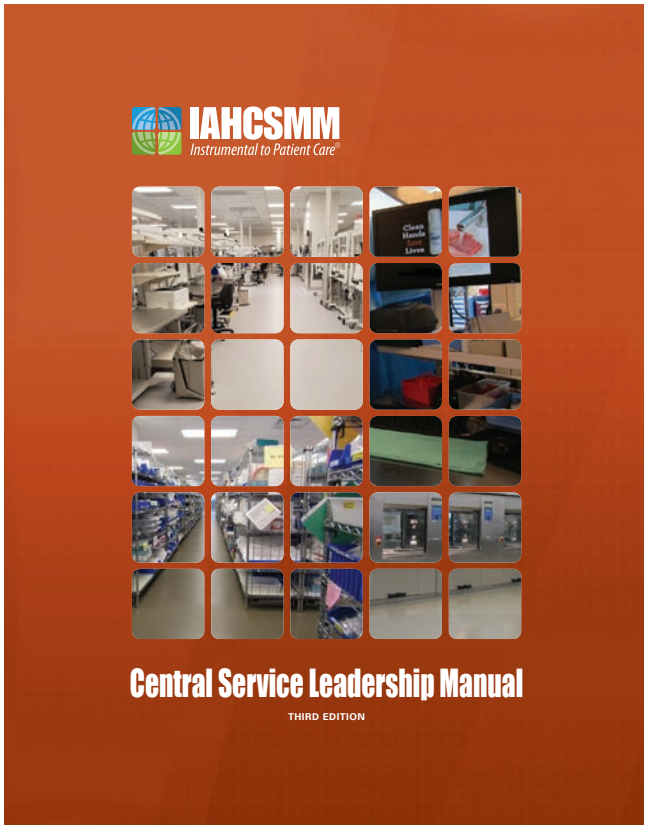
IAHCSMM's fully revised ***Central Service Leadership Manual***

by Julie E. Williamson

In today's fast-paced, ever-changing and challenging Sterile Processing (SP) environment, those who are currently in leadership positions within the discipline — and those who wish to grow into those essential roles — need a solid foundation of knowledge to effectively tackle their many critical responsibilities, including staff recruitment, hiring, training and professional development; management of various resources and functions required for planning and day-to-day operations; compliance with regulations, standards and guidelines; and customer service and stakeholder interactions.

The International Association of Healthcare Central Service Materiel Management's (IAHCSMM's) updated third edition *Central Service Leadership Manual* will help build that knowledge base through a deeply expanded range of topics that cover key aspects of departmental management and leadership. The first section of the revised manual provides a comprehensive introduction on leadership and its core facets as they pertain to the SP discipline. Of course, SP leaders must also be technical specialists and possess a broad understanding of sterile processing science. The decisions they make and the processes they develop can literally result in life or death patient outcomes as well as staff safety issues.

"SP leaders must be well-rounded in their skills and abilities. They are the ones steering the direction of the department each day and they must not only understand the managerial aspects of the position, but also have a solid grip on all technical aspects, all while ensuring the team fully understands its role in patient care, safety and customer service delivery," explained Natalie Lind, CRCST, IAHCSMM's Director of Education. "The latest edition of the Central Service Leadership Manual helps leaders stay on top of those needs by broadening their knowledge scope to meet the department's many needs and demands."



The second section of the revised manual provides essential new technical and operational information on:

- Safety and disaster preparedness;
- Construction projects;
- Work areas and workflow;
- Instrument and information system management;
- Soiled item processing systems;
- Clean item assembly systems;
- High-temperature and low-temperature sterilization;
- Sterile storage and distribution systems; and
- Purchasing and inventory management systems.

In addition to these expanded topics, the new-edition manual includes revised content on other previously published chapters, including maintaining collaborative relationships with the Operating Room and Infection Prevention; improving intra- and interdisciplinary communication; understanding the leader's role in Human Resources; effective staff development and training systems; and much more.

"Leaders in Sterile Processing have incredibly demanding positions with a diverse set of responsibilities. Overcoming those workplace demands and pressures requires all SP leaders to marry their managerial, business and technical acumen to ensure their teams have the tools, resources, training and support to safely, effectively and consistently tackle their roles each day, even in the event of unforeseen challenges and disasters," Lind continued.

The Central Service Leadership Manual is a useful resource for today's SP leaders wishing to learn new information and brush up on previously learned topics, and it also serves as a valuable tool to help leaders navigate on-job challenges and prepare management training sessions for their team members. Beyond that, the manual can help guide others within the department who express an interest in preparing for a leadership position.

To order the new edition manual, visit www.iahcsmm.org/leadership. IAHCSMM member rates are as follows: $150 for the boxed course [a key preparation tool for those studying to become a Certified Healthcare Leader (CHL). The box set includes one textbook and one workbook. ($180 non-members)]; $110 for the textbook only ($135 non-members); and $65 for workbook only ($75 non-members). ***A 15% discount will be offered on online orders received by Dec. 31, 2020 (using discount code: Leader2020).***

Note: The CHL exam has been cross-referenced to both the second and third edition Central Service Leadership Manual; however, moving forward, IAHCSMM will only be selling the third edition materials.

SUBMIT YOUR QUESTIONS: **editor@hpnonline.com**

Inspection of cannulated devices, cleaning of personal items, arm covering in SPD

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

Q Borescopes have become the new wave for inspecting cannulated items on the clean side along with ATP testing. We do not have a borescope with a diameter that is small enough to fit through the very small channels of some scopes and small instruments, such as the baron suctions. Is there an alternative for inspecting these items? I know many hospitals fill a syringe with water and flush over a white linen towel to inspect for blockage or debris. Same is done with lap instruments that cannot be taken apart. Is this still an acceptable practice? Is there a water requirement?

A In last month's *HPN* edition, I addressed the importance of cleaning verification for cannulated medical devices and provided information and recommendations that would address your concerns. Visit the November "CS Solutions" column (https://hpnonline.com/21159592) to learn more. If it is absolutely necessary that you do this inspection on your clean side, I would recommend that you have a designated/segregated workstation dedicated to this function and that the staff performing the inspection process wear the appropriate PPE.

Q I am the manager of surgical services, which includes the OR, SPD, and RR. All these areas occasionally have outside consultants, service personnel, vendors, and educators coming into their work areas. We require them to change into scrubs or jumpsuits and basically follow the same dress code as the personnel in the work area they are visiting. Frequently they come in with briefcases and carrying cases that they need to bring into the area where they are meeting. We try to discourage them from doing this, but often they really do need the contents during the meeting. We currently do not address this matter in our policies. What would you recommend?

A Unclean items brought into the OR and other areas you mentioned can be contaminated with dust, microorganisms, bacteria, and pathogens. Any personal items, such as briefcases, backpacks or other carrying cases, should be cleaned prior to bringing them into your restricted or semi-restricted areas. If this becomes an issue, then I would suggest they remove what is needed and place it in a clean hospital tote box or container that they can bring into the area. Once cleaned, any of these carrying cases should not be placed on the floor.

Frequently I get questions relative to other personal items, such as cell phones and tablets, being brought into semi-restricted and restricted areas; these items should be cleaned before and after use in these areas. Ultraviolet (UV) sanitization or disinfection units are quite popular for These units are effective, with a rapid cycle of three minutes or less. (See Figure 1.)

Figure 1

Photo courtesy: Healthmark Industries

Q We have a new manager who has changed our dress policy, which now requires that we wear scrub jackets in the instrument assembly and packing area. She claims that the long sleeves support a cleaner work area preventing foreign particles from possibly falling into sets and packages. I, as well as other staff members, dislike wearing the jackets as they are uncomfortable and very warm. Many of my coworkers are wearing the same jackets for several days without laundering them, which certainly cannot be very sanitary. What do you suggest?

A Sterile processing personnel who are preparing and packaging surgical instrument sets should wear scrub attire that covers the arms fully and is fitted at the cuffs. Wearing long-sleeved attire, such as warm-up jackets, prevents the shedding of scaled skin (squames) and hairs on bare arms from depositing into instrument sets or packages. Organic matter, such as skin or hair, could attach to instruments and be transferred to the surgical incision site, exposing the patient to a greater risk of getting a surgical site infection or other serious postoperative complications.

An option for the warm-up jacket that many find more comfortable and cooler are arm sleeves. (See Figure 2.) Just as is the case with scrub attire, a clean warm-up jacket should be worn each day and be changed whenever it becomes soiled during the day. Hospital attire, such as scrub wear and warm-up jackets, should only be laundered by the healthcare facility's laundry services and not allowed to be laundered at home. Both AAMI and AORN standards and guidelines address these issues. **HPN**

Figure 2

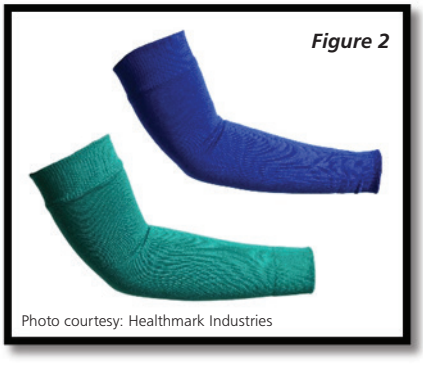


Photo courtesy: Healthmark Industries

Note to readers *- In 2021, my life's career path will transition to one of new opportunities and adventures. As a result, after nearly 19 years and 225 CS Solution columns, this edition will be my last.*

"All changes, even the most longed for, have their melancholy; for what we leave behind us is a part of ourselves; we must die to one life before we can enter another."– Anatole France

I wish you and your loved ones a healthy and joyful holiday season and a beautiful New Year! God Speed, Ray

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email: raytaurasi@gmail.com

MEDICAL DEVICE HALL OF FAME

Honoring products, technology that expand healthcare's reach

by Rick Dana Barlow

Earlier this year, *Healthcare Purchasing News* surveyed readers for their suggestions about key products they thought healthcare could not succeed without having and using. Surprisingly, against the backdrop of the pandemic and in context of COVID-19, infection prevention products only occupied a small percentage of the suggestions.

Interestingly, information technology dominated the initial responses. *HPN* will share more details about that next month as it features its inaugural Medical Device All-Stars.

The *HPN* survey actually functioned as a litmus test for a much bigger exercise, a larger franchise designed to bring – if not rekindle – much-needed recognition and respect for products and technology long taken for granted.

The inaugural Medical Device Hall of Fame.

Honestly, this year *HPN* fretted that the voting would coalesce around all things pandemic-related. Not that there's anything wrong with that, of course, but thankfully, respondents demonstrated more open-mindedness to *HPN*'s project concept. While at least one or two of the 10 honorees this year is directly related to infection prevention and the pandemic, several of the remaining eight are indirectly, if not peripherally related, which demonstrates the heterogeneity surrounding homogeneous function – namely, different products and technologies geared toward a singular honorable purpose, which is patient care.

Industry support gravitated around a broad mix of genuine hall of fame-worthy products and product categories befitting the lifetime achievement recognition for their stalwart and steadfast contributions to patient care over the decades – and for several honorees this year – centuries!

Of the 10 making the first class of *HPN*'s Medical Device Hall of Fame, four are diagnostic imaging-related (computed tomography, ultrasound, X-ray and vein visualization), four are patient monitoring-related (glucose monitor, pulse oximeter, cardiac defibrillator/AED and stethoscope) and two are commodity-oriented and -related to infection prevention (hypodermic needle and syringe and the three veterans of PPE – personal protective equipment).

Some may contend these represent low-hanging fruit. But a new franchise must start at or near the ground floor with the opportunities for plenty more to be harvested in Hall of Fame classes to come.

Without further delay, here are the 10 members of *HPN*'s Medical Device Hall of Fame Class of 2020 with an approving nod to the companies that brought them to market over time.

Disposable hypodermic needle/syringe

KEY SUPPLIERS: Abbott, Argon Medical Devices, **BD**, B. Braun, Bracco Diagnostics, Cardinal Health, DeRoyal, Duopross Medtech, Exel International, Genus Medical, Hamilton, Healthmark, Henke-Sass Wolf, Integra Lifesciences, MHC Medical Products, Medline, Medrad, **Medtronic**, Merit Medical, Nipro Medical, Novo Nordisk, Owen Mumford, **Retractable Technologies**, Sartorius, Smiths Medical, Sol-Millennium, Summit Medical, Teleflex Medical, Terumo, Ultimed, Vesco Medical, Viscot Medical, Vyaire Medical, Westmed, Whatman

ORIGIN (earliest known debut): The hollow metal needle reportedly debuted in 1844, invented by Irish physician Francis Rynd. Another nine years would pass until Scottish physician Alexander Wood and French surgeon Charles Gabriel Pravaz each invented his own version of the earliest type of hypodermic syringes. Some researchers, however, refer back to the second century when Galen crafted a simple piston syringe for non-invasive medical use or the 10th century when another reported using glass tubes for suction for extracting cataracts. Others trace the "modern" syringe to Pascal's experimental work around 1650. But the traditional, typical disposable syringe with the glass enclosures and plastic valves and different gauges emerged in the early to mid-1950s, mass produced by Becton, Dickinson and Company (BD) and Roehr Products (the Monoject).

BD is a pioneer in developing disposable syringes and needles, according to Chee Lum, Vice President, Medication Delivery at BD. "In 1954, in response to the polio epidemic, the company supplied the first sterile disposable syringes for the Salk polio vaccine field trials, helping to inoculate one million school children in the U.S.," Lum noted. "In the early 1960s, BD pioneered the use of disposable needles and plastic syringes."

A variety of safety-engineered models designed to prevent needlesticks debuted in the late 1990s, spurred in large part by the burgeoning movement to prevent occupational exposure to blood-borne pathogens, alongside the passage of several state needle-safety laws and in advance of the federal Needlestick Safety and Prevention Act in late 2000.

WHY IT MATTERS: Hypodermic needles and syringes, by and large, serve to deliver accurately measured drug doses for disease and sickness treatment and vaccinations as well as to extract blood and other body fluids with minimal contamination, discomfort and pain. Larger bore needles and syringes also are used for surgical biopsies to take tissue samples from lesions and tumors to determine whether they are benign or malignant.

"With the development of these products, clinicians have the ability to deliver medications, advance therapies and deliver immunizations while avoiding cross-contamination among patients due to sharing devices," BD's Lum indicated.

Stethoscope

KEY SUPPLIERS: 3M Health Care (Littman), American Diagnostic Corp.(ADC), Cardionics, Eko, Heine, **Hillrom (Welch Allyn)**, ThinkLabs and WA Baum.

ORIGIN (earliest known debut): French physician and musician René Laennec played the flute, carving his own wooden models, and used that interest to invent what became the earliest known stethoscope, which in 1816, started off as a wooden tube with brass fittings. He fashioned it to listen to the heartbeat of a rather weighty female patient who was exhibiting symptoms of heart disease. Until the stethoscope, doctors would listen to a patient's heartbeat by placing his or her ear directly against the chest of the patient. The concept generated mixed reception among doctors until Irish physician Arthur Leared

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developed the binaural stethoscope with the dual earpieces in 1851, and a year later the design more recognizable today was improved for commercial production.

WHY IT MATTERS: Arguably, the heart represents the engine/motor of the human (and animal) body. Skilled and talented automobile mechanics and engineers can discern what may be wrong with a motor simply by hearing it run and listening to the sound it makes. The same holds true for the heartbeat.

"The human body produces a symphony of sounds that reveal much about our state of health," observed David Tufenkijian, Global Welch Allyn Product Manager, Hillrom. "There are normal sounds caused by the beating of a healthy heart. Breath sounds as healthy lungs fill with air and then exhale. The rumbling of our bowels as peristalsis propels matter through our intestines. The reassuring sounds of a fetal heartbeat.

"Then there is the lack of normal sounds or the presence of other sounds that are diagnostically significant," Tufenkijian continued. "A subtle whoosh between the normal 'lub-dub' sounds of a beating heart, the absence of breath sounds, a wheezing sound upon exhalation or a crackling sound upon inspiration, a lack of bowel sounds, the telltale sounds of carotid stenosis. Listening to the sounds made by the body is called auscultation."

Tufenkijian likens the sounds produced by the human body to a "symphony" with each organ as an instrument contributing to the "opus.

"Dr. W. Proctor Harvey, a famous and distinguished cardiologist, introduced his students to the art of auscultation by impressing upon them that the sounds produced by a beating heart are composed of many different components, each with its own timbre," Tufenkijian noted. For more than 50 years until his death in 2007 Harvey worked with engineers at Welch Allyn, which manufactured his stethoscopes.

"Dr. Harvey required a stethoscope that would detect and transmit the full spectrum of subtle, diagnostically significant sounds produced by a beating heart," Tufenkijian said. "At Hillrom, we are honored by our long association with Dr. Harvey and proud to offer the Harvey DLX Double Head, Triple Head, and the more compact Harvey Elite Stethoscopes as part of our comprehensive Welch Allyn portfolio of stethoscopes."

Cardiac defibrillator/AED

KEY SUPPLIERS: Cardiac Science Corp., Defibtec, HeartSine Technologies, Philips Medical Systems, **Stryker (Physio-Control)**, Zoll Medical Corp.

ORIGIN (earliest known debut): In 1899, two physiologists in Switzerland, Jean-Louis Prévost and Frédéric Batelli, applied small electrical shocks in dogs to induce ventricular fibrillation. More than three decades later, a New York heart specialist and an electrical engineer, Dr. Albert Hyman and C. Henry Hyman, respectively, wanted to find a way to deliver an electrical shock to the heart in lieu of injecting drugs. They developed a hollow needle device through which they threaded an insulated wire to deliver the shock. The cardiac defibrillator device/automated external defibrillator recognized today was invented by electrical engineer William Kouwenhoven in 1930 who studied the concept in college, created the device and tested it successfully on a dog. Seventeen years later, a surgery professor would test the device on a human for the first time.

WHY IT MATTERS: Imagine being in a public place and witnessing someone suddenly experiencing cardiac arrest. Until the advent and convenient availability of AEDs, much like fire extinguishers and public telephones (in the pre-mobile communications era) calling 9-1-1 for an ambulance was the common sense reaction by reasonable people. While emergency vehicles might arrive within minutes, accessing and activating a conveniently located AED might take seconds to a minute, which could delineate between life and death of the patient.

Vein identifier/locator/visualization

KEY SUPPLIERS: AccuVein, CAREstream Group (Christie Medical, Luminetx), Illumivein, Miralth, Oxy-Amp, Polymer Technology Systems, Respironics, UMTEC, Veinlite and Vivolight.

ORIGIN (earliest known debut): The technology that helps nurses and phlebotomists find veins in which to insert needles, syringes and catheters accurately, effectively, efficiently and safely represents the youngest honoree in the 2020 class with a lifespan rooted in the 21st century. The technology, which resembles an articulating arm on wheels that projects a near-infrared light reflection onto the patient's skin, debuted in 2006 by a company called Luminetx, followed two years later by its first competitor, AccuVein. Today, there are several prominent and well-known brands used in many healthcare facilities and about a half-dozen other products.

WHY IT MATTERS: Ask a nurse or phlebotomist about of the frequent, repetitive tasks they train for and do every day and he or she likely will mention needle injections on patients. They practice their techniques on fruit – typically oranges – so that they can learn to minimize, if not eliminate, causing pain to the patient from poor technique or frequent attempts, which only add to the fears and discomfort of the patient. In fact, for more than a decade you'll find a "Vein Viewer" on display in the healthcare exhibit of Chicago's Museum of Science & Industry. (See "From sci-fi to sci-fact, healthcare supply chain spies Star Trek wonder," April 2013, *HPN*).

You'll also find one in the St. Louis Science Center & Planetarium, the Terry Lee Wells Nevada Discover Museum, Reno, NV, and in the Discovery Place, Charlotte, NC, among others.

CT scanner

KEY SUPPLIERS: Carestream Health, Fujifilm, GE Healthcare, Hitachi Medical, Hologic, Philips Healthcare, Shimadzu, **Siemens Healthineers** and Toshiba Medical Systems

ORIGIN (earliest known debut): Back in the early 1900s, Italian radiologist Alessandro Vallebona started experimenting with what was known as tomography. He used radiographic film to view a slice of the body. But "conventional tomography" still struggled to capture images of soft tissue. Then in the 1960s, researchers started exploring how to use computers to generate tomographic images. In 1967, British enginner Sir Godfrey Hounsfield used X-ray technology to craft

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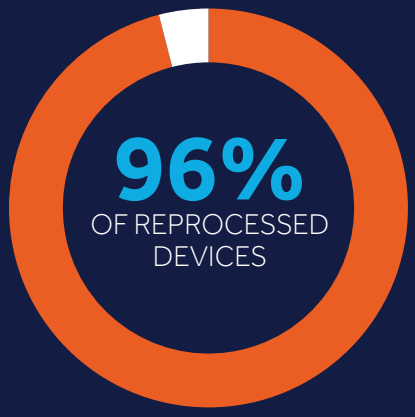
CONTROLLING COSTS. AT WHAT COST?

Study published in *Surgical Endoscopy* raises questions about the ability to effectively clean and sterilize with reprocessed vessel-sealing devices[1]



1 OUT OF 165 REPROCESSED DEVICES **GREW BACTERIA IN CULTURE.** AND THE LEVEL WAS **166X FDA GUIDELINES.**[1,†]

FAILED ACROSS A MIX OF 4 DIFFERENT TESTS THAT CHECKED FOR ORGANIC MATERIAL[1,‡]

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Read the full study here.

†Sterility assurance level of 10-6 accepted by the FDA as laid out in the Association for the Advancement of Medical Instrumentation (AAMI) standards ST67 and TIR 12 for devices contacting normally sterile tissue.

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

§Medtronic will not perform complaint investigations on competitive devices.

ΩOptional risk-sharing and indemnification programs include the LigaSure™ Technology Performance Pledge and Project Zero collections programs.

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what is regarded as the first CT – as in "computed tomography" – scanner at EMI Central Research Laboratories. Six years later, the first CT scanners emerged in the United States. Back then the term "computed axial tomography" or CAT scan was considered synonymous. By the 1980s, CT scanners were more widely available in hospitals. Those early "single-slice" CTs now have evolved into multi-slice models that can exceed 512 slices in a single scan, demonstrating improvements in speed, radiation dose (exposure) and image quality.

WHY IT MATTERS: Until the advent of CT, clinicians and engineers used ultrasound and X-ray for internal views of the body, the latter involving considerable exposure to radiation to generate clearly visible images of hard tissue like bone and the former using sound waves to generate images. Before CT, generating clear images of soft tissue remained a goal.

"Imaging as a field has given us tremendous insight into understanding the human body without having to dissect it," Matthew Fuld, Ph.D., Clinical Excellence Segment Product Manager for CT, Siemens Healthineers North America, told *HPN*. "It is one thing to understand what happened after death via an autopsy, but another to understand it when someone is living. When X-ray debuted in 1895, it was just the beginning of the diagnostic imaging journey that expanded to CT in the early 1970s. CT gives us much more in details than did the early views from X-ray, specifically due to speed and quality level of the image."

X-ray machine

KEY SUPPLIERS: Carestream Health, Fujifilm, GE Healthcare, Hitachi Medical, Hologic, Philips Healthcare, Shimadzu, **Siemens Healthineers** and Toshiba Medical Systems

ORIGIN (earliest known debut): In 1895, Bavarian physics professor Wilhelm Roentgen actually discovered X-rays by accident as he tested whether cathode rays could pass through glass. Roentgen removed the air from the glass tube, filled it with a special gas and then passed a high electric voltage through the tube that emitted a fluorescent glow. Then he covered the tube with some heavy black paper and did the same thing. He saw a barium-coated screen in his lab begin to glow, which led him to experiment with other substances, learning that the glow or "ray" would cast shadows of solid objects on film.

WHY IT MATTERS: Despite the emergence of CT and Magnetic Resonance (MR), X-ray remains prevalent and useful, certainly as a baseline, according to Laurie Falk, Clinical Product Manager, X-ray, Siemens Healthineers North America. And with low-dose capabilities, the modality retains its staying power.

"X-rays can be transmitted at a lower radiation dose than CT, which makes X-ray an effective baseline or precursor to more advanced modality imaging when necessary. X-ray is the backbone of imaging modality. You can detect a lot with X-rays but you also can use X-rays to determine if additional diagnostic imaging tests are needed."

Falk praises the scientific minds over the decades that developed X-ray's ongoing potential.

"If we didn't really have those medical engineers thinking of new technology like this, we wouldn't be where we are today," she noted. "We went from basic X-ray in their time to what we have now, from fluoroscopy to radiography. Now we can do 3-D cone beam X-ray imaging, and we're adding artificial intelligence (A.I.) to help technologists in the control room via touchscreen to maneuver the system to open up the collimation to detect the lung fields in the chest. These types of advancements increase the imaging quality, reduce the need for repeat exams and radiation dose exposure. From moving equipment around to dedicated X-ray rooms – bringing the equipment to patients or the patients to equipment – the speed at which you can treat patients now is amazing. The progress of getting from there to here is phenomenal."

Falk remains an avid fan of the X-ray modality, noting that five days after her interview with *HPN,* Siemens and everyone in diagnostic imaging/radiology would be celebrating the 125th anniversary of the discovery of X-rays.

Siemens also maintains a close connection with X-ray's roots, according to Falk. When Roentgen discovered X-rays in 1895, he asked for scientific reviews and for people and companies to submit ideas and products for further research, she recalled. Within three days of Roentgen making that call, executives from the company Reiniger, Gebbert & Schall (RGS) reached out to him and shared its prototype of X-ray tubes. RGS later would become part of the company founded by Werner von Siemens. *[In fact, the original RGS factory on the outskirts of Erlangen, Germany, today serves as the official site of the Siemens Healthineers MedMuseum that welcomes visitors from all over the globe.]* RGS didn't meet with Roentgen directly at first but with his assistant, and when Roentgen actually worked with the RGS product he was impressed, Falk noted. Four months later in March 1896, RGS patented the X-ray tube that became the foundation of Siemens' diagnostic imaging business.

Carestream emphasizes access, convenience and utility as key attributes of X-ray popularity.

"Carestream developed the industry's first mobile X-ray system with a collapsible column and by doing so, we offered healthcare providers and radiologists improved workflow and easier access to high-quality images at the patient's bedside," said Sarah K. Verna, World Wide Marketing Manager, X-ray Solutions. Verna cites the user-friendliness of Carestream's DRX-Revolution Mobile X-ray System that contributes to the speed of exams and higher productivity. "High-quality images with low-radiation dose capabilities enable accurate diagnoses and planning of effective treatment and in turn, improved patient care," she added. "Without the images necessary to make a diagnosis, treatments could be delayed, and patients may take longer to recover."

Carestream relied on customer feedback to create and improve products, such as the DRX-Revolution, according to Verna. "We redesigned the unit with a smaller and lighter tube head and collimator for easier use and faster positioning. It helps support quicker exams and increased workflow and productivity. Additionally, the DRX-Revolution's display screens are more responsive, with improved functionality to boost speed and efficiency. The screens also are redesigned with flush mounting to better protect the system against fluid ingress, which helps support maximum uptime and may decrease maintenance and service calls and costs."

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MEDICAL DEVICE HALL OF FAME

Once customers told them that the mobile X-ray systems can be noisy during transport, Carestream worked to make the brakes and driver motors quieter, according to Verna. Storage bins also were expanded to accommodate large and small detectors.

Mobility drives access, which is something Carestream pursues, Verna indicated. "Radiologists are focused on capturing high-quality images that facilitate accurate diagnoses. In the past, mobile units were not used as frequently as they are now, because of low image quality," she said.

Ultrasound machine

KEY SUPPLIERS: BK Medical, Bovine, Carestream Health, Chison, Edan, Esaote, GE Healthcare, Mindray, Philips Healthcare, Samsung Medison, **Siemens Healthineers**, SonoScape, SonoSite and Toshiba Medical Systems.

ORIGIN (earliest known debut): In 1794, an Italian biologist, physiologist, professor and priest named Lazzaro Spallanzani studied the movement of bats and how they navigated by sound instead of sight. He found they would emit sound waves that would bounce back from or reflect off objects they hit. This concept became known as echolocation. Similarly, ultrasound used frequencies higher than what is audible to the human ear in short bursts to reflect off hard and soft organic tissue. In 1942, Austrian neurologist Karl Dussik first applied Spallanzani's research on ultrasonic waves as a diagnostic tool for use on humans. To detect brain tumors, Dussik transmitted an ultrasound beam through a skull. Dussik previously had been researching the concept of radar or sonography, which was used to detect objects atop and under water and even was used as a form of physical therapy for athletes. He called the diagnostic method of using ultrasound on humans for diagnostic purposes hyperphonography. Within the next two decades, ultrasound would be used to detect gallstones and breast tumors and become integral to obstetrics and gynecology by 1960.

WHY IT MATTERS: By and large, it's safe and effective on patients for its intended applications as it relies on high-frequency sound waves to form images, according to Nikki Troiano Gainey, Senior Vice President, Strategy & Business Development, Global Ultrasound, Siemens Healthineers, and unlike other imaging tests, ultrasound imaging does not utilize radiation, offering an alternative clinical imaging option to patients.

"Exams with ultrasound are generally painless and offer a low stress procedure for patients," Gainey indicated. "With ultrasound real-time needle guidance, clinicians are able to conduct procedures with more precision. And, in some cases, elastography tissue assessment (definition) can potentially help to avoid biopsies.

Gainey also stressed its accessibility, cost effectiveness and overall utility to reinforce its workhorse nature.

"Ultrasound is the most widely used and fastest growing imaging modality used, widely accessible and offers high-quality imaging that is less expensive than other imaging," she noted. "Clinicians and [healthcare practitioners] often rely on ultrasound testing as the first-line imaging modality. For example, high-quality ultrasound imaging addresses increasing cost of healthcare by providing imaging at the primary care level with systems like our ACUSON Redwood. This is particularly important with the fast-growing aging global population."

Additional developments include mobility and portability.

"Due to its small form factor, ultrasound systems are mobile, able to be moved to a patient's bedside," Gainey said. "With portable ultrasound, imaging is possible on sports fields. With the COVID-19 pandemic, easily movable ultrasound systems were available for pop-up stations to quickly scan and assess patients. With little to no special preparation required, ultrasound procedures are rapidly performed and usually last only a few minutes, providing a comfortable and low stress patient experience. Additionally, ultrasound captures real-time images of soft tissues – images that do not show up well on X-rays."

Glucose monitor

KEY SUPPLIERS: Abbott, AgaMatrix, Bayer, LifeScan, Medtronic, Nipro Diagnostics, ReliOn, Roche, Tandem

ORIGIN (earliest known debut): Clinicians and researchers worked to find glucose in urine as far back as the mid-1800s, but it wasn't until the early 1900s with the commercial availability of urine glucose testing, followed some four decades later with the "Clinitest" product that made testing a bit more convenient. By the mid-1960s, the blood glucose test strip called Dextrostix was used for testing. The first glucose meters using the Dextrostix product emerged during the 1970s. Glucose testing at home by diabetes patients surfaced in the 1980s, pairing a Dextrostix with a small digital display. From there, device manufacturers improved the products such that diabetes patients could test their own glucose levels using less blood and less painful ways of doing it, such as needles, to small sticks to skin-attached monitors that can be recorded by mobile telephone apps.

WHY IT MATTERS: Diabetes patients must consistently monitor their blood glucose levels for their ongoing health record trending data but also to determine the frequency of taking medication, insulin and other remedies to manage the disease effectively and efficiently.

Pulse oximeter

KEY SUPPLIERS: American Diagnostics Corp. (ADC), Drive Devilbiss Healthcare, Dynarex Corp., Fabrication Enterprises, Graham-Field, Heal Force, Hopkins Medical, Invacare, Masimo, Mediaid, Medline, Medsource Labs, Medtronic (Nellcor), Nonin Medical, Performance Health, Philips Healthcare, Sarnova, Sharn, Smiths Medical.

ORIGIN (earliest known debut): The first device created to measure oxygen levels in the blood was invented by Japanese bioengineer Dr. Takuo Aoyagi in 1974. Clinicians, engineers and researchers first became aware of the need to measure blood oxygen levels in the late 1800s through the first World War, when early aircraft elevated humans to oxygen-deficient and depleted heights with drastic life-threatening consequences. Aoyagi was motivated by a newspaper interview with the founder of Nihon Kohden Corp. where he worked at the time. He started experimenting with the waveform produced by the arterial pulse to measure and calculate SpO2, according to the National Center for Biotechnology Information (NCBI). Aoyagi's

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groundbreaking work attracted enough competition, leading to the development and growth of an important product segment for patient safety. "In 2007, the World Health Organization (WHO) included pulse oximetry as an essential component of its surgical safety checklist for reducing complications," according to the NCBI report.

WHY IT MATTERS: By the late 1980s, some clinicians saw pulse oximetry as so important that they chose to graft it in as the fifth vital sign to join the traditional four of blood pressure, pulse rate, respiratory rate and temperature.

PPE family (gloves, masks, scrubs only)

KEY SUPPLIERS: 3M Health Care, Adenna, Ahlstrom Munksjö, Alpha ProTech, Ansell, Cardinal, Cypress Medical, Kitex Medical, Owens & Minor/Halyard, **Healthmark**, Hutchinson Healthcare, MediPort USA, Medline, **Mölnlycke Health Care**, Premier Manufacturing Group, Prestige Ameritech, ProTEC-USA, **Ruhof Corp**., Sempermed, Shermond, Standard Textile.

ORIGIN (earliest known debut): Doctors, nurses, clinicians and technicians started dressing the part, protecting themselves with necessary garb – scrubs, masks and gloves – as far back as the mid-to- late 1800s as an outgrowth of an early understanding of rudimentary aseptic technique that can be traced through to hand-washing advocate Paul Revere as the first President of colonial era Boston's Board of Health in the late 1700s. Certainly, the concept of PPE exists outside of healthcare and predates the last few hundred years to encompass construction workers, firefighters and even soldiers.

But here's the rub in healthcare. Until the Occupational Safety and Health Act of 1970, and the debut of the Occupational Safety and Health Administration (OSHA), wearing PPE was *optional*. So five decades ago, it became mandatory for people in the workplace to protect themselves from exposure to illness and injury that could result in death, healthcare being no exception due to exposure to blood, other bodily fluids and other visible and microbial materials. Within two decades, clinicians and other healthcare workers would see their PPE reliance ramped up as they navigated through the HIV era, glove shortages, latex allergy era, needlestick safety era and beyond. In the early 1980s, companies rolled out alternatives and upgrades to PPE products to solve the particular challenges of the day.

Corinne Schmid, Director of Marketing, Biogel, Mölnlycke Health Care, recalls 1983 as a pivotal year for the glove segment of PPE. That's when the Biogel powder-free glove came to market using a proprietary polymer coating with hydrophilic properties to make donning easy and to conform to the hand like a second skin, she explained. Biogel products stressed safety with tactile sensitivity, she added.

WHY IT MATTERS: Imagine if Batman didn't have access to his cape, cowl, uniform … and all of his "bat tools." How could he engage evil-doers and fight crime effectively without all of that and protect himself from harm? Now apply similar common sense and logic to healthcare workers – clinicians and administrators – clad in PPE – primarily scrubs, masks and gloves as they may be exposed to all kinds of dangerous solid, liquid and gaseous (aerosolized) materials in the surgical suites, patient rooms, sterile processing areas or even the hallways.

Healthmark Industries offers a broad line of PPE that is intended for use in the decontamination area of healthcare facilities.

"Wearing the proper PPE and wearing it correctly is vital to the safety of healthcare workers responsible for the cleaning and decontamination of surgical instruments, endoscopes and other clinically used medical devices," said Ralph Basile, Vice President, Healthmark. "There is no doubt that their jobs are hazardous, and PPE, along with proper training, is their first line of defense against injury and infection."

Basile describes the environment from which clinicians protect themselves by wearing PPE. The milieu involves surgical instruments arriving in the decontamination area "grossly soiled with human secretions, including blood, mucus, feces, urine, and other potentially infectious materials." If the instruments weren't precleaned or soaked in the OR, then sterile processing technicians typically will rinse the instruments with water to remove the gross soil before manually cleaning them. "This involves directly handling the contaminated devices – often devices that have sharp edges, points, etc. The most common specific hazards include splashing, puncture, aerosolization of contaminants, exposure to irritating chemicals found in cleaning agents and disinfectants," he said. The dangers include getting contaminants or chemicals in the eye, mouth, hair and other areas of the body and on clothing; puncture of the skin leading to blood-borne infection by contaminants, including blood and microbial agents; rash or other skin irritation."

Basile points to comfort as another concern.

"By its nature, PPE does not breathe well," he noted. "So the wearer gets hot. The tasks in decontam are physically demanding, so that further exacerbates the discomfort of the wearer. Also, often there are heat sources within decontam – washer-disinfectors, ultrasonic machines, hot water, etc. – that are also a factor in creating discomfort. We know that if someone is uncomfortable in their PPE, they are more likely not to wear the PPE correctly."

As a result, Healthmark makes a line of PPE to address these concerns, including its thick "Lined Sleeve Glove" that extends all the way up to the end of the arm, its "Decontam Gown" that sports an impervious "strike-through" zone while enabling breathability and a host of additional products such as shoe and boot covers, aprons with thumb loop, bouffants, scrub hats, domestically produced face shields with attached draping and neck-worn evaporative Cool Aid packs.

"Surgical gloves are an integral part of the prevention measures in the [operating room]," said Mölnlycke's Schmid. "Glove breaches or barrier failures can pose an increased risk of surgical site infections (SSIs) for patients and expose healthcare workers to blood-borne pathogens. At least 60 different blood-borne pathogens can be transmitted to healthcare workers due to accidental exposures with HIV, Hep B and Hep C, accounting for most of the risk." HPN

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Fixing equipment supply chain breakdowns starts with communication

by Cindy Juhas

Since the COVID-19 pandemic hit the United States every part of the supply chain has been affected. American resiliency has been truly tested as processes broke down all along the chain. As we reconnected virtually with our customers, we asked them what has kept them up at night. One issue was identified repeatedly: Healthcare supply chains need more visibility and more accurate communication when it comes to equipment logistics.

As temporary field hospitals, labs and triage units popped up all over the country, the demand for equipment to outfit them skyrocketed. Most of these temporary units required a quick turnaround. The state of Rhode Island engaged CME Corp. needing all equipment for three different temporary medical facilities assembled and delivered three weeks later. You can imagine what this type of demand did to the equipment supply chain! When it comes to equipment, there are not significant quantities of excess inventory anywhere along the supply chain, so almost everything had to be built. The manufacturers jumped into action and worked multiple shifts to produce much of the equipment needed. The communication flow between the manufacturer, the distributor and the customer, however, was anything but smooth, accurate and timely. So how do we fix it?

CME uses a sophisticated, proprietary Project Management software program designed for our industry, so we thought we were well prepared. CME's software can track products in real time from the moment we send the purchase order to a manufacturer to when we deliver it direct to site. Yet, we were having some of the same problems as everyone else. We started looking into every part of the process that the software did not control and found some interesting gaps.

Manufacturer communications

When we studied the communication flow with manufacturers, we found a few troublesome holes. Most equipment manufacturers send an order confirmation containing an estimated ship date. This ship date is computer generated and is based on internal workflow and inventory availability data. When the pandemic hit, manufacturer workflows were over-taxed and incorrect ship dates abounded. When items were delayed or backordered, we found that some manufacturers contacted our sales representatives, some contacted our internal order process team and others did not contact us at all!

Internal distributor communications

We realized that some of the communication coming from our manufacturers was going to wrong email addresses. Most times the information ended up in the right place, but it meant extra time was spent forwarding the emails. Unfortunately, there were times the information never got to the correct person and, therefore, crucial data was not entered into our software.

Customer communications

Every customer had different considerations and needs. Some customers had us communicate with several people in the supply chain, and that usually worked the best. We had one point of contact in some circumstances with varying degrees of success. We also received inconsistent direction from different contacts within the *same* healthcare system, which had to be sorted out, and this created further delays.

Possible solutions

One adage proven to be true is that any garbage we input into our software program created garbage out! Whether a healthcare entity works with a medical equipment distributor or not, getting the most accurate and timely information is paramount to having a successful equipment transaction. Most importantly, we need to ensure that the confirmation, backorder, and shipping information we get from our manufacturers are factual and up to date. Everyone in the supply chain needs to focus internally to shore up his or her own communication. If a manufacturer sends something to the wrong department, we must go to the source, follow up and make sure that next time the information goes to the correct department first. Further, we need to make sure, at the inception of the equipment purchase, to get all of the customer contacts with whom we will need to communicate to ensure a smooth transaction and delivery. When an equipment purchase is time-sensitive, making the supply chain as efficient and agile as possible is *the* key to success! HPN

For access to relevant case studies on this topic, visit www.cmecorp.com

Cindy Juhas is Chief Strategy Officer for CME Corp (CME), a national full-service healthcare equipment distributor, whose mission is to help customers reduce the cost of the new equipment they purchase, and make their equipment specification, delivery, installation, maintenance and disposal processes more efficient. CME offers a full array of logistical, biomedical and technical services to serve their healthcare partners. She can be reached at cjuhas@cmecorp.com.

CME Corp is a distributor that focuses on equipment only. Our mission at CME is to help healthcare facilities nationwide reduce the total cost of the equipment they purchase and make their equipment specification, installation, maintenance, and disposition processes more efficient. CME carries more than two million items from more than 2,000 manufacturers and offers customized services that include direct-to-site delivery, biomedical services and disposition services.

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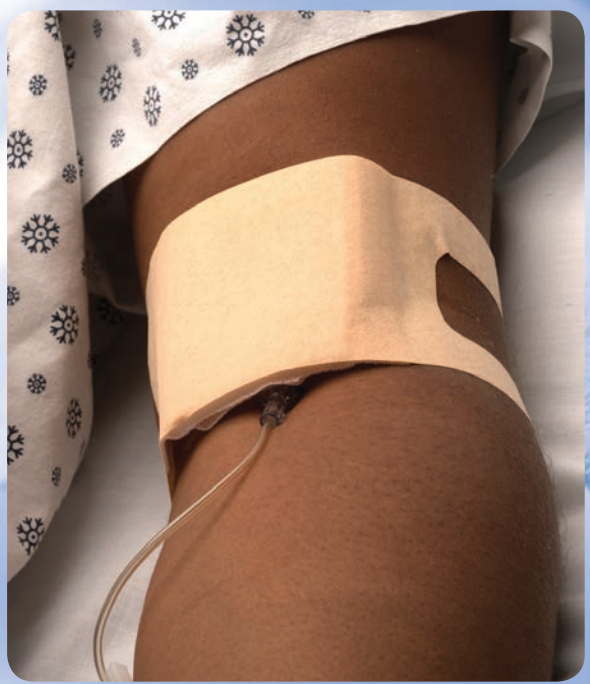

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