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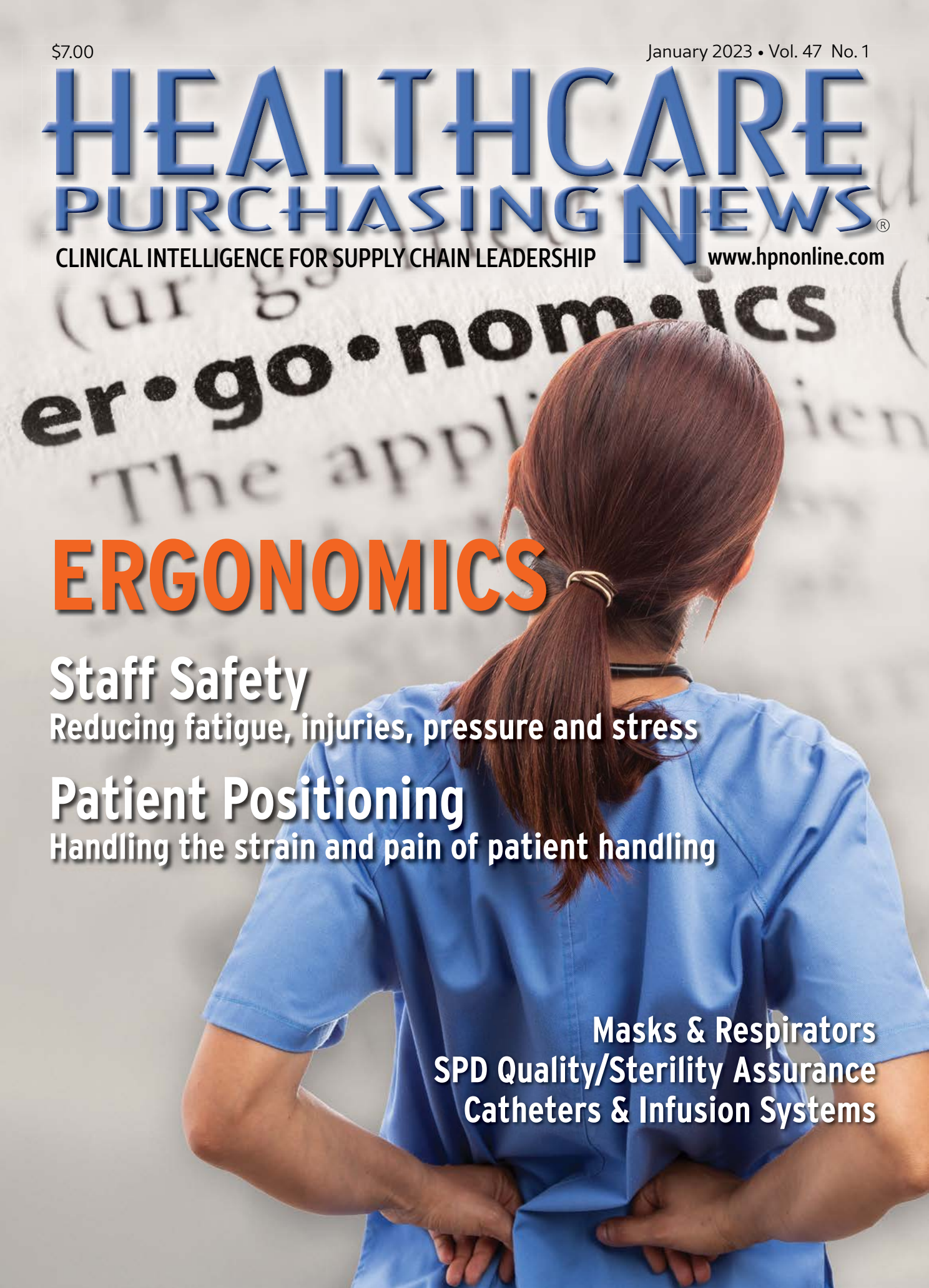

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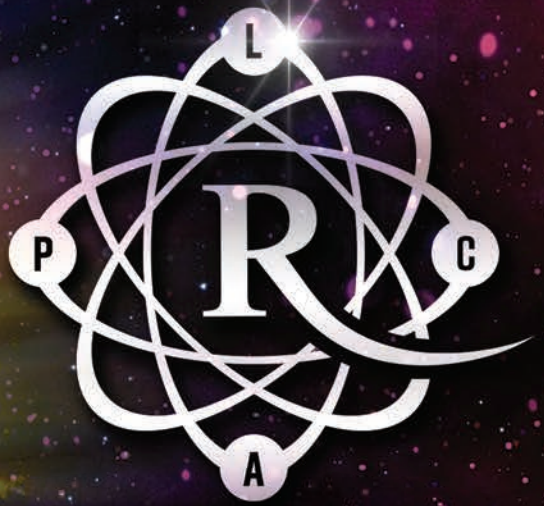

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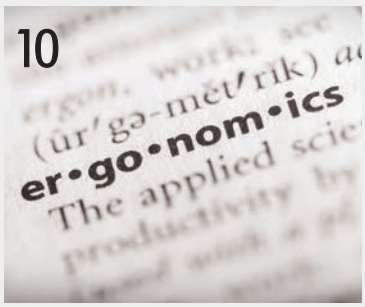

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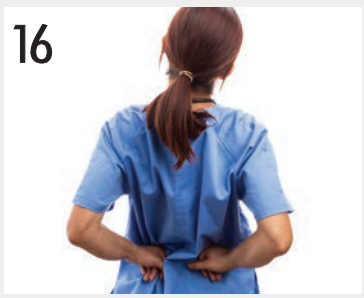

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Rick Dana Barlow
Senior Editor

Supply Chain shouldn't be rated PG or R

Managing the healthcare supply chain within a provider enterprise/organization should not be like parenting underage children.

To be successful in healthcare, supply chain requires leaders as well as managers – much like their occupational kinfolk in other industries, such as foodservice, hospitality, manufacturing and retail.

As you likely know, in the film industry the Motion Picture Association of America (MPAA) operates under a rating system that it uses to classify movies based on content. Intentionally omitting the rated content that falls under the 24th letter of the alphabet, cinephiles and moviegoers alike recognize four common levels – G for General, PG-13 for Parental Guidance if under 13, PG for Parental Guidance and R for Restricted.

For far too long, healthcare supply chain managers have been relegated to PG and R ratings.

How so? Think of PG as indicating "Professional Guidance" by the C-suite; think of R as indicating "Restrictive" by the C-suite.

So what? Not so.

A quote by Vizient's David Hermann, shared second-hand and paraphrased here, motivated this edition's Buyline topic to start 2023. Hermann has a storied history with *Healthcare Purchasing News* in that more than a decade ago, he periodically penned *HPN*'s "Clinical Business Strategies" column while an executive with Aspen Healthcare Metrics, which became part of MedAssets, which then became part of Vizient.

Hermann's quote went something like this: Healthcare supply chain managers are only as good as saying "no." They're not authorized or empowered to say "yes."

This. Must. Change.

We may roll our eyes out loud referring time and again to the global COVID-19 pandemic and the resulting supply chain disruptions, but so be it. If anything, the events of the last two years (2020-2022) have showed us problems with performance, process and workflow but they also should have taught us – warned us – about problems with decision-making … as in hierarchy.

Disagree all you want but the ongoing labor shortages and the folding of purchased services – which includes third-party labor, by the way – within the healthcare supply chain bucket translates into SUPPLY CHAIN BEING THE NO. 1 COST CENTER IN A HEALTHCARE ENTERPRISE/ORGANIZATION. Emphasis in all caps intended.

It's time for the industry to wake up to that fact. Like in non-healthcare industries, Supply Chain – as a titled proper noun that earns capitalization – is a big deal because it represents a key component of the economy. Think of it as a stent used to prop open healthy commerce.

Whether the C-suite invites Supply Chain to the mahogany table at the same level as the other C's and O's, or relegates Supply Chain to third-party purchased service status with a dotted line to the gilded executive tower, know this: Supply Chain will make or break an organization. Some useful advice? Look no further than the Knight Templar guarding the Holy Grail in the 1989 film, "Indiana Jones and the Last Crusade," who instructed the ill-fated antagonist and the successful protagonist to "Choose wisely."

Needlessly melodramatic? Maybe. But do you want to take that chance long-term?

If your organization does not have a "leader" to run Supply Chain, then determine the qualities you seek, find and train the internal professional who possesses them or find and recruit the qualified external professional.

The last two years demonstrated that Supply Chain must be empowered to pivot and go – quickly if necessary – with the C-suite's full support, trust, authorization and blessing.

Bottom line: To be successful in healthcare supply chain needs to be run by leaders – those who the C-suite rates as G for "Go" – as in go make the decision.

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FAST STATS

'Hurting' industry

The strain and pain on our nurses is very real, and it's toll on the healthcare workforce cannot be denied.

Collectively, the hospital subsector's workforce has dipped nearly 90,000 people since March of 2020, according to preliminary November data from the U.S. Bureau of Labor Statistics.

Among nurses alone, the American Nurses Association expects there will be more than 100,000 registered nursing jobs available annually by next year.[1]

One major source of injury to healthcare workers is musculoskeletal disorders (MSDs). In 2017, nursing assistants had the second highest number of cases of MSDs.

As many as 20% of nurses who leave direct patient care positions do so because of risks associated with the work.

Direct and indirect costs associated with only back injuries in the healthcare industry are estimated to be $20 billion annually.[2]

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NEWSWIRE

A nationwide shortage in contrast media

According to a release from Premier, PINC AI data shows that up to 10 percent of hospital inpatients who should have received an advanced image as part of their recommended care did not due to a nationwide shortage of contrast media.

Contrast media went into shortage in mid-April after COVID-19 lock downs in China halted the Shanghai-based production center responsible for nearly 80 percent of product for one of the two primary suppliers serving U.S providers. Premier fill rate data shows that the shutdown triggered an almost immediate dip in contrast media fill rates that persists today.

Premier leverages manufacturer data, member reporting and fill rate trends as mechanisms to help determine the health of the supply chain. For drugs, Premier considers a healthy fill rate to be above 90%, and anything that falls below 80 percent is an early indication that demand is outpacing supply and that shortages may be imminent.

During the shortage, providers were forced to conserve supplies, which often meant limiting imaging services with contrast media to medical emergencies only.

However historically, less has been known about exactly how many procedures are deferred due to a particular shortage, or the effects on patient care.

To determine the impact, PINC AI data scientists examined five clinical conditions typically reliant on advanced imaging with contrast media (COVID patients, mothers and babies, hip/knee and spinal surgical patients). The data showed deep drop offs in imaging utilization starting in April and continuing through the summer, when the contrast media shortage was most acute.
Read on: https://hpnonline.com/21288297

New, simpler procedure effective at relieving carpal tunnel syndrome

A minimally invasive treatment for carpal tunnel syndrome provides complete and long-term relief to patients without the use of corticosteroids, according to research being presented at the annual meeting of the Radiological Society of North America (RSNA).

Carpal tunnel syndrome is a form of nerve entrapment neuropathy, which is when one of the body's peripheral nerves is being pressed on or squeezed. It occurs when the median nerves and tendons inside the carpal tunnel, a narrow and rigid passageway that runs from the forearm to the palm of the hand, are being pressed or squeezed at the wrist. This results in tingling, numbness and/or weakness of the fingers and hands. Carpal tunnel syndrome is the most common and widely known form of entrapment neuropathy, affecting about 3% of the U.S. population.

Surgery is often required to treat carpal tunnel syndrome when non-surgical methods, such as physical therapy or corticosteroid injections, are insufficient. The most common and widely used surgical method involves cutting the carpal ligament to reduce pressure on the median nerve. This method requires making an incision into the wrist.

But this new study shows that a technique called hydrodissection effectively treats nerve entrapments without the need for surgery or corticosteroids. It involves the injection of a liquid, usually saline, into a nerve to separate it from the surrounding tissue. Ultrasound guidance is used to accurately identify nerves.
Read on: https://hpnonline.com/21288756

New supply chain solution for Cardinal Health bringing hospital into the home

Cardinal Health has announced the launch of Velocare, a supply chain network and last-mile fulfillment solution capable of reaching patients in one to two hours with critical products and services required for hospital-level care at home. Through a strategic collaboration with Medically Home, Cardinal Health at-Home Solutions is now supporting a Medically Home health system customer with Velocare, collectively enabling scaled, high-acuity care in the home.

Velocare brings together Cardinal Health capabilities through a combined offering intended for health systems, payers, digital health companies, telehealth providers and other entities moving high-acuity care to the home. Legacy Cardinal Health capabilities include global logistics and distribution expertise, management of a large network of suppliers and vendors, and access to a wide range of home-based care providers. The pilot will test the use of new technology, new order handling processes, small-format depots and short-haul delivery vehicles to enable safe and consistent hospital-level care in the home.

"We're excited to further expand our at-Home Solutions supply chain and logistics excellence to now reach patients receiving hospital-level care at home," said Rob Schlissberg, president, at-Home Solutions. "With their mission of putting the patient at the center of care, combined with their differentiated supply chain network, Medically Home leads the way in bringing

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the hospital home. Our collaboration is driving scale and efficiency, and ultimately provides positive patient outcomes."

With the right infrastructure in place, patients who were historically admitted to brick-and-mortar hospitals such as those with severe pneumonia, complicated urinary tract infections, cellulitis, blood infections and congestive heart failure exacerbations can now receive high-quality, safe, hospital-level care in the comfort of their homes. The Velocare pilot includes real-time evaluation of the technology, service levels, effectiveness, patient experiences, plus consideration for future growth in new markets.

A recent study by McKinsey & Company estimates that up to $265 billion worth of care services for Medicare fee-for-service and Medicare Advantage beneficiaries could shift to the home by 2025 without a reduction in quality or access1. The same research demonstrates how stakeholders — including payers, healthcare facilities and physician groups, home-based care providers, technology companies and investors—could see substantial value by providing patients with care in the comfort of their homes. Potential benefits include cost savings due to reduced overhead and more efficient clinician protocols, increased safety due to a reduced risk of hospital-acquired infections and medical errors, plus increased patient satisfaction.

Read on: https://hpnonline.com/21287561

HHS issues report focusing on patient experiences with Long COVID

A new report released by the U.S. Department of Health and Human Services (HHS) highlights patients' experience of Long COVID to better understand its complexities and drive creative responses by government leaders, clinicians, patient advocates and others.

Long COVID is a set of conditions. Researchers have cataloged more than 50 conditions linked to Long COVID that impact nearly every organ system. Estimates vary, but research suggests that between 5 percent and 30 percent of those who had COVID-19 may have Long COVID symptoms, and roughly one million people are out of the workforce at any given time due to Long COVID. This figure equates to approximately $50 billion annually in lost salaries.

The Health+ Long COVID Report builds on the President's Memorandum on Addressing the Long-Term Effects of COVID-19 and the two previously issued HHS Long COVID reports. The report was commissioned by HHS and produced by Coforma, an independent third-party design and research agency. It provides recommendations on how to deliver high-quality care, and relevant and intentional resources and supports to individuals and families impacted by Long COVID.

Last week, the Administration sent a $750 million-dollar supplemental funding request to Congress to support Long COVID research and treatment. This funding request would support HHS and their continued work on Long COVID, providers who serve patients with Long COVID and its associated conditions, and community-based organizations that assist with case management and provide other essential services and supports. By developing a wrap-around response this funding will assist in answering the report's call to action.

"Listening to and learning from the experiences of Long COVID patients is essential to accelerating understanding and breakthroughs," said Adm Rachel Levine, M.D., Assistant Secretary for Health. "*The Health+ Long COVID Report* is evidence of our commitment to engaging communities to provide patient-led solutions."

Read on: https://hpnonline.com/21287999

Amazon Clinic to begin operations in 32 states, providing virtual care for common health conditions

Amazon has announced that they will be introducing Amazon Clinic, a message-based virtual care service that connects customers with affordable virtual care options when and how they need it—at home, after dinner, at the grocery store, or on the go—for more than 20 common health conditions, such as allergies, acne, and hair loss.

Amazon Clinic will be available as a means through which people can further take control of their health, as it will provide access to convenient, affordable care in partnership with trusted providers. The new health care store lets customers choose from a network of leading telehealth providers based on their preferences. Every telehealth provider on Amazon Clinic has gone through rigorous clinical quality and customer experience evaluations by Amazon's clinical leadership team.

Amazon Clinic is designed to be simple and easy to use. To get started, customers select their condition, then choose their preferred provider from a list of licensed and qualified telehealth providers. Next, they complete a short intake questionnaire. Customers and clinicians then directly connect through a secure message-based portal, giving customers the flexibility to message their clinician when it's most convenient for them—anytime, anywhere. After the message-based consultation, the clinician will send a personalized treatment plan via the portal, including any necessary prescriptions to the customer's preferred pharmacy.

Read on: https://hpnonline.com/21287390

Survey confirms enhancing patient access remains top priority

Improving patient access to medical services remains a top priority for U.S. health systems as they grapple with economic uncertainty and the continued impact of the COVID-19 pandemic, which has altered patient behavior.

According to a new report from the Center for Connected Medicine (CCM), health system leaders ranked patient access as the top challenge that could be improved with technology in the coming year. It was the second year in a row that the CCM's "Top of Mind for Top Health Systems" research identified improving patient access as a priority.

To address the challenge, health systems are investing in telehealth technology, patient portals and other digital tools, updating their organizational structures and focusing on fixing processes within their organizations.

The "Top of Mind for Top Health Systems 2023" report has been published on CCM's website.

The report identified telehealth, patient portals and patient appointment reminders as the technologies most often implemented by health care organizations to improve patient access. Other digital tools, such as self-scheduling, cost estimators and navigation solutions, have not seen implementation at the same high levels.

"It's no secret that health systems have been facing significant challenges since the start of the COVID-19 pandemic and must address consumer demands for greater convenience and accessibility from their health care providers. This report reflects the priority that we and others are placing on patient access, including more options for virtual care, greater self-scheduling functionality and higher engagement with patient portals," said Joon Lee, M.D., executive vice president of UPMC and president of UPMC Physician Services.

The CCM, which collaborates with a wide range of experts to produce resources and events on the future of health care, is operated by Nokia and UPMC.

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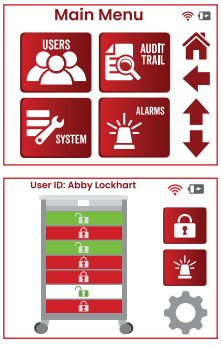

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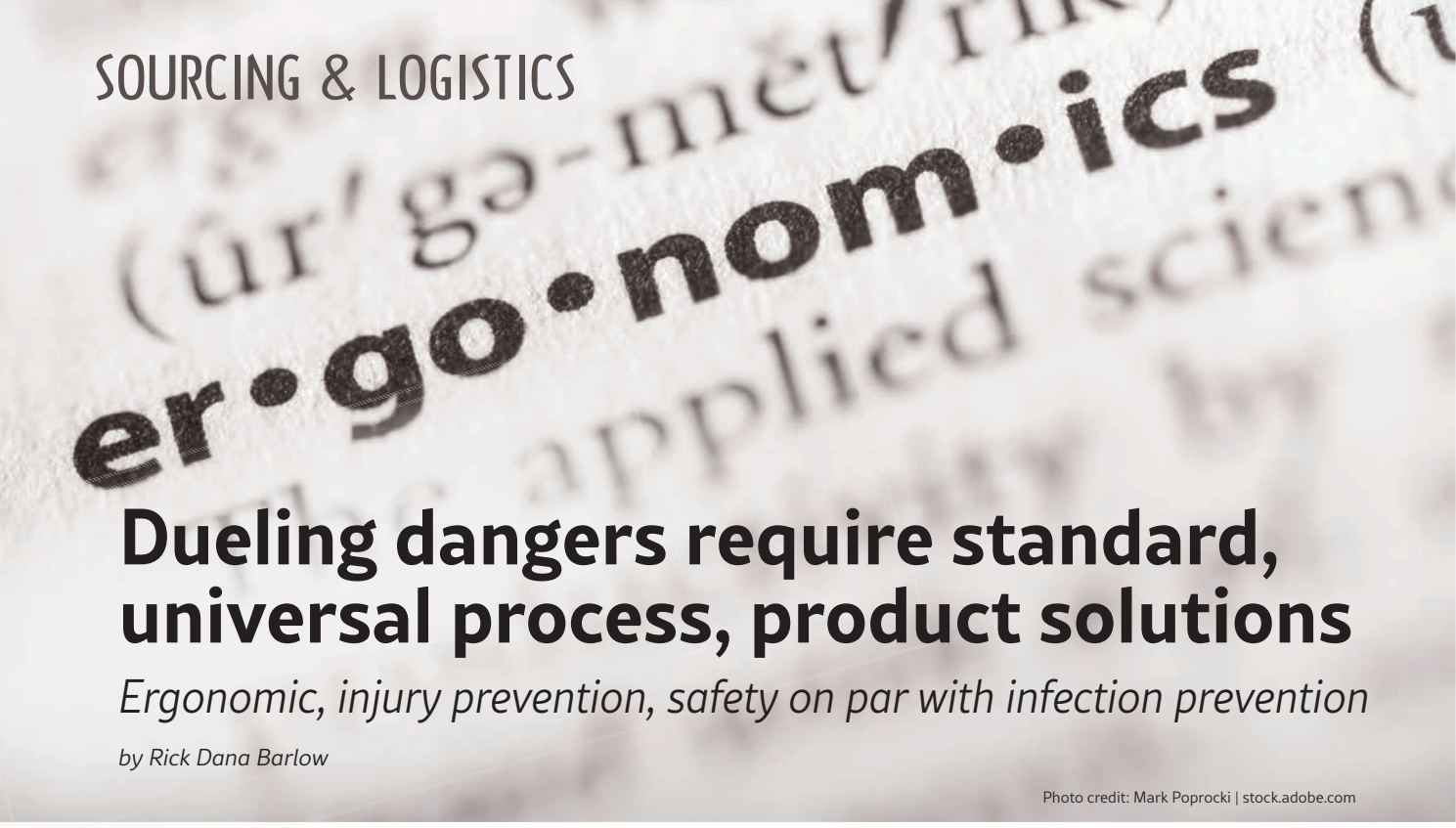


Dueling dangers require standard, universal process, product solutions

Ergonomic, injury prevention, safety on par with infection prevention

by Rick Dana Barlow

Photo credit: Mark Poprocki | stock.adobe.com

Against the backdrop of staff shortages and employee fatigue fomented in part by the global pandemic during the last two years, healthcare organizations recognize the need to protect and value the professionals that deliver patient care and manage operations from dual dangers.

This support involves sourcing, evaluating and purchasing products designed to reduce fatigue, injuries, pain, pressure and stress. From suffering carpal tunnel syndrome, back and shoulder pain, foot and knee pain, falls, sharps injuries and workplace violence, those on the front lines and back offices of healthcare organizations face a great deal of tension during any given day. While personal protective equipment (PPE) provides safeguards from dangerous exposure to blood and other bodily fluids and tissues that can spread infectious pathogens on the one hand, ergonomic, injury-prevention and safety-related products cover what they face on the other hand.

The market offers a plethora of products designed to ease emotional, mental and physical burdens that include adjustable furniture, flooring, mats, injury-prevention and safety-designed devices and more.

Leaping over hurdles

Healthcare organizations grapple with several impediments that can slow or even stymie investment in ergonomic, injury-prevention and safety-related products.

One involves priority.

Brian Hazelwood, Marketing Manager, Midmark, remains optimistic but realistic.

"The good news is that over the last few years, there has been growing attention toward the comfort and well-being of healthcare staff," Hazelwood said. "The healthcare community continues to make great strides in understanding and addressing safety and ergonomics-related issues.

Brian Hazelwood

"Many of our healthcare customers tell us that ergonomics and safety at the point of care are priorities," he continued. "However, executing on that priority can often be a challenging task as a host of other day-to-day operational challenges and priorities understandably demand attention and resources. Sometimes customers are not fully aware of all the safety and ergonomic issues in their facilities. For example, the demographics of healthcare workers are associated with specific issues that may not be recognized."

Hazelwood cites data from the Bureau of Labor Statistics that reports 76% of healthcare workers are female and further notes that the average height of females in the U.S. is just under 5 feet 4 inches.

"The typical equipment found in clinical environments often is not designed for average-height healthcare workers," he indicated in a bit of deductive reasoning. "For example, in many instances healthcare workers resort to using stools or other devices to see or reach supplies on upper shelves of cabinetry. Not only is this a safety issue, but the overstretching can cause aches and pains."

Another involves economics.

Several obstacles can come into play when sourcing ergonomic and safety products, according to Jessica Grenwis, Director of Customer Marketing, Healthcare, Ergotron.

Jessica Grenwis

"Budget is a common one," Grenwis acknowledged. "There can be financial pressures to purchase based on price rather than selecting the most suitable option for the work to be done. Similarly, there can be a tendency to stick with familiar products or manufacturers rather than choosing something different, even if it may be an improvement.

"Additionally, some customers may not clearly understand the differentiation between products and manufacturers, which can create confusion, especially among heterogenous purchasing groups with different experiences, pain points and needs," she continued. "But ultimately, healthcare organizations are oriented toward providing patients with excellent care and equipping caregivers with the support and resources they need to provide that care. When that focus remains top of mind, finding solutions that meet the stakeholder group's needs becomes easier."

Kathryn Duesman, RN, Vice President of Clinical Affairs, Retractable Technologies

Inc. (RTI), however, cautions against any economic- or priority-induced hesitation.

"In the face of high hospitalization rates and staff shortages, healthcare worker safety is paramount," Duesman told *Healthcare Purchasing News*. "Hospitals must look to the safest technology, regardless of contracts, to effectively protect workers. Innovative safety technology, such as retractable syringes and needles, have proven to significantly reduce needlestick injuries."

Kathryn Duesman

Mary Kelly Jagim, RN, CEN, FAEN, Principal Consultant, CenTrak, recognizes that staff support and buy-in can be significant hurdles when considering new technology or equipment, particularly when it's designed to protect against workplace violence. The purchasing process and workflow for such automated technology needs to be outlined and streamlined.

"When it comes to a new internal equipment launch or campaign, the key components for success are early transparency, proactivity and staff education of the technology's use cases," Jagim said. "Successfully deploying new solutions, such as Real-Time Location Systems (RTLS), requires incorporating the proper expertise from the healthcare facility, vendor and key stakeholders in nursing, marketing, patient experience, security, and administration. Bringing together leadership with varying viewpoints and expertise allows healthcare facilities to better develop proactive communication strategies and comprehensive educational programs.

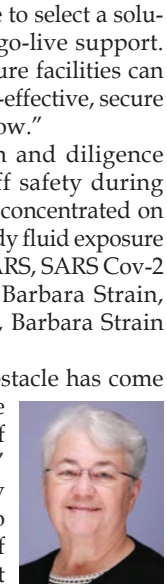
"By providing transparency and early education on the technology's purpose and how it can benefit workflow, patient care and safety without concern for negative consequences, leadership and healthcare professionals are more likely to accept and adopt the technology," she continued. "This is especially important when it comes to new safety equipment. Without widespread staff adoption, it won't be as effective. As an example, it's beneficial to incorporate or enhance the system-wide culture of safety. This ensures staff know they have the facility's support as workplace violence continues to increase. Strong support can lead to greater peace of mind, retention, and help with hiring purposes."

Jagim recognizes the economic and resource hurdles that have surfaced during the last few years, but she encourages healthcare organizations to establish and carry out an effective plan.

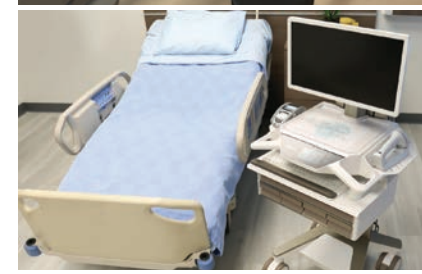
"The first step to remedying these concerns is to properly identify and prioritize the major pain points impacting your healthcare facility and implement a solution that solves the challenge," she advised. "When incorporating the new technology, make sure your team selects a solution with infrastructure that can scale and support multiple use cases with minimal rework or downtime. In addition to infrastructure, make sure to select a solution partner that offers go-live support. These key decisions ensure facilities can quickly implement a cost-effective, secure solution with room to grow."

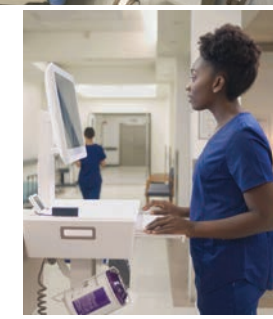
Much of the attention and diligence toward patient and staff safety during the last few decades has concentrated on respiratory, blood and body fluid exposure from influenza, Ebola, SARS, SARS Cov-2 and RSV, according to Barbara Strain, MA, CVAHP, Principal, Barbara Strain Consulting LLC.

"The biggest safety obstacle has come through lack of knowledge in how to protect staff from novel pathogens," Strain observed. "It may take weeks or months to learn the true route of transmission and what type of protection already exists or will need to be developed, approved, manufactured, purchased and put into use. In the late 1970s early 1980s the first cases of what was later identified as AIDS caused by HIV started to emerge and serve as the genesis of OSHA's Blood-borne Pathogen Standard that was first issued in 1991. The staff protection industry grew exponentially to what is found today; Gloves, eye protection, masks, gowns and sharps safety to list a few."



Barbara Strain





Ergotron's CareFit Combo System (top), CareFit Pro (middle) and CareFit Slim 2.0 LCD Medical Cart (right)

Ergonomics concerns have emerged due in part to the rise in obesity in the U.S., Strain continued, citing a 2020 briefing by The Advisory Board Co. (https://www.advisory.com/daily-briefing/2020/12/17/obesity) as affecting patients and caregivers alike.

"The development of patient comfort products/equipment to adapt to the comfort and ability to treat patients has caused safety and ergonomic issues for bedside staff," she noted. "End-user equipment and products with a staff ergonomics focus involve patient movement – positioning in bed, transfer out-of-bed to chair or stretcher, and in OR/Procedures/Treatment situations, especially of long duration."

Strain points to patient and product transport, such as staff pushing wheelchairs and stretchers, moving and using radiology or other portable equipment, and being

Midmark's 626 Barrier-Free Exam Chair, mobile workstations with height adjustment, and wall-hung cabinetry showing the lower upper height and more shallow cabinet depth, as well as gravity-fed, angled flow shelving that improves visibility and access to supplies.

able to access permanently placed small equipment or dispensing products used in patient rooms, such as suction, paper towels, used sharps or regulated medical waste dispensers that need to be conveniently reached on either side of patient by only one staff member.

She also targets storage areas as another area of concern in terms of easy and safe access with assistance when needed. Strain quips that this shouldn't be a "10 pounds of sugar in a 5-pound bag" syndrome, an adage that references effective and efficient capacity, convenient access to equipment and products being in the right place at the right time.

Pushing 'ESP' to the forefront

What will motivate healthcare organizations to propel ergonomics, safety-designed and protective-related products (ESP) to a higher priority of awareness and action?

For Ergotron's Grenwis, it's involvement, research and time.

"In healthcare, safety really matters," she emphasizes. "According to current data from the U.S. Bureau of Labor Statistics, workplace illness and injury rates are higher in healthcare than in any other industry. Healthcare safety encompasses much more than preventing well-known dangers like accidental needle sticks — there are a vast number of risks that caregivers are exposed to that can result in illness or injury.

"Safety and ergonomics are interdependent and work together to enhance the caregiver experience," Grenwis continued, promoting an eBook that Ergotron offers. "Research has demonstrated the importance of ergonomics in healthcare settings and how ergonomic solutions support caregiver health and well-being. This information is useful to share when working with a team of stakeholders making purchasing decisions."

Healthcare organizations naturally should consult with their staff members for input, too, she urged.

"Relevant research data paired with feedback from caregivers and staff on what's working well and areas for improvement in the hospital, clinic or facility can be a valuable starting point to engage with healthcare solution providers," she said. "Demos or learning sessions with manufacturers or resellers allow members of the purchasing and clinical teams to come together to explore various products or workflow improvements that best address the pain points and meet stakeholder needs."

Midmark's Hazelwood stresses the incorporation of evidence-based clinical design.

"One important way to elevate safety and ergonomics features in the purchasing of products is for healthcare organizations and workers to make clinical design a factor in the consideration of new equipment and furniture," he noted. "Understand the role clinical design can play in helping improve safety and ergonomics and make it a priority to purchase equipment that is designed specifically for the healthcare environment and staff. Caregivers should not have to adapt to the equipment and furniture; rather the equipment and furniture should and can be adapted to them."

Hazelwood further recommends talking to equipment and furniture suppliers about safety and ergonomic issues and ask about features of their products that might be able to address these issues.

RTI's Duesman refers to regulatory agencies such as OSHA for guidance when appropriate and necessary, particularly in the area of injury.

"OSHA requires an annual review of new technology that will eliminate or minimize exposure to contaminated sharp," she said. "This review also will shed light on the devices that continue to be associated with injuries. Facilities must consider new technologies that reduce exposure to bloodborne pathogens and implement available, safer medical devices designed to eliminate or minimize occupational exposures."

CenTrak's Jagim acknowledges that disruption from the global COVID-19 pandemic "amplified staff burnout and stressed the labor market, driving the turnover rate for registered nurses in 2021 to increase by 8% and greatly reduce the retention of knowledgeable staff." That's why she encourages healthcare organizations to invest in their staff.

"Lessening the stress placed on healthcare professionals is a critical aspect of combating burnout and promoting staff retention, and healthcare leaders will find that investing in their staff during the coming year makes sense for satisfaction, safety and the facility's bottom line," she noted. "According to The Joint Commission, reducing workplace burnout and violence can improve patient care and decrease distress, job dissatisfaction, turnover, and costs. The cost of injuries from workplace violence now lands around $94,156 per incident." She also cites that the cost to replace a nurse who leaves has climbed to $60,000.

Jagim further indicates that disruption from the pandemic heightened pressure and stress among everyone, which has increasingly vented through workplace violence.

"Violence against healthcare staff is not new," she insisted. "Since the start of the pandemic though, violence has surged. Some hospitals have experienced more than a 50% increase in dangerous incidents. An IoT-enabled RTLS safety solution provides a reliable, secure and real-time duress alerting system that prevents threats from escalating into violent situations by arming healthcare professionals with the ability to discreetly send panic alerts to the security team and their colleagues from an easily accessible button on their wearable badge. Advanced duress systems can easily integrate with a variety of existing systems, including automated nurse call."

Strain advises planning ahead and communicating needs before they become an issue.

"Assure that all current policies and regulations are up-to-date, staff are trained, and products and equipment are available," she said. "Most importantly is providing an environment where staff are part of the decision-making process when it comes to their own safety, comfortable to report issues, expected to immediately report to Employee Health or other internal/external source of care per your organizations policy (e.g., ED after regular hours or weekends) and aware of workman's comp, disability or HR policies concerning their health and safety."

Strain advises healthcare organizations to maintain an active organization-wide staff safety committee that reviews injury rates by type of staff injured, what were they doing when they were injured, where the injury occurred-hand, arm, eye, etc., and physical location as well as preventive recommendations.

"Survey staff at least once a year about the culture of safety in your organization," she said. "Take actions by adopting work practice controls, review current products or physical situations identified as concerns or found to be problematic through data collection, and take immediate action when potential life-threatening incidents occur. These and other actions can instill trust that your organization has created a safe work environment." **HPN**

Before (top) and after (bottom) activation images of RTI's 1mL VanishPoint safety low dead space (LDS) syringe

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TOUCH THE FUTURE

Shopping for ergonomic, safety-designed, protection-related products

What are some key elements to consider when sourcing, evaluating and purchasing products designed with ergonomics, injury prevention and safety in mind? Experts share their strategies and tactics.

"A reputable manufacturer or reseller will have representatives to help set the healthcare team up for success. Leverage their expertise and knowledge of workflows to identify solutions that best meet the needs of healthcare workers and other stakeholders, like the IT team.

When evaluating ergonomic solutions, ensure that adjustment is simple, such as lifting and lowering a workstation's worksurface to accommodate sitting or standing. Make sure computer monitors are adjustable for comfortable viewing. Mobile workstations should be easy to move in and around patient rooms and hallways. Access to supplies, technology and other tools should be intuitive."

Jessica Grenwis, Director of Customer Marketing, Healthcare, Ergotron

"Key elements to consider when looking at equipment and furniture for the exam room include:

- "Exam chairs that are fully adjustable to prevent caregivers from having to overreach, twist or bend their back or torso too much during exams. The chairs should also be able to lower to a height that allows patients to transfer onto it without being lifted by a caregiver. Additionally, exam chairs should have built-in, retractable roller bases that allow caregivers to safely move the exam chair for cleaning and disinfecting.
- "Mobile workstations that have easy vertical adjustment, tilt and rotation functionality to promote proper posture with neck, shoulder, arm and wrist alignment, allowing proper working positions so as not to cause unnecessary strain. Workstations should also feature fully adjustable arms to allow monitors to be easily positioned for both sitting and standing postures.
- "Cabinetry that is designed to enable caregivers to easily reach frequently accessed supplies without unnecessary bending or stretching or constant overreaching. This includes a lower upper height and more shallow cabinet depth, as well as gravity-fed, angled flow shelving that improves visibility and access to supplies.
- "Clinician stools that are easily adjustable and maneuverable to allow caregivers to find the most comfortable working height and maintain neutral postures, while also providing a backrest to promote better posture and support the back."

Brian Hazelwood, Marketing Manager, Midmark

"Key elements include efficacy, workflow, and sustainability. With regard to needlestick prevention, automated retraction devices that allow for pre-removal activation have demonstrated the highest rate of efficacy, without impairing workflow. In addition, devices with integrated safety mechanisms, such as retractable syringes, reduce disposal volumes, which not only saves money, but also promotes sustainability through a reduction of a facility's ecological footprint."

Kathryn Duesman, RN, Vice President of Clinical Affairs, Retractable Technologies, Inc.

"Many organizations have a desire for a single application when they first explore [Real-Time Location Systems], such as staff duress or infant protection. Leaders often have a desire to implement additional use cases though as the team experiences the technology and associated safety benefits. Selecting an RTLS partner with a comprehensive suite of solutions makes it easier to scale to other use cases and departments in the future. The most advanced RTLS deploys clinical-grade visibility, which allows healthcare teams to securely capture the precise movement and exact locations of staff, patients, infants, visitors, etc. Accurate location data is crucial in speeding up emergency response times and efficiently locating staff under duress, viewing any unauthorized location changes to protect newborns, and providing wander management. Additional RTLS offerings include capabilities such as nurse call automation, automated hand hygiene monitoring, asset management and temperature monitoring using easy-to-implement, cost-effective technology that benefits the patient, staff and facility.

"When considering a new tech solution, take the time to assess the current pain points and the anticipated roadmap for the next few years. In addition to a comprehensive suite of solutions, healthcare facilities should look to truly partner with a strategic vendor who will explore the organization's objectives and pain points and deliver a three-to-five-year implementation plan with associated [return-on-investment] projections and necessary operational resourcing. Through practical guidance, healthcare facilities can maximize new technologies and drive meaningful change throughout their enterprise. After a comprehensive and collaborative review of current processes, an advanced solutions partner will offer recommendations on ways to increase efficiency and reduce operating costs using a thoughtful application of the solution."

Mary Kelly Jagim, MS, RN, CEN, FAEN, Principal Consultant, CenTrak

"When new products are reviewed by value analysis or referred to value analysis to find more effective safety or ergonomic styles the key elements they look for are based on internal and external data driven evidence along with human factor engineering applications. Examples of internal data are related to the who, what, where, how analytics and root cause analysis/A3 assessments. External data sets come from reports such as FDA's MAUDE, MedSun-Medical Product Safety Network, recalls, alerts and warnings. Reference articles in the literature focused on healthcare workplace injuries and resolution strategies are another external resource to call upon.

"If the reason for injury clearly points to a product failure or product use complexity issue, then looking for products whose manufacturer conducted human factors engineering in their final review before launch is serious consideration. Healthcare organizations will also want to review if they included or will include a human factor engineering approach during their evaluation process prior to implementation of products into their environments.

"For those not familiar with human factor engineering may want to review to the FDA guidance document, "Applying Human Factors and Usability Engineering to Medical Devices," (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices) to 'assist industry in following appropriate human factors and usability engineering processes to maximize the likelihood that new medical devices will be safe and effective for the intended users, uses and use environments.'

"A simple risk assessment approach to reviewing and decision-making for products may include questions such as:

- "Is there the potential for patient or staff harm?
- "Would adopting this product require a practice or procedure change?
- "How complex is the product by specifying qualitative or quantitative standards, such as the number of steps to operate, program or assemble the product for use?
- "Are human factors design elements, such as buttons and controls, intuitive and easy to follow?

"An extra layer of difficulty in shopping and sourcing safety and ergonomically designed products is finding specific key words in a site search or the manufacturer's website or when contacting your sales representative or inside customer service this may not be topic they have been trained to answer.

"Time for a 'easy button' approach to facilitate doing the right thing every time and take variation and waste out of the healthcare system."

Barbara Strain, MA, CVAHP, Principal, Barbara Strain Consulting LLC

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Under pressure

Handling the strain and pain of patient handling

by Scott Tomko

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The proper handling of patients in our healthcare facilities is more of a concern in 2023 than ever before.

Yes, we are living in an age that is synonymous with advances in methods and technologies, but we are also living in an era wherein the strain and pressure on healthcare workers are at unprecedented levels.

Thus, it is often the stressed and overworked nurse who is tasked with the vital role of routinely repositioning patients, lest they develop health risks from pressure ulcers or infection.

Yet, at the very same time, the members of our healthcare staffs are not only under pressure from performing positioning tasks properly (and in specific accordance with the specialized needs of patients), but all too often, from becoming the bearers of their own personal injuries, incurred from the harsh realities that often accompany the duties of moving the persons under their care.

In fact, while the very act of repositioning dependent patients in bed is the most common type of patient handling activity, it is also one that is accompanied by great potential danger, as evidenced by the high rates of musculoskeletal disorders in healthcare workers.[1]

Calling all nurses

According to Marie K. Moss, MPH, RN, BSN, CIC, CPHQ, FAPIC, Director of the Department of Infection Prevention and Control at Mount Sinai Beth Israel, "there are a lot of competing pressures on staff in the provision of care to patients. At any given time in a shift, the turning and positioning every two hours required for patients at risk for pressure ulcers may have to take a "back seat" to routine and stat medication administration, multiple treatments, caring for central venous catheters and midlines, etc., for as many as 9 patients who may be under one nurse's care. RNs who are understaffed in the acute care setting may have too many patients assigned to them and/or not enough nurse's aides to assist them in the provision of care."

Marie K. Moss

Lisa Murtagh, LPN, IP, works as an Infection Control Nurse in a Massachusetts nursing home. She spoke at length not only concerning a lack of nurses, but a lack of time, both of which are immeasurably linked to patient positioning routines.

Lisa Murtagh

"Patient positioning challenges we are currently facing on the floor in nursing directly coincide with staffing shortages. As a nurse on the floor one of the primary problems we face along with our nurses' aides is too large of a patient to staff ratio. Turning a patient every two hours may be needed, or ideal, and it is the responsibility of the floor nurse to make sure these care plans are followed and implemented by us and our nursing assistants.

"But as a working floor nurse accompanied by extremely hard-working staff, maintaining the consistency needed to follow through on every aspect of a care plan is sadly not real life in nursing. Nurses can have 20-40 patients in LTC at a time, and often aides can have 10-13 people to care for apiece. While the intention and goal are there to do everything right, in reality it is a different story with these types of ratios," said Murtagh.

Patients with limited mobility, or who regularly demand repositioning, are typically kept on strict 'turning schedules;' such schedules are quite often set at intervals of 2 hours, though these times can certainly vary based upon a wide variety of patient specifications and/or limitations.

Murtagh emphasized that the window of opportunity for nurses and aides to perform such positioning duties is quite often a narrow one, and can potentially set a course for longer, and thus more negative reactions. She states:

"When units are running short for nurses and nurses' aides, the time in between repositioning patient, and patient care itself, is inevitably increased. This means longer times wherein patients are in the same position and the likelihood of a pressure sore is much greater. Patients that have limits to their mobility, coupled with waiting longer times for their personal care, such as toileting or changing briefs, are then at an even greater risk for skin breakdown such as in the peri area or coccyx due to incontinence, which creates a portal for infection, as well as pain and discomfort for the patient."

Simply put, nurses are constantly under pressure, and relieving pressure through patient positioning is just one of many tasks that they are called to regularly perform in high-stress environments. In cases where the numbers of staff members are dwindling or limited, the pressure on balancing countless duties (of which patient positioning technically only qualifies as one) can be hard to fathom.

The numbers don't lie

According to Katie McKinley, the Senior Marketing Product Manager at AliMed, "our customers have been increasingly focused on the importance of safe patient handling and positioning. We know how vital it is for them to establish a culture of safety and routine, to have easy access to devices that reduce injury risk to both patients and staff—especially as labor shortages continue. This has helped guide our portfolio enhancements, adding products such as air-assisted transfer devices that require significantly less pull force to laterally move patients or even reposition them, and a new line of surgical gel positioners that redistribute pressure to reduce injuries."

Katie McKinley

McKinley was also adamant to point out the key role of education for hospital staff in ensuring that all the processes involved with moving and mobilizing patients is done with due diligence and care.

"We've learned that education is a fundamental component—which has led to our newly created resource hub with some sobering statistics and key tips to not only remind staff about the everyday risks of patient handling, but what they can do to mitigate them," added McKinley.

Healthcare Purchasing News did not hesitate to take a deeper glance into AliMed's resource hub, which included a detailed pamphlet on patient handling, entitled, "Making Safe Patient Handling Safer."

In addition to providing many key insights on proper methods and strategies for directing and conducting the movement of patient (in a wide range of situations), the guide presented some very real numbers on the potential negatives the workforce can encounter in these critical and highly specific handling actions:

- As many as 20% of nurses who leave direct patient care positions do so because of risks associated with the work.[2]
- Patients are 100% heavier than 30 years ago, which places nurses at risk for patient-handling injuries such as neck or back strains. In spite of education and no-lift campaigns in the work unit, many nurses admit to moving patients alone due to the perception of time constraints.[3]
- Hospitals and nursing homes have become dangerous industries in the United States. According to the Bureau of Labor Statistics, hospitals have injury rates that are nearly double than that of the average of all private industries; the incidence of musculoskeletal disorders in hospitals in 2016 was 60.5 per 10,000 full-time workers compared with 29.4 per 10,000 full-time workers in all private industries. One of the most common sources of musculoskeletal disorders in hospitals involves moving the patients.[4]

AliMed's PS Glide in use

Slip sliding away

When a patient is on the operating table, the necessity for proper positioning and limited movement weigh extra heavy, as even slight slides can have a potential grave impact on surgeries, especially procedures requiring specialized positions, such as laparoscopic GYN surgery.

"Patient sliding during laparoscopic GYN surgery can cause the surgeon to lose range of motion with the uterine manipulator requiring patient repositioning," said Dan Allen, President of D.A. Surgical.

Allen proceeded to highlight how in certain positions (such as the Trendelenburg), the advanced robotic technologies of the modern OR can provide their own unique dilemmas.

"Surgical robots create additional unintended consequences as robotic arms do not compensate for patient sliding. This sliding results in the trocars acting as 'meat hooks' as they are used to restrain sliding patients on the table."

Dr. Ali Ghomi, a well-renowned specialist in gynecologic procedures and robotic surgery, released a paper on this very subject, entitled "Robotics in Practice: New angles on safer positioning." In the paper, Dr. Ghomi addresses the subject by stating: "Patient slippage during the use of fixed robotic trocars creates a serious potential for patient risk, as it can cause incisional tear, post- operative hernia formation, and increased postoperative pain secondary to over-stretching of the anterior abdominal wall."

Specializing in the development of patient positioning solutions that are geared towards both conventional and robotic surgeries, D.A. Surgical's TrenGuard Trendelenburg Patient Restraint was the recent focus of a 10-month, 503-patient study on Trendelenburg patient positioning. The study was a testament to the great potential in the ever-enhancing industry of patient positioning technology, as not one patient slid, suffered discomfort, or was injured.

Pressure to train to relieve the pressure from strain

When it comes to handling patients, positioning and pressure management go hand in hand, as the proper monitoring and conducting of patient movement will prevent the emergence of pressure wounds, which can lead to further, more complicated issues such as infections.

As an Infection Prevention Nurse, Lisa Murtaugh is very familiar with the necessary steps to prevent these sores, and she

was quick to highlight the need for further education and training in the positioning methods required to prevent pressure management injuries.

"In the day-to-day environment in a typical LTC facility, pressure sores are taken very seriously. They are monitored, often photographed, and should always be documented on. So, on the floor, there is certainly focus on it; however, LPN and Nurses Aid Programs will be well served to highlight how important patient positioning is, as it feeds into so many other complex areas of patient care such as wounds and their dressing and management, infection control, safety, and respiratory issues. By having patients properly positioned, you will decrease the risk of aspiration pneumonia and/or pressure ulcers, among many other possible ailments."

Murtagh also stressed the vital activity of learning about the specific conditions of each patient, as there are never two patients exactly alike, and, often, a wide range of preexisting conditions will demand more intensive actions in terms of patient positioning.

"Often, a patient will have specific orders for positioning, such as, for example, a hip replacement; in this case improper education on the positioning required poses the risk of dislocating the hip. Furthermore, patients with respiratory issues will have positioning recommendations due to increased risk for comorbidities, such as pneumonia if they are improperly positioned."

Limited mobility and unlimited (negative) potential

Though they go by many names (pressure injuries, bed sores, pressure sores and decubitus ulcers) pressure ulcers result from force being applied to the surface of the skin, and normally occur over bony parts of the body, such as the heels or sacrum, just to name a few.

Thus, it is certainly no surprise that persons with limited amounts of mobility are those at greatest risk for such injuries, as they simply lack the physicality and/or health to reposition themselves under their own power.

Hoverteh HoverMatt SPU

However, it must be also realized and greatly emphasized that patients of all kinds are prone to be subject to pressure injuries, as surgical procedures routinely demand little to no movement, and can place great amount amounts of pressure on parts of the body that are vulnerable for any person.

"There is always risk for pressure ulcer development during a surgical procedure," says Moss. "This has been a long-standing issue, and there should be more emphasis on the operative team to plan for the proper positioning of patients during surgeries. This is especially crucial for hours-long surgeries, like open heart (CABG) or solid organ transplants, where prolonged pressure on the skin and deep tissue from prolonged contact with a hard operating table surface can potentially lead to skin breakdown."

Moss was firm in her stance on the need for further education regarding proper patient handling, referring to the notion that the staff is just as prone to perform mishaps in moving patients and incorrectly diagnosing pressure injuries as they are to encounter personal injuries from applying faulty techniques.

"There needs to be a greater emphasis on providing classroom education of frontline staff, RNs and nurse's aides, on pressure ulcer prevention. There are "Skin Saver" programs where staff can learn about pressure ulcer prevention, early detection and treatment. All patient-facing staff, including RNs, nurse's aides, transporters and radiology technicians, should learn about safe body mechanics to prevent them from sustaining back and other body injuries when performing patient care. The Environmental Health and Safety department, often referred to as "Life Safety" of a hospital should facilitate the provision of Body Mechanics classes to hospital and Nursing home employees. Safe handling of patients is an important part providing of a truly safe environment of care for our staff and patients."

Moss was also inclined to stress another key (and often overlooked) role in the management of pressure wounds, and that is the vital duties performed by wound ostomy care nurses (WOCNs).

"Health care institutions often underestimate the vital role that wound ostomy care nurses (WOCNs) play in preventing and healing skin breakdown. WOCNs not only treat patients with pressure ulcers, but they also prevent skin breakdown in high-risk patients (i.e. those patients who are immobile, have poor nutrition, are incontinent of urine and/or stool, or who have altered mental status). These high-risk patients are often pressure ulcers waiting to happen."

Putting the issue to beds

Suboptimal positioning of patients is a continual concern in all areas of healthcare facilities, as it remains a major contributor to injury and infection. Therefore, its proper execution is a fundamental function that must be always carried out at optimal levels.

The advances in technologies, specifically of the hospital beds themselves, is something that must be learned and practiced by staffs to ensure that the practice is not only performed but done so in the most effective way possible.

These ways and means not only protect the patient, but the healthcare worker as well.

"It is a major risk when staff don't use the functions of the hospital bed that allow it to be raised, lowered, or otherwise positioned in a way so that stress on the healthcare worker body can be minimized or prevented entirely. Hospital beds are very advanced and specialized to perform a lot of tasks, like turning and positioning, that staff used to have to do manually," stated Moss, who was quick to recall the times when she and her fellow co-workers were routinely manually hand-cranking hospital beds.

Hospital beds have come a long way in a very short time and possess capabilities today that are immeasurable in enabling proper patient positioning and care.

According to Moss, "nursing should evaluate a patient to see if they would benefit from one of many types of specialty beds. Hospitals usually have contracts with specialty hospital bed suppliers who can help determine which bed would be right for a patient with special needs. These beds can relieve pressure on patient skin and on the staff who care for them. The bed supplier rents out these beds to the hospital for as long as the patient needs it. The bed supplier will pick up the bed when it is no longer needed."

Manual labor

HoverTech International specializes in the development of air-assisted technologies.

The company's HoverMatt Air Transfer Mattress enables lateral transfers, boosting, turning in bed, positioning in the OR and proning, and has enhanced safety measures that provides for the caregivers doing the moving.

Shosha Beal

However, according to Shosha Beal, MSN, RN, CNOR, and Clinical Education Specialist at HoverTech International, "we estimate that 40%-60% of hospitals still do not use air-powered transfer devices. This implies the nursing staff is manually moving the patient."

Beal went on to highlight some of the potential issues that regularly accompany manually moving patients.

"The challenges pertaining to positioning has many variables," she noted. "Patient size, mobility, and illness along with the loss of nursing staff can impact patient positioning and the unit where the patient is located. Positioning needs change depending on the patient. A critically ill patient in the ICU will require more positioning aids, and positioning aids must protect the patient and the nurse.

"In the Operating Room, we are navigating the movement of patients of ever-increasing size, and just a simple movement up' toward anesthesia for intubation and back into position for the procedure requires manual labor. This often leads to staff injuries or the need for additional OR room resources."

Beal also recommends that a greater emphasis be placed on the further development and application of educational methods pertaining to pressure wounds.

"There is a need for more education in the hospital setting to help decrease pressure injuries because these wounds are very complex," Beal continued. "It can be difficult to identify and stage pressure injuries unless you are knowledgeable about pressure injuries or are a wound care nurse. A pressure injury may appear on the surface as a small slit, but when it is thoroughly assessed it is a wound that has exposed bone. More tools need to be developed to help the nursing team correctly identify and direct the correct treatment." **HPN**

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Catheter care is as complex as it is crucial

by Kara Nadeau

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As a device that enters the body, a catheter has the potential to cause infection, while some designs and purposes present greater risk than others. Clinical staff training and education on proper hygiene practices, catheter component disinfection, safe catheter handling, and wearing of personal protective equipment (PPE) while caring for patients with indwelling catheters is of critical importance to minimizing the risk for contamination. Compliance monitoring and reporting is essential as well.

But at a time when there are too few nurses, not enough supplies, and a steady stream of new research around reducing catheter-associated infection risks, there is also a need for technology interventions that can augment the human element. Innovations targeted at catheter related care must address not only hospitalized patients but those in non-acute care facilities, as well as those living their lives with indwelling devices in their homes and in their communities.

PIVC insertion presents risks to patient and staff safety

Peripheral intravenous catheter (PIVC) insertion is the most common invasive procedure performed in hospitals today.[1] As many as 80% of hospital inpatients require intravenous access at some point in their stay.[2]

PIVCs have long been considered as having a lower risk of infection than central lines, but their frequent use and high volume has made them responsible for a greater number of infections.[3]

"Contamination associated with peripheral catheters is most often touch contamination from clinician hands, gloves that have touched other surfaces, contamination during final clean up or touching of the catheter or insertion site after skin antiseptic preparation," said Nancy Moureau, PhD, RN, CRNI, CPUI, VA-BC, CEO, PICC Excellence. "Peripheral catheters are most at risk of contamination with the use of nonsterile supplies such as tape at the insertion site, when an extension set is attached, and during ultrasound guided insertions using gel. Inability to understand aseptic non touch technique that protects sterile key parts is a common problem that contributes to contamination during insertion and catheter management."

Nancy Moureau

"The greatest opportunity to reduce the risk of contamination during the (PIVC insertion) procedure is for healthcare providers to comply with their hospital's policies related to proper hand hygiene, proper use of gloves and compliance with protocols to prepare the PIVC insertion site with an antimicrobial solution," said Stephanie A. Pitts, DNP, RN, CPN, VA-BC, NEA-BC, Director, Strategy-Therapy Solutions & Programs, Healthcare Strategy & Innovation, B. Braun Medical. "Also, following the Aseptic Non-Touch Technique (ANTT) is recommended when starting a PIVC.[4] These are basic skills that, through live observations, are often skipped or done improperly and create a risk of contamination/infection to patients."

Stephanie A. Pitts

Moureau noted how certain peripheral intravenous catheter features can help reduce contamination during insertion. Finger-grips, easy slide catheter advancement tabs, integrated extension sets, and blood control valves can aid the clinician in performing an ANTT without contamination of the catheter or insertion site.

According to Pitts, PIVC insertion presents risks to not only patients but also healthcare providers as needlestick injuries can be sustained during the procedure exposing providers to potentially infectious materials.[5]

B. Braun offers programs and technologies to help improve safety on both sides of the caregiver/patient equation. Through the company's Peripheral Advantage Program, real-time observations of healthcare workers are observed while performing PIVC insertions in participating hospitals.

"Technologies like passive safety with blood control found in the B. Braun Introcan Safety family help to protect the healthcare provider from needlestick injuries and blood exposure," said Pitts. "The passive safety feature allows the safety mechanism of the PIVC to activate automatically through the natural removal of the needle from the catheter and doesn't rely on user-activation, proving to be more

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effective in preventing needlestick injuries. In addition, catheters with a multiple access blood control septum also help to prevent blood exposure during catheter insertion and while disconnecting a device from the catheter hub."

Speaking specifically about ultrasound guided peripheral catheter insertions, Moureau said lack of standardization in the procedure with much variability makes contamination during insertion common. She stated:

"Protective products that work together with catheters for ultrasound guided peripheral catheter insertions help to reduce contamination. Products like sterile barrier dressings that allow separation of the ultrasound and gel reduce contamination from the probe and gel, and sterile probe covers all provide a level of probe and insertion site protection that reduce contamination during the insertion."

"While nothing can eliminate touch contamination 100% of the time, education and training are also requirements to increase safety and reduce risk to the patient," Moureau added. "Standardization of procedures leads to greater consistency with steps and safety, reducing contamination and patient risk."

Scrub the hub compliance requires sustained education, compliance monitoring and supply access

Needleless connectors (NC) used with central venous access devices (CVAD) play an important role in preventing needlestick injuries but may increase the risk for central line-associated bloodstream infections (CLABSI) as microorganisms can collect on the external surface of the NC.[6] Disinfection of the NC with an antiseptic scrub (chlorhexidine/alcohol or alcohol) before device access has been shown to reduce infection risk.[7]

"As facilities continue to strive for zero infections, following all aspects of the bundle has never been more important," said Amanda Thornton, RN, MSN, CIC, VA-BC, PDI Clinical Science Liaison. "However, studies show that even though this is the case, there continues to be huge variances in the consistency in processes of nurses caring for central lines, with one study showing that 31% of healthcare workers failed to disinfect the needleless access site prior to use,[8] and another study showing differences that range from 6% to 51% compliance with scrubbing the hub."[9]

The challenge lies in clinician adherence to required scrub and dry times, as revealed by a new human factors analysis presented at the Association for Vascular Access (AVA) 2022 Annual Scientific Meeting. While the critical care nurses studied generally recognized the importance of NC disinfection, they lacked knowledge around antiseptic products' instructions for use (IFU) and facility specific protocols.

Joan N. Hebden

"I was a little surprised participants didn't seem to actually know the scrub and dry times," said study co-author Joan N. Hebden, MS, RN. "It was better for the chlorhexidine group but with alcohol alone, there were clearly some clinicians who didn't know facility protocol which stated 15 seconds of scrub time. Therefore, education is an important piece of compliance."

Bedside availability of NC antiseptic products was found to be a strong facilitator of NC disinfection best practices, as Hebden explained:

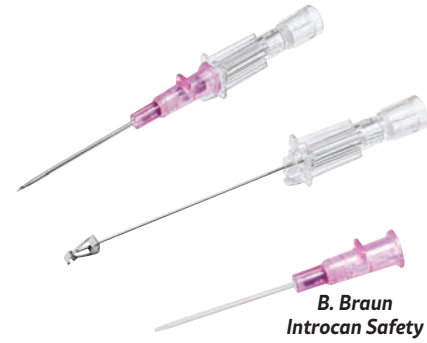
"There's absolutely no question that having the supplies right there at the bedside is a facilitator of practice and not having them there is clearly a barrier. I really think we need to get more innovative in how we assist the provider with not only the product availability but also the timing. For example, providing antiseptic pads on a tear off strip hanging from the IV pole, along with a tool for counting down the seconds for scrubbing and dry times."

The amount of time required per NC access when following best practices for disinfection was another barrier discovered during the research. As Hebden noted, with continued staff shortages, nurses are looking for ways to alleviate their workloads. In some cases, compliance monitoring of NC disinfection has fallen to the wayside in the face of competing priorities.

"This kind of research where the care providers are fitting the practice into their workflow is really critical in terms of adoption and sustainability," she added. "We need to ensure that whatever we're asking them to do is scientifically based and that we continue to look for technology or tools that will make it easier and more adaptable to their workflow."

Thornton explained that by utilizing practices for scrubbing the hub that set nurses up to succeed, patients are protected and CLABSIs are avoided:

"Over the past 15 years, significant evidence continues to emerge that when needleless connectors are scrubbed prior to access using a CHG and alcohol combination versus alcohol alone, CLABSI rates not only drop, but are sustained.[10] Part of this is due to the very potent antimicrobial combination, but perhaps the more important piece of the puzzle is the fact that when nurses scrub the hub using CHG and alcohol, they only have to scrub for five seconds to achieve disinfection of the needleless connector which nearly eliminates poor compliance and variances in the scrub the hub practices seen across the nation."



B. Braun Introcan Safety

Safe and effective CVC disinfection for ESRD patients

Among the 600,000+ end stage renal disease (ESRD) patients receive hemodialysis in the U.S., 20% of them receive their chronic therapy via a central venous catheter (CVC).[11]

"Far from ideal, this means of accessing the vasculature to dialyze their blood appears to be a constant due to factors like emergent dialysis starts, poor peripheral vessel availability to create a fistula or graft, and patient fear of needles with cannulation," said Michele Padovan, RN, CNN, Product Education Specialist, Angelini Pharma. "These CVCs can remain in place as the sole access for months or years, putting the immune-compromised ESRD patient at risk for infection, hospitalization, and death from sepsis."

"Care of the CVC requires diligent and aseptic practice when accessing the catheter limbs during dialysis therapy and when cleansing the skin at the CVC insertion site," Padovan continued. "Products used for CVC disinfection and antisepsis should be safe, effective, broad spectrum, fast acting, and most importantly, compatible with the catheter materials."

Angelini Pharma has a 40-year presence in dialysis and manufactures sodium-hypochlorite products specifically for use on these long-term catheters. Alcavis 50 is an FDA-cleared disinfectant used on catheter limbs before accessing the bloodstream. ExSept Plus in an all-purpose skin, wound and catheter exit site antiseptic.

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in tandem to decrease the risk of infection in this fragile population," Padovan added.

PICC protection with the patient in mind

Prolonged maintenance of CVCs, including peripherally inserted central catheters (PICC), is a major risk factor CLABSI, but patients living with these devices don't always get the information or products they need to prevent risk for contamination. Emily Levy, Mighty Well Co-founder, President and CBO, described her experience:

"I was diagnosed with neurological Lyme disease when I was 19 and had my first PICC at 20, knowing nothing about vascular access. Following the procedure, I was not properly prepared to go home. When I asked about covering the PICC placed in my arm, the hospital gave me some thin mesh and said the other option was to wear a sock on my arm. I was horrified from an infection prevention perspective, maintaining the integrity of the line. And as a young woman living with a very visible medical device the idea of wearing a sock over it was crushing to my self-esteem."

Emily Levy

Recognizing how other patients living with disabilities, chronic conditions, and illnesses were faced with the same challenge, Levy and her two best friends, María del Mar Gómez and Yousef Al-Humaidhi, founded Mighty Well, launched its Friends in the Fight patient community, and developed the company's "hero product" the PICCPerfect PICC Cover.

PICCPerfect is a patented sleeve constructed of advanced fabric technology featuring antimicrobial, moisture-wicking, and anti-odor properties. Double access points make it easy to access single and double lumens without exposing the PICC insertion site. Patients can choose from 12 color options in seven different sizes.

The company's motto says it all: "You are not a diagnosis — you're Mighty Well!"

"Patients are more than a diagnosis, but healthcare providers often look at us as names on a chart and medical device manufacturers typically don't consider our experience going home with their devices," said Levy. "I want clinicians, hospital leaders and device companies to think about how we're their customers, and we're paying for care. With the trend of more patients receiving home care, I believe the industry must evolve to accommodate our needs."

A study on PICCPerfect, presented at the 2018 AVA Annual Scientific Meeting, found the use of protective garments increase patients' quality of life and are an important part of the continuum of care post-PICC placement, especially considering the lack of quality of options in the standard of care. Key findings include:

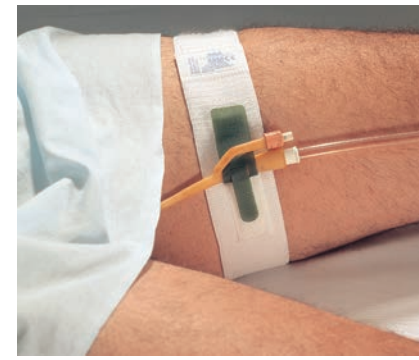
- 21.2% of clinicians recommend patients wear a cut-off sock to protect a PICC, and 29.4% recommend stockinette
- 67.1% of patients report they never experience pulling on the line when using PICCPerfect, double that of patients using stockinettes (33.8%)
- 54.5% of patients reported that they felt considerably more comfortable when wearing a PICCPerfect vs. using a stockinette provided by the clinician
- 12.8% of patients reported more than one infection while using stockinette. The number is reduced to 4.7% for patients while using PICCPerfect

In 2020, Mighty Well designed, launched, and registered the PICCPerfect Pro (Rx) with the U.S. Food and Drug Administration (FDA) as a Class 1 medical device. It has another level of securement with a velcro wrap, triple "X"-shaped access points, and offers more visibility to the insertion site with airflow perforation. PICCPerfect Pro was created with input from over 250 medical experts, patients and PICC nurses, as well as the learnings from the analysis of the published iPoster at AVA. While patients can purchase the original PICCPerfect directly from Mighty Well's website using their FSA/HSA dollars, the Pro version requires a doctor's prescription. PICCPerfect Pro (Rx) is patent pending.

Mighty Well PICCPerfect PICC Cover

Foley catheter securement for safety

According to the Centers for Disease Control and Prevention (CDC), between 15-25% of hospitalized patients receive urinary (also called Foley) catheters during their hospital stay.[12] Traumatic, unintended Foley catheter removal (patient-initiated or accidental), "can cause permanent urologic complications, affect hospital length of stay, decrease patient satisfaction grades, increase catheter-associated urinary tract infections (CAUTI), and lower hospital quality scores."[13]



Dale Medical HnP Foley securement products

"Foley securement devices, whether they be leg bands or adhesive anchors, are designed and used primarily to secure many types of indwelling urinary catheters," said Dale Medical Product Manager Joe Zilaro. "The main objective of them is to prevent any type of urethral trauma that may result from unintended movement or unexpected pullout of the Foley catheter. This can apply to male or female patients. When the catheter gets dislodged, it can lead to inflammation or even damage to the urethral area."

Joe Zilaro

"Dale urinary securement products help prevent this unexpected movement from occurring by way of the design of their products," Zilaro continued. "All Dale HnP Foley securement products allow for a degree of adjustment through unique latching straps to deter unintended movement and provide both safety and comfort to patients that wear them."

PICC securement without sutures or adhesives

With CLABSI being a major concern among healthcare organizations, researchers have studied how various PICC line securement methods impact CLABSI rates: adhesive, subcutaneous, tissue adhesives, integrated dressings, and sutures.

An analysis published in the June 2020 American Journal of Infection Control compared outcomes of patients whose PICCs were secured with the SecurAcath Subcutaneous Anchor Securement System (SASS) to those secured with an adhesive device.[14]

The study found a substantial difference in relative risk among securement devices utilized in their population. The analysis showed those who had an adhesive device had a 288% increase in risk of CLABSI

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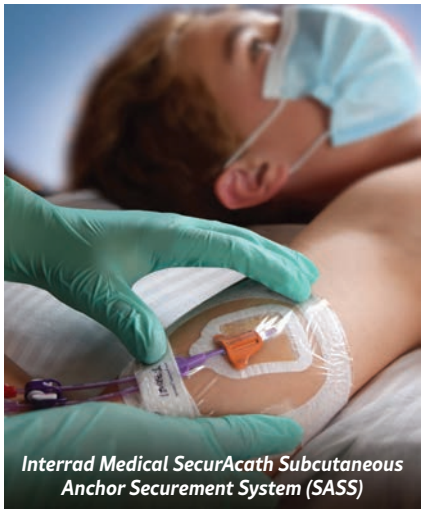

Interrad Medical SecurAcath Subcutaneous Anchor Securement System (SASS)

compared to those who had a SecurAcath. The difference in practice demonstrated direct positive impact on patient outcomes when using SecurAcath verses an adhesive securement device.

The design features of the SecurAcath believed to have positively impacted CLABSI rates are improved catheter stability at the insertion site, reduced catheter movement, including migration and dislodgement requiring catheter replacement, and the ability to disinfect skin/insertion site 360°.

"The occurrence of CLABSIs yield tremendous negative consequences affecting patients and health care facilities associated with morbidity, mortality, and financial burdens," said Jeff Killion, Executive Vice President, Interrad Medical. This retrospective, observational quality review found a substantial difference in relative risk among securement devices utilized in their population. The difference in practice demonstrated direct positive impact on patient outcomes when using SecurAcath verses an adhesive-based securement device. The use of SecurAcath may improve nursing practice and patient outcomes lowering CLABSI rates in patients with PICCs."

Looking ahead

Researchers and manufacturers continue to study and develop new technologies and techniques to improve catheter safety.

Tetra EDTA catheter flush stops microbes in their tracks

"Due to their invasive nature, CVADs are prone to complications such as bacterial biofilm production and colonization, catheter-related bloodstream infection, occlusion, and catheter-related venous thrombosis," stated a group of Canadian researchers studying the effectiveness of the KiteLock Sterile Locking Solution, a 4% percent tetrasodium ethylenediaminetetraacetic acid (EDTA) fluid, in controlling these types of complications. KiteLock is approved by Health Canada as a catheter locking solution.

They are planning to perform a multi-center, cluster-randomized, crossover trial evaluating the impact of KiteLock on a primary composite outcome of the incidence rate of CLABSI, catheter occlusion leading to removal, and use of alteplase to resolve catheter occlusion compared to the standard of care. The study will be performed at five critical care units.[15]

David Hatton, CEO of Aseptica, the co-inventor of KiteLock (also known as Tetra EDTA 2%), points out how most catheter surfaces are vulnerable to microbial attachment:


David Hatton

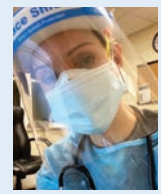
"Invading micro-organisms require calcium and/or magnesium for conversion from a planktonic (or traveling phase) to attachment phase. Once attachment is achieved, biofilm and microbial spread begins. If the invading organism cannot attach to the surface of the catheter, there is unlikely to be a proliferation of microbial-biofilm growth and microbial spread."

Hatton said while specialty coatings can reduce the risk; they have a limited "resistant life" that eventually leaves the catheter vulnerable to microbes. Instead, Hatton points use of a repeatable, liquid application that can "renew the resistant characteristics" as a potential solution.

"A broad-spectrum efficacy range is needed for true protection," Hatton

The EBP complexities of catharized nursing home patients

According to the CDC, more than 50% of nursing home residents may be colonized with a multidrug-resistant organism (MDRO), and patients with indwelling medical devices, including central vascular lines and urinary catheters, are at high risk for MDRO transmission and infection. To reduce the risk for MDRO spread, the CDC expanded recommendations for the use of Enhanced Barrier Precautions (EBP) when caring for not only patients with an MDRO, but also those with wounds or indwelling devices, regardless of their MDRO colonization status.[1]


Lisa Murtagh

Prior to performing high contact resident care activities (e.g., dressing, bathing/showering, transferring, changing linens/briefs, toileting assistance, device care or use, wound care), the caregiver must don personal protective equipment (PPE), including gloves and a gown, and potentially face protection if there is a risk of splash or spray. After care is completed, they most doff the used PPE and don a new set before caring for the next patient.

Infection preventionist Lisa Murtagh, LPN, IP, who works in a Massachusetts nursing home, says while the EBP are an important step in reducing the transmission of MDROs among residents, they present challenges as well, especially as facilities face ongoing staff shortages. She presents the scenario of patient rehab as an example of the complexity:

"Typically, when rehabbing a patient, even those with a catheter, the physical therapist (PT) and occupational therapist (OT) will ambulate the patient in the hallway. Because the CDC considers this a high-contact activity, under the new EBP guidelines the PT and OT are required to wear gloves and gowns but doing so in a hallway goes against policy. I asked the Massachusetts Department of Public Health about the conflicting requirements, and they told me that we would have to end hallway ambulation for patients where EBP are required."

Murtagh explains that to perform PT and OT on a catharized patient in the facility's gym, a caregiver would need to don a gown and gloves, transfer the patient out of their bed into their wheelchair, doff the PPE at the door, push the wheelchair to the gym, don a new set of PPE to transfer and ambulate them, doff the PPE again to transfer the patient back to their room, don yet another set of PPE to transfer them back to their bed, and doff that PPE and don another set before caring for a new patient.

"Not all PPE is made equally," said Murtagh. "Some of it is easy to get off, others are extremely difficult and when you can't get what you need you have to order what is available. The next thing you know is you're trying to get a gown off that won't untie and end up stepping out of it. It's a mess. There's just not enough time in the day."

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explained. "When the catheter in use has an option to have the interior of the catheter filled (or rinsed) with a broad-spectrum EDTA solution (as with vascular or urological catheters) the resulting protection can be significant and the resulting prevention of microbes available to 'spread' will impact the cross-contamination process."

"With a broad-spectrum EDTA liquid in use, the prevention of microbial attachment is inherent," Hatton added. "The Tetra EDTA solution (both 2% and 4%) will also chelate, or grab, the organism's nuts and bolts (minerals), causing deterioration of the organism. A less than diligent moment by an individual may be offset with a broad-spectrum barrier to provide the insurance needed to prevent microbial transfers. Appropriate formulation details will need to be studied for multiple environments to assure the Tetra EDTA solution will be successful."

The future of Foley catheter construction

Despite efforts to reduce CAUTIs among patients, they remain the most common nosocomial infection, accounting for 1 million cases per year in U.S. hospitals. The associated costs of preventable CAUTI are estimated to range from $115 million to $1.82 billion annually.[16] Duration of catheter placement is a primary risk factor for CAUTI, with some Foley catheters remaining indwelling for up to 30 days.

David J. Vachon, CEO and Founder of Iasis Molecular Sciences Corporation (IMSC), an "advanced materials and medical device company" located in Spokane, Wash., comments on urinary catheter complications and challenges:

David J. Vachon

"Microorganisms can colonize urinary catheters because of contamination during placement, the migration of intestinal microbes to the urinary tract, or the reflux of collected urine into the bladder. Catheter surfaces enable microbial attachment and growth into biofilm and result in bladder tissue invasion and CAUTI. If untreated, CAUTIs can lead to sepsis. The most common remedy for CAUTI requires catheter replacement and antibiotic therapy. Over time, this can promote microbial resistance."

"Today, urinary catheter manufacturers employ antimicrobial catheter coatings to prevent CAUTIs," Vachon continued. "Overwhelmingly, the antimicrobial agent employed is silver in its various forms. However, antimicrobial silver catheters have not solved the problem as demonstrated by large randomized clinical trials. Poor outcomes have been attributed to the challenging biological environment and perhaps the inability of coatings to deliver microbicidal doses of silver over 30 days."

IMSC is developing a unique, next generation antimicrobial catheter that does not use an antimicrobial coating. Instead, IMSC utilizes a proprietary antimicrobial (silver) composite silicone to construct its catheter. The composite silicone (reservoir) remains microbicidal for at least 30 days by virtue of its unique controlled release mechanism. IMSC catheter development has been funded by the Congressionally Directed Medical Research Programs (Peer Reviewed Medical Research Program, W81XWH-16-1-0697 and the CDMRP Spinal Cord Injury Research Program, W81XWH-22-1-0540).

"The IMSC catheter will provide safe, adjunctive protection against infection beyond good standard of care and accepted clean (aseptic) insertion of urinary catheters. The novel IMSC biomaterial is not a replacement for this standard of care," said Vachon. HPN

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STERILE PROCESSING

The QUALITEAM!

Best practices get best results when applied with best efforts

by Kara Nadeau

Throughout the healthcare delivery continuum, stakeholders are trying to improve quality, whether it is quality of operations, clinical processes, patient outcomes or some other factors. Quality improvements in the Central Sterile Supply Department (CSSD) department have the potential to positively impact clinical customers (e.g., procedural areas) and their patients in terms of safe and effective instrumentation available when needed.

While the healthcare industry likes to talk about quality, what does this mean to CSSD department leaders and their teams and how do they concretely identify, pursue and achieve and measure improvements that make a difference?

When thinking about the CSSD and Infection Prevention (IP) functions, it seems obvious why the two teams must work together on quality improvements. Sterile processing plays a central role in infection prevention, by decontaminating, cleaning and sterilizing instruments and devices for safe patient care.

But in today's healthcare environment where preventing hospital acquired infections (HAIs) is critical to not only patient outcomes but also payer reimbursements, the IP team can be pulled in many different directions. Quality oversight of the CSSD may take a backseat to more high-profile priorities, such as an outbreak of central line-associated bloodstream infections (CLABSI) or catheter-associated urinary tract infections (CAUTI).

The same holds true for operating room (OR) clinicians. While the patient on the table is their priority, their work to prepare used surgical instruments prior to their trip to decontamination, including point of use (POU) cleaning, ultimately impacts care and safety.

"It is important for the OR and SPD staff to work hand in hand to raise the bar on sterility and quality assurance," said Healthcare Sterile Processing Association (HSPA) Secretary-Treasurer Jan Prudent, BA, CRCST, CIS, CER, CHL, CFER, FCS, Sterile Processing Manager at Eastern Idaho Regional Medical Center in Idaho Falls. "Continual education and better understanding about processes are vital to both departments. What one does not see, someone else often does. A well-rounded, in-depth system provides that needed protection."

CSSD, IP and Perioperative professionals offer their advice on collaborative quality improvements and share success stories working with multidisciplinary teams in U.S. healthcare organizations.

A roadmap to surgical services and SPD quality

Advantage Support Services' Jhmeid Billingslea, CRCST, CIS, CER, CHL, CST, CMRP, Managing Director Surgical Services, and Angela Lewellyn, CRCST, CER, CHL, LPN, Director of Development & Research, bring a combined 50+ years of experience in surgical services and sterile processing to their consultancy.

Jhmeid Billingslea

As voting members on the ANSI/AAMI ST90 Processing of Health Care Products - Quality Management Systems (QMS) for Processing in Health Care Facilities committee (Lewellyn the main, Billingslea the alternate), they are committed to helping teams establish strategies and action plans that improve quality throughout the surgical services and CSSD continuum.

Angela Lewellyn

"When working with CSSD teams, what we mainly see is they have no quality program or one that is focused on one element and totally blind to others,"

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said Billingslea. "We have built our reputation on an education program with seven quality checkpoints in sterile processing similar to what you see in manufacturing. Quality is not just checking trays for bioburden. It's assessing the integrity of instruments at every stage."

Quality audit and planning

As Lewellyn explains, there is no one-size fits all quality plan. Therefore, establishing a QMS begins with performing an audit of the CSSD department. "Walk through the touchpoints in your process for producing a tray for the end user and compare them to your policy and procedures or even to best practice of care and handling of the instrumentation," she stated.

Lewellyn and Billingslea stress the importance of having a multidisciplinary team that performs the rounding to examine processes and identify potential quality issues and improvements. In addition to the CSSD team members, it should also include personnel from infection prevention (IP), risk management, and end user customers, such as operating room (OR) staff and stakeholders from the other departments served by the CSSD (e.g., wound clinics, labor & delivery).

Lewellyn says they've found rounding teams are not always clear on what they should be inspecting throughout the process, so they've developed a program to teach them the critical quality checkpoints. She stated:

"Rounding is the key to a quality program, but the key to initiating a program is to first teach the rounding team what to audit. Do they understand the tasks and hands on touchpoints they should be looking for that might be missed during the round? How do you teach them to poke their head in the door and identify right off the bat what they could be doing better or even seeing missteps?"

Start small with quick wins

The rounding and audit process helps a CSSD team prioritize target quality improvements. It instills a culture of best practice among staff members, says Lewellyn, teaches them to keep an open mind, set aside old bad habits, and learn how to perform their roles in compliance with policy and procedures.

If there are no "big fires" identified in terms of quality, such as bioburden on trays coming down from the OR, Lewellyn recommends CSSD leaders prioritize "low hanging fruit" in their quality action plans.

"One of the easiest quality check points to start with is the sterilization record because most CSSD techs are aware of the importance of having a complete and accurate record. Acclimate and cross-train all techs to this best practice, not just the techs on the sterile side but those in decontamination as well. Huddle for five minutes each day to discuss recording requirements and audit the record at every shift. In my experience, beginning with one area of quality, and demonstrating successful improvement trickles down through not just the CSSD but also other departments, resulting in a much higher quality of care."

Gaining support from key stakeholders

While some CSSD leaders are fortunate to have the support of hospital leadership and clinical stakeholders in making improvements, others must garner it, sometimes having to mend previously strained relationships.

"Part of it's a mirrored look," said Billingslea. "How well is your CSSD department partnering with the OR? Let go of negative interactions from the past and look for ways to make things easier for the OR even if it makes things temporarily harder for your department. Because in the big picture, if you're taking stuff off their plate, it will be easier to get that partnership. I promise, if you go out of your way, they will soon be going out of their way to support you."

Sometimes CSSD teams get pushback from other departments when attempting to engage them in quality improvements. In Lewellyn's experience, a central cause for this discord is lack of understanding and comfort with the sterile processing workflow.

"One of the things we have done to help overcome this challenge is having the CSSD team host a lunch in their breakroom for their clinical customers and others critical to quality initiatives," Lewellyn commented. "It can initiate a great beginning, helps everyone acclimate to the CSSD, and even facilitates healing of relationships that had been previously burnt."

"Be sure to include your hospital's IT team and teach them about the CSSD," Billingslea added. "The investment you make in that relationship will pay off. We've seen IT become a CSSD team's best advocate and help them avoid survey hits."

Keep the CSSD team at the core

Billingslea has seen situations where the CSSD leader will share their action plan with all involved departments but not their own, but as he explains, "your players need to know the score."

"It's like the scoreboard at a game. The people watching on TV know the score but imagine how a game would go if the players on the field didn't know who was winning? One of the things I always remind leaders is we must make sure we include our team in the scoreboard if we want them to hit a home run. Without that visibility, they don't know whether they are behind or not. It shouldn't be just the CSSD manager sharing it with stakeholders. It's about the entire team working toward same goals."

Billingslea recommends that CSSD leaders advocate for designated quality technicians to lead quality improvement initiatives. He stated:

"There's probably nothing that will increase your quality quicker than assigning quality techs, whether this is a full-time responsibility or an assignment they carry out as part of every shift. When we go to turn around an account, that's one of the first things we do. It's a tried-and-true approach that always works. For the technician, it's a very pleasing role that adds steps to their clinical ladder. It's a win-win."

Intermountain SPD and IP unite in quality improvements

During the Association for Professionals in Infection Control and Epidemiology (APIC) 2022 Cleaning, Disinfection, Sterilization Conference, held November 10-11, 2022, Caitlin Brown, MPH, MLS(ASCP), Infection Prevention Coordinator, and Eduardo Velazquez, CRCST, CHL, CFER, Sterile Processing Department Manager, both of whom work at St. Joseph Hospital in Denver, Colorado, shared some of their experiences with collaborative quality improvement.

Review of sterilization practices in the OR and SPD

Saint Joseph Hospital, now part of Intermountain Healthcare, has a robust sterile processing department comprised of 40 technicians. There are 21 ORs and approximately 230 cases/week. The health and safety of Saint Joseph Hospital's patients,

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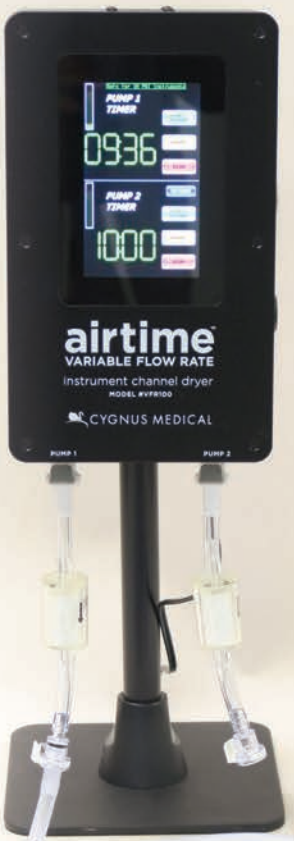

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physicians, associates, and community are top priorities. The hospital recently took the opportunity to review its internal infection control processes thoroughly.

Given the focus on Infection Control and knowledge that sterilization practices are areas of regulatory scrutiny, an intensive review of all practices was performed using tracer tools that followed the requirements outlined in their Sterilization Policy and Procedure. Process issues were internally identified that triggered performance improvement initiatives.

The IP department wasted no time making enhancements when it discovered some challenges with pre-cleaning. "Saint Joseph's has long had processes regarding infection control that exceed the basic industry standards," noted Brown. "However, the IP department is not satisfied with exceeding expectations. We want to always be the best!"

Team effort for process improvement

"We jumped into action," Brown recalled. "This was a collaborative endeavor. Infection prevention partnered with the stakeholders, from frontline staff and all levels of leadership to refine and enhance processes as described below."

OR point of use precleaning and pretreatment

"We started out in the OR where pre-cleaning occurs, and we looked at every detail," said Valasquez.

To address pre-cleaning, and end-of-case pretreatment at the point of use (POU), OR and other staff began performing additional audits at the end of cases to ensure proper instrument preparation. This also ensured that instruments were returned to their proper trays, with all hinged items open for thorough pre-treatment. It also helped ensure the consistent use of non-enzymatic spray to keep instrumentation moist and disposable items were removed, creating efficiencies for SPD to clean instruments and prevent paper from entering washers.

Decontamination

SPD leadership and IP round in the decontamination area once per week and conduct audits of the OR carts and make notes about how well the techs are cleaning the instruments and following existing protocols, including:

- Proper brush size use on all instrumentation
- Appropriate disassembly of equipment
- Verification of items that require sonic decontamination
- Proper sink detergent dosage and sink temperature
- Ensuring techs follow instrument instructions for use (IFU)

The SPD and IP also implemented a new case cart protocol that requires the cart to be delivered from OR to decontamination with:

- No sharps in any of the instrumentation
- No biohazard bags and waste
- All instrumentation unlatched
- All instrumentation adquately saturated with a non-enzymatic spray

If the SPD receives into decontamination a cart that appears not to meet the protocol standard, they return the cart to the tech to fix it.

Assembly

Velazquez outlined the standards in place to maintain quality, noting how instrumentation is carefully inspected for cleanliness, proper function, and possible defects, including:

- Testing insulation on a laparoscopic instrument (functionality)
- Testing the sharpness of scissors (functionality)
- Testing instruments for proper lubrication (functionality)
- Inspecting items with the borescope (cleanliness)
- Inspecting items with the lit magnifying glass (cleanliness and functionality)
- Inspections can consist of looking for debris, rust, pitting, and bioburden

Once properly inspected after coming from decontamination, the instrumentation is assembled, packaged, and labeled for sterilization. If an instrument doesn't meet inspection expectations, the SPD uses a "White Tag System" to record which instrument has an issue, what the issue is, and the tech who found it at what time. The information is then communicated to decontamination. The team also gathers data related to the White Tag system along with data from weekly tracers by IP and SPD leadership.

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Quality assurance

Saint Joseph Hospital uses audit tools, such as tracers and instrument inspection logs. To ensure a sustainable quality assurance program in the SPD, a multidisciplinary team analyzes data collected throughout their processes and sends regular reports to an internal Infection Control Committee, Perioperative Services Committee, and Quality Committee. They follow up on audit findings, then aggregate and trend data to find commonalities that can be systematically addressed.

Saint Joseph Hospital is proud of its reputation for clinical and operational excellence. Over the past five years, numerous independent agencies have recognized the hospital for quality and operational excellence (CMS Five-Star Quality Rating, Healthgrades "America's 250 Best Hospitals Award" for delivering clinical quality and outstanding patient experience, Leapfrog Group "A" rating for best safety measures and strong track records).

As Brown stated: "We all work toward improved patient safety and improved patient outcomes every day here. That's what we are always aiming for."

Atlanta's Northside Hospital takes a team approach to CSSD quality

"Here at Northside Hospital, we have developed a robust Sterile Processing quality management system that includes participation from SPD and OR leaders, Infection Prevention, Quality & Education, and Quality Improvement departments," said HSPA Board of Directors Member Tracy Davenport, CRCST, CIS, CHL, Sterile Processing Manager, Northside Hospital, Atlanta.

Davenport explained how the program's foundation began with the creation of several sterile processing focused quality leadership and support roles: "Pre and post sterilization quality inspections are performed by Quality Specialists, who report to our SPD Quality Manager and are based within our sterile processing department. Our Infection Prevention department has also added Infection Prevention Sterilization Specialists, staffed by experienced Sterile Processing Subject Matter Experts."

Northside Hospital also leverages a quality tracking system, which is based on a low-code, cloud-based platform called TrackVia. It is available for users to access in each of the Surgical Service areas, including inpatient and outpatient OR departments, along with Labor and Delivery, and Sterile Processing.

"With this system we are able to track and document quality in all steps of the reprocessing cycle, including point of use (POU) instrument care, decontamination, inspection and assembly, sterilization, and transport," said Davenport. "It was necessary to provide easy and automated reporting and notification to all stakeholders."

In decontamination

Quality Specialists perform audits on trays coming from the OR and record their findings in the quality tracking system database. Scheduled notifications are sent via email to OR leaders at that same time each day, listing the specific trays that were not pre-cleaned and/or treated (sprayed) appropriately before being sent to decontamination.

"This allows OR leaders to follow up with the nurses and technicians who were assigned to those cases to provide just-in-time education," Davenport explained.

In assembly

In the assembly area, Quality Specialists perform quality audits on trays that are straight out of the washers to ensure minimum cleaning criteria are met (e.g., instruments fully opened, levels are separated, etc.).

In sterilization

They perform audits on assembled and containerized trays waiting for sterilization to ensure staff have not missed inspection points, and trays and containers are assembled appropriately.

"In our sterilization area, audits are also performed on sterilizer loading and documentation," said Davenport. "All SPD findings are recorded in our quality tracking system and the results are automatically sent to the SPD managers and employees' direct supervisors."

In the OR

In the OR, clinical staff utilize a customer feedback tool to submit quality tickets when they discover instrument tray errors. Findings such as no indicators or missing locks are sent to the SPD Quality Specialist assigned to the person who completed the tray. Upon receiving a quality ticket, the Quality Specialist performs an investigation and provides just-in-time education to the SPD technicians.

"If bioburden or foreign objects are discovered and reported through customer feedback, an urgent notification is immediately emailed to all SPD leadership so that someone can go directly to the room to follow up for an investigation," said Davenport. "At that time, we provide service recovery, and have often found that some reports were not a sterility concern at all, allowing the surgery to move forward without delays."

Continuous monitoring and feedback throughout the continuum

Northside Hospital's IP Sterilization Specialists perform environment of care rounds within SPD, as well as a broader Sterilization Tracer performed once per quarter in collaboration with the hospital's Quality & Education department and the health system's Quality Improvement team.

"Those findings are also reported back to SPD leadership to take action where necessary," Davenport commented. "Solutions and improvements are reported back to our Quality Improvement leaders during our weekly tracer report calls."

To close the gap with everything tracked and compiled during the audits and provide follow up information to SPD's customers on the issues that have been reported, SPD Quality and Operational leaders pull and review data from the prior month's customer feedback submissions.

"Together we are able to identify potential causes and provide completed and/or proposed action items during our monthly SPD/OR Leadership meetings," said Davenport. "During these sessions, we can collaborate with our customers to come up with solutions to quality issues, proactively prevent new occurrences, and find new ways to educate staff on opportunities to improve quality, and most importantly, our care to our patients." HPN

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HSPA VIEWPOINT

Creating optimal SPD takes planning, keen assessment

by Julie E. Williamson, Director of Communications & Editor-in-Chief, HSPA

Many Sterile Processing (SP) professionals are happy to share their visions of a "perfect" department. This often includes the most sophisticated processing equipment; enhanced automation; sufficient instrumentation inventory to prevent requests for rapid turnover; larger work areas that are uncluttered and facilitate proper flow; height-adjustable sinks and tables; top-quality inspection tools such as lighted magnification and borescopes; and an adequate number of well-trained employees for all shifts, among other wish list items.

Although few can argue the merits of sprawling SPDs and the latest and greatest technologies, experts routinely point out that creating an optimal SPD is more about effective layout and workflow and ensuring all technicians are provided the proper essentials for all reprocessing tasks (correct brushes, detergents and inspection tools, ongoing training, and the latest guidelines and instructions for use, etc.).

Lay of the land

Whether an SPD is old, cramped and outdated or a grand and expansive environment filled with all the latest and greatest equipment, ensuring a good flow that keeps proper separation between clean and dirty areas and keeps needed supplies and work areas in easy reach of technicians to prevent inefficiencies and wasted steps is imperative. Uni-directional flow is essential to ensure soiled instruments move progressively to clean work areas, and this point is highlighted repeatedly in standards and guidelines from professional organizations such as the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), the Facility Guidelines Institute (FGI), the American Society for Healthcare Engineering (ASHE), the Association of PeriOperative Registered Nurses, the Association for the Advancement of Medical Instrumentation (AAMI), and the Association for Professionals in Infection Control and Epidemiology (APIC).

ANSI/AAMI ST79 *Comprehensive guide to steam sterilization and quality assurance in health care facilities* states that the SPD should include separate areas within the decontamination area for receipt and processing of contaminated items that will undergo terminal sterilization after decontamination; receipt and processing of contaminated items for which the decontamination process incorporates decontamination procedures; and receipt and processing of equipment that requires manual disinfection post-cleaning. There should also be a separate clean work room for packaging, sterilization and storage of clean items; walls or partitions between functional work areas to control the spread of contaminants; enough space for all functions and equipment; systems to contain contaminants and minimize staff exposure to bloodborne pathogens and other potentially infectious organisms; and a workflow pattern that allows safe handling of items across every stage of processing.

Citing the 2018 edition of the FGI guidelines, Gail Horvath, MSN, RN, CNOR, CRCST, Patient Safety Analyst and Consultant for ECRI Institute, reminds SP professionals to carefully explore the minimum requirements for their SP spaces. Will a two-room processing area sufficiently be able to meet the facility's procedural volume and demand or will more rooms be needed? Also, is the facility using countertop sterilizers or large, floor-loading units? It is important to routinely evaluate the facility's volume, along with the SPD's capabilities, to ensure customers' and patients' needs are being safely and efficiently met. A three-zone workflow is ideal for ensuring flexibility and adaptability of the space and is recommended by the Department of Defense for military health system facilities. This design uses double-door or pass-through steam and low-temperature sterilizers to directly connect the clean room and sterile storage area. Additionally, a triple-zone setup allows instrument inspection, assembly, wrapping and containerization to occur in a dedicated area, with minimal movement.

Track current supplies, equipment, staffing

Once current and future projections are determined, SP leaders must assess whether the SPD is equipped to meet those demands. Prior to purchasing new capital equipment, Biomedical Engineering and Facilities Management staff should verify that the facility has the necessary mechanical, electrical and utility requirements and that the SPD has enough square footage to accommodate the equipment and its required plumbing and ventilation and also allow access for proper cleaning and repairs.

HVAC and utility requirements should also be prioritized, and temperature and humidity levels should be carefully monitored and documented. ASHRAE Standard 170 states that temperature for sterile storage areas should not exceed 75 degrees F, and relative humidity should not exceed 60%. When a variance occurs, a thorough risk assessment should be performed, Horvath explained. If temperature or humidity levels only momentarily drop outside of acceptable ranges, breaking everything down and reprocess it may not be required like it would be if condensation is present or there is other evidence of compromised sterility.

Workstations, tables, chairs and sinks should be properly sized. Comfort and safety can be further improved by ergonomic equipment that can be raised or lowered to accommodate technicians of varying heights. Ensuring proper lighting is also critical, and this involves both overhead and task lighting; bright light is especially helpful when performing detailed instrument inspection, and SP technicians should also have ready access to borescopes to allow illuminated viewing of lumens and other interior components. Of course, staffing and an emphasis on continuing education, certification and professional development are equally vital to successful SPD operations.

"[Employees] should be qualified and competent across all aspects of Sterile Processing, including biohazard transportation, decontamination, preparation, packaging, sterilization, sterile storage, and distribution of sterile medical devices," Horvath said. "We are always going to promote certification because it validates the expertise and the employee's commitment to the profession and increases the recognition as a healthcare professional." HPN

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SUBMIT YOUR QUESTIONS:
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Qualitative vs Quantitative

by Stephen M. Kovach

Q "Can you explain the difference between the terms qualitative and quantitative?"

A Qualitative indicators are not presented as a number (e.g., consider a color change test of a pass/failure). They are indicators that help predict the outcome of a process being monitored. A great example is an indicator you use for steam sterilization.

Quantitative indicators are presented as a number. For example, temperature or humidity monitoring it is a number such as in the decontamination room. You might say it is hot in the room, but it is the number that tells how hot it is. Also, quantitative numbers are often used in your department's key performance indicator (KPI) process—a quantifiable measure of performance over time for a specific objective. KPIs provide targets/goals for teams to shoot for and help gauge progress into what you are monitoring.

Q "I have noticed some of my liquid cleaning solution is "separating" when I look at the container. Why is that, and can I still use it?"

A First, you should be commended for your keen observation skills (noticing something different) when you were handling the cleaning solutions.

We all know temperature plays an important factor in how cleaning solutions work. Each cleaning solution has an "optimum range".

Liquid cleaning solutions can separate. In my view, it happens more during the shipping/transit process of getting the cleaning solution to your facility. It can also happen if the distribution storage warehouse is not temperature controlled. Sometimes, cleaning solutions sit on the receiving dock for long periods of time in a very hot environment and this could also be a cause. I recommend customers ask how the cleaning solutions are stored and transported to their facility.

In shipping, assuming the distribution routes are not temperature controlled, thus separation could take place if temperatures exceed the limits of that cleaning solution. The same goes for storage—if not temperature-controlled, then separation could take place. The question you are asking is actually, "Can the cleaning solution be reconstituted?" Only the Original Manufacturer (OM) can answer that and your reviewing of their IFU.

Therefore, if you see a splitting or separation of the cleaning solution at any time, contact the OM of the cleaning solution to ask when you can use it (what can you do, if anything, to reconstitute it), and then find out why it happened.

Here are two examples of containers of cleaning solution with a temperature warning (Figs. 1 & 2).

Remember, each cleaning solution has its own limits. You must know the limits to get maximum cleaning power out of them. Storage and transportation also have an impact on how they perform.

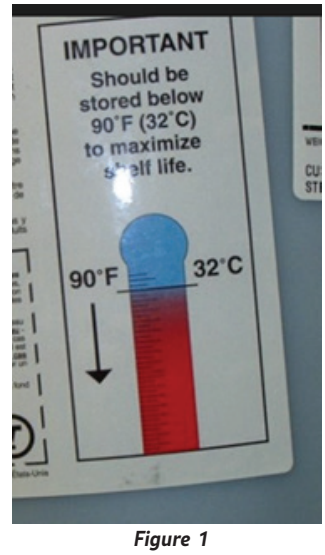

Figure 1

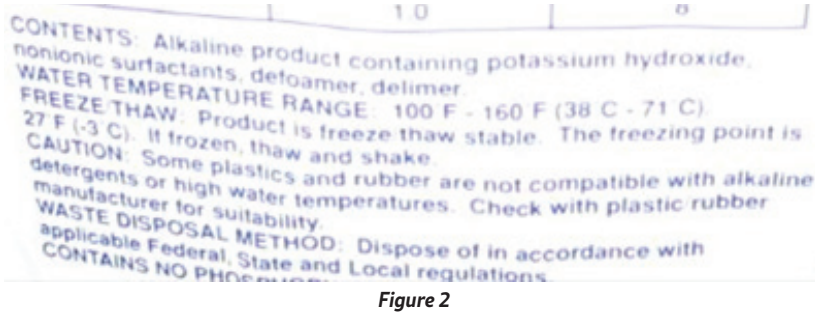

Figure 2

Q "We ran out of sterilization tape, and we were told we could use masking tape. Can I use masking tape?"

A I have heard of this before with some low-temperature sterilization systems but not with steam.

Here is why you want to use indicator tape for any sterilization process. It is considered by ANSI /AAMI ST79: 2017 to be a "Type 1 (process indicators): chemical indicators intended for use with individual units (e.g., packs, containers) to indicate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units."[1]

As per the definition, it is a simple indicator: Your first view if the items have been exposed. If it does not indicate exposure per that specific IFU, then that individual unit (item) is in question.

Concerning masking tape, I have heard of some people using it. I would not. In any case, I would want to know if the items inside the chamber, regardless of the type of sterilization, were exposed. HPN

References:

1. AAMI. (2017). ANSI/AAMI ST79: 2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities [Section 2.10 chemical indicators (CIs); p 4]. Association for the Advancement of Medical Instrumentation (AAMI).

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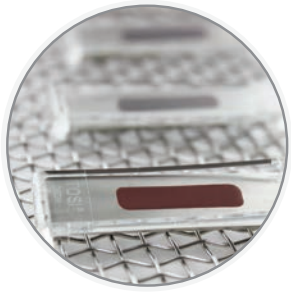

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LEARNING OBJECTIVES

1. *Identify testing types that are available for cleaning verification and discuss how they work.*
2. *Explain the technician's role and responsibilities for cleaning verification*
3. *Discuss the elements of a cleaning verification quality program.*

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As medical technology continues to advance, reusable instruments and devices are becoming more complex. Devices with channels, seams, joints, moving parts and other complex components present serious challenges when it comes to ensuring that they are "clean," which in this case means free from all visible organic and inorganic soils[1] and ready for the next reprocessing step.

Historically, visual inspection was the only tool available to assert cleanliness, but clinical experience has shown that medical devices are not always clean even if the naked eye thinks they are. So-called clean instruments have been documented to cause infectious outbreaks, loss of limbs, and even death, even if they were put through a sterilization cycle after cleaning.

This avoidable patient safety issue has led to the development of numerous tools to help technicians determine whether or not a medical device is verifiably clean and ready for high-level disinfection or sterilization. A review of these tools will help department managers assure they have the right methods and procedures in place for their device inventories.

Cleaning verification

Cleaning verification is the process of confirming that the soil removal goal was achieved, and that the medical device can safely proceed to the next phase, which is either disinfection or sterilization. If any residues remain, whether visible to the naked eye or not, they may prevent the subsequent disinfection or sterilization cycle from being effective and may result in a device that is still contaminated.

While visual inspection (using lighted magnification to inspect surfaces and box locks, and borescopes to look inside channels and lumens) remains a recommended practice and can help technicians discover visible organic soils, residual soil and microbial contamination may remain even though the device looks clean. Residual soil can lead to the formation of biofilm and can inhibit disinfection and sterilization. This is why tools are needed to go beyond *visual* inspection to *verifiable* inspection.

The technician's role in inspection and cleaning verification

Optimal patient safety and outcomes are the objectives of all healthcare functions, including the reprocessing department. Sterile processing technicians are the guardians who stand between contaminated instruments and the next patients on whom they will be used. Because inspection is such a critical step in medical device reprocessing, technicians must have a thorough and detailed understanding of how to visually inspect every type of medical device that comes through their department. They must also know how to use the testing tools available to them to effectively verify that devices are clean.

For example, all techs should receive ongoing education and competency testing in the use of lighted magnifiers and borescopes. If, for whatever reason, a technician doesn't know how to use these tools, or which instruments to use them on, they are responsible for proactively notifying their supervisor or manager. The same applies to competency in the handling and use of verification tools and supplies.

Establish a cleaning verification program

Because of the critical importance of cleaning verification in the health and safety of patients, healthcare facilities should include their cleaning verification program in their quality management system (QMS).

A thorough quality program requires the collaboration of a multi-disciplinary team that represents all departments connected to the reprocessing function. Team members may include sterile processing management and technicians, surgical department representatives, infection preventionists, risk management professionals, materials management/supply chain/purchasing professionals, and any others who may have a stake in the process.

Identify and evaluate available products

Reprocessing managers should begin by identifying the products available in the marketplace and performing an evaluation and trial to select the best products for their facility. Although sterile processing technicians do not typically make supply chain/purchasing decisions, they should have input into the products selected to ensure they are appropriate for the technician's scope of work.

To help with product evaluation, sterile processing personnel should know the ANSI/AAMI recommended criteria for selection of products. According to ANSI/AAMI, testing products should be:

- Rapid in their function
- Easy to perform
- Sensitive (i.e., meet realistic benchmarks)
- Accurate
- Repeatable
- Free of interfering substances
- Robust (i.e., do not require exacting conditions or time constraints that cannot be achieved in routine reprocessing areas)

Next, the team should familiarize themselves with the specific products; what they are, what they do, and which would be most suitable for the specific soils their department deals with. Because they work with these soils every day, technicians may be able to provide valuable input to assist in making optimal product choices.

The verification products on the market today test for:

- Protein – they detect amino acids (small subunits of a large protein molecule).
- Carbohydrates – a glucose oxidase test method that measures glucose.
- Hemoglobin – originally designed to detect blood in stool but is also a bioburden detection tool for SPD.
- Adenosine triphosphate (ATP) – ATP is an energy-carrying molecule present in the cells of all living things. When the cells die, the concentration of ATP decreases over time.

Protein soils are the most common surgical soils, which makes protein tests a good choice for residual soil testing on reusable medical devices. There are many proteins encountered during invasive procedures, so a protein test that detects a broad spectrum of protein-based substances is ideal.

Carbohydrate tests only detect glucose, which is one of a variety of potential surgical soils.

Likewise, hemoglobin tests detect only blood, which may also be far too specific to account for all possible surgical and procedural soils on instruments.

ATP tests require the use of a luminometer, which adds an extra step to the verification process. Since a test should ideally be simple to perform, having to use an additional piece of equipment and potentially maintain multiple luminometers in the department is inefficient and can become costly. In addition, the fact that the concentration of ATP decreases as cells die may make detection less accurate.

Once the tools are understood and matched to the soils the department is addressing every day, the ANSI/AAMI criteria can be applied to select the optimal products for the facility and its needs.

Build the steps for the verification program

A cleaning verification program involves more than selecting the product and then telling staff to use it. To assure that the cleaning verification program is successful and sustainable, verification steps need to be developed and staff need to be trained. The program should also be audited for compliance to current standards, during which gaps in the process can be identified and process improvement steps can be developed to address the gaps.

There are three parts to cleaning verification:

- Inspecting cleaned devices with appropriate tools (e.g., lighted magnifiers, borescopes)
- Testing cleaned devices with cleaning verification products
- Testing cleaning and inspection equipment using testing products

Conduct training

Once the verification products have been selected, technicians will need to be trained on the new products and have their competence assessed.

Figure 1: ANSI/AAMI ST91 states that high-risk endoscopes should be tested every time they are processed.

The training should include but not be limited to:

- Reviewing the testing product manufacturer's written instructions for use
- Providing hands-on instruction on how to use the product
- Requiring handwashing and donning of clean gloves before performing the testing to reduce the risk of cross-contamination
- Teaching the appropriate storage of the product
- Documenting expiration dates (if applicable)

Decide on device types and frequency

The next step is to determine which instruments/devices need to be tested and how often. Guidance for this can be found in the device manufacturer's written instructions for use, in ANSI/AAMI standards, and from risk assessments performed in the department. This is where the multi-disciplinary team can also be valuable. Each stakeholder will have a different perspective on risk and device complexity, and each may add important information to the decision-making process.

For example, ANSI/AAMI ST91 lists high-risk scopes as endoscopes associated with infections due to documented cross contamination or outbreak events. These include bronchoscopes, cystoscopes, duodenoscopes, endobronchial ultrasound endoscopes, linear ultrasound endoscopes,

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

ureteroscopes, and others as determined by the facility. High-risk endoscopes are recommended to be tested every time they are processed. However, if a device is not classified as high risk, it becomes the responsibility of the facilities to determine testing frequency.

It is also important to stay informed about outbreaks within your community and nationwide, to determine if scopes previously considered low risk should be treated as high risk. Ultimately the team may choose to test every flexible endoscope to reduce the risk of any cleaning failures.

Because it would not be efficient to test every cleaned instrument/device, the department should establish criteria for identifying those that will be tested on a routine basis. Criteria such a device's complexity, cleaning difficulty, and/or associated surgical site infections are a good place to start. Surgical and reprocessing staff would be good sources of information for selecting these instruments, which could include laparoscopic, robotic, orthopedic, neuro and specialty items.

Once the instrument/devices are identified, the frequency must be established. To be consistent with the system for flexible scopes, high-risk, medium-risk and low-risk items can be categorized. High-risk items would be tested every time, while medium and low-risk items would be tested less frequently.

Test the equipment

A thorough quality management system should also include routinely testing the cleanliness of the borescope, to reduce the risk of cross-contamination causing a positive result when testing the endoscopes.

Document the testing

The tests and their results should be entered into a log sheet. If the department has a tracking system, this can be created in the database. If not, then a manual log can be created.

In addition, a policy, procedure, and work instructions should be written so technicians can respond appropriately to failed cleaning verification tests. Standard practice is to send failed items back through the decontamination process, then perform cleaning verification testing again. If there is another failure, the department should consider removing the item from service to determine whether it should be tested further (cultured, e.g.) or sent back to the manufacturer or a repair company for examination and refurbishing, if appropriate.

If the failure is traced to a borescope, the policy and procedure should include the steps to clean and disinfect the borescope before using it on another item. The inspection workstation should also be cleaned and disinfected. Once staff members have identified a cleaning failure, they should wash their hands per facility policy.

In the same manner as sterilization data, all failures should be documented and routinely reported to the infection preventionist, including details such as:

- The number of items tested
- The number of identified failures
- The number of cleaning equipment tests
- The number of cleaning equipment test failures

Documenting the numbers and failures will also support a sustainable, high quality process because staff are aware that data is being collected and reported.

Audit and investigate causes

A physical audit of the reprocessing function should be performed by observing the actual reprocessing workflow and every step of the process to confirm compliance and/or identify gaps. An audit of the records should also be performed routinely to ensure that testing is being performed to the established schedule and that it follows relevant manufacturers' written instructions for use.

Once a failure has been identified, a root cause analysis should be performed to identify potential causes for the cleaning failures. A multi-disciplinary team may be necessary to find the root cause because equipment testing failures can be the result of water quality issues, equipment malfunction, process drift, gaps in the process, lack of training, and other variables overseen by various experts. The medical device manufacturer may also need to be a part of the investigation to ensure that the cleaning process is compliant with manufacturer's written instructions.

Optimize your cleaning verification program

To be effective and reduce infection risks, the cleanliness of medical devices must be verified through a robust process that includes more than just a visual inspection of cleaned items. A number of cleaning verification products are available today, and each reprocessing department must select the testing tools that are appropriate for their inventory of devices. While each type of test has value, protein testing provides the ability to detect the widest range of retained soils, which may make it the most efficient tool for most departments.

The cleaning verification protocol must also be included in the department's quality management system to assure continuous improvement and quality of the process. Among other elements, a high quality cleaning verification program establishes the items to be tested and the frequency of that testing. This includes selected medical devices and cleaning equipment. It also requires that testing be documented and routinely reported to maintain a sustainable process and identify failures and root causes quickly. Ongoing staff training is another element that helps reduce the risk of processing failures.

It may be wise to review your existing cleaning verification process to assure that it's a thorough, high quality program. If you don't have a formal cleaning verification protocol, these guidelines can help you get started. An evidence-based program that reduces infection risk is worth the effort. **HPN**

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CONTINUING EDUCATION TEST • JANUARY 2023

Beyond the visual:
The importance of quality cleaning verification programs

1. **Cleaning verification is the responsibility of:**
   A. EVS
   B. Sterile Processing Technicians
   C. Infection Control
   D. Facilities
   E. None of the above

2. **Cleaning verification includes:**
   A. Visual inspection with lighted magnification
   B. Borescope
   C. Validated cleaning verification products
   D. All of the above

3. **The decision on what cleaning verification product to use is the responsibility of:**
   A. Materials management
   B. Risk Management
   C. Periop Director
   D. A multi-disciplinary team of stakeholders
   E. The CFO

4. **Cleaning verification products available today measure/detect:**
   A. Protein
   B. Carbohydrates
   C. ATP
   D. Hemoglobin
   E. All of the above

5. **Per ANSI/AAMI recommendations, a cleaning verification product should be:**
   A. Rapid and easy to perform
   B. Expensive
   C. Stored at a certain temperature
   D. Colorful
   E. From your favorite rep

6. **The most common procedural soil contains:**
   A. Fats
   B. Proteins
   C. ATP
   D. Sugars
   E. Sweat

7. **Cleaning verification should be performed:**
   A. Daily
   B. Weekly
   C. As determined by the facility risk assessment
   D. When there is time
   E. Never

8. **Criteria to select items to be tested can include:**
   A. One of every type
   B. Complex devices
   C. Devices that are hard to clean
   D. Devices that are designated as high-risk
   E. B, C, and D

9. **Cleaning failures can be determined by:**
   A. Visible soil
   B. Failed equipment test
   C. Failed cleaning verification test
   D. All the above
   E. None of the above

10. **Stakeholders for a cleaning verification quality team could include SPD technicians and management, an OR representative, an infection preventionist, a risk management professional, and a supply chain professional.**
    A. True
    B. False

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Pandemic reveals new concerns about facial protection products

Design may be the answer to altering behaviors, habits ushered into standard practice

by Rick Dana Barlow

When it comes right down to fighting the spread of any airborne-transmitted respiratory viruses, people generally have three ways to protect themselves: Get vaccinated, disinfect the air or cover your face – mouth and nose specifically.

Each of the three raise the hackles of some interest group with the overarching opinion being something akin to "don't tell me what to do if it's costly, inconvenient and may infringe on freedom, privacy or religious beliefs." During the last two years or so, air disinfection strategies and tactics drove interest and growth in ultraviolet radiation delivered through lighting products and premium air filters.

People didn't need an airborne respiratory pandemic to learn about covering their mouths and noses because children tend to – or should be – taught to cough or sneeze into their hands or the inside crux of their elbows. With an airborne respiratory pandemic, however, you likely don't want to walk around covering your face with your hands or arms. That's where masks, respirators and shields enter the scene.

During the last two-plus years people learned quite a bit about face coverings, including access, comfort, durability and fit. The most affordable models tend to be disposable, single-use-only textiles that must either be replaced – or in the case of desperation, the Food and Drug Administration gave details on how to clean, disinfect and sterilize for limited reuse enroute to replacement. Other products, like respirators, were molded from harder materials or required attached filters to be changed. Reusable face shields, molded with clear plastic materials attached to a plastic frame, needed to be cleaned, disinfected and sterilized routinely.

For masks and respirators, comfort and convenience posed problems as they needed to be fitted properly and tended to pull on the wearer's ears. Further, they generally obscured facial expressions during conversations, which created challenges for children and the mentally and sensory disabled who must see facial expressions and read lips. Finally, they all needed to be approved or cleared by FDA via NIOSH.

The global pandemic years of 2020-2022 should have taught suppliers (e.g., manufacturers and distributors) and providers (e.g., hospitals and other healthcare organizations) about how to prepare for the next airborne respiratory virus, whether any outbreak becomes endemic or pandemic. What, in fact, did everyone learn?

Schooled by crisis

Lessons learned by suppliers and providers during the COVID-19 pandemic should lead to dramatic changes in product design and process workflow over time. The amount of time, however, remains in question.

Jason Burnham

The pediatric segment raised considerable concerns for Jason Burnham, Senior Director of Facial Protection, Owens & Minor.

"One of the biggest challenges was in regard to children's masks, or the lack thereof," Burnham declared. "Currently, the FDA does not recommend N95 [respirators] for children – leaving parents and healthcare workers uncertain about how to protect their children's health. While some manufacturers offer a small respirator, they are not designed nor tested to be worn by children. Children need masks that are not only sized appropriately for their face, but that also provide the filtration needed to help protect them – an opportunity that is certainly worth exploring further with research and design."

Burnham warns against moving on from making improvements as the healthcare industry heads into COVID-19's "endemic" phase.

"Even as COVID-19 cases decline and PPE is readily available, we continue to see use of facial protection that is not aligned with recommendations from health agencies and authorities or product IFUs (instructions for use)," he noted. "Since the inception of the pandemic, staff are often re-wearing disposable face masks due to scarcity rather than disposing and donning a new mask between patients. This is a significant departure from the CDC's Standard Precautions, a set of infection prevention practices first developed in 1996 designed to protect both healthcare workers and patients from the spread of infections. The CDC's Standard Precautions and Isolation Precautions emphasize removing and discarding PPE before leaving a patient's room."

As trending evidence of pandemic-relaxed behaviors morphing into workflow acceptance, Burnham cited a recent 2022

study conducted by Owens & Minor that found that 40% of respondents, including surgeons and surgical support, said they were re-wearing masks due to habits that began during the pandemic.

"During the pandemic, the reduced supply of facial protection led healthcare workers to wear whatever type of facial protection that was available even if it didn't match the protection needed in certain settings – oftentimes causing them to wear more or less protection than required," Burnham continued. "Now that supply of facial protection is healthy, staff should return to choosing the right mask with the level of protection needed for the task at hand to rebalance proper product demand planning. For instance, if entering a setting where there is a high risk of splash, an ASTM Level 3 mask should be selected rather than a Level 1 mask.

"Additionally, scarcity of eye, nose and full-face protection led many healthcare workers to find makeshift solutions or to reuse contaminated protection devices meant for single use," he said. "CDC Standard and Isolation Precautions previously established the importance of using masks with attached shields, face shields and/or eyewear in patient interactions where fluid splash or aerosol-generating procedures might create risk of eye, nose, mouth, or face contamination."

Time to retighten the rules?

Some contend that once the FDA issued "emergency use" guidelines for PPE to accommodate product shortages, alleviate panic buying and prevent desperate decision-making without a designated endpoint or strict policy of returning to standard precautions the federal agency, by and large, enabled a "put the genie back in the bottle" situation.

"Masks, shields, and especially N95s are designed for single-use and to be worn for a limited time, but now they're being worn all day," lamented Gary Harris, Vice President Sales and Marketing, Prestige Ameritech. Prestige Ameritech has focused [product design] on skin sensitivity, comfort and durability … in this new environment. The entire industry needs to accommodate this shift in product usage."

Gary Harris

Still, Harris hopes the FDA steps in to help providers get back on track.

"We agree that the emergency use measures will continue in a significant number of facilities unless the FDA takes action to stop it," he told *Healthcare Purchasing News*. "Two things come into play: One is the longer they use the product, the fewer products you will need so the healthcare systems are incentivized to use the products longer than their original design to save money. Second factor is that the healthcare providers are becoming accustomed to wearing products longer as opposed to changing masks each time between patients. In some cases, the mask is worn all day long. Overtime the healthcare provider thinks that wearing a product all day long is normal.

"This paradigm shift will not go away anytime soon," Harris warned, "and so manufacturers need to understand this and adapt to making design changes and improvements to accommodate this shift. As it is prudent for the protection of the healthcare provider, when dealing and interacting with the patients, single-use products should continue to be the norm. Reprocessing of some products is acceptable under specific conditions, but with N95s this is not proven to be a successful strategy."

What did COVID-19 teach providers about facial product design?

Against the backdrop of what was learned during the 2020-2022 global pandemic and supply chain disruptions, what are some relevant and useful capabilities and features for manufacturers to incorporate in "redesigned" or "updated" mask, respirator and shield products? Experts share their thoughts.

"A number of improvised innovations surfaced during the pandemic, from different mask attachments for comfort and fit to visibility modifications for easier communication. While a number of these creative ideas emerged out of necessity from healthcare workers on the front lines and were uniquely driven by unusual work conditions in the pandemic environment, some learning from these home-grown innovations will likely find their way into regular features and benefits as the pandemic recedes and as manufacturers apply research and development assessment to these insights from front line healthcare workers."

Jason Burnham, Senior Director of Facial Protection, Owens & Minor

"We are seeing a shift toward reusable solutions to protect inventory levels and also complement sustainability initiative to reduce waste and lower costs. Reusable PAPRs [powered air-purifying respirators] became more popular when the pandemic started as they can be wiped down and are resilient and efficient in their shape and mobility.

"Medline introduced a PAPR to its product portfolio last year called the PureFlo 3000. Most PAPRs have an attached hose and belt. Ours is fully head-borne to increase mobility and to make it easier to don and doff, and does not require fit-testing.

"As we continue to think about product development, the following are a few factors we're looking at:

- "Comfort as long-term use becomes more common
- "Sustainability: We are looking at the environmental impact of our masks and respirators and thinking about how we can produce greener PPE.
- "Accommodating patient backgrounds and figuring out how we can create PPE that caters to people who need to read lips or cannot shave their beard for religious reasons and therefore cannot wear an N-95 mask."

Mark Chua, Vice President of Preventive Care, Medline Industries

"PPE are life saving devices and cannot be chosen on price alone. These products should be purchased from a domestic manufacturer that utilizes domestic raw materials. Otherwise, supply is controlled by foreign countries."

Gary Harris, Vice President Sales and Marketing, Prestige Ameritech

"Manufacturers today are focusing on enhancing comfort wherever possible, including through the use of innovative fabrics that offer adherence to ASTM standards while still being cool and comfortable. Driving comfort in this space without sacrificing quality and protection helps increase compliance and can make life better for healthcare workers.

"Additionally, our suppliers are focused on reducing their environmental footprint, and mitigating waste is at the forefront of future development initiatives. While single-use products still represent the best foot forward for infection prevention and control, manufacturers of single-use products are working hard to find ways to reduce their impact on the environment and doing so through multiple initiatives both directly related to product design and development and overall, with their organizational efforts."

Michelle Schwebel, RN, Senior Director of Product Development, S2S Global, a direct sourcing wholly owned subsidiary of Premier Inc.

Addressing complications

Comfort, fit and facial communication continue to complicate extended wearing of masks, respirators and face shields, according to experts.

"Comfort is a concern as healthcare professionals are wearing masks, respirators and shields for longer periods than they [were] used to prior to the pandemic," said Mark Chua, Vice President of Preventive Care, Medline Industries. "We're also seeing more frontline caregivers face skin sensitivities from wearing masks for longer time periods."

Mark Chua

Michelle Schwebel, RN, Senior Director of Product Development, S2S Global, (a direct sourcing wholly owned subsidiary of Premier Inc., concurred that comfort is key.

"Our market assessment showed that comfort is the No. 1 criterion for healthcare workers when selecting a mask," Schwebel said. "Pre-pandemic, many suppliers (including PremierPro via S2S Global) offered a broad assortment of ear loop and surgical tie designs to help ensure the 'right mask for the right case.' Post pandemic, buyers have trended purchasing toward one or two ear loop masks. We have reintroduced a broader – but still focused portfolio – of comfortable masks we feel will go a long way in improving user satisfaction, safety and give purchasers a sense of ownership of their selection."

Michelle Schwebel

Comfort should accompany fit, according to Medline's Chua.

"It is also critical that healthcare workers pass a fit test," he said. "An N95 mask should be fitted annually or when they use a new respirator. If they do not pass a fit test, they should not use that N95. This requires coming up with alternative options, such as powered air-purifying respirators (PAPRs)."

Facilitating facial communication may be causing another product design shift going forward.

"Something that was more prominent during the pandemic is the ability for a physician and patient to create human connection or read lips," Chua noted. "You have people with disabilities or who are hard of hearing, or really they just need that lip reading as an extra tool for them. Creating that connection and being able to see your physician's face is really helpful. Some solutions that are becoming more popular on the market include clear masks or powered air-purifying respirators (PAPRs) that have that clear shield in front."

Healthcare resistance to wearing facial protection must be alleviated

Roger Machson

Roger Machson pulls no punches when he points to some of the key challenges the global COVID-19 pandemic brought to the forefront of recognition and discussion.

"The premise that healthcare workers reject wearing protective gear is one of the biggest problems we face today," said Machson, President, Onyx Medical Inc., which manufactures facial protection products sold through distributors. "Many, if not most airborne transmissions are a result of sneezing and or close contact with aerosol from infected individuals. Contamination and infections are a result of liquid droplets and airborne virus. In order to be effective in combating transmission of a virus, the best approach is one that addresses all means of exposure. Just concentrating on airborne alone and ignoring exposure of liquid droplets is an ineffective approach to combat the spread of virus infections."

Machson questions how ultraviolet radiation may be used.

"Ultraviolet radiation does not directly address face to face contact," he said. "Ultraviolet is only effective in keeping random airborne virus from migrating, leading us to ask what other solutions are available. Let's start with the original blood-borne pathogen regulations. These regulations were meant to protect healthcare workers from the effects after the discovery of [HIV] the AIDS virus. This virus was a death sentence if contracted. It was the hospital's/employer's responsibility to provide and protect the healthcare worker under penalty. Why, and how has this changed over time?

"The healthcare worker refusing to wear protective gear against viral contamination can only be justified if the protective gear is ineffective. Many of the current arguments against wearing protective gear would be diminished if the gear protected well and was comfortable to wear without interfering with the users' job description. This baseline of effectiveness is subjective and difficult to quantify. Common sense tells us that the more complete the barrier between a healthcare worker and the contamination source, the better the outcome is for all involved.

"As a starting point for basic protective gear, we can start with the simple mouth mask. Surgical masks can provide decent viral protection if well sealed around the nose and mouth. However, they leave both the eyes and skin exposed and open as potential ports of entry. Masks used in conjunction with a simple full-face shield provide additional protection. The biggest problem with this is the quality of anti-fogging on the face shield. Most inexpensive shields are poor quality with regard to anti-fogging. Due to poor vision quality, people don't want to wear them. If the anti-fogging is good, the shield becomes an improvement.

"Reusable shields with plastic frames have a number of issues to consider. First is comfort. Plastic frames tend to be uncomfortable due to rigidity and use of hard plastic. The soft, pliable, medical grade head piece foam that holds a shield against the forehead is gone. Next, reusable shields are hard to clean correctly. Many anti-fogged shields lose their effectiveness when sprayed or cleaned. The anti-fog solution originally sprayed on a plastic sheet can wipe off during cleaning mitigating usefulness in subsequent uses. Cleaning a shield after potential contamination is time consuming and hit or miss. Simply wiping down a shield is difficult to ensure eradication of all viral material under less than sterile processing conditions.

"User instructions state that all Respirators need fit tests to ensure a good seal. It is difficult to ensure this test is available and is done before each respirator use. Even so, a respirator provides good nose mouth protection, however there is no protection to the eyes, neck and facial skin.

"New designs have incorporated barrier fabric added to a face shield with strong anti-fogging qualities. New shield designs like the patent pending Drape-U shield, found at www.onyxmedical.com, offer the most complete coverage against aerosol and droplet exposure short of a hood or full body suit. The Drape-U shield incorporates excellent anti-fogging and an AAMI III barrier fabric that encircles the entire face and neck to protect against splash or airborne particles. AAMI III barrier fabrics offer as much protection and are as effective as the materials used in surgical masks. The Drape-U shield is comfortable to wear, scope of vision full and breathing is easy.

"When one looks at the costs involved due to lost time, illness, incapacitation, or worse, compared to the money wasted on ineffective PPE gear, good PPE is worth the expense. Healthcare is expensive. Surgery is expensive. In comparison, the small additional cost of effective protective products for healthcare workers offers real value to all."

Tracking inventory, origins

Consequently, Chua encourages providers to pay close attention to product development.

"Keeping up with the latest advances in respiratory protection technology is critical to helping staff, patients and residents stay safe," he advised. "Understanding the differences between the most common devices and ensuring that healthcare workers can access and wear them properly are key to preventing the spread of healthcare-associated infections (HAIs).

"Additionally, working with your supply vendor can help a healthcare organization be more of their inventory levels and be prepared for future public emergencies. Knowing in advance what your needs are will allow more time to work with a supply vendor to identify the right solution," he added.

Owens & Minor's Burham recommends keeping track of what's in stock and available for immediate use.

"While it is important to have a safety stock of facial protection, facilities should review the product they have on hand to assess if it truly meets their needs in quality and product mix," he said. "Healthcare professionals should review the products and take note of their expiration date, if they are clinically acceptable, tested to meet ASTM standards and if they are FDA 510(k) cleared. As a recent example, a hospital had a large supply of ear loop masks on hand. However, when they began assessing their stockpile of ear loop masks, they realized that the masks were tight and did not comfortably fit staff, nor did they meet ASTM standards."

Product origin matters, too, according to Burnham, particularly due to logistics and transportation issues suffered by supply chain operations during the last two years.

"Today, healthcare organizations should have a healthy supply of facial protection products," he indicated. "As they assess long-term partners, it is important for them to understand where their product originates from. Providers should ask suppliers where their raw materials come from and where they are manufactured with questions like – does the fabric from the mask originate from overseas or is it made domestically? Or are the components assembled domestically or overseas and then shipped to the U.S.? This can support better planning for potential industry supply challenges in the future. Organizations should also consider the depth and breadth of the supplier's portfolio, ASTM levels offered and if the products have received 510(k) clearances. Having a domestic product isn't helpful unless the product meets the quality standard as well."

Prestige Ameritech's Harris emphatically supports and promotes American-made products as superseding price.

"Don't make price the deciding factor, but instead whether your PPE comes from a domestic manufacturer or not," he urged.

"Domestically produced products in general are more expensive than products from some areas of the world," Harris acknowledged. "When it comes to protective apparel, particularly in facemasks and respirators, the cost differential is just a few pennies. This additional cost should be measured against the result of providing inferior protection to the healthcare providers and patients, and in many cases, as we saw in the pandemic, no protection whatsoever. The question gets down to whether an institution is willing to pay a few cents more to have a solid, guaranteed supply of quality product for their workers or if that few pennies is worth risking infection, supply issues and lack of adequate protection for their workers. We had customers during the pandemic who chose to purchase less expensive products from overseas suppliers and many of these customers were provided with products that offered subpar quality at best – if they even showed up."

S2S Global's Schwebel recognizes that as the pandemic regresses into more of an endemic and supply channels refill with product, healthcare organizations should be able to return to more stringent practices and precautions.

"With supply of masks no longer strained, changing masks between patient visits can help reduce the risk of cross contamination across situations," she noted. "Long-term use of the same face mask can also result in a hot or humid feeling that can result in skin irritation and general discomfort. Frequent changing of face masks helps to increase comfort by keeping the space around users' nose and mouth clean and dry."

Schwebel encourages informed purchasing and use.

"When possible, grab a mask that has foam across the nosepiece. This foam is designed to reduce fogging of eyewear, but it also goes a long way in providing both a comfortable feel and snug fit to the mask," she said. Masks with attached visors are a great way to protect the mucous membranes of the eyes in addition to the nose and mouth of a wearer. These mask designs can provide all-in-one protection and ensure eye protection is not forgotten." **HPN**

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VALUE. DELIVERED.

UDI, recalls and labor shortages – time for a reset?

by Karen Conway, Vice President, Healthcare Value, GHX

This month, we return to the topic of recalls, but with an added lens - the labor shortages and the need to reduce unnecessary and often error-ridden manual work. In past columns, we have discussed the value of unique device identifiers (UDIs) to support the automation of processes around recalls. UDIs, as a reminder, are the U.S. FDA-mandated identifiers for medical devices, which manufacturers must assign to their products, at each packaging level, and include on the label of their products (in human and machine-readable formats). My premise has been that IF UDIs were adopted broadly across the healthcare supply chain as THE way to identify medical devices, e.g., in purchase orders, inventory management systems, electronic health records, etc., we could rely more on technology to help providers determine 1) if they purchased a recalled product, 2) if that product is being held in inventory and if so, where, and 3) if it was used in patient care and documented in electronic patient records. But, this is a simple view, and the reality is, UDIs alone will not get us where we need to be. We need to look more closely at the current processes and regulations around recall management.

The issue of workforce shortages is also worthy of exploration from a variety of perspectives. Since the global pandemic, hospitals and healthcare systems continue to suffer from labor shortages. While most are among nursing staff, many supply chain departments also have unfilled positions; this is important given that supply chain is being asked to take on the more supply chain-related tasks that nurses had been handling in a pre-pandemic environment. Suppliers, too, have reported challenges in recruiting and retaining staff. In coverage of some of the more high-profile recalls of late, staffing shortages at the FDA have also been noted as to why the agency relies on manufacturers to self-report safety issues with their devices and why most recalls are considered "voluntary" (although the FDA has mechanisms to mandate a recall if necessary).

To explore these issues further, let's take a closer look at how recalls are typically handled today. According to the U.S. FDA, the manufacturer, as the recalling firm, is responsible for notifying its customers, which it says "can be accomplished by telegrams, mailgrams or first-class letters conspicuously marked...medical device recall." For this reason, manufacturers spend millions each year sending paper-based recall notices via one of the major overnight delivery services. With the rise in recalls in recent years, many providers have now designated recall coordinators, but many manufacturers still send multiple notices to multiple locations at each of their individual accounts. Because manufacturers must also update the FDA on the status of the recall response, the notices include a means, often a postcard, for providers to return with information on how they have responded. If manufacturers do not hear back, they will often send a second, third, even a fourth notice, further increasing the avalanche of paper sent to their customers. NotiSphere, a technology company in the recall space, estimates half a million trees are consumed annually to support these paper-based processes and that does not even consider the greenhouse emissions from transporting those notices or the substantial costs involved.

As a result of this paper-based, voluntary and scattershot approach, NotiSphere has documented numerous downstream issues:

- On average it takes more than two weeks for a recall notice to reach the official "recall coordinator"
- Many recall notices do not apply to the healthcare providers to which they were sent (they did not buy the product), resulting in extra and unnecessary work (as much as 95% of the time)
- Confusion over the term "voluntary" may cause some providers to ignore the recall or at a minimum fail to respond to manufacturers.

On the other hand, some providers will respond to recalls beyond what is necessary. For example, some recalls only relate to specific batches or lots, but because it can be cumbersome to manually match the lot and serial numbers on the recall notice with the physical products, the provider may remove more devices than necessary. As discussed in prior columns, use of the full UDI, which includes both the device identifier and the production data (lot, serial number, expiry date), can help identify which products are covered by the recall and which are not. But the lack of an automated, machine to machine process continues to limit the ability to leverage that value.

The good news is that the percentage of recall notices including the UDI has risen substantially in recent years. Unfortunately, the paper-based processes still limit the ability to automate the response. Further, providers still need to determine if they need to respond (did they buy it) and if so, where is it? As healthcare delivery continues to move outside the acute care hospital and into the community and patient homes, product locations are proliferating. Further, the nature of how hospitals are reimbursed limits the level of granularity of data in patient records as to what products were used in their care. If not chargeable, those products may not be specifically documented. In other cases, not all products, e.g., those sold directly to consumers in addition to healthcare providers, are not subject to the UDI regulation; these products can range from bandages to self-powered wheelchairs.

As we seek to automate processes (to address labor shortages and the costs of healthcare) and improve recall response (for patient and healthcare worker safety), it is once again incumbent upon the myriad players in healthcare (both public and private) to come together to explore these issues at the system level. It starts with education, helping providers and suppliers better understand each other's current processes and regulatory requirements and expectations, followed by process mapping to identify where we can potentially eliminate and/or improve how work is done. If the industry (providers, suppliers and solution providers) can come together, we can speak with a single and more authoritative voice to regulators, offering ideas on how to update the regulatory requirements such that they meet the needs of all parties, to ensure the safety and efficacy of not just devices, but of the entire recall process itself. **HPN**

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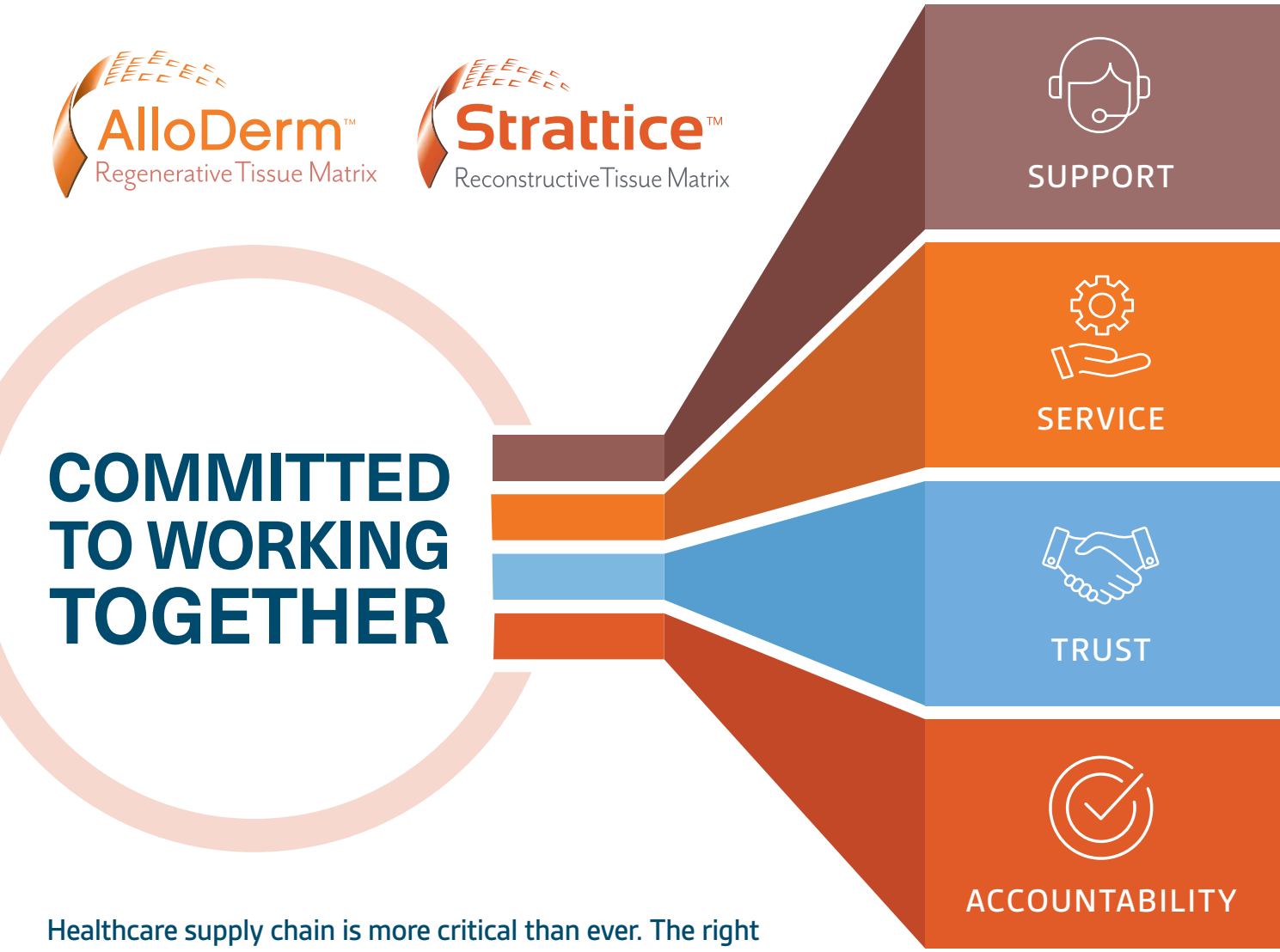

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