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February 2023 • Vol. 47 No. 2

HEALTHCARE PURCHASING NEWS®

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Green Cash Flow Offer

Q: How does the $100 upgrade credit work?

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

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

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

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

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

Q: What does a 1 year payback mean?

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

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

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

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

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

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

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

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

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

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More info: www.exergen.com

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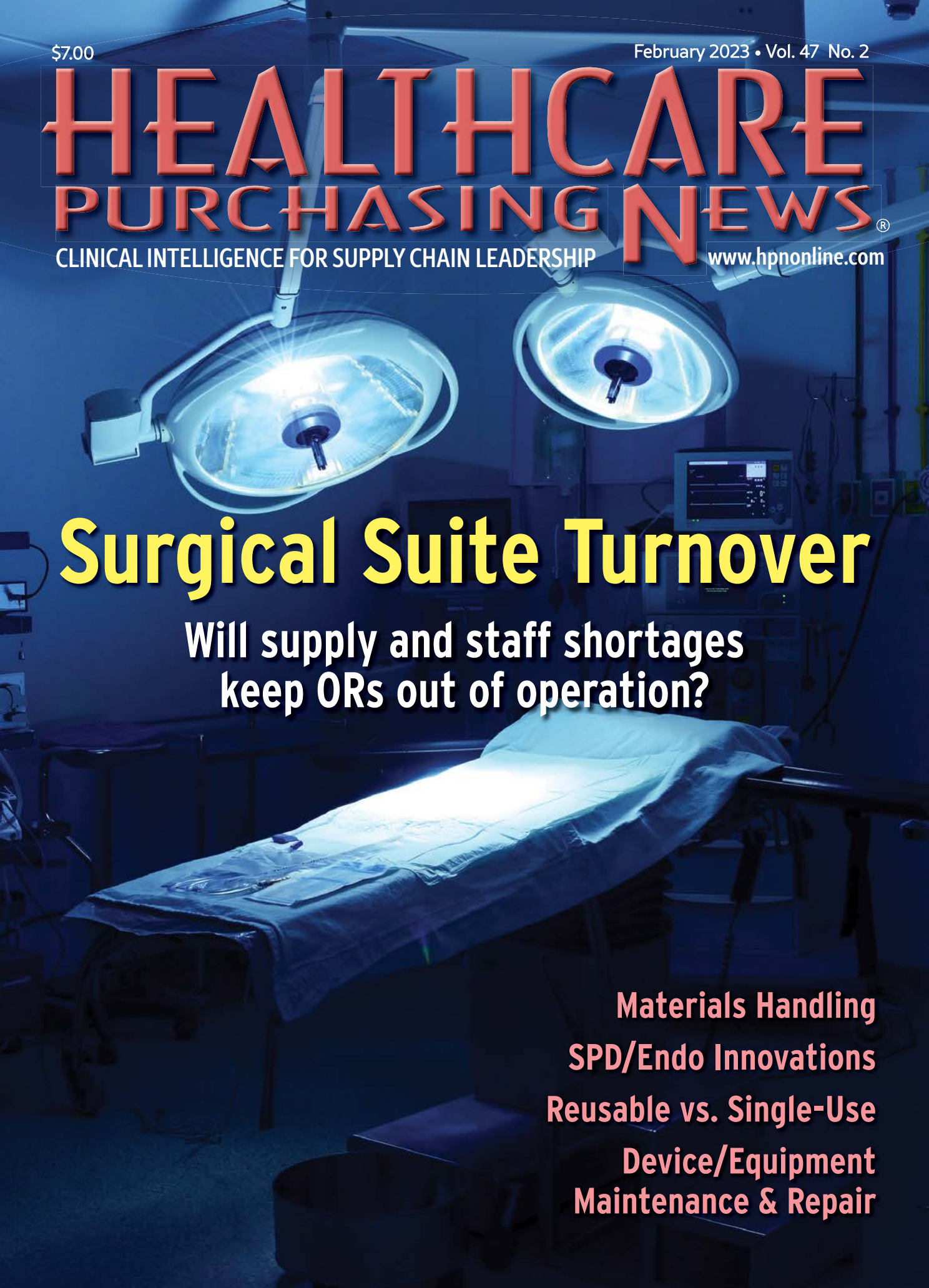

Surgical Suite Turnover

Will supply and staff shortages keep ORs out of operation?

Materials Handling

SPD/Endo Innovations

Reusable vs. Single-Use Device/Equipment

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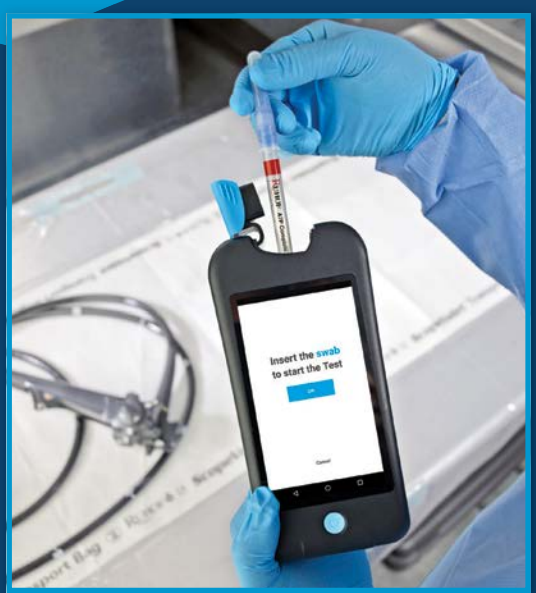

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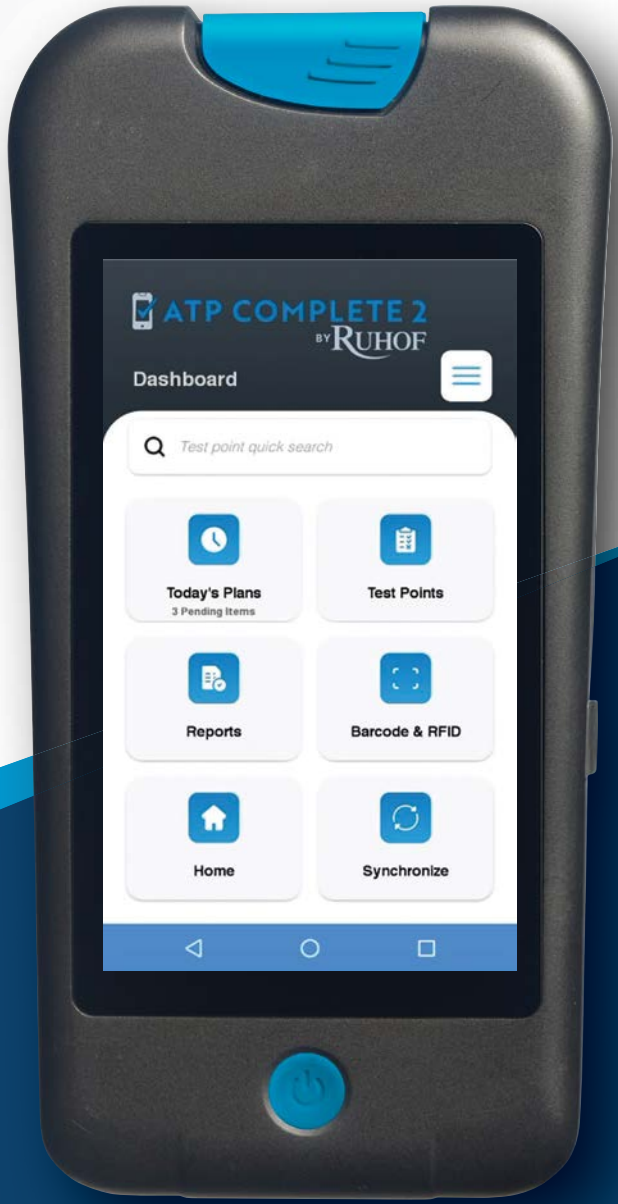

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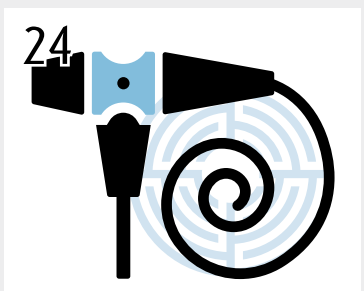

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Rick Dana Barlow
Senior Editor

Many of us favor and prefer choice. Those of us who don't, either find comfort in being told what to do, or simply don't want the hassle of making decisions that interfere with whatever else interests us.

However, the privilege (or right in some cases) of choice, as well as the compliance to edict, lead to a similar outcome: Consequences. Whether we make a choice or a choice is made for us, we must deal with the consequences – good or bad, attractive or ugly, healthy or sick.

Healthcare workers, managers and leaders deal with choices daily that result in administrative, clinical, financial and operational repercussions. Whether it's to offer, continue or cease a clinical service line; whether it's to hire, lay off or fire a person or product- or service-related business; whether it's to contract with this supplier or vendor or another; whether it's to pursue diversity, equity, sustainability; whether it's to invest in reusable or disposable/single-use only products; whether it's to work with original equipment manufacturers (OEMs) or third-party independent service organizations (ISOs) to maintain and repair costly devices and equipment. All those decisions bear consequences.

Healthcare Purchasing News has explored the reusable vs. disposable and the OEM vs. ISO debates for decades, acknowledging the controversies, passions, personalities and points of view of proponents and opponents of either "side." Where choice may be preferred and demanded, accountability and responsibility must be accepted.

Healthcare organizations can, do and should have the choice to invest in reusable and/or disposable/single-use only items. They can, do and should have the choice to contract with OEMs and/or ISOs for maintenance and repair of costly devices and equipment.

But adjustments must be made to budgets, processes, strategies, tactics and techniques. Disposables affect the waste stream; reusables involve sterile processing, maintenance and repair cycles. OEMs intimately know how to maintain and repair their own devices and equipment; ISOs offer similar quality services with a caveat … the customer understands that the OEM may/will void any warranty on a product on which service is performed by an unauthorized third party. OEMs don't want to be liable for a product serviced by someone else that may not function properly and that may lead to patient harm.

Most everyone agrees that one incident – patient harm/injury stemming from malfunction or misdiagnosis (including missed diagnosis) – is too many.

Amid all the clinical, corporate, legislative and regulatory clamor, three tenets may make a difference.

Limited access. OEM-authorized, certified and contracted ISOs should be granted access to sections of product manuals so that they can provide necessary repairs when and where the OEM cannot or will not for whatever reason. In this regard, the approved ISO partner functions like a physician assistant or nurse practitioner – patient-treating "subcontractors" in retail outlets. Think of it as choosing between the car dealership for an oil change or a lube shop franchise. But OEMs should not be forced by government decree to "open source" their product manuals for all ISOs any more than Coca-Cola should be coerced to share its soft drink formula with beverage distributors.

Universal quality. The application of quality service and system standards should apply to all OEMs and all ISOs alike. Everyone who wants to participate in the maintenance and repair game should be able to play, but by the same rules and standards for complete or component service.

Responsible liability. If an OEM or an OEM-endorsed ISO is determined to be responsible for some problem, then either or both should be held accountable. If an ISO not affiliated with or endorsed by an OEM is found to be responsible for some problem, then that ISO alone should be held accountable. This will prevent capital budgets from being diverted to legal expenses.

If this issue truly revolves around patient safety, then it's paramount for clinical and corporate common ground on quality – not conundrum – to be achieved.

Senior Editor Rick Dana Barlow can be reached at rickdanabarlow@wingfootmedia.biz.

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FAST STATS

Hospital Turnover

The "Great Resignation" is evident in healthcare with hospital turnover exceeding every previous survey conducted by NSI Nursing Solutions Inc. This exodus was fueled by COVID, the competition for labor, employee burnout, and retirement. Healthcare executives need to be concerned since turnover is a leading indicator of future financial pressure, and patient & employee satisfaction.

- The national hospital turnover rate is **25.9%**, with the median and mode recorded at 23.5% and 25.4%, respectively.
- Over the past year, hospital turnover increased **6.4%** and ranged from 5.1% to 40.8%.
- Over the past 5 years, the average hospital has turned over **100.5%** of its workforce.
- Last year, RNs exited the bedside at an alarming rate and hospitals shed **2.47%** of their RN Workforce.
- In 2021, RN turnover increased by a staggering **8.4%**, resulting in a national average of 27.1% and ranging from 5.1% to 64.1%.

All statistics courtesy of the 2022 NSI National Health Care Retention & RN Staffing Report: https://www.nsinursingsolutions.com/Documents/Library/NSI_National_Health_Care_Retention_Report.pdf

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NEWSWIRE

New York becomes 10th state to enact legislation for smoke-free operating rooms

Legislation in New York (S.8869 (Rivera)/A.9974 (Gottfried)) advancing AORN's efforts to mitigate surgical smoke in the workplace was signed by Governor Kathy Hochul on December 16, 2022, as Chapter 701 of the Laws of 2022. New York is the tenth state in the U.S. to enact legislation that requires all licensed hospitals and freestanding ambulatory surgical facilities to adopt policies to use a smoke evacuation system for surgical procedures that generate surgical smoke. The law will take effect on June 14, 2023.

According to the Occupational Health and Safety Administration (OSHA), each year "an estimated 500,000 workers, including surgeons, nurses, anesthesiologists, and surgical technologists, are exposed to laser or electrosurgical smoke." This smoke, also known as plume, includes carbon monoxide, polyaromatic hydrocarbons, and a variety of trace toxic gases. Prolonged exposure can lead to serious and life-threatening respiratory diseases.

Read on: https://hpnonline.com/21291221

Omicron subvariant responsible for almost half of U.S. COVID cases

According to a report from Reuters, over 40% of COVID-19 cases in the United States are now caused by the highly contagious Omicron XBB.1.5, data from the U.S. Centers for Disease Control and Prevention showed on Friday, with the subvariant doubling from the previous week.

Although many public health experts are expressing concern about the rising COVID-19 cases in China, infectious disease experts have been increasingly worried about the XBB.1.5 variant.

Osterholm added that seven of the 10 U.S. states where cases and hospitalizations are rising are in the Northeast, concurrent with an increase of XBB cases there, he said.

Read on: https://hpnonline.com/21291503

Tough year serves as affirmation of Vizient's commitment to supply assurance

2022 was a year that brought Hurricane Ian, mpox, the resurgence of polio and a contrast media shortage — not to mention the Russia/Ukraine conflict, talk of port and rail strikes, severe cases of R.S.V., and destructive droughts, all of which intensified supply constraints and margin pressures.

As relentless as 2022 was, Vizient's approach to supply assurance in the face of these challenges was equally unyielding. The company's commitment to ensuring providers had exactly what they needed to provide the best possible patient care was — according to the experts responsible for tackling the supply challenges of 2022 — "innovative, progressive, supportive and necessary."

Here's a look at a few key lessons that have shaped (and reshaped) the way Vizient works to help its providers make the best of difficult situations — and stand firm in the face of adversity.

Read on: https://hpnonline.com/21291383

Reusable scalpel provides enhanced illumination of critical anatomy areas

"A surgeon's scalpel handle has not significantly changed since it was first introduced 100 years ago," says Dr. Steven Hacker, Founder of Nano Surgical, LLC and Inventor of Lumohs, a patented reusable scalpel that enables shadowless illumination millimeters from surgical site. And, Dr. Hacker should know, after having surgically treated over 50,000 skin cancers the last 30 years.

"The problem Lumohs solves is the difficulty of getting adequate unobstructed illumination underneath and at all angles to the skin. This illumination can be lifesaving when performing Mohs surgery, flaps, excisions, plastic surgery or any office-based surgeries in anatomic danger zones of the head and neck or anywhere on body, for that matter. Expensive overhead lighting and loupes don't solve the problem and are cost prohibitive to outfit in every procedure room." Hacker's invention, Lumohs, solves these problems and enhances all existing lighting solutions.

"The risks to patients are great when shadows or blind spots, obscure tiny critical nerves and blood vessels that can be accidentally severed during surgery. There had to be a better way," Hacker explains.

Read on: https://hpnonline.com/21291503

Surgical masks and n95 masks offer equal COVID-19 protection

Surgical masks are not inferior to N95 masks for preventing the spread of COVID-19 to healthcare workers, says a study led by McMaster University researchers. The results follow the tracking of 1,009 healthcare workers providing COVID-19 patient care at 29 sites in Canada, Egypt, Israel, and Pakistan between May 2020 and March 2022.

Study participants were randomly assigned to either a surgical mask, which was already the standard used at all of the study sites, or an N95 respirator. As with any randomized clinical trial, study

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participants were volunteers who could exit the study or switch to an N95 at anytime.

The findings have been published in the *Annals of Internal Medicine (AIM)*.

"The surgical masks were not statistically less effective than N95s in preventing COVID-19 infections in healthcare providers looking after patients with COVID-19," said lead author Mark Loeb, professor of McMaster's Department of Pathology and Molecular Medicine and a Hamilton infectious disease physician.

Read on: https://hpnonline.com/21291740

Joint Commission reviews and revises accreditation requirements

The Joint Commission previously announced that it would review accreditation requirements that are above and beyond the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation (CoPs). This initiative aims to help our customers address the many challenges that health care is facing by eliminating requirements that do not add value to accreditation surveys so that health care organizations and surveyors can focus on other strategies and structures that support quality and safety.

The review began with hospital elements of performance (EPs) that met all of the following criteria:

- The EP does not support a CMS CoP or state regulation.
- The EP has been in effect for at least three years.
- The EP has been scored five times or less during full triennial surveys between 2017 and 2019 (the three years prior to the COVID-19 public health emergency).

Staff across multiple divisions reviewed each of the selected EPs and reported the possible reasons why scoring was low, including organizations are compliant with the requirement because they have adopted it as a standardized practice, the EP is redundant to another requirement, and the EP is difficult to assess compliance objectively and consistently during surveys. As a result of this review, 56 hospital EPs were identified for deletion, and 4 EPs needed minor revisions to make them more effective. Many of these EPs were also accreditation requirements for other programs, and these were deleted or revised from those programs as well.

Read on: https://hpnonline.com/21290778

Novel blood test identifies Alzheimer's disease biomarker

A group of neuroscientists led by a University of Pittsburgh School of Medicine researcher developed a test to detect a novel marker of Alzheimer's disease neurodegeneration in a blood sample. A study on their results was published in Brain.

The biomarker, called "brain-derived tau," or BD-tau, outperforms current blood diagnostic tests used to detect Alzheimer's-related neurodegeneration. It is specific to Alzheimer's disease, and correlates well with Alzheimer's neurodegeneration biomarkers in the cerebrospinal fluid (CSF).

"At present, diagnosing Alzheimer's disease requires neuroimaging," said senior author Thomas Karikari, Ph.D., assistant professor of psychiatry at Pitt. "Those tests are expensive and take a long time to schedule, and a lot of patients – even in the U.S. – don't have access to MRI and PET scanners. Accessibility is a major issue."

Currently, to diagnose Alzheimer's disease, clinicians use guidelines set in 2011 by the National Institute on Aging and the Alzheimer's Association. The guidelines, called the AT(N) Framework, require detection of three distinct components of Alzheimer's pathology—the presence of amyloid plaques, tau tangles, and neurodegeneration in the brain—either by imaging or by analyzing CSF samples.

Read on: https://hpnonline.com/21291717

An increased focus on medical misinformation in academia

While Kim Lundeen was serving as a resident doctor in the Minneapolis area early in the pandemic, a patient asked her about a remedy rumored to cure COVID. The patient, who had tested positive for the virus, said she had heard advice circulating through her community that collecting and drinking her own urine would help her recover. The patient wanted to know whether Lundeen recommended the treatment.

Lundeen was prepared for this sort of conversation and the balancing act of accuracy and openness it would require. She had taken one of the University of Minnesota's first classes on misinformation. It taught her to spot, research, and counter false advice and faulty sources.

Misinformation courses, like the one Lundeen took, have been popping up in medical schools since the pandemic, which ushered in a myriad of conspiracy theories challenging doctors' reputations as trusted health experts. Equipping young doctors to spot misinformation and effectively educating the public and their patients is now integral to a successful medical practice, several medical educators told Medscape Medical News.

Read on: https://hpnonline.com/21291717

Important insights into COVID's assault on sense of smell

The reason some people fail to recover their sense of smell after COVID-19 is linked to an ongoing immune assault on olfactory nerve cells and an associated decline in the number of those cells, a team of scientists led by Duke Health report.

The finding, publishing online Dec. 21 in the journal Science Translational Medicine, provides an important insight into a vexing problem that has plagued millions who have not fully recovered their sense of smell after COVID-19.

While focusing on the loss smell, the finding also sheds light on the possible underlying causes of other long COVID-19 symptoms -- including generalized fatigue, shortness of breath, and brain fog – that might be triggered by similar biological mechanisms.

"One of the first symptoms that has typically been associated with COVID-19 infection is loss of smell," said senior author Bradley Goldstein, M.D., Ph.D., associate professor in Duke's Department of Head and Neck Surgery and Communication Sciences and the Department of Neurobiology.

Read on: https://hpnonline.com/21291130

UNM Children's Hospital receives enhanced medical support from HHS

The U.S. Department of Health and Human Services (HHS), through the Administration for Strategic Preparedness and Response (ASPR), deployed a National Disaster Medical System (NDMS) team to the University of New Mexico (UNM) Children's Hospital – providing much needed support to an overwhelmed emergency department.

With the UNM Children's Hospital at over 100 percent capacity, ASPR worked closely with the New Mexico Department of Health to quickly evaluate and grant their request for federal medical assistance. The Biden-Harris Administration has committed to supporting states as they face a confluence of respiratory illnesses this winter and has already taken a series of actions to help states address the increased strain on hospitals and heightened demand for medications that treat seasonal illnesses.

Secretary Becerra sent a letter to Governors on December 2 outlining supports and resources available to them from HHS, including federal medical personnel such as from the National Disaster Medical System, and last week the Agency increased access to Tamiflu through the Strategic National Stockpile (SNS).

Read on: https://hpnonline.com/21291130

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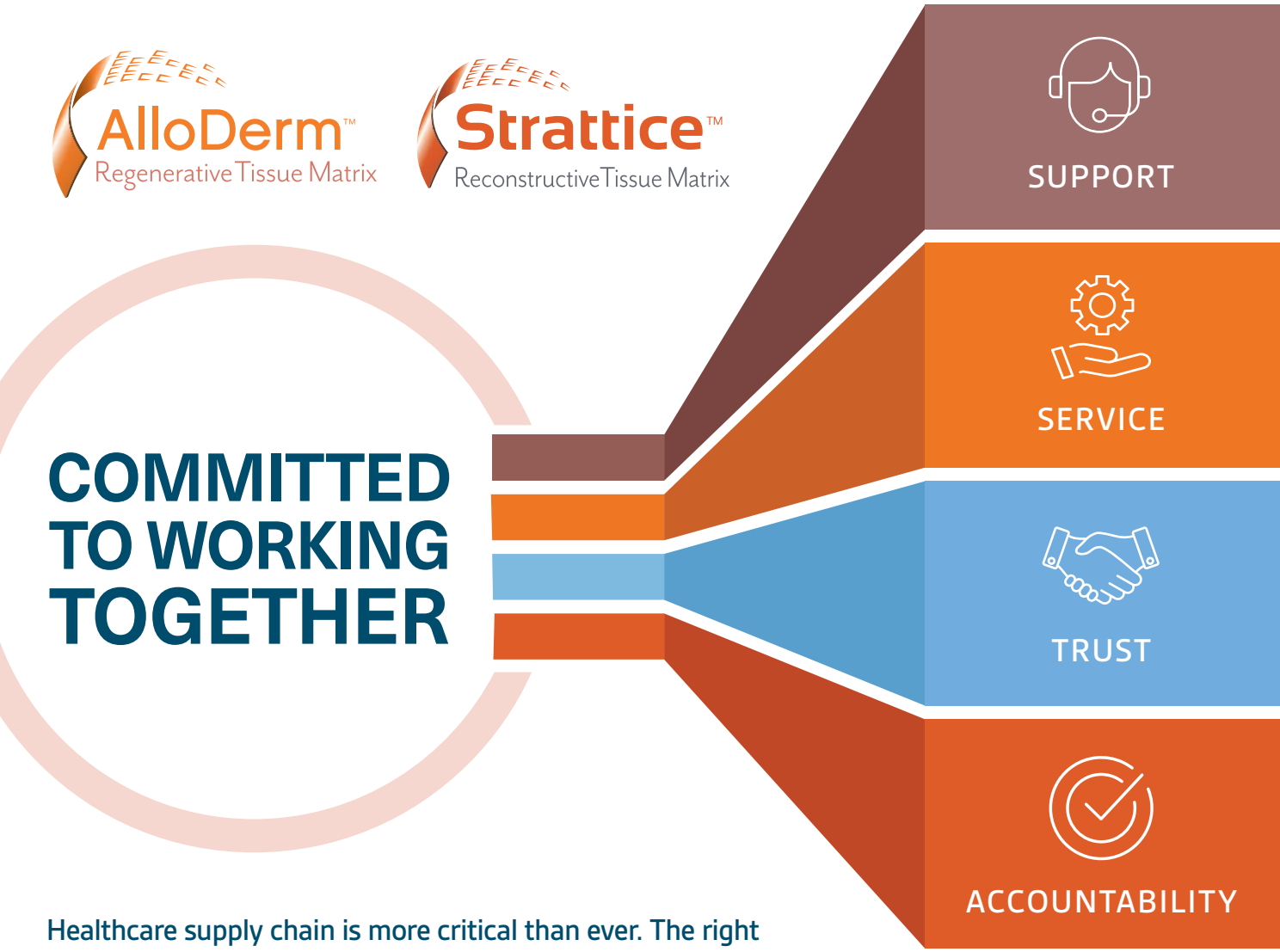

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References: 1. Data on file, Allergan Aesthetics, July 2022; Aesthetic Monthly Tracker. **2.** Data on file, Allergan Aesthetics, July 2022; PRM Customer Summary. **3.** Data on file, Allergan Aesthetics, July 2022; Tissue Contracts. **4.** Data on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

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Choose proper material handling tools to prevent warehouse from becoming a war zone

by Rick Dana Barlow

Aside from gaining access to products (which has been an enduring challenge the last two years), one of the primary tactics of supply chain is moving products effectively around with an inherent strategy of handling materials as efficiently as possible.

Labor, process and workflow and technology and tools drive effectiveness and top it off with efficiency if healthcare organizations choose their options wisely based on their organizational needs.

That's why provider organizations must determine what product and process improvements they may need based on self-assessments of their materials handling operations. As a result, *Healthcare Purchasing News* queried a small group of executives well-versed about material handling and supply chain operations about relevant and useful products and technologies for storerooms and warehouses.

Fortifying the storeroom and/or warehouse with the gamut of material handling products and technologies may seem like a luxury to some but a necessity to others. So *HPN* asked material handling experts to evaluate more than 18 options to determine which were luxuries versus necessities to manage supply chain operations. Those products and technologies generating unanimous decisions are listed in the "Complete" categories. Those gleaning mixed decisions are listed in the appropriate "Leaning" categories. Based on current events and against the backdrop of supply chain disruptions during the last two years, the points of view may be surprising to some, realistic to others or not forward-thinking enough to a third group.

Tom Redding, Senior Managing Director, Healthcare Services, St. Onge Co., initially points to "the availability of reliable labor" as a continual challenge for most industries, including healthcare, when looking to improve material handling performance and that likely motivates increasing interest in technology.

Tom Redding

"Supply chain leaders will explore options to proactively manage potential service failures with technologies as [automated guided vehicles], process automation, demand management and cloud-based solutions," Redding told *HPN*. "These types of technologies and systems will provide visibility, access and control across the enterprise to manage the business more effectively. Leveraging these types of technologies will require a more thoughtful and coordinated effort with the broader IT/IS business plan. Making decisions in a silo will no longer work with the future of high-integrated solutions."

However, striving for operational improvement must be balanced with the realistic capabilities of future-oriented technologies, according to Redding.

COMPLETE LUXURY

- 3D printing
- Augmented reality (AR) (e.g., for directions, instructions, locating, mapping, teaching, training, etc.)
- Blockchain
- Drones (e.g., for aerial views of high shelves and transport to various buildings on campus)
- Robotics (including "co"botic arms, exoskeleton harnesses, etc.)
- Self-driving vehicles (e.g., cars, trucks, pallet carts/tugs and jacks)

ON BLOCKCHAIN: "There are areas where this can make an impact, i.e., with [personal protective equipment] in response to COVID shortages and medical devices," acknowledged Dave Salus, Market Manager, Healthcare Division, InterMetro Industries Corp. "This will become more widespread as use cases emerge."

ON SELF-DRIVING VEHICLES: "While this one may be a luxury for 2023, it is the next evolution of AGVs," Salus said. "As more care is performed in remote facilities, the cost of replenishment rises as well. Self-driving vehicles, cars for services like labs, to trucks for supplies, will become another tool to combat labor shortages and the resulting labor inflation."

LUXURY LEANING

- Artificial intelligence (AI) (heavily)
- Robotic Process Automation (RPA) (including advanced dashboards, using "bots" to accomplish basic, mundane and routine tasks and automatic reorder points)
- Virtual reality (VR) (e.g., for demonstrations, designing, inservice training and education, etc.) (heavily)
- Wearable computing/sensors (e.g., wearable and wireless sensors, watches, wristbands, pins, neckware) (closer to even)
- Carousels (closer to even)
- Internet of Things (IoT)/Machine-to-machine (M2M) interoperability (heavily)
- Robotic Process Automation (RPA) (including advanced dashboards, using "bots" to accomplish (closer to even)

ON CAROUSELS: "I have talked to customers about putting these systems in, as well as taking them out," InterMetro's Salus reflected. "Like any major change, stakeholder buying and planning, planning, planning are needed to have carrousels fulfill their ROI."

EVEN

- Automated guided vehicles (AGVs) (including remote-control tugs and roving delivery carts)

ON AGVS: "With ongoing labor shortages, delivery is one area where automation can help," said InterMetro's Salus. "Fully automated vehicles provide higher efficiency, where a higher portion of the investment can be recouped against labor costs. Non-automated tugs will have a place, too. While it won't replace the laborer, it will provide better hiring flexibility for staff to work a vehicle rather than physically push hundreds of pounds on a repetitive basis."

NECESSITY LEANING

- Automated product dispensaries (e.g., closed cabinetry, open/weight-based cabinetry/carts) (heavily)
- Cloud-based software for virtual ERP to virtual MMIS to virtual item masters to virtual physician/surgeon preference cards, etc. (heavily)
- Demand management/predictive analytics software for tracking deliveries to the dock and dispensing to the clinical areas (heavily)
- Wayfinding (e.g., digital flatscreens/interactive touchscreen or voice-activated signage and kiosks, etc.) (heavily)

ON AUTOMATED PRODUCT DISPENSARIES: "Delivering the correct product to patients requires automated product dispensing," said Jessica Bernardo, Senior Product Marketing Manager, Label Print Solutions, Toshiba. "This process additionally involves bidirectional billing and patient data collection. Such technology grants healthcare organizations the insight to understand the costs of patient care in a multitude of circumstances."

InterMetro's Salus points to efficiency through data as well.

"Eliminating waste is the best way to make staffing most efficient," he noted. "Automated storage can communicate replenishment requirements, eliminating the need for a trip to see what's needed, allowing staff to make just one trip to a designated storage area, creating the capacity for a supply tech to service more locations."

However, Zach Malingowski, Senior Director, Supply Chain Optimization, Medline Operations, remains somewhat split.

"For controlled substances, automated product dispensaries are often necessary for compliance, control and tracking access," he said. "For [medical/surgical] supplies, closed cabinetry or weight-based bins can automate steps in the reordering process and provide visibility to inventory – but are still considered a luxury for many hospital storerooms and warehouses."

ON CLOUD-BASED SOFTWARE SUPPLY CHAIN: "As providers standardize their supply chain procedures across acute care facilities, using the same operating system decreases the amount of system integration required and allows for easy cross-training and inventory sharing/visibility across all perpetual inventories," Malingowski said.

ON DEMAND MANAGEMENT/PREDICTIVE ANALYTICS SOFTWARE: "Dynamic inventory level setting can allow a health system to adjust on-hand inventory ahead of a change event," he added. "This – along with proof of delivery/in-transit inventory tracking – is particularly important with high-value physician preference items (PPI) as supply chain challenges continue to impact supply availability."

ON WAYFINDING: "With hospital consolidation, the remaining hospitals are getting bigger," observed InterMetro's Salus. "Wayfinding is not only necessary for employees to find their way. It will also be one of the small things that could enhance the patient's and their visitor's experience."

COMPLETE NECESSITY

- Mobile devices/technology (e.g., multifunctional smartphones for operational tasks)

ON MOBILE DEVICES/TECHNOLOGY: "Mobile devices deliver further insight into the whereabouts of supplies," said Jessica Bernardo, Senior Product Marketing Manager, Label Print Solutions, Toshiba. "Deploying barcode technology within such devices best enables healthcare professionals to immediately pull the correct product. Such efficiency better allows healthcare staff to fulfill their primary mission: Providing the best patient care possible."

Medline's Malingowski concurred.

"Provider systems need to be able to push work instructions to supply chain end users while they are working and end users need to have access to create re-orders, pick confirmations, etc., live versus manual system confirmations and documentation at a workstation/computer terminal," he said.

"Technologies like virtual reality are becoming more readily available as an immersive training experience for new hires, and to facilitate the change management process for incorporating operational improvements," he indicated. "Supply chain leaders are under pressure to prepare for the future, and there is a lot of confusion in the market on what technologies are real and here to stay versus vaporware. We are seeing many potential use-cases for artificial intelligence (AI) in supply chain, but it will take time for the technology to mature and become more reliable for further adoption."

Sidestepping away from tactical and transactional philosophies drives the migration, Redding observes.

"Health system leaders are slowly shifting their approach from a transactional supply chain mindset to a strategic one," he noted, "and that shift brings new requirements and expectations for technology and systems, and how they will support a decentralized model of care."

Cory Turner

Cory Turner, CMRP, Senior Director, Healthcare Strategy, Tecsys Inc., recognizes the appeal that some of the leading-, cutting- and bleeding-edge technologies provide.

"There are more futuristic tools on the market today than ever before – everything from VR robotics to Iron Man-like exoskeletons," Turner enthused. "With such a glut of innovation, it can be challenging for supply chain leaders to determine which ones are distractions, and which can be truly valuable to their operations. However, by embracing tools that can streamline processes and ease the reliance on human resources, healthcare supply chain leaders can address labor shortages while prioritizing patient care.

"Underneath the shiny veneer, there are great technologies that are being field tested with impressive results," Turner continued. "When the right tools are brought together in the right environment, the possibilities for growth are endless. A strong and industry-tailored [warehouse management system] with demand forecasting capabilities coupled with AGVs, conveyance and wearable devices can not only increase productivity and efficiency, [but] it's a formula that can empower the human workforce to be more effective."

While AI continues to capture interest among many supply chain leaders, some experts urge caution about embracing and implementing it before operations are in proper working order.

"AI is such a broad topic and can mean different things in so many different areas and within functions," noted Jennifer Nageotte, Partner, Diamond Storage Solutions. "AI can improve patient engagement, enhance storage and supply availability/retrieval, lower supply chain costs, decrease time for diagnostics, improve billing and coding and physician documentation, etc. But yes, the underlying theme is understanding current state, improving upon what you have, ensure good process and systems currently exist, and obtain buy-in from people. Otherwise, no matter how sophisticated the system, AI opens up opportunity for failure."

Jennifer Nageotte

How do supply chain experts categorize material handling product and technology offerings along a spectrum? Check out the Material Handling Technology Grid to learn where they generally assigned options. **HPN**

Finding material handling solutions may be more than minding the store

Healthcare supply chain leaders and professionals may have a wealth of products and technologies from which to choose probable solutions for their material handling needs and wants, but experts urge careful consideration and planning before taking the plunge.

Why? The aftershocks from the plunge may be severe and unexpected. Six share useful tips that should motivate and direct decision-making.

Finding balance

"For the storeroom, it comes down to a balance of capacity and visibility. Storerooms are often undersized rooms with a need to store a large number of supplies. Careful consideration should be given to balancing how many items get stored, how much of each item and how often they will be replenished. It is also important to make it easy for clinicians to find what they need. Lower counts and higher replenishment frequency may be the best option to provide the best patient experience. Physical space will be the only constant in this formula. Once the [stock-keeping units] are figured out, the next step is to find the best way to fit them in the defined area. There are many options, traditional shelving, high-density track systems, bin wall, cantilevered baskets or a combination. Metro representatives provide free space audits to help decipher the best combination of solutions for your space.

"Warehouses are similar, just on a larger scale. Bulk storage is fairly straightforward. Pallet racking is typically the go-to. The unit-of-use items is where some complexity comes into play. Once items are broken down from their packaging, you begin looking at individual items of various shapes and sizes. This also increases the amount of space needed for these items. So again, it's a look at how many SKUs will be supported from the warehouse and how many to store at the individual level. Figuring out these two metrics will determine the space required, which can be compared to the space dedicated. Once this factor has been identified, it comes down to the best combination of storage solutions to fit the items in the predefined space. This is where the Metro rep can again step in and provide free space audits to help decipher the best combination of solutions for your space."

Dave Salus, Market Manager, Healthcare Division, InterMetro Industries Corp.

Look to overarching automation

"As a health system looks to improve materials handling efficiency across facilities, analysis of its current or implementation of an enhanced health provider-focused Warehouse Management System (WMS) becomes Job One. A fully functional WMS drives improvements in the hospital storeroom and is an absolute necessity when operating a warehouse/distribution center. A WMS can provide a higher utilization of storage space, increase labor productivity, improve warehouse activity accuracy, and most importantly, provide clear visibility and traceability to provider inventory. The WMS review or selection process also helps inform what storeroom or warehouse technology is actually 'necessary" versus "luxury" based on provider resources, processes and goals."

Zach Malingowski, Senior Director, Supply Chain Optimization, Medline Operations

Striving for accuracy

"One of the biggest challenges for a storeroom/warehouse is maintaining an accurate inventory value for all of their stocked products. Without an accurate storeroom/warehouse inventory, there are many operational challenges that occur, such as: Perceived stock-outs/killed orders, lack of inventory replenishment automation, incorrect financials as a result of inventory variance, and additional labor to reconcile daily inventory requests.

"At a minimum, weekly cycle counting of the highest activity products is a small investment in keeping the overall operation running more effectively and efficiently. Additionally, create a dashboard of your storeroom/warehouse inventory with key metrics, such as order fill rate by product, inventory turns by product, product lead time by product and stock-outs by product to name a few. Tracking inventory metrics will enable a storeroom/warehouse manager to proactively assess their performance and address issues before they result in a service delivery failure.

"Lastly, storeroom/warehouse inventory slotting is a critical function to achieve higher picking and replenishment efficiency. Too often, the fast movers are stocked in the same aisle, which may create congestion for supply technicians to execute their duties. As a result, picking and replenishment efficiency is impacted and ultimately it will require more labor to process the daily inventory requests."

Tom Redding, Senior Managing Director, Healthcare Services, St. Onge Co.

Go Lean for green – and gold

"First and foremost, it is essential to have a system that takes into account all those good Lean principles. Deep dive into process by streamlining inventory control, cycle counts, stocking policy, expiration and recall maintenance. To allow for more efficient and quicker order fulfillment, make sure to maintain the 'gold-zone' in picking areas with the use of technology sources.

"Your data is a powerful ally in strategic decision-making. Rather than relying on intuition, basing decisions on empirical data provides an objective and accurate reference point. This is becoming more and more important as we integrate automated processes that are more attuned to the trends and patterns that may otherwise be overlooked.

"Finally, your most valuable vendors are also your partners. Building reliable vendor relationships with your technology, distributor and manufacturer counterparts provides a solid foundation for mutual wins."

Cory Turner, CMRP, Senior Director, Healthcare Strategy, Tecsys Inc.

Enabling predictability, efficient workflow

"It's essential for today's hospitals and supporting healthcare organizations to safeguard data relating to patient supplies. With AI, such data enables predictability as well as the capability to forecast critical patient interventions and unprecedented changes in medical requirements.

"Robotic Process Automation and cloud-based software are still other technologies healthcare organizations may deploy for improving workflow and increasing efficiencies. Robotic automation helps staff retrieve supplies more quickly and accurately. Moreover, cloud-based software allows for efficient data collection and retrieval. Such software is also essential considering the need to maintain and access medical data across extended timeframes as supply usage affects medical outcomes. Toshiba's innovative duplex liner-less printer, which combines two separate labels – including shipping and packing lists – into a single, two-sided label is yet another technology benefitting healthcare logistics professionals while helping their respective organizations operate more sustainably."

Jessica Bernardo, Senior Product Marketing Manager, Label Print Solutions, Toshiba

Plan operational readiness first

"In the face of ongoing labor shortages and the need for cost efficiencies, warehouse managers and supply chain leaders undoubtedly are weighing the benefits of investing in warehouse automation solutions and artificial intelligence. The benefits are attractive: Dramatically improved productivity, reduction in operational costs, reduced (or eliminated) safety risks, space optimization, and enhanced customer satisfaction. When done well, these improvements – and the efficiencies gained from them - lead to enhanced profitability.

"While enticing, pause and consideration should be given before diving into such an endeavor. We have seen many failed automation projects – not due to a lack of capital investment or understanding of how it should work – but because of a lack of proper pre-planning and data analysis. And in some instances, automation may not be the right answer or the right next step. A facility may not have the right size, budget or resources or – in our opinion, the most important consideration – appropriate operational readiness. It is critical to focus first and foremost on the *current* processes in place. And, if automation is appropriate, it should support these optimal processes and drive engineering and supply chain best practices.

"Perform Value Stream Analysis. You do not want to automate a broken system. Have a comprehensive understanding of your processes and the interdependencies of various work areas (i.e., how does a change in picking product affect packaging and/or outbound delivery?). Map out current state of the flow of goods in and out of your space, identify bottlenecks and inefficiencies within the chain, list all available resources (human, tangible, and intangible) and determine if they are being utilized to their fullest potential, outline future state with goals and objectives.

"For any design, plan for future growth. Is the system flexible, mobile, expandable? Can the footprint be quickly redesigned or built vertically versus horizontally? Being able to quickly make changes ensures you maintain speed and accuracy in the future.

"Highly variable operations are typically not suitable for fully integrated automation. Implement advanced demand planning strategies within various areas of your health system. Are there predictive algorithms found within historical data that are based on seasonality or within specific treatment areas? Understanding this information is a good exercise before implementing strategies.

"Consider partial implementation strategies versus fully automated systems. We typically see partial implementation within cells at 'end of line' (i.e., shrink-wrapping and palletizing). Be sure your pre-planning identifies all potential bottlenecks from a future state design. For instance, we have witnessed companies increase conveyor belt speed to drive more thruput and then fail miserably when the packing cell employees could not handle the increased volume. Not only did it 'break the system' but it drove worker frustration and hurt morale.

"There is arguably nothing more important than employee buy-in. Even the most sophisticated system lacks value if your team members don't understand it. Incorporate visual management and craft training programs that focus on AI and technology, drive innovation and educates employees on how to utilize the tools around them."

Jennifer Nageotte, Partner, Diamond Storage Solutions

Surgical Suite Turnover

Will supply and staff shortages, keep ORs out of operation?

by Kara Nadeau

Photo 88326725 © Mohamed Osama | Dreamstime.com

U.S. hospitals began 2023 with tremendous financial losses and are at the same time struggling with increased expenses, labor shortages and supply disruptions. The operating room (OR) is a main driver of reimbursement/revenue so there is tremendous pressure on perioperative teams to turn over ORs faster to facilitate more cases in a safe and effective manner.

"The overall economy will slowly settle down and this will reduce staff turnover," said Suneil Mandava, Founder & CEO, Mobile Aspects, commenting on the current state of U.S. ORs. "On the flip side, Americans will increase their use of hospitals and so volumes will continue to go up. Perioperative teams should be evaluating solutions that can take some of the onus off their team members. This will reduce burnout and reduce training required for new team members."

Suneil Mandava

Insights on surgical suite challenges and opportunities for more efficient turnovers from Mandava and others are presented alongside recent peer-reviewed research on proven approaches to improving OR turnover time (TOT).

Set the standard

Effective change starts with setting a baseline for improvements. To improve OR turnover times, Sheri J. Voss, MS, RN, CNOR (E), Associate Principal Consultant, Global Solutions, Owens & Minor, says perioperative leaders must first define the goal they want to achieve.

"Hospitals continue to face compounding obstacles of increased labor costs and staff shortages – factors that can increase the burdens on OR leaders and cause delays in the amount of time it takes to turn over an OR between patients," said Voss. "This makes it critical for ORs to create efficiencies in terms of both time and resources, regardless of case complexity."

Sheri J. Voss

"Defining the standard turnover time and gaining surgeon buy-in to pinpoint specific areas for improvement is one way OR leaders can identify barriers to OR efficiency," Voss continued. "With barriers identified, OR leaders can address surgical turnover delays through streamlined supply chain processes, services and technology, creating a more efficient environment for high-quality, cost-effective procedures."

Communication

"As with most operational challenges, the greatest issue facing Perioperative teams as it relates to surgical suite turnover begins with communication," said Matt Rechin, Chief Commercial Officer, Ready Set Surgical. "Most delays are caused because of a breakdown in communication; between housekeeping and the OR, the SPD to the OR, etc."

The impact of effective communication on OR TOTs was demonstrated in a study published in the July 2022 edition of BMJ Open Quality. The researchers stated:

Matt Rechin

"Operating room (OR) management plays a pivotal role in the healthcare system due to the high cash flow it yields. Enhancing communication in the OR, which is the common root problem for delays, might improve OR efficiency and revenues for healthcare."

They studied the impact of a "OR relay strategy" on TOT, where a certified registered nurse anesthetist (CRNA) was stationed outside of the OR, coordinating the steps to get the next patient ready. This CRNA communicated with the anesthesia providers within the OR via a Microsoft Team chat. The researchers used the electronic anesthesia record system to record the TOT for the control group.

They found the relay strategy decreased TOT for most ORs, with statistically significant results for three of the ORs and the overall ORs system. They also saw decreased variability between TOTs for the overall OR and the majority of the ORs evaluated individually.

Staff productivity

"In talking with hospital executives around the country, the number one challenge for surgical suite turnover continues to be finding and training staff members," said

Mandava. "Hospitals have dealt with the issue of burnout and turnover by continually finding and hiring new people and utilizing traveling clinicians."

"This means that every step along the way will be slower – how rooms are cleaned and setup, where things are or where to put them away, who should be in the room, etc.," he added. "On top of this, volumes have returned to, and are often exceeding, their pre-pandemic levels. In every meeting and survey we do with hospital executives, staffing is still the number one issue."

"Today's periop leaders have rightly recognized the best way to overcome turnover challenges is to build a process to increase agility," said Rechin. "One example may be as simple as a process where any staff member who isn't actively engaged with a patient helps to alleviate suite turnover challenges. On busy days, it helps to have dedicated teams to help increase turnover efficiencies…from housekeeping to room prep. Unfortunately, not every hospital or ambulatory surgical center (ASC) has the luxury of a dedicated team and needs to adopt an "all-hands-on-deck" approach."

Researchers from Georgetown University School of Medicine and MedStar Georgetown University Hospital in Washington, DC, studied the impact of surgical team consistency on OR TOT, where OR cases were scheduled with the same team and surgeon. They published their findings in the January 2022 issue of the Journal of Medical Systems.

The Georgetown researchers conducted a retrospective analysis of 2,714 cases completed on weekdays between 6:00 a.m. and 11:59 p.m. from July 2017 through March 2018. They found OR cases with the same surgeon and anesthesia team had a significant lower TOT ($p < 0.0001$). They also discovered OR cases in rooms with the same specialty had significantly less mean TOT compared to rooms switching between different subspecialties.

Lean methodology

"Most high performing OR teams have embraced lean principles to help improve OR Suite turnover," said Rechin. "Consider establishing a project team to evaluate current processes, step-by-step. Measure improvements as well as team member engagement. Strive to develop seamless communication responsibilities. Make sure the SPD is involved in all process decisions to ensure it creates synergies through reprocessing."

Researchers from Switzerland applied Lean methodology, including Gemba walks, Process Mapping, Root-Cause-Analysis, and the Single Minute Exchange of Dies (SMED) system, to processes in the OR suite and those before and after the patient is in the OR. Their aim was to understand the causes of variability and waste in TOT for gynecological and general surgery cases.

"Lean thinking allowed the team to re-evaluate how the whole operating suite performs as a system, by starting from a sub-process as changeover," the researchers stated in their findings published in the April 2022 edition of Frontiers in Medicine.

They found "standardized and safer work enabled effective parallel processing" improved patient flow and inter-professional collaboration, enabling the hospital to reduce TOT between operations by 25% on average, without no changes in infrastructure, technology or resources.

One solution for measuring progress toward improved TOT is Stryker's Dash iQ Surgical Dashboard, noted Tommy Van Galder, Vice President and General Manager of Stryker's Communications Business Unit. He said OR teams can use the solution to monitor live OR performance and turnover to identify opportunities for improvement through a series of reporting and benchmarking tools.

OR set up and supply management

Supply management in the perioperative space is notoriously complex and challenging because many items fall outside of the hospital's enterprise resource planning (ERP) system, and therefore beyond the eyes of the supply chain team.

As a result, clinicians often assume the burden of inventory management and tracking. When they are challenged with finding the items they need for a case, it can prolong OR set up time. And when a surgeon finds an item is missing during a procedure, a team member may have to leave the OR and look for that item, causing further delays.

Voss comments on the impact of supply chain challenges on OR efficiency, stating:

"Turning over an OR is a choreographed affair where every minute matters, but it is just one aspect of improving OR efficiency. Streamlining supply chain activities in the new year can go a long way toward building a smooth transition from one case to another and minimizing the time that clinical staff spend searching for supplies. A strong relationship between perioperative and supply chain teams is crucial to building trust, improving communication, and ultimately optimizing clinical staff's involvement in supply chain activities."

According to Van Galder, it is not only supply tracking but also OR set up, including where supplies are stored and how easy it is to clean the room, that impact perioperative workflow efficiency. He stated:

"Customers can set themselves up for success on the front end by ensuring their operating rooms are ergonomically designed and built for room turnover, such as storage for regularly needed suppliers or intentionally selecting easier to clean materials designed to support faster room turnover."

"The ability to effectively clean and disinfect a room, as well as understanding the availability of materials, supplies and equipment needed in the room, are two of the changes we foresee on the horizon that may impact room turnover," he added. "In response to these anticipated changes, Stryker's Connected OR/Hospital Status support interdepartmental communications, especially with respect to patient scheduling, understanding SPD turnaround times, and supply chain management."

Perioperative workflow automation

"Perioperative executives are seeking automation," said Mandava. "Even when they hire people, they are often new and require a lot of training. They are looking for systems that automate a lot of the workflows, data entry, and even training of staff. Many of our hospital clients are highly responsive to new features around guiding team members on next steps in their workflows and the real-time location of items throughout the hospital, amongst other benefits."

"With increased workloads and staffing shortages likely to continue throughout 2023 and beyond, it is critical for perioperative leaders to streamline non-clinical tasks for their team members so they can drive efficient room turnover while maintaining positive patient outcomes in the OR," said Voss. "Leveraging technology solutions that can manage aspects of OR room turnover that typically require manual processes, thereby freeing up time and space, is a key strategy for achieving these goals."

Voss pointed to Owen & Minor's SurgiTrack clinical supply delivery service as a solution, which provides technology and staff to help ensure accurate inventory. She noted how SurgiTrack leverages rigorous analytics of preference cards to help surgical teams standardize product preferences, improve the accuracy of case pick activities, and reduce time spent on removing unused items.

"When the right technology is aligned with the right processes, backed by the right vendor expertise, outcomes like on-time starts and case pick accuracy can be improved, which may in turn help to help alleviate the burden on a perioperative team, and most importantly, drive high-quality patient care," she added.

"Many technologies are available to automate caregiver workflow," noted Van Galder. He referenced Stryker's Connected OR platform, describing how it stores surgeon preferences, enables communication

from the operating room, and automates post-operative workflow to securely store and share surgical case data.

Loaner tray readiness

"In spite of the best staff dedication, a key factor in room turnover is case readiness," said Rechin. "Specific to loaner sets, sterile processing departments are often at the mercy of when inventory gets delivered for a case. If as an example, a vendor delivers 20 trays the evening before a case, that adds enormous pressure and complexity to the sterile processing team, and typically leads to surgical case delays, and poor room turnover."

"Utilizing a loaner tray solution such as ReadySet Surgical would eliminate that pressure by providing the SPD better visibility into inventory arrival, as well as eliminating all the last-minute run around in trying to see when inventory will arrive," Rechin continued. "The solution helps increase case readiness; including when inventory will be delivered, what inventory will be delivered, and even providing tracking information to see carrier status. These types of efficiency improvements allow staff to increase productivity and can positively impact staff availability to assist in room turnover."

A look ahead

"Hospital and health system leaders are preparing to navigate what could be an exceptionally turbulent 2023," said Tina Wheeler, Health Care sector leader, Deloitte, commenting on the results of Deloitte's Health Care Industry 2023 Outlook survey. She notes how "many patients continue to put off non-emergency procedures, which continues to squeeze revenue" and how "an increasing number of patients are shifting to ambulatory centers over hospitals for surgical procedures."

Pressured by staff shortages, inflation, shrinking margins, and increased competition from ambulatory surgery centers (ASC), hospital leaders are looking for ways to get back in the black. Improvements in OR efficiency can help refuel the engine driving hospital revenues, while alleviating perioperative teams of non-value-added tasks.

As Wheeler stated in her blog post on the 2023 Outlook survey findings:

"Hospital and health system leaders might also look for ways digital technology could take over some administrative and menial tasks so that clinical staff can spend more time interacting directly with patients. This could help relieve stress and improve care delivery and staffing models. Many employees are demanding more flexibility in how they work."

In the conclusion of her post, Wheeler summed up her thoughts on this new year, emphasizing the importance of patient satisfaction:

"I believe 2023 is going to be another challenging year for hospitals and health systems as they work to balance financial pressures with the need to invest in the future while ensuring high-quality care. These organizations will likely need to do all they can to attract and maintain patients. Deloitte's recent research shows that consumers are less likely to return for care after having a negative experience with a health care provider or staff. Ensuring that patients have a positive experience could help improve trust in hospitals and health systems." **HPN**

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Digitizing surgery, play-by-play

Processes in and around healthcare delivery are becoming increasingly digital, replacing inefficient, labor-intensive manual tasks. Electronic health records (EHR), virtual health platforms, and automated supply management solutions are just some of the digital technologies used by healthcare provider organizations today.

A recent survey of 50+ digital health venture capital investors conducted by GSR Ventures, shows expansion of digital technology investments in 2023 will be driven by challenges facing providers today, with nearly half of those surveyed (48%) citing provider shortages/burnout as the challenge presenting the greatest opportunity for digital health solutions.[1]

David L. Joyce, MD, MBA, Cardiovascular Surgeon, Medical College of Wisconsin, comments on how the digital procedural playbook by Explorer, a GHX Company, delivers meaningful data on procedural workflows that surgical teams can use to increase efficiency and decrease operating room (OR) turnover times (TOT).

"Despite employing 11% of the American workforce,[2] the health care sector faces disabling personnel shortages with limited options for rapid recovery. If one considers the operating room of the cardiac surgeon as a case study, improvements in efficiency serve as the only practical solution to the challenges at hand. Nowhere is this opportunity more pronounced than in the execution of surgical suite turnover. The complexity and duration of open-heart procedures means that the ability to develop a high performing surgical team carries with it the potential for as much as a doubling in overall productivity. "Despite the significant unrealized potential, very few programs are successful in achieving this kind of capacity for growth. In the famous words of Peter Drucker, 'you can't manage what you don't measure.'[3] Even with the invasion of electronic medical records into the operating theater and their associated demands on the circulating nurse staff, meaningful data remains elusive.

David L. Joyce

"This long-standing problem may very well be on the verge of a solution in 2023 as disruptive new technologies emerge to address the challenges of operating room efficiency. In the case of Explorer Surgical, a procedural playbook has been shown to identify bottlenecks in the procedural workflow.[4] This approach utilizes a set of detailed, step-by-step procedural instructions to provide clinical teams with a comprehensive guide to new techniques. "The benefits of moving from analog to digital have already been seen in the retail industry, where barcodes have become indispensable in managing inventory. It is somewhat ironic that these types of operational improvements have not become more commonplace in the actual operating room. Nevertheless, in the case of open-heart surgery where time equals myocardium, these competitive advantages may very well extend to clinical benefits for our patients."

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Economy, ecology and efficacy demand a combination of resources and contingencies for all

by Scott Tomko

Fueled by a pandemic that wreaked havoc throughout the healthcare supply chain, the debate continues over using reusable versus disposable medical devices and equipment.

Each and every day, countless surgical instruments and medical devices are reprocessed and reused. A Quick Safety Report from the Joint Commission states that because of the costs of physical space, supplies, equipment, and personnel to perform reprocessing and sterilization of reusable devices, some organizations choose to use disposable instruments and devices for critical procedures in some or all areas of their facility. For organizations performing reprocessing, ensuring that those instruments and devices are reusable – that they are in good condition, and can be cleaned and sterilized following validated manufacturer's instructions – is critical to patient safety.

The FDA requires that reprocessing instructions are part of labeling, and in 2015 published guidance to ensure that the appropriate level of reprocessing is addressed based on the intended use of the device.

Although reprocessing has become an essential part of hospital operations, its maintenance and effective operations hinge on staff and resources that must be adequately trained and provided for. Human error is undoubtedly one of the main hurdles in assuring that proper disinfection/sterilization has been achieved.

The category is clean

Reusable devices are equipped with a set of instructions that directs the facility how to clean and sterilize them for another use; disposable devices do not come with such instructions and are supposed to be discarded after a single use.

"The distinction is useful and important," states Lars Thording, VP, Marketing & Public Affairs for Innovative Health LLC. "Devices that are labeled "single-use" are devices that cannot safely be re-used, because the devices cannot be safely cleaned or because their functionality is compromised after a single use. Devices that are labeled "re-usable" are devices that can be cleaned easily and do not lose functionality after one use.

Lars Thording

It is important to note that re-usable devices also come with Instructions For Use (IFUs) that limit reusability to a certain number of uses, after which the manufacturer cannot determine that reuse is safe or effective. The categorization is very sound."

However, according to Thording, there are three practical problems with this categorization that providers routinely experience:

1. Single-use devices are often very expensive and very well designed, leaving the provider wondering why they have to be thrown away after a single use. During the pandemic, this problem came up close when nurses had to wear yesterday's mask or gloves in order to serve their patient population. In cardiology labs, single-use devices that cost $2,000-4,000 are routinely thrown away after a single use. This creates massive financial problems for the service line and the hospital, limits their ability to provide for patients, and threatens service line financial viability at the hospital. Single-use is not financially viable for the hospital, and at critical times, the over-reliance on single-use devices limits the ability of the provider to provide proper care.
2. Hospital operations are typically not designed to have their Sterile Processing Department (SPD) treat each device per its IFU. SPD departments typically treat all re-usable devices the same way: They get wiped down, and they get cooked in the sterilization unit. Consequently, how many times the device has been reused is neither recorded nor responded to: Devices are used until they fail. And devices are not tested prior to reuse to determine if they will fail with the patient on the table, raising patient safety concerns as well as operational flags.
3. The single-use label is a luring concept to the manufacturer that shifts the economic burden downstream. In the 1990s and 2000s, U.S. medical device manufacturers routinely shifted labeling from reusable to single-use, as they saw profits drop due to hospital device re-use. This often happened to the label without substantial changes to the IFU. This continues today. A single-use device is valuable to the manufacturer, because the more the hospital throws away, the more they have to buy more devices. Meanwhile, the more the hospital throws away, the bigger the environmental impact, the higher the spending, and the more vulnerable the provider is to supply chain shortages. These are three consequences US hospitals cannot ignore today, and therefore, the single-use label, as important as it is to patient safety, has also become a contentious issue.

However, the prevalence of single-use device usage in healthcare has come under much criticism of late, as the current political climate focuses on the environmental footprint of healthcare as well as the economic consequences of the "single-use" label and the supply chain vulnerability associated with the reliance of a single supplier.

This has resulted in the emergence of "third parties which have been approved by the FDA to reprocess specific medical devices labeled for single use and must abide by strict rules that may be even more strict than those applicable to the original manufacturers of the SUD."

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According to Thording, "the single-use device reprocessing industry is comprised of highly sophisticated medical device re-use companies that have FDA clearance to reprocess single-use devices for hospitals. With this, a third category has emerged alongside reusables and disposables; the single-use reprocessed device. Hundreds of medical devices, from OR devices to patient care devices and cardiology devices have received clearance to be reprocessed (these are "single-use" labeled devices that can cost thousands of dollars). They have been cleared by FDA to be reprocessed and sold to hospitals because their functionality and patient safety characteristics are similar to a new device."

Pandemic to Post-pandemic

The impact of COVID-19 on the healthcare supply chain caused an increased focus on the reusable versus disposable debate, as hospitals and facilities were soon scrambling with the ways and means to have all the necessary supplies available.

"In many ways, the pandemic changed the single-use mindset in US healthcare," states Thording. "Product shortages emerged (and some of these continue today), that have made supply chain and other hospital staff question the extensive use of disposable devices. The lesson learned from the pandemic is that providers need to ask manufacturers to stop focusing on designing products for single use and start developing products that can be reprocessed and reused. Today, the trend is going in the opposite direction, which is not sustainable, neither from an environmental standpoint, from a patient care standpoint, or from a cost standpoint."

In September of last year, the Agency for Healthcare Research & Quality came to the same conclusion, stating that "Reliance on single-use disposable medical supplies and devices not only leaves health systems vulnerable to supply chain disruptions, as seen with the COVID-19 pandemic, but they are frequently cited as containing higher life cycle emissions per use compared with equivalent application of reusable alternatives. Healthcare organizations should strongly encourage and facilitate resource stewardship."

Now that we appear to be entering a post-pandemic era, strategies and tactics are continuing to evolve in favor of reprocessing devices.

According to Thording, "we still see supply shortages really challenging hospitals, to the point where at times, it is hard for them to conduct important procedures because key devices are not available. As a regulated single-use device reprocessing company, we often get calls from hospitals asking us to send a reprocessed device, because, 'we either use a reprocessed device, or I have to go tell the doctor that we have to cancel the procedure.' Reprocessing provides a means for hospitals to find a stop-gap solution in supply shortage situations, but more importantly, the re-use of devices simply increases supply chain resilience, which impacts not only physician satisfaction but also patient care quality. Many of our hospital partners are realizing this and signing up for more extensive reprocessing programs.

Not all devices can be reprocessed and reused. Some are simply too technically complex, fragile, or physically/mechanically impossible to clean. Some devices should be disposable. The point is this: Manufacturers have, over the past decades, focused on making more and more devices disposable (or single-use), and this trend needs to be reversed. Over-reliance on disposable devices creates great vulnerabilities, increases environmental harm, and they simply cost too much. While manufacturers change their strategies, single-use device reprocessing provides a safe, regulated solution for hospitals when it comes to certain types of devices. Reprocessing has become a very advanced practice, and even very delicate devices can often be reprocessed."

A steady balance

Maintaining an appropriate and effective balance in the types of medical devices, whether reusable or disposable, is proving to be a difficult one to achieve and maintain.

According to Marie H. Wilson, MSN, RN, CIC, Infection Preventionist, Quality Division at Fred Hutchinson Cancer Center, "the pandemic has emphasized the need for balance between single-use and reusable items in healthcare. While organizations may prefer single-use products because of the decreased risk of transmission due to reprocessing errors, this risk needs to be balanced with the risk of the product not being available. We're having to produce tiered plans to ensure supply stocks to continue care, requiring nimble purchasing departments and training resources when a product shift occurs."

Marie H. Wilson

In order to develop strategies and tactics for properly using reusables and single-use-only products, Wilson added that it is vital to have regular practices and methods that enable smooth processing across an entire facility.

"Ensure there is a routine process for product evaluation by key stakeholders in the organization, including an Infection Preventionist," Wilson continued. "These don't have to laborious meetings, as I've seen them successfully managed via a form sent through email.

"Additionally, if at all possible, limit the ability for new (and potentially unapproved) products from entering the healthcare setting. Ensure staff have at least an awareness that an approval process exists.

"Finally, one of the most valuable lessons out of the pandemic is the development of robust tiered contingency plans ready to be deployed at a moment's notice. Consider drafting a list of products required to continue providing care and explore possible alternatives so key stakeholders may evaluate/approve prior to shortages. Theoretically, this allows for quick pivots in purchasing to secure supplies in times of shortages. We're also seeing a shift/inclination to invest more in reusable items (for example, laundered gowns for personal protective equipment) where appropriate."

The bottom line

Cost-effectiveness is the primary issue that hospitals and healthcare facilities focus on in determining whether or not to use disposable or reusable medical devices.

In addition to medical gowns and PPE, scalpels are one of the more frequently used items that are offered as reusable as well as single-use equipment.

Some of the pros of reusable scalpels include the ability to sterilize them after each use which provides cost-effective benefits. However, this cost-effectiveness relies upon proper autoclavability. On the other hand, disposable scalpels ensure bacteria is not transmitted due to their single use. Although, cost is more of an issue with disposable scalpels because they have to keep being purchased.

All things considered, it is clear that there is still plenty of space for both reusable and disposable devices in the healthcare industry, and it is an issue that deserves strict attention to assure that the best option is always taken. HPN

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A•MAZE•ZING Endoscope Care

Navigating the complex cycle of endoscope sterilization

by Kara Nadeau

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The Association of periOperative Registered Nurses (AORN) recently released its newly revised Guideline for Processing Flexible Endoscopes, with recommendations for hand-over communication to decontamination personnel, borescope inspection, cleaning verification tests, and drying processed endoscopes.

HPN gathered insights from AORN, Central Sterile Supply Department (CSSD) professionals, endoscope manufacturers, and reprocessing solutions providers on how these new guidelines align with/differ from the ANSI/AAMI ST91:2021 Comprehensive guide to flexible and semi-rigid endoscope processing in health care facilities, and their impact on CSSD teams.

Why the changes?

Amber Wood

Amber Wood, MSN, RN, CNOR, CIC, FAPIC, Senior Perioperative Practice Specialist at AORN and lead author for the AORN Guideline for Processing Flexible Endoscopes, comments on why AORN updated its flexible endoscope processing guidelines:

"Flexible endoscope processing remains a critically important patient safety issue because there have been more outbreaks associated with these complex endoscopes than any other medical device. When the AORN Guideline for Processing Flexible Endoscopes came up for its 5-year revision cycle, we knew there were many important new published studies on the topic in addition to timing the update with the release of the updated ANSI/AAMI ST91:2021.

What are the changes?

In an AORN Periop Today article, Wood said while there are many changes in the new guidelines, these four major practice changes can "help teams fall within the narrow margin for safety when processing flexible endoscopes."

1. ***Redefine hand-over communication***: Refine the hand-over process from the transporter to decontamination personnel, recommending direct communication and documentation including the time the point-of-use treatment was completed and whether the endoscope was exposed to factors during the procedure that may require additional cleaning.
2. ***Borescope inspection***: Use a clean borescope to visually inspect accessible channels of flexible endoscopes before sterilization or high-level disinfection (HLD). Borescopes allow for visual inspection of internal channels and may identify damage or debris that would otherwise be undetected.
3. ***Cleaning verification tests***: Use cleaning verification tests to verify manual cleaning of flexible endoscopes before sterilization or HLD. Cleaning verification testing such as with ATP, protein, carbohydrate, or hemoglobin is recommended to provide an objective method for verifying cleanliness.
4. ***Drying processed endoscopes***: Dry all accessible channels of HLD-processed flexible endoscopes in accordance with the manufacturer's instructions for use (IFU) with pressure-regulated instrument air or HEPA-filtered air for a minimum of 10 minutes or until no visible moisture remains.

How do the new guidelines compare to ANSI/AAMI ST91:2021?

"There are many similarities, which will make it easier for sterile processing teams to implement recommendations into practice," Wood explained. "The main difference is that the AORN Guideline cites research that is critically appraised and systematically reviewed, so you will see a ranking for the level of evidence and scores for each article in the reference list."

"For the major changes to practice, there is harmony, such as performing cleaning verification testing, borescope inspection, and drying endoscopes after high-level disinfection for a minimum of 10 minutes with pressure-regulated instrument or HEPA-filtered air," she added. "The AORN Guideline is unique in that is has a review of evidence comparing single-use and reusable flexible endoscopes that will be very helpful when making evidence-based purchasing decisions."

Susan Klacik, BS, CRCST, CIS, CHL, ACE, FCS, Clinical Educator for the Healthcare Sterile Processing Association (HSPA), compared and contrasted the ANSI/AAMI ST91 and AORN guidelines.

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"Both the ANSI/AAMI ST91 and AORN's Flexible Endoscope Processing Guideline provide guidance in the processing of flexible endoscopes, and they emphasize the importance of training and education for personnel to process a safe endoscope for patient care," said Klacik. "Still, there are differences between the two documents."


Susan Klacik

"AORN's guideline recommends using an automated process for HLD instead of a manual process because automated processes may be more efficient and consistent and may reduce personnel exposure to high-level disinfectants. ANSI/AAMI ST91 provides detailed guidance on how to manually perform high-level disinfection on flexible endoscopes, as well as properly use automatic endoscope reprocessors (AER) and liquid chemical sterilant processing systems (LCSP)," Klacik added.

What impact will these changes have on CSSD teams?

Wood acknowledged how some of the guideline changes will "take time to work out the kinks," especially those around cleaning verification testing and borescope inspection.

"Leaders should conduct a gap analysis to determine what changes are needed, and then form a team to evaluate feasibility, conduct a trial, and develop an implementation plan," said Wood. "Cleaning verification testing and borescope inspection may be challenging with regards to identification and interpretation of findings, so a clear protocol and competency verification will be essential."

"Start small with your highest risk endoscopes (e.g., bronchoscopes, ureteroscopes, duodenoscopes) and limiting the frequency of inspection," Wood added. "As your team becomes before proficient, you can expand your program. Remember Rome wasn't built in a day!"

Veronica Holder, CRCST, CHL, Certified Registered Sterile Processing Technician II/Certified Healthcare Leader, believes two of the greatest challenges to compliance are lack of training and equipment.


Veronica Holder

"Technicians want to do what is correct and work within the guidelines, but it can be very challenging," said Holder. "Most of the time the Endo suite functions like its own community, performing procedures and processing scopes in a small decontamination room. When working in CSSD you may hear about HLD but are not trained on it because it happens outside of the department. Processing of instruments and devices should all take place in the CSSD, and technicians should be trained on all techniques, but that is not the reality today."

"It is not up to the SPD technician, supervisor or department to purchase endoscope drying cabinets or boroscopes, it is the facility's decision whether to allocate resources to these purchases," Holder added. "Perhaps it is a financial reason preventing the acquisition of this equipment. If the facility doesn't come into alignment with AAMI or AORN guidelines on endoscope processing equipment, that leaves the technician to do the best they can with what they have. You can only do what the facility allows you to do, and that gets frustrating."

Which changes will be the most impactful on the CSSD?

When asked which of the four major practice changes will have the greatest impact on CSSD teams with regards to endoscope reprocessing workflows, here were the responses from the others interviewed on the topic.

Ron Banach, Dir. of Clinical Education & Training, Ruhof

"Cleaning verification tests will have the greatest impact on CSSD teams with regards to endoscope reprocessing workflows as they provide objective methods for verifying endoscope cleanliness. Of the types of cleaning verification systems available, ATP (adenosine triphosphate) testing stands out as the best way to verify cleanliness and measure microbial contamination. ATP is the universal energy molecule found in all human, animal, plant, bacterial, yeast, and mold cells. Product residues, including blood, bioburden and microbial contamination contain ATP.


Ron Banach

"ATP testing is both reliable and quick – providing results in just 15 seconds—and is also easy to use. After manual cleaning at the sink, the endoscope's surfaces and channels are swabbed to collect ATP, after which the test swab is placed in a handheld luminometer to measure the level of ATP collected. The results will immediately determine if the effectiveness of the cleaning process is acceptable, and the endoscope can then move on to HLD or sterilization.

"Beyond endoscope reprocessing, an ATP contamination system can be used throughout your healthcare facility for verifying the efficacy of cleaning protocols for all surfaces and surgical instruments. For the crucial detection of contamination and an uninterrupted cleaning regimen there is no better testing program than one that utilizes an ATP testing system."

Christian Escobar, Director of Marketing, Endoscopy, Ambu

"Regarding the new AORN guidelines, there is a lot for CSSD and point-of-care endoscopy managers to consider. Out of the four key AORN recommendations, the extended use of boroscopes might pose the biggest workflow impact.


Christian Escobar

"Since reusable endoscopes are used across a wide variety of settings and the interior channel wear, tear and damage can present in very subjective ways, the time it takes to perform this vital reprocessing efficacy step could take longer than expected, creating workflow challenges in busy settings. I expect implementing all the recommendations for reusable endoscopes will be daunting, though there are clear reasons to do so.

"For CSSD leadership, it's important to take into account both short- and long-term planning for solving the demand crunch and complexity challenge. This will provide relief for staff and an ideal compliance solution for infection prevention and quality."

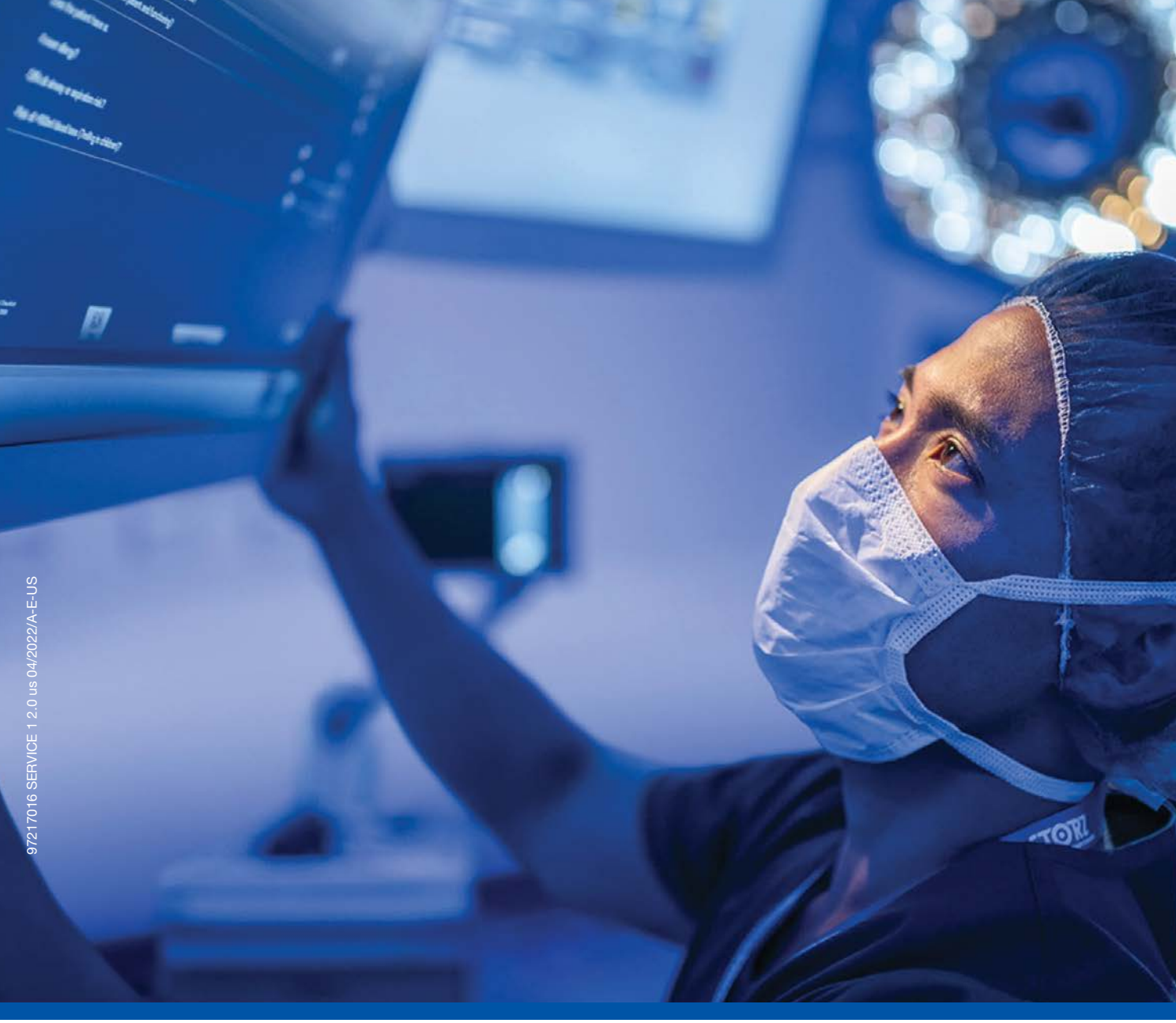
Crit Fisher, CST, FAST, Director, On-site Service & Operations, KARL STORZ Endoscopy-America

"The AORN recommendations all are important in their own rights. They center around ensuring that the scope is adequately cleaned and reprocessed so that is safe for use on the next patient. The difficulty is that all manufactures have their own IFUs. These IFUs are what govern the use and the reprocessing of these critical medical devices. In all the [recommendations], time is the critical component. How much time, and in some cases, financial investment in inspection/testing equipment is needed to meet the recommendations."


Crit Fisher

Angela Lewellyn, CRCST, CER, CHL, LPN, Director of Development & Research, Advantage Support Services

"All four AORN recommendations will impact endoscope reprocessors, leaders and management in that they will have to



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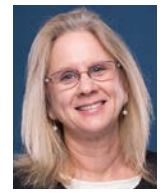
Angela Lewellyn

Suneil Mandava, Founder & CEO, Mobile Aspects

"The biggest impact of all the new AORN recommendations will be on drying processed endoscopes. Hospitals are facing higher and higher volumes of patients. Therefore, scopes have to be reprocessed and ready for the next case even faster. We have several hospitals that utilize our scope tracking and drying systems to reprocess over 100 scopes a day."


Suneil Mandava

"Drying the channels of scopes, as recommended by AORN and AAMI, adds time to the reprocessing time of the scope. This will increase frustrations with physicians and staff. Hospitals must find a way to meet these new guidelines, while minimizing time. Solutions, such as our iRIScope Channel Drying systems, meet the 10-minute drying time guidelines of several agencies without adding a minute more for high volume centers."

What role should the CSSD play in pre-purchase evaluation of flexible endoscopes?

To Holder's point that many CSSDs do not have the required equipment to comply with the AORN guidelines, perhaps those departments responsible for reprocessing flexible endoscopes should have a say on the procurement of these complex devices.

Another key change in AORN's guideline is related to the pre-purchase evaluation of single-use and reusable, flexible endoscopes, including the role of the CSSD team. When asked what role the CSSD team should play in this evaluation process, here were the responses from individuals interviewed on the topic.

Escobar

"One area ripe for impact is the inclusion of single-use endoscopes in the pre-purchase planning section of the guidelines. This is perhaps the first time that CSSD and endoscopy management have guidance on how to strategically handle the expansion of endoscopy use without increasing labor and complexity for CSSD staff.

"Consider outpatient clinics, on campus and off, where recommendations call for scope handling and transportation to be highly documented and CSSD reprocessing routines can't be replicated. Single-use is an ideal solution for workflow, readiness, and alleviating the pressure on CSSD to turn around equipment quickly."

Fisher

"While there are some CSSD teams that are involved in the evaluation process, many departments learn about the clinical choices after the fact. A single use solution may assist in the costs and difficulties of reprocessing re-usable scopes, but it will put pressures on PAR levels and supply chain management."

Klacik

"AORN recommends that before the purchase of flexible endoscopes, equipment or supplies that will be used for processing, an interdisciplinary team be convened to develop a standardized process for product evaluation and selection. Having the correct people on the interdisciplinary team is essential, and this revised guideline suggests key stakeholders, including Sterile Processing professionals, to participate on this team.

"This recommendation also provides a list of what to evaluate during product reviews, and specific criteria are identified to review flexible endoscopes, AERs, storage cabinets, borescopes, cleaning solutions, and detergents.

"In regard to purchasing flexible endoscope processing equipment, ANSI/AAMI ST91 includes an Annex, 'Purchase considerations in selecting AERs and LCSPS.' AORN has also added a new recommendation on purchasing decisions surrounding single-use or reusable flexible endoscopes and accessories; this revised guideline provides criteria to review when making these decisions."

Lewellyn

"The CSSD contributes valuable information to the pre-purchasing process of reusable endoscopes. They will ask questions about the item that other team members may not consider. Not only will they request the manufacturer's IFU that will provide the decontamination, assembling, inspection, and sterilization/HLD information, they will also ask if the sterilization department has the equipment to reprocess the endoscope.

"The equipment to consider upon purchasing a new is instrument is the sterilizer, AER, HLD equipment, a drying cabinet and others. But, just as necessary, they will request information about the inspection tools needed to properly clean and inspect the instrument during the decontamination and assembling tasks of processing. Some may be the correct brushes, the expected usage of those brushes, and if they will be able to have access to those inspection tools consistently.

"They will also need to consider if the department has the staff capacity to reprocess the brushes if they are not disposable. The staff in CSSD is usually pushed to complete the volume of instrument volume they currently have, so adding another task of reprocessing brushes could be daunting. Those reusable brushes should also be added to the in-service when initiating the new reusable endoscope. The collective team must consider the residual duties specified by the tool. Not only will they have to reprocess consistently, but they must also keep track of the number of times it was processed by documenting the reprocessing task according to the brush manufacturer's IFU."

Mandava

"CSSD is very important in this process. CSSD should be looking at both single use and reusable flexible endoscopes. For reusable, they should be reviewing the IFUs from the manufacturers to properly clean the scopes. Additionally, they should be evaluating whether they have appropriate documentation processes and systems to meet regulatory guidelines. If there is a delta, they should be contacting industry experts, such as at Mobile Aspects, to review the gap analysis and help them close the gap. For single-use items, CSSD should be evaluating how those items should be ordered, stored and documented for regulatory purposes."

What resources are available to help CSSD teams?

As Holder and Wood indicated, it is unreasonable to believe these changes can happen overnight. When asked what resources are available to help CSSD teams implement the new guidelines, Fisher and Mandava offered these suggestions.

Banach

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Fisher
"There are plenty of studies out there pointing to the most effective use of time to keep the department running efficiently while maintaining the highest standards. There is inspection/testing equipment that have various applications to achieve the results indicated by these recommendations. Ease of use is something that you want to be able to look for in a product."

Mandava
"Mobile Aspects' iRIScope solution is a simple way to meet the new endoscope drying guidelines while minimizing time, space, and cost impacts. Our iRIScope solution dries the channel in 10 minutes, and not a minute more. Our compressors are built into our systems without taking up valuable real estate in the hospital. They can be up and running in a matter of 30 days for a hospital. We have had several hospitals who asked us to install quickly before a regulatory visit and they were up and running within weeks."

What is one piece of advice for CSSD teams regarding endoscope reprocessing?

Beyond the updated AORN guidelines, HPN asked the article contributors for their general advice on effectively and safely reprocessing scopes.

Banach
"I would suggest that the CSSD teams work closely with their respective Endoscopy and OR departments to ensure endoscopes are kept moist during transport and an effective pre-cleaning treatment program is followed."

Escobar
"My biggest piece of advice is to incorporate long-range planning, since endoscopy volumes are likely to continue increasing. Look at all available options in reusable and single use to best plan out what will support high-volume patient throughput without straining CSSD staff and systems.

"There's a real opportunity to allocate single-use to offset the expense of additional reprocessing equipment, to limit the documentation needs, eliminate cross-infection risks, and support critical areas of patient care that require endoscopes be ready when needed."

Fisher
"Make sure that all the staff is trained and competent on the IFUs and reprocessing instructions for the flexible scope portfolio. Following these steps helps to assure that the scope is reprocessed in a manner to rid it of bioburden and make it safe for patient use. Finally, take pride in the critical role that the CSSD team plays in the continuum of care. You may be the last person to touch that medical device before it is used on a patient. That is a very humbling feeling."

Lewellyn
"When reprocessing endoscopes, the CSSD should initiate two or three Super-Users. The Super-Users role is defined by having in-depth knowledge of the design intricacies of each endoscope used, the processing steps recommended by the manufacturers, and best practice recommendations of AORN, SGNA, HSPA, the CDC, and others. The position/s must be educated about the MIFU and standards of care with extensive hands-on training by a vendor or an experienced re-processor that has completed a high competency level.

"We at Advantage Support have had the privilege of educating and training endoscope reprocessing technicians to a full competency using instrument instructions for use and industry resources. An excellent resource for the educator/trainers of the Super-Users is the Second edition of the Healthcare Sterile Processing Association (HSPA) Endoscope Reprocessing Manual. Many chapters provide step-by-step instructions from the point of use to the sterilization/HLD tasks. This manual will also help prepare the technician to achieve a Certified Endoscope Reprocessor (CER) status.

"As the CSSD, OR leaders, and their customers successfully achieve consistent delivery of endoscopes to the end-users, the Super Users can be not only the 'go-to' experts for the department but also advance the department by cross-training all technicians to the proper care and handling of endoscopes."

Mandava
"The rules and regulations around endoscope reprocessing are constantly changing. Be ready for it, and not surprised. Most of our hospitals clients are looking at the guidelines and purchasing our systems to ensure they meet guidelines today and can meet guidelines in the future." HPN

SUBMIT YOUR QUESTIONS:
editor@hpnonline.com

Dirty silicone mats & DIN trays

by Stephen M. Kovach

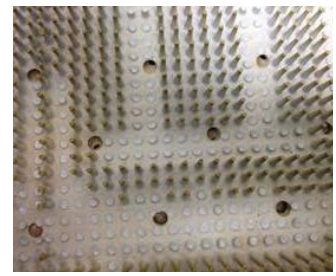

Figure 1- Dirty Silicone Mat

Figure 2- Improper loading of instruments
(with silicone mat in bottom of tray).

Q "We have silicone mats in my department. Some people leave them in trays with instruments when going through the medical automatic washer, and some people don't. Also, some of our mats are very dirty. What advice do you have?"

A I have captured two pictures that will help highlight your concerns about the proper way to use silicone mats (right).

Your question indicates that dirty silicone mats are cleaned inconsistently and without a standardized practice at your facility.

Silicone mats are purchased with a purpose that they can add an extra level of protection (a "cushion") to instruments in the tray or basket and are often used for delicate instruments.

Silicone mats (or pads) come in many sizes and shapes. Some are:

- On rolls or sheets that can be cut.
- Precut to the DIN tray size.
- In different colors.
- With specific trays designed to fit snugly in the tray.

In my view, all departments have silicone mats, and I have seen exactly what you are talking about—the inconsistency in cleaning silicone mats, which can cause them to look dirty. Thus, how can you reduce having dirty silicone mats in any department?

As in almost all my responses, you need critical thinking. This entails finding the instructions for use (IFU) for the silicone mats you are using. Dove tail that with research to put in a "Best Practice" in your Standard Operating Procedure (SOP). Ensure your SOP includes information on inspecting, cleaning, sterilizing, and any other relevant information.

As per your questions, it seems your department does not have any SOP.

Here is a very generic SOP you can use as a guideline and adjust based on the specific type of mat your department uses.

SAMPLE SOP FOR SILCONE FINGER MATS[1-3].

1. When received, the silicone finger mat should be cleaned prior to first use in accordance with the cleaning instructions found in the IFU.
2. Configure the mat properly to where the fingers point upward to accommodate the instruments that will be sterilized. The mat should be used to help hold, organize, and protect instruments.
3. Instruments should be arranged in a single-layer with adequate spacing to prevent them from contacting each other.
4. The silicone finger mat is reusable and should be cleaned and decontaminated prior to reuse according to the IFU for the mat.
   a. Mats can be manually cleaned (preferred method) or can go through medical automatic washer.
   b. Mats should not be washed (or placed inside) with the tray of instruments because they could prevent exposure of the cleaning solutions and rinsing of the instruments by blocking impingement.
5. Visually inspect the mat before placement in a tray or storage to ensure the complete removal of soil. Inspection should verify cleanliness, lack of damage (e.g., cracking in the mat, missing finger points), and proper function.
6. Mats should be dry before being placed in a tray with instruments.
7. Review the IFU for specific sterilization instructions (types/methods/cycles) for the silicone mat.
8. It is the processor's responsibility to ensure processing using equipment, materials, and personnel in the processing facility to achieve the desired result. This could require routine verification monitoring of their process.
9. All staff will be trained in this policy by demonstrating how to properly use, clean, and inspect silicone mats.
10. The silicone finger mat has a life span and will require replacing if there are any signs of deterioration or loss of functionality. Dispose of product following the facility's policy.

This should give you a start on resolving your concern and get cleaner silicone mats.

I used the term "DIN tray" in my response, and I am not sure everyone knows what this means; so, here is an explanation of the term DIN.

DIN stands for Deutsches Institut für Normung meaning German Institute for Standardization. The most common sizes of sterilization trays are DIN sizes. DIN sizing refers to a German Standard (DIN EN 285: 2016), which specifies requirements and the relevant tests for large steam sterilizers primarily used in health care for the sterilization of medical devices and their accessories. HPN

DIN Reference	Size – Width
Full DIN	480 mm (sometimes also known as 500 mm / 515 mm / 540 mm)
¾ DIN	360 mm (sometimes also known as 400 mm / 405 mm)
½ DIN	240 mm
¼ DIN	120 mm
The trays can be any length and depth/height, but the most common length referred to is 250 mm.	
Common DIN tray sizes would be (length x width x height): 480- x 250- x 50 mm, 240- x 250- x 50 mm	**Combining DIN sizes together as width and length:** 480- x 360- x 50 mm, 240- x 120- x 50 mm.[4]

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HEALTHCARE PURCHASING NEWS

SELF-STUDY SERIES Sponsored by 3M Health Care

Washer disinfector release for use after maintenance

by Paulo R. Laranjeira, PhD

Surgical instruments and other reusable devices can be washed and disinfected prior to sterilization in an automated washer disinfector. The use of automated equipment helps standardize the cleaning process, providing optimal cleaning and improving patient safety. These types of equipment are subject to maintenance and repairs, and this article aims to present critical operational assessments to be performed by the end-user after maintenance, before release for use.

February 2023

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For more information, direct any questions to *Healthcare Purchasing News* (941) 259-0832.

LEARNING OBJECTIVES

1. *Review the importance of cleaning a reusable medical device before sterilization*
2. *Identify critical mechanical components in an automated washing phase*
3. *Discuss automated washer performance verification*

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Reusable medical devices that are processed in a hospital sterile processing department (SPD) are cleaned, inspected, packaged, and sterilized according to manufacturer's instructions for use (IFU). A medical device is considered sterilized only if the sterility assurance level (SAL) of 10^{-6} was obtained at the end of the sterilization cycle[1].

The SAL requirement is normally seen as a goal of the sterilization process, but in fact it depends on the correct execution of the cleaning and packaging steps that precede the sterilization step. In this article, it will be discussed the cleaning step of sterile processing.

Sterilizer manufacturers validate their sterilization cycle based on a bioburden load (viable spores present on the medical device) of one million spores, 1 x 10^6, and configure the sterilization cycle with process parameters to deliver a medical device with a SAL of at least 10^{-6} at the end of the cycle. The inactivation of viable spores follows a logarithmic expression and the SAL of 10^{-6} is achieved after a 12-log reduction (Figure 1). Medical device manufacturers validate their IFU using the same criteria of a 12-log reduction[2].

Since sterilizers can't measure the bioburden load on each medical device before the sterilization cycle begins, they will always deliver a sterilization cycle that achieves a 12-log reduction. Therefore, if the bioburden load on a medical device is higher than predicated, the sterilization cycle will not achieve the SAL of 10^{-6} and the medical device cannot be considered sterilized and safe to use on a medical procedure.

Therefore, cleaning before sterilization is extremely important to reduce the bioburden load to the level that the medical device can effectively be sterilized. A dirty instrument will have a higher bioburden load, and the SAL on that device will never achieve 10^{-6}.

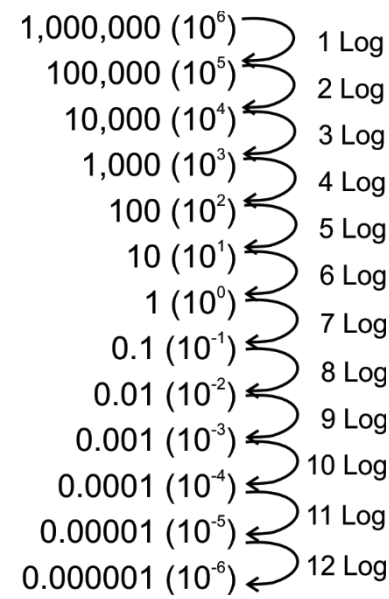

Figure 1: Graphical representation of a logarithmical spore reduction

Automated washers today are an essential tool for an SPD to standardize their cleaning process of reusable medical devices and are expected to deliver the same clean result every time. These washers today aren't considered an expensive replacement for manual cleaning, and they are a mandatory tool for the cleaning of new medical devices that have physical conformities that prevent effective manual cleaning.

Automated washers are complex equipment that require preventive maintenance and have the possibility to break, undergoing corrective maintenance. To illustrate the criticalness of releasing equipment used in an SPD, a steam sterilizer release after maintenance relies on engineering testing performed by the maintenance technician. This will be confirmed afterwards by an SPD professional that will run a Bowie & Dick cycle, an empty chamber cycle with a process challenge device that contains a biological indicator, and an assessment of the printouts from both cycles. If the physical, chemical, and biological indicators show satisfactory results, the steam sterilizer is cleared for use. Unfortunately, automated washers only have cleaning monitoring indicators that are applied on a medical device or are placed in a process challenge artefact, requiring more attention from the SPD professional when assessing the performance of the equipment[3].

As shown above, if a reusable medical device is loaded into a sterilizer with a bioburden above standard, the 12-log reduction that will be obtained at the end of the cycle will not reach SAL of 10^{-6}. Therefore, cleaning plays a critical role in the sterility assurance of reusable medical devices and requires monitoring practices as rigorous as, or more than, of what is used for the steam sterilizer.

Automated washers use pressurized water and detergent that are sprayed on reusable medical devices, at a high temperature, continuously for a period of time, to mechanically remove all residues and dirtiness. A thermal disinfection phase is normally present in a cleaning cycle program, where hot water with temperatures ranging from 140°F (60°C) to 203°F (95°C) is sprayed for a period of time, reducing the bioburden load. The last phase is the drying phase, where hot air is blown on the instruments (Figure 2). The cycle configuration must follow automated washer and reusable medical device manufacturer's IFU.

The main component used in an automated washer is water. It is essential for the water quality to meet all equipment manufacturer specifications and be evaluated frequently to assure cleaning effectiveness. If the water quality is not specified, a good reference to follow is the Association for the Advancement of Medical Instrumentation (AAMI) Technical Information Report (TIR) 34 – Water for the reprocessing of medical devices[4]. This TIR also suggests the water quality analysis frequency. It is important to know that AAMI is currently working on a new water quality guideline, ST108, that is on the final stages of development.

To improve water cleaning, detergents are added during the cleaning process. There are many different detergents available in the market, and automated washer's and detergent manufacturer's IFUs must be followed, and the correct dosing programmed into the equipment. The correct dose is required on every cycle to assure the desired performance, and a dosing verification device should be used to verify if the dosing system is working correctly. Also, it is important to verify if empty switches are working properly.

In the cleaning phase, water is admitted into the washer chamber at the same time as detergent is dosed. During the washing process, water is continuously circulated and sprayed on medical devices through rotatory arms with holes or injected into lumen devices using specific connectors, linking the washer cart rack to the medical device.

These rotatory arm holes and lumen connectors have very small diameters, and any debris can cause clogs (Figure 3), preventing water to pass through, reducing the cleaning efficiency of the equipment.

Figure 3: Example of debris found inside washer's rotatory arm. Tape, plastic markers, human hair, and other.

Washers are fitted with debris screens to retain all debris, preventing clogging during water recirculation. These screens must be cleaned frequently and correctly installed. If a small space is left, debris will go through and clog the rotatory arms and lumen connectors (Figure 4, next page).

Rotatory sprayers have O-rings on their fixation to the washer cart that allow the rotatory arm to move freely. The rotational movement must be verified on each arm, and if the arm shows any resistance to movement or excessive wobbling, these O-rings have to be replaced.

The procedure and frequency to perform these mechanical verifications should be part of the automated washer manufacturer IFU. Monitoring the clean-

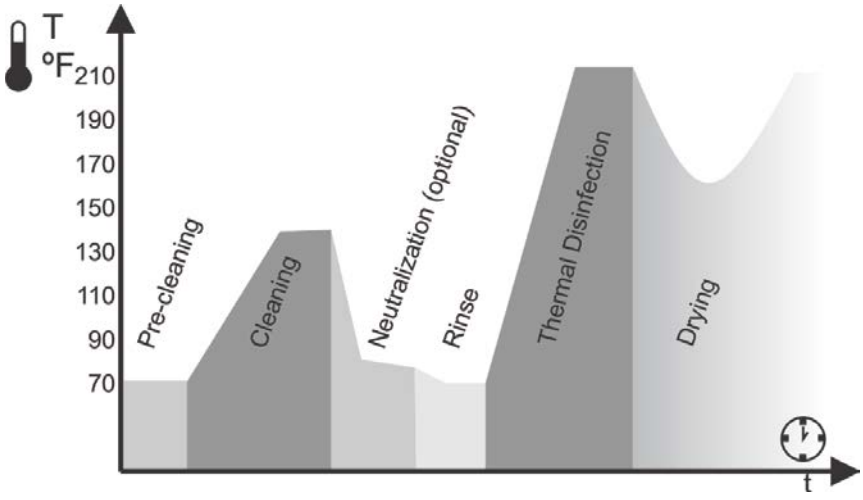

Figure 2: Example of an automated washer cycle phases

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

ing efficiency using chemical indicators and residual soil tests is a routine requirement and must follow manufacturer's IFU and guidelines.

After preventive or corrective maintenance of an automated washer, a comprehensive testing and analysis should be performed, including everything that was covered in this article, manufacturer's IFU and guidelines, before the equipment is cleared for use. HPN

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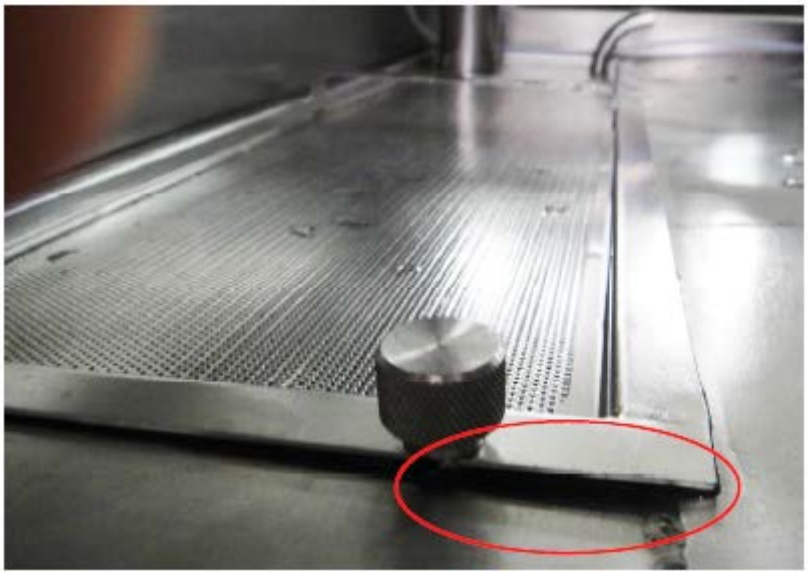

Figure 4: Washer debris screen installed incorrectly.

Dr. Paulo Laranjeira is a process development and qualification professional for sterilization, using steam, hydrogen peroxide, and ethylene oxide, in the pharmaceutical, biomedical, and healthcare areas. He has conducted many investigations with biological and chemical indicators, with different sterile barrier systems, leading to several publications in peer reviewed journals. He is also the author of book chapters, technical documents, and standards in the sterilization of healthcare products area. He is an active participant of AAMI working group 1, 2, 3, 4 and 6; and ISO TC198, Sterilization of Healthcare Products. He is a professor at post graduate schools on equipment qualification and monitoring for the pharmaceutical and healthcare market. Dr. Laranjeira has extensive experience managing multiple professionals in companies in Brazil for over 25 years, has worked as a consultant for multinational medical products companies; and been a globally sought-after speaker at Conferences, Congresses and Symposia.

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CONTINUING EDUCATION TEST • FEBRUARY 2023

Washer disinfector release for use after maintenance

Circle the one correct answer:

1. **Medical devices are considered to be sterile only when:**
   A. the device appears clean
   B. the device has been put through a sterilizer
   C. the sterility assurance level of 10-6 was obtained
   D. the device has been washed

2. **Which of the below statements are true about sterilizers?**
   A. Sterilizers can measure the bioburden load on each medical device before the sterilization cycle begins.
   B. At the end of a sterilization cycle, a 12-log reduction of bioburden has been achieved.
   C. Cleaning before sterilization is unimportant.
   D. All of the above

3. **Which of the below statements are true about steam sterilizer maintenance?**
   A. Preventative maintenance is unimportant for everyday sterilization assurance.
   B. Corrective maintenance when a sterilizer breaks is the only type of maintenance that is required.
   C. Regular maintenance provides an opportunity to verify that all parts of the sterilizer are in working order.
   D. None of the above

4. **After maintenance, steam sterilizer release requires:**
   A. engineering testing by the maintenance technician
   B. assessment of a Bowie & Dick cycle and an empty chamber cycle by an SPD professional
   C. inspection of screens and moving parts
   D. All of the above

5. **Which of the below statements of water quality are true?**
   A. Water used for automated washers has the same quality requirement as for drinking water.
   B. Debris contained in water is not a cause for concern with steam sterilization.
   C. The AAMI Technical Information Report 34 suggests the appropriate frequency for water quality analysis.
   D. All of the above

6. **The correct detergent dosing volume to be used with washers is determined by:**
   A. following the detergent manufacturer IFU
   B. following the washer manufacturer IFU
   C. using a dosing verification device
   D. All of the above

7. **Automated washers increase cleaning efficiency by:**
   A. washing at higher temperatures than manual cleaning
   B. reducing the bioburden load on the medical device being sterilized
   C. standardizing the cleaning process
   D. All of the above

8. **When should the rotation of washer cart rotatory arms be verified?**
   A. Never
   B. Only the first time the washer is used
   C. Once a year
   D. Frequently, according to manufacturer IFU

9. **If the automated washer manufacturer does not inform the water quality for its equipment:**
   A. use tap water
   B. assume the same water quality that was used on a different washer is fine
   C. follow the AAMI Technical Information Report 34
   D. assume the water quality doesn't matter

10. **After maintenance of an automated washer, mechanical verification should be performed:**
    A. according to manufacturer IFU
    B. by visual inspection only
    C. only if there are noticeable leaks
    D. as quickly as possible

HSPA VIEWPOINT

Is your department meeting current water quality standards?

by David Taylor III, MSN, RN, CNOR

The quality and consistency of water used in Sterile Processing departments (SPDs) are critical. Evidence has shown the importance of proper water quality across all stages of instrument and endoscope reprocessing; however, water quality issues continue to present themselves and negatively impact the SPD (and Endoscopy department) in numerous ways.

While municipal water supplies are required to meet the U.S. Environmental Protection Agency's (EPA's) safe drinking water standards, surgical instrumentation and medical devices are frequently more sensitive to harmful contaminants and chemicals found in water today. Water systems within healthcare facilities are also comprised of complex distribution pathways that can become compromised over time. Additionally, water quality throughout the U.S. varies, and the impurities (i.e., bacteria and endotoxins, chemical additives, dissolved salts, high mineral contents, heavy metals, pathogens, and parasites) found in that water can have a profound impact on an organization's ability to effectively manage the reprocessing of surgical instrumentation, flexible and rigid endoscopes, and probes.

Water impurities can decrease decontamination effectiveness, reduce the useful life expectancy of instrumentation and devices, and jeopardize patient health. This is why ANSI/AAMI ST91:2021 Comprehensive guide to flexible and semi-rigid endoscope processing in health care facilities, added to Section 4.3.11 *Water quality*). Note: Additional information on water quality can also be found in AAMI TIR34:2014/(R)2017 *Water for the reprocessing of medical devices*; however, TIR34 guidelines for water use in the SPD will soon be replaced with AAMI ST108 Water for the Processing of Reusable Medical Devices, which at the time of this writing was still under development. ST108 will emphasize proper water system design, monitoring, testing and maintenance as well as establish minimum requirements for the appropriate grades of water used at different points in the processing sequence.

To ensure that the correct water quality is used in each stage of processing, SP professionals should be familiar with— and have ready access to—the manufacturers' written instructions for use (IFU) for all used and reprocessed items within their department. This includes surgical instrumentation, instrument and cart washing equipment, endoscopes and accessories, automatic endoscope reprocessors (AERs), chemicals, detergents and lubricants, and other products and supplies.

Diligent water monitoring essential

Quality water helps prolong the life of medical devices, facilitates effective functioning, and reduces the risk of medical device contamination. Every healthcare organization should continuously monitor and control the water supplied to the device processing departments/areas. Water testing should be performed whenever major repairs occur or changes to the water utility system are made.

When developing a water quality monitoring program, SP professionals should consider performing their own daily tests and documenting and trending those results over time. This may help SP leaders prevent problems proactively. It is also prudent to compare test results with the organization's Facilities department to ensure the results match. Again, SP leaders and technicians should carefully review all IFU for detergents, cleaning products, degreasers, lubricants and other chemicals used in the department, and they should validate water quality requirements for automated and manual cleaning equipment, instrumentation, endoscopes, probes, and other medical devices reprocessed within the department.

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When implementing a water treatment process, consider the following:

- Working with the Facilities department to implement a practical monitoring program
- Developing a routine water quality monitoring process
  - o Test water entering the facility
  - o Test water entering the SPD
  - o Compare the tests and rectifying discrepancies
- Upgrading water purifying systems, as needed, until water quality standards are met or exceed industry standards
- Documenting your work, test results and actions taken to rectify problems

Conclusion

There is no one-size-fits all approach when dealing with water quality issues within healthcare facilities. The key having SP leaders collaborate and engage with key stakeholders that help put the necessary controls in place to handle any water situation that arises.

Today's SP leaders must understand the common water treatment options and methods used to monitor these systems—now and in the future—and they should collaborate with administrative personnel to implement adequate procedures that will comply with the latest standards. Doing so will allow SP professionals to spend less time worrying about water quality and more time focusing on processing items for patient use. HPN

As healthcare delivery evolves, so will the supply chain

by Karen Conway, Vice President, Healthcare Value, GHX

Late last year, I was asked to offer my predictions as to what healthcare delivery will look by 2030. For this month's column, I thought I would spend some time discussing some of those trends and what they might mean for the evolution of the supply chain.

Restructuring the system from a primarily acute care focus to chronic disease management

For both clinical and economic reasons, the healthcare system will be restructured to better support chronic disease management, which consumes almost 90 percent of our national healthcare expenditures. Today, nearly 60 percent of Americans have at least one chronic disease, and 40 percent have more than one, which increases both the costs and risks associated with their care. Going forward much of the innovation in healthcare delivery will center on primary care to help prevent and/or manage chronic disease and the ability for patients to take a more active role in their care.

Potential Supply chain implications:

- Pursuit of the clinically integrated supply chain will include engagement with more primary care practitioners and those specializing in chronic disease, as opposed to today's emphasis on those specialists who utilize high dollar devices in their practice, e.g., orthopedic and spine surgeons.
- The medical-surgical and pharmaceutical supply chains will collaborate more closely given the importance of both drugs and devices in chronic disease management.

Data-driven, platform-enabled, personalized healthcare

With advances in genomics and the availability of additional clinical and social data, we will see the development and expansion of platforms that aggregate and analyze data from multiple sources to predict what kinds of care specific patients will likely need, and to manage prevent chronic disease. Artificial intelligence will consider a broader range of information (including data from patients themselves, implanted and connected devices, and digital health apps). While the end result will be more individualized care pathways, the data analyzed will be based on information gathered from an increasingly large and diverse set of patients, to more effectively understand what works best for which patient populations, e.g., those with similar comorbidities, gender, age, ethnicity, lifestyles, genetics, etc.

Potential Supply chain implications:

- With this forward-looking data, supply chain professionals can more precisely determine the supply (including pharmaceutical) bundles that will be needed by covered patients to help generate longer term demand signals.
- Value analysis and strategic sourcing will evolve from a primary focus today on new product introductions and conversions to the use of real-world evidence as to which therapies (and associated supplies) improve quality and lower the total cost of care delivery.
- Healthcare supply chain professionals will spearhead more outcomes-based contracts with suppliers to not only share risk but also help generate the real world evidence needed to continually inform care pathways.

Changing location of healthcare

Both of the trends above will further accelerate the move to care delivery outside of the acute care setting. This is driven in large part by research documenting the ability to deliver care in community settings, including ambulatory surgery centers and the home, at lower costs and often at higher quality. Locally delivered care also increases satisfaction and convenience for many patients. ASC volume is expected to increase between 15 and 25 percent by 2030, while the delivery of acute level care in the home will likely grow by nearly one-third. The move to more non-acute locations is further supported by the increase in the types of procedures that can be conducted in ASCs and the advancement of remote patient monitoring and the extension of waivers for acute hospital at home programs.

Potential Supply Chain implications:

- Supply chain professionals will become increasingly involved in ensuring the availability of qualified personnel to deliver care in the home and other community settings. This will include coordinating the logistics to make sure the right people and products are available where needed and in the most efficient and cost-effective manner. Supply chain will also be asked to address issues related to making individual home environments conducive to healthcare delivery.
- ASCs will increasingly rely on health systems, device vendors and/or independent outsourcing and technology companies to help manage their supply chains.
- Value analysis and strategic sourcing teams will seek data on how devices perform in different delivery environments.
- Efforts to standardize products will expand beyond single or jointly owned facilities and institutions to support more continuity of care and product familiarity among caregivers and patients working or being cared for in a variety of locations, even when operated by disparate organizations.

More focus on sustainability and equity

Both environmental sustainability and health equity are capturing more attention in the C-suite. Both issues also contribute to chronic disease. Health disparities are correlated with higher rates of chronic disease and are more prevalent among the poor and persons of color. Disparities in turn are correlated with barriers to access to care and the social determinants of health (e.g., nutritious food, safe housing, transportation, etc.). Climate change has also been shown to increase rates of respiratory disease and deaths, which are higher among the poor and persons of color who often do not have the resources to mitigate the negative consequences of extreme weather-related events.

Potential Supply Chain implications:

- Supply chain will be increasingly involved in efforts to address health equity, by using the power of procurement dollars to support economic development in disadvantaged communities.
- Value analysis will look beyond just price and efficacy of products to consider how they support environmental sustainability, local economic vitality and whether the evidence on performance is based on a diverse study group. HPN

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Device, equipment maintenance and repair driven by yin–yang yearning

Potential healthcare sting related to state "right-to-repair" laws blunted for now

by Rick Dana Barlow

If healthcare organizations wanted to log their utmost desire and deepest fear about the devices and equipment clinicians and administrators use within their facilities, they likely would record dueling acknowledgements: Devices and equipment work continuously as designed when needed without ever going down and that devices and equipment fail to work as designed when needed and go down, respectively.

Aside from the idyllic desires, the reality is that devices and equipment endure normal wear-and-tear from continual use and need to be maintained and repaired as part of the total cost of operation and ownership.

Healthcare organizations, by and large, can choose between three options to care for their devices and equipment, and all three require access to technological knowledge, component parts and labor without negatively affecting any warranty.

1. Contracting with the original equipment manufacturer (OEM) via extended warranty program or time-and-materials package
2. Contracting with a third-party independent service organization (ISO) in lieu of an OEM
3. Working with biomedical/clinical engineering professionals on staff that may be trained and certified.

Each option offers certain benefits and challenges that must be recognized and managed. Not surprisingly, providers and suppliers alike favor specific preferences that generally line up like this: OEMs want to service their own devices and equipment because they stress they have the experience and materials to provide quality service to retain and satisfy customer relationships; ISOs want to compete and generate revenue by offering what they promote as quality maintenance and repair services at lower costs than the OEMs; and healthcare organizations simply want the best of both worlds – that is, OEM reliability and service quality at ISO prices.

OEM vs. ISO

OEM supporters maintain the advantage that the constructors of the equipment know it the most intimately and have the manpower and material resources to keep it working. This can add to the cost of the equipment, which they cover through retail pricing that can be reduced through skillful contract negotiations by group purchasing organizations (GPO) , integrated delivery networks (IDN) or hospital supply chain department leaders. OEM supporters also contend that they must meet federal quality manufacturing and service regulations for their products to be marketed for sale.

"Medical technology companies must follow strict regulatory quality system regulations in order for their serviced devices continue to be safe and effective," said Manish Singh, Business Unit Vice President, Service Delivery, Olympus America Inc. "OEM repair technicians are extensively trained and specialize in maintaining and repairing OEM devices. The standards and level of training provides confidence that the medical equipment is brought back to manufacturer specifications during each repair event, thus making the device operate as it was intended with a resultant effect being prevention of patient harm. Further, OEMs are required to report adverse events to the FDA, which is critical

Manish Singh

information in determining the root causes of healthcare incidents."

Jatin Thakkar, General Manager, Global Services and Solutions, Carestream, echoes Singh by emphasizing equipment experience and knowledge.

Jatin Thakkar

"All staff are directly trained and supported by the OEM," Thakkar indicated. "Staff has highest level of expertise on the entire portfolio with a total knowledge of the overall production design and functionality. They have access to all levels of support – engineering and manufacturing for unique issues or escalations – and to genuine and certified parts and accessories to keep equipment running optimally."

These attributes grant OEMs something of an advantage, according to Lynn Salmon, Director of Hardware Sales, Tecsys Inc.

Lynn Salmon

"OEMs are masters of their domain," Salmon noted. "As builders of the devices, they possess unmatched from-the-source expertise and know them inside and out. This inherent wealth of product information should give you every confidence that they can provide expert guidance on troubleshooting and support for virtually any repair.

"Similarly, they are likely to have certified service technicians who are equipped with suitable specialized tools and authorized parts and equipment," she continued. "OEMs also tend to maintain extremely high standards for their own products as it is a direct reflection of their brand. As a result, you can reasonably expect a sophisticated support infrastructure with quick response times. It is also not uncommon to find OEMs that offer favorable warranties as part of their value proposition and as a means to maintain a relationship for future sales. Their incentive to provide cost-effective service through a product's lifecycle may very well be mutually beneficial. This is compounded by the common practice of offering contract rebates on any outstanding balance to be applied to new devices, providing more flexibility in your upgrade cycle.

"Finally, OEMs often have device-commissioning services, which help organizations configure, test and deploy equipment more efficiently and consistently according to the exacting standards of your selected manufacturer," Salmon added.

Healthcare Purchasing News reached out to ISO sources for comment, but none responded at press time.

The International Association of Medical Equipment Remarketers and Servicers (IAMERS) is a trade association that represents resellers and servicers of used medical imaging equipment that promotes "the safe and successful roles of independent sellers and servicers," according to its website. IAMERS refers to the FDA's 2018 Report on Safety and Effectiveness of Servicing Medical Devices, "the objective evidence indicates that many OEMs and third-party entities provide high quality, safe, and effective servicing of medical devices" and that "the continued availability of third-party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system."

IAMERS works to "ensure healthcare providers have choices" and that "independent service providers are committed to 'best practices' for patient safety."

The Repair Association, a group that doesn't specialize in healthcare, offers a more blunt and sacrosanct philosophy via its web site message: "You bought it, you should own it. Period. You should have the right to use it, modify it, and repair it wherever, whenever, and however you want. We fight for your right to fix."

Convenience clouds decisions

Company executives who responded to *HPN* acknowledge that providers may experience hurdles when working with OEMs for maintenance and repair services.

Most notably, "the challenges of OEM service and repair contracts are purported to be higher costs," Olympus' Singh indicated. Carestream's Thakkar points to the possibility that the OEM may not offer coverage in a specific location or area.

Tecsys' Salmon highlights a variety of preference and workflow issues.

"Not all OEMs prioritize maintenance and repair, favoring instead to sell a new piece of equipment," she noted. "This is especially true of older or discontinued technology that may have a lot of functional life left in it since supporting multiple generations of tech drags on margin. Because of this, it is possible that OEMs are not well set up to provide maintenance services, leading to longer lead times on replacement parts, which may result in longer repair timelines. It is also possible that out-of-warranty service from OEMs may not be the most cost-effective option."

Salmon also homes in on customer supply chain operations.

"Another consideration is your device mix and service contract management," she said. "If most of your equipment and devices are from a small pool of OEMs, juggling a few repair service contracts is simple enough. However, if you have a miscellany of devices from several manufacturers, it may be operationally more complex to work with each OEM over having a third-party service provider that can handle multiple brands and products simultaneously."

But ISOs can offer benefits under certain caveats, according to Thakkar.

"[ISOs] may be able to support equipment from multiple OEMs and can provide a similar level of support if they are trained and certified by the OEM(s)," he said. "That could present some cost savings if they have the ability to bundle equipment from multiple OEMs."

However, ISOs present several key challenges, Thakkar added.

"Typically, they don't have access to all levels of specific training and/or documentation from OEMs," he observed. "They also don't work exclusively on OEM equipment so their expertise may be lacking on unique issues. They might still need secondary support from the OEM on complex items and may not be up to speed on the latest features, software and capabilities."

Singh uses clinical reasoning to justify selecting the OEM over an ISO.

"Healthcare providers must consider the potential costs to patients well-being and the overall health system when medical technologies malfunction because the device was inadequately repaired or serviced by an ISO or the ISO uses materials that have not been proven to work according to specifications and have not been tested for material compatibility with approved methods for cleaning and disinfection," he said.

Thakkar also recognizes the appeal of healthcare organizations relying on their internal biomedical/clinical engineering professionals for device and equipment maintenance and repair.

"They are internal staff so they're generally more accessible and their capacity can be flexed based on needs," he indicated.

But he cautions about their expertise.

"Since they have infrequent contact with equipment, they typically are not the experts on any OEM equipment," he noted. "They may not be up to date on all current solutions, releases, etc., and may find it difficult to maintain regular training and certifications on all equipment."

Legislative response

Due to the global COVID-19 pandemic and the resulting supply chain disruptions that hampered access to products, interest in the "right-to-repair" movement and legislation at the federal and state levels continues to percolate. Back in 2021, a New York federal legislator on the House Energy and Commerce Committee introduced H.R. 4006 – Fair Repair Act – for discussion.

Essentially, "right-to-repair" proponents call for ISOs to be granted access to OEM

device and equipment service manuals as well as component parts so that end users have more choices for maintenance and repair, which reinforces competition, and therefore leads to lower pricing.

OEMs counter that such information is intellectual property so it should not be provided to any company not authorized, certified and contracted by the OEM to work on proprietary equipment. Further, they contend that price reductions may be offset by longer-term cost increases stemming from any ISO maintenance and repairs that do not meet OEM quality standards as stipulated by the FDA. This could result in equipment failure, downtime, warranty voidance and potential harm to patients, which can open the healthcare organizations, clinicians and OEMs to liability.

Near the end of December, New York became the first state to pass a "right-to-repair" law, the Digital Fair Repair Act (A7006B/S4104A). New York's law goes into effect in July 2023. Legislators in more than 20 other states continue to debate and develop their own measures.

New York's "right-to-repair" law, however, exempts three product areas: Motor vehicles, off-road equipment and medical devices.

"The 'right-to-repair' movement was created primarily as a consumer products campaign," said Olympus' Singh. "However, the legislation being considered in states nationwide goes beyond consumer goods to include medical technologies. If passed, these laws may give unregulated, untrained third-party servicers the right to maintain and repair sophisticated medical equipment without having to comply with applicable patient safety regulations.

"We are urging hospitals to give manufacturers the ability to continue standing by their products' quality and efficacy, which is based on extensive testing of materials and careful regulatory review," Singh continued. "Going to third-party repair, even in crisis, is a dangerous proposition, as they may not have the proper training, equipment and replacement parts. Patient safety must be the top priority, and there is no substitution for the extensive training, knowledge, and expertise OEMs and authorized servicers must have to maintain and repair these complex medical technologies."

Singh refers to supporting documents provided by the Advanced Medical Technology Association or AdvaMed, which represents OEMs. *[See the Editor's Note below for relevant links that support the viewpoints of OEMs and ISOs.]*

AdvaMed issued its stance to the FDA in February 2019, the formal comments of which are publicly available via the online links below.

"We believe most service manuals, particularly the complex service manuals companies use to repair their own products, diagnostic or specialized software, specialized tools or hardware and routine service or maintenance (as distinct from user manuals) fall into the category of protected intellectual property which FDA cannot compel manufacturers to provide,"

AdvaMed further explains the reasons behind OEMs not distributing "OEM manuals and specialized tools to non-affiliated or non-authorized third-party servicers" with five distinct points:

- "Security concerns (e.g., cybersecurity concerns);
- "HIPAA and patient privacy concerns;
- "Safety and efficacy concerns; OEMs have processes in place to alert purchasers and OEM authorized/affiliated third parties when significant device changes have occurred. However, it is impossible to notify unauthorized/unaffiliated third-party servicers when significant device changes have occurred since OEMs have no information on which 3rd parties are servicing their devices;
- "OEMs cannot verify if third-party servicer(s) have acceptable device maintenance processes in place."

AdvaMed stated that "poor quality servicing may lead to poor device performance, malfunction and adverse events.

"AdvaMed believes high-quality third-party servicers – that are required to follow the QSR – are needed to ensure sufficient device servicing capacity. The QSR covers the entire device lifecycle from device design, manufacturing and installation to servicing."

AdvaMed called on the FDA to set formal guidelines to provide quality services, including:

- "Require third-party servicers to register and list with FDA (including publication of which OEM equipment they service);
- "Require third-party servicers to establish a Quality Management System that is appropriately scaled to the products and types of servicing they conduct as required by the QSR;
- "Clarify that FDA will routinely inspect third-party servicers for compliance with the QSR;
- "Require third-party servicers to report MDRs [Medical Device Reporting] to FDA and OEMs;
- "Ensure that MDR codes include identifiers for third-party servicers."

Healthcare is different

Like Singh, Thakkar draws distinction between healthcare and other industries for which the "right-to-repair" movement originated.

"Healthcare is a bit unique as compared to the general consumer electronics industry," he said. "We are a tightly regulated industry, and a lot of the capital equipment is used on people for diagnosis and treatment, thus the stakes are a lot higher.

"OEMs spend considerable time and develop comprehensive processes for building and maintaining capabilities in their service organizations so they can ensure safe and effective operations of the equipment," Thakkar continued. "This includes incorporating serviceability and reliability requirements up front in the product design. There is also constant testing and quality compliance before the product is released. They also have dedicated teams for training; and for parts and performance analysis for optimal equipment use and for meeting safety and regulatory requirements. Finally, they proactively monitor all installed units for early indications of potential issues so they can remediate [them] immediately."

Depth of experience should drive decisions, Thakkar insists.

"Much of this is possible only if they have access to the design and development staff that built the equipment, and the knowledge base of all the areas of the product," he said. "This cannot be replicated with external parties. So even as there is a place for self-service – typically in basic maintenance and initial triage levels – at some point the OEM provides many more capabilities and deeper expertise to ensure optimal equipment performance." HPN

Editor's Note: For more information on the "right-to-repair" movement and legislation, visit the following links:

AdvaMed:

https://www.advamed.org/2022/04/28/the-fallacy-of-right-to-repair-for-medical-devices/

https://www.advamed.org/industry-updates/policy-issues/right-to-repair-wrong-for-patients/

Consumer Reports:

https://advocacy.consumerreports.org/press_release/new-york-governor-signs-historic-digital-right-to-repair-bill-into-law/

IAMERS

https://iamers.org/2022/06/fda-to-amend-quality-system-regulation/

https://iamers.org/legislative-initiatives/

The Repair Association

https://www.repair.org/legislation

U.S. Congress

https://www.congress.gov/bill/117th-congress/house-bill/4006

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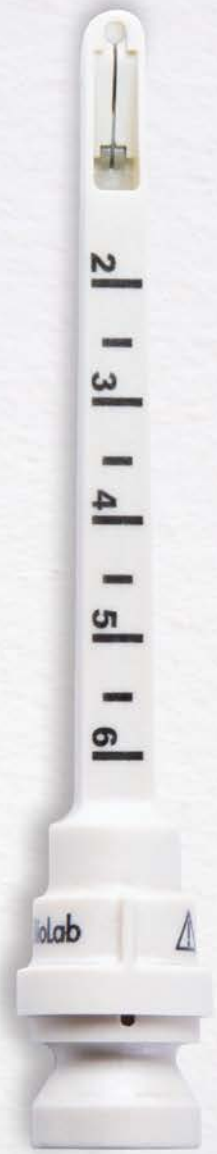

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