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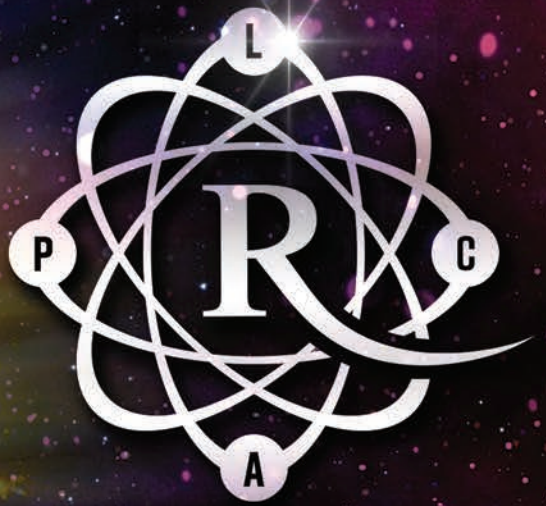

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Amazon Rising 2.0

Rick Dana Barlow
Senior Editor

Four years ago, I wrote in this space about how the healthcare industry should neither fear nor be irked by Amazon burrowing into the marketplace (See "Amazon Rising," April 2018).

Earlier that year, Amazon formed something of a high-financed, high-powered corporate collaboration with Warren Buffett's Berkshire Hathaway company and JP Morgan Chase. Through their loosely defined partnership that materialized under the short-lived startup Haven Healthcare, Amazon-Berkshire-Chase wanted to explore the A-B-Cs of healthcare administration, finance and operations with aims to improve all of it while also providing more affordable access to medical treatments and prescription drugs.

Three years later, come January 2021, the trio allowed Haven to fade even as they ran a victory lap around the media track, taking credit for generating ideas and insights that they planned to use when necessary to design healthcare program improvements for their individual and respective employee populations.

There's nothing wrong with three multibillion-dollar companies throwing a lot of money at a problem they deem requires fixing. They have the resources, the skills and the talents to do it, so why not?

Most people recognize that true innovation starts not with a simple idea, but with someone willing to take that risky first step to try something different and new. Check.

This trio had two years to concentrate on their goals before the global pandemic disrupted everything in the Spring of 2020.

Amazon drilled through the pandemic, which exposed the long-hidden seedy underbelly of supply chain shortcomings, a necessary revelation to motivate companies to act. Amazon kept going and proved its freight-and-shipping, and distribution-and-logistics meddle to businesses, consumer residences and even healthcare organizations. Meanwhile, it also used intelligence gained during the Haven years to fortify its Amazon Care virtual health services that offered home health, telehealth, urgent care and primary care to a growing number of customers. They started in about 20 major cities and finally went nationwide earlier this year.

[Full disclosure: I do not own shares in Amazon, nor am I seeking to curry favor with Amazon Business to advertise.]

Amazon continued its march. Back in late July, the company acquired One Medical, which operates a network of boutique primary care practices – nearly 190 medical offices in 25 markets – to deliver on its Haven aims.

If you package One Medical's primary care operations with Amazon Care's remote care operations, along with its PillPack-driven online pharmacy, Amazon Health Services seems to be stitching together a curious model of distributor-provider-payer mix.

Still, we know that Amazon Business is making serious clinical and supply chain inroads with a growing number of healthcare organizations. This latest deal now positions the company as owner, provider and supplier of healthcare products and services. Imagine the supply chain implications if they can demonstrate how to get stuff to hospitals and physicians quickly and efficiently as well as provide clinical services to a growing patient base? Now imagine if Amazon chose to tunnel deeper into the market, acquiring an ambulatory surgery center chain next? Could an Amazon One Healthcare emerge by mid-decade?

All these dynamics – real or speculative – remain rather intriguing and should not be viewed as a threat. If anything, it should nudge the entire industry to break out it's "A" game, encourage competition and motivate progress, even among the brays and howls of competitive anxiety.

What follows that first risky step of innovation? Another step.

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FAST STATS

The statistics on Healthcare-Associated Infections (HAIs) and Surgical Site Infections (SSI) make it all too apparent that getting infected while we are addressing health concerns is a major concern in itself.

The most common HAIs are as follows:	
Catheter-associated urinary tract infection (CAUTI)	32%
Surgical site infection (SSI)	22%
Pneumonia (ventilator-associated pneumonia - VAP)	15%
Central-line associated bloodstream infection (CLABSI)	14%

The CDC estimates that, on average:

1 IN 31	hospitals patients
1 IN 43	nursing home residents

have an HAI on any given day.[1]

CDC data from 2020 states that every year there are

1.7 MILLION	infections
99,000	associated deaths

from HAIS.[2]

The estimated costs of HAIs on the US healthcare system range from

$96 TO 147 BILLION.[3]

HAIs are most often caused by antibiotic-resistant bacteria, which have potential to lead to sepsis or death; the following 6 are labeled by the CDC as most serious:

1. Carbapenem-resistant *Enterobacteriaceae* (CRE)
2. Methicillin-resistant *Staphylococcus aureus* (MRSA)
3. Extended spectrum *ß-lactamases* (ESBL-producing Enterobacterales)
4. Vancomycin-resistant *enterococci*
5. Multidrug-resistant Pseudomonas
6. Multidrug-resistant Acinetobacter.[4]

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For more dirt on germs read "Playing the odds of prevention" on page 22.

NEWSWIRE

Sutter Health's supply chain team celebrated at AHRMM

Healthcare Purchasing News and Sutter Health's supply chain team celebrated their Supply Chain Department of the Year award at *HPN's* booth #345 at The Association for Health Care Resource & Materials Management (AHRMM) on Monday August 8.

A number of Summit Healthcare's suppy chain team members accepted their congratulatory plaque and six foot cover blow up of their team picture *HPN* August magazine cover on the AHRMM trade show floor.

The northern California-based Sutter Health Summit's team was selected by *HPN's* editorial advisory board members the value their ability to change processes, strategies to improve tactics, partnerships, and professional relationships to generate desired results.

Read on: https://hpnonline.com/21276847

FDA issues update on monkeypox response

The U.S. Food and Drug Administration is providing an update on its multipronged response to monkeypox in the United States, including its efforts in the areas of diagnostics, vaccines and therapeutics.

The agency has also established a dedicated website to provide important information about the FDA's ongoing regulatory activities related to monkeypox along with frequently asked questions. The FDA will provide updates as developments occur and will continue to work with federal public health partners and industry to ensure timely access to all available medical countermeasures.

"The FDA has been closely tracking reports of monkeypox transmissions in the United States with our federal public health partners and coordinating preparedness efforts accordingly," said FDA Commissioner Robert M. Califf, M.D. "We understand that while we are still living with COVID-19, an emerging disease may leave people feeling concerned and uncertain, but it's important to note that we already have medical products in place, specifically an FDA-approved vaccine for the prevention of monkeypox disease and an FDA-cleared diagnostic test. The FDA is using the full breadth of its authorities to make additional diagnostics and treatments available. We will continue to collaborate with our partners across all sectors to expand accessibility to countermeasures and bolster the tools in our arsenal as appropriate."

The monkeypox virus is part of the same family of viruses as variola virus, the virus that causes smallpox (a virus that has been eradicated globally). Both monkeypox and smallpox fall into the category of "orthopoxviruses." Monkeypox is generally not fatal and typically resolves on its own without treatment. The current outbreak in the U.S. usually presents as a rash on the body, face or genital area. Although there is a very low risk of dying, there have been reported complications including severe pain, at times requiring hospital admission.

Read on: https://hpnonline.com/21275947

Common chemicals linked to billions in healthcare costs

According to a release by NYU Langone Health, daily exposure to a class of chemicals used in the production of many household items may lead to cancer, thyroid disease, and childhood obesity, a new study shows.

The resulting economic burden is estimated to cost Americans a minimum of $5.5 billion and as much as $63 billion annually.

The new work revolves around per- and polyfluoroalkyl substances (PFAS), a group of more than 4,700 manmade chemicals that experts have detected for decades in the blood of millions of people. The chemicals are used, for example, in the production of water- and oil-resistant clothing, electronics, and nonstick cookware, and people are thought to ingest them as food comes into contact with packaging. The substances are believed to disrupt the function of hormones, signaling compounds that influence many bodily processes.

Led by researchers at NYU Grossman School of Medicine, the new study in roughly 5,000 Americans identified 13 medical conditions that may result from PFAS exposure, such as infertility, diabetes, and endometriosis, a painful disorder of the uterus. Together, the diseases generate medical bills and reduce worker productivity across a lifetime to create the costs measured by the study, say the study authors.

"Our findings add to the substantial and still-mounting body of evidence suggesting that exposure to PFAS is harming our health and undermining the economy," says study co-author Linda G. Kahn, PhD, MPH, an assistant professor in the Departments of Pediatrics and Population Health at NYU Langone Health.

Previous investigations have quantified the medical burden and financial costs of low birth weight due to PFAS exposure. However, the new study, published online July 26 in the journal Exposure and Health, incorporates a much broader range of health consequences across the lifespan, says Dr. Kahn.

For the investigation, the researchers determined how many Americans were

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likely exposed to PFAS chemicals in 2018 using blood samples obtained from adults and children who participated in the U.S. National Health and Nutrition Examination Survey. Next, the study team analyzed data from dozens of studies in the past decade that explored diseases connected to the substances.

Read on: https://hpnonline.com/21276215

Premier joins forces with association championing supply chain resiliency

Premier, Inc., a leading technology-driven healthcare improvement company, announced today it has joined the Healthcare Industry Reliance Collaborative (HIRC), a nonprofit healthcare supply chain association that champions standards and best practices in supply chain resiliency.

The provider-led, supplier-supported organization brings together key stakeholders across healthcare to align on solutions to supply disruptions that impact patient care.

Premier will lend HIRC insight from its unique experience as the only healthcare company to virtually integrate the supply chain, co-invest with its members in domestic manufacturing, and provide tech-enabled visibility into the procure-to-pay process for supplies. The HIRC membership builds on Premier's work to protect healthcare providers and patients from shortages using a unique combination of clinical, operational and financial data, as well as supply chain expertise and a commitment to transparent collaboration across healthcare.

"Participation in the HIRC is yet another step forward in Premier's steadfast action on supply chain sustainability and building healthier markets," said David A. Hargraves, Senior Vice President of Supply Chain for Premier. "Premier partners with some of the most forward-thinking, innovative health systems in the nation, and when we all come together under a common banner, we believe we can help eliminate vulnerabilities, mitigate disruptions and build a healthier supply chain now and for the future. We look forward to driving this vital work forward with HIRC."

Read on: https://hpnonline.com/21276080

FDA committed to innovations in medical device sterilization

The sterilization of medical devices is a vital process for helping to prevent serious infections. The U.S. Food and Drug Administration continually works to oversee sterilization methods for these devices to ensure they are effective and used in amounts that are safe for the patients and healthcare professionals who use them.

Ethylene oxide, or EtO, is a gas used during manufacturing processes to sterilize a variety of both medical and non-medical products. Use of ethylene oxide is a well-established and scientifically-proven method of preventing harmful microorganisms from reproducing and causing infections without degrading the product, unlike some other sterilization methods. It is currently the most commonly used method in the U.S. to sterilize medical devices and is widely used by medical device manufacturers and contract sterilizers worldwide.

In fact, more than 20 billion devices sold in the U.S. every year are sterilized with ethylene oxide, accounting for approximately 50% of devices that require sterilization. These devices range from wound dressings to more specialized devices, such as stents, as well as kits used in routine hospital procedures or surgeries that include multiple components made from different materials. Inadequate sterilization can lead to life-threatening infections in patients undergoing a wide range of medical procedures.

Read on: https://hpnonline.com/21276379

Hospital PMI continues to climb

Economic activity in the hospital subsector grew in July for the 26th consecutive month, say the nation's hospital supply executives in the latest Hospital ISM Report On Business.

The report was issued today by Nancy LeMaster, MBA, Chair of the Institute for Supply Management (ISM) Hospital Business Survey Committee: "The Hospital Purchasing Managers Index (PMI) registered 54.9 percent in July, a 3.1- percentage point decrease from the June reading of 58 percent, indicating a 26th consecutive month of growth. The Business Activity and New Orders indexes remained in growth territory; however, the Business Activity Index increased while the New Orders Index decreased compared to June. The Employment Index also a decreased in July compared to June. The Case Mix Index remained in contraction territory, registering 47.5 percent, a decrease of 1 percentage point compared to the June figure of 48.5 percent. The Days Payable Outstanding Index registered 57 percent, up 7.5 percentage points from the 49.5 percent reported in June. The Technology Spend Index registered 53 percent, a 0.5-percentage point decrease from the June reading of 53.5 percent." HPN

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GRIME SCENE INVESTIGATION

Evidence-based room decontamination

by Kara Nadeau

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Cleaning and disinfection of environmental surfaces is fundamental to reduce potential contribution to healthcare-associated infections," states the U.S. Centers for Disease Control and Prevention (CDC). The agency goes onto add, "No single 'blueprint' exists for the best cleaning and disinfection method,"[1] leaving hospitals to ask, "what is best for our facility?"

Here's a look at some of the products and solutions available today to clean and decontaminate hospital rooms, information on their effectiveness, efficiency and safety, and comments from their manufacturers on what improvements may be needed in the future.

The battle against COVID, HAIs and emerging threats

As the old adage goes, "Better the devil you know than the devil you don't." Health systems and hospitals today are battling a broad range of well-known healthcare acquired infections (HAIs), the near endemic SARs-CoV-2, and emerging threats such as Monkeypox. Because nobody can predict what's next around the corner, room decontamination that targets a broad range of dangerous microbes is top of mind for infection prevention.

CURIS 3 Hybrid Hydrogen Peroxide (HHP) fogging system

Hands-free decontamination reaches high touch points

"Hospital rooms and surgical suites require high-level disinfection to minimize microbial contamination and protect patients against pervasive pathogens such as *Candida auris* and *C. diff*," said Jeff Woodson, Product Manager, CURIS System. "Traditional manual cleaning often misses high touch point areas that can lead to dangerous HAIs or leave behind chemical residues that create a sticky environment for pathogens to cling to and grow."

The CURIS 3 Hybrid Hydrogen Peroxide (HHP) fogging system helps eliminate these risks by providing hands-free automated disinfection through a powerful combination of vapor and micro-aerosolized hydrogen peroxide. It targets pathogens anywhere air touches, leaving behind no sticky or corrosive residues

that can damage sensitive equipment like ventilators, computers and electronic devices.

The solution envelops each room in a hydrogen peroxide mist and maintains a dwell time to ensure no contaminated areas are left behind. Its hand sprayer attachment can be used to target high touchpoint areas in the room like bedrails and call bells.

"The CURIS 3 disinfection process is efficacious on even the toughest to kill hospital microbial threats like *C. diff* in a tri-part soil load with a 6-log reduction (99.9999%)," said Woodson. "CURoxide 7% H2O2 solution is an EPA-registered sporicidal disinfectant that is paired with the CURIS 3 device and is featured on Lists K, N, and Q for use against *C diff.*, SARS-CoV-2, Monkeypox, and more."

Pandemic lessons learned drive disinfection innovation

It has been two and half years since SARs-CoV-2, the virus responsible for COVID-19, took the healthcare world by surprise. Sharon Ward-Fore, MS, MT(ASCP), CIC, FAPIC, Infection Prevention Advisor, Metrex Infection Prevention, Envista Holdings Corporation, says the industry has learned some lessons, albeit the hard way.

"One thing we learned is that we *must* begin now to prepare for future outbreaks and pandemics," said Ward-Fore. "One way to do this is to consider surface disinfectants that are Environmental Protection Agency (EPA) approved to meet the Emerging Viral Pathogens (EVP) claim. When rare or novel viruses, like SARs-CoV-2 and now Monkeypox, cause outbreaks of disease, there may be few if any disinfectants that have been tested and registered for use against these specific pathogens. This is how we prepare for the future."

Metrex CaviWipes 2.0 fully qualifies for the for all virus types (enveloped, large and small non-enveloped viruses) to meet current and potentially future infection prevention needs, helping provide a safer environment for patients, staff and visitors. CaviWipes 2.0, which can be incorporated into daily room cleaning and disinfection, features:

Metrex CaviWipes 2.0

- Enhanced efficacy claims against 61 pathogens including Norovirus, *Candida auris,* and multi-drug resistant organisms (MDROs).
- Excellent material compatibility with a neutral pH of 7.5, low alcohol content, and multi-pronged approach to attack and eliminate pathogens while remaining gentle on material surfaces.
- Easy to use label making it quick and easy to find critical efficacy, compatibility and safety information.
- Is bactericidal, tuberculocidal, virucidal and fungicidal with a 2-minute universal contact time.

Addressing HAIs throughout the healthcare continuum

"Outbreaks of new and re-emerging pathogens are adding additional pressure on healthcare facilities," said Emily Rosenberg, MPH, Senior Specialist, Clinical and Scientific Affairs at CloroxPro. "Further, more care is moving to non-acute settings. Healthcare surface disinfectants need to be ready to meet the unique challenges facing infection preventionists and cleaning professionals across the healthcare continuum."

"Clorox Healthcare solutions continue to improve to meet the needs in both acute and non-acute facilities," Rosenberg continued. "Our ready-to-use solutions are designed to deliver fast surface disinfection efficacy and convenience for the ever-changing demands of the healthcare environment."

Clorox Healthcare Bleach Germicidal Wipes

Clorox Healthcare products have been formulated to meet the evolving healthcare landscape. Each of the ready-to-use, 1-step disinfectant wipes maintain fast disinfection efficacy while improving surface compatibility to help drive efficiencies across healthcare facilities without compromising patient safety.

Clorox Healthcare Bleach Germicidal Wipes are a convenient sporicidal surface disinfectant built to kill nearly 60 microorganisms in three minutes or less, including *C. difficile* and *C. auris*. They deliver an improved formulation maintaining fast disinfection efficacy when it matters most while improving surface compatibility and residue profile.

Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes are designed for use daily on common hospital surfaces. With better surface compatibility, less residue, and fast kill times, they are ideal for high-turnover areas.

Clorox Healthcare VersaSure Cleaner Disinfectant Wipes have low odor, low residue and high efficacy in a 2-minute, alcohol-free quat wipe. They are formulated for surface compatibility and offer the versatility to use everywhere, with the assurance of broad-spectrum disinfection.

The focus on whole-room disinfection

Over the past decade, healthcare professionals have increasingly recognized the importance of whole-room disinfection, according to Maryalice StClair, Chief Commercial Officer, Halosil International. She states:

"Awareness is improvement when it comes to room disinfection. Ten years ago, the concept of whole-room disinfection was unknown. Facilities of all kinds used only manual spray and wipe methods and it's widely recognized that this is not sufficient to effectively reach and treat all surfaces against infection causing pathogens."

"True whole-room surface decontamination must be exactly that, whole-room," StClair continued. "This means every exposed surface must be treated, with no possibility to miss surfaces that aren't always reached by electrostatic sprays or UV lights. Dry-mist fogging with the Halo Disinfection System reaches every surface, every time."

Halosil Halo Disinfection System

The Halo Disinfection System provides EPA registered whole room sporicidal decontamination at the touch of a button using dry-mist hydrogen peroxide fogging that doesn't wet surfaces, leave sticky residue, or harm electronics/supplies and requires no rinsing or wiping. Aerosolized HaloMist (5% H2O2, 0.01% silver ions) evaporates into a vapor to

eliminate pathogens everywhere in a room, including floors, walls, ceilings, and all surfaces of complex equipment.

Touchless application makes room preparation simple and quick, saves on labor, and protects EVS staff from harmful chemicals. With no daily flushing or draining required, the system saves on disinfectant as well.

"Finally, affordability equals efficiency," StClair added. "The Halo Disinfection System is the most affordable EPA registered dry-mist or vaporized hydrogen peroxide system on the market today."

Decontamination in a world of shortages

Healthcare facilities have long been burdened with doing more with less. That has never been so true as today. Shortages in labor, supplies and natural resources are prompting facilities to rethink how they approach room decontamination.

Single-use disinfectant pads save time, labor, resources

"The current labor shortage and ongoing supply chain issues can make cleaning critical areas more difficult than in the past," said Jane Easler, Marketing Manager, Contec. "Reducing water waste will continue to be a key issue for many facilities, especially for those in drought-affected areas."

Contec Professional Premira Portables

Premira Portables from Contec Professional is a simple yet effective way to help reduce cross-contamination when servicing floors. Each Portables pouch contains single-use Premira microfiber mop pads that can be saturated on demand.

"Premira microfiber mops feature a patented design that removes debris you can see (and the scary stuff you can't) much better than cheap disposable mops," Easler continued. "Simply pour the chemistry of your choice directly into the Portables bag and reseal it using the handy zip closure. Because the pouch is lightweight even when full of saturated mop pads, it's easy to carry from room to room or area to area. There's no need to pull out the heavy cleaning cart each time a floor needs to be cleaned or disinfected."

An independent product life cycle analysis also showed that using Premira single-use mop pads wastes less water and energy than traditional laundered microfiber mop pads.

"Premira Portables can help reduce cross-contamination while contributing to positive patient outcomes and overall staff efficiency," Easler added.

More efficient room turnover focused on patient safety

Larinda Becker, Executive Director of Marketing - Infection Prevention, Diversey, says facilities are looking for ways to simplify, streamline and standardize room turnover protocols, and having products and procedures that are compliant and effective is key.

"Emerging needs are to have products with shorter dwell times, effective against key pathogens of concern, including emerging viral pathogens, and products that are safer for users and patients," said Becker. "Having these simplified product solutions that can be trained and implemented are more critical than ever."


Diversey Oxivir Wipes

Diversey Perfect Turnover is an integrated program that makes it effective and efficient to turn over rooms for the next patient, without compromising quality. It includes products, best practice procedures, and training tools to help simplify, standardize, and execute cleaning and disinfection. The program's validation tools help enhance performance based on objective measurements of cleaning and disinfection, which guide the cleaning and clinical staff for ongoing improvement refinement.

"Cleaning and disinfection solutions that save time and money are critical," said Becker. "Examples include Oxivir wipes that are effective against a broad array of pathogens in 1 minute, or CleanPatch mattress and stretcher repair system can save money, waste and time."

"Also, facilities continue to seek additional assurance of disinfection and deploying technologies, such as UV-C disinfection devices, which can provide the comfort of ensuring disinfection where surfaces may have been missed. Having the safest and most satisfying environment of care is the ultimate goal," she added.

The realm of UVC in room decontamination

Ultraviolet-C (UVC) has been used for decades in the battle against microbes, to the point where UVC lamps are sometimes referred to as "germicidal" lamps.[2]

"Interest in ultraviolet-C (UV-C) irradiation as a strategy for decontaminating surfaces in the health care environment has skyrocketed during the COVID-19 pandemic," states the U.S. National Institute of Standards and Technology (NIST).[3]

Today, healthcare facilities have a variety of UVC options to choose from when it comes to room decontamination, some of which leverage automation and robotics.

Disinfection documentation for the cleanest environments possible

"The UVC disinfection market has grown exponentially in the past five years as hospitals have been more receptive to adopting the technology and as health care facilities placed higher emphasis on cleanliness throughout the COVID-19 pandemic," said Jennifer Picker, Director of Support Services and Program Development for Tru-D SmartUVC. "Now, more than ever, hospitals are realizing that it's critical to provide the cleanest environments possible."

The Tru-D device, part of PDI's market-leading environment of care solutions, is a portable UVC disinfection robot that delivers one automated, measured dose of UVC to consistently disinfect a room, resulting in the ability to document disinfection results after each and every room treatment.

The Tru-D device ensures significant microorganism inactivation in direct and shadowed areas, reducing human error in the disinfection process and documenting results for each cycle. Validated by more than 10 independent studies, the Tru-D device's combined automated, measured dosing capabilities and real-time usage-tracking features make it one of the most advanced UVC disinfection systems available, according to the company.

Tru-D SmartUVC

"As the emphasis on providing the cleanest environment possible grows, hospitals will continue to seek out new ways to utilize technology in all areas of a facility. Further, as prominent organizations such as the AHA, the CDC and ASHE begin to stress the use of enhanced terminal room disinfection technology, I believe UVC disinfection will become a standard of care for health care facilities."

The future of healthcare is autonomous

An Accenture survey found 71% of health executives believe robotics will enable the next generation of services in the physical world.[4] Aaron Chau, OhmniLabs Product Manager & Team Lead, comments on how its OhmniClean autonomous UV-C disinfection robot improves room disinfection in the hospital environment.


OhmniLabs OhmniClean autonomous UV-C disinfection robot

"We developed OhmniClean to address a critical need in the healthcare market for fast, simple and effective disinfection. The future is autonomous, which is why OhmniClean uses autonomous tech to deliver more consistent disinfection without shadowing. The result is whole room coverage not a-chievable by manual units."

Chau notes how OhmniClean's autonomous operation improves staff efficiency. Since the robot navigates on its own and does not require repositioning several times in one room, operators have more time for higher-level work. Its proprietary mapping technology, QuickMap, makes the robot easy to use; new operators can be trained in as little as five minutes.

Independent testing shows OhmniClean rapidly eliminates pathogens like MRSA, VRE, and SARS-CoV-2 with an efficacy of 99.999%, improving environmental and infection prevention standards aimed to combat HAIs.

Plus, auditable reports are available in real-time to demonstrate that proper disinfection has been completed. EVS

directors, infection prevention specialists, and managers can immediately view data saved in the cloud through the company's web-based portal.

"We've are privileged to work with EVS teams at major hospitals where staff members report faster turnaround times, less required labor, and an overall cleaner healthcare environment," Chau said in closing.

Automated technologies address labor shortages

Healthcare facilities are increasingly adopting automated technologies to streamline workflows and room decontamination holds tremendous opportunities in this space. Ed Navarro, Director of Marketing, UBTECH North America, comments on how the company's ADIBOT-A Autonomous UV-C Disinfection Robot boosts disinfection efficacy and efficiency.

"As workforce shortages continue in the healthcare space, the greater the potential for continuous tasks—those that require detail and attentiveness to prevent infections among staff and patients—to be less effective. Being able to set recurring disinfection runs scheduled at optimal times and with desired frequency, with minimal staffing or supervision required, and with high-efficacy rates, is where the ADIBOT-A really shines."

The ADIBOT-A Autonomous UV-C Disinfection Robot is designed as a highly cost-effective, feature rich, and fully autonomous solution to mitigating pathogens and preventing infections in healthcare facilities such as hospitals, operating rooms (OR), surgical centers, and more.

UBTECH ADIBOT-A Autonomous UV-C Disinfection Robot

"Both a tool and a robotic team member, the ADIBOT-A significantly improves efficacy and efficiency through state-of-the-art artificial intelligence," Navarro commented. "The ability to move around patient and ORs using operator designated disinfection points, or AI self-mapped points, means it can provide 360-degrees of complete UV-C light coverage. This drastically mitigates the 'shadowing' effect where solid objects block the UV-C light from one side—an often-misunderstood limitation of UV-C light solutions using single disinfection points."

"Included reporting tools offer valuable data to all involved in the infection prevention efforts," said Navarro. "EVS teams, Infection Preventionists, and executive leadership will find information to help monitor usage, improve efficiency, and to make informed decisions."

Eradicating pathogens in the shadows

"While surfaces and floors remain targets for enhanced cleaning, to effectively disinfect surface and air pathogens, UVC robots must both properly overcome obstacles that introduce variables in treatment. According to Brian Donahue, with Finsen Tech, "Shadows are our enemy; however, cross contamination is a specific hazard Finsen is trying to shed light on."

"EVERY UVC robot casts a shadow underneath itself, ranging from 8 – 80 square feet." says Donahue. "Pushing or driving a robot from one room to another increases risk of cross contamination. Some place additional items on the floor as part of their cleaning cycles, but all robots cast shadows, and boxy robots are particularly shady."

Finsen Tech THOR UVC system

"THOR offers an innovative design combination: a low, open "spider" base coupled with an integrated undercarriage UVC system inches from floor pathogens lurking in the shadows," Donahue continued. "THOR delivers UVC at ground level and then telescopes up to 7.5 feet – true floor to ceiling disinfection."

Donahue stresses that dosage calculation must be calculated every cycle since room dimensions, contents, as well as relative placement of the robot can drastically change dosage calculation. "Be careful of systems that ignore these important factors in determining proper UVC dosage. Don't believe that accurate cycle times can be calculated without accounting for these critical variables each cycle: power, distance, time and shadows."

On demand UVC with fixed mount system

"More and more healthcare systems are turning to fixed mount UVC systems as an adjunct to their cleaning processes," said Sam Guzman, Global Sales Director, American Ultraviolet. "These fully automated systems are operated by the existing staff with training available through an online portal."

American Ultraviolet's Fixed Mount UVC system achieves high levels of air and surface disinfection in minutes. Two taps on the touchscreen controller will run a fully automated disinfection cycle in under three minutes, which makes use in-between cases possible. The multiple fixtures delivering energy from the top-down limits or eliminates any shadows. Separate disinfection and procedure modes allow the facility the option to use the system during knee, hip or spine surgeries

American Ultraviolet's Fixed Mount UVC system

to lower the microbial load in the air and on surfaces while the wound site is exposed.

"The future of room decontamination is automation, more of a controls-based automation then a robot invasion," Guzman added. "Built in fixtures, always available, no storage or transport issues, operated by the existing staff on demand, and pre-programmed for automated run times with no user input. It is a 'set it and forget it' approach to adding an additional layer of safety for your staff, patients and visitors. Building Automation Systems (BAS) are already used for controlling air conditioning, visible lighting, and other facilities maintenance procedures. It is a natural evolution to automate enhanced cleaning procedures like fixed mount UVC systems."

Casting light on air disinfection

Earlier this year, the Environmental Protection Agency (EPA) announced its Clean Air in Buildings Challenge to assist building owners and operators with reducing risks from airborne viruses and other contaminants indoors.[5]

"Global demand for clean, reliable disinfection has and always will be a crucial requirement, particularly following the emergence of COVID-19," said John Yerger, CEO, Eden Park Illumination. "This move by the EPA further demonstrates the growing concern over improving indoor air quality for public health."

Eden Park Illumination's (EPI) latest Far UV-C product in the battle against airborne viruses, MobileShield222, is a versatile device with EPI's patented UltraSlim Lamp Technology, disinfecting air and surfaces continuously in occupied spaces. The lamp provides the output necessary to inactivate 90% of the COVID-19 virus in air at 3 feet in 12 minutes, according to current research.

"Far UV-C is a technology which is safe to operate in spaces occupied by people, due to the shorter wavelength range which prevents the UV rays from penetrating even the outermost layer of human skin or eyes," Yerger explains. "Our MobileShield222 lamp provides safe and efficient disinfection of airborne pathogens. It is easy to use, right out of the box, and its compact, lightweight design makes it a portable solution. Far UV-C is the future of disinfection, creating a cleaner and safer world."

Eden Park Illumination (EPI) MobileShield222 Far UV-C

High quality disinfection without the high cost

Cost, quality and outcomes are critical to hospitals in today's value-based environment. Implementing room decontamination solutions to reduce the risk for HAIs can help hospitals achieve all three goals – lower costs from fewer HAIs, deliver higher care quality and achieve healthier clinical and financial outcomes.

Sanuvox Technologies provides high-performance air and surface disinfection systems of the highest quality, without

Sanuvox ASEPT.2X whole room disinfection unit

high cost, says the company's Chief Scientist Dr. Wladyslaw Kowalski, stating:

"Sanuvox offers a wide range of UV products designed to provide a complete solution for any type of disease control application. Our unique Biowall system for ventilation disinfection applications, with its axial lamp configuration (lamp axis parallel to the airflow) reduces lamp cooling effects and operates more efficiently than typical 'crossflow' systems where the lamps are positioned perpendicular to the airflow."

Dr. Kowalski says the company's ASEPT.2X whole room disinfection units provide rapid disinfection of surfaces in less time than virtually any other system available. Its ASEPT.1X systems disinfect whole bathrooms or other rooms continuously when the rooms are unoccupied, and its S300 unit recirculates room air and removes in excess of 99.9% of airborne pathogens.

Customized UVC disinfection with intelligent design

Healthcare spaces vary broadly from waiting areas to surgical suites and, as defined by the CDC, from critical to non-critical items with regard to disinfection.[6]

"Every hospital is different. Cleanis believes that hospitals need customized disinfection solutions that are tailored to each hospital's specific needs," said De Ann Siebert, Product Manager, Cleanis. "More than 100 years of scientific research confirm the effectiveness of UVC disinfection, and no other method has been proven superior. Cleanis offers a wide range of customizable and economical UVC products."

OR UVC disinfects surgical sites, between procedures and at automatically scheduled times. Mobile units are available in multiple size and cost options for terminal disinfection of patient rooms. Cleanis UVC products can also continuously reduce microorganisms in pharmacies, as well as open spaces like waiting rooms.

Cleanis UVC products are environmentally friendly and leave no chemicals, no ozone, no secondary contaminants, and no waste behind, so rooms are available for immediate use. Fast cycles improve room turnover time. Intelligent design makes its products easy to use, with safety features to protect against human error. Data analytics are available with some options. Cleanis is proud to say that all its UVC products are made in the USA.

Cleanis Operating Room UVC

The five UV-C must-haves for room decontamination

When asked how UVDI's technology helps drive room decontamination effectiveness and efficiencies, the company's Director of Global Marketing and Product Strategy Will Gerard stated:

"First, it starts with independently proven efficacy. Independently proven 99.99% inactivation of over 35 microorganisms in 5 minutes at 8 feet --- and proven in-field efficacy in 15 published, hospital studies.

"Second, operational efficiency that fits into – as opposed to disrupts – hospital workflow. The UVDI-360 Room Sanitizer decontaminates an average patient room in 10 minutes."

"Third, enhanced ease of use. The UVDI-360's new Smart Device communications automatically transfer usage data to the cloud, and enable simple operation via on-device touchscreen and intuitive remote control."

New UVDI-360 Room Sanitizer with UV Smart Connect

Fourth, 360° surface coverage confirmation technology *during-and-after use* to ensure all targeted surfaces have received a sufficient dose of germicidal UV-C.

"Fifth and foremost, the UVDI-360 is carefully designed for operator safety. Polymer-encapsulated UV-C lamps that will not shatter if broken. Long-range motion sensors immediately shut down the device if people are present. The device is lightweight at 88 lb for ease of mobility by Environmental Services professionals."

With regards to what improvements in room decontamination he foresees happening in the future, Gerard added:

"Effective, enhanced environmental hygiene is possible today – and increasing in the future - without necessitating extra work. Technology enhancements that streamline operational steps and the amount of work required to get the job done. Advancements such as what we see in our homes more and more frequently – smart devices that automatically communicate with each other and humans to make things happen quickly." **HPN**

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STRATEGIC SOURCING & LOGISITICS

Stripes, tags can chip away at supply chain inefficiencies, tracking-and-tracing troubles

by Rick Dana Barlow

As the world struggles to emerge from a lingering global pandemic that exposed underlying vulnerabilities in the supply chain, healthcare organization interest in bar coding and radiofrequency identification (RFID) tools for tracking and tracing products and services should be that much more alluring.

But industry experts tell *Healthcare Purchasing News* that sourcing and evaluating bar coding and RFID products need to be accomplished with the right intentions, motivations and priorities.

Strategies vary somewhat, yet an overarching theme remains: Start with the endgame and work backwards rather than merely salivate and yearn for the latest gadgets, gizmos and technology generating buzz in conversations and in social and traditional media outlets.

"It can be tempting to look at technology first," cautioned Jody Costa, Vice President, Marketing & Strategic Partnerships, Barcoding Inc., "but resist that temptation and start with the process or challenge you need to solve. We recommend building out a current state workflow and a future state workflow before reviewing technology. It's vital to talk to users and/or nurses who are handling items and/or caring for patients, as well as the people who access and use the inventory data. That's where the path toward your best solution will begin to reveal itself.

Costa recommends the following considerations:

- Always start with the process first. Starting with process flows and user interaction will allow you to determine if bar coding or RFID (or both) is the right path forward. Often these technologies are best working together.
- The nature of the materials and environment – radio signals, metals, and liquids can interfere with RFID signals, while certain environments or exposure to chemicals (like disinfectants, for example) could damage some barcode labels and/or devices. That's why it's vital to have the right partner helping you.
- Understand the amount and nature of the data you're handling—RFID tags and labels can carry more information than barcodes, and can be "read" in bulk, but if you're looking at patient item tracking, for example, barcode labels are a more appropriate solution.
- Integration – how is the data being used, stored, accessed, analyzed, and reported? What will be needed to integrate the data into your organization's data management system? What level of visibility do you need to meet business goals? These questions will help with solutioning.
- When reviewing the process, does a person need to be involved? That's one of the key differences between bar coding and RFID. Bar coding needs line-of-sight scanning and RFID does not.

To maximize return on investment, Costa encourages keeping an eye out for any opportunities to improve accuracy and efficiency by implementing technology. Examples might include identifying places where cycle counting is taking significant time. "RFID can often speed up the cycle count process from days/weeks to hours," he said. "Identify any workflows that are currently tracking assets

or inventory on paper or Excel – that's a perfect spot to start to implement a bar code- or RFID-based solution. One particular niche we've seen is with patient belongings and valuables. Using a solution like IntelliTrack's Patient Belongings Tracking application will improve the patient experience immensely."

Concentrate on labor early

Healthcare organizations should focus on three key areas when evaluating the type of track-and-trace technology sought as well as the brand, according to Rich Leitermann, Director of Engineering, WaveMark Supply Management and Workflow Solutions, Cardinal Health.


Rich Leitermann

Healthcare staff time is one. "How do you value the time of healthcare staff?" Leitermann asked. "Day-to-day use of bar codes requires gaining 'line-of-sight- access to each bar code, pointing and shooting. Conversely, reading RFID tags does not require line of sight and will read at up to 100 tags per second at a distance. Think about taking away the tedium of using staff time to find the bar code, point and shoot over and over for each product being counted. I'd ask if the healthcare providers really have the time to do this?"

Tracking individual item attributes versus stock-keeping units (SKUs) is another. "Is it important to track individual item attributes versus only SKUs?" he indicated. "Bar codes often do not include information that identifies individual items. Instead, the bar code may represent just manufacturer and manufacturer's part number. RFID systems usually uniquely identify products down to the 'each,' including serialization, lot number, etc. This is possible because RFID tags contain a worldwide unique identifier that can be associated with all relevant information about the product to which it is affixed. The unique identification from RFID enables richer data that can be used for more advanced reporting and analytics."

Automation and inventory accuracy is a third. "Is automation and inventory accuracy important to you?" he noted. "Using bar codes is predominantly a manual operation. A person has to point the bar-code reader at a bar code. By definition, this makes bar code an error-prone process and will result in lower inventory accuracy. RFID is the path to automating item identification and can provide highly accurate inventory information without taking the time and attention of staff."

Labor should be a key consideration, acknowledges John Freund, Founder and CEO, Jump Technologies. He points to nursing and supply technician compliance in recording transactions.


John Freund

"I think most would agree that if nurses found scanning bar codes to be a simple and efficient part of their everyday workflows, they would do so," Freund said. "However, while bar coding as a technology is less expensive, compliance with scanning is the challenge."

Nursing compliance represents the first factor in that any system should be user-friendly and integrated with other systems, according to Freund. "For example, the ability to update lot and serial numbers, along with expiration dates in the [electronic health record], would be a valuable feature to look for in a system," he said. "Other features to look for in a system include: Does the system decrement inventory and create reorders for items? Does the system create requisitions for bill-only, consignment, and trunk stock items? And does the system update the implant log in the EHR?

"You can have an RFID system that makes recording the transaction simple, but if it doesn't interface with the back-end systems properly and nurses have to do dual entry, then clinical issues will arise, which can complicate implementation and reduce the savings potential of an RFID-based system," he continued. "Therefore, nursing should play a critical role when evaluating these technologies."

Naturally, economics plays a role. "The monetary value of the items being tracked is also an overriding factor in this decision," Freund noted. "RFID technology is good, but not inexpensive. Not only are there facility charges associated with physically implementing the technology, there are ongoing costs associated with getting RFID tags on the items you want to track. That's why RFID doesn't make sense for inexpensive med/surg materials. However, for more expensive materials like implants, it may make sense."

Consequently, Freund recommends bar coding as affordable for tracking med/surg items in sub-inventory locations. "For example, the Jump Technologies system supports Kanban as an inventory method using a bar-code scanner costing just $105," he said. "It's important to remember that the technology being deployed can't drive the costs to track them beyond the reimbursement hospitals receive for them."

Focus on value of labor, products

Any product or service decision designed to improve a process should see roots in a value assessment, according to Jason Rosemurgy, Senior Vice President, Sales and Marketing, Terso Solutions.


Jason Rosemurgy

Staff efficiency must be obtained and maintained. "If making the most of staff time is important, then it's important for providers to consider technology that enables their team to perform the jobs they were hired to do," Rosemurgy said. "Nurses' core responsibilities revolve around providing patient care. A recent study found that nearly 40% of an average nurse's shift time is spent on 'wasteful' activities — often looking for items like supplies and critical inventory. RFID technology, further enabled with the right integrated software platform, can direct nurses to the right inventory in a department or facility. And if that inventory or item isn't where it is supposed to be, it can direct staff to who may have handled it most recently, allowing nurses to refocus on patients and urgent procedures."

Criticality of the inventory needing to be tracked is important, too, and that doesn't always involve costs, Rosemurgy indicates. "As we learned in the pandemic, while expensive inventory is often critical, critical inventory isn't always expensive," he said. "Supplies and items like [personal protective equipment] were often in short supply, sometimes hoarded, or simply not located where they were meant to be stored. Barcode-based systems can be 'confused' by users scanning an individual item and inadvertently taking more than one thing, throwing inventory levels out of balance and possibly overstating inventory levels on these critical items."

Additionally, certain cold chain implants are often best tracked using RFID, specifically RFID enclosures, Rosemurgy recommends. "Knowing for certain that a particular product has been stored at the proper temperature can be a requirement for items like tissue and biologics," he said. "Some of these items have been donated or are related to a trauma-specific surgical case and could truly be considered priceless. Misplacing them or having to scrap them due to not knowing whether an item was kept outside of specified temperature

ranges does tragically happen in the world of healthcare inventory management but can be prevented with the right technology safeguards in place."

Accurate data in real-time can be an important asset, Rosemurgy insists. "Often, hospital inventories are only as good as the last time somebody completed a physical assessment utilizing bar codes, logbooks or spreadsheets," he noted. "Within hours they can be considered completely out-of-date. Barcode-based and other manual systems require compliance by team members, and with today's staffing challenges, these tasks might not be able to be completed as regularly as needed. RFID is automated, requires no line of sight, and connects inventory data to the proper software platforms in real time as inventory and assets are transported or consumed within a facility. The more real time data a provider has, the better decisions their team can make."

Still, bar coding and RFID are data capture technologies that both have their place in healthcare and should not be considered mutually exclusive, Rosemurgy urges.

"Bar-code technology is a solid performer in applications where item value is often lower, and accuracy of the items tracked doesn't need to be 100%," he said. "High-turn, med/surg products often utilize bar codes and workflows like patient charting and tracking applications are also common for barcode-based systems."

As demand for automation increases and the cost of RFID technology decreases, interest in and application of RFID likely will become more pervasive in healthcare, Rosemurgy predicts. "While often part of a barcode-based tracking system, the lower-cost med/surg products could also be incorporated into an RFID two-bin Kanban system, where RFID tagged bins – not individual items – can create automated demand signals and save materials staff tremendous amounts of time not having to run from PAR location to PAR location checking bins. Similarly, we are seeing the emergence of RFID room-based systems in healthcare [that] focus on tracking a product as it moves throughout a healthcare facility, providing data as products make their way from storage all the way to usage."

Functional span, history shape interest

Scott Hondros

In general, bar coding is more widespread because it has become an established technology within the industry for decades, observes Scott Hondros, Vice President, Professional Services, CenTrak, but he sees RFID as more effective for actively locating assets, patients, staff, and visitors.

"Once the appropriate tag and infrastructure are in place, RFID allows healthcare workers to efficiently share data, know real-time locations and conditions of equipment, and avoid human error from manual data entry or human intervention," he noted.

Bar coding can be more prevalent with bulk consumable type items in high demand, such as with bandages and gauze, Hondros compares, but for medication, surgical instruments and very small items in a group, passive RFID can be more efficient, accurate and effective. "Both active and passive RFID have the potential to read multiple assets simultaneously, whereas bar codes require line-of-sight and must be read one at a time. Additionally, mobile medical equipment (MME), such as wheelchairs, stretchers, infusion pumps, etc., tend to come with a higher price point, so it's often beneficial to invest in asset locating technology that can provide real-time locations [via active RFID]."

Hondros further highlights RFID benefits in terms of expanding scale for greater capabilities. "When partnered with a Real-Time Location System (RTLS), it enables healthcare organizations to analyze data to find opportunities for improvement, like shortening patient wait time, reducing bottlenecks, and increasing hand-hygiene compliance, as well as automating workflows, like biomed reprocessing and nurse call response. RFID also allows healthcare facilities to keep patients and staff safe, with solutions like duress location detection tied to panic buttons and tags that help prevent infant abduction. Additionally, healthcare facilities can enhance their asset tracking solution to automate biomed workflows such as PAR-level management, preventative maintenance management functions, and equipment distribution.

Hondros also emphasizes the crucial application of active RFID in dealing with ongoing staff shortages, workplace violence and supply chain challenges to deliver staff satisfaction and retention, peace of mind and availability to critical supply data.

Six degrees of evaluation

James Moore

James Moore, Vice President, Electronic Healthcare Systems, issued six questions healthcare organizations should ask themselves prior to reaching out to prospective bar-coding and RFID vendors to determine the optimal choice for their facility.

1. Will tracking cover the supply chain end to end? Receiving through distribution to patient?
2. Will patient charges be captured and processed to the billing system?
3. Will compliance or the lack of compliance be an issue with organization's personnel?
4. What information needs to be captured?
5. What information will need to be shared with other systems?
6. Is it practical to have part of the supply chain using bar coding while other parts are using RFID?

Any automatic identification technology is meant to reduce errors and increase efficiency by providing identification, location, and at times, health/status data, according to McLeod Williamson, Intelligent Edge RFID Solutions Specialist, Zebra Technologies. He cites a basic example of how bar codes add value with meds administration and how RFID amplifies capabilities.

McLeod Williamson

"With bar-coded patient wristbands and meds containers, fast and accurate scanning of these bar codes helps clinicians adhere to 'The 5 Rights' without slowing down care," he said. "RFID extends this functionality with its capability of scanning multiple items at a time, [such as] taking inventory of a supply room where you have perhaps hundreds of items to be scanned. RFID can be utilized to accomplish this in seconds, whereas scanning each barcode individually would take much longer and could be prone to user error."

Williamson recommends healthcare organizations to consider their own workflows to understand where a lack of data impacts operations and patient care. "Bar codes should be considered table stakes and employed wherever accurate data entry is required," he said. "From there, consider how inventory and durable assets move, are replenished/serviced, or are audited, and determine where a bar-code scan wouldn't be feasible but the more automated, one-to-many scanning from RFID can provide visibility at critical points as these assets travel across the organization." HPN

More Online:

Shopping, sourcing for bar coding, RFID tools and vendors? at https://hpnonline.com/21276179

Navigating overt, covert red flags in the search for bar coding, RFID technology at https://hpnonline.com/21276180

The ABCs on NFC as alternative to bar coding, RFID at https://hpnonline.com/21276181

BELLWETHER LEAGUE FOUNDATION

Bellwether League Foundation inducts the Bellwether Class of 2022 into the Hall of Fame for Healthcare Supply Chain Leadership at its 15th Annual Bellwether League Foundation Induction & Recognition Event to be held at:
Marquette University, Milwaukee, WI, on Monday, October 3, 2022.

Bellwether Class of 2022 to be inducted:

Teresa L. Dail
Edward J. Hisscock
Thomas M. Lubotsky, FACHE
John F. Sasen Sr. (1942-2013)
David R. Myers
Susan M. Tyk
John H. Hammergren
Rosaline Parson

Future Famers Class of 2022 to be recognized:

Ryan R. Burke
René A. Gurdián
Caroline Marion
Allison T. Tidd

For VIP Reception and sponsorship information on celebrating the 15th anniversary of this event, visit www.bellwetherleague.org or contact Rick Dana Barlow at rickdanabarlow@bellwetherleague.org.

Visit www.bellwetherleague.org for more details about the 15 Bellwether Classes, eight Future Famers Classes and two Ammer Honorees.

HEALTHCARE PURCHASING NEWS salutes all 137 healthcare supply chain innovators, pioneers and visionaries in Bellwether League's Hall of Fame for Healthcare Supply Chain Leadership.

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Playing the odds of prevention

by Scott Tomko

Photo credit: Spiroview Inc. & sborisov | stock.adobe.com

Not many people like going to the hospital.

However, as we continue through our life's journeys, we will often encounter illness or injury that either sends us or our loved ones to the hospital.

That being said, most of us all associate 'going to the hospital' with the process of receiving the treatment we need to get better.

We certainly don't equate it with getting worse.

However, in the U.S., 1 out of 31 hospitalized patients are affected by a Healthcare-Associated Infection (HAI). Every year, that equates to 1.7 million infections and 99,000 associated deaths.[1]

MAX impact

Surgical site infections (SSI) account for up to 20% of HAIs, and surgical patients who develop SSIs have a 2 to 11-fold increase in mortality risk.[2,3]

There are countless means and methods, products and technologies involved in infection prevention today, and companies are continually developing strategies to combat infections spreading within healthcare facilities.

BD (Becton Dickinson) has been in the business of preventing HAIs for a long time, first with conventional, plated media and more recently, via molecular diagnostics. The company's BD MAX system provides advanced testing to help clinicians make faster, more appropriate treatment decisions..

John Printen serves as Worldwide Business Line Leader, Acute Molecular Diagnostics, for BD Integrated Diagnostic Solutions (IDS).


BD MAX

"Since the launch of the BD MAX platform over 10 years ago, we have offered assays for *Staphylococcus aureus* (StaphSR) and Methicillin-resistant *Staphylococcus aureus* (MRSA), and that has long been our primary offering for surgical site infection (SSI), infection prevention and monitoring.

We do have a broader portfolio that fits into this HAI space, which includes *Clostridium difficile (C. diff)* and carbapenamase producing organism (CPO). With *C. diff*, many consider this an enteric or GI type of assay, however, at BD we include *C. diff* in the HAI space because it really is an HAI, as incidence of community-based transmission is relatively low.

Most recently, we launched our carbapenamase producing organism (CPO), which was introduced in the US right at the beginning of the COVID crisis, so the timing wasn't right. In 2023, we are planning a relaunch of our CPO assay."

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❷ Accurate, Consistent BP Capture

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❸ EMR Connectivity

Seamless connectivity from the **IQvitals Zone** device to the **EMR** saves time and reduces the likelihood of data transcription errors. **Midmark Zone technology** transfers data to the EMR using a secure Bluetooth® Low Energy connection at the point of care.

1 Proper Patient Positioning + **2 Accurate, Consistent BP Capture** + **3 EMR Connectivity**

= Better BP

Learn more at: **midmark.com/BP3**

Bluetooth is a registered trademark of Bluetooth SIG, Inc.

1 https://www.ama-assn.org/system/files/2020-11/in-office-bp-measurement-infographic.pdf

All aboard the "stewardship"

According to Lauren Cooper, Senior Manager, Scientific Affairs for BD IDS, "driving diagnostic stewardship is an integral part of BD's overall antimicrobial resistance (AMR) strategy and our extensive diagnostic capabilities—like the BD MAX—can help reduce the burden of drug-resistant infections through infection prevention and control, antimicrobial stewardship and surveillance.

Antimicrobial stewardship is a key factor in the battle against HAIs. Bacteria and viruses are often able to develop antimicrobial resistance to standard treatments.

To keep our assays current, we monitor different strains of MRSA that are becoming more prevalent, and we are always focused on keeping our assays up to date with emerging strains and emerging mechanisms of resistance.

The data is pretty clear; molecular screening is, by far, superior in quickly identifying and, therefore, helping support faster clinical decisions to reduce surgical site infections."

A glove above the rest

The proper use of sterile gloves during surgery is one of the vital components of preventing SSIs.

Headquartered in Katy, Texas, Isikel specializes in the production of nitrile gloves.

Bill Williams, Isikel's VP of Operations for glove manufacturing, is well established as the company's 'glove expert.' He is firm in his statements that Isikel's commitment to 'gold gloves' (they are actually blue) is second to none.

"One of the things that differentiates us from all our competitors is that we are bringing a wealth of glove making and PPE knowledge to the table. We have a particularly good proprietary formulation and dipping process. Our gloves provide maximum comfort with a very ergonomic feel, considering the dexterity that's needed every day for nurses, and, it's a powder free product.

We have helped Houston hospitals and others maintain their supply levels. When other suppliers just were not getting them what they needed, we did. And, we have reinvested that philosophy into making sure that we are helping our customers maintain supply chain resiliency. We take pride in our American production and our glove design. We use a very lengthy leaching process to make sure that our glove is as non-allergenic as possible. Meaning that we go to great strides to make sure that we have the minimum number of accelerators and other chemicals that might have sensitivity issues."

In addition, Isikel is one of the few companies that are manufacturing normal saline in the continental US; saline flushes play a key role in infection prevention by keeping tubes clean and sterile.

Williams added, "we are also doing saline flushes. It is just saline in the syringe form. As far as preventing infection, saline flush goes a terrific way toward that."

Isikel gloves

Disinfection on a 'cellular' level

The hygiene of our hospitals is, quite literally, in our hands. And, it's not just our hands, but what's in our hands.

Claire Dobbin is the Sr. Product Manager at CleanSlate.

"It is known that 1 in 4 cell phones are contaminated with pathogenic bacteria in hospitals. It is an unfortunate fact that mobile devices are often forgotten and neglected to be properly sanitized; we even refer to them as the 'third' hand we never wash! This can pose a risk for cross-contamination between staff and patients."

CleanSlate is a company that has gone beyond wipes or solution, and into the world of UV to guarantee cleanliness. The company's latest development, the CleanSlate UV Versa, is an advanced UV sanitizer that conveniently fits into the work environments of hospitals and healthcare facilities.

Dobbin continued, "the idea (for Versa) originated due to high demand for UV solutions in healthcare, but, there was an issue with limited floor space available. We were able to penetrate the market with our other products into entrances, nurse's stations, waiting rooms, etc. However, due to their large size, we were not able to deploy in high enough density to sanitize devices between patient care, creating gaps in accessibility for sanitizing devices.

The CleanSlate Versa was designed to not only be more accessible with our wall-mount feature, but to enhance the overall user experience. We've added more features like a customizable HD display, long-lasting bulbs, and a completely touchless model to help limit the spread of infections."

It is also developed to ensure the best efficacy and product safety. We've made significant changes in the engineering design to improve both UV performance and device intelligence in a compact form. Our goal here is to provide hospitals with a solution that not only sanitizes phones but ensures that they also get the data insight needed to help improve their infection prevention & control practices."

At the APIC show in 2022, healthcare professionals reacted very positively to seeing the new product.

Dobbin continued, "many agreed that a wall-mounted option was great for their facility as it would now provide better access for staff to sanitize their phones. It was great to hear this from many of the attendees as it was exactly what we had designed the Versa for."

Cleanslate Versa sanitation station

A wipe of a different color

Kinnos is a company that is turning many heads in the disinfectant industry with their application of 'color technology.' Their technological innovations revolve around the development of a colorizing additive for disinfectants known as Highlight, which is now being used by first responders, transit agencies, and several healthcare systems.

Highlight colorizes the wipes hospitals already use so staff can confirm their surface coverage and learn that wiping technique matters. The bright blue gives users instant visual confirmation of surface coverage, and fades if the surface is clean. Where

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it doesn't fade is indicative of dust, debris, or gross contamination bound to a surface that requires another pass of wiping.

Rachael Sparks is Kinnos' VP Marketing.

"Highlight is a solution to a basic limitation of disinfectants: they are transparent. When surface disinfection is critical, performing it with clear disinfectants amounts to cleaning a patient's room with a blindfold on. Highlight colorizes the wipes hospitals already use so staff can confirm their surface coverage and learn how wiping technique matters. When you see what you're doing with Highlight, you suddenly can also see what you're not doing. It's empowering to correct your own work, and most importantly, it's better protection for patients.

COVID heightened our awareness of how germs spread, yet the CDC reports that HAIs are now trending back upward. Hospitals are looking for innovations that can fix the weaknesses in the cleaning process. Highlight is providing hospitals with a simple but effective tool to improve the cleaning process quickly; and, it's useful in every patient care space.

Hospitals utilize Highlight wherever they use bleach, comparing their cleaning scores without Highlight to with Highlight, and the results are staggering — essentially they are going from random A,B,C,D to Fs on their cleaning scores to consistent, 100% A+ scores. Many are beginning to standardize Highlight facility-wide as we launch quats compatibility this month, including daily cleans where patients can see and learn about the patient safety effort and reflect it in HCAHPS cleanliness scores."

Kinnos Highlight deminstraton on bedside table

Smooth operator

Ecolab is a company that specializes in the areas of water, hygiene, and infection prevention solutions. The Ecolab Operating Room Program ensures proper cleanliness within the operating room and transforms turnover rates, while at the same time eliminating the chances of infection.

According to Olivia Broaddus, the Senior Marketing Manager, Healthcare, Digital Strategy, "the Ecolab Operating Room Program is designed to help monitor and standardize processes, optimize infection control and decrease turnover time in the OR. Ecolab delivers customized digital tools that collect data on OR Turnover time and high-touch object cleaning, as well as measures compliance and pinpoints precisely where corrective action is needed. These actionable insights allow higher operating room utilization and process improvements where they are needed most – standardizing workflows and keeping patients safe.

Operating room program by Ecolab

In addition, the Ecolab OR Program includes a digital training element to help hospitals improve the quality and consistency of clean for this critical care area.

Broaddus continued, "Ecolab offers both in-person and on-demand virtual training for OR staff to develop and refresh core competencies for environmental cleaning and disinfection in the OR, standardize the knowledge base across the team, and sustain program outcomes. Depending on facility size, we can spend up to 3 weeks initially implementing the OR Program at a facility. We then provide refresher training and quarterly status reviews to identify successes and opportunities for improvement. Our goal is to ensure that every member is confident in our OR Program."

ASP for sterilization

Advanced Sterilization Products (ASP) is focused on the proper care of instruments used in healthcare facilities, in particular, the reprocessing of endoscopes.

Julie Gorog RN, BSN, is a CNOR Clinical Education Consultant for ASP.

"One of the most challenging factors with reprocessing of endoscopes is failure to adhere to standards, guidelines, and manufacturer's instructions for use.

"With ASP's AEROFLEX Automatic Endoscope Reprocessor and EVOTECH Endoscope Cleaner and Reprocessor, MRC/MEC monitoring is automated and accurate for every cycle, reducing the patient risk associated with test strip errors."

ASP's STERRAD sterilisation systems utilize a low-temperature, hydrogen peroxide gas plasma technology to sanitise instruments efficiently.

Gorog continued, "best practices in quality monitoring of sterilization include every load monitoring with a biological indicator to confirm adequate conditions were met for sterilization. Improperly sterilized instruments put patients at risk for surgical site infections. Both AAMI and AORN recommend the use of a process challenge device which provides a challenge greater than or equal to your most challenging instrument to sterilize.[4,5] AAMI standards state 'PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle.'[4]

STERRAD VELOCITY BI/PCD is an all-in-one Process Challenge Device for STERRAD Systems that meets AAMI recommended guidelines and AORN recommended guidelines for monitoring with PCDs every cycle."

Give them a hand

Vaask CEO Jon Olsen focused on the unique challenges of healthcare settings when designing the company's hand sanitizing fixture.

"Hospital personnel have told us they are particularly concerned about the slip risk caused when sanitizer spills on the floor," Olsen said. "Vaask's laser sensor and high-end motor and pump take this hazard away."

Even if a hand is pulled away just before dispensing, the pump will immediately stop and retract. The PalmPilot sensor accurately detects hands of all sizes and colors.

"You can also adjust the amount of sanitizer solution dispensed, which is something no other fixture offers," Olsen said. "For example, you could reduce the dispensing volume in a pediatrician's office to accommodate children's smaller hands."

Vaask PalmPilot hand sanitation unit

Vaask also takes a more sustainable approach to hand sanitizing.

"Our fixture is built to last using aluminum and steel, uses AC power or PoE (power over ethernet), and features a large-capacity, refillable sanitizer cartridge," Olsen said. "No need to dispose of batteries or single-use cartridges."

With Vaask's connected platform, units don't have to be individually checked and instead can be monitored from an app on your iPhone or Android device or PC.

"Facilities managers can get real-time estimates of how soon each unit will need to be refilled, saving on time and labor costs," Olsen said.

Facilities have three options for installing Vaask's hand sanitizing fixture. It can be recessed into a wall, in a mount attached to the wall or on a tip-resistant free-standing mount.

Global impact

Molnlycke has continually advanced their powder-free, low protein, Biogel gloves over the past 3-plus decades, always focused on materials that are healthier and provide better protection.

This includes moving away from natural rubber latex - which can cause allergies and even anaphylaxis - to polyisprene, a synthetic material that mimics the fit, feel and comfort of natural rubber latex.

In addition, every Biogel glove undergoes a 13-point quality review to ensure quality; this includes mechanical, chemical, and microbiological testing.

Corinne Schmid, Molnlycke's Senior Director of Marketing, discussed the company's newest facility in Malaysia, as well as it's in-depth conversion process.

"This same stringent inspection process will be in place at the newest Biogel factory opening this fall in Malaysia. The facility will manufacture Biogel surgical gloves with an aim to increase capacity by 50% and produce millions of gloves every year in a less energy intensive way.

Mölnlycke Biogel PI Ultratouch 5

Molnlycke draws upon deep experience to help facilities achieve their goals around standardization and reduced utilization, and deploys a surgical support team to optimize use across clinicians.

The high-touch conversion process begins with glove sizing, style selection and in-servicing. During the actual conversion stage, Biogel glove experts provide on-site support, including coordinating stocking. Post-conversion includes follow-up visits, efficiency reviews and CE edication on topics such as infection prevention, sharps safety, and other practices that increase effiency and enhance safety." **HPN**

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Eight tales of transformation

Sterile Processing Innovation

by Kara Nadeau

Photo credit: Beboy | stock.adobe.com

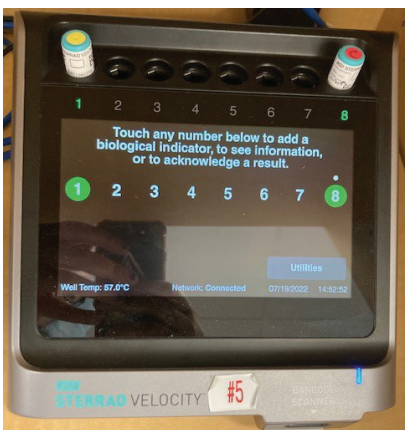
The Central Service/Sterile Processing & Distribution (CS/SPD) teams and suppliers to the department are constantly collaborating on the development and implementation of innovative products, services and technologies.

Here are eight innovation stories in the CS/SPD space that have generated value, including greater efficacy, accuracy, efficiency and safety, as well as cost savings and improved customer service to clinical teams.

1 Sterility validation automation increases efficiency and safety for Sanford Health

The American National Standard/Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities recommends a process challenge device (PCD) with the appropriate biological indicator (BI) be used at least daily, but preferably in every sterilization cycle.[1]

If the Joint Commission walked into your CS/SPD and asked for evidence of BI use for sterilization monitoring, how easy would it be for your team to produce accurate and complete records for their review?



STERRAD VELOCITY BI System at Sanford Health Bismarck

When a sterile processing team manually records load monitoring, there is always the risk for human error, as Brandi Everding CRCST, CER, Manager of Sterile Processing, Sanford Health Bismarck in Bismark, N.D. explains. Her facility monitors every load with a BI – which amounts to up approximately 50 low temperature loads per day. She states:

"Just think about manually logging the BI information – lot and load numbers, BI time in/time out – for that many loads. With all the interruptions we face in sterile processing there are plenty of opportunities for error. In some cases, information would be missing from the log, which caused frustration among staff members. Let's say you arrive for your shift and find a load sitting there with no BI time out recorded. That means extra work having to run that load again."

Everding and her team wanted a way to eliminate manual processes to lower the risk for incomplete or inaccurate documentation and bring greater efficiency to the department.

They implemented the ASP Ecosystem, consisting of STERRAD Systems with ALLClear Technology,

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[1]15 or 30 minutes to results dependent on software version. Refer to the IFU for actual time to results.

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Important Information: Prior to use, refer to the complete instructions for use (IFU) supplied with the device(s) for proper use, indications, contraindications, warnings and precautions.

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the STERRAD VELOCITY Biological Indicator (BI) System, and ASP ACCESS Technology, in conjunction with the CensiTrac instrument tracking system they already had in place. This enabled the team to eliminate manual recordkeeping for its low temperature sterilizers.

"It's pretty amazing because when you scan the BI into the sterilizer, the system knows to match the BI with the load and all of the data electronically transfers," said Everding. "From a compliance standpoint, load documentation is complete and accurate. That's what we're looking for from a patient safety perspective and that's what Joint Commission is going to look for when they conduct a survey. In my opinion, this system has improved this task and the workflow in our department by 100%."

Everding's advice to other CS/SPD teams implementing this solution: "Make sure you get everyone on board who needs to be involved – your SPD manager, IT department, a couple of super users – and work collaboratively so there is a smooth transition."

2 Instrument protection trays alleviate CS/SPD and OR headaches, cut down on instrument damage for Buffalo VA Medical Center

As the intricacy of surgical instrumentation continues to increase, so does the obligation of the CS/SPD and OR teams to protect these valuable assets from damage and loss. A study of one hospital's cataract instruments repair costs found it was spending $7,361 annually – and that is for just one surgical service line.[2]

When Loretta Collins, Asst. Chief SPS, Buffalo VA Medical Center, Buffalo, N.Y., joined the healthcare organization, she found holes in wrapped instrument trays to be a "big issue."

"There were a lot of headaches from the OR because they had to check for holes," Collins explained. "Then for us in the CS/SPD, we were reprocessing trays that had already been sterilized."

The hospital was also bearing the financial burden of repairing or replacing delicate instruments that were damaged during reprocessing or transport from the CS/SPD to the OR and back again. Buffalo's poor water quality meant they could not use tray liners to aid in protection.

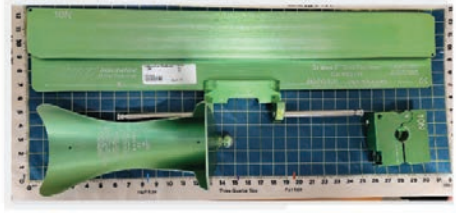
Collins, who had used InstruSafe Instrument Protection Trays from Summit Medical, an Innovia Medical Company, in a previous facility, once again turned to the solution in her new facility. InstruSafe trays are perforated metal trays — or cassettes — with feet, handles, latches, and medical grade silicone instrument holders – designed to provide 360 degrees of protection during sterilization, transportation and storage.

"The trays are a huge asset to our department and the OR," said Collins. "They have an organized set-up with bumpers on them so when we do wrap them, they are less likely to get holes. This has cut down on reprocessing big time. They have also saved us money on buying new instruments because they don't get damaged in the pan."

When asked for her advice to other CS/SPD teams, Collins stated:

"I would tell others to do it – invest in the InstruSafe trays. When you break down how much you spend because of holes in wrap and reprocessing, the staff time and materials needed, and the cost of instrument repairs, you'll realize that you will save money in the long run."

BEFORE



AFTER

3 Instruments CTO Tray - Orhtopedic, Stryker De Mayo leg positioner - arranged in Instrusafe Tray from Innovative Medical

3 Instrument storage system helps UMC Tucson better meet surgery demands

Before implementing the HALYARD* and BELINTRA STERISYSTEM, Banner-University Medical Center (UMC) Tucson SPD department was struggling to effectively address the system's influx of surgeries while simultaneously welcoming two new orthopedic surgeons who required at least 150 more tray spaces in the SPD.

"We knew we had to keep cases and scheduled procedures on track, so after hearing about HALYARD and the BELINTRA STERISYSTEM storage system, we turned to them as a new, efficient solution to the challenge at hand," said Lester Hubbard, Senior Manager of Sterile Processing at UMC Tucson.

To ensure a seamless installation process, team members from O&M Halyard and BELINTRA started with a free, onsite assessment of UMC Tucson's SPD – measuring the current space, understanding equipment in use and procedures, and identifying specific opportunities to maximize the space and improve workflow.

"From there, we made sure UMC Tucson had the knowledge and information needed to get the full game-changing value of the HALYARD and BELINTRA STERISYSTEM," said Cory Ezell, North American Sales Director for BELINTRA. "All implementation work was performed by our own employees who coordinated the installation to prevent disruption to the OR and worked directly with UMC Tucson staff to ensure they felt confident in how to best use the system and maintain the new efficiencies it started to provide."

The HALYARD and BELINTRA STERISYSTEM provided an immediate impact to UMC Tucson's sterile processing department, according to Ezell. The facility went from processing 700 trays a week to close to 1,000 after the installation. With the STERISYSTEM, there is now additional room for 400 more trays, allowing for an increase in procedures, better ability to meet surgery demands, and improved outcomes.

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"With increased tray storage and decluttered space, it is now extremely easy for them to walk down an aisle and find what they need," Ezell commented. "Before, you would see stacking and other clutter that introduced safety hazards, especially in times of staffing challenges. We know their staff has been pleased with the results and that our work has exceeded the employees' expectations."

"Not only did the implementation of the HALYARD and BELINTRA STERISYSTEM improve efficiencies and storage capabilities, but it also allowed us to address other problems like staffing burnout and morale," said Hubbard. "At our facility, we have a 6,000 sq. ft. sterile processing department with 54 employees. After installation, members of the OR teams came down to the SPD to see the new layout. It was very rewarding to hear shared excitement about the new space. Though some outside of sterile processing may not realize it in the day-to-day, everything we do is aimed at improving the patient experience and providing high quality care."

"After the STERISYSTEM installation, our employees became more excited to come to work with the storage system increasing efficiency and organization – helping them succeed and provide a high-quality patient experience," Hubbard added. "Their feedback led to exploring and identifying innovative ways to tackle the ongoing dilemma of addressing efficiency and safety in a new way."

4 Reprocessing sinks and automated flushing solutions optimize decontamination workflow and ergonomics for greater efficiency and safety

In the CS/SPD department of NorthShore Skokie Hospital, the decontamination area was generally regarded as uncomfortable and crammed, with staff members bending over sinks, manually flushing with syringes, and having low visibility due to poor lighting.

Quality of work environment changes were needed to ensure the quality of the sets coming out of the department. Additionally, enhanced ergonomics and organization would make it easier for technicians to perform at the high level required. To accomplish these goals, NorthShore Skokie Hospital implemented Pure Processing healthcare reprocessing sinks and the FlexiPump Independent Flushing System in its CS/SPD department.

Pure Processing sinks in NorthShore Skokie Hospital's CS/SPD department

Pure Processing's sinks delivered several features that improve the quality of the working environment for technicians, including:

- Pegboards that enabled the consolidation of necessary equipment and materials to minimize movement within the department when completing tasks. Technicians also benefit from being able to see when something is out of stock or missing more readily, helping to keep necessary materials in-stock and available.
- Workflow etch plates to easily identify various areas/purposes of each sink. Coupled with the streamlined workflows realized from the use of pegboards, workflow etch plates helped make it much easier to guide new and experienced technicians through processes.
- Height-adjustability of every sink in the department allows every technician to do their work within an optimal ergonomic range, based on their height.
- Light hoods above each basin that enhance visibility.
- Timers were implemented to help technicians meet instructions for use (IFU) flush/soak requirements.

Attached to pegboard panels are FlexiPump Independent Flushing Systems, which eliminated the need to syringe flush, not only making it easier for technicians to flush devices, but reducing time spent flushing. Consistency of flushing now guarantees compliance with IFUs.

"This was our first time working with Pure Processing," said NorthShore's Director of Sterile Processing. "Going in, my disposition was 'they're just sinks.' Now, I wouldn't want to use anything other than Pure Processing sinks. They are high quality, but the more important aspect of this project was the customer service. We always felt supported when we had questions or needed help with something."

Set quality has increased, processes and workflow have been optimized and clearly laid out, and the department is more well-lit, organized and ergonomically friendly throughout.

"These solutions have made it easier for staff to do the right thing, every time," the Director added. "Team members now look forward to working in decontamination at NorthShore's Skokie location, and technicians are generally more comfortable doing their work.

Her advice to other CS/SPD teams:

"When doing a project, it's important to find a true partner. Pure Processing is trying to elevate technicians and the reprocessing profession. Things happen, things come up throughout a project; this truly felt like a partnership between NorthShore and Pure Processing. That's value added beyond the products."

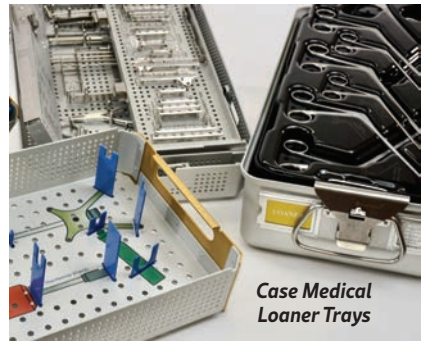
5 Containerizing loaner trays maintains sterility, saves time and money

Loaner trays present unique challenges to sterile processing. In some cases, their late arrival to the CS/SPD department means staff members don't have enough

time to properly process or review the manufacturer's instructions for use (IFU).[3]

Prior to joining Case Medical as a Clinical Specialist, Tonya Mochin served as a CS/SPD Manager for Penn State Hersey Medical Center in Hershey, Penn., and Geisinger Community Medical Center in Scranton, Penn., where she struggled with holes in wrapped loaner trays. As Mochin explains, this created unnecessary operating room (OR) delays and extra work for the CS/SPD staff:

"Loaners come into facilities with only a brief time to process. The loaners we wrapped were heavy and a challenge ergonomically as there are no handles for lifting. Further, they need to be transported in multiple case carts because wrapped trays cannot be stacked. Then, if there is a puncture or tear, it now requires reprocessing. At the time 'flashing' was used too frequently, which is not recommended for implant trays."


Case Medical Loaner Trays

To protect the integrity of sterilized loaner trays, Mochin spearheaded an effort to move from wrapped sets to sealed containers at both Penn State Hersey Medical Center and Geisinger Community Medical Center. Her contribution was two-fold: (1) developing a justification to sterilize loaners in sealed containers and (2) listening to the customer's voice to reduce processing times and delays with loaners.

As a result of Mochin's efforts, both healthcare facilities made the decision to switch to SteriTite sealed containers, which are American made, compatible with all devices that can be sterilized, dry very quickly in steam sterilization, and DIN sized to accommodate DIN sized trays.

"My staff found it far easier to drop loaner trays into containers than wrap," said Mochin. "The dimensions of the SteriTite container (width and length) were a perfect fit for the loaner trays. In some cases where the tray system was too wide for the container, we removed the wrappable outer case and lid and used the inner trays only within the SteriTite container or placed some items in an instrument basket for proper fit."

Mochin and her team established a "lending library or loaner bank" on the clean side of their department to store the SteriTite containers for when loaner trays arrive.

The results: A happy staff and well-functioning department, greater process efficiency and better service to the customer – the OR team.

"With no more tears or punctures, the staff was very happy that sets were now in use and not returned for reprocessing," said Mochin. "OR delays were no longer caused by reprocessing delays. We were able to reduce sterilization times, because the containerized sets were now dry in less than 10 minutes. We eliminated 'flashing' or IUSS so we could provide the same level of care to all patients."

Her advice to other CS/SPD teams:

"My advice is to transition to sealed containers. Demonstrate how sterilization containers can save time and money over wrapped items. This will reduce stress, turnaround time, increase surgeon satisfaction, and contribute to the bottom line. While loaners are not hospital property, placing them in containers may in the end show the greatest savings to the facility, as one container can be used frequently for any set coming in and out of the facility. More turns, more value."

6 Automating robotic surgical instrument reprocessing drives efficiency and consistency

In 2018, the U.S. Food and Drug Administration (FDA) provided guidance around reprocessing instructions for reusable medical devices, which includes robotic surgical instruments. This FDA guidance outlined requirements for manufacturers of washer/disinfectors to validate reprocessing instructions, specifically when indicating them for use with reusable medical devices, such as with da Vinci EndoWrist instruments.

"The only reprocessing option was to process da Vinci EndoWrist Instruments using a labor and time intensive manual process," said Sarah Brown, Senior Product Manager, STERIS. "Customers sought out Intuitive and STERIS asking for a solution that automated the cleaning process for these complex devices. STERIS and Intuitive worked together to help simplify the automated cleaning process, creating easy-to-follow instructions that help create cleaning outcomes consistent with the manual cleaning process."

They added a RAS (Robotic Assisted Surgery) cycle and racks to the AMSCO 7000HP washer/disinfectors to help facilities reduce the soak time and completely eliminate ultrasonic cleaning for select devices. The process reduces the number of manual steps at the sink for cleaning select da Vinci EndoWrist devices by using the 7000HP washer/disinfectors and RAS cycle and Racks to clean da Vinci EndoWrist devices.

"We have seen many customers adopt the use of the RAS Racks and Cycle and transform their process for cleaning da Vinci EndoWrist instruments," said Brown. "They are able to reduce total processing time without sacrificing consistent cleaning outcomes."

One customer using the AMSCO 7000HP washer/disinfectors with RAS racks and cycle is Memorial Hospital, Jasper, Ind. Toni Cibak, CST, CRCST, the hospital's Sterile Processing Manager comments on the benefits:

"Our STERIS 7053HP Washer/Disinfector with RAS cycle has been a game changer. The RAS cycle that washes da Vinci [EndoWrist] instruments saves us time. Previously, we had to wash them in our ultrasonic and then washer to clean them. Now we have a special rack and cycle to do the same thing. It saves us steps and time."

7 Off-site sterile processing serves multiple hospitals with increased accuracy and efficiency

Space is often at a premium for healthcare facilities based in urban areas. With surgical volumes growing along with the number of instruments and devices that must be reprocessed, it can be a tight squeeze to include a large enough CS/SPD department to meet a hospital's needs.

A major metropolitan hospital system on the East Coast was in the process of designing a new hospital in the city center,

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Hänel Rotomat installation in SPD

but without a sterile processing department onsite. They had a desire to create a central processing area offsite that would manage five hospitals across the network, so space was needed to consolidate these separate entities to one single location. This "surgical warehouse" is intended to house not only all surgical instrument trays, but soft goods as well.

The hospital system implemented a "just-in-time" (JIT) distribution philosophy and new trucking distribution model that delivers case carts into each individual hospital only as needed. They deliver carts from the offsite CS/SPD the day before scheduled surgeries, and later retrieve used materials for reprocessing offsite.

As Craig Sinclair, Manager of Systems Integration & IT with Hänel Storage Systems, explains, JIT is meant to increase efficiency and decrease waste by receiving supplies only when needed for surgeries, which in turn reduces inventory costs and increases inventory turnover.

"All materials are sterilized and packaged outside the hospital environment, which was a completely new process," said Sinclair. "Also new was the majority of picking labor. Rather than use sterile processing specialists at a satellite location separate from the hospital, the SPD model was turned into more of a distribution center model."

The offsite CS/SPD employs warehouse and distribution center specialists who are experienced in picking and placing inventory items from a pick list. "In this way, the surgical instruments and soft goods are just a different type of item found in a warehouse," Sinclair explains. "Think of an Amazon distribution center on a smaller scale, but with only SPD inventory."

According to Sinclair, the results have been unique in the industry: An offsite CS/SPD that serves multiple hospitals at the same time, while increasing accuracy and efficiency at each respective location.

"Don't discount creating a new strategy culled from best practices found in a different industry," Sinclair added. "There are tried and true business models from other types of businesses that can be applied to in a hospital environment if you're open to changing your paradigm."

8 Automated sterility expiration date tracking drives compliance for a growing number of health systems

In its Guideline for Disinfection and Sterilization in Healthcare Facilities (2008), the Centers for Disease Control and Prevention (CDC) states: "Any item that has been sterilized should not be used after the expiration date has been exceeded or if the sterilized package is wet, torn, or punctured."[4]

Peter Hawryluk, Account Executive, MedVantage, notes how this presents a what comes first, "chicken versus egg" scenario for CS/SPD teams. He states:

"Hospitals used to do things based on the integrity of a sterile package. A tray was always assumed sterile unless it was damaged, open or wet. Now hospitals are noticing that instrument manufacturers want them to manage integrity by sterilization expiration date. So, what comes first - the expiration date or integrity of the package?"

Hawryluk says he sees a growing number of hospitals switching from event related (e.g., hole in wrap) to time related (e.g., expiration date) sterility monitoring. For these facilities the challenge lies in keeping track of when trays have been sterilized and when they are set to expire.

MedVantage's solution is the SteriDate, an automated labeling system for the CS/SPD department. It improves efficiencies by eliminating human error handwriting mistakes while ensuring patient safety and regulatory compliance. It comes as a standalone kiosk monitor that pairs with one or two printers via Bluetooth, or as software downloaded to an existing computer that can be paired with one or two printers per station.


MedVantage SteriDate automated labeling system

"Our SteriDate system captures expiration dates for facilities and fulfills that need," said Hawryluk. "It automatically captures the date a tray has been sterilized and includes the corresponding fixed expiration date. The user can print a label from the system to affix to the tray that includes the expiration date, sterilizer number, cycle/load number and the initials of the employee who ran the load."

Hawryluk says customers can choose from a variety of label formats, including those color coded by sterilization expiry (e.g., yellow for 180 days, red for 265 days, etc.), to serve as a visual aid in helping the CS/SPD team manage trays in sterile storage. The system alerts users to trays nearing expiration. The system also allows users to record event-related sterility breaches, such as when a tray's wrapping is found damaged, open or wet.

"We find that once a flagship hospital in a system adopts the technology, the rest of the hospitals in the system soon follow," said Hawryluk. "It's a great way to standardize." **HPN**

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

LEARNING OBJECTIVES

1. *List eight types of expiration dates commonly used in medical device reprocessing and preparation*
2. *Identify ways to manage expiration dating in sterile processing departments*
3. *Discuss expiration dating activities to help keep departments ready for regulatory surveys*

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Expiration dating in the SPD

by Michele McKinley and Tammy Gentry

Is this expired? It seems like the question should be an easy one to answer by looking at the label of any time-sensitive item in a sterile processing department (SPD). But what if the labeled expiration date isn't the one you need to follow? Many items in the SPD are labeled with expiration dates, but some require new expiration dates once a bottle is opened. Others receive expiration dating after they have gone through a process. Still others must be determined from a combination of items that have different individual expiration dates. In order to be sure that all sterile processing functions are safe and compliant with product instructions, department policies, and regulatory standards, it's important to understand which expiration dates should be followed and where to find them.

Expiration dating purposes and terms

Expiration dates inform users when an item is no longer acceptable to use safely. What makes an item unsafe depends on the type of item. For example, one common item used in SPDs is microbicidal chemistries such as sterilants and disinfectants. As they age, the active ingredients in these formulations can lose their ability to kill or inactivate microorganisms over time. The expiration dates printed on sterilants and disinfectants help prevent staff from using a microbicidal chemistry that is ineffective.

Products that use active biological components can also lose potency over time. One example is enzymes in cleaning chemistry formulations, which can decline and lose effectiveness against their targeted soils. Another example is bacterial endospores in biological indicators, which can weaken or die as they age. Without strong bacterial spores to challenge the sterilizer, the sterilization process may test as "acceptable" but actually be failing to deliver the required kill level, resulting in potential undetected infectious material remaining on the devices after the sterilization process completes.

Many expiration dates are assigned at the time of production by the manufacturer. There are also dates assigned by the sterile processing technician, either when the item is opened or after it has been processed. Technicians must understand when expiration dates are assigned, which are their responsibility, and where they can find the expiration date for every item in the department. Identifying expiration dates requires an understanding of the types and terms for all relevant expiration dates.

- *Expiration or expiry date:* This date is assigned at the time of manufacture. Typically, it is the last day the item

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can be used. The majority of expiration dates include the month, day, and year. However, a few may still have only the month and year printed on the labeling. The instructions for use should state whether it is the first day or last day of the month. These include:

- *Hang time:* Hang time refers to the number of days that a reprocessed endoscope can be stored after drying before it's reused.
- *Open bottle dating:* This refers to the practice of assigning a new expiration date based upon the first opening of a bottle. This date gives the maximum time that an item is stable after the bottle is opened and the contents are exposed to air. Water test strips, high level disinfection test strips and some cleaning chemistries have defined open bottle dating rules. Open-bottle dating does not extend the labeled expiration date of the item; it often shortens the usage time of the contents.
- *Period after opening (PAO) date:* similar to open bottle dating, this is the amount of time that an item remains safe for human use after opening. Although PAO is typically used for cosmetics, it is occasionally seen in instrument processing areas.
- *Post-sterilization shelf life:* This refers to the length of time after a sterilization process that the sterilized item can be safely used. This dating is independent of product expiration dating. Sterilization pouches are a great example. When manufactured, sterilization pouches are assigned an expiration date. This date is related to the pouch's ability to seal and the chemical indicator's performance in the sterilization process. Once the sterilization pouch is used in a sterilization process, the pouch expiration date is no longer valid, and the post-sterilization shelf life date is followed. This date is based upon the ability of the pouch to protect the sterile contents from microbial invasion and the stability of the chemical indicators after they have been sterilized.
- *Shelf life:* This is the time frame within which an item remains fit for use. The shelf life is used to define the expiration date. It can be used to assign the expiration date at time of manufacture, at package opening, or after a process. Labels and instructions for use may include directions based on shelf life such as "stable for two years from date of manufacture" and "use within six months of first opening the bottle."
- *Event-related shelf life/expiration:* This indicates that the item is fit for use until a specified event makes the item unfit. This type of expiration dating is used primarily with sterilized packages of surgical instrumentation. Items are safe for use until an event that can potentially allow microorganisms to enter the package and reach the sterilized items occurs. Tears in wraps, popped pouch seals, and evidence of moisture are examples of events that could allow microorganisms to enter the package.
- *Endpoint stability:* This refers to the timeframe during which a visible test result will remain unchanged. This relates to chemical indicator strips and other test strips that have a visible test result that is interpreted. Although this is not an expiration date, it is often considered in the assignment of expiration dates for sterilized packages that contain chemical indicator strips.

Managing expiration dating

The first step when managing expiration dating is to identify all forms of it used in the department and to document them in policies, procedures, and work instructions as appropriate. Four things should be considered when developing expiration dating documents:

1. Inventory rotation/ first in-first out (FIFO)

Inventory rotation is critical when managing expiration-dated items. Practicing a first in/first out approach ensures that the oldest items are used first. Workstations, local storage cabinets and decentralized storage locations should all be included in the rotation schedule.

Monitor how often each item is rotated through inventory. The longer an item sits in an inventory location, the more likely it is to be moved, handled and exposed to environmental contamination such as dust. If an item is exposed to an event that requires reprocessing and the SPD is unaware, surgical delays can result while replacements are sought and reprocessed.

2. Reconciling expiration dates

When a pack contains more than one item with an expiration date, the pack's label should show the expiration date from the item with the shortest time remaining.

Remember to consider the endpoint stability for any indicators that are inside sterile packages. Chemical indicators (CIs) within sterile packages may give a false fail or false pass result if interpreted after the endpoint stability timeframe has passed. Technicians may need to understand what the result may be and determine, through a risk assessment, the policy for expiration dating of the package to ensure a safe interpretation of the CI before using the sterile items.

Chemical test strips are used to ensure that a disinfectant has the minimum recommended concentration of the active ingredient to obtain disinfection. The result of a test strip cannot be used to extend a disinfectant's open bottle expiration date. Procedures and work instructions should clearly state this.

3. Reprocessing

Items assigned a hang time or expiration date after processing may not be used within the specified hang time. Polices should include instructions for reprocessing expired items and should include which decontamination steps must be repeated. For example, do expired hang time endoscopes require all steps, including leak testing, cleaning, and high level disinfection, for expiration reprocessing?

4. Reconcile event-related and post sterilization shelf life of sterilized items

Event-related expiration dating is commonly used throughout healthcare when labeling sterilized pouches, wrapped items and containers. Observable events include holes and tears in packages, faded external indicators, broken or lifting tape, moisture and spotting, compromised seals, packages showing signs of excessive handling, inappropriate storage and transport, and items dropped on the floor. Other events can happen over time that are not so easy to see, including packaging material degradation, loss of adhesive stickiness, and exposure to environmental bioburden. The manufacturers' post-sterilization shelf life guidance becomes important in these cases. Manufacturers of products such as sterilization wraps must provide a post-sterilization shelf life timeframe so users will know when the effects of time could result in a microbial breach. Each facility should evaluate the vendor-provided post-sterilization shelf life, along with the events that could occur in the facility, to set their policy and procedures for event-related shelf life. A risk assessment may be used to help with this decision.

Expiration dating and regulatory surveys

Credentialing bodies help facilities comply with the requirements of the Center for Medicare and Medicaid Services. Compliance allows a facility to treat individuals taking part in these government

SELF-STUDY TEST ANSWERS: 1. D, 2. D, 3. C, 4. D, 5. A, 6. A, 7. B, 8. B, 9. D, 10. C

programs and obtain payment for the treatment. To qualify, healthcare facilities must pass an initial assessment and then maintain passing results from subsequent inspections and surveys. Sterile processing and endoscope reprocessing activities continue to be a focus of surveyors, with findings that may include expiration dating issues.

"Expired product"

This finding usually involves remote areas that maintain expiration-dated supplies. A few examples: The decontamination area where cleaning solutions are stored beneath sinks, sterile storage areas where bins are used to store peel packs, and product-in-hand sanitization dispensers that are not frequently used.

"Expired indicator strips within sterilized pouches"

In these findings, the expiration date printed on the chemical indicator strip within a sterilized pouch is beyond the indicator's expiration date. The surveyor states that the sterilization pouch should be reprocessed. In this case, it's possible the surveyor may not be knowledgeable about what the chemical indicator's expiration date signifies (the date by which the indicator must be put through a sterilization process). An indicator strip sterilized on the last day of its expiration date will show an expired expiration date within the sterilized pouch the next day but will still be within its endpoint stability shelf life as specified by the chemical indicator's instructions for use. In essence, the chemical reaction or physical change that occurs creates the opportunity for a new expiration date.

When presented with this finding, it is important to share the facility's policies and procedures that address the reconciliation of expiration dates and endpoint stability. Be prepared for the follow-up question, "How do you ensure that the indicator strip is read within the endpoint stability time frame?"

"No open-bottle expiration dating"

This finding is usually noted when surveyors are evaluating high level disinfection practices, but it can be found wherever chemistries (including cleaning chemistries) are used. It often occurs in departments where the entire contents of a bottle will be used within a single shift, so team members do not see the need to document an open bottle expiration date on this container. To avoid this finding, it's important to train staff to label all open bottles every time and to audit staff practices to ensure that instructions for use are followed.

Solutions decanted into basins or sinks also fall within this finding category. Basins should be labeled with the appropriate expiration date as defined in the solution's instructions for use. Be aware that some solutions may have different expiration dating rules between decanted solution and solution that is stored in the opened original bottle.

Preparing for the surveyor

While the SPD and team should always be in a state of survey readiness, day-to-day issues can grab people's attention and allow important processes to be missed. Managing expiration-dated items is one of those tasks that can be overlooked. Here are a few tips to help manage expiration dating so that the department will be survey-ready:

- *Establish a regularly scheduled department walk-through*. Inspect all areas that have expiration-dated items to ensure that all are within their pre-expiration periods and that proper inventory rotation is occurring. Remember that time-limited items are not all labeled with a typical expiration date. Examine work areas to look for product labeling, work bin locations, open bottles, basins and any other items that expire. Check inventory rotation in department storage, sterile storage and remote storage areas. Confirm that FIFO is followed.
- *Audit policies, procedures, and work instructions to assure the inclusion of expiration dating in all its forms*. Confirm that staff demonstrates understanding of and competence with expiration dating policies, procedures and work instructions, which are often included in the training and competency testing for product use and department processes. Remember to include any operating room staff with responsibility for evaluating items supplied by sterile processing in your training and competency evaluation.
- *Have justifications written and approved per facility policies for all expiration dates set within the department*. This can include event-related packaging, hang time, and reconciliation of multi-expiration dated items within a single pack. Risk assessments may be necessary to establish facility policy regarding expiration dating. They should be available or included with each justification.

Understanding and competency will optimize expiration dating

Sterile processing technicians must manage and adhere to expiration dates on time-limited items used for medical device reprocessing and preparation. These dates are in place to assure fully effective decontamination and sterilization products and processes. Some are set by the manufacturer, and some are determined within the department. By developing complete and effective written policies, procedures and work instructions for expiration dating, a department can simplify the nuances and complexity of this function. And by providing regular training and competency testing, managers can maintain proper protocols and avoid expiration dating findings during surveys. In the end, it all comes back to supporting optimal patient outcomes, which is the goal of everyone in healthcare.

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Tammy Gentry, CCSVP*, is the global product manager of sterility assurance products at STERIS Corporation. She has been in medical device product management for many years, beginning with a career in field sales for Baxter Healthcare, and then managing medical devices for companies like B. Braun, McGaw, Allergan and Invacare before joining STERIS. She currently manages sterilization consumables such as chemical indicators, cleaning indicators and sterilization packaging. Tammy holds a BA from Miami University in Speech Communications and Public Relations and a CCSVP from HSPA.*

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CONTINUING EDUCATION TEST • SEPTEMBER 2022

Expiration dating in the SPD

Circle the one correct answer:

1. **Which of the following do not have an expiration date?**
   A. Sterilants and disinfectants
   B. Chemical indicators
   C. Reusable brushes
   D. None of the above

2. **_____ indicates that a sterilized item is fit for use until a specified event makes it unfit for use.**
   A. Expiration date
   B. Shelf life
   C. Endpoint stability
   D. Event-related shelf life

3. **This is assigned at the time of manufacture.**
   A. Shelf life
   B. Endpoint stability
   C. Expiration date
   D. Event-related shelf life

4. **This term refers to the number of days that a processed endoscope can be stored after drying and before use.**
   A. Post-sterilization shelf life
   B. Shelf life
   C. Endpoint stability
   D. Hang time

5. **The timeframe during which an item remains fit for use is its _____**
   A. Shelf life
   B. Endpoint stability
   C. Expiration date
   D. Hang time

6. **Once a sterilization pouch is used in a sterilization process, the pouch expiration date is no longer valid, and the post-sterilization shelf life date is followed.**
   A. TRUE
   B. FALSE

7. **The timeframe in which a visible test result will remain unchanged.**
   A. Shelf life
   B. Endpoint stability
   C. Expiration date
   D. Event-related shelf life

8. **FIFO refers to**
   A. Sterilization order
   B. Inventory rotation
   C. Survey findings
   D. None of the above

9. **To prepare for an audit:**
   A. Establish a regularly scheduled walk-through.
   B. Audit policies, procedures, and work instructions for inclusion of expiration dating in all its forms.
   C. Have justification written and approved per facility policies for expiration dates set within the department.
   D. All of the above.

10. **_____ continue to be a focus of surveyors.**
    A. Staff findings
    B. Washer disinfectors and ultrasonics
    C. Sterile processing and endoscope reprocessing
    D. Ergonomics

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The approval number for this lesson is **STERIS-HPN 220508.**

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Last month's column highlighted hidden risks associated with endoscope storage cabinets. This month's follow-up is to ensure safe, consistent scope storage is being performed.

Decentralized processes expose problems for scope storage

by David Taylor, MSN, RN, CNOR and Scott Pasternak BSN, M.Div., MBA, RN

Endoscope storage is a practice that deserves careful attention and must never be taken lightly. Contaminated flexible and semi-rigid endoscopes have been associated with more healthcare-associated infections than any other medical device.[1] The reprocessing of such devices has a narrow margin of safety, and deviations from the recommended reprocessing procedures or manufacturer instructions for use (IFU) can increase the risk of infection, or worse.[2]

The Association for the Advancement of Medical Instrumentation's (AAMI's) updated ANSI/AAMI ST91:2021 *flexible and semi-rigid endoscope processing in health care facilities* standard addresses concerns about endoscope cleanliness, new technologies, and patient safety. In addition to accounting for regulatory concerns, the new standard has extensive appendices citing peer-reviewed research and data to support the new recommendations.

A proper storage environment is one that protects the endoscope from damage and minimizes environmental contamination. With decentralized control and ownership of medical devices in many healthcare organizations, it is not always easy to maintain consistent practice standards. Over time, monitoring and cleaning processes, as well as appropriate storage of medical devices, can lead to process variations over prolonged periods. Although the storage cabinets should be cleaned regularly (daily and weekly), filter changes are more complicated, requiring specific skills and resources (knowledge, tools or equipment) to be performed safely and effectively. Further, in many healthcare organizations, Facilities Engineering regularly maintains other filters, such as ventilation and water filters for automated endoscope reprocessors (AERs). In some cases, the filters in endoscope storage cabinets may be overlooked, and end users may unknowingly fail to maintain their cabinets properly.

Hospital's scope storage review spotlights concerns

As a result of ANSI/AAMI ST91:2021, a large U.S. teaching hospital reviewed endoscope storage throughout its system, and the findings were surprising. Not only were issues identified within the endoscopy department, but problems and unexpected issues regarding scope storage also occurred outside the department. Specifically, the in-depth assessment found: Scopes stored in transport containers (clean-a-scope bins); scopes stored in carpeted offices with medical supplies; inconsistent temperature and humidity monitoring; multiple cabinet manufacturers/generational storage options; fans installed improperly, with unfiltered room air drawn from vents on the floor discharging through the top; dirty filters unchanged for years; numerous cabinet fan systems no longer functioning or had no HEPA filter option; roller door cabinets broken or nonfunctioning; dust accumulation near roller mechanisms and on back of the door; several departments' failure to perform recommended preventative maintenance; inconsistency format and frequency of cabinet cleaning documentation; lack of knowledge of basic requirements for scope storage and maintenance; and nonexistent cleaning logs (incorrect year or incomplete).

To improve compliance, subject matter experts from Endoscopy, Sterile Processing, and Facilities Engineering formed a task force to initiate the upgrade/replacement of storage cabinets. First, Endoscopy and SP reviewed their records to determine which units they supported in HLD and sterilization. Those units were notified of the situation and asked to validate the type of scope(s) they stored and maintained. They also were asked to provide the make and model of the scope cabinets, and photos, where appropriate. Most of the identified issues could easily be remedied through the installation of new doors, fans and filter system to ensure the circulation of HEPA-filtered or instrument air through the cabinet at passively or via continuous positive pressure. Monitoring of storage time could prove burdensome to some departments that utilized the scopes infrequently, as unused HLD and LCS scopes require routine reprocessing at certain time intervals. Additionally, cabinets meeting standard EN 16442-2015 [47] have specific manufacturer-recommended safe storage intervals based on validated test methods, which may add confusion if an organization uses different varieties of storage cabinets. In some cases, where it made sense, single-use and sterilized endoscopes could be used for those areas; therefore, funding for updating or purchasing new storage was redirected toward new devices.

The interdisciplinary team should be able to help answer the following: Should the current scope inventory be kept (based on age and maintenance history)? Are new devices available with better features? Have IFU changed regarding HLD and sterilization options? Is SP capable of sterilizing a higher volume of endoscopes? Are single-use devices available in sufficient qualities to meet therapeutic needs and align with the organization's environmental impact goals? Many older cabinets can be easily upgraded to positive pressure with HEPA filtration, but upgrades must be done in a manner supported by the vendor. Some vendors have upgrades to convert conventional endoscope storage cabinets to drying cabinets, for example.

To further enhance scope storage safety, the following steps should be performed: Before use, read and follow the IFU for each endoscope storage cabinet; ensure the cabinet is cleaned per the IFU and with approved hospital-grade solutions or disinfecting wipes (document the cleaning); visually inspect the drip tray for evidence of insufficient drying before routine cleaning; change HEPA filters according to the IFU (and document); maintain cleaning and filter change logs, based on the organization's document-retention policies; and develop consistent scope storage policies and procedures in all appropriate areas.

Conclusion

Endoscopy and SP professionals must remain vigilant and ensure that all practices and equipment surrounding endoscope management, processing and storage are performed safely and consistently and in line with the latest standards, IFU and facility policies. Storage cabinets are critical to ensuring that endoscopes remain protected and free from dust, debris and other potential contaminants. HPN

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IFU confusion

by Stephen Kovach

Q "Some of my fellow techs in SPD have a hard time following certain instructions for use (IFUs) because they just don't understand the instructions. Either the instructions aren't clear enough or the specific steps are so vague that they can be interpreted differently. I've brought this up with our clinical educator, my supervisor, and our director and nothing has been done so far. What else can I do?"

A I have heard similar statements during my 40-plus years in the Healthcare Industry. "They are too long, too many steps;" "… too short, not enough steps;" "…don't give me enough information;"; "…too hard to follow…."

I have also heard many people try to explain the IFU, but few look at the history and talk about the standards and regulations that medical device manufacturers must follow.

I attended and presented my paper on the *Parametric Release from a Hospital Perspective* at the 1999 World Symposium for CSSD (Central Sterile Services Department) in Orlando, Florida.

"A quality system for the cleaning process will require implementation of standard procedures based on device manufacturers' recommendations along with documented competency of staff. Two prevalent factors make this a difficult task. Many device manufacturers have considered the question of how an item should be cleaned as the concern of the hospital. The United States Food and Drug Administration (FDA) has required manufacturers since 1996 to furnish this information to the users. However, many reports still indicate that it is difficult to get this information from the manufacturer."[1]

Sounds like not much has changed based on your question. It's a complicated process. Many people do not understand the FDA regulations that medical device manufacturers must follow.

In April 1996, the FDA issued a document called "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" for manufacturers to use to develop their instructions for reprocessing clinically used reusable medical devices. This document, along with others, was the road map followed to get medical devices cleared to market, and all that information was to be included in the Directions for Use (or IFU).

Between 1996 and 2015, users were still making statements like the one in your question. In 2015, the FDA updated its guidance and then also revised it in 2017 (Fig. 1).[2]

This revision is excellent! However, any older medical devices given approval before this new document are not required to be resubmitted to meet the updated guidance document. This means older items do not necessarily have to follow this new document. Thus, any medical device that goes to the FDA after the issue date of March 17, 2015, must follow this updated document. This would help explain why some items' IFUs are more complete than others. Also, AAMI (Association for the Advancement of Medical Instrumentation) has also been working on updating its various standards about medical device reprocessing to help make IFUs more user friendly.

So, to answer, you need to know when the item was cleared to be marketed by the FDA. If you have issues with an IFU, regardless of when it was approved, work with the company to update the IFU. You can always use the MAUDE (Manufacturer and User Facility Device Experience) reporting system to help make the changes, too.

Figure 2

As in many of my replies, critical thinking skills must be used and applied to resolve any concern. This is a great question. Here's an example for you:

I bought a Frazier Suction Tube (STR 6 Fr). Here is what came with the device. (Fig. 2).

Important information:

- Cleaned and sterilized before first use.
- Lubricated after every cleaning and before autoclaving.
- (Ratchet type) Never locked during autoclaving.

It gets back to you (the user) and your facility's Standard Operating Procedure (SOP). Here are some questions you need to ask about your own SOP:

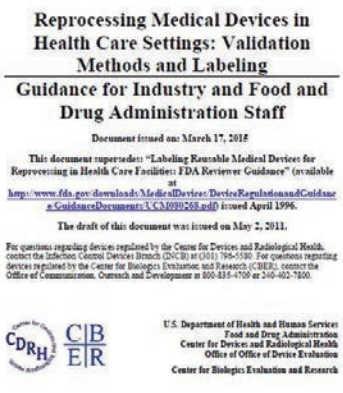
- Do you have an SOP for cleaning lumens/cannulated medical devices?
- What does it say about cleaning lumens/cannulated devices at your facility?
- Is it based on reviewing various IFUs on lumens/cannulated devices in your department and putting an SOP in place that addresses all types of lumens/cannulated devices?
- Does it cite various standards (e.g., ANSI/AAMI ST79 sections 6.3.1, 7.6.1, 7.6.2, 7.6.4.2, 7.6.4.3.4, 7.6.4.4.1, 7.6.4.4.2, 7.6.4.5, 8.2) and other information (e.g., articles) to support your practice at your facility? (If not, a surveyor could have a field day of your area for not having the correct SOP in place.)

I understand your frustration on reviewing IFUs and how you can adapt them to your department to provide a clean and functional medical device that can either be sterilized or high level disinfected.

There is not a simple answer, and I just touched the surface concerning/adapting IFUs to your practice. Your management team has been made aware of the concern and should address it ASAP, or you might not have clean and functional lumens/cannulated medical devices. HPN

For more information. check out #IFUcan on LinkedIn.

FDA Guidance to Manufactures as of 3/17/2015



Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015

This document supersedes: "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf) issued April 1996.

The draft of this document was issued on May 2, 2011.

For questions regarding devices regulated by the Center for Devices and Radiological Health, contact the Infection Control Devices Branch (ICDB) at (301) 796-5580. For questions regarding devices regulated by the Center for Biologics Evaluation and Research (CBER), contact the Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Office of Device Evaluation
Center for Biologics Evaluation and Research

Figure 1

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Sweeping improvements needed for bed, mattress maintenance

Products, processes, priorities must be adjusted, experts say

by Rick Dana Barlow

Photo credit: Gorodenkoff | stock.adobe.com

On average, Americans will spend 36 years in bed over the course of their lifetime, according to a report in the *New York Post* (March 21, 2019) based on a research study conducted by OnePoll for Slumber Cloud.

However, this doesn't account for lying in a hospital bed or stretcher or a long-term care facility bed, which likely – and logically – increases those numbers.

From a healthcare perspective, experts say that inpatients spend a great deal of time in bed (whether stationary in rooms or in transit around the facility) and that mattresses represent the No. 2 touchpoint for caregivers and potentially the No. 1 touchpoint for patients.

This raises the question about a healthcare organization's bed and mattress maintenance procedures, which include cleaning, disinfecting, sterilizing, repairing and even replacing when necessary.

Healthcare Purchasing News reached out to more than a half dozen experts in beds, mattresses, and disinfection and sterilization products and procedures for their insights in a brief, non-scientific poll.

Save for laundering linens and sheets, healthcare staffers remain marginally better than ordinary citizens at home when it comes to maintaining hygiene with their beds – but then they have to be because of all the exposure to bacterial and viral microorganisms that cause infections.

Report card

HPN asked these experts to assess their impressions of how well healthcare organizations keep their beds and mattresses hygienic. Nearly 85% responded "fair" to "poor" with the majority of that group leaning toward fair (67%). At the extremes, no one rated efforts as excellent but at the same time no one classified efforts at "those need to be maintained?" Roughly a third, however, rated efforts as "good," based largely on product offerings in active use and a multidisciplinary program in place to maintain beds and mattresses.

"When looking at cleaning, disinfecting, sterilizing, repairing it is important that health systems or organizations have standard work in place designed to hardwire the practice of ensuring that beds and surfaces are maintained," James B. Waddell, BLS, ICRA, CSCMP, SW Patient Care Support Manager, Nursing Administration, Cone Health, said. "In order for the process to be effective, it takes a multidisciplinary effort of all areas to sustain standard work." Waddell also serves as Capital Service Line Chair, IT Administrator and Unit-Based Fit Tester for the health system.

James B. Waddell

Root causes?

HPN then posed an appropriate follow-up to the bed and mattress maintenance assessment question on what experts attribute their initial response. They could choose more than one option among five specific reasons or derive one of their own.

"Lack of priority (among so many other growing priorities)" led the tally with 67%, followed by "failure/lack of following appropriate and optimal cleaning/disinfecting/sterilizing/repair instructions and protocols" from product manufacturers at 50%. Only a third indicated a "failure/lack of appropriate and optimal cleaning/disinfecting/sterilizing/repair instructions and protocols." While some claimed hospital staffers didn't have necessary instructions, more expressed they didn't adhere to whatever instructions they had anyway. Another third chose a simple "lack of awareness" as the culprit.

Experts acknowledge the challenges and try to place activities – or lack thereof – in context. Staffing and timing play a key role.

"It is no secret hospitals are short-staffed and need to quickly turn over hospital beds for the next patient," indicated Jessica Mathieson, General Manager and Vice President, Acute Care, Stryker Corp. "Sometimes the cleaning/disinfecting/sterilization/repairing process can be rushed because of this tight window of opportunity and very few staff on hand. In addition, not all cleaning products are created equal, and some wipes that are used may congeal fluids rather than disinfect and sterilize surfaces. If every hospital adopted a product such as Stryker's SideKick cleaning and disinfecting solutions into their cleaning procedure, this would help reduce time taken, staff needed, and wipes used, which in turn leads to a safer and cleaner environment."

Jessica Mathieson

But Mathieson urges caution in that this issue isn't "as black and white as it seems," she noted. "Deeper in, it's not that facilities

do not have protocols or do not follow protocols. It's a combination of factors. It's not so much about intensity, but rather how often/prevalent each issue is seen across the country based on the current environment." She ranks short staff that leads to rushing protocols at the top, followed by a lack of optimal products and services to do the job, followed by the lack of adhering to appropriate instructions and protocols.

Even so, the room turnover demands add pressure to what can be tense scheduling situations, according to Linda Lybert, Founder/Executive Director, Healthcare Surfaces Institute Inc.

Linda Lybert

"Healthcare facilities are typically faced with a time limit when turning over patient rooms, which rarely provides sufficient time to effectively clean and disinfect the beds and mattresses, let alone the rest of the room," Lybert noted. "It is incredibly important that the manufacturer take this into consideration during design and provide instructions that support this process. Healthcare professionals often use the same type of disinfectant for everything they are cleaning. Testing and validating that these disinfectants can be used is needed. If not, there may be a process for getting the correct disinfectant approved."

Still, Don Rotter, RD&E Program Leader, Healthcare Infection Prevention, Ecolab Inc., credits healthcare staffers against the backdrop and context of their operating environment.

Don Rotter

"I believe hospital staff have the best of intentions to ensure beds and mattresses are thoroughly cleaned, treated and maintained," he said. "In recent years, the industry's work of highlighting the shortcomings of hospital bed and mattress maintenance and the risks they present to patient safety have helped increase awareness of these challenges. Despite this increased awareness, the incidence of the fluid ingress into patient mattresses and beds still occurs far too often.

"Staff turnover will always present a challenge around education and awareness," Rotter continued. "Hospitals must prioritize and emphasize best practice as part of standard protocol to ensure beds and mattresses can be properly cleaned and treated. This means following manufacturers' instructions which often suggests avoiding oversaturation of the surfaces to prevent fluid ingress as well as wiping down the mattress surfaces with water after treatment and allowing the mattress to fully dry before placing it back on the bed or surgical table."

Such awareness motivated Cone Health to organize a project to oversee quality in this area, according to Waddell.

"I had the pleasure of leading a multidisciplinary team in a project called 'The Clean Bed Initiative,'" he told *HPN*. "This body of work involved input from Nursing, Environmental Services, Patient Transport, Radiology and Repair Technicians. In creating the work, we were able to track bed movement through all aspects of hospital workflow and observe movement of the patient from admission to discharge." *(For more details on Cone Health's CBI, read "Cone Health elevates bed, mattress maintenance to higher priority" on page 52.)*

Potential solutions

HPN then asked experts how bed and mattress maintenance efforts and outcomes could be improved. They could choose more than one option among six potential selections or generate one of their own.

Not surprisingly, education topped the list as all chose "Provide more frequent and more in-depth inservice education and training on proper inspection and cleaning/disinfecting/sterilizing/repair." Next up involved calls for a specific type of product, as in "Provide cleaning/disinfecting/sterilizing products that don't harm the bed and mattress (raw) materials while successfully destroying/killing infectious microbes."

Two viewpoints split third place with one focusing on mattress composition and the other on enhancing the maintenance process. Half of respondents opted for "Manufacture beds and mattresses using (raw) materials that either can withstand or repel harsh chemicals in the cleaning/disinfecting/sterilizing products needed to destroy/kill infectious microbes," while "Encourage going beyond manual wiping, visual inspection, single-step procedure," captured another 50% response.

No one picked switching to disposables/single-use products for everything or to outsource the entire process to an independent third-party service company.

Ecolab's Rotter urges providers and suppliers alike to gain a "clear understanding of the factors that impact life expectancy of the patient equipment and the trade-offs" to get control of the process.

"One of the most common challenges I hear from hospital staff preventing the following of manufacturer instructions is the added burden and resources required to do so," he said. "Staff, already under extreme time and resource constraints, simply do not feel it is feasible. They lack the support and buy-in from management to ensure these additional steps can be taken. Consequently, the hospital may bear the extra burden of replacement costs if they are not following manufacturer instructions intended to maximize the life expectancy of the equipment.

"Manufacturers often establish life expectancy of equipment based on compatibility testing, expected use and treatment patterns using commonly available cleaning/disinfecting agents in the regions [where] the products are sold," Rotter continued. "This life expectancy determination is most likely based on best practices being utilized and extra steps being taken."

Rotter recognizes what providers really want in context of the demands placed on them.

"The reality is, hospital staff want cleaning/disinfecting products that provide rapid kill of the organisms of concern, while being the most economical, lowest toxicity, in any format of choice, residue-free, compatible with as many surfaces possible and requiring only a one-step application," he noted. "Such a product would be ideal, yet there always must be a compromise with these factors. The tradeoffs end users must choose, change with the chemistry used, the materials of construction of the equipment, the desired hospital infection control strategies, available budget, or the need for hospitals to turn rooms quickly to maximize profits."

This is where infection prevention must step in.

"What infection preventionists are charged with is striking a balance as best they can, acknowledging there may never be the ideal process for all surfaces," Rotter said. "This is not an easy task. Specifically for patient mattresses, the product selected for the degree of soiling might require removal of unsightly residues left behind, or a budget to support replacement costs of the mattresses that are not lasting as long, either because the chemistry chosen is too aggressive for the substrate, there is a lack of use of the best practices intended to prolong the life of the equipment, or a combination thereof."

Rotter credits manufacturers for trying to do their part as well.

"Disinfectant and equipment manufacturers alike continue to innovate, so there is hope that some of these challenges can be solved through new product offerings," he said. "In the meantime, until the ideal scenario is achieved for patient mattresses specifically, awareness of these variables and ownership of those [that] can control are necessary for infection control strategies around patient beds. Patient safety is of the utmost importance. It should not take a back seat to hospital budgetary constraints."

Healthcare Surfaces Institute's Lybert believes that providers should ask that bed and mattress manufacturers go one step further in their process.

"Request manufacturers test for surface disinfection compatibility," she insisted.

"There currently are no requirements or guidelines or validation that products and surfaces can be effectively cleaned and disinfected using standard disinfectants. Cleaning and disinfection are a fundamental requirement, yet we have very little information about what disinfectants can be used on mattresses and beds without damage. We also aren't sure when damage begins to happen. Microscopic damage provides microbial reservoirs once the surface on the outside has been damaged the ability to clean and disinfect beneath the surface is impossible. Understanding that the mattress has the potential to be cleaned sometimes up to 14 times a day, it is important to understand which disinfectants can be used to minimize damage." **HPN**

Infection prevention battle plan: Time to go to the mattresses

by Rick Dana Barlow

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For a product and process that occupies a significant portion of our lives (roughly a third), not nearly enough effort and time is being dedicated to maintaining beds and mattresses used in healthcare facilities for patient recovery and rest.

Experts point to a number of roadblocks and speedbumps complicating the maintenance of beds and mattresses, which includes cleaning, disinfecting, sterilizing, repairing and even replacing the products when necessary. Reasons span a lack of manufacturers' instructions for use (MIFUs) – both for the reprocessing products and for the material compatibility of beds and mattresses on which they are used – as well as the lack of following the MIFUs they may have in place already. Reasons also span awareness of any problems, shortcomings of the manual technique used to spot potential problems as well as the raw materials used to make the beds and mattresses and whether the reprocessing agents used to kill infectious microorganisms may also harm the structural materials of the beds and mattresses.

Experts recognize that the manual technique used to spot potential problems relies on the "visual method" or what you can see. Coupled with pressure to return a room to high-quality hygienic status may mean you miss the gouges scrapes along bed decks and rails that can harbor hard-to-reach microorganisms or the fluid that soaked through surface cracks and punctures in the mattress, leading to mold germinating in the foam core.

"Patient treatment surfaces such as mattress covers are particularly susceptible to damage from frequent use, mechanical penetration from sharp objects and abrasive chemical disinfectants," Iwain Lam, President and CEO, Surface Medical Inc. told *Healthcare Purchasing News*. "When these surfaces are damaged, they can no longer be properly disinfected because bodily fluids and bacteria can enter the mattress and escape decontamination on the surface. Harmful pathogens can accumulate in rips and punctures and lead to healthcare-associated infections (HAIs), posing a risk to vulnerable patients and staff."

Iwain Lam

One of the leading authorities in bed and mattress sterility, who has published detailed research studies in the clinical journals for years and who spoke about his work during an *HPN* Online Forum two years ago, acknowledges that the challenges remain.

Edmond A. Hooker, MD, DrPH, Professor, Department of Health Services Administration, MHSA, Associate Director for Accreditation, Xavier University, points to four areas of concern about which healthcare organizations should be aware.

Edmond A. Hooker

1. Lack of efficacy of cleaning disinfection processes used by most hospitals

"Mattresses are medical devices," Hooker said. "Although mattresses used to be made of a very tough vinyl, today, most acute care mattresses are made of a polyurethane-coated fabric, which makes them a soft/porous surface. Single-step cleaning and disinfection processes using hard surface disinfectants are not recommended by mattress manufacturers because they don't work and they destroy the mattress cover. Although many hospitals use one-step cleaner/disinfectants on healthcare mattresses, they are not approved for this use.

"The manufacturer's instructions for cleaning and disinfection of mattresses require many distinct steps: Pre-cleaning (removing obvious soil), cleaning, rinsing off the cleaner with water, disinfecting, rinsing off the disinfectant and inspecting the mattress for damage," he continued. "In a previous survey of infection control nurses, we showed that most hospitals use one-step processes, do not perform routine inspections, and have experienced mattress failures with patient exposure to blood and body fluids."

2. Complex MIFUs that require multiple steps are not practical in a high-turnover environment and requires significant staff training and oversight.

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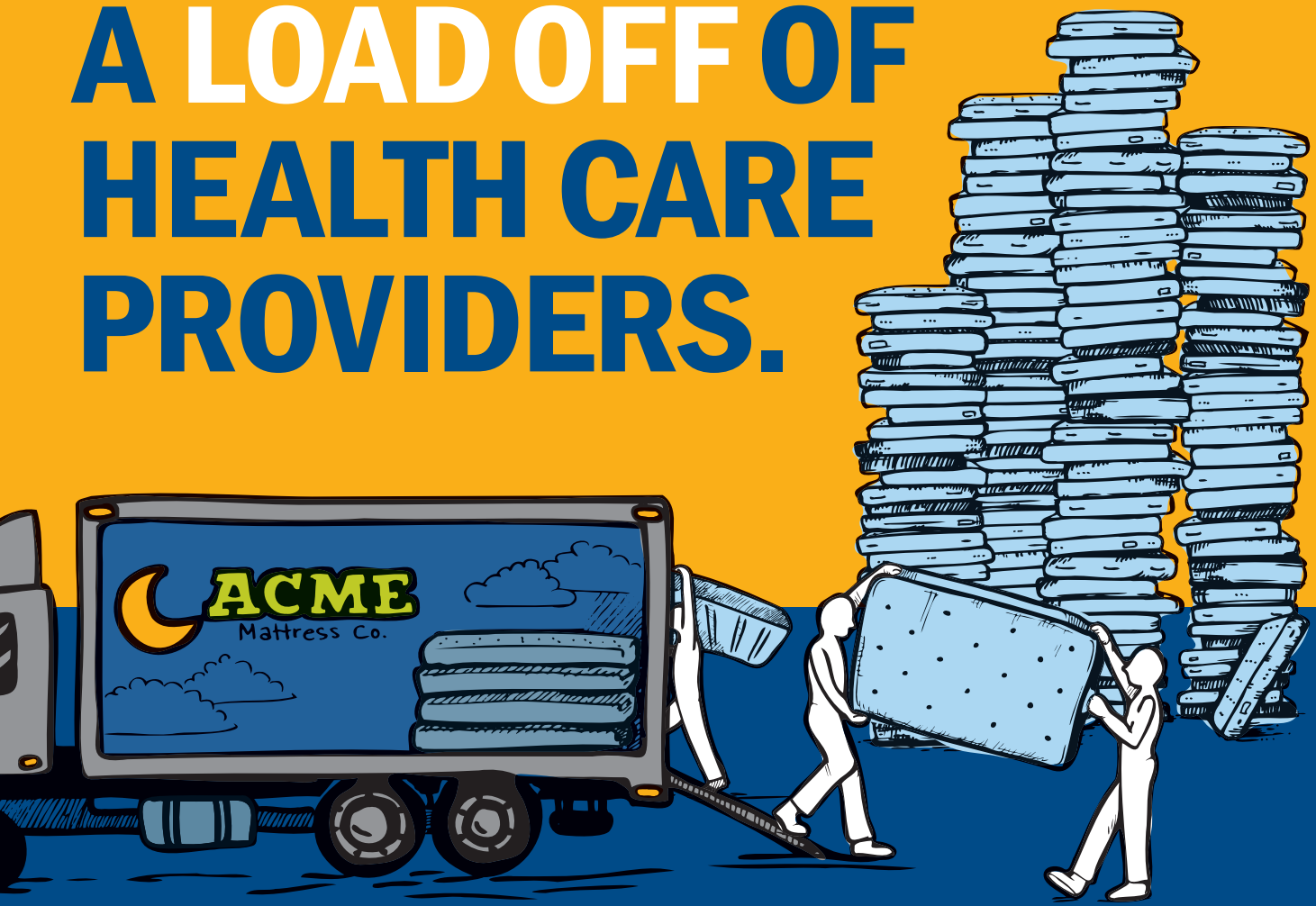

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"The manufacturer's instructions for use require the multistep process that is difficult to remember and takes around 45 minutes to perform on just the mattress and bed frame," Hooker indicated. "Training environmental services personnel and ensuring that they have performed adequate cleaning is difficult. Also, hospitals need rooms turned over quickly, which does not give EVS personnel time to do perform adequate cleaning."

3. Non-fluid proof seams

"Many healthcare mattresses have sewn zipper seams that create 3,000 holes around the perimeter of the mattress surface, allowing fluids to leak into the mattress," he warned.

4. Mattresses that cannot be opened

"Although many mattresses have zippers to allow for routine inspection of the inside for damage, most hospitals fail to routinely open these mattresses and inspect them," Hooker noted. "Some mattresses, especially those used in operating rooms and emergency departments, cannot be opened and inspected for damage and contamination. This allows contaminated mattresses to remain in use, which is a clear and present danger to patients."

Linda Lybert, Founder/Executive Director, Healthcare Surfaces Institute Inc., takes aim at the first step after stripping the bed of linens.

"We are trying to deal with a microbial issue at a macro level," she observed. "We cannot see microbes, yet we assume that a mattress is clean and not damaged based on a visual inspection. When we see the damage, microbes have already penetrated the surface. Not only is the outside of the mattress cover potentially harboring pathogens the mattress's core may as well. Pathogens may be released from the inner core when someone lays and moves on the mattress. There have been reports of moisture seeping up from the inside of the mattress through seams and damaged outer surface."

Watch for covert vs. overt effects

Among the "covert" dangers and hazards arising from improperly decontaminated mattresses, fluid entry into patient mattresses is the first thing to come to the mind of Don Rotter, RD&E Program Leader, Healthcare Infection Prevention, Ecolab Inc.

"No patient should ever experience getting wet from a patient mattress," he said. "Patients deserve better and should not be exposed to biohazardous material ever, let alone in their most vulnerable state."

Much depends on the cleaning/disinfecting products used on the beds and mattresses.

"A variety of cleaners/disinfectants exist in the marketplace, giving end users a great deal of options for addressing sources of hospital-acquired infections," Rotter continued. "Most of these products, however, are not sporicidal and provide no efficacy against spore-forming bacteria. Generally, end users must rely on oxidative chemistry for this level of efficacy, but manufacturers rarely recommend such chemistry for routine use, if at all, on their equipment. End users with no options must either adopt their infection control protocol of proactively using sporicidal chemistries, sometimes going against manufacturer instructions, or not use sporicidal products and risk addressing potential sources of hospital acquired infections."

Jessica Mathieson, General Manager and Vice President, Acute Care, Stryker Corp., alerts healthcare staffers to the types of products being used to decontaminate beds and mattresses. She cautions about "cleaning wipes that don't truly disinfect and sterilize surfaces; there is a difference," she said.

"Minimal cracks and crevices can harbor hard to reach microorganisms," Mathieson indicated. "The differential of cleaning products and a system's ability to acknowledge that changes may be made to cleaning protocol is an issue that has been popping up occasionally. However, with hospitals adhering to new auditing guidelines being set by governing organizations, we are seeing a decline on issues related to this.

How do you make a used mattress sustainable? Recycle it

As healthcare organizations strive to maintain their mattress stock amid normal wear-and-tear usage through cleaning and decontamination, they eventually have to replace them.

Short of general or specialized disposal, they have another option: Recycling.

"All mattresses, no matter how well maintained, eventually need to be replaced," said Tom Smith, Marketing Manager, Mattress Recycling Council (MRC). "Our recyclers have found secondary markets for more than 75% of the mattress components to be reused in other industrial and consumer products. In our first six years of operation, MRC has recycled more than 10 million mattresses, diverting more than 380 million pounds from landfills."

The Mattress Recycling Council currently operates statewide mattress recycling programs in California, Connecticut and Rhode Island with the ultimate goal of reducing the number of old mattresses being disposed of in landfills, according to Smith.

How does it work?

MRC programs are funded in California, Connecticut and Rhode Island by a recycling fee, varied by state, and charged on the sale of each mattress and/or box spring, according to Smith.

"Whenever a healthcare facility in any of these three states purchases a new mattress, it is paying the local state fee," he said. "Thus, when a hospital or nursing home replaces in bulk a number of mattresses, the fee is being paid in multiples on the number of units purchased. In each state, MRC has assembled a statewide collection network composed of the existing solid waste infrastructure to aggregate mattresses from waste haulers, landfills, transfer stations and public works yards as well as mattress retailers and other commercial sources.

"MRC has a special unit to organize the bulk pick-up of discarded mattresses from healthcare facilities, hotels and universities," Smith continued. "It can arrange for the free pickup of these old mattresses that will be transported to a recycling facility. The fee the healthcare facility paid when purchasing a large number of new mattresses will be covering the disposal. In a number of cities in the other 47 states, there are individual non-profit organizations or for-profit recyclers that will also recycle mattresses for a fee."

Throughout its network, MRC has transported more than 15,000 truckloads of mattresses each year to recycling facilities for disassembly, he adds.

In California, Connecticut and Rhode Island, mattress recycling makes economic and environmental sense for healthcare organizations looking to dispose of old mattresses, according to Smith.

"The healthcare facility will pay a disposal fee to trash an old mattress," he noted. "The original natural resources within the mattress will be lost forever either buried in a landfill or consumed in an incinerator. [Meanwhile], recycling a discarded mattress with MRC is economically sound because the cost of recycling has been paid by the recycling fee – which is considerably less than a landfill fee. The steel, foam and wood within a mattress and foundation are readily recycled and sold on the scrap market."

Smith adds that MRC has funded more than 20 research projects to find new and/or higher value uses for the remaining fabrics and materials.

But Smith issues some caveats about mattress quality needed for recycling.

The recyclers within the Mattress Recycling Council network will accept any mattress that is not infested or excessively soiled," he said. "Contaminated mattresses must be properly disposed of in a landfill." Smith encourages healthcare organizations to visit MRC's website, MattressRecyclingCouncil.org, for access to guides, resources and videos, and for information about bulk pickup services for healthcare facilities, https://byebyemattress.com/programs-by-state/commercial-recycling/.

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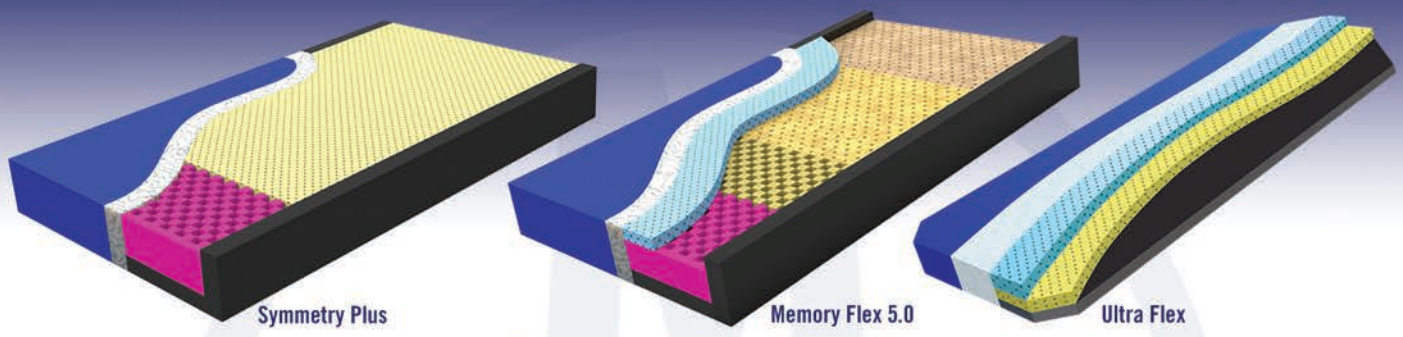

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"Disinfection is the process of eliminating or reducing harmful microorganisms from the surfaces, while sterilization is the process of killing all microorganisms," she continued. "End users can also tell the difference by adhering to the wet contact time needed to eliminate the stated pathogens of a cleaner. Oftentimes, the customer may not actually be keeping a surface wet enough or using enough wipes/solution to achieve the attended kill. We see The Joint Commission prompting audit guidelines to incorporate more stringent cleaning protocols."

Approximately 70% of all mattress failures – including stretchers – occur through physical damage, the remaining 30% result from chemical, according to David Willoughby, Vice President, Marketing & Business Development, Medtrica Solutions Ltd.

David Willoughby

"Most common physical damage is caused by punctures, tears and abrasions, which if left undetected, overlooked or improperly repaired, lead to serious cross contamination risks for current patients, incoming patients and staff," he said. "Damaged soft surfaces can never be properly cleaned regardless of how good your CDP is. When the integrity of a mattress cover is compromised the there is always a high risk of occult damage occurring from fluid ingress of blood and body fluids."

Thanks to the Clean Bed Initiative (CBI) at Cone Health, clinicians and administrators underwent a great awakening to the need for proper bed and mattress decontamination, according to James B. Waddell, BLS, ICRA, CSCMP, SW Patient Care Support Manager, Nursing Administration. *(For more details on Cone Health's CBI, read the sidebar on p. 52.)*

"One of the main issues identified was that repair technicians often discovered that downed beds were delivered and not properly cleaned," he said. "Our [CBI] work group discovered that receiving departments (patient care or repair) trusted that beds came already cleaned and disinfected. However, it was an 'aha moment,' finding that was not always the case. This became a highlighted standard work point of focus."

What should manufacturers do?

Experts believe manufacturers can help improve this process in several ways but stop short of placing blame or pointing fingers at anyone.

Proper bed and mattress maintenance generates hygienic and economic benefits, according to Surface Medical's Lam.

"Manufacturers should place greater emphasis on the importance of equipment maintenance to protect the health and safety of vulnerable patients," he noted. "Because hospital mattress covers are one of the highest touchpoints in the patient environment, comprehensive cleaning practices are essential to reduce the spread of dangerous pathogens to patients and staff. Hospital mattress covers must be maintained in an intact state to be effectively cleaned, so manufacturing guidelines should reinforce the importance of frequent mattress cover inspection for signs of damage. Clear and focused messaging from manufacturers on the importance of maintaining equipment in good working condition, would support infection prevention protocols that address cleaning, disinfecting, sterilizing, and repair of mattresses.

"Because the immediate replacement of damaged hospital mattresses is not always logistically or economically feasible, surface repair with an approved product enables healthcare facilities greater control over the timing of equipment replacement, while ensuring that the mattress surface can be safely used by patients," Lam added.

Ecolab's Rotter acknowledges that manufactures emphasize proper care and maintenance for beds and mattresses but recognizes that more could be done.

"Most bed and mattress manufacturers provide a great deal of emphasis on the cleaning and disinfection process of equipment surfaces including cautionary language against practices, procedures or use of products that might adversely affect the equipment," he said. "Manufacturers should continue to try to improve upon these instructions, so they are clear and cover comprehensively the various types of cleaning/disinfecting agents available in the marketplace that are either suitable or contraindicated. Unfortunately, end users can be left confused when specific classes of ingredients or actives in disinfectant cleaners are neither recommended nor contraindicated in manufacturer's instructions for use."

Rotter admits the difficulty hospital staffers may face here, which is why manufacturers should step up.

"Mattresses are challenging to inspect with failure of the moisture barrier commonly only being noticed after fluid ingress," he noted. "Manufacturers should stress the importance of routine inspection and how to properly inspect the equipment for signs of needing repair or service. Products showing any sign of degradation should be removed from service."

Manufacturers must keep customers front of mind when they release products and IFUs, according to Stryker's Mathieson.

"Manufacturers should provide clear and in-depth information on cleaning protocols and accepted chemicals/products that can be used for cleaning/disinfecting/sterilizing and repair when making a sale," she indicated. "We believe in transparency and ease of use for our customers, and that includes how to take care of our products.

"Our customers motivate us to make cleaning/disinfecting/sterilizing/repair instructions and protocols clear," Mathieson continued. "Through our partnership with customers, we've found that operations manuals are not always as straightforward as one may think for busy staff. We go beyond 'good enough' by creating cleaning videos that showcase best practices when taking proper care of our products. The customers should be at the forefront of all manufacturers motivation to provide quality products and information – maintenance being one of them."

Medtrica's Willoughby contends that content is king.

"Manufacturers should always provide very detailed IFU for the proper storage, use and maintenance of the mattress – cover and core," he insisted. "However, these recommendations are not designed to replace cleaning and disinfection protocols implemented and managed by infection control and/or the hygiene officer of the hospital overseeing soft-surface infection prevention."

Xavier University's Hooker places great value on manufacturer IFUs making a difference.

"The hospital bed and mattress manufacturers need to emphasize the importance of hospital personnel following the MIFUs every time they clean (reprocess) the bed and mattress for the next patient," he emphasized. "The salespeople do not explain the importance of proper reprocessing not only for patient protection [but also] to extend the life of the bed/mattress. Most hospitals incorrectly assume that they can use a one-step cleaning processing, which is simply inadequate. Also, The Joint Commission requires hospitals to follow the MIFUs."

Hooker further notes that "newer MIFUs have been required by the FDA Reprocessing Guidance for Reusable Medical Devices since 2015. Per the FDA Guidance the process must have established efficacy against key organisms, including myco-bacteria, state a process to achieve those results as well as the expected life of the device (outer mattress cover) using those processes."

Lybert from Health Surfaces Institute urges that maintenance issues logically be explored at the very beginning.

"Of all medical devices the bed is what the patient has the most contact with," she noted. "Cleaning and disinfection should be one of the top three most important design features and should be evaluated with a team of Infection Preventionists and

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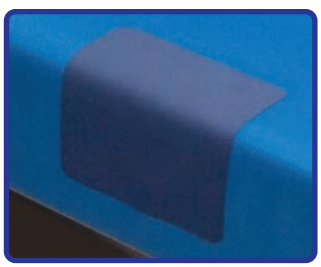

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Environmental Services professionals before design. These are the professionals who will be responsible for cleaning and disinfection to ensure the bed is safe for the next patient. Understanding that there are time constraints often imposed during room turnover times and during daily cleaning, it is important to consider that during design."

Cone's Waddell requires emphasis on this always to be high.

"It's important to keep all equipment clean and fully functional, especially when it comes to the safety of everyone involved, including patients, repair techs and transporters," he said. "Depending on the acuity of a patient, a bed could potentially be a single touchpoint of every aspect of hospital operations." HPN

Cone Health elevates bed, mattress maintenance to higher priority

The staff at Cone Health simply wasn't satisfied with the quality of their bed and mattress maintenance efforts and outcomes so they decided to do the rational thing.

Rather than punt, procrastinate or postpone, they formed a multidisciplinary task force to evaluate the issue and devise actionable solutions.

James B. Waddell, BLS, ICRA, CSCMP, SW Patient Care Support Manager, Nursing Administration, Cone Health, who also serves as Capital Service Line Chair, IT Administrator, and Unit-Based Fit Tester for the healthcare system, notes their "Clean Bed Initiative" (CBI) really dove into the deep end of practices and protocols to make a difference.

"Our process made incredible improvements because of the Clean Bed Initiative," he said. "Data was collected regarding flow and all touchpoints of bed movement. The data collected in combination with the created standard work improved cleanliness and created a safer environment for patients and caregivers."

Waddell shared some additional perspective with *Healthcare Purchasing News.*

HPN: How did the Clean Bed Initiative originate?

WADDELL: During staff meetings of our Patient Transport Department, staff expressed concern over cleanliness of hospital beds being transported from nursing units to ancillary departments. The Clean Bed Initiative started in 2018 at our flagship campus and expanded to all hospitals in 2019. Due to the extensive work of the project, adjustments have been minimal and still in place today.

Who came up with the concept?

The conversations during staff meeting prompted the Patient Transport Manager to seek guidance from the Clinical Nurse Specialist. Once the initial research started it was quickly identified that there were gaps in our process that needed attention. The name of the project – Clean Bed Initiative – came during collaborative discussions with clinical and non-clinical staff.

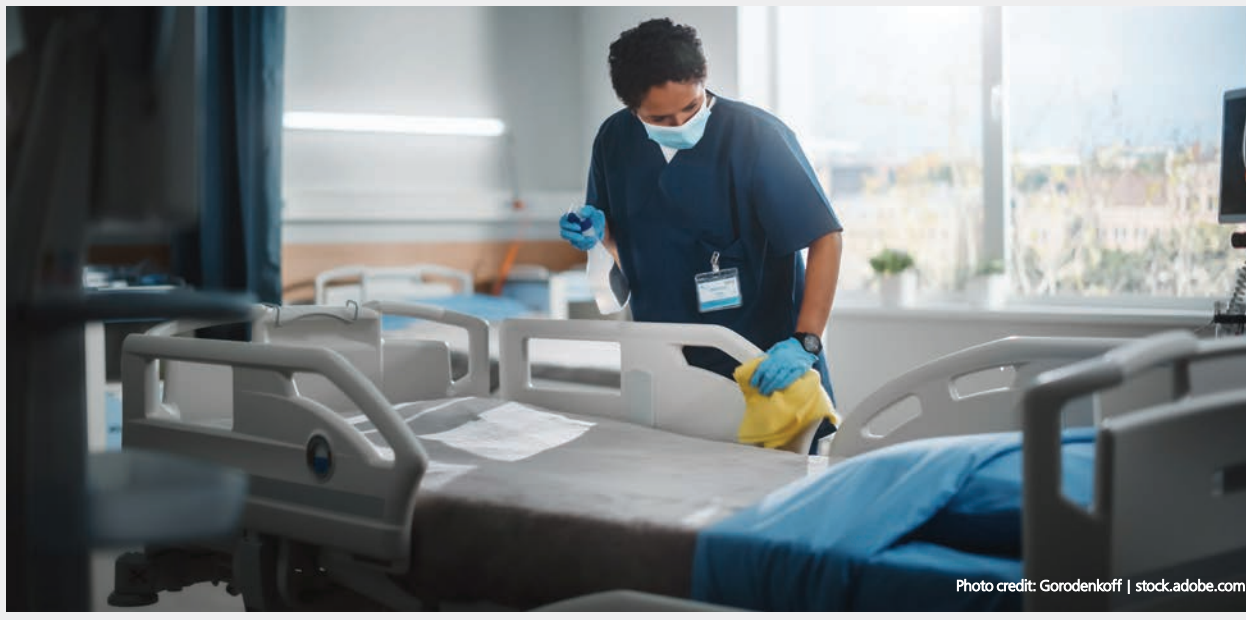
How did you determine the composition of the group?

The composition of the group was determined during the data collection phase. Our process improvement team literally followed beds from origin to destination and took notes. Following observations, the team sent out surveys to receive additional feedback from frontline staff. The group consisted of Nursing, Patient Transport, Environmental Service, Bed Repair Technicians, Portable Equipment and Imaging Services.

How challenging or "easy" is it to establish and operate a CBI?

Once all key stakeholders were identified, that enabled the team to setup weekly meetings to evaluate and talk through processes. The largest challenge was standardizing the work across multiple hospitals, in addition to not creating additional work for our already extremely busy frontline staff. During the discovery phase it was determined that each hospital had similar processes; however, there were some differences based on workflow. Once an agreed 'standard work' was written, the process was trialed for several weeks, evaluated and eventually rolled out across the enterprise. The biggest win was establishing a multidisciplinary team to create an understanding of how our work impacts each other. The most important factor is that this work was a win for the patient and staff by creating a cleaner and safer environment.

All told, Waddell says his team is very proud of this initiative. "It is a great success story and embodies how collaboration between multidisciplinary teams can impact and improve outcomes," he added.



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Shopping for beds, mattresses extend beyond comfort, costs

What are some of the key factors that providers should consider when comparing, evaluating and purchasing beds and mattresses from the perspective of maintenance – including cleaning, disinfecting, sterilizing, repair and even replacement? Experts share their tips with Healthcare Purchasing News.

Photo credit: petrovk | stock.adobe.com

Edmond A. Hooker, MD, DrPH, Professor, Department of Health Services Administration, MHSA, Associate Director for Accreditation, Xavier University

- All major manufactures' instructions for use (MIFUs) that are compliant with FDA Reprocessing Guidance are similar in terms of the number of cleaning and disinfection steps, internal inspection requirements and replacement of outer cover at the end of the expected life. Demand that the salespeople provide this information in writing before deciding. Do not depend on verbal promises.
- Ensure that all key stakeholders (Environmental Services, Infection Control, Wound Care, Facilities, Finance) are involved in the purchasing decisions. Require all promises to be made in writing.
- Get a commitment from hospital leadership to allow Environmental Services the required time to correctly reprocess the bed/mattress using the required multi-step process.
- nderstand that most manufacturers only warrantee their mattress for one year, and we have shown that many mattresses will fail starting soon after that time. All mattresses must be opened and inspected after every patient to ensure they have not failed.
- Many hospitals are using bleach to kill Clostridioides difficile. Unfortunately, concentrations of 5,000 PPM of bleach are required to kill C. diff spores. Some MIFUs do not permit this level of bleach to be used without rinsing.
- For more information, visit: https://cdn.ymaws.com/npiap.com/resource/resmgr/s3i/S3i_NPIAP_Cleansing_Disinfec.pdf

Iwain Lam, President and CEO, Surface Medical Inc.

- What material is the mattress cover made from?
- Can the mattress cover be repaired or replaced when damaged?
- What cleaners are compatible with the mattress cover?
- What is the anticipated service life of the mattress and cover?
- How comprehensive are the maintenance guidelines provided by the manufacturer?

Don Rotter, RD&E Program Leader, Healthcare Infection Prevention, Ecolab

- End users should look for equipment that is designed with routine cleaning and disinfection in mind, where the manufacturer has evaluated the compatibility of products widely available in the regions in which those products are sold.
- Equipment should be easy to manipulate for the purpose of cleaning, disinfection, and inspection and should be constructed of materials that can withstand the routine cleaning and disinfection with sporicidal chemistries that have become instrumental in proactive infection control strategies.
- Impermeable mattress covers may offer a potential to protect against damage and fluid ingress to the core product and could be considered for some applications.

Linda Lybert, Founder/Executive Director, Healthcare Surfaces Institute Inc.

- Can these surfaces be cleaned and disinfected using hospital-grade disinfectants without causing damage?
- What is the expected life cycle of the mattress and components?
- Have the surfaces been tested using all categories of disinfectants, get data and validation?
- Evaluate [whether] the IFU is consistent with Infection Prevention Guidelines used within the facility.
- Do they provide training for staff around the cleaning and disinfection process for the bed and mattress?

David Willoughby, Vice President, Marketing & Business Development, Medtrica Solutions Ltd.

- There are several very important factors that need to be considered when evaluating and purchasing a mattress from the perspective of maintenance, two of which are durability and performance, that when combined, provide both superior patient comfort and safety.
- Good quality materials, when used in a mattress, not only reduce pressure-related injuries, dishing and thermal build-up issues but can also withstand proper application of CDP. They are way less likely to experience premature cover or core failure.
- Another important consideration that goes hand in hand with durability and performance is the implementation of an effective mattress auditing program that identifies not only the effectiveness of CDP but also identifies those mattresses that require either immediate repair or replacement especially during terminal cleaning.

Jessica Mathieson, General Manager and Vice President, Acute Care, Stryker

- What is the quality of this product?
- How long will this product last?
- Will this product improve our process (cleaning/disinfecting/sterilizing/repair) and/or our facility?
- Can this product be added to our facility without changing cleaning process/procedure and can it take away steps from the process?

James B. Waddell, BLS, ICRA, CSCMP, SW Patient Care Support Manager, Nursing Administration, Capital Service Line Chair, IT Administrator, Unit-Based Fit Tester, Cone Health

- Some main factors to consider when looking at beds and surfaces are safety, durability and reliability of the product.

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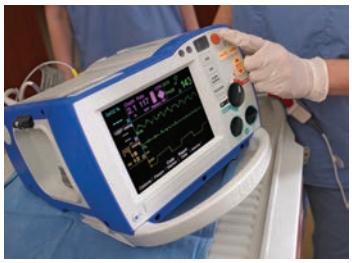

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VALUE. DELIVERED.

Building the moral and business case for supply chain visibility

by Karen Conway, Vice President, Healthcare Value, GHX

As inflation hits a 40-year high, hospitals are facing some of their most challenging financial headwinds in at least as many years. Conversations among trading partners have shifted, from resiliency to intense price negotiations. This can be an uphill battle, with many products still in short supply and suppliers, too, facing higher prices. It can also spell problems down the road, if we divert our attention too much from trying to create a more transparent, resilient, and socially conscious supply chain.

Before inflation reared its ugly head, many providers and suppliers were actively discussing how to create upstream visibility into potential supply chain risks, from fires at a production facility to longer term disruptions caused by geo-political conflicts, major natural disasters and the likely potential for another pandemic. Among the most coveted information by hospitals and healthcare systems has been the countries of origin for both finished medical products and the associated raw materials and/or components. By knowing where a product is made, as well as the sources of the critical ingredients, hospitals can better target vigilance efforts. Case in point: when the Ukraine war started, industry observers rightly predicted shortages in many of the raw materials sourced from Ukraine that are used in the production of surgical instruments, orthopedic devices and durable medical equipment.

In the early stages of the pandemic, several large global medical device manufacturers told me it would be difficult to answer what seems to be a simple question: "Where are your products made?" That's because the supply chain is complicated. The raw materials and components come from different regions, and the products themselves are often constructed in stages across geographies. During times of disruptions, manufacturers may move production lines. Many products are also produced, at least in part, by contract manufacturers.

Supply chain complexity further reduces upstream visibility,[1] which can impact more than just the ability to predict and respond to potential shortages. Manufacturers can expect these requests to increase, as regulators and commercial customers seek information to address multiple issues. Knowing the parties and places involved in the production of medical devices is also key to addressing other critical healthcare issues, including:

- Health Equity – Many hospitals and health systems can include their manufacturers' upstream purchasing with diverse suppliers in their own diversity spend reports.
- Environmental Sustainability – Knowing where and how products are produced helps measure the carbon footprint of healthcare products, which will become more of a regulatory and/or market requirement going forward.

A third critical question has to do with an issue that is only beginning to receive the attention it deserves in healthcare – the use of forced labor in the supply chain. Other industries, e.g., garment, electronics, have already begun tackling this issue, in response to the public outcry following the 2012 collapse of a textile factory in Bangladesh, which killed more than 1,100 workers, and a spate of suicides among technology workers at a manufacturing plant in China. According to research[2], two-thirds of surgical instruments are manufactured in Pakistan, often in unsafe conditions by children as young as 7 years of age who are forced to work to pay off family debt. Plants making personal protective equipment (PPE) in both India and Mexico have also been found to have violated similar labor laws, while there is increasing evidence that Uyghur people in China are being forced to make PPE.

Beyond the criticality of a well-functioning supply chain, the pandemic also raised awareness of longstanding labor violations in glove manufacturing plants in Malaysia, where most of the world's medical exam and surgical gloves are made. In March 2020, at the very start of the pandemic in the U.S., the federal government had just lifted a ban on imports from Malaysian glove manufacturers accused of violating the rights of migrant workers. A year later, as the pandemic raged on, the U.S. government once again banned certain Malaysian glove imports and ranked the country among the most egregious for human trafficking.

According to research[1], the exponential demand for certain products during the pandemic shifted the balance of power to manufacturers, while hospitals competed to secure necessary products. But even without a pandemic, the rising demand for surgical procedures (and associated, often disposable, products) only further increases the potential for labor violations.

Medical ethicists have pointed out the tragic irony of the use of products to support the health of individuals in one part of the world leading to a decrease in the health of the people in other regions who (are forced to) make those products.[3] Beyond the moral dilemma, governments around the world, including the U.S., are taking a more aggressive stance against forced labor in the supply chain. The U.S. has prohibitions against both the importation of product produced with forced labor and human trafficking by any entity receiving federal financial assistance. The Biden Administration has multiple strategies addressing human trafficking and recently launched a working group on forced labor in the healthcare supply chain.*

Given the challenges faced by providers (from inflation to labor and supply shortages), this may seem like another highly complex problem to add to an already full plate. While that's true, I would argue that it also further builds the business case for more end-to-end supply chain visibility. How can we work across the entire supply chain to address these issues? Even starting with more visibility into country(ies) of origin could help target our efforts to combat human trafficking and minimize the potential for more supply disruptions due to ethical and legal issues. HPN

** The opinions expressed in this article are the author's own and do not necessarily reflect the view of the Department of Health and Human Services or the working group.*

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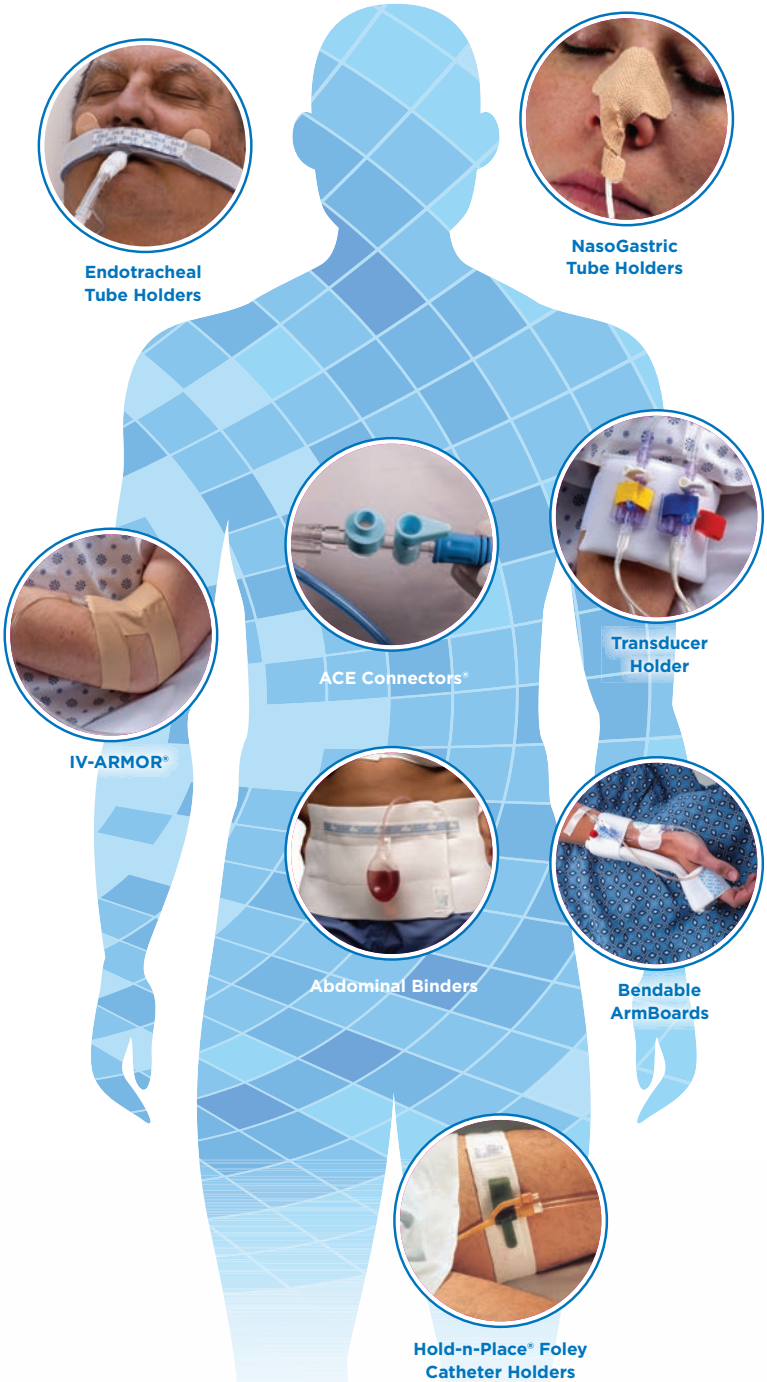

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