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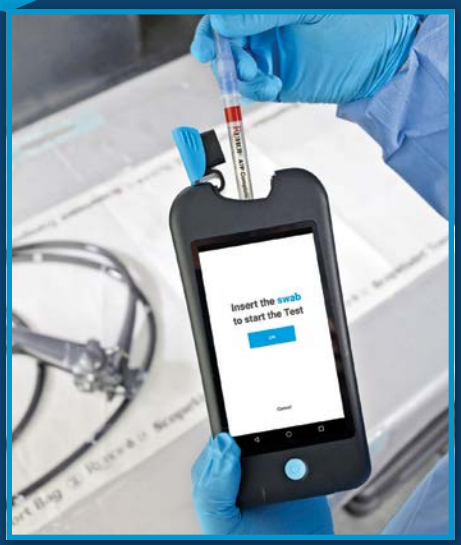

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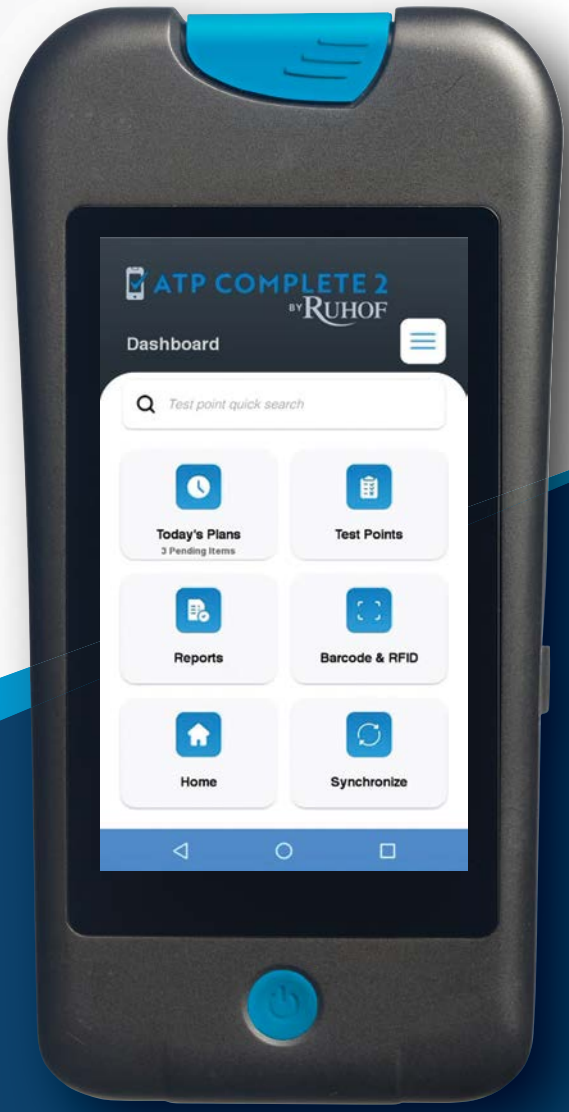

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NEWS

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EDITOR'S NOTE

Janette Wider
Editor-in-Chief

Bake Until Done

My grandmother lived with my family in my parents' home in Connecticut before I was born until she passed away in 1997 when I was 9 years old. Her parents immigrated from Sweden to the United States in the early 1900s. If you have any Swedish lineage, you might suspect that she was raised to know her way around the kitchen when it came to delicious baked goods. My mother held on to her recipes that were stored in an ornate wooden box. The recipes were handwritten, in cursive of course, on notecards in pen or pencil.

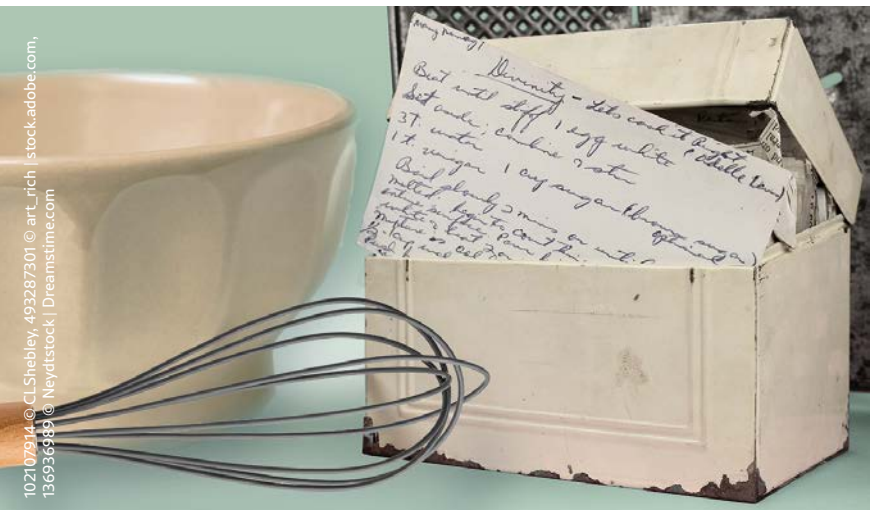
My mother came across a recipe for Toscakaka, which is an almond cake with caramel almonds. (Are you drooling yet?) Of course, the recipe was written in the aforementioned cursive, in pencil and the instructions on the notecard said to preheat the oven to 350 degrees and "bake until done." No mention of how long this might take—20 minutes? 30 minutes? 45 minutes? If you've ever baked, you know that it is imperative that a recipe has a window of time to check to see if your cake, cookie, or pastry is complete, or nearing completion.

In my grandmother's case, I'm sure she knew how long to bake the cake for and didn't realize the instructions she was leaving her family were confusing. I'm guessing she also didn't anticipate that this incident would become a long-running family inside joke that still makes us laugh today. (What were we supposed to do? Put a chair right next to the oven and peek through the window for who knows how long?!)

But in the case of manufacturer's instructions for use (IFU) for sterile processing (SP) professionals, "bake until done" doesn't cut it.

I've received several requests and suggestions from our readers that *Healthcare Purchasing News* should be producing more IFU content online and in print. And it is no wonder why I've received these messages—the lack of standard IFU format and terminology and confusing or incomplete information only adds to the pressures SP departments are facing. This month, we're featuring an article on the SP community's "IFU wish list" and present a top 5 list of most requested improvements. You can read it on page 18.

Now, in case you are wondering, Toscakaka needs to be baked for 35-45 minutes until the top is light golden brown and a cake tester inserted into the center of the cake comes out clean.



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FAST STATS

Artificial Intelligence: Patient Perceptions

Six-in-ten U.S. adults would be uncomfortable with their provider relying on artificial intelligence (AI) to diagnose disease and recommend treatments

38% say AI being used in such a manner would lead to better health outcomes for patients

33% say it would lead to worse outcomes

27% say it wouldn't make a difference in outcomes for patients

40% think the use of AI in health and medicine would reduce mistakes

57% say the use of artificial intelligence would make the patient-provider relationship worse

37% think using AI in health and medicine would make the security of patients' records worse

Source: https://www.pewresearch.org/science/2023/02/22/60-of-americans-would-be-uncomfortable-with-provider-relying-on-ai-in-their-own-health-care/

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NEWSWIRE

Baxter International Completes Successful Pilot Program for Recycling IV Bag Waste

Baxter International Inc. has announced in a Dec. 14, 2023 press release that they were successfully able to recycle used IV bag waste into material for other products, lending it a useful and sustainable second life. In conjunction with Northwestern Medicine in Chicago, the program is the first of its kind to launch in the U.S.

More than six tons of IV bag waste made of polyvinyl chloride (PVC) was "successfully diverted from landfill to be recycled for a useful second life." Baxter is a manufacturer and supplier of the IV bags, which are "ubiquitous in hospital care—particularly single-use plastic containers that provide patients clinically essential solutions including fluids, nutrition and medicines." The normal process for post-use collection for IV bags involves "draining of residual fluid and disposing as waste that ultimately ends up in a landfill," underlining the need for a more sustainable means of disposal. As part of this pilot program, collected IV bags are "transported and inspected to ultimately be recycled into products such as industrial floor mats and protective edging for docks and landscaping." PVC, the plastic material the IV bags in the program were made of, is "one of the most widely used plastic materials in medical products."
Read on: hpnonline.com/53081659

CDC Encourages Flu, COVID-19, RSV Vaccines for Seniors in Care Facilities

According to a Dec. 23, 2023 press release, CDC is reporting that most nursing home residents have not received an updated COVID-19 vaccine or an RSV vaccine. This news comes despite CDC's attempts to stress the importance of the shots because of the greater risk of serious illness in older people who contract the diseases.

CDC stresses that this year [2023] marks the "first time" that "vaccines are available to protect older adults in the United States against all three fall/winter respiratory illnesses: flu, COVID-19, and RSV."

For its part, CDC states in the release that it "regularly monitors all reports and data about the safety and effectiveness of these vaccines" while also convening "bi-weekly calls with long-term care partners to address challenges [and] develop solutions." CDC's own Bridge Access Program "works to improve equitable access to vaccines by connecting manufacturers with long-term care pharmacies to prioritize vaccine distribution." The agency also "distributes a weekly newsletter with respiratory virus resources and information specific to long-term care providers," hosts "speaking engagements and webinars" with information about the vaccines and illnesses, and works with "the Centers for Medicare and Medicaid Services (CMS) to identify solutions to address feedback…around billing and reimbursement challenges which have been a barrier to vaccine administration," which led to CMS issuing "a letter to plans and pharmacy benefit managers to outline the concerns and provide guidance on ways to improve practices."
Read on:www.hpnonline.com/53081563

Pertussis Cases on the Rise in Suffolk County, NY

According to a Dec. 30, 2023 news story from the public health department of Suffolk County in New York, pertussis cases are on the rise in the county, which encompasses about two-thirds of Long Island. Of the 108 reported cases, the vast majority of them are school-aged children and their parents.

Most of the infected individuals are vaccinated, according to the health department, leading their symptoms to be "milder than would be expected in unvaccinated persons." No hospitalizations have been reported as a result of the outbreak thus far. According to Dr. Gregson Pigott, the Suffolk County Health Commissioner, pertussis, "also called whooping cough, can be treated with antibiotics if diagnosed early." He added that "whooping cough can be very serious for infants too young to be vaccinated," which is what led public health officials to sound the alarm about the outbreak in the first place.

Pertussis is a highly contagious respiratory tract infection whose most common symptoms are cough, nasal congestion, and fever. Infants, especially those who are not vaccinated at all or have not completed the whole vaccine

regimen, "are the most likely to have severe disease or have complications such as pauses in breathing, pneumonia, convulsions, diseases affecting the brain, and death." The efficacy of the vaccine makes it the best method to prevent the disease or lessen its severity if contracted, and it is recommended for all children and adults.

Read on: hpnonline.com/53081765

Joint Commission Publishes Special Anniversary Issue

On Jan. 4, The Joint Commission Journal on Quality and Patient Safety (JQPS) published a special 50th anniversary issue on healthcare equity. The announcement, made via a press release, said that the issue has several original articles, review articles, and other reports to assist healthcare organizations to take a system-based approach to achieving health equity.

One study entitled, "Investigating Racial and Ethnic Disparities in Maternal Care at the System Level Using Patient Safety Incident Reports," is featured in the issue and takes a deep drive into the disproportionate rates of mortality and maternal morbidity (SMM) in regard to women and birthing people of color.

Further, "Researchers reviewed incidents reported in the labor and delivery unit (L&D) and the antepartum and postpartum unit (A&P) at a large academic hospital in 2019 and 2020. Deliveries associated with a reported incident were described by race/ethnicity, age group, method of delivery and other process variables. Differences across racial ethnic groups were statistically evaluated."

According to the press release, researchers analyzed 528 incident reports that occurred among:

- Non-Hispanic white (NHW) patients – 43.9%
- Non-Hispanic Black (NHB) patients – 43.2%
- Hispanic patients – 8.9%
- Other patients – 4%

Read on: hpnonline.com/53081865

Atrium Health Joins Medical Device Information Analysis and Sharing Initiative

According to a recent press release, MITRE, an independent third party for the Medical Device Information Analysis and Sharing (MDIAS) Public Private Partnership (PPP), announced the addition of Atrium Health. The Charlotte-based health system joined the voluntary MDIAS collaboration between the Food and Drug Administration (FDA) and stakeholders across the private sector that includes patients, hospital providers, and medical device manufacturers. The collaboration aims to analyze medical-device-related data to improve healthcare outcomes for consumers.

"As an early adopter—and the very first health system to join MDIAS—Atrium Health's active participation will benefit patients, regulators, and the medical device ecosystem," said Kim Warren, vice president of MITRE's Center for Transforming Health, operator of the CMS Alliance to Modernize Healthcare, a federally funded research and development center (Health FFRDC).

Participants of MDIAS share relevant data with MITRE for analysis and development of recommendations for organizational and industry-wide performance improvement.

Read on: hpnonline.com/53081672

Florida's Drug Importation Program Authorized by the FDA

According to a Jan. 5 press release, the U.S. Food and Drug Administration (FDA) authorized Florida's Agency for Health Care Administration's drug importation program under section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This act signifies the first step toward Florida facilitating importation of certain prescription drugs from Canada.

The press release states that "Through this pathway, the FDA may authorize section 804 importation program (SIP) proposals from states or Indian tribes to import certain prescription drugs from Canada if the SIP will significantly reduce the cost to the American consumer without imposing additional risk to public health and safety. President Biden's Executive Order on Promoting Competition in the American Economy directed the FDA to work with states and Indian tribes on these plans to reduce costs to American consumers while supporting public health and safety."

Florida's SIP is authorized for two years from the date the FDA is notified of the first shipment of drugs to be imported. Including other requirements related to this SIP, before drugs can be imported, Florida's Agency for Health Care Administration must:

- Submit additional drug-specific information to the FDA for review and approval
- Ensure that the drugs Florida requests to import have been tested for authenticity and compliance with the FDA-approved drugs' specifications and standards
- Relabel the drugs to be uniform with the FDA-approved labeling

"In addition, Florida's Agency for Health Care Administration must submit a quarterly report to the FDA that includes information about the imported drugs, cost savings and any potential safety and quality issues," the press release adds.

Read on: www.hpnonline.com/53081843

Penn Medicine Researchers Develop New AI Tool

According to a Jan 2. press release from Penn Medicine, a new artificial intelligence (AI) tool can interpret medical images that potentially could allow clinicians to dedicate more time to critical aspects of their job.

The press release states that "The tool, called iStar (Inferring Super-Resolution Tissue Architecture), was developed by researchers at the Perelman School of Medicine at the University of Pennsylvania, who believe they can help clinicians diagnose and better treat cancers that might otherwise go undetected. The imaging technique provides both highly detailed views of individual cells and a broader look of the full spectrum of how people's genes operate, which would allow doctors and researchers to see cancer cells that might otherwise have been virtually invisible. This tool can be used to determine whether safe margins were achieved through cancer surgeries and automatically provide annotation for microscopic images, paving the way for molecular disease diagnosis at that level."

Daiwei "David" Zhang, PhD, a research associate, and Mingyao Li, PhD, a professor of Biostatistics and Digital Pathology, published a paper on the method in *Nature Biotechnology*. HPN

Read on: hpnonline.com/53081760

Supply Chain Strives for Shelf Respect in Storage

by Rick Dana Barlow

The chief supply chain executive at an award-winning integrated delivery network (IDN) in the southeast once quipped that he knows precisely when his team excels at their craft – the phones are silent and the emailboxes empty of clinician complaints about backorders, depleted shelves, empty cubbies and general stockouts.

Similar to the hospitality and retail industries, shelf, storeroom and warehouse space among healthcare providers and suppliers house precious cargo – assets that must be used by clinicians on patients for the organization to be reimbursed by insurance companies and payers.

That's why the skeleton of a storeroom or warehouse must be designed and organized to take advantage of the available footprint and conform to desired workflow.

As a result, configuring and custom-designing shelf and storage space to maximize, if not optimize, access to inventory, ease of stocking and retrieving, tracking, tracing and transporting must start as a science before refinement as art.

Shelf, storage configuration

Eight experts in supply chain inventory and storage management share their recommendations for making shelf and storage space work effectively and efficiently.

Eliminate, use wasted space

Supply chain professionals should start with the big picture, according to Randalyn Harreld, CRCST, CIS, CER, CHL, C.S.P.D.T, C.A.S.S.P.T, BLS, AAS, clinical education manager-US, BeliMed.

"When configuring a storage area, it's important to first have an idea of what inventory you plan to store in that space," she told *Healthcare Purchasing News*. "There are a few common practices that will help streamline this process. Begin by rightsizing the instrumentation trays, sets and items to be stored in the space so there is a reduction in wasted space. Many times, with simple storage racks that offer open shelf space, it can be difficult to utilize all available space. In todays' healthcare world, space is limited and should be used efficiently. Another consideration is to eliminate the need for redundant handling and touching of all sterilized items. Find a way to do an analysis of inventory so your team can determine the end destination of all items processed. This will help you to configure storing those items in a manner that either allows them to be closest to their end destination or easily accessible for care team members or patients. For example, completing a "tracer" of inventory to and from its starting point and ending point over a set period can help you to determine how often an item is used, who uses it, when does it need to be transported and what is the best way to transport it."

Randalyn Harreld

Harreld encourages supply chain pros to pursue intuitive custom designs that enable ergonomically friendly handling, various sizes and configurations and frameworks that eliminate rusting. She further emphasizes the visual element.

"Place the inventory in a systemic manner, whether that be alphabetically, or maybe by specialty or numerical order," she indicated. "Make sure to label each section with signage that is easy to see and visible. During the 'tracer' investigation you can also monitor the number of steps the employees are taking when retrieving these items and place the inventory in the best place possible to make it easily accessible."

Wed design to workflow

Configure a layout that conforms to staff traffic, particularly for equipment, advises Todd Stewart, vice president, Solution Sales, CenTrak.

Todd Stewart

"Healthcare organizations must understand where the need for equipment lies, where it is being used and where tools are being underutilized," Stewart noted. "Technology such as real-time location systems (RTLS) can manage, track, and automate the ebb and flow of logistics and courier operations moving in and out of the warehouse and storage spaces. By implementing an asset management solution in a hospital, staff will know which assets are going to which destinations, how often, when and if they're appropriately cleaned. These details will help an organization develop a storage strategy to inform equipment location, based on proximity to the point of patient care – when and where it is needed most.

"Optimizing storage locations increases cost savings, reduces excess waste, informs rental decisions and can eliminate inefficient movement throughout the facility," he added. "Furthermore, it

can help management teams understand if something is over or under-utilized and determine if there is a need for additional equipment, storage space, etc."

Place footprint in context

Jennifer Nageotte-Elliott

Designing efficient storage and shelf space always starts with a well-thought-out plan and involves a blend of organization, accessibility and optimization, emphasizes Jennifer Nageotte-Elliott, partner, Diamond Storage Solutions.

"At Diamond, we help our customers with pre-planning by focusing on stating intended goals, identifying successful outcomes and building the pathway through support of 3-D renderings and visualization of design layouts with our staged products," Nageotte-Elliott noted. She highlights seven strategies and tactics her firm uses to stress best practices for healthcare environments.

- Material construction. "Our products are constructed with materials that limit dust attraction and offer ventilation to contents being stored, driving cleanliness and infection prevention support," she said.
- Ease in installation. "Our shelving solutions can be installed in less than 13 minutes!"
- Regulatory requirements. "Ensure supplies are stored away from sprinkler deflectors, off the floor, away from outside walls, etc."
- Safety and ergonomics. "Store liquids and heavy items on lower or bottom shelves, keep aisles clear of clutter to prevent tripping, stage products close to point of use and frequently accessed items at waist level for easy reach."
- Operational efficiencies. "Consider categorization and labeling, implement zoning strategies, incorporate signage or color coding to drive visual management, develop clear [standard operating procedures] for stocking, organizing, and retrieving inventory, arrange items based on their frequency of use and expiration dates (FIFO/LIFO)."
- Adaptability. "Incorporate flexibility in storage design to ensure readiness to address any ongoing and future surges or emergencies."
- Ask your team! "Gather feedback from staff involved in the inventory process as they might have insights into optimizing the space based on their day-to-day experiences."

Block and tackle

Ian Loper

Ian Loper, vice president, DSI, offers a football motif for shelving and storage design.

"Storage system mobility, product adjustability, enhanced labeling, and custom designing a department's workflow through the lens of a storage consultant are all keys to optimizing the throughput in a department's overall storage space," Loper said. "With supplies constantly changing, having the ability to adjust the bin, compartment size or shelf location is key to maximizing the space. It's like the game of football. As they say, it's a game of inches. One cubic inch lost in one spot adds up to hundreds of cubic feet lost throughout a department. Every inch counts in the hospital, especially in the OR and Sterile Processing departments. If you can't relate to the football analogy, then maybe you can relate to the video game Tetris. You want a storage system in your department that is good at the game of Tetris, knocking out solid lines one after the other."

Go out on a limn

Joseph Hagedorn

For Joseph Hagedorn, senior manager, Supply Chain Optimization, Shelving & Storage, Medline, supply chain pros should embrace their inner artist.

"The first recommended step is to draw out the room and layout racking to maximize square footage while ensuring that the drawing is to scale. Also note where light fixtures and fire sprinkler heads are to align with isle space," he said. "The most effective way to produce a 2-bin Kanban set-up is comprising racks three feet in length and two feet wide. Casters give each storage rack mobility for cleaning and emergencies, such as water leaks, to move the racks.

"Open access or freestanding designs allow multiple staff members to be working in the same area at the same time to put up products, pull items for distribution or case pick and put away any returning items," Hagedorn continued. "Adding as many shelves as possible will minimize potential lost vertical space in between shelves and combat the issue of dead space. Creating these spaces is all about creating a flow that is best for efficiency, so it is important to consider that from the beginning. High-density storage systems that are on a track system can sometimes aid in condensing the storage of items that aren't accessed frequently. When the sliding racks are compressed together you lose visibility to PAR levels and access to product is limited to one staff member. Some room designs benefit from a blended mix of both traditional and high-density storage systems."

Hagedorn further recommends healthcare organizations standardize on grocery/retail shelf strategies for shelf layout. "Find the areas that are most easily accessible and add most frequently used and critical items there," he noted. "The items that are used the least should be placed in areas that are less accessible. The guidelines for this process should continue to be followed until all the shelves are filled and products are placed. Size, category and other compliance rules such as agencies, local/state/regional rules, and infection prevention should also be considered through this process, ensuring your set up fulfills guidelines. Having this standardization ensures all team members touching the product from supply chain to clinical have both efficiency in the room and ergonomic best practice by reducing the amount of movement needed to manage and use supplies."

Healthcare organizations should work with the right company to design and implement shelving and storage operations, according to Hagedorn. "Working with an experienced partner/supplier that has a full portfolio of storage solutions, implementation support and design support can help administer day to day support staff to see how the storage systems will fit and look within the given space," he said. "Medline has recently offered customers the ability to see the 3-D modeled drawings as a photographic render image. This new tool is utilized when project leaders present the overall goals and concepts of a design to administration and key stakeholders."

Standardize to prioritize

Derek Naylor

Derek Naylor, director, Supply Chain Optimization and Technology, U.S. Medical Products and Distribution, Cardinal Health, concurs about standardization as a viable and valuable strategy.

"I've seen less customization and more standardization play the biggest part in a successful storage and inventory strategy," Naylor insisted. "When creating a warehouse that is too customized, the records alignment and target utilization requirements are more challenging. Having a

standard profile strategy and matching inventory parameters, such as cube and ti-hi [the number of boxes/cartons stored on a tier and the number of layers high they will be stacked on a pallet], can maximize utilization and flexibility across a multitude of items and [stock-keeping unit] profiles.

"Additionally, the standardized warehouse physical slot can enable more flexibility with any inventory slotting optimization software, that would facilitate a more optimized stocking and retrieving strategy based on SKU velocities, reducing waste in the form of excess travel," he continued. "Finally, having a precise single location per SKU versus multiple SKUs being stored on a single shelf location enables more precise tracking and tracing down to the pallet level. Having multiple SKUs per location can increase quality defects without proper countermeasures such as check digits/strings, supplemental pictures, bar-code or RFID scanning."

Link workflow steps

Kurt Baker

Kurt Baker, consulting director, Vizient, refers to a fundamental element of supply chain for shelving and storage connections – the link between workflow steps.

"Each warehouse workflow must be identified along with an understanding of how each warehouse process relates to the other," Baker said. "Comprehending how inventory flows from the receiving dock, to put-away, to shipping is crucial to the design and configuration of storage space. The placement of shelving, pallet racks and conveyors, along with workflows and traffic patterns, affects the ability to use the available space."

Options abound, Baker adds. "Vertical space for storing bulk items should be used when available. Vertical storage is accomplished with selective pallet racks, pallet flow racks and drive-in racking, etc. Wire shelving is the most efficient way to store logical unit-of-measure items. It is adjustable and can help maximize the use of available storage capacity. Gravity-flow racking, which as the name suggests, relies on gravity to load, organize and retrieve items, should be considered for high-volume items with expiration dates to help with ease of stocking and to ensure first-in-first-out rotation is followed. Product slotting of fast-moving/high-volume items in the storage area is another method to increase efficiency and ease of shipping."

Organize to size

Tom Redding

Adapting a retail mindset can prove beneficial to healthcare providers for enabling access to necessary products, observes Tom Redding, senior managing director, Healthcare, St. Onge Co.

"One of the most useful strategies to maximize storage space is to stock similar products together, which will most likely require similar storage bin/component sizes and allow the available storage space to be utilized effectively," he said. "Having multiple bin/component sizes together will impact storage utilization. There is a balancing act of grouping products together to maximize storage utilization while also accommodating clinical preference for products that may be used together but may require different sizes of storage bins."

Redding notes the many different types of storage alternatives on the market and emphasizes the importance for hospitals to understand their available storage footprint versus the frequency of access. "Too often we see hospitals that focus on minimizing their storage footprint to turn around and waste value clinical labor because there is an inventory access pinch point (e.g., using a high-density storage option when there is a high frequency of accessing the same inventory location will impact labor utilization)," he noted. "Selecting the right storage solution requires a thoughtful approach to understand the availability of storage, velocity of inventory, storage utilization and labor utilization to access the inventory – either from the 'clinical picking' or 'restocking' point of view."

What providers want

Based on their interaction with provider customers, supply chain product and service experts see a range of attributes, benefits and features of shelving and storage equipment favored within hospital storerooms and warehouses for which supply chain pros request.

Enable flexibility, variation

Providers simply want to control their options and pivot when necessary, observes BeliMed's Harreld.

"When looking at the variety of storage options out there in the industry today, some of the most important benefits and criteria that drives their decision making and selection process is the ability to custom-design the layout and structure in various ways throughout their department," she said. "Not having a one-size-fits-all option is critical to the success of any department. Another important factor is the ability to accommodate all sizes of inventory – from shelves that can hold one tray of any weight from one pound to 25 pounds and be sturdy enough to last, and durability that can withstand the heavy wear and tear that comes with use. Each lane and aisle and row much be customized to hold inventory for that set configuration. Another factor that has helped many departments be successful is the unique labeling, options that are visible and color-coded so they can accommodate many different specialties and items and see from far distances clearly and legibly."

Optimize available space

Because space can be a premium, managing it fully makes sense, urges DSI's Loper.

"Unequivocally, the biggest benefit to innovative shelving is its ability to save space," he noted. "Ever heard of the domino effect? When one tile falls, they all fall. When a shelving system can save a department up to 40% to 50% floor space, this reduces the time spent searching for the inventory. Less time equals better patient care with better outcomes. Saved space also saves the hospital money by removing the need to renovate or move walls to create more space for supplies, equipment, etc. Most hospitals are busting at the seams and can't find ways to create new space without a renovation or new construction. This bottleneck becomes very costly. The positive domino effect with space savings is reduced cost, quicker retrieval, better organization, increased employee safety, better patient outcomes and a boost to the hospital's bottom line."

Cleanliness matters

Cleanliness is by far the most important benefit to shelving and storage design, according to Medline's Hagedorn.

"In a healthcare setting, avoiding unwanted infections and any potential issues that stem from it is of high priority across the continuum," he observed. "Proper storage room setups create an organized and clean environment allowing for efficiency and less physical touching of each product. Second to cleanliness would be the ability to alter the storage medium when supply mix changes. As we have seen through supply chain disruptions, there are constant changes to the items that will be stored in the room. Thus, being able to alter the height of shelves, location of items due to increased usage, and/or the ability to move and reposition racking is a vital benefit when it comes to creating

a storeroom that has the ability to change with the products it is housing. Along with the ability to alter storage on a need base, health systems traditionally want to maximize the space and utility of a department or room. Creating an individualized and customized storage space not only allows it to change with your need but also maximizes the amount of space that is given. It is important that every square inch of space be used to the fullest to allow the best care."

Squaring up the cube

Cardinal Health's Naylor reminds supply chain pros not to overlook quality and service-level issues.

"For customers I've interacted with, they often seek to enable key and contractual obligations like service level agreement (SLA) and quality," he noted. "Having shelving and storage can help maximize the cube within the warehouse, enabling our operations team to meet any contractual obligations around inventory days on hand (DOH). The more density, the more DOH we can store without negatively impacting internal flow or inventory peaks. Additionally, properly segmenting shelving into SKU-specific locations can enable greater inventory accuracy, reducing potential errors. Both attributes help us ensure we can hold sufficient on-hand quantities to support customer demand as well as supply the highest quality standards for inventory accuracy. Our customers expect products on time, with the right SKUs, and in the right quantities—so a warehouse that is flexible with system driven optimization in place helps fulfill the foundation of our contractual obligations and enables optimized picking and fulfillment strategies."

Flex and control

Space adaptability through flexible sizing for storage can give providers desired inventory control, St. Onge's Redding insists.

"The most important attribute for shelving is its customization capability to provide multiple storage bins sizes and the flexibility to quickly customize the vertical space within a shelving unit to maximize the use of available space," he said. "Additionally, having the option to control access while also providing internal customization has further benefits for the right mix of inventory." HPN

Searching for shelf, space upgraders

Just about everyone probably has an idea or two on how to improve a product or service, shelving and storage being no exception. So *Healthcare Purchasing News* asked supply chain product and service experts for their notions on how they might improve shelving and storage design, functionality, structure or utility during the next decade and why their suggestions may matter. *HPN* cautioned them against revealing any production pipeline or trade secrets to concentrate on creative expression instead. Here's what they shared.

"One important consideration in a season of change is the safety factor for shelving requires robust mechanical fastening, but a strong enough quick-release system for re-configuring would be helpful. From a technology perspective, proliferation of pick to light (a system that uses lights on racks or shelves to indicate pick locations) throughout an entire warehouse could help to improve accuracy of picking. There are more and more creative periphery technologies emerging such as augmented reality (AR) that I see potentially impacting general activity in a warehouse in the future. However, the more a general/standard warehouse can support emerging technologies like autonomous mobile robots (AMR)/autonomous case-handling robots (ACR) and goods-to-person (GTP) from the start can prevent obsolescence and prepare for future capabilities. I see minimizing the change and facility impact associated technology implementation will be a huge future opportunity. A technology that can best leverage existing infrastructure but facilitate greater storage density and throughput specific to fulfillment channels would be exciting to see."

—Derek Naylor, Cardinal Health

"If I could make one improvement to the shelving and storage design, it would include an easy-to-clean function or process. One of the most difficult things is keeping our storage organized, easy to navigate in such a high-paced and highly rigorous environment. We are also tasked with keeping it clean so we can house our inventory safely for patients. Most often, especially with the highly technical storage solutions, there are crevices and small areas that hold dust, dirt and debris and limited cleaning guidance if any. I would like to see materials used that are easy to clean, durable and provide instructions and recommendations on the cleaning protocols for these devices we rely on so heavily. Maybe even a built in HEPA filter system that keeps the internal components dust-free, or a hand-held cleaning device or tool to help us maintain the life of the units."

—Randalyn Harreld, BeliMed

"I can imagine the use of artificial intelligence (AI) to support inventory optimization by predicting future demand, storage space adjustments, and safety enhancements."

—Jennifer Nageotte-Elliott, Diamond Storage Solutions

"Through the years, I have noticed that storage mediums in healthcare have stayed pretty consistent over time due heavily to controlling costs as it is a non-value-added expenditure. I would project that any advancements in the storage medium space would need to come with a serious value-added ROI. To dream, I would say something that has some voice-activated AI capabilities where a nurse or clinical staff member could say what they need, then a robot would pull that item and deliver it to the room they were in and also documenting the item on the patient chart. That would be pretty life-changing in this space. I think this could serve as an important function in efficiency, accuracy and ensuring that storerooms are consistently being stocked at the appropriate level. With anything, there is going to be human error, and in healthcare every second counts. This could save clinical staff time when trying to find a product or ensuring that the product is the correct version of the one they are looking to use."

—Joseph Hagedorn, Medline

"Although wire shelving is relatively easy to adjust, I would like to see the ability to adjust the shelves without having to fully remove the shelves from the poles. With the current design, clips that hold the shelves in place must be repositioned after the shelf is removed. Once the clips are repositioned, the shelf is returned to the pole and secured to the clips. If the clips were built into the corners of the shelving, the shelf could be moved in one step."

—Kurt Baker, Vizient

"One improvement I would make to shelving and storage design is to incorporate lighting solutions and voice command technology for clinical and materials management staff to quickly identify where certain products are stocked. Clinical and materials management staff spend a considerable amount of time searching for products within a supply room. The ability to use voice commands and quickly illuminate a product bin could be a tremendous improvement over the existing approach of labeling and color-coding."

—Tom Redding, St. Onge Co.

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Surgical Suite Turnover: Best Practices from Gundersen Health

by Janette Wider

According to an article published by AORN in 2022 entitled "Speed Up Room Turnovers," "It's important to have a standardized method of communication to alert team members that an OR is ready to be cleaned and prepped for the next case. When the surgery is finished and the patient is waking up, we call out 'status two.' ("Status one" signifies at the start of the case that the patient is in the room and being anesthetized and "status three" is used when the patient is ready to be transported to recovery.) The status two call notifies our perioperative tech and any available staff members that the patient will be going to recovery, and we will need all hands-on deck to help clean and turn over the room.

"Establishing a methodical approach to room cleaning with clearly defined steps — and educating every staff member on the process — will help your team turn over a room efficiently and correctly. Upon completion of the surgery, task a surgical tech with immediately taking the dirty instruments to the decontamination area while other members of the surgical team stay in the room and start cleaning. After a nurse takes the patient to recovery, they should also assist in the turnover process upon returning.

"Clean the OR from the outside in, from the cleanest to the dirtiest areas. This system also works well because no one is getting in each other's way or cleaning the same surface twice and wasting time. It also lets any staff member who comes in and asks if they can help to know exactly where the team is in the room turnover process and what still needs to be done."

Production and Operations Management Society (POMS) published a paper entitled, *Maximizing Operating Room Turnover Efficiency via Process Mapping and Critical Path Modeling*, by Drew Stapleton, Ph.D. University of Wisconsin La Crosse, and Nada Ghandour, MBA, MD Gundersen-Lutheran Health Systems.

The paper states "Operating room (OR) turnover between surgical cases involves a multitude of variables and individuals that renders tackling the subject quite complex and multifaceted. Creating OR turnover efficiencies is extremely important as OR turnover impacts a number of performance metrics and analytics. For surgeons the time spent transitioning from one case to the next is considered wasted and non-productive and is often the cause of surgeons' dissatisfaction and complaints. For patients, the time spent waiting for their surgery is often stressful and nerve-racking during which they could be in pain or in serious morbidity. For hospitals' administration, OR turnover is non-value-added and non-productive since the time spent transitioning OR is most often not reimbursed nor allocated on a shared cost basis which negatively affects

return on investment (ROI) and overall productivity. In an era of decreasin g reimbursement and the resultant nonescalating pressures to improve efficiency throughout, hospital OR administrators are oftentimes lackadaisical in their effort to improve OR turnover."

Healthcare Purchasing News wanted to get an update on this topic as we enter 2024, marking four years since the COVID-19 pandemic began. The healthcare system fought the challenges associated with the pandemic, but it should come as no surprise that volume surgical procedures slowed down when COVID was at its highest.

La Cross, Wisc.-based Gundersen Health System (Gundersen Health) is a comprehensive non-profit health system. The system includes multi-specialty group medical practices, a teaching hospital, regional community clinics, affiliate hospitals and clinics, behavioral health services, vision centers, pharmacies, and air and ground ambulances.

Leah Schild MSN, RN, is the clinical operations director, Surgery & Procedures and Dept. of Anesthesiology for Gundersen Health. *Healthcare Purchasing News* connected with Schild's team about surgical suite turnover challenges, best practices, and more.

What has Gundersen Health seen in terms of successes or wins in the last 12-28 months?

Alysha Esteves Del Rosario, MSN, RN, professional development nurse, Main OR: We have performed over 100 more surgical procedures in the year 2023 compared to 2022. This highlights the increase in access to care for our communities by introducing service line efficiency—surgery, surgical blocks, and also decreasing patient wait times for surgery.

Carlye Hart, RN, professional development nurse, Gundersen Department of Nursing: We've had a really large increase in cases, especially in OSC [outpatient surgery center] and in the main OR. And really just with the increase in volumes, I think our turnover rate has been consistent along with our outcomes in patient satisfaction—we look at that factor too. I think with this high-volume increase, we really stayed consistent with the standard of care we offer.

Tanya Brueggen, DNP, MBA, RN clinical manager, Integrated Platform and Surgery: We have dramatically increased our first case on time starts as well. About a year ago, we were approximately 65% to 68% of first case on time starts, whereas now, between the main OR and outpatient surgery center, we are consistently approximately 75% on time.

What has recently changed regarding surgical suite turnover? Anything to note pre-COVID vs. post-COVID?

Esteves Del Rosario: Pre-COVID times and during COVID: substitutions and cleaning supplies, which had affected the consistency for IFUs. Also, inconsistent surgical volume during COVID times affected our staff knowledge, so there was not consistent staff being assigned to the perioperative cleaning areas.

Hart: I think post-COVID, having unpredictable staffing shortages, with people being out with COVID and staff having to adapt with the number of help [staff] they may have for that day. We're feeling those effects [now], but definitely during COVID it made staff have to be adaptable to those changes, but that's what we're seeing now post-COVID is just the inconsistency in staffing.

Brueggen: Certainly, the staff turnover was probably the biggest impact that we had during COVID. At one point we were up to 12 travelers in the operating room and main OR. We are now down to zero. So, we've had an impressive turnaround and stabilization in our staffing workforce. We are now rebuilding that and trying to level set, especially in terms of turnover and what the expectations are.

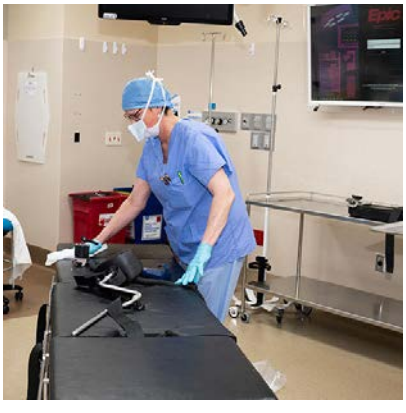
In general, what are the biggest pain points when it comes to surgical suite turnover?

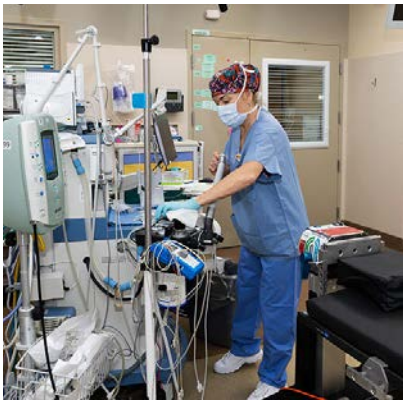
Esteves Del Rosario: The inconsistency of our environmental assist staff being assigned to the perioperative areas. Because of that inconsistency, not all of them are on the same page regarding our perioperative cleaning workflows, which did affect our education and workflow in general.

Another pain point related to turnover is all of the different equipment as our operating rooms grow. There is much more equipment inside each of our operating room suites, so to be able to build that knowledge base with the staff that are doing those turnovers to understand which cleaning products they should be using based on the type of equipment they're cleaning has been a challenge.

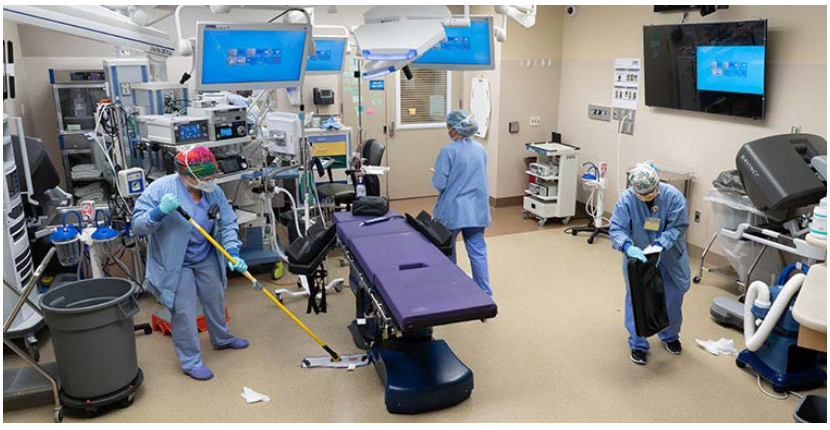
Any tips on these pain points?

Hart: First, continuously reevaluating our new procedures, new equipment,





All photos courtesy Gundersen Health



and then updating our educational materials and resources for staff helps with those pain points. That is, making sure that staff has the most up to date IFUs, so they know kind of what's going on in our ORs. Continuing to reevaluate and update our resources for staff has helped.

Esteves Del Rosario: For us, with the number of new hires joining our department, it's being consistent with the education that we share with each staff member and ensuring that they follow through with the same processes and workflows.

What kind of education do nurses get in school regarding this?

Brueggen: I started with my associate degree, all the way up to my doctorate degree. And I can tell you I don't believe I received any education as it relates to cleaning and disinfecting specifically within an operating room. And so, this is all very much trained on the job. We really rely on our educators, as well as our quality folks to be providing us data on how we're doing in terms of turnover cleaning and terminal cleaning. Our quality folks do testing on a monthly basis looking at ATP testing, and that provides us with a measure that helps us determine how well we are disinfecting surfaces. Based off of that, we are able to do some targeted action plans with our teams. So, figuring out where are those areas that we're missing, and then really focusing and reminding that team to be concentrating on those areas.

Esteves Del Rosario: In addition, as I recall during my nursing program, there was absolutely no information in regard to perioperative cleaning. We do have students that do a shadow within our operative departments and the focus on that is mostly on the actual surgical procedure and learning about the roles, each role within the OR. They are only present during the surgical procedure and do not see anything in regard to turnover time and opening for a new surgical case.

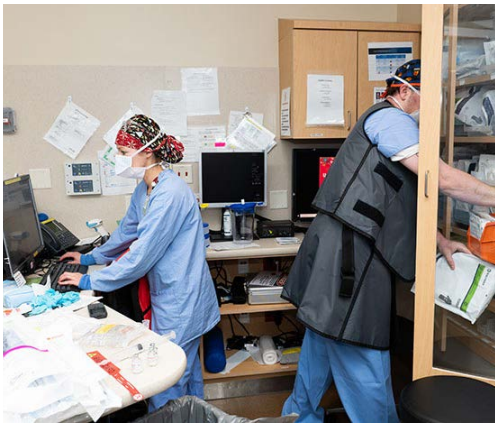
What are some surgical suite turnover best practices that our audience should be aware of?

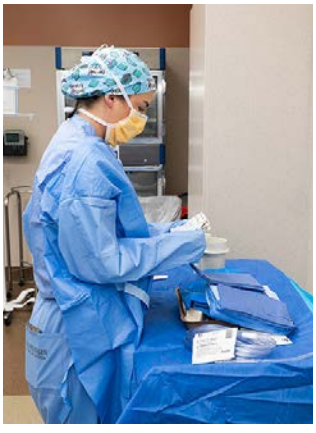
Brueggen: We follow AORN's [Association of periOperative Registered Nurses] guidelines. We also really focus on a team approach to understanding who's doing what when it comes to turnover cleaning. We try to minimize it to keep it to three folks because if you get more than that it gets to be hard to understand who has cleaned what and then there ends up being duplication or things ended up getting missed. And so really setting the expectations of who's doing what during that turnover cleaning so everybody knows their role to help make it more efficient. We have historically compared this process to a racetrack. When the car pulls into the pit stop and you have your pit crew, everybody knows the role. It's quite efficient. It's done well. And then that race car goes back out on the track.

Esteves Del Rosario: One of the main focuses for perioperative cleaning for our surgical procedures was developing competencies for all our perioperative areas and ensuring that the education and the resources provided were all the same or basically on the same page, therefore being consistent in training and keeping up the workflows for our ORs.

What does the next 5-10 years look like in this space? Any innovations to note?

Brueggen: I am not sure what is possible out there in terms of increasing cleaning and disinfection for operating rooms, but in terms of turnover there are a lot of different products coming out to help increase room turnover. So, an example would be the sterile bubble pack. Instead of opening multiple pans for a total joint case — we typically have a lot of pans involved in those cases — there's a kind that comes in a bubble so you would open it up, take the lid off, and all of the pans would be right there. So that saves a ton of time in terms of the amount of pans that the circulator and scrubs are having to open prior to the case getting started. That type of advancement is definitely going to help increase turnover. HPN





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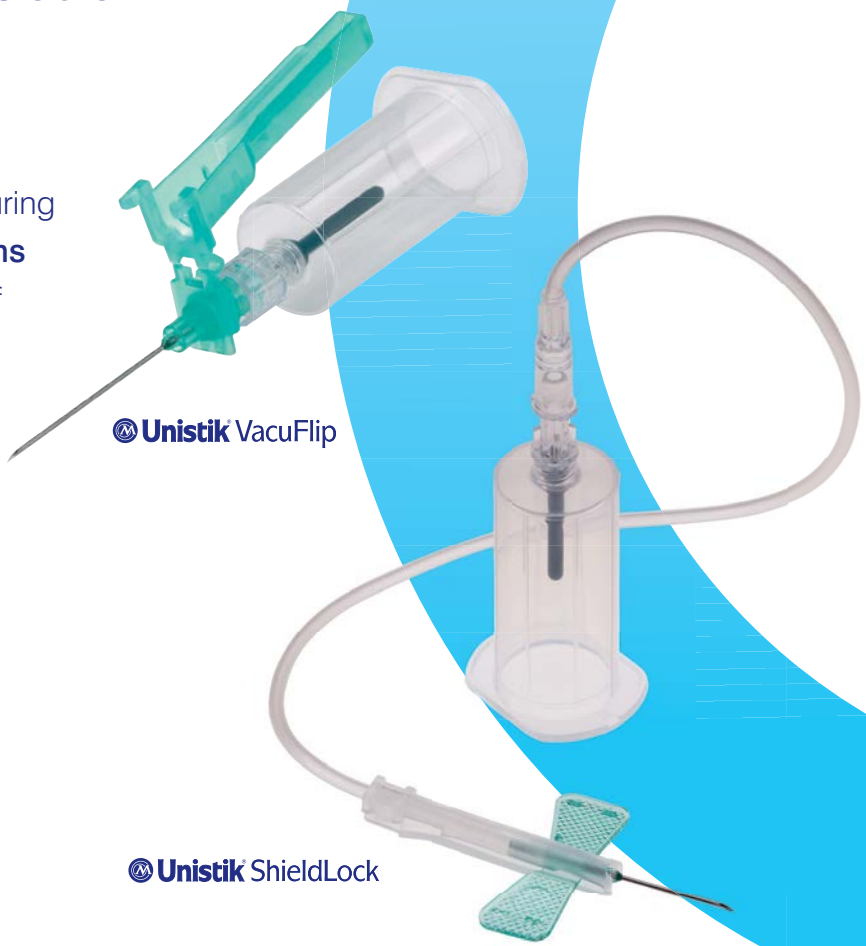

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Nursing's Role in Reducing Wrong-Surgery Incidence

by Mark Hagland

In April 2023, the Joint Commission published its "Sentinel Event Data 2022 Annual Review." Leaders of patient care organizations rely on this annual report for an understanding of the U.S. healthcare system-wide sentinel events that are the most significant. And while "wrong surgery" is not one of the most common sentinel events that take place in U.S. hospitals every year, when it happens, the impact is potentially devastating and even life-threatening. In its report, the Joint Commission noted that consistent with previous reporting patterns, most reported sentinel events in 2022 occurred in the hospital settings (88 percent). Leading event types associated with the hospital setting included falls (45 percent), unintended retention of foreign object (7 percent), and wrong surgeries (6 percent). In the behavioral health setting, leading event types were patient suicide (23 percent), falls (18 percent), and delays in treatment (16 percent). Fires (e.g., smoking while on oxygen) (43 percent) and patient falls (20 percent) were leading event types in the home care setting. Wrong surgeries (25 percent), patient falls (22 percent), and fires (16 percent) were leading event types in the ambulatory care setting, and patient falls (43 percent) and perinatal events (14 percent) were leading event types in the critical access hospital setting.

The report defines "wrong surgery" as a "surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for a patient regardless of the type of procedure or the magnitude of the outcome."

Of the 85 wrong surgeries documented by the Joint Commission in 2022 (compared with 119 in 2021 and 94 in 2020), 65 percent involved the wrong site; 17 percent involved the wrong procedure; and 9 percent each involved the wrong implant or the wrong patient.

An important backgrounder published in September 2019 by the federal Agency for Healthcare Research and Quality (AHRQ), through its Patient Safety Network collection of primers, under the title "Wrong-Site, Wrong-Procedure, and Wrong-Patient Surgery," notes that while much publicity has been given to these high-profile cases of WSPEs [wrong-site, wrong-procedure, wrong-patient errors], these errors are in fact relatively rare. A seminal study estimated that such errors occur in approximately 1 of 112,000 surgical procedures, infrequent enough that an individual hospital would only experience one such error every 5–10 years. However, this estimate only included procedures performed in the operating room; if procedures performed in other settings (for example, ambulatory surgery or interventional radiology) are included, the rate of such errors may be significantly higher. One study using Veterans Affairs data found that fully half of WSPEs occurred during procedures outside of the operating room."

Importantly, the AHRQ primer notes that while "early efforts to prevent WSPEs focused on developing redundant mechanisms for identifying the correct site, procedure, and patient, such as 'sign your site' initiatives, that instructed surgeons to mark the operative site in an unambiguous fashion…it soon became clear that even this seemingly simple intervention was problematic. An analysis of the United Kingdom's efforts to prevent WSPEs found that, although dissemination of a site-marking protocol did increase use of preoperative site marking, implementation and adherence to the protocol differed significantly across surgical specialties and hospitals, and many clinicians voiced concerns about unintended consequences of the protocol. In some cases, there was even confusion over whether the marked site indicates the area to be operated on, or the area to be avoided. Site marking remains a core component of The Joint Commission's Universal Protocol to prevent WSPEs."

In fact, the primer emphasizes, "root cause analyses of WSPEs consistently reveal communication issues as a prominent

underlying factor. The concept of the surgical timeout—a planned pause before beginning the procedure in order to review important aspects of the procedure with all involved personnel—was developed to improve communication in the operating room and prevent WSPEs. The Universal Protocol also specifies use of a timeout prior to all procedures," and the protocol can be applied to all invasive procedures.

Per all this, the Denver-based Association of periOperative Registered Nurses (AORN) provides its members with a wealth of informational resources on best patient-safety practices in surgery on its website. Indeed, AORN offers its members an entire page of links containing information on Wrong Site Surgery.

Per all the latest advice from leading entities like AORN, Mark Hagland, Editor-in-Chief of *Healthcare Innovation* and a Contributing Editor to *Healthcare Purchasing News,* recently interviewed Lisa Spruce, DNP, RN, CNS-CP, CNOR, ACNS, ACNP, FAAN, senior director of evidence-based perioperative Practice at AORN, about this important topic. Below are excerpts from that interview.

Starting from a 40,000-feet-up view, what is AORN's overall strategic objective in providing alerts to its members to educate them on wrong-patient and wrong-site surgery?

Lisa Spruce

AORN educates our members regarding the importance of preventing wrong-site surgery through our guideline on Team Communication, which includes establishing a culture of safety and communication tools and the accompanying guideline essential resources. In addition, AORN has an educational toolkit on wrong-site surgery and every year AORN celebrates National Time Out Day on June 14th, when we provide a day where all perioperative teams can review the ways they keep patients safe in every procedure.

Are rates of patient safety errors in this area declining at an adequate pace?

Wrong-site surgery was the third most common sentinel event from 2018-2020; in 2021, it was the second most common; and in 2022, it was the fourth most common. However, these events are voluntarily reported, so actual numbers could be much higher. Of course, even one wrong-site surgery is tragic for patients which is why we aim for zero events.

What do you see as the biggest challenges to achieving near-zero levels of errors in this area?

The perioperative environment is stressful and fast paced, and perioperative team members are under increasing pressure from numerous demands and complex functions that lend themselves to error. The operating room is a high-risk socio-technical environment with various professionals working in proximity. Effective team communication in the perioperative and procedural environment is the foundation of optimal patient outcomes. Perioperative RNs play a crucial role in facilitating communication among the interdisciplinary team. Research has demonstrated that communication breakdowns in the perioperative setting are a factor in wrong-site surgery. Challenges to adequate team communication and empowerment to speak up are two important issues that need to be addressed.

What is the role of the bedside nurse in reducing and eliminating wrong-patient and wrong-site surgeries?

Reducing and eliminating wrong-site surgeries is really a function of the entire team—not one individual—so it begins with creating a patient safety culture and encouraging individual members of perioperative teams to actively engage in and support the culture. Respecting each other, encouraging honesty, and encouraging nurses to speak up is extremely important for patient safety. Nurses can take the lead on the time out process to conduct a final check that the correct patient, correct site, and correct procedure are identified. This is the time for all perioperative team members to speak up and address any concerns or problems that would affect the safety of the patient.

Can technology help? If so, how?

We recommend the use of a standardized surgical safety checklist during the time out process to improve communication and reduce the potential for errors in perioperative and procedural settings. Using technology to implement the checklist is a great tool to not forget anything critical that is included in the surgical safety checklist. This can be in the form of whiteboards, electronic whiteboards, computerized SSCs, or other emerging technology.

Early efforts to reduce wrong-site surgeries focused on processes such as marking the patient's body prior to incision. Did such efforts yield positive results?

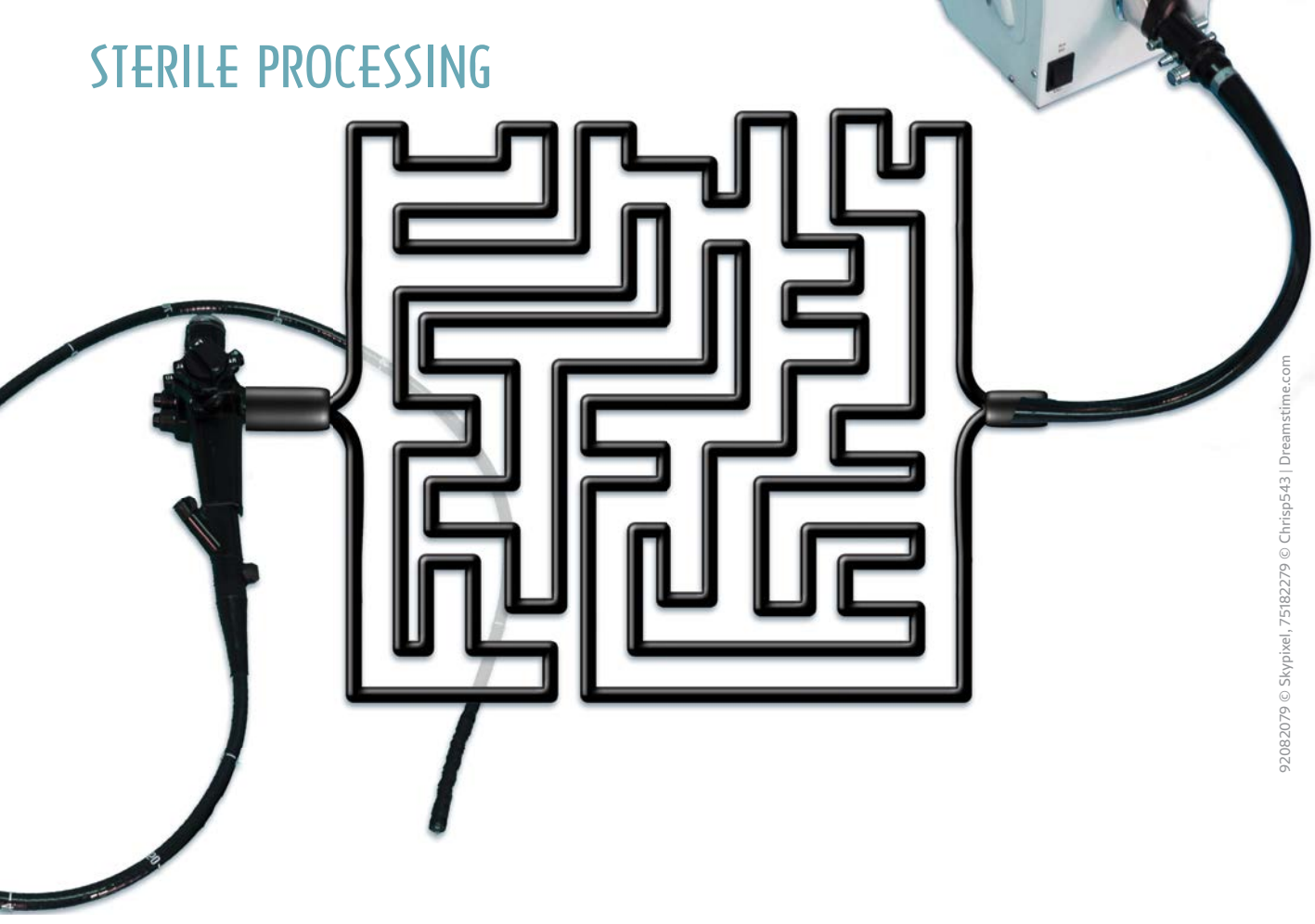
Yes, focusing on these processes has helped in nationwide efforts to decrease wrong-site surgeries and many facilities across the country that are using standardized processes do not experience wrong-site surgeries. The use of standardization, checklists, and protocols mitigates the human factor risk.

AHRQ has reported that communication breakdowns are actually the most common core cause of wrong-site (and wrong-patient and wrong-procedure) surgeries. What are your thoughts on that finding?

I agree it is one of the most common causes. During our writing of AORN's guideline for Team Communication we also reported that communication failure and incomplete or missing patient information are the most common contributors to sentinel events such as wrong-site surgery.

How can nursing managers and leaders improve processes?

A culture of safety begins and is led by perioperative leaders. They are of vital importance to set that expectation and to lead the process of standardizing safety processes that are based on evidence. Leaders begin by assessing their culture of safety by surveying their teams on topics such as teamwork, safety climate, job satisfaction, stress recognition, and working conditions that could contribute to an unsafe environment. After they have an idea of the measurement of safety culture in their organization, then they can begin to make improvements such as promoting mutual respect; creating a trusting environment with open communication; establishing a safe platform to report errors, near misses, unsafe conditions, and intimidating behaviors; as well as establishing patient safety goals and implementing communication tools. HPN



IFU Confusion

Here's what sterile processing professionals have on their manufacturer IFU wish lists

by Kara Nadeau

Sterile processing (SP) professionals must abide by manufacturer instructions for use (IFU) when reprocessing instruments and devices – but today that's no easy task. Lack of a standard IFU format and terminology, confusing or incomplete information, **and** even differing font from IFU to IFU adds to the already tremendous challenges facing SP teams as they work to complete reprocessing steps efficiently, effectively, and safely.

Industry stakeholders have attempted to drive IFU standardization. For example, the Association for the Advancement of Medical Instrumentation (AAMI) TIR12:2020 working group convened end users, manufacturers, and testing labs to review IFU commonalities and differences. Based on their work, they published TIR12:2020, a guide to help manufacturers standardize their IFUs, in September 2020. Despite their efforts, SP professionals are still struggling with IFU inconsistencies.

HPN reached out to the SP community and asked the professionals what is on their manufacturer IFU wish list. Based on their responses, we present a "Top 5 List" of requ-ested improvements.

Additionally, we contacted these IFU industry thought leaders in the SP field for their perspectives on the road ahead and progress made to date: Healthcare Sterile Processing Association (HSPA) President Monique L. Jelks, BA, MSOL, CRCST; HSPA Vice President of Strategic Initiatives and AAMI Fellow Damien Berg; and Certified ISO 9001 Lead Auditor, DNV, Lisa McKown, DrPHc, MBA, CRCST, CIS, CHL, MBTI.

Top 5 IFU improvement requests

1. Standardization

Unsurprisingly, requests for IFU standardization topped the list, including standardized formatting, language, and font across manufacturers. Multiple SP professionals pointed to data safety sheets (SDS) as a model for IFU standardization.

"There should be a 'model' IFU so that they are all compiled in the same form, in particular for the decontamination instructions," said David I. Hill, PGCert MDD, MIDSc (Chtd), Head of Decontamination at NHS Lothian in Edinburgh, Scotland, UK. "There should be an acknowledgement about purpose, so disinfection has agreed criteria that the IFU has to describe compatibility with. No more 90 deg for 5 mins or 93 for 3 mins. 90 deg for 1 minute and that's it. The same with sterilization time x temp."

David I. Hill

Rebecca T. Alvino, System Director, Sterile Processing, UCSF Health, San Francisco, stated, "If a nutrition label on the side of a cereal box, a bag of potato chips, and even a soda needs the same information provided in the same standardized fashion, certainly medical device IFUs could be required to adhere to a standard format."

2. Accessibility

Lack of accessibility to manufacturer IFUs was voiced as a concern by many of the SP professionals who weighed in on the topic. Regardless of whether an SP team has access to an IFU electronic database, respondents expressed the desire to access IFUs from manufacturer websites. They expressed frustration about having to track down updated IFUs when manufacturers should make them readily available.

Keicha Brock

"Calling the manufacturer or looking online is a waste of valuable time," said Keicha Brock, CSPM, CFER, MBA, CEO: Eyes to See Management & Consulting. "Some vendors want you to contact the sales rep and sometimes they are not aware of what is in the IFU."

Sarah B. Cruz, CSPDT, CRCST, CHL, CIS, CS Quality & Education Program Development Coordinator, The Bone & Joint Institute at Hartford Hospital, in Hartford, Conn., called on manufacturers to provide QR codes that link to PDF versions of their IFUs that can then be linked to the instrument or device in an electronic tracking system.

Sarah B. Cruz

"Scanning, cropping, and enlarging is tedious and outdated," said Cruz. "This could be a great opportunity for those who do not have access to an IFU electronic database."

3. Clarity

SP professionals cited "vague" or "gray" areas that exist in manufacturer IFUs today, requesting clarity of language and clarity of instructions, particularly those associated with complex processes, and clarity of revisions and the dates they were made.

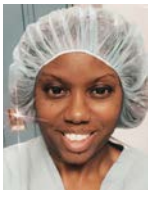
Janene McGlynn

"Clear language," said Janene McGlynn, CRCST, CIS, CER, CHL, Sterile Processing Lead, Cleveland Clinic in Cleveland. "You can do x, y, z; you cannot do x, y, z. There is such a gray area. On top of that, depending on who is reading the MIFU, it can be interpreted differently."

4. Real world considerations

A major concern among the SP professionals commenting on this topic was how manufacturers do not have the end user in mind, including real world conditions, when developing their IFUs. There were calls for manufacturers to involve SP professionals in IFU development to make them more representative of the true reprocessing environment.

"Too often IFUs describe what was validated (and) that bears no relation to 'normal' CDU parameters or process capabilities without tedious variations in machine programming that achieve nothing other than compliance with a poorly written IFU," Hill commented.



Veronica Holder

"Maybe have a technician who actually has to process the instruments there," said Veronica Holder, CRCST II, CHL, Endoscopy and Reprocessing Technician. "Then maybe they would get a better understanding of what it takes to process instruments from the decontamination room to the prep and pack side."

Shawn M. Flynn, Co-Founder and CEO of Bedrock Surgical, suggested manufacturers add "work instructions that can be specific to the location in the workflow." He added, "Make it part of the labeling requirement, which includes standard formatting and rev control."

Shawn M. Flynn

5. Charts and graphics

SP professionals also called for the inclusion of charts, graphs, and other images in IFUs to help the end user interpret instructions at each stage of reprocessing.

Michael West, CRCST, CER, Quality and Education Coordinator, SPD, UVA Health, Charlottesville, Va., proposed manufacturers include wording and pictographs similar to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) for SDS.

Michael West

Where do we stand today?

HSPA President Monique L. Jelks, BA, MSOL, CRCST; and HSPA Vice President of Strategic Initiatives and AAMI Fellow Damien Berg spoke about progress made to date on IFU improvements, and emerging initiatives to harmonize IFUs on a global level.

Monique L. Jelks

Current standing with AAMI TIR12:2020

According to Berg, the published TIR12 has been recognized by the U.S. Food and Drug Administration (FDA), and IFUs for newly FDA-cleared products are already starting to follow the new format that TIR12 recommends. However, TIR12 does not reach backwards, as Berg explained:

Damien Berg

"When a manufacturer is developing an IFU for a new product as part of the 510(k)-clearance process, the FDA recommends they follow TIR12 as a blueprint for its design. If a manufacturer has older IFUs prior to the TIR12 release date, there is no requirement to update the IFUs unless there is a safety issue. The burden to update them would be too great for the manufacturer given they would essentially have to go through the 510(k) clearance again."

Berg noted how the FDA has always worked very closely with medical device manufacturers and third-party testing labs for the clearance of their IFUs. The manufacturer must prove that they have validated their instructions and testing methods in the lab environment through the FDA process. What's been missing is end-user input. But that is changing.

"The FDA has reached out to the HSPA because they want to get more feedback and input from IFU end users so they are better informed when overseeing manufacturers and testing labs on IFU development and verification," said Berg.

Berg added how, in 2024, the HSPA is working on efforts to get subject matter expert (SME) end users in front of the FDA. When asked how SP professionals can voice their concerns with manufacturer IFUs, Berg stated:

"For IFUs that are vague, reach out to your medical device manufacturer and talk to the people in their quality/regulatory department to see if they can help with clarification. More importantly, explain to them why it is important to have an IFU that is cleared for hospital cycles. Manufacturers can clear their device IFUs in a testing lab with whatever technique the lab uses, but that isn't something we have in the hospital."

"Conversely, if there is truly a safety concern with the IFU, there are avenues to the FDA to help rectify the issue, such as the Manufacturer and User Facility Device Experience (MAUDE) reporting system," Berg added. "The FDA wants to know about IFU safety issues and HSPA does too."

Emerging global initiatives

"Standardizing IFU would be a tremendous benefit to the world of sterile processing—and I mean 'world' literally," said Jelks. "We must consider that manufacturers of surgical instruments and medical devices exist around the world. The goal of IFU standardization should pertain to all human beings receiving medical and surgical care, regardless of where they live in the world."

On the global front, AAMI TIR12 has a "mirrored group" in ISO called Working Group 12. Representatives from the FDA, testing labs, medical device manufacturers and the HSPA sit on the ISO working group as U.S. experts, with Berg serving as AAMI TIR12 co-chair and Working Group 12 end-user expert. Together, these stakeholders are collaborating with their counterparts in other countries to define a path to global IFU harmonization.

Berg noted, "A manufacturer that sells its product in the U.S. must gain FDA clearance but if it also sells that same product in Germany or Japan they must work with regulators for those countries/regions to gain clearance there. We've all seen those long, unfolding IFUs in many different languages. AAMI and ISO are saying, why don't we harmonize globally? Let's all come together and identify what makes sense from an IFU standardization standpoint."

Jelks noted how IFU standardization was a "hot topic" at this year's World Sterilization Congress in Brussels, hosted by the World Federation of Hospital Sterilisation Sciences.

"Professional sterile processing organizations, including the HSPA, and leaders of manufacturing organizations understand the importance and huge undertaking associated with standardizing IFU," said Jelks. "Discussions and plans were shared for how manufacturers and world leaders of infection prevention (World Health Organization and the international infection control branch) will soon be meeting to explore opportunities to standardize information and reprocessing standards to improve patient safety globally."

"There had been a general assumption that because manufacturers' devices were so complex and diverse IFUs should be too. "Now, I think everything is coming to a head because there is a lot more awareness of the issue. This has led to a big push on the grassroots end for standardization."

—Lisa McKown

Where do we go from here?

Lisa McKown, DrPHc, MBA, CRCST, CIS, CHL, MBTI, Certified ISO 9001 Lead Auditor, DNV, offered her perspective on the road ahead for IFU improvements.

"There had been a general assumption that because manufacturers' devices were so complex and diverse IFUs should be too," said McKown. "Now, I think everything is coming to a head because there is a lot more awareness of the issue. This has led to a big push on the grassroots end for standardization."

"I think the answer is multifaceted," she added. "Part of the answer will be on the manufacturer side where there might be some policy levers from the FDA that can help shape more of an IFU framework and how it should look. I also believe there will be continued shaping from the AAMI perspective."

"Standardizing IFUs will also require the advancement of technology," McKown continued. "There is a race going on among many players to utilize AI technology and computer vision to assist where the gaps exist today. But again, even with technology, which can do wonders as we know, we must have good data from the manufacturers. Because if there are gaps in the instructions, then even advanced technology won't be able to have inferences into that."

When asked who needs to make the first move, McKown acknowledged that while the heaviest weight of responsibility falls on the manufacturers' shoulders, she believes there could be opportunities for SP technicians (aka 'users') to have some input into that process.

In conclusion, she stated, "manufacturers need to be listening and pay attention to this call" from SP professionals. HPN

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HEALTHCARE PURCHASING NEWS

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Importance of Water Quality for Medical Device Reprocessing

by Ana Laura Villalón

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Water quality is critical in any process within a Sterile Processing Department (SPD). Inadequate water quality during medical device reprocessing can cause a number of negative outcomes, including:

1. Malfunction of the device during the patient's procedure, such as corrosion and difficulties with mechanical movement of surgical instruments due to salt deposits and debris.
2. A shortened service life of equipment and medical devices due to the gradual accumulation of organic and inorganic deposits.
3. Tissue irritation resulting from residues in a device or implant. For example, pyrogenic reactions due to high levels of endotoxins or other pyrogenic agents left as residues from water containing high microbial levels.
4. Infection of the patient resulting from the use of contaminated devices. Salt or organic deposits from water used in reprocessing could inactivate disinfectants or sterilizers, protecting microorganisms from the disinfection or sterilization process.
5. Non-condensable gases in the steam supply to sterilizers, which can significantly affect sterilizer performance and process efficiency, causing inconsistencies in sterilizer performance and Bowie-Dick test results.

Therefore, water quality and its effective treatment are issues of relevance in the reprocessing of medical devices.

Water plays various roles during medical device reprocessing, such as solvent for cleaning products and other chemicals used in processes, mechanical and thermal transmission, dissolution of water-soluble waste, and steam source for sterilization. Water can contain various undesirable substances that adversely affect all stages of medical device reprocessing. For this reason, water quality must be carefully considered, beginning with the planning phase of sanitary facilities.

The AAMI defines two categories of water quality for medical device reprocessing: utility water and critical water.[1] Utility water is water from the tap that is predominantly used in medical device washing and rinsing. This water should have a hardness level below 150 mg/L, chloride concentration below 250 mg/L, and pH ranging from 6 to 9. Conditioning (such as with a water softener) may be required for tap water to meet these specifications. Critical water is treated using a multi-step process to ensure the removal of microorganisms, organic and inorganic material. This water is mainly

February 2024

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LEARNING OBJECTIVES

1. *Understand the importance of water quality in the reprocessing of medical devices and its impact on patient safety and device performance.*
2. *Identify the types of water hardness and their effects on medical device reprocessing, including the formation of lime crusts and deposit accumulation.*
3. *Describe various methods of water treatment and their role in improving water quality for medical device reprocessing.*

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used for final rinsing after washing and steam generation, and has more stringent quality limitations. Critical water hardness should be below 1 mg/L, chlorides should be maintained under 1 mg/L, and the recommended pH is 5-7.[1]

Water Hardness

Water hardness is dependent upon the amount of minerals dissolved into it. Hard water contains a high concentration of soluble salts, primarily calcium and magnesium.[2] It is classified into two types: temporary hardness and permanent hardness. Temporary hardness is caused by soluble salts of calcium and magnesium bicarbonates. When water is heated to high temperatures, these salts convert into insoluble salts of calcium and magnesium carbonates. These insoluble salts form a hard lime crust that settles on surfaces in contact with water (Figure 1). Permanent hardness is typically caused by calcium and magnesium sulfates, which do not precipitate when heated.

Treating Water for the SPD

Water incoming to the SPD is first treated via filtration, with the aim of removing as many suspended particles as possible. The quality of the filtered water depends on the pore size of the filters used in the water treatment system, and different types of filters can be employed in sequence (Figure 2).[3] The type of filtration system depends on the water source and intended use in the SPD.

Water softeners are systems that retain the salts responsible for the formation of limescale when the water is heated. These water softeners use the ion exchange principle, by using exchange resins containing sodium cations. When hard water passes through these columns, the resins trade the sodium cations for calcium and magnesium cations. Water containing calcium and magnesium bicarbonates exits with sodium bicarbonate (i.e., baking soda). Softeners are effective at removing temporary hardness, but will not address the permanent hardness of water.

Reverse osmosis is a process by which pressure is used to pass water through a semipermeable membrane from a more concentrated solution to a less concentrated solution (Figure 3). This process removes most dissolved minerals, as well as virtually all microorganisms, endotoxins, colloids and organic compounds. Water treated by reverse osmosis meets the requirements for use in steam generation for sterilization and in the final rinses of washers/disinfectors.[1]

Water Quality Testing and Monitoring

Testing is necessary to assess the quality of water received from utilities. These tests must be performed by an accredited external company with experience in water quality. The goal is to determine whether the inlet water requires treatment and, if so, what type of treatment is needed. These tests should consider the geographic location of the facility and seasonal variations. The water quality specification must ensure that no contaminants are present in concentrations that could damage the sterilizer, affect process performance, or damage the product. Contaminant levels in supplied water may be specified by the manufacturer or provided by international, regional or national standards or guidelines.[1] Failure to comply with these recommendations may shorten the life of the sterilizer and invalidate the manufacturer's warranty.

The maintenance of the water treatment system and the monitoring of its quality require collaboration between the personnel in charge of water maintenance in the sanitary institution and the staff of the SPD. Both must work together to ensure that the treatment system is properly maintained and that regular tests are carried out to verify water quality. They should receive education, training and verification of competencies with respect to their tasks in this regard.

Health institutions should provide for the maintenance of the water treatment system for the production of steam for sterilization through a monitoring system as described and an alarm system to timely alert about failures in the quality of the water supply. As an example, a monitoring system could implement the use of QR codes that allow users to send notifications via email.[4] Two types of QR codes can be made available: one for daily control, when routine tests are carried out, and another for maintenance or necessary corrective actions. Scanning these codes using a mobile device can open a form where monitoring information can be recorded and submitted. The forms can be set up to arrange the data in logs to be reviewed by the responsible persons, usually the heads of the SPD and Maintenance of the institution. Such a system offers the ability to verify whether the corresponding analyses have been completed, providing updated information on their execution. In addition, it supports immediate notification of those responsible in case of failure or incident during the process, which ensures a timely response to problems and provides traceability for future audits.

Conclusion

In conclusion, water quality is crucial in the reprocessing of medical devices. Inadequate water quality can lead to device malfunction, shortened service life, toxic effects, infections, and inconsistent sterilizer performance. Effective treatment is necessary to ensure the safety and efficacy of medical devices. Water hardness, both temporary and permanent, can cause issues like lime crust formation and deposit accumulation. Water softeners remove temporary hardness, while processes like distillation or reverse osmosis address permanent hardness. Filtration removes suspended particles, and reverse osmosis eliminates dissolved minerals and microorganisms. Regular testing and monitoring are vital to ensure the water treatment system meets specifications. Collaboration between water maintenance personnel and SPD staff is crucial. By prioritizing water quality and implementing appropriate treatment, healthcare institutions can ensure safe and effective medical device reprocessing, benefiting patient well-being. **HPN**

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Dr. Ana Laura Villalón is the Head of Sterilization Service and Endoscope Reprocessing Unit and member of the Infection Control Committee at the Santa Isabel de Hungria Hospital in Mendoza, Argentina. Villalón has over 20 years of experience in device reprocessing and sterilization management, and she participates on the Permanent Committee on Sterilization of the Ministry of Health of Mendoza. Dr. Villalón advocates for improving efficiency and education within Sterilization Processing Departments in Latin America.

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

CONTINUING EDUCATION TEST • FEBRUARY 2024

Importance of Water Quality for Medical Device Reprocessing

Circle the one correct answer:

1. **What are some of the adverse events associated with inadequate water quality during medical device reprocessing?**
   A. Device malfunction and shortened service life
   B. Tissue irritation and infection
   C. Non-condensable gases in steam supply
   D. All of the above

2. **What is the main role of water in medical device reprocessing?**
   A. Solvent for cleaning products
   B. Mechanical and thermal transmission
   C. Dissolution of water-soluble waste
   D. All of the above

3. **What are the two categories of water quality defined by AAMI for medical device reprocessing?**
   A. Utility water and critical water
   B. Hard water and soft water
   C. Temporary hardness and permanent hardness
   D. Filtration and reverse osmosis

4. **What happens when water containing calcium and magnesium carbonates is boiled?**
   A. The water does not create steam.
   B. The salts stay in solution.
   C. The salts precipitate can form a lime crust on contacted surfaces.
   D. All of the above.

5. **Water softeners loaded with sodium cations exchange calcium and magnesium bicarbonates for _____.**
   A. calcium and magnesium carbonates
   B. oxygen and nitrogen
   C. sodium bicarbonate
   D. carbon dioxide

6. **What is the process by which water passes through a semipermeable membrane to remove dissolved minerals and microorganisms?**
   A. Filtration
   B. Water softening
   C. Reverse osmosis
   D. Distillation

7. **What is the recommended hardness level for utility water used in medical device washing and rinsing?**
   A. Below 150 mg/L
   B. Below 1 mg/L
   C. Below 250 mg/L
   D. Below 5 mg/L

8. **The type of water used for sterilizing steam generation must be _____.**
   A. Tap water
   B. Critical water
   C. Utility water
   D. None of the above

9. **What is the recommended pH range for critical water used in final rinsing and steam generation?**
   A. 1-3
   B. 4-6
   C. 5-7
   D. 8-10

10. **What is the purpose of collaboration between water maintenance personnel and SPD staff?**
    A. To ensure the water treatment system is properly maintained
    B. To conduct routine tests to verify water quality
    C. To provide education and training on water quality management
    D. All of the above

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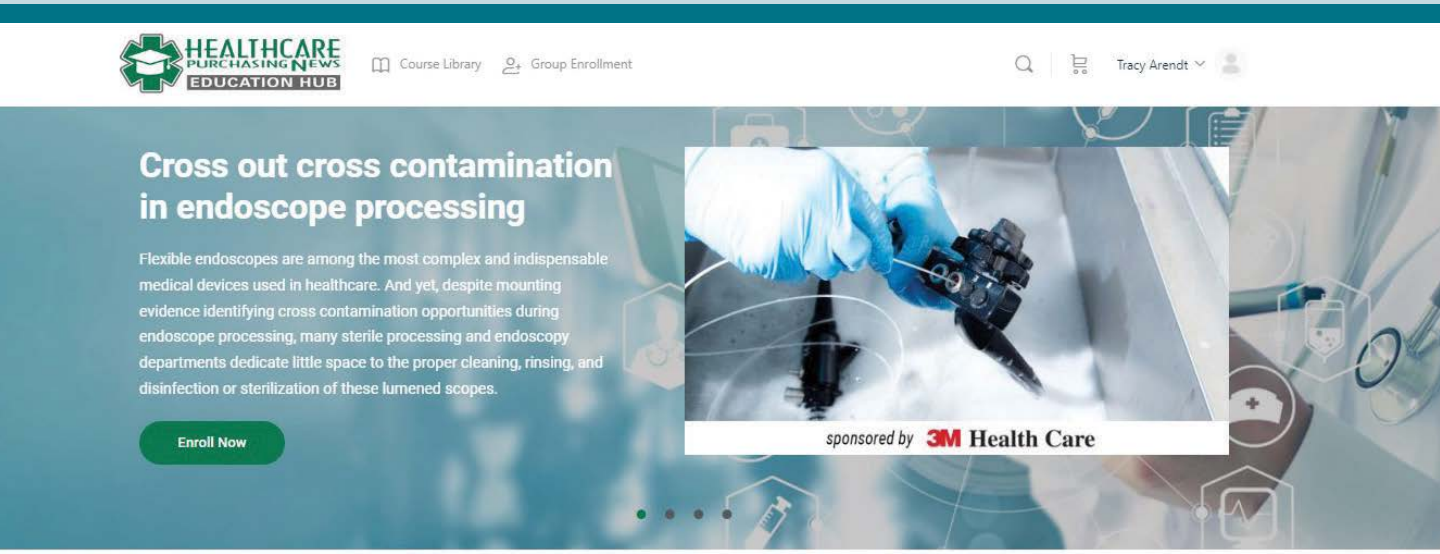

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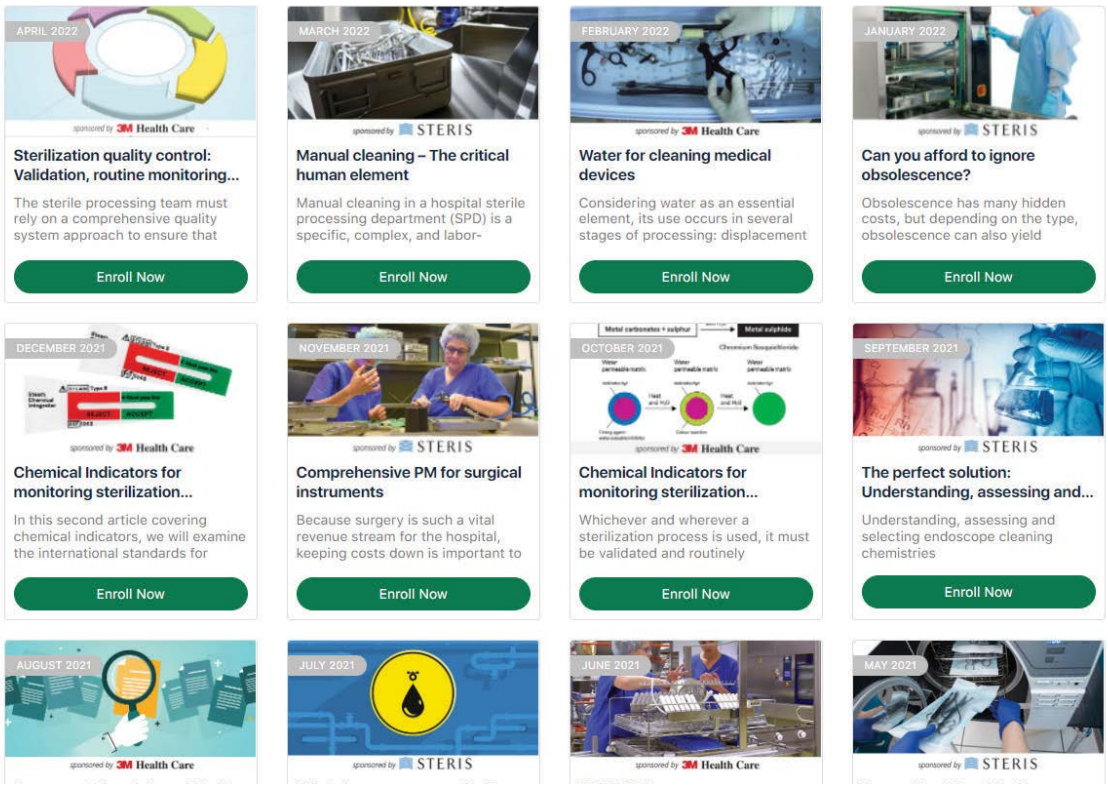

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Nitrogen

by Stephen M. Kovach

Q "We recently had a consultant come in and tell us we need nitrogen compressed air in prep/pack to blow out cannulas. I have never heard this before. I only know about medical instrument air. Any insight?"

A First, any time a consultant/surveyor tells you to change your practice, you have the right to address them (in a positive way) to ask for specific standards or guidelines they are citing. Once you know, then you can determine whether your department needs to comply.

To answer your question: generally yes, with an explanation. Nitrogen has been used for power equipment for as long as I have been in the Sterile Processing industry. Since nitrogen is a very dry gas, it is great when it comes to powered equipment. What about being used for drying?

ANSI/AAMI ST79 states, "*2.56 instrument air*: Medical gas that falls under the general requirements for medical gases as defined by *NFPA® 99 (Health care facilities code)*, is not respired, is compliant with the *ANSI/ISA 7.0.01 (Quality standard for instrument air).*"[1] The next step is to understand *NFPA® 99-2018*. How are medical gases defined, and does the definition address instrument air and nitrogen? Instrument air and nitrogen can be found under section *3.3.107 Medical Support Gas*, which states, "Nitrogen or instrument air used for any medical support purpose (e.g., to remove excess moisture from instruments before further processing, or to operate medical–surgical tools, air-driven booms, pendants, or similar applications) and, if appropriate to the procedures, used in laboratories and are not respired as part of any treatment. Medical support gas falls under the general requirements for medical gases. (PIP)"[2] To complete the research, another section that must be reviewed is section *"3.3.102* Medical Air.* For purposes of this code, medical air is air supplied from cylinders, bulk containers, or medical air compressors, or reconstituted from oxygen USP and oil-free, dry nitrogen NF. (PIP)"[3] Personally, I would say Yes to the question posed above with these caveats. I would request your manager to ask the consultant to state where they gained the information to make such a statement, and not just take their word for it. Nitrogen can meet the parameters set out in the *NFPA® 99-2018*, based on my research, and each department must come to their own conclusion about what type of medical air/medical support gases they want to use in their department. I also recommend documenting why and have that documentation available in case you are asked for it.

In closing, a few important points need to be made about using gases in the department.

- Regulate the flow of gas that you use–this is a safety issue.
- Train your staff to use the gas and drying medical devices properly (e.g., wearing appropriate safety equipment such as safety glasses), and document the training.
- If using standalone tanks, they must be secured in the department according to Occupational Safety and Health Administration (OSHA) standards.
- Have documentation and a policy on why you are using that specific type of gas in your department.
- Review your IFU to ensure you are meeting the requirements for drying medical devices used in your department. HPN

Good SPD-OR Relationships Enhance Resource Utilization, Cut Waste and Risk

by David Taylor III, MSN, RN, CNOR and Robert Leenan, BS, CRCST, CIS, CCSVP

No other departments are more aligned than the Sterile Processing department (SPD) and operating room (OR), with each playing a vital role in the successes and failures of the other. SPD professionals are responsible for applying proper principles of cleaning, testing, assembly, packaging, and sterilization, and OR staff must manage devices while in use and return them to the SPD in good working order. Unfortunately, much attention is paid to the SPD and its failure to manage resources to support the OR, while less focus is placed on the OR's responsibilities.

A comprehensive, year-long study was conducted at a large U.S. hospital. Nearly 42,000 cases were reviewed, and 3,900 defects were recorded. Many of those defects pertained to the assembly process, which included missing, broken, malfunctioning, or incorrect instruments.[1] The findings suggest that broken, missing, or inappropriately cleaned instruments are a frequent problem for surgical teams. On its surface, that assumption is correct; however, the study's authors suggest that the problems identified point to deeper, systemic problems. Considering the SPD's pressure to turn instrumentation around quickly, insufficient inventory, challenging instrument designs and unclear manufacturers' instructions for use—as well as environmental factors (hot, humid, noisy, and prone to distractions)—it become clear how shortcuts and errors can occur. *Note: Although the study provides a thorough review of the workload SP professionals typically perform daily, it does not paint the complete picture of the far-reaching responsibilities and the problems associated with devices delivered to the SPD from procedural areas.*

The relationship between the OR and SPD should be closely aligned to elevate the quality of the work coming from each department. Point-of-use treatment and the reorganization of trays, for example, should begin in procedural areas.[1] When instruments are not pretreated, cleaning becomes difficult, and when devices are improperly mixed or absent from the tray, the workload deepens further for the SPD. Many departments fail to understand all that takes place in the SPD, and for what purpose. Imagine receiving hundreds of instruments and sets daily, many of which may not have been treated at the point of use or returned to their trays in an organized manner. The SPD must effectively, efficiently, and safely manage complex, delicate medical devices and many challenging processes, often without adequate resources such as staffing, equipment, education and training, and effective leadership.

The number of instruments required for surgical procedures today continues to climb; however, it is important to consider how many devices are needed. Studies have shown only 13–21.9% of instruments opened are used for any procedure. No one is discounting a surgeon or service line coordinator's role regarding the devices needed for a surgical procedure, but if as many as 87% of instruments go unused during a procedure, organizations have an opportunity to manage the instrument set size to save money, speed up processing, and make patient care safer.[2]

Leading an effective partnership

The success or failure of any department hinges on the quality of its leadership. Developing an understanding and shared commitment from all involved, with each accountable for their roles (including surgeons), is imperative. There must be a consistent platform for evaluating, prioritizing, and resolving issues. It's vital that the departments have a unified approach to addressing problems and reviewing opportunities instead of holding only one side responsible. Leaders from each department should always be visible and accessible, ask questions, and seek to understand processes. Encouraging overcommunication between SPD and OR staff to facilitate real-time dialogue and share insights is beneficial. Finally, both departments should have shared governance and regular meetings to develop strategies to overcome problems and gauge effectiveness and consistency with quality initiatives.

Improving SP's many processes takes time and a commitment to evaluating current processes, determining countermeasures, allocating resources, implementing changes, and sustaining improvements. *Note: It is essential to change the culture and evaluate the systems controlling the newly implemented processes to ensure long-term success. This can include specific leadership tasks, real-time internal metrics specific to the process, and problem-solving techniques to address any necessary modifications.* Soliciting staff feedback is crucial for evaluating the success of any new process. Once the processes are underway, it is helpful to designate SPD and OR liaisons to coordinate and oversee daily activities between the departments and facilitate efficient case flow and real-time problem solving. Liaisons can help facilitate a new culture and find additional ways to improve and sustain processes proactively.

Conclusion

Stronger relationships between the SPD and OR requires a focus on quality, safety, and customer service. Focusing on interdisciplinary objectives, managing data, striving to meet the metrics, and taking responsibility are key to sustaining improvements. HPN

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Patient Monitoring Check-In with GE Healthcare

Healthcare Purchasing News connected with general manager of monitoring and patient care solutions at GE Healthcare to discuss challenges and solutions surrounding patient monitoring in 2024

by Janette Wider

Patient monitoring technologies and techniques have evolved at a rapid pace over the past few years, in part due to the COVID-19 pandemic. Recent studies show that patient monitoring, especially remote patient monitoring (RPM), has a high level of patient satisfaction and compliance.

According to a study from the Mayo Clinic, patient engagement improved with RPM. Over 7,000 patients across 41 states participated in the study, which found patient engagement with digital RPM tools was as high as 80%. Additionally, the study found that patient compliance with care plans among high-intensity patients who use RPM devices was slightly over 70%.

Further, a KLAS Research survey found that 38% of healthcare organizations running RPM programs focused on chronic care management reported a reduction of admissions, while 17% reported cost reduction.

Healthcare Purchasing News conducted a Q&A with Neal Sandy, general manager, Monitoring Solutions, Patient Care Solutions, GE HealthCare, to get an update on the current state of patient monitoring from the organization's perspective.

Editor's Note: The study mentioned in Sandy's responses, entitled, "The State of Flexible Healthcare Delivery", has some interesting statistics on the state of healthcare delivery today. GE HealthCare commissioned healthcare consultancy Sage Growth Partners to research and develop the report (double blinded research, conducted independently by Sage). They surveyed 204 hospital and health system executives and leaders in the U.S. and held qualitative interviews with several respondents. The study can be found here: https://clinicalview.gehealthcare.com/article/state-flexible-healthcare-delivery.

What trends are you seeing when it comes to patient monitoring? What were you seeing pre- and now post-COVID?

Neal Sandy

In the past, patient monitors were generally purchased for a specific care area. For example, hospitals have specific monitors for the intensive care unit (ICU) and different monitors, typically with fewer capabilities, for the emergency department (ED). However, the COVID pandemic highlighted the need to have flexible patient monitoring technologies that could easily adapt to meet a patient's acuity level. As hospitals had to quickly adjust from normal to surge operations to respond to the increase in COVID cases, it would have been ideal if the monitors deployed in lower acuity settings had the capability to provide ICU level monitoring. Flexible, scalable solutions allowing institutions to customize on the fly for all patients and case types help drive more efficient, confident care.

What are challenges hospitals/health systems experience when it comes to patient monitoring?

Flexibility

What we hear from customers every day is that they need flexibility, now and into the future. At GE HealthCare we term this FlexAcuity, the ability to flex capabilities based on individual patient needs and transition seamlessly between care areas across the enterprise. It means you have a unified monitoring platform that can adapt with your needs and is ready for the future.

For example, imagine one monitoring ecosystem with the potential for a hospital to have a single unified approach to patient monitoring that can be easily tailored for each patient, where software and patient parameters can change in a very nimble manner. This enables care teams to focus on the patient, not the technology.

Burnout/Staff Shortages

Clinicians and care teams are plagued with burnout, alarm fatigue, and staff shortages. They need reliable technologies that deliver meaningful alarms and actionable data.

Scaling Technology

Purchasing patient monitoring [technologies] often includes not only the individual monitoring devices, but also the ecosystem. This can take many forms but often includes connectivity to central stations, remote viewing, integration to electronic health record systems, and data exchange with other hospital IT systems and platforms. Therefore, it's important to evaluate a vendor's ability to support your purchasing needs not only today, but also into the future. Can future purchases work with past investments? Can the technology scale as your enterprise grows or changes over time? Is there an easy path to give

your clinicians access to new technology as your standards of care evolve or new parameters and clinical measurements are introduced? Backward compatibility allows healthcare systems to upgrade to the latest capabilities at their own pace.

What are organizations doing to overcome these challenges?

Flexible healthcare, or a health system's ability to purposefully innovate in the face of changing conditions with speed of implementation, scale, and organizational alignment, will be key. A recent study finds that ongoing workforce shortages are a main factor driving the increased movement toward flexible care models. Continuous patient monitoring to alert changes in acuity, visual dashboards for monitoring patient status, and standardizing monitoring devices to reduce training time were all considered important to a flexible care model. 66% of respondents felt organizations implementing flexible care models had a stronger bottom line as a result and even more said these models increased staff efficiency.

Increasingly, organizations are seeking longer term partnerships because they understand that an enterprise-wide monitoring solution requires a commitment from both the hospital and the monitoring solution provider. Organizations are asking about total cost of ownership over the lifecycle of the products and solutions they intend to purchase. They are asking for evidence that the proposed solutions deliver either clinical or economic benefit, or both.

Where do you see this space in the next 5-10 years?

Clinicians and care teams are plagued with burnout, alarm fatigue, and staff shortages. They will need reliable technologies that deliver meaningful alarms and actionable data.

Continuous patient monitoring in subacute care settings will be increasingly important, yet relevant only when patient mobility is elegantly addressed.

The evolution of artificial intelligence/machine learning based multiparameter intelligence, including predictive algorithms and clinical decision support, will accelerate when the liberation of deidentified patient data becomes standard and access to vast, annotated datasets becomes readily available.

Finally, the evolution of technology is accelerating, so business models will need to change to allow organizations to keep pace. Monitoring, as a service, will overtake standard capital equipment purchasing as clinicians and hospitals make note of how this pace of change affects clinical and operational outcomes.

Any additional thoughts?

Patient mobility is key to recovery so monitors, especially in MedSurg and recovery units, need to support the patient getting up out of bed and walking around. Wireless and wearable continuous monitoring that complements efficient nursing workflows provides a real-time personalized view of the patient while encouraging mobility. Clinicians are increasingly asking for the leading indicators of deterioration, respiration rate, oxygen saturation, and pulse rate to be measured continuously in order to intervene proactively. HPN

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Health and the Supply Chain Have Their Day at COP28

by Karen Conway

Just over 11 years ago, Superstorm Sandy hit the New York City and New Jersey coastlines. I still recall the awe and the pride I felt as my friend Christopher O'Connor, then president of Greater New York Hospital Association Ventures and Nexera, provided a first-hand account of the measures taken to evacuate patients in the wake of the historic weather event. In the past decade, weather- and climate-related hospital evacuations have become more commonplace as a result of more frequent and severe hurricanes and wildfires. Healthcare workers are to be commended for their emergency preparations and effective responses when evacuations are required; hospital administrators, meanwhile, are investing in mitigation measures, such as installing iron and steel flood barriers and purchasing high water trucks that can move people and products in the event of severe flooding.

Given the rise in disasters and the not so insignificant steps being taken to respond, it is surprising that this year's COP28 climate conference was the first time there was a day dedicated to the relationship between climate and health. While the international forum focused considerable attention on the developing world, where resources are far more limited, there is no shortage of challenges in developed countries like the United States. According to *Science Daily*, in 2022 researchers at the Harvard T.H. Chan School of Public Health found that many hospitals along the Atlantic and Gulf Coasts are at risk of flooding, even from relatively weak storms. Despite the precautions taken, such as building flood barriers and moving sensitive equipment to higher floors, hospital operations are at the mercy of the surrounding infrastructure. The researchers identified 18 metropolitan areas where roads leading to hospitals are at risk of flooding, making it difficult, if not impossible, for patients, healthcare workers, and supplies to reach the facilities.

Ironically, while climate-related weather events are threatening hospital operations, they are also increasing the demand for services. As an example, according to an article from *CBS News*, 2023 was declared the hottest year on record; just ask those living in Phoenix, where temperatures topped 110° on 54 days, breaking a previous record set in 2020. Beyond the usual health impacts, such as heat exhaustion, Phoenix area hospitals saw a significant increase in the number and severity of burns from individuals -- often the elderly with medical conditions -- who fell on extremely hot asphalt.

Those attending Health Day at COP 28 noted other health-related consequences of climate change, including a higher potential for infectious diseases and other diseases attributed to worsening water and air pollution. Climate change can also threaten access to the social determinants of health, such as employment and housing, disproportionately impacting the poor and more marginalized communities.

Sadly, just as the demand for healthcare services increases with climate change, the use of more healthcare operations also contributes to climate change. Globally, hospitals and other healthcare facilities account for about 5% of the world's carbon footprint, with some estimates as high as 10% in the U.S.

While fighting climate change is a multi-stakeholder battle, supply chain professionals are once again on the cutting edge, with 70% of healthcare-related greenhouse gas (GHG) emissions linked to the supply chain. Given the severity and urgency of the issue and its ties to supply chain, here are some steps supply chain professionals can take today:

1. Ask your suppliers what they are doing to reduce the greenhouse gas (GHG) emissions and other negative environmental impacts, such as plastic use, in their product lifecycle. Consider all aspects, including production, shipment, use, and disposal.
2. When data is available, choose more environmentally friendly products. Anesthesia gases are a great place to start, given the significant difference in GHG emissions between different products.
3. Consider how changes in business practices between you and your suppliers can reduce GHG emissions, such as consolidating orders to reduce shipments.
4. Work with finance to understand the total lifecycle costs of products to justify higher per unit acquisition prices that can have a lower total cost of ownership. Also, remember that more environmentally friendly products are not always more expensive.
5. Collaborate with clinicians to:
    a. Identify opportunities to use fewer disposable and single use products without sacrificing clinical quality.
    b. Help clinicians by providing peer-reviewed and other substantiated evidence to support decision making.
    c. Capture actual product utilization using unique device identifiers (UDIs) to:
        i. Optimize inventory levels to reduce expired inventory.
        ii. Clean up procedure cards and eliminate waste from products opened but not used.
        iii. Support real world evidence generation to help identify and reduce use of medical procedures and products that deliver no value.
6. Ask senior leadership about what their environmental priorities are (e.g. investing in climate mitigating strategies) and offer to provide procurement and logistics expertise where applicable.

At COP28, more than 120 countries, including the United States, signed the Climate and Health Declaration, which supports a two-pronged approach to transform "health systems to be climate-resilient, low-carbon, sustainable and equitable and to better prepare communities and the most vulnerable populations for the impacts of climate change." Once again, the world will turn to supply chain professionals to help lead this charge, further reinforcing the power of procurement and effective resource management in fostering the resiliency of the health system as a whole and the populations served. **HPN**

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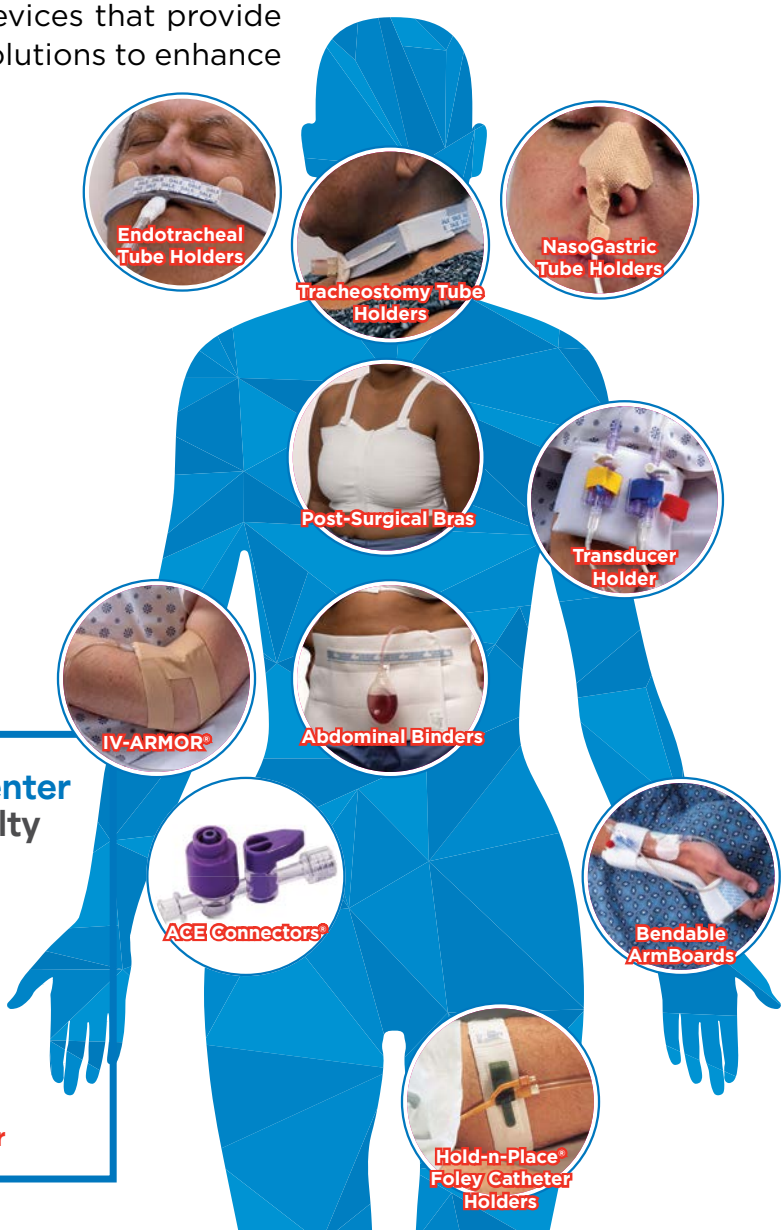

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