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HEALTHCARE PURCHASING NEWS®

CLINICAL INTELLIGENCE FOR SUPPLY CHAIN LEADERSHIP

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Q&A's on Thermometer Accuracy

Q: What makes thermometers accurate? What should we know about thermometer accuracy?

A: Published peer-reviewed clinical studies. Without such studies by medical professionals, there is no assurance of accuracy on children and adults in all settings.

Accuracy specifications by manufacturers of thermometers are laboratory accuracy, not accuracy in actual use on people being tested for fever. Laboratory accuracy tests do not include important physiological effects which vary from person to person, and setting to setting, which can affect the actual accuracy well beyond their laboratory accuracy.

Published peer-reviewed clinical studies are the gold standard for accuracy, since they include actual use on people in many settings, which automatically includes the physiological effects that vary from person to person and setting to setting. Only these studies can provide the assurance that the thermometer will provide accuracy in detecting fevers for all ages in all settings.

With more than 80 published peer-reviewed clinical studies attesting to the accuracy on all ages from newborns to geriatrics, in all settings where fever detection is needed, the Exergen Temporal Artery Thermometer is by far the most proven accurate, compared to thermometers which have no or very few clinical studies.

Q: How about non-contact thermometers?

A: Non-contact thermometers are highly inaccurate for detecting fevers, here is why: Accuracy specifications by manufacturers of non-contact thermometers (NCIT) are laboratory accuracy, not accuracy in actual use on people being tested for fever. Laboratory accuracy tests do not include important physiological effects which vary from person to person, and setting to setting, rendering NCIT's unreliable, regardless of their laboratory accuracy. For non-contact devices, these physiological effects can overwhelm the normal laboratory accuracy of the device, to the point that its actual error is 2 deg C rather than 0.2 deg C.[1]

Studies have demonstrated NCIT's detected fever in from 4% to 90% of the people with fevers, and did not detect fever in from 75% to 100% of people who lacked fever.[2] Studies of real-world efficacy of fever screening at airports and borders found that almost no disease cases had been caught across several nations and pandemics.

Q: Have non-contact thermometers been compared to Exergen Temporal*Scanner* thermometers?

A: Yes, in a new study published in 2020.[3] Independent researchers conducted a prospective observational study on a sample of 265 non-infectious patients at two hospitals. When body temperatures read below 99.5 degrees Fahrenheit, the thermometers showed similar results, but as temperatures rose above that, non-contact scanners' accuracy decreased. Temperatures were farther apart as they rose. The non-contact scanners missed five out of every six fevers detected by Exergen temporal artery thermometers.

According to the authors, "This is the first study to compare the accuracy of non-contact infrared thermometers (NCIT) to TAT in adult patients. Although mass fever screening is currently underway using NCIT, these results indicate that the NCIT may not be the most accurate device for fever mass screening during a pandemic."

1,2,3: References at exergen.com/tradeup

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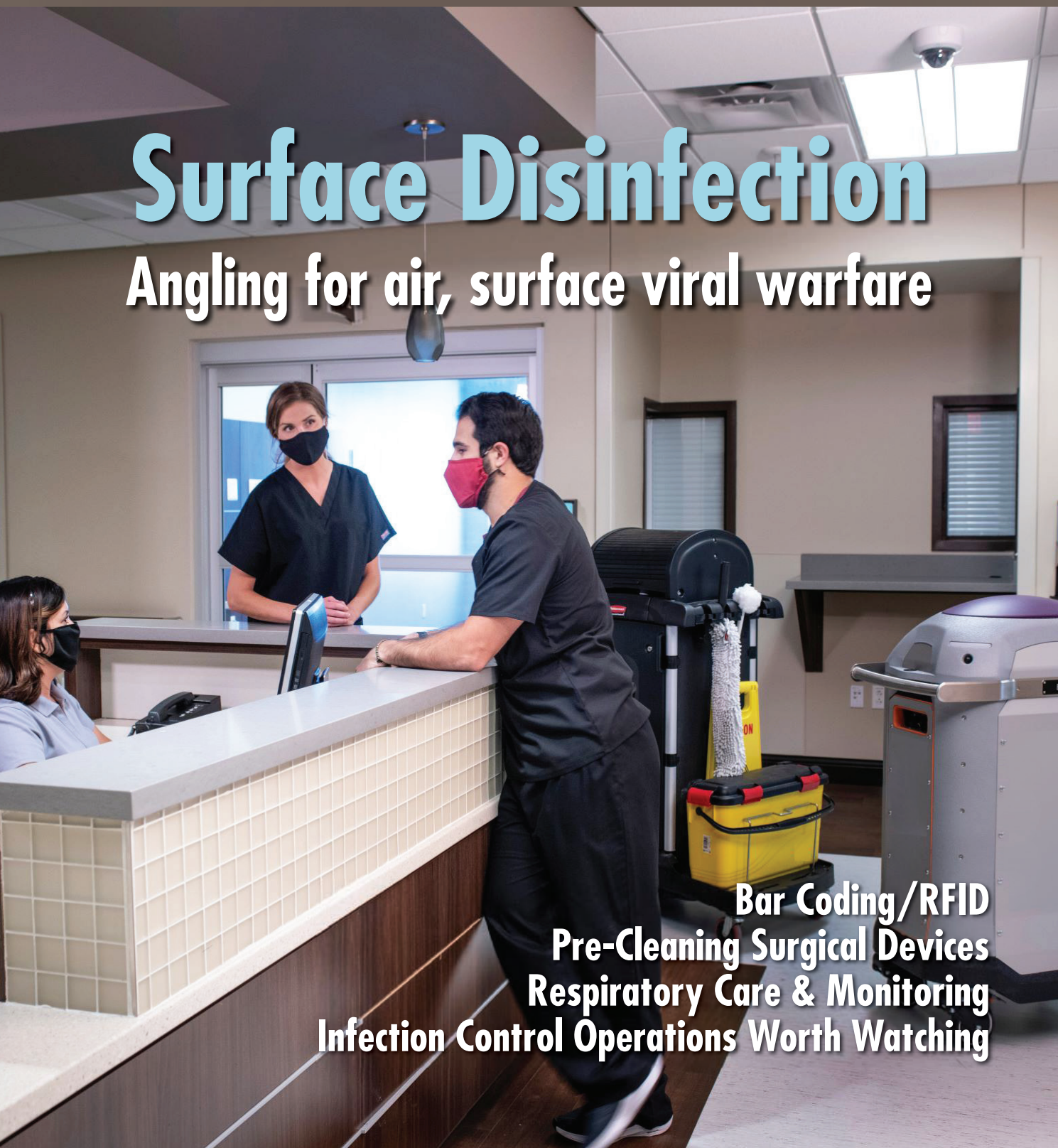

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Redfern et al Pain Manag Nurs 2019 Apr;20(2):164-169.

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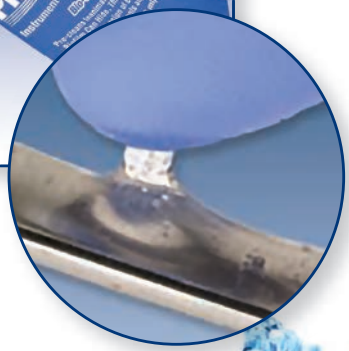

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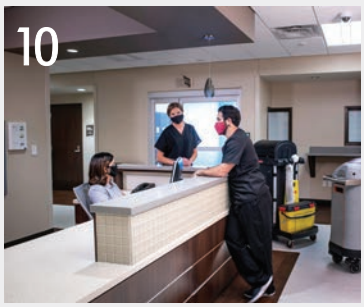

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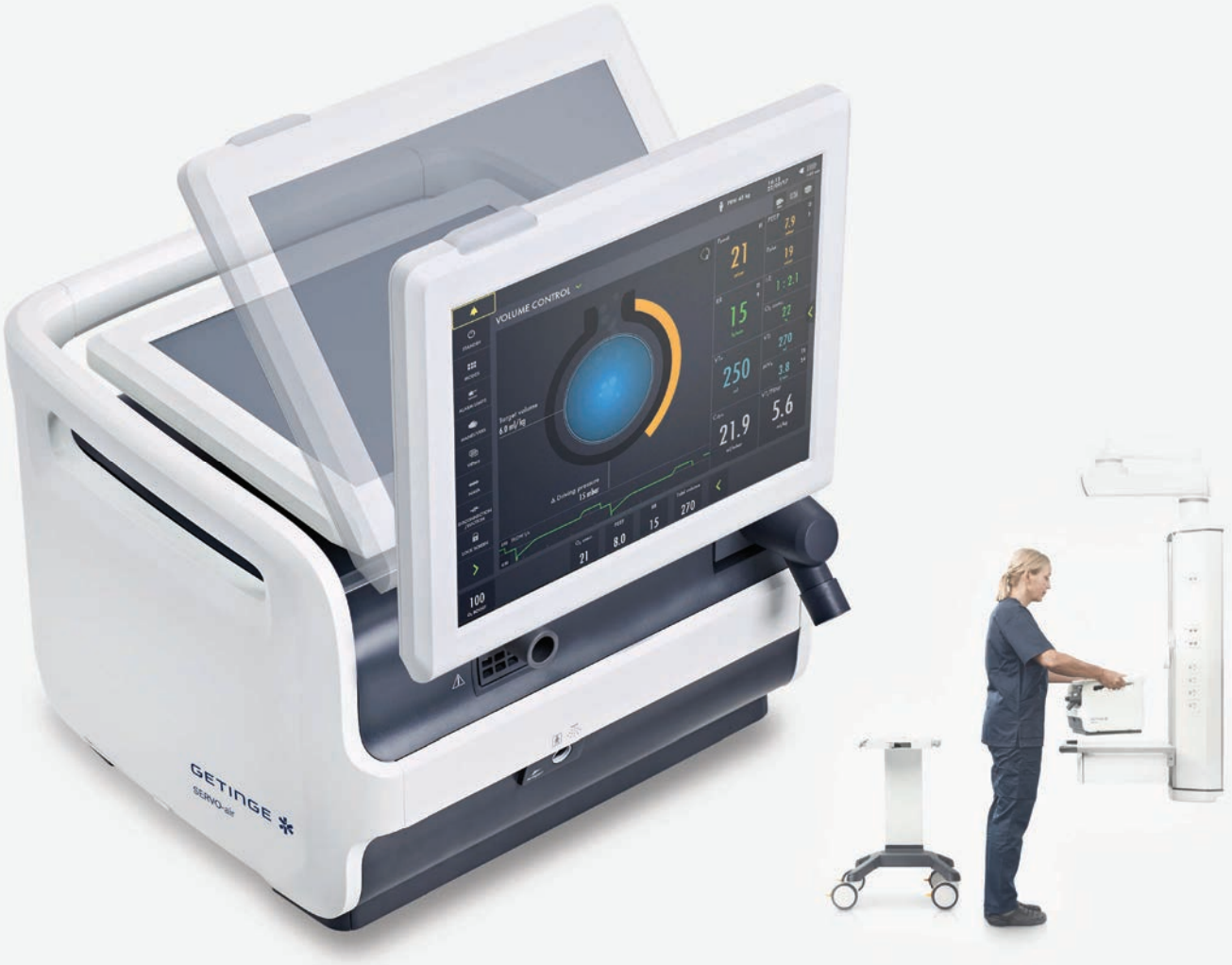

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RELIANT

Are you essential?

Here we are "officially" a full year deep into the pandemic (even though purists and realists technically could and would have backdated this designation a few months), pondering how much we've learned.

If this COVID-19 pandemic – much like its Spanish flu predecessor a century earlier – taught us anything it embodies these two tenets:

1. Following orders is essential – even if those "orders" are suggestions, recommendations and pleas with no compensatory or punitive damages for disobedience save for the spreading of the virus and the needless and senseless deaths of many from non-compliance.
2. Supply chain is essential – something the manufacturing, retail and military industries already acknowledge.

For some, quarantining at home, wearing masks when out and about, maintaining physical/social distance of six to 12 feet apart, washing hands and practicing proper physical hygiene (which includes not touching your face and eyes, picking your nose, biting your fingernails or scratching your hair without immediately washing your hands), seems like logical, normal, selfless behaviors. Unfortunately, not all share this perspective for a variety of reasons that only can be classified as the anathema of the three behaviors listed in the previous sentence.

Three industries recognize the essential nature of supply chain. For two of them – manufacturing and retail, the inability of getting products in the hands of buying consumers/paying customers means that assets emerging from production assembly lines become paperweights booked as liabilities.

For the military, an effective, efficient, flexible and fluid supply chain can turn the tide of battle and war. Examine the art of warfare – ancient and modern. To cripple an opponent, the proponent almost always attacks and disrupts supply lines and transportation early, which includes bridges, railroad tracks and roads as well as notable factories. Disrupting production and supply frustrates demand, which leads to public and societal regress.

In healthcare, each one of us knows better than to allow and accept this because we are all essential.

DATA BANK

How are physicians at your organization involved in the supply chain process?

	2020	2019	2018	2017
Physician-owned distribution (POD) program(s)	0.80%	1.30%	4.20%	2.20%
They are part of the supply chain staff	1.50%	1.70%	2.60%	3.50%
They are part of the supply chain staff and lead/oversee certain functions	2.30%	0	0	0
Bundled payments	3.80%	3.50%	5.20%	5.70%
Gainsharing	4.50%	3.00%	5.50%	7.80%
Other	4.50%	7.40%	5.50%	7.80%
They actively collaborate/participate in supply/service contract negotiations	9.10%	9.60%	15.30%	10.40%
Don't know	10.60%	7.80%	7.10%	8.30%
They are not involved at all	26.50%	29.10%	24.70%	28.70%
They actively collaborate/participate via Value Analysis Committees/Projects/Teams	50.00%	51.70%	54.50%	52.20%

Source: 2020 Healthcare Purchasing News readership survey

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ANGELINI PHARMA

FAST STATS

To examine perceptions toward COVID-19 vaccine and intentions to be vaccinated, in September and December 2020, the CDC conducted household panel surveys among a representative sample of U.S. adults.[1] Among the survey findings:

59.3 MILLION

doses of vaccines to prevent COVID-19 had been distributed in the United States, and 31.6 million persons had received at least one dose of the COVID-19 vaccine, as of Feb. 8, 2021.

39.4%

to 49.1% was the increase overall for vaccination intent (defined as being absolutely certain or very likely to be vaccinated); the largest increase occurred among adults aged 65 years or older.

61.9%

to 68.0% was the increase overall for intent (defined as being absolutely certain, very likely, or somewhat likely to be vaccinated).

38.1%

to 32.1% was the decrease for vaccination nonintent (defined as not intending to receive a vaccination) among all adults and among most sociodemographic groups.

49.1%

to 66.2% was the increase in intent among adults aged 65 years or older, 37.1% to 45.9% among essential workers, and 36.5% to 41.8% among adults aged 18 to 64 years with underlying medical conditions.

Reference:

1. Nguyen KH, Srivastav A, Razzaghi H, et al. COVID-19 Vaccination Intent, Perceptions, and Reasons for Not Vaccinating Among Groups Prioritized for Early Vaccination — United States, September and December 2020. MMWR Morb Mortal Wkly Rep. ePub: 9 February 2021. https://www.cdc.gov/mmwr/volumes/70/wr/mm7006e3.htm?s_cid=mm7006e3_w

www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7006e3-H.pdf

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NEWSWIRE

Government investigating massive counterfeit N95 mask scam of fake 3M masks

Federal authorities are investigating a massive counterfeit N95 mask operation in which fake 3M masks were sold in at least five states to hospitals, medical facilities and government agencies, according to a news report by Colleen Long published February 10 in The Associated Press (AP), which has been picked up and distributed by multiple media outlets.

Officials could not name the states or the company involved because of the active investigation, the AP report continued. 3M, based in Maplewood, Minnesota, is among the largest global producers of the N95 mask, which has been approved by the U.S. National Institute for Occupational Safety and Health and is considered the gold standard in protection against the coronavirus.

During the pandemic, Homeland Security Investigations has used its 7,000 agents in tandem with border officials, the Food and Drug Administration and the FBI to investigate scams, seize phony products and arrest hundreds of people to help stop fraud, the report added. The effort is based at the National Intellectual Property Rights Coordination Center, a government watchdog aimed at enforcing international trade laws and combating intellectual property theft.

There have been already more than 1,250 raids by law enforcement that resulted in the seizure of 10 million counterfeit 3M masks alone, the report continued. The company has filed more than a dozen lawsuits over reports of fraud, counterfeiting and price gouging.

On February 11th, 3M released a letter to customers stating that the company, "has been receiving increasing reports of counterfeiting and fraud related to the following three 3M respirator models: 3M Healthcare Particulate Respirator and Surgical Mask 1860; 3M Healthcare Particulate Respirator and Surgical Mask 1860S; and 3M Aura Healthcare Particulate Respirator and Surgical Mask 1870+. These have included reports of fake/counterfeit product as well as fraudulent offers where product is offered but not delivered."

The 3M letter continued, "We have been working with law enforcement to get counterfeit respirators off the market. These enforcement actions have resulted in the seizure of millions of counterfeit model 1860, 1860S, and 1870+ surgical respirators."

Additionally, the company advised in the letter, "In evaluating offers for these respirators, please consider some common signs of counterfeit:

- All 3M model 1860, 1860S, and 1870+ respirators imported into the United States from any other country are likely to be counterfeit. 3M is not currently importing these respirator models into the United States. If you have been offered these models coming from outside the United States, they should be viewed as counterfeit.
- All 3M model 1860, 1860S, and 1870+ respirators exported from China/ Hong Kong should be viewed as counterfeit. We do not manufacture these respirators in China/Hong Kong.
- Do not rely on TUV, SGS, or similar certification reports. All shipments of 3M model 1860, 1860S, and 1870+ respirators accompanied by a TUV, SGS, or similar certification report are likely counterfeit.
- 3M does not use a "Peru Seal" or other similar seals. Respirators bearing these seals are likely counterfeit."

Additionally, 3M stated in the letter, "We strongly recommend that 3M respirators be purchased only through 3M authorized distributors, or through existing contracting vehicles (i.e., Federal Supply Schedules), as this will provide the greatest assurance of receiving authentic product. Please contact our anti-fraud hotline at 1-800-426-8688 or 3M.com/covidfraud:

- If you are considering an offer for product that raises one or more of these concerns,
- If you have purchased product from a seller who is not a 3M authorized distributor, or that raises one or more of these concerns, and want to authenticate the product,

Visit the 3M website for any respiratory protection product questions . https://multimedia.3m.com/mws/media/1934748O/3m-counterfeit-communication-letter.pdf

Pandemic-focused McKenna virtual lecture this month

The Lessons from the Pandemic: Building a Secure Health System 2021 McKenna Virtual Lecture & Symposium will be presented on Tuesday, March 9 from 1:00 p.m. to 2:00 p.m. MST, announced The Mckenna Foundation.

The COVID-19 pandemic has exposed the frailties of the U.S. healthcare system, while spurring unprecedented innovation and collaboration as healthcare delivery shifted to televisits, traditional competitors shared information and resources, and businesses large and small stepped up to produce critical supplies.

The lessons from the COVID-19 pandemic are laying the foundation for healthcare institutions to ensure their ongoing ability to serve the needs of patients and

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communities, in times of both normalcy and crisis. The supporting strategic pillars of a resilient health system are its infrastructure, workforce, and supply chain/logistics.

The 2021 McKenna Lecture features Denis Cortese, M.D., Emeritus President and CEO, Mayo Clinic and Director of the Center for Healthcare Delivery & Policy at ASU. Dr. Cortese will share the results of work he is leading as President of the Healthcare Transformation Institute with eight competing health systems in the Phoenix area. Multidisciplinary leaders from each of the health systems identified the strategic pillars and are collaborating to develop the critical capabilities required in each of the pillars.

Denis Cortese

This special series is presented at no-charge by the McKenna Foundation, Department of Supply Chain Management and CAPS Research, at Arizona State University.

In addition to the McKenna Lecture & Symposium, attendees are invited to participate in additional post-lecture interactive topical sessions. Each session is designed to further advance each of the strategic pillars of a resilient health system addressed in the McKenna lecture. Each 90-minute session will begin at 1:00 p.m. MST on Thursdays, free of charge and open to the public, with findings published in a whitepaper. Topics will include:

- March 11: The Infrastructure and Facilities to support a Secure Future
- March 18: Securing and Supporting the Healthcare Workforce
- March 25: Matching Supply and Demand
- April 1: A Systemic Approach to Collaboration (across pillars, organizations, public & private sectors)

CAPS Research has the event and registration:
https://www.capsresearch.org/events/mckenna-lecture-symposium/

SMI mourns passing of Thomas Hughes, Executive Director

SMI, a non-profit, member-driven community of healthcare supply chain organizations, is saddened to announce that Tom Hughes, Executive Director, passed away at his home on Tuesday, January 26th. Hughes has been the leader of SMI since its inception 16 years ago and drove its mission as an organization that strives to make transformational change to improve the healthcare supply chain and patient care.

Tom Hughes

Under his leadership, SMI now consists of 130 of the most influential and powerful healthcare providers, suppliers, manufacturers, and distributors in the US. The extent of his influence on our industry cannot be measured.

Hughes' long and exemplary career began on the front lines of hospital administration and materials management at Beth Israel Hospital and Tufts New England Medical Center over 40 years ago. He founded Concepts in Healthcare, a healthcare supply chain consultancy and after the sale of this company to BD, became the Vice President of BD Healthcare Consulting & Services before moving into his role as executive director with SMI.

Throughout his career, he was a beloved mentor to countless supply chain professionals and was a tireless leader who championed an elevated and strategic role for supply chain in the healthcare industry. He is recognized for pioneering new approaches for provider and supplier collaboration that have forever changed the trajectory of trading partner relationships in healthcare. He developed quality assurance programs that are now implemented into all functions of supply chain management.

His lifetime achievements include past president of HCMMS, lifetime member of AHRMM and recipient of the George R. Gossett Leadership Award, Bellwether League Award Recipient, and he has been recognized by *Healthcare Purchasing News* (*HPN*) as being among supply chain management's most influential people.

Jane Pleasants, Vice President of Supply Chain at Duke Health, said, "The passing of Tom Hughes is a profound loss. He will be remembered as a true giant in the industry – a colleague, mentor, and friend. Tom will be in my heart and the hearts of so many people forever – our thoughts are with his family during this difficult time. "

SMI will be scheduling an event to celebrate Tom's life and recognize the many contributions he made to the industry. Other memorial plans are pending.

The entire *HPN* staff and our Editorial Advisory Board join SMI in mourning the loss of Tom and the multitude of contributions he made and continued to lead in the development of supply chain practices and process improvements.

HPN remembers Supply Chain leader Ed Hardin

Ed Hardin, Vice President and Chief Supply Chain Officer at Froedtert Health in Milwaukee, passed away Wednesday, February 10th. It's hard to accept the loss of a man with so much energy and compassion, who was only in his early 50s. Our condolences go out to his family and his team.

Ed Hardin

Before joining Froedtert Health, Hardin served as Senior Vice President, Supply Chain Management at Beaumont Health, Michigan's largest health care system.

In 2016, his Supply Chain team at CHRISTUS Health earned the *HPN* Supply Chain Department of the Year. As was characteristic for Hardin, he lauded his team for the accomplishment. At the time, he was CHRISTUS Health System's Vice President of Supply Chain Management.

"There's a saying amongst the Supply Chain Management (SCM) team. We're building the plane as we're flying it. That takes boldness and tenacity but we've found that chartering a group ... is as much about pulling people together who share a vision and understand that doing something new oftentimes means it won't be perfect, but we don't let perfection get too much in the way of progress," Hardin said.

Hardin was an industry thought leader, always thinking about what he could share from his experiences to educate and guide his colleagues. He was honored by Bellwether League Foundation last October for his 25 years of contributions and support to the healthcare supply chain.

Remembering Henry Berling

Henry Berling, after nearly 50 years in healthcare supply chain accomplishments, passed suddenly on February 9th. Berling was instrumental in building Owens & Minor into the largest healthcare supply distribution company in the country.

Henry Berling

Berling was directly responsible for signing new customers at Owens & Minor, including American Medical International, Voluntary Hospitals of America, Premier, Inc. and US Surgical.

Berling was honored by Bellwether League Foundation in 2014 for his supply chain contributions. HPN

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Angling for air, surface viral warfare

Here's how to evaluate products, technology for cleaning, disinfection in COVID-19 era

by Rick Dana Barlow

Photo courtesy:Xenex

As an outbreak of COVID-19 mushroomed into a global pandemic, public reactions outside of the healthcare community ranged from panic buying to rebellion against recommended practices for protection and prevention. Within the healthcare community, however, reactions by clinicians and administrators alike ranged from frustration about product access to consternation about public reactions.

Arduous but not Sisyphean.

While clinicians and administrators continue to carry out their duties and responsibilities as the pandemic slogs on through the start of another year, they now more than ever must count and rely on Supply Chain expertise to evaluate devices, products and technologies to make more informed buying decisions.

As with any crisis or disaster, troubled times bring out the best and brightest in people but also draw out the dim and dishonorable who strive to capitalize on the misfortune of others for personal gain.

To help *Healthcare Purchasing News* readers become more informed purchasers of air and surface cleaning and disinfection devices and products, *HPN* recruited more than a dozen executives with varying backgrounds in infection prevention, medicine and sterile processing at 12 of the leading companies that supply ultraviolet light devices and equipment and advanced clinical formula disinfectants (products generally inaccessible to the general public and instead targeted for healthcare organizations) to share useful and valuable insights.

HPN specifically asked them to cut through the hyperbole and jargon cluttering the context of what truly informed buyers need to know to make the optimal decision for them and their facility(ies). Curiously, most of the experts provided recommendations and suggestions in sets of three or four without having been prompted for a precise number.

Counting the options

David St. Clair, Executive Chairman, Halosil International Inc., echoes a well-known refrain from a prominent clinical infection prevention figure. St. Clair posits four major ways of making patient care spaces safer from pathogens, and all are useful under different circumstances.

David St. Clair

"As Dr. William Rutala is fond of saying, a 'bundle' approach is necessary to truly control the spread of infections in most settings," St. Clair noted. Rutala, Ph.D., M.P.H., serves as Professor, Division of Infectious Diseases, Department of Medicine, and Director and Co-Founder, Statewide Program for Infection Prevention and Epidemiology at University of North Carolina School of Medicine, Chapel Hill. Back in May 2017, Rutala retired as Director, Hospital Epidemiology, Occupational Health and Safety Program at UNC Health Care System.

St. Clair stresses that disinfection can occur only after cleaning an area via four techniques.

1. Spraying, Waiting and Wiping. "As the most basic approach to disinfection, using an appropriate EPA-registered chemical disinfectant in a spray bottle or in a pre-soaked wipe is currently 'the standard of care' in most environments," St. Clair indicated. "It can generally be used while a space is occupied by others without too much concern about exposing oneself or others to harmful vapors or chemicals, and often the disinfectants used can be quite inexpensive per unit volume.

"The caveats are that the only surfaces actually disinfected are those on which the chemical has been sprayed and has been allowed to sit, wet and undisturbed, for the necessary contact time of the disinfectant (1-10 minutes)," he continued. "Since that limitation is very real outside testing laboratories, this method generally results in less than 50 percent of pathogens being killed on surfaces."

2. "Electrostatic" Spraying. "Using spray systems that electrically charge droplets of chemical disinfectants has become increasingly common in the last year," St. Clair reflected. "These devices produce a cloud of droplets of varying sizes to try to envelope the targeted surfaces with a wet film that will stay wet for the required contact time of the disinfectant being used. Depending on the requirements of the disinfectant being used, the surfaces may need to be wiped down after the contact time. These devices, often called 'electrostatic guns' – and improperly called 'foggers' from time to time – are superior to normal spray bottles because they promote a wider distribution of the disinfectant than one could normally accomplish with a manual sprayer. So when properly used, electrostatic spraying is very likely to be more effective than manual spraying and wiping."

But St. Clair expresses caution with two key alerts.

"The caveats with this technology are related to the fact that it is still a spray technology, so spending the time to allow all surfaces to actually get wet and stay wet for the required contact time is a challenge," he indicated. "If one watches videos of people using these spray devices, often one sees the nozzles being waved around very quickly. That approach might give some observers a sense of protection, but in fact that would be a false sense of security – the disinfectant isn't being allowed to function properly. One high-quality manufacturer of these devices that actually received a rare EPA registration for the electrostatic application of their disinfectant is required, according to the EPA 'Master Label,' to spend at least five seconds per square foot of surface area. So a simple conference table that is 10 feet long and five feet wide requires more than four minutes of spraying just to properly disinfect the top surface and parts of the underside."

St. Clair urges the healthcare professional to protect himself or herself, too.

"The other major caveat with electrostatic spraying is that the person applying it is generally required to wear full [personal protective equipment] to reduce the inhalation and exposure risks from being near the cloud of small droplets," he said. "Any 'overspray' might increase the possibility of helping to kill pathogens in the air, but the droplet sizes tend to settle relatively quickly. That overspray also then raises the risk whenever that approach is used in occupied common areas, for instance – bystanders can be exposed easily. And the 'advanced clinical formulas' used in institutional settings are more likely to be irritants than those chemical disinfectants found in consumer-oriented stores."

3. UV/UV-C Light. "Properly built, modern UV/UV-C light fixtures and robots have proven to be very useful when one wants to sanitize (versus disinfect) many surfaces in a space in a relatively short period of time," St. Clair observed. "The labor required to do so is minimal, and most systems have record-keeping capabilities that let the institution know how often the asset has been utilized. When supplied with sensors that can be spread around a room, the UV/UV-C dosage is more likely to be effective at sanitizing the spaces in complex rooms (with equipment, furniture, etc.)."

St. Clair acknowledges that UV/UV-C systems come with their own caveats, which generally include costs – both capital and maintenance, the trade-off between efficacy and material compatibility – especially in complex spaces, and in some cases, safety.

"The fact that UV/UV-C systems are not subject to regulation by the EPA or FDA mean that efficacy claims are often made that are limited to very specific and very simplified situations," St. Clair cautioned. "The laws of physics apply – effectiveness is generally line-of-sight and diminishes by the square of the distance between the source and the target. Shadowed surfaces, including those surfaces that are essentially parallel to the light path, will get little or no benefit from the light. While there is potentially a little benefit from light bouncing off walls, etc., the distance issue then becomes paramount since the rays need to travel to the wall and bounce back some distance."

St. Clair offers this example: "A surface three feet away will receive four times the energy of a surface six feet away, and nine times the energy of the surface nine feet away. That means that delivering enough energy to effectively kill pathogens at nine feet requires the surface three feet away to absorb or reflect nine times the energy needed to kill pathogens. That difference is what contributes to material compatibility issues, particularly with many types of plastics.

"UV/UV-C systems will sanitize surfaces – reduce the bio-load on many of them, with some surfaces being essentially devoid of viruses and vegetative bacteria (probably leaving spores) and some being essentially untreated, depending on the complexity of the surfaces in a room," St. Clair assured. "By moving the light source(s) around a room a few times, the level of sanitation might well rise to disinfection – 99.99 percent – for pathogens other than spores, but then the advantage of time is greatly diminished and material incompatibility with devices and furniture in the room might become more of an issue."

Understanding exactly how a UV/UV-C light system was tested is critical when listening to kill-rate claims, according to St. Clair. "If a 99.99 percent kill rate is claimed, what exactly did that test environment look like? Were the biological indicators placed perpendicular to the light or parallel to it – or in shadows, and how far away were they? Then consider the surfaces and spaces in which you will use the lights – how real-world were the tests for your environment?" he asked.

4. Fogging & HPV. St. Clair considers aerosolizing (fogging) or vaporizing a disinfectant in an enclosed space "the newest regulated disinfection technologies – and the most efficacious for 'whole room disinfection.'

"Depending on whether the approval being sought is 'sporicidal' or 'sterilant,' either the EPA or the FDA [is] involved in setting the parameters of [Good Laboratory Practice] testing used," he said. "The highest kill rate normally assigned by the agencies – if reduced to percentages – is 99.9999 percent of bacterial spores. They do not allow a claim of 100 percent."

Fogging differs from spraying in significant ways, according to St. Clair, starting with droplet size. "Typically, a true fogger will dispense a reasonably uniform plume of chemical droplets under 10 microns; electrostatic sprayers droplets are about 40 microns or larger," he noted. "That size difference allows a number of advantageous things to happen: Concentration of active ingredients in increasingly small droplets as the water in the disinfectant evaporates before the droplet falls; the potential vaporization of an active ingredient to aid in the destruction of the pathogens and to penetrate into crevices; and the ability to kill pathogens on all surfaces while keeping all those surfaces in the space dry."

St. Clair indicates that fogging systems are often referred to as "dry mist foggers" for a reason.

"The close interaction between a fogger and its disinfectant is the reason that the EPA will only register a combination of a specific machine design and a specific disinfectant – both the fogger and the disinfectant matter," he clarified. "Vendors cannot legally claim that their fogger, for instance, has a 99.9999 percent kill rate against spores when using any disinfectant unless the EPA registered that unique combination. That requirement allows customers to be comfortable that the efficacy of a fogging system will deliver the results they seek."

Meanwhile, just as the three EPA-registered fogging systems that use a hydrogen peroxide-based disinfectant, hydrogen peroxide vapor (HPV) systems are able to claim a 99.9999 percent kill (inactivation) against spores and other pathogens, St. Clair continued. "HPV systems use highly concentrated hydrogen peroxide as a source of vapor that fills a room without creating an aerosol of any type. Like the fogging systems, they rely on a specific formulation of the disinfectant to create reliable results."

Purchasers should pay close attention to the expected "turnaround time" for spaces being treated, St. Clair advises. "Since the most common systems all rely on

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hydrogen peroxide and all create a vapor at some level, the space being treated has to remain closed until it's either actively vented to the outside or until the H_2O_2 vapor has naturally broken down into oxygen and water vapor. But in that time, essentially all surfaces in that space have been totally disinfected without any significant labor beyond the normal cleaning of the space," he added.

As with any investment in devices, products and technology, cost must be taken into account.

The UV/UV-C systems are typically the most expensive to purchase and to operate, according to St. Clair, followed by the HPV systems, both in terms of equipment, maintenance and consumables. While a wide range of system prices across vendors exists, the fogging systems are significantly less expensive on average than the UV/UV-C and HPV systems. Most – but not all – electrostatic sprayers are much cheaper than the fogging systems and can use a wide variety of disinfectants with different characteristics and costs, he continued. Not surprisingly, the spray-and-wipe approach is cheapest – and the least effective overall – especially if one doesn't count labor costs, he added.

Still, a modular strategy makes the most sense, according to St. Clair.

"In total, the tradeoffs tend to be overall efficacy, cost and time – not of a specific disinfectant, but as a result of its application in a space," he summarized. "Low-risk and occupied spaces might need only manual spray and wipe, larger spaces that can't be easily isolated might benefit most from an electrostatic sprayer approach, 'normal' hospital rooms and spaces might be best sanitized with a quick UV/UV-C treatment, and terminal disinfection of isolation rooms, [operating rooms] and the like might be best with fogging or HPV treatment."

Being instinctual


Sam Guzman

An informed buyer should start with the fundamentals, suggests Sam Guzman, Global Sales Director, Healthcare, American Ultraviolet Co.

First, define the goal of the project. "Are they looking at air disinfection, surface disinfection, or a combination of both?" Guzman questioned.

Second, where are they looking to apply UVC technology? This may span patient rooms, ORs, common areas, HVAC systems, etc. Within that framework, Guzman encourages asking if there are any time constraints? "If they are looking at a patient room in a high turnover hospital with a full census, they will want to minimize the cycle time," he indicated. "A powerful mobile unit or a fixed mounted system would keep the cycle times short. If they are looking at a patient room at a long-term care facility, they might not be under such a time crunch and a smaller mobile unit might be a more economical choice."

Third, will the space be occupied when using the UVC equipment? Examples include the use of upper air UVC disinfection equipment in a patient intake area or waiting room or the use of a mobile unit after the terminal cleaning of a patient room, using a fixed mounted system during an orthopedics procedure in an OR, or adding a UVC lamp array to the buildings heating and cooling (HVAC) system, he explains.

Fourth, focus on the targeted pathogens of concern. "You will find different pathogens in different places," Guzman said. "In an HVAC system, we might look to target Aspergillus Niger or black mold growing on a cooling coil or an airborne pathogen, such as influenza or SARS CoV-2, in the return or supply airstream. Both types of pathogens can be found in an HVAC unit and they require a different dosage level of energy for deactivation. In some cases when sized properly they can achieve both goals with the same equipment.

"In a patient room or an OR they might look to target MRSA, *C-diff*, Candida Auris, influenza, or these days SARS CoV-2," he continued. "Viruses tend to require a lower UVC dose than bacteria, which tends to require a lower dose when compared to spore forming pathogens and spores. So they would look to target the worst of the lot with the understanding that you are delivering sufficient energy to destroy the pathogens requiring a lower dose on the way to achieving the lethal dose for the toughest ones."

Research ties that bind


Irene Hahn

Evaluating UV light devices should focus on effectiveness and efficiency, insists Irene Hahn, Senior Vice President, Sales & Marketing, Xenex Disinfection Services, but purchasers should be cognizant of research sources.

"Carefully evaluate the scientific literature validating that the technology is effective," Hahn said. "Don't be misled by marketing brochures or white papers. Make sure you have access to peer-reviewed and published studies validating the manufacturer's claims. As far as efficiency, look at the cost-per-room disinfected. LightStrike robots disinfect dozens of rooms per day, bringing the cost per room disinfected to about $3. Check references: What kind of service do they provide? Make sure the vendor will provide not just technical support but offer your facility recommendations on how to incorporate the UV device into a comprehensive disinfection program with best practices. Where you run the robot is as important as how often you run it."

When choosing a UVC disinfection system for a healthcare facility, according to Alice Brewer, MPH, CIC, CPHQ, FAPIC, Clinical Affairs Director, PDI Healthcare's Tru-D SmartUVC, it is important to look at independent research on the device's efficacy.


Alice Brewer

"Beware of studies that are company-funded or have conflicts of interest," Brewer advised. "Also, it is important to consider a device's limitations, such as distance, as well as the potential need to move the device to multiple positions to reach every surface. Many UVC device manufacturers claim efficacy within a certain distance limitation, leaving the potential for harmful germs and pathogens to be left behind. Multiple studies have found that a measured dose of UVC that can compensate for room variables, such as size, shape, and contents of the room, can destroy up to 99.9 percent of pathogens left behind after manual cleaning."

Recognize functional aims

UV devices occupy two general classes – one covers surfaces and the other air, according to David Kirschman, M.D., President and CEO, Aerobiotix Inc. Because they are "quite different," hospitals need to explore them in-depth, he added.

"Surface UV systems are for terminal cleaning of surfaces in unoccupied spaces, such as patient room turnover," Kirschman described. "Air UV systems are for continuous disinfection of occupied spaces, such as during a surgical procedure. It is critical to avoid systems [that] can expose room occupants to UV rays. Surface UV systems require an operator, so hospitals need to budget for that. Air UV systems run autonomously, so no specific operator is needed.

"Hospitals need to look for the devices with the best clinical data and experience

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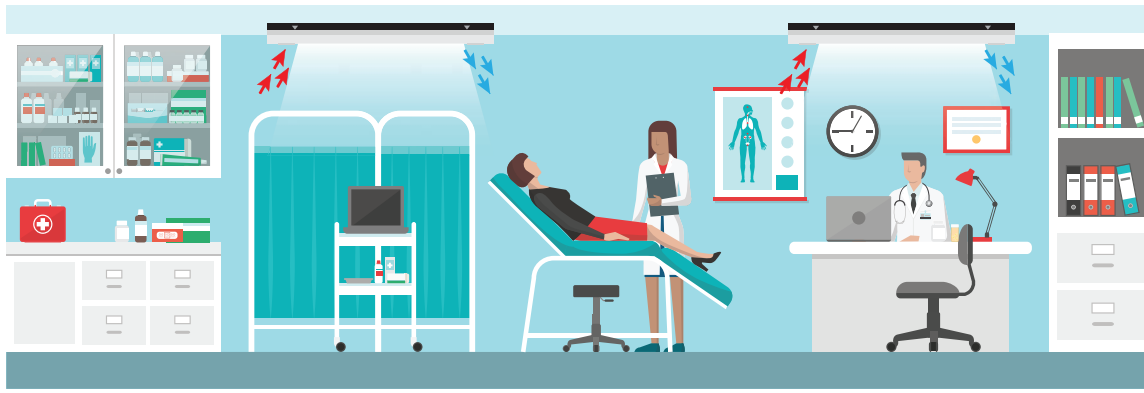

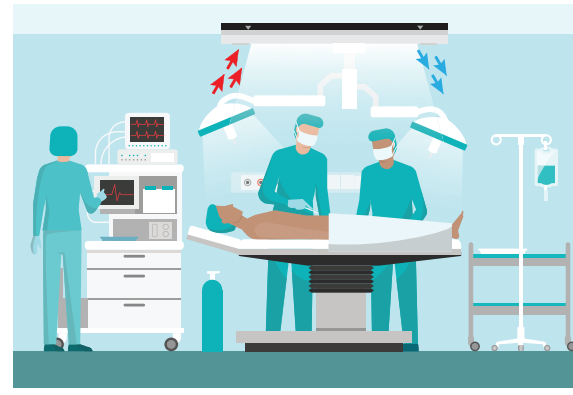

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in an acute care environment," he continued. "An additional layer of security should be considered by using UV-C in areas of high potential SARS-Cov-2 load, particularly near symptomatic patients and/or aerosol-generating procedures. Hospitals should look for technologies [that] have been specifically tested against SARS-Cov-2, either on surfaces or in air."

UV/UV-C light devices may be improving continually but they also must keep pace with science, notes Seth Hendee, CRCST, CIS, CHL, CER, CSPDT, CFER, IAHCSMM Approved Instructor, Clinical Education Coordinator, SPD, Healthmark Industries.

Seth Hendee

As healthcare organizations evaluate these devices, they must concentrate on certain critical questions geared toward facility needs, Hendee recommends.

The first homes in on location for use. "UV light is dramatically affected by distance," he said. "The UV system's capacity must be compared to the physical space(s) in which it will be used. Also, UV light is less effective when it is not direct. Shadowing due to the physical space design, the equipment that may be present in the room, and where the UV system can be placed within the space can all create 'shadowing' that will reduce disinfection efficacy. [Consequently], multiple cycles may need to be run or extra emitters could be required to reach all surfaces effectively."

The second involves the UV light's position in the larger cleaning and disinfecting puzzle.

"As with other disinfection processes, initial cleaning must be thorough for the disinfection to take place," Hendee noted. "This is because UV does not easily penetrate soils that remain on surfaces. [UV light] should be considered a complement to a quality manual cleaning process and not a magic pill."

The third relies on vendor service. "What kind of support does the UV system manufacturer offer their customers? Companies supplying technical support and educational support for all those involved in utilizing the system should be considered," he added.

Know your priorities

Safety, efficacy and efficiency remain the three primary issues when considering an environmental ultraviolet germicidal control device, insists Karen Hoffman, R.N., CIC, FSHEA, FAPIC, Infection Preventionist Consultant, Vidashield UV24, a division of Medical Illumination.

Karen Hoffman

"From a safety perspective, healthcare organizations should assess if the ultraviolet device allows for operation in occupied spaces and whether it produces an ozone byproduct," Hoffman said. "Some UV lamps – such as those used for tanning – radiate energy in the UV-A and/or UV-B range and over extended periods may have adverse health consequences for exposed persons. UV lamps that are designed to emit radiation at 184.9 nanometers (nm) produce ozone, which is hazardous to humans even at low concentrations." Hoffman joined Vidashield after serving as a Clinical Instructor in the Division of Infectious Diseases at the University of North Carolina's School of Medicine in Chapel Hill.

"From an efficacy perspective, UV-C devices should operate at a peak wavelength of 253.7 nm to optimally neutralize pathogens," she continued. "Since 1997, CDC/NIOSH has conducted and funded studies to determine the ability of upper-room ultraviolet germicidal irradiation (UVGI) systems to kill or inactivate airborne mycobacteria in a simulated healthcare room. These studies have shown that a properly designed and maintained upper-room UVGI system may be effective in killing or inactivating hardy environmental TB bacteria. In response to the COVID-19 pandemic, the CDC has recommended use of upper-room UVGI as an adjunct to increasing ventilation efficiency for SARS-CoV-2 in dental settings. Multiple studies have shown that one upper-room UVGI system can eradicate aerosolized particles of viruses, bacteria and molds (bioaerosols) in the air, preventing fallout of viable pathogens onto surfaces."

When analyzing for efficiency, upper-room UVGI systems that run independently and continuously 24/7/365 are the most efficient, Hoffman indicates. "This utilizes a human factor engineering strategy because it removes the reliance on turning on and off and location or placement of the system, helps reduce the unintentional shut-off of the system or blocking of the directional flow," she added.

Acknowledge the obvious

To combat the airborne COVID-19 using technology, Bryan Stone, M.D., Nephrologist and Chief Medical Officer, RxAir, urges healthcare organizations to set logical priorities.

"Any indoor environment, no matter how well the air and surfaces are disinfected, is contaminated immediately when a person enters and talks, coughs or breathes," Stone said emphatically. "Time and money are best spent on efforts and technologies that can disinfect the air in occupied spaces on a continual basis without risk to the occupants. Certain UV light air purifiers are uniquely suited to this purpose."

Stone recommends distinct parameters that any UV light air purifiers under consideration for purchase in healthcare institutions must include: They should be FDA-cleared as Class II Medical Devices, be manufactured under ISO 9000 quality systems to ensure the device is safe and performs as described and be tested in independent laboratory tests for effectiveness against target pathogens. He further emphasizes that RxAir UV-C light Air Purifiers meet all three of these criteria. "There are myriad new devices on the market as the result of COVID that have not undergone these critical steps," he warned.

"Simply passing virus-laden air past a UV light does not guarantee viral inactivation," Stone continued. "The virus must maintain close proximity to the UV bulb for a period of time for inactivation. Many small UV light air purifiers rapidly pass air over small, weak UV bulbs, which may not provide the length of exposure to be effective. It is important that UV lights in the 254um wavelength that are to be used in occupied spaces be shielded from the users as they can be harmful to the skin and eyes. Shielded lights enable the units to continue cleaning the air as occupants expel [it], thereby reducing the risk of inhalation and viral load."

UV light air purification be considered a complementary prevention protocol used in conjunction with social distancing, wearing masks and frequent hand washing, Stone further suggests. "While the UV light air purifiers work continuously to inactivate airborne viruses, users are cautioned that it is unlikely to sufficiently act upon pathogens exhaled by an infected person who is mere inches or a few feet away," he added.

Make a checklist

Larinda Becker, Senior Director of Marketing – Infection Prevention, Diversey Inc. encourages informed buyers – clinically, economically and operationally – to

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explore seven key areas and glean answers to more than 20 critical questions.

1. **Efficacy.** Do cycle times enable effective patient flow? Does the device kill pathogens of concern in realistic contact times? Does the device effectively direct energy to both horizontal and vertical surfaces?
2. **Safety.** Does the device have multiple safety features to ensure staff, patients and visitors are shielded from UV-C energy?
3. **Portability.** Is the device easy to transport within and between facilities, or does it require special handling? Is the device compact enough to both use and store in tight spaces? Does the unit weight allow all staff to handle the unit easily?
4. **Durability.** Will the device stand up to repeated use associated with terminal / discharge cleaning and transport? Are the device and bulbs protected during transport and storage?
5. **Usability.** Is the devise easy to set up, reposition and operate? Are the cycle times required short enough to incorporate into the discharge workflow process? Can the device be stored at the point of use to reduce transport time?
6. **Affordability.** What is the acquisition cost of the device? What are the operating costs (parts, labor, etc.)? What is the total cost to run – including the device, labor and time that the room is out of service? What are the options for acquisition (purchase, lease, rent)? What are the expected service/maintenance costs once purchased? Is a warranty / service contract provided? How long? How much?
7. **Manufacturer support.** Does the manufacturer provide tools to demonstrate the effectiveness of the device? What training and tools are provided to ensure smooth operationalization? What reporting tools are provided? What is the ongoing support for service and any repair?

Identify parameters, pathogen targets for exposure

As you evaluate any UV light sources for disinfection it's critical to understand your objectives – air and/or surface, the pathogens you want to eradicate, the proximity of people to the UV output when the device is active and the UV wavelength needed to satisfy all of these parameters, according to Mike Olsen, Chief Marketing Officer, Far-UV Sterilray.


Mike Olsen

"This provides a general frame of reference for the amount of exposure time and the power of the UV source required to effectively disinfect each area," Olsen noted. "When considering air and surface disinfection, is the healthcare organization taking the 'shadowing' effect into account – the effect of dead spots where the UV rays might not be within line of sight? They'll want to work with a reputable company that can custom design their UV disinfection solution to guarantee complete coverage of the affected area.

"How safe is the UV solution?" Olsen continued. "A UV solution that is environmentally friendly by being chemical-free and mercury-free, while not producing ozone are all important factors to consider when assessing the environmental impact of their disinfection objectives. Lastly, how long has the supplier been in business? What is the warranty period for their proposed solution? Is the supplier infringing on any patents that could drag

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Raising the Standard for **Whole Room Disinfection**

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the healthcare organization into a patent dispute? The supplier should also provide a complete safety profile for their solution. Careful thought as to the vendor's experience with UV technology assures the healthcare organization will be in good hands and will provide an effective, safe, licensed and guaranteed solution."

Getting to the surface

Because airborne bacteria and viruses eventually fall to surfaces if left untreated, choosing the optimal hospital-grade disinfectant is akin to the order of cleaning before disinfection: It's not rocket science.

"There are published criteria for selecting a hospital-use disinfectant product, and I would suggest that the same criteria could be applied to any type of disinfectant you are considering for hard surfaces," said Linda Homan, R.N., CIC, Senior Manager, Clinical Affairs, Ecolab Healthcare. "Each organization has to determine what the most important considerations are, given their circumstances."

Linda Homan

Regardless of unique circumstances, Homan highlights three considerations for selecting the appropriate chemical disinfectant.

"First, ensure that there are well-designed studies that support its use in a clinical setting," she said. "Second, consider the organisms of highest concern in your facility and ensure that any disinfectant you are considering using has kill claims against these organisms. And third, ensure that it can kill them within a reasonable contact time. These three considerations will ensure that you are using an effective product. Beyond that, material compatibility and ease of use are also important. Note that any chemical disinfectant must also be EPA-registered for the intended use to be used in a healthcare setting."

For Noreen Costelloe, Director, Marketing, Ruhof Corp., the decision for healthcare professionals represents a matter of time.

"In light of the emergence and spread of COVID-19 chemical surface disinfectants need to be effective in a short period of time," Costelloe told *HPN*. "Busy healthcare professionals don't have time to wait 10 minutes for a surface spray to kill SARS-CoV-2. [They] should look for products with kill times of no more than one minute. In addition, healthcare professionals would be wise to use a 'multi-purpose' formulation that not only works against viruses but is also effective against a broad-spectrum of pathogenic microorganisms, including bacteria, antibiotic resistant bacteria, fungi, mold and mildew. All the better if the product also cleans and deodorizes."

Caitlin Stowe, MPH, CPH, CIC, CPHQ, VA-BC, Clinical Affairs Research Manager, PDI Healthcare, concurs that time must be on the side of the healthcare professional. She specifies three preferred qualities that an advanced clinical formula chemical disinfectant should have.

Caitlin Stowe

"First, the treatment (contact time/dwell time) should be short enough to be acceptable to a facility, as time is of the essence when it comes to room turnover," Stowe said. "Second, a facility should ensure that the disinfectant kills the most epidemiologic important pathogens that are pertinent in healthcare, including SARS-CoV-2 – the virus that causes COVID-19. This will ensure that the surfaces are safe for patients, visitors and staff. Finally, it's important to ensure that the product itself is easy to use. Ready-to-use disinfectant wipes are excellent for rapid room turnover and ensure thoroughness of surface cleaning, because there is no mixing of chemicals or the need for clean fabric cloths. You can simply pull the wipe out of the package to quickly and effectively clean and disinfect hard, nonporous surfaces." HPN

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EXECUTIVE BRIEF

Realizing the total value in healthcare product purchasing

Optimizing clinical, patient and financial outcomes

Presented by Healthcare Purchasing News in collaboration with Mölnlycke

For hospitals and healthcare systems, a healthy bottom line correlates with multiple factors. Operational/supply chain efficiencies, evidence-based clinical practice and safety, and patient quality scores should all be considered as part of a facility's strategy and financial planning for long-term viability.

But how does this overarching knowledge translate into everyday decision making, such as product selection?

Today, healthcare purchasing decisions take a more expansive approach because the products purchased are tied directly to a facility's financial standing and patient experiences. Healthcare purchasing requires critical examination beyond the upfront acquisition costs and pursuit of lower product prices, as those factors may not necessarily produce improved patient or financial outcomes. Instead, the process should encompass a broader outlook of the downstream impact on quality of patient care, operations, and bottom line–total value.

Because operational decisions, clinicians and patients all contribute to a facility's financial health, it's imperative to use products and solutions that help support the desired quality of care. This is even more vital now and bears repeating as facilities strive to balance resources, sustain operations, and deliver positive care experiences, all while facing increasing financial pressures caused by the COVID-19 pandemic.

No matter what products or solutions are selected, it's important for everyone involved in purchasing decisions at a hospital or healthcare system to feel a sense of responsibility and ownership for not just the health of its patients, but also for the system's financial well-being. For facilities looking to create efficiencies, savings, and satisfaction in care, now is the time to adopt a total value approach to healthcare purchasing.

What is total value?

Total value is a holistic view of cost, quality and outcomes. This philosophy provides a more complete value-based perspective of purchasing aimed at improved clinical, patient, and financial outcomes. It considers total cost of ownership, including downstream effects of additional factors affecting value such as utilization, quality and payment penalties.

Total value is not simple to measure for every product, but it should become a decision-maker's focus to ensure the well-being of a facility's bottom line. As the stewards of the bottom line, non-clinical decision makers, who also maintain high standards regarding patient outcomes, should expect more from manufacturers. Companies should be willing to come to the table with real evidence about not just improvements in care, but also positive financial impacts their solutions have made at other facilities. Financial benefits cannot be automatically assumed to transfer from one manufacturer's product to another manufacturer's products, reinforcing the need for all companies to present supporting evidence.

Metrics used to measure total value

Total value takes into account four major metrics:

- Operational and supply chain efficiencies
- Quality outcomes
- Clinician safety
- Patient experience.

But how does this total value approach work in practice, and how can it benefit operations, patient care and the bottom line?

Again, non-financial decision makers must rely on their suppliers to provide hard evidence that their solutions can result in savings through these four metrics, but without compromising clinician safety or clinical outcomes. Additionally, facilities should engage with vendors that offer specialized guidance, education, support, and data to help achieve better quality, efficiencies, and safety in care for staff, patients, and communities, such as:

- Standardizing products, improving utilization and improving consistency in care
- Focusing on solutions proven to be the most clinically effective and cost-efficient
- Reducing waste
- Reducing high cost of workplace injuries
- Preventing and managing hospital-acquired conditions (HACs)
- Delivering better treatment outcomes

"For facilities looking to create efficiencies, savings, and satisfaction in care, now is the time to adopt a total value approach to healthcare purchasing."

- Promoting patient satisfaction
- Minimizing true patient care costs and total cost of ownership
- Reducing complications

These measures all play an important role in improving financial positioning and enhancing care. In terms of patient satisfaction, for example, an analysis of Centers for Medicare & Medicaid Services (CMS) data consisting of 19,792 observations from 3,767 hospitals confirms that a positive patient experience is associated with increased profitability and, similarly, that the correlation between negative experiences and decreased profitability is even stronger.[1]

Outcomes realized by total value

Many organizations have already done some of the operational hard work to support better outcomes and total value. One medical center, for example, had a goal of increasing standardization by reducing SKUs to gain supply chain efficiencies, without sacrificing outcomes. The hospital decided to implement a project to focus on a large scope category of surgical gloves. After standardizing to synthetic gloves, the glove styles were not only reduced from 13 to 3, but OR-related tear downs also dropped to zero by eliminating latex gloves, representing $43,020 in cost avoidance and 36 to 60 fewer staff hours over one year – all while eliminating potential exposures to latex.[2] While these outcomes may not have been easy to measure prior to the project, the result was validation that the facility was able to access additional value while reducing patient and clinician safety exposures.

Another facility wanted to understand how the products they selected impacted a major downstream financial pitfall for them – clinician injuries. As many as 85 percent of nurses develop musculoskeletal disorders in their lifetime, with 79.6 percent reporting lost time from work.[3] At this facility, staff injuries arising from patient care positioning and handling had resulted in significant costs and affected the bottom line by decreasing staff efficiency, increasing worker compensation claims, and generating litigation expenses. By implementing products and programs to ensure proper patient turning and positioning, a significant cause of clinician injuries, one acute care hospital achieved a $222,000 cost avoidance.[4] The investment paid off in terms of total value.

In the U.S., one major factor to the bottom lines of many facilities is their quality scores. These are impacted by HACs, such as infections and injuries, and can result in millions of dollars in penalties for hospitals. There are many HACs to consider and there has been much interest in understanding the potential for improvements to these often expensive penalties. Because the work is complex, long-term, and may be product- or practice -specific, hospital value analysis committees must pressure test their product selections and practices, especially the downstream and long-term impacts, ensuring their decisions will produce improved HAC results. Furthermore, manufacturers providing solutions aimed at improving outcomes and costs should be pressed to provide evidence of the downstream and long-term financial impacts of their products.

Improved financial outcomes can be realized by hospitals and healthcare systems now and for years to come by ensuring all decision-makers focus on total value. This total value approach by all decision-makers, including supply chain stakeholders, will help facilities achieve excellence in care for patients and communities, provider safety, and a healthy bottom line. HPN

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HEALTHCARE PURCHASING NEWS & Mölnlycke®

Respiratory relief

Pandemic puts pressure on patient treatment, positioning and monitoring in critical and post-care

by Ebony Smith

Photo courtesy: Fisher & Paykel Healthcare

COVID-19 care is draining. COVID-19 disease, caused by the SARS-CoV-2 virus, fatigues bodies and deflates airways of patients. The care shifts wear down minds, emotions and energy of healthcare workers as well as places them at risk for infection. The case volumes deplete supplies, equipment and capacities of hospitals and facilities.

Somehow, though, this critical care must forge on, even in dire times of patient deluge and virus variant evolution. To perform their essential jobs on the front lines, medical personnel and teams, however, need to be outfitted and equipped with the supplies they need for infection prevention and the machines they need to help patients breathe and live.

Arik Eisenkraft, Chief Medical Officer, Biobeat, stresses how caring for COVID-19 patients ultimately takes a whole-team and multi-treatment approach.

Arik Eisenkraft

"When looking at the COVID-19 patient population admitted, the best practice should be comprised of highly skilled healthcare providers from several different disciplines, an advanced and well-equipped medical facility, advanced monitoring platforms, preferably such that can provide continuous remote patient monitoring with integrated automated early detection of deterioration and alert systems, and advanced oxygen supplement and diverse ventilation capabilities," Eisenkraft said. "Surveillance closed-circuit cameras deployed in the contaminated treatment area help in monitoring patients in real time by personnel located outside the contaminated treatment zone."

He continued, "Ideally, in order to provide high quality treatment and allow rapid response, there should be a healthcare provider on each COVID-19 patient. However, due to the large numbers of patients, and despite their complexity and multi-system injury, this is not possible. As time goes by, we see more and more medical staff suffering from burnout and exhaustion, as a result of numerous intensive shifts in the last year."

Supporting staff safety, patient care

Comprehensive care during the COVID-19 pandemic, of course, has elevated concentration on infection control and supply accessibility.

"I believe there are two key challenges for healthcare workers (HCWs) across the nation," stated Chris Hutchinson, Director of Clinical Affairs, Fisher & Paykel Healthcare. "The first is access to their patients. The ongoing COVID-19 surge requires HCWs to continually don and doff personal protective equipment (PPE) to protect themselves and limit the spread of contamination. This sequence is time-consuming for the HCWs and supply chain professionals who must maintain the never-ending availability of PPE."

Chris Hutchinson

He added, "The second is access to the appropriate equipment to provide the appropriate therapy. In early 2020, the focus was providing invasive ventilation to COVID-19 patients with hypoxemic respiratory failure, or insufficient oxygen in their blood. This focus drove the manufacture, stockpile, and purchase of thousands of mechanical ventilators."

A year ago, at the start of crisis in the United States, the "U.S. Food and Drug Administration took significant action to help increase the availability of ventilators and accessories, as well as other respiratory devices, during the COVID-19 pandemic to support patients with respiratory failure or difficulty breathing," according to a press release from the agency.[1]

The FDA continued, "First, the guidance describes the agency's intention to exercise enforcement discretion for certain modifications to these FDA-cleared devices. The guidance also helps manufacturers ramp up their manufacturing by adding production lines or alternative sites, for instance, using non-medical device manufacturers such as automobile manufacturers, to start manufacturing ventilator parts. Second, hospitals and healthcare professionals may use ventilators intended for other environments. The FDA also provides recommendations for other alternatives that should be considered such as devices for treating sleep apnea. The FDA's policy also applies to health care facilities that use ventilators beyond their indicated shelf life, which should increase ventilator capacity. Finally, the agency encourages manufacturers, whether foreign or domestic, to talk to FDA about pursuing an emergency use authorization (EUA), which would allow them to distribute their ventilators in the United States."[1]

Fast forward to today, ventilator and other medical supplies and equipment remain crucial to care.

"We have continued to support health care, and the pharmaceutical companies that are rapidly developing and manufacturing COVID-19 vaccines," said Mattias Perjos, President & CEO, Getinge in a press release.[2] He added, "We also achieved our full-year target of delivering 26,000 advanced ICU ventilators, and the

demand for our ECMO therapy products remains high."[2]

Noninvasive treatment is another method that may be provided in care for patients.

"From a clinical perspective, the initially high ventilator mortality rates led the refocus away from mechanical ventilation towards noninvasive therapies like Nasal High Flow (often described as the interface high flow nasal cannula, or HFNC) for COVID-19 patients," Hutchinson explained. "The challenge for hospitals now is sourcing equipment to provide these new therapies. A study by Patel et al (2020) published in *BMJ Open Respiratory Research Journal* suggested that high flow nasal therapy use was associated with a reduction in the rate of mechanical ventilation and overall mortality in patients with COVID-19 infection. In this example, patients received therapy beginning around 35 L/min and were steadily increased up to 60 L/min to achieve the desired patient outcomes."[3]

Kylie Gilberg, Marketing Manager, Midmark Corporation, points to spirometry treatment for use post-recovery.

Kylie Gilberg

"As the patient population with COVID-19 continues to recover, it will be essential to monitor the long-term effects the disease may have had on their pulmonary lung function," Gilberg said. "Because COVID-19 is a new disease, studies are ongoing to determine what these long-term effects may be and how spirometry may be able to help. Due to the number of Americans impacted by COVID-19, it will be essential for physicians at the primary care level to monitor their patient's recovery. Yet, prior to COVID-19, 47 percent of primary care physicians reported not having a spirometry device within their clinic."[4]

Enhancing airways, breathing

When they go to hospitals, patients with COVID-19 often arrive in extreme and fragile conditions. Consequently, they require special movement and care.

Jennifer Gassman

"When patients in critical conditions are ventilated, the risk of ventilator-associated events increases. Prolonged immobility often leads to delirium and generalized weakness," stated Jennifer Gassman, Clinical Nurse Specialist, Medline. "Early mobility and safe patient handling are mission critical for helping patients return to their baseline level of health."

One research-based practice that may help improve breathing for patients who receive ventilation treatment is proning.

"Proning is now considered the standard for treating COVID patients in respiratory distress," Gassman indicated. "As more data has become available, peer-reviewed evidence has emerged that supports proning as a part of COVID-19 protocols for ventilated patients. Proning is the process of turning patients onto their stomachs for extended periods of time. Up to this point, hospitals have justified proning COVID-19 patients based on established treatments for other respiratory diseases such as Acute Respiratory Distress Syndrome (ARDS). For patients with ARDS, the prone position is used in an attempt to improve oxygenation and reduce ventilator-induced lung injury, according to the American Association of Colleges of Nursing. We are hearing from healthcare providers that they are seeing improvement in oxygenation in COVID patients when practicing prolonged proning.[5] Furthermore, providers are noting improvement when patients turn on their stomachs at home."

She noted, "The process can be done manually or by using a patient lift. Lifts and friction-reducing devices can help reduce the amount of physical exertion required by staff to perform the task."

Eisenkraft adds that proning is performed by several healthcare providers and may help decrease the risks of complications or ventilation.

"The prone position allows for better expansion of the back regions of the lungs, helping to enhance removal of secretions," he explained. "This, in turn, leads to improved breathing and oxygenation. In many cases, this improvement is vital in preventing patients experiencing mild respiratory distress from deteriorating, avoiding being ventilated or progressing to severe respiratory distress."

Proning additionally may be helpful for patients receiving Nasal High Flow therapy, says Hutchinson.

"Anecdotally, initial clinical evidence to date has suggested that early prone positioning with Nasal High Flow may reduce the number of COVID-19 patients escalating to severe or critical status."

Preventing injuries, infections

Care for COVID-19 patients encompasses proper positioning and handling along with continuous care and monitoring for safety.

"Patients placed in the prone position can be in this position for 12 or more hours," Gassman said. "Patients in the critical care unit are also at a higher risk of developing pressure injuries due to the severity of their illness, immobility, mechanical ventilation and infrequent repositioning. To prevent pressure injury while patients are in this position, it is important to perform routine skin assessments and off load and pad bony prominence areas."

She recommends tactics to help reduce the risk of pressure injuries in patients in the prone position, including:

- Reposition patient every two to four hours.
- Turn head and alternate raising arms in a swimming position.
- Use wedges or pillow to off load bony prominences.
- Keep the patient's body in good spinal alignment to reduce risk of muscle strain and contractures.
- Routinely check skin around medical devices, securement devices and tubing to prevent pressure injuries and rotate devices and securement sites to redistribute pressure. Be aware that edema under devices have a potential for skin breakdown. Also, make sure to document all skin assessments and preventive measures.
- Position in reverse Trendelenburg to reduce optical pressure and swelling.
- Use dressings as prevention for injury. Moisture can be managed with dry pads, liquid protectants/sealants, and absorbent dressing such as foam dressing, hydrofiber/calcium alginate.
- It is also important to assess adequate nutrition.
- When using any type of equipment or products, such as beds, positioning devices, and dressings, make sure to follow manufacturer instructions."

COVID-19 infection, as found, may cause other serious complications and long-term health effects.

"COVID-19 patients show multi-system injuries, with cardio-pulmonary involvement being the most prevalent," Eisenkraft explained. "The pulmonary injury damages the ability to properly oxygenate, often leading to rapid and unexpected deterioration. There is more and more evidence that the cardiac injury also has an important role. This makes these patients complex and unpredictable, and when adding the fear of exposure and infection, treatment is highly challenging."

He added, "It is not often that we encounter a situation in which improper handling of ventilation equipment might lead to environmental contamination with the potential of infecting healthcare providers. Moreover, these complex patients require

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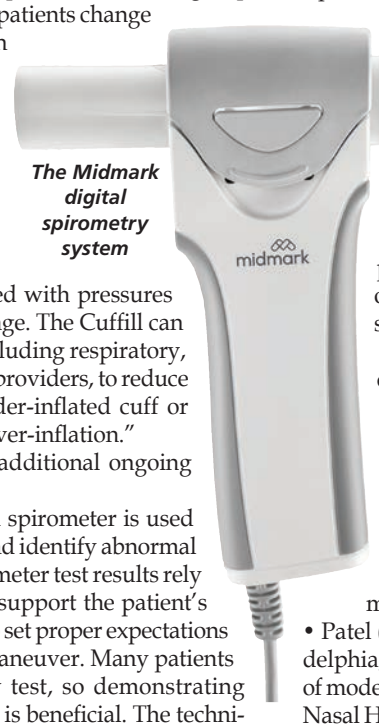
intense handling by medical staff with continuous monitoring, to allow timely alerts if and when they deteriorate. Most devices used for monitoring COVID-19 patients do not provide all the necessary vitals, and respiratory monitoring is only partially achieved."

Tracking vital signs and functions is important throughout care.

"Measuring and adjusting cuff pressure is critical for patients intubated with a cuffed endotracheal (ET) tube, trach tube, or laryngeal mask airway (LMA), but cuff pressures can change rapidly, especially during transport or as patients change position, such as proning," Gassman emphasized. "In the U.S. market, Medline is now an exclusive distributor of Hospitech Respiration Ltd.'s AG Cuffill, a device that enhances patient safety while diminishing the risk of cross contamination.[6] AG Cuffill allows clinicians to make monitoring cuff pressure a standard of care while reducing the risks and costs associated with pressures above or below the recommended range. The Cuffill can be used by various care providers, including respiratory, anesthesia, first responders and home providers, to reduce potential for aspirations with an under-inflated cuff or ischemic injury that can result from over-inflation."



The Midmark digital spirometry system

Patients, post-recovery, may need additional ongoing monitoring and treatment.

"Pulmonary function testing with a spirometer is used to measure a patient's lung function and identify abnormal lung function," Gilberg stated. "Spirometer test results rely heavily on the patient effort. To best support the patient's effort, it is essential for the technician to set proper expectations and coach properly throughout the maneuver. Many patients have never performed a spirometry test, so demonstrating proper position and testing technique is beneficial. The technician can also encourage the patient to continue blowing as hard and as fast as they can."

Gilberg adds that the spirometer process and protocols include:

- Patients need to ensure they are seated, with their shoulders back and chin up. They should also use a nose clip to ensure all air capacity from their lungs is being exhaled through the mouth.
- Clinics should calibrate their device daily, prior to use, with a 3L calibration syringe according to ATS guidelines.[7] This ensures the device is performing accurately before any tests are completed.
- Follow CDC and ATS guidelines on the proper PPE to use and environment disinfecting processes.
- Mouthpieces are single use and should be replaced between each patient.
- The Midmark spirometer has a unique eject lever to avoid handling of the mouthpiece, reducing risk of cross contamination."


The AIRVO2 by Fisher & Paykel Healthcare

Making strides with practices

As COVID-19 persists and evolves, healthcare agencies and providers move forward to adapt care and improve outcomes for patients.

"Since the first signs of COVID-19 in early 2020, treatment guidelines from numerous national and international societies have been published including ATS, ACEP, SSC, DoD, NIH, AARC and ANZICS to name a few," Hutchinson noted. "Each of these treatment guidelines favor the use of Nasal High Flow over other noninvasive therapies because of patient tolerance, increased efficacy, and lower mortality. In addition, one notable clinical practice guideline published by Rochwerg et al (2020)[8] described the role of high flow nasal cannula as a respiratory support strategy."

He shares two published examples of positive results of Nasal High Flow therapy, including:

- Jackson (2020) described UnityPoint Health in Des Moines, IA, where at the time of writing, 116 of 321 (36 percent) of hospitalized COVID-19 patients required escalation of care due to acute hypoxemic respiratory failure and 96 (83 percent) received Nasal High Flow as respiratory support. Of the 70 patients discharged at the time of writing, 49 (70 percent) did not require mechanical ventilation.[9]
- Patel (2020) described Temple University Hospital in Philadelphia, PA, where at the time of writing, 67 of 104 (64 percent) of moderate-to-severe respiratory failure COVID-19 patients on Nasal High Flow avoided escalation to noninvasive ventilation or invasive ventilation.[10]"

With regard to new treatment testing, The National Institutes of Health reported that, "Early data from a clinical study suggest that blocking the Bruton tyrosine kinase (BTK) protein provided clinical benefit to a small group of patients with severe COVID-19. Researchers observed that the off-label use of the cancer drug acalabrutinib, a BTK inhibitor that is approved to treat several blood cancers, was associated with reduced respiratory distress and a reduction in the overactive immune response in most of the treated patients. In some patients with severe COVID-19, a large amount of cytokines is released in the body all at once, causing the immune system to damage the function of organs such as the lungs, in addition to attacking the infection. This dangerous hyperinflammatory state is known as a 'cytokine storm.' At present, there are no proven treatment strategies for this phase of the illness."[11]

In terms of updated guidance for hospital and at-home care, "WHO recommends that patients who have COVID-19 – both confirmed and suspected – should have access to follow-up care if they have persistent, new or changing symptoms. This is one of the recommendations made by WHO in revised clinical management guidelines. Evidence was gathered on the post-COVID condition, so-called 'long COVID,' where people who have recovered from COVID-19 continue to have longer-term issues like extreme fatigue, persistent cough and exercise intolerance."[12]

WHO continued, "For COVID-19 patients at home, WHO suggests the use of pulse oximetry to measure oxygen levels in the blood. This needs to be coordinated with other aspects of home care, such as education for the patient and care provider

and regular follow-up of the patient. For hospitalized patients, WHO suggests the use of low dose anticoagulants for preventing the blood clots forming in blood vessels (thrombosis). For hospitalized patients who are taking supplemental oxygen (including high-flow nasal oxygen) or non-invasive ventilation, WHO suggests positioning patients on their stomachs to increase oxygen flow (awake prone positioning)."[12]

Eisenkraft additionally points to achievements with automated monitoring technology.

"When Biobeat deployed its systems – wireless, wearable, non-invasive, continuous remote patient monitoring sensors and web application – to manage the patients all across Israel, we were asked about providing an early warning score (EWS)," he explained. "We saw the currently used score, in which healthcare personnel had to fill manually the vitals and calculate the score, performing that once a shift. Within one week we integrated an automated EWS system into our platform, allowing them to get the updated score automatically every five minutes, helping to prevent patient deterioration. We were approached by many healthcare providers, telling us that our platform helped them as an important decision support tool with difficult choices, such as whether to ventilate a patient or not, as well as deciding on the discharge of patients." HPN

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INFECTION PREVENTION

IP Operations Worth Watching

Reaching new heights in protecting healthcare environments

by Ebony Smith

Photo credit: Mikhaylovskiy | stock.adobe.com

One of the most critical roles in healthcare is protecting patients and staff from dangerous and deadly pathogens and infections. Everyone's lives ultimately depend on it.

This, of course, is no small task. It entails attention, resources and teamwork from care teams, environmental services workers, sterile processing technicians, infection preventionists and others to maintain hygienically clean patient surgical sites, sterilized medical instruments and equipment, and disinfected rooms and facilities to deliver high-quality and safe patient care.

Healthcare Purchasing News recognizes and salutes the 2021 Infection Prevention Operations Worth Watching at a variety of hospitals and health systems. These organizations are noted for their outstanding dedication, practices and successes in infection prevention:

Stopping SSIs with nasal, skin decolonization

A Georgia-based hospital

Surgical site infection (SSI) after total joint replacement results in significant patient suffering and healthcare costs. In a 2020 study[1] published by *The American Journal of Infection Control*, a 300+ bed hospital in Georgia introduced a preoperative universal nasal and skin decolonization protocol to reduce the risk of surgical site infection after total joint procedures. The study outcome data demonstrated reduced infection rates, a decrease in associated patient morbidity and lower costs to the facility.

This facility utilized a universal decolonization protocol as recommended by the Nozin NOVA program and was able to reduce colonization risk and decrease total hip SSI rate from 0.91 to 0.00 and total knee SSI from 0.36 to 0.00 per 100 procedures. Along with the reduction of patient infections, the hospital achieved $400,000+ in estimated cost savings.

Nozin NOVA colonization risk mitigation programs are also being introduced to help replace traditional strategies, such as screen and isolate, while lowering costs and improving care. NOVA programs include a proprietary method powered by Nozin Nasal Sanitizer antiseptic.

Hunterdon Medical Center, Flemington, NJ

Hunterdon Medical Center targets zero preventable infections for all surgical patients. Nasal decolonization is a proven intervention to help reduce the risk of infections by removing harmful pathogens that live in the nose and could transfer to the patients during surgery. Hunterdon evaluates new solutions on an ongoing basis that allow the facility to improve outcomes, improve patient satisfaction, and reduce cost.

Hunterdon selected PDI's Profend Nasal Decolonization Kit as its nasal decolonization product for a number of reasons, including:

- efficacy profile, killing 99.7 percent of *Staphylococcus aureus* at 10 minutes and 99.9 percent up to 12 hours after a 60-second application
- time savings for staff, due to the pre-saturated swabs and easy patient application
- patient experience, allowing nurses to help explain to patients the importance of nasal decolonization

Ultimately, Hunterdon was able to improve outcomes, improve patient satisfaction, and reduce cost as a result of its implementation of the kit for the prevention of surgical site infections.

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Learn more at www.DefendwithProfend.com

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*Healthcare-associated infections

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Combating COVID-19 with PPE, room disinfection

Houston Methodist System Infection Prevention and Control department, Houston

Throughout the last year, the team has worked very closely with every department, each hospital in the system, and the various ambulatory care settings within the system to coordinate efforts with COVID-19. This included strengthening their relationship with Supply Chain Management to ensure that they had adequate supplies to keep staff safe while caring for patients and could quickly transition to alternative items when supply lines to usual supplies began to be threatened.

Infection Control team, Sturdy Memorial Hospital, Attleboro, MA

This team is noted for their effectiveness in dealing with the COVID-19 pandemic. Under the oversight of Dr. Fine, Donna Sears and others, they have worked tirelessly to protect the health and safety of the patients and staff of this hospital.

Children's Mercy Hospital Kansas, Kansas City, MO

Children's Mercy Hospital Kansas is on a mission to ensure the cleanest environment possible for both its patients and staff. The facility implemented three Tru-D disinfection robots in 2019 and has since added to its fleet as well as has expanded use of the technology throughout the hospital. The facility has the highest volume of Tru-D robot disinfection cycles completed of all other Tru-D device customers, often using them up to 40 times daily.

When the COVID-19 pandemic hit, the devices gave staff peace of mind knowing that the facility was taking additional measures to make the staff feel safe, and nurses were paid overtime to run the devices as much as possible.

Currently, the facility is using the devices to disinfect the following:

- Inpatient rooms (320 rooms) at patient turnover
- Radiology clinic on weekends
- Sedation rooms and orthopedic procedure rooms weekly
- Inpatient procedure rooms and playrooms weekly
- Hematology/oncology clinic rooms weekly
- Dental clinic procedure rooms weekly
- GI procedure rooms weekly

"Our broad use of Tru-D disinfection across our institution provides an additional level of protection to both our patients and staff. I am extremely pleased with this product," said Michael Sayer, senior director at Children's Mercy Hospital - Kansas City.

Safety in the workplace and care

Hospitals and health systems strive for clean, healthy and infection-controlled settings of care for patients and staff. That means having the right supplies and equipment in place for staff to perform at the highest and safest level.

The emergence of COVID-19 disease, caused by the SARS-CoV-2 virus, undoubtedly, struck the world like no other health crisis before. Personal protective equipment (PPE), air and surface disinfection, patient and family isolation, contactless deliveries, and other safety guidelines and measures became top priorities in preventing cross-contamination and transmission of the virus.

Accessing supplies for infection control

Healthcare facilities

According to a press release from the Association for Professionals in Infection Control and Epidemiology (APIC), "As cases of COVID-19 surge in the U.S., a national survey of infection prevention experts, conducted October 22 to November 5, 2020 by the Association for Professionals in Infection Control and Epidemiology (APIC), found that while healthcare personnel have better access to PPE than they did in the spring, many healthcare facilities have implemented PPE crisis standards of care."[2]

Healthcare-associated infections (HAIs) have risen amid the COVID-19 crisis.

"Respondents also reported an increase in healthcare-associated infections at their facilities since the pandemic began, with 27.8 percent reporting specific increases in central line-associated bloodstream infections (CLABSI), 21.4 percent in catheter-associated urinary tract infections (CAUTI), and 17.6 percent in ventilator-associated pneumonia (VAPs) or ventilator-associated events (VAEs)," [2] continued APIC.

Lack of supplies and an increase in patient volumes have further impeded care.

"The survey also asked IPs about possible medical supply shortages and capacity issues during the confluence of the pandemic and the 2020/2021 flu season," added APIC. "Nearly three quarters (72 percent) are strongly (35 percent) or somewhat (37 percent) concerned about their facility's surge capacity; more than half of respondents (54 percent) are strongly (23 percent) or somewhat (31 percent) concerned about their facility's ability to provide safe care. Nearly 80 percent of respondents said that they are concerned about the impact of medical supply shortages in their healthcare facility related to the current flu season, and 84 percent are more concerned about supply shortages compared to previous years because of the pandemic." [2]

New guidance on PPE in healthcare settings was established by the industry.

The Society for Healthcare Epidemiology of America (SHEA) reported in a press release that, "To guide facilities and healthcare personnel in management of suspected or confirmed COVID-19 patients amid ongoing critical shortages of personal protective equipment, the Society for Healthcare Epidemiology of America (SHEA) joined with the Infectious Diseases Society of America and the Pediatric Infectious Diseases Society in releasing the infection prevention and control portion of a three-part guideline based on the best evidence available."[3]

The eight recommendations cover:

1. "Masks
2. Masks in shortage scenarios
3. Gloves
4. Shoe covers
5. N95 masks
6. Reprocessed N95 masks
7. Extended use of N95s through face shields and surgical masks
8. Reuse of N95s with face shields and surgical masks"[3]

APIC, additionally, set forth a new collaborative initiative to strengthen infection prevention practices in medical settings, APIC announced in a press release.

"The APIC Strategic Partner program establishes long-term relationships with industry partners united in the common goal of reducing the risk of infection in healthcare facilities," stated APIC. "According to the Centers for Disease Control and Prevention, an estimated 633,000 hospitalized patients get healthcare associated infections (HAIs) each year and 72,000 die during their hospital stay. APIC Strategic Partners play an important role in supporting many of the educational initiatives and services that benefit APIC's almost 16,000 infection preventionist (IP) members fighting on the front lines against the spread of harmful microorganisms and viruses, such as *C. diff*, MRSA, and SARS-CoV-2 in healthcare facilities."[4]

Page 30 ▶

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AD-42-2 REV 2

Shielding infants from *Staph* infections

Neonatal intensive care units (NICUs)

Aiming to keep infants safe from infections, the "*SHEA neonatal intensive care unit (NICU) white paper series: Practical approaches to ylococcus aureus disease prevention* provides expert opinion and evidence-based responses to frequently asked questions clinicians may have in implementing the updated CDC guidance for preventing, detecting, and controlling the spread of Staph infections, including methicillin-resistant *S. aureus* (MRSA) and methicillin-susceptible *S. aureus* (MSSA),"[5] according to a SHEA press release.

"Staph infections can become serious in NICU patients and are often associated with medical devices, like catheters used for feeding and medication, as well as direct and indirect exposure to bacteria on healthcare personnel, parents, caregivers, family members, other critically ill infants, and the healthcare environment," added SHEA. "The document discusses how to safely handle Staph bacteria colonization and infection in parents or visitors and in NICU patients, including hospitalized multiples (e.g., twins or triplets) with different colonization or infection statuses. The document can also help guide decisions about when and how to decolonize infants who have asymptomatic *S. aureus* or MRSA, while taking into account safety considerations for this patient population." [5]

Improving care and safety practices

Identifying FDA-EUA products risks

Observing possible risks of harm and infection from products with Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration, an ECRI press release announced that, "Hundreds of medical products have been authorized for temporary use in the past year to meet the unprecedented need for life-saving equipment and supplies during the COVID-19 pandemic. ECRI listed the complexity of managing devices that have been authorized through the EUA process at the top of its 2021 Top 10 Health Technology Hazards report."[7]

ECRI added, "Through its EUA process, FDA can green-light previously unapproved products—or new indications for previously cleared products—as acceptable for use during an emergency. Hospitals need to watch for safety and performance issues, monitor the device's authorization status daily, and know what to do with the device when the EUA ends. For example, in August 2020, FDA revoked the EUA for a class of protective barrier enclosures after they were found to increase healthcare workers' exposure to airborne particles, rather than limiting exposure."[7]

Raising the bar on patient and staff infection prevention

Advancing global efforts to decrease HAIs, SHEA announced in a press release that, "More than 700 studies, including 250 international abstracts, highlighting worldwide progress in preventing and controlling healthcare-associated infections and addressing antibiotic resistance were published. The committee reviewed international advances of the previous decade and future trends in the fields of healthcare epidemiology, infectious diseases, infection prevention, patient safety and antibiotic stewardship. Three key topics emerged:

- "Innovation
- Data for Action
- Addressing Antimicrobial Resistance Without Borders"

Strengthening PPE and infection prevention protocols for frontline workers and patients during the COVID-19 pandemic, an APIC press release reported that an "online survey of 1,083 infection preventionists (IPs) located in U.S. hospitals and health facilities found that 73.0 percent of respondents reported that their healthcare facilities have implemented PPE crisis standards of care for respirators, 68.7 percent for masks, and 75.8 percent for face shields or eye protection. This means healthcare personnel are reusing or extending the life of PPE traditionally meant for single use."[8]

APIC continued, "For those who reuse respirators or masks, three-quarters (75.9 percent) of respondents said that their healthcare facilities allow staff to reuse their respirator either five times or as many times as possible before getting a new respirator. Nearly three-quarters (73.6 percent) of respondents said that their facilities allow staff to reuse their masks either five times or as many times as possible before getting a new mask."[8]

Testing floor cross-contamination

Northeast Ohio VA Healthcare System

Examining hospital floors as carriers of pathogens and potential spread, SHEA reported in a press release that, "Researchers with the Northeast Ohio VA Healthcare System closely tracked contamination in hospital rooms of 17 newly admitted patients to identify the timing and route of transfer of bacteria within patients' rooms."[6]

SHEA continued, "Before testing, rooms were thoroughly cleaned and sanitized and all patients screened negative for methicillin-resistant *Staphylococcus aureus* (MRSA) and other healthcare-associated bacteria. Researchers then observed patients' interactions with healthcare personnel and portable equipment, collecting cultures one-to-three times per day from patients, their socks, beds and other high-touch surfaces, as well as key sections of the floor. Nearly half of rooms tested positive for MRSA within the first 24 hours, and MRSA, *C. difficile*, and vancomycin-resistant enterococci (VRE) pathogens were identified in 58 percent of patient rooms within four days of admission. Contamination often started on the floors, but ultimately moved to patients' socks, bedding, and nearby surfaces."[6]

Additionally, SHEA noted that, "In a related study published in August in *Infection Control & Hospital Epidemiology*, the authors reported similar findings of frequent detection of SARS-CoV-2 nucleic acid on floors and on shoes of personnel on a COVID-19 ward. The authors note that further research is needed to clarify the role of floor contamination in transmission of both bacterial and viral pathogens and to identify practical approaches to address contamination. On the COVID-19 ward, contamination was reduced with simple modifications of floor cleaning and disinfection protocols."[6] HPN

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Educate, communicate, collaborate

Getting OR, SPD to cooperate on pre-cleaning surgical instruments

by Kara Nadeau

Photo courtesy: Olympus Corporation of the Americas

While COVID-19 has shaken the foundation of healthcare delivery in the U.S., changing the way care is delivered in many ways, there is one thing that remains the same – the need to effectively and efficiently reprocess soiled instruments and devices. Furthermore, the challenges remain the same, most notably device pre-cleaning in the operating room (OR) or other procedural area, which makes it easier for central sterile/sterile processing department (CS/SPD) professionals to remove stubborn debris and bioburden when the items arrive in decontamination.

According to the experts, the COVID-19 pandemic has added complexity to the pre-cleaning process. Janet Pate JD, MHA, BSN, RN, Nurse Consultant, The Ruhof Corporation, explains how staffing shortages and the need to relocate procedures to other areas of a hospital in order to accommodate the influx of COVID-19 patients "may cause challenges for facilities related to reprocessing instruments in an environment which is already strained due to high patient volumes."

"Often, facilities are required to move employees to different areas of responsibility or hire temporary employees to meet the needs to provide patient care," she stated. "In either case it is difficult to ensure they are trained appropriately to perform the critical tasks of instrument reprocessing preparation. Many facilities have also had to rearrange clinical areas to meet the needs for the influx of patients. As a result, procedures may have been moved to different locations. The new locations may not be designed with the appropriate environment for the pre-cleaning and reprocessing of instruments."

"The practices haven't really changed, but the focus on ensuring the compliance of pre-cleaning has been more intense," said Mary K. Lane, MHA, CSPDM, CSPDS, CSPDT, MK Lane SPD Consulting. "Additionally, there has been a lot more attention placed on ensuring that all soiled items transported are covered appropriately and/or transported in the correct solid leak-proof containers, and that staff transporting the soiled devices are wearing the correct personal protective equipment (PPE).

Seth Hendee, CRCST, CIS, CHL, CER, CSPDT, CFER, IAHCSMM Approved Instructor, Clinical Education Coordinator, SPD, Heathmark Industries, says that while SARS-CoV-2, the virus that causes COVID-19, is no harder to kill than many other viruses, those staff members performing pre-cleaning must be cautious if aerosols or the potential for aerosols are present in the pre-treatment process, such as when cleaning some flexible endoscopes.

"Increasing air exchanges and performing steps under some sort of cover are novel ideas that may have some effect," said Hendee. "As with many new challenges to hospitals, a risk assessment performed with input from a multidisciplinary committee should be conducted to decide the best course of action."

Brandon VanHee, CRCST, CIS, CER, CHL, AGTS, Clinical Education Manager, Key Surgical, notes how point-of-use cleaning is an area that most facilities can improve upon. While historic challenges in this area, including device complexity, emphasis on turnover times and strained relationships between CS/SPD and OR staff, have presented barriers to improvement, VanHee says it is one that must be addressed:

"Add the personal and professional stressors of a global pandemic to the mix and finding ways to improve a subpar pre-cleaning process may seem impossible, but sterile processing and perioperative leaders must be up for the challenge because effective point-of-use cleaning has a direct impact on patient safety."

Start with IFUs and industry standards

Hendee says understanding the level of pre-treatment directed by each instrument's instructions for use (IFU) is the first step towards improving the process.

"Surgical cases can have instruments of extremely varying complexity, with the range of pre-treatment steps being just as varied," said Hendee. "Pre-treatment of an instrument may be as simple as wiping gross debris from the external surface or disassembling a device. On the other hand, it could also be complex and require multiple measured steps, as in the case of flexible endoscopes. Understanding the require-

ments outlined in the pre-treatment portion of the IFU will require point-of-use staff to review and train on those directions. Facilities wishing to have a quality pre-treatment process will find a way to make this happen."

Juan Ramos, Aesculap CSD Lead Consultant, BSBA, CRCST, CIS, CHL, LGBC, points to "the holy grail" of surgical instrument reprocessing, ANSI/AAMI ST79:2017, as a prime resource for information on point-of-use preparation of surgical instruments. He recommends that health facilities base processes and policies on these standards, noting how section 6 of the standard discusses point-of-use cleaning of medical devices (AAMI, 2017).

"Having a best practices program in place for the point-of-use preparation of surgical instruments can help ensure compliance with voluntary and regulatory agencies; decrease turnaround time of surgical instruments; and preserve the value of your surgical instruments," said Ramos.

Being too busy is no excuse

In facilities where pre-cleaning process compliance is low in the OR, the excuse often given by staff members is they can't perform the necessary steps in the short time provided to turn around the room for the next case.

"Point-of-use cleaning in the OR should be 'standard work' for every person responsible for the instrumentation," said Gregg Agoston M.B.A., Vice President Business Development, SPD Transformation Services, SpecialtyCare. "Time pressures to quickly turn over rooms, unless it is an emergency situation, should never be an excuse for improper pre-cleaning. If time pressure is given as the reason why pre-cleaning cannot be performed; then a formal review of the processes should be done to find the root cause."

Megan Pietura, Business Operations Manager, Pure Processing, recommends that the OR and CS/SPD teams start with a clear and well-defined definition for what is considered "clean" in terms of the condition of instruments arriving in decontamination. Through this process they can identify conflicting expectations.

"Establishing best practices among OR and SPD staff can be challenging, because each person has a different relationship with their instruments, and what clean really is, meaning what's clean to OR might not be clean to SPD, and vice versa," she stated. "You can't understand each other if you're not speaking the same language."

To help improve point-of-use cleaning compliance in the OR, Rick Schultz, President, RMPS Publishing, and author, inventor, lecturer in the field of sterile processing, suggests that OR staff use a checklist to mark off pre-cleaning steps after each and every case.

"Operating room personnel have so many urgent responsibilities at the end of every surgery, like turning over the operating room, that proper pre-cleaning of the instruments and devices, unfortunately, becomes low on the priority list," said Schultz. "A checklist would help ensure all instruments and devices are getting properly cleaned before they go to the CS/SPD."

The importance of education and training

OR staff members' lack of understanding of the instrument reprocessing steps in the CS/SPD is another factor cited for improper pre-cleaning. CS/SPD professionals often witness frustration among OR surgeons and other clinicians when they believe the process is taking too long. By educating the OR on the challenges and complexity of device reprocessing, and how failure to pre-clean can prolong the process, the CS/SPD can help correct some of the confusion that leads to clashes between the two departments.

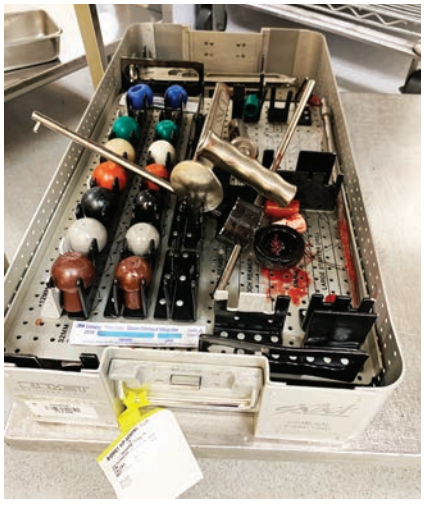
"Instrument pre-cleaning is often overlooked if the process is not optimized or if education is not provided to the staff responsible for pre-cleaning," said Ann Mangskau, Marketing Manager Ecolab Healthcare. "A key to ensuring proper pre-cleaning processes are followed is to educate OR staff about how proper pre-cleaning prevents damage to instruments and improves the removability of soils. Staff in the OR have an interest in making sure the instruments stay in good working condition and are clean and knowing the 'why' behind the task empowers them."

As patient care and safety are the number one priorities of the OR team, Lynn Burbank, DNP, RN, CRNP, Global Senior Manager for Infection Prevention, Olympus Corporation of the Americas, stresses the need to educate them on how pre-cleaning helps the CS/SPD deliver instruments that are safe and effective for use.

"One factor inhibiting users from performing this task is lack of awareness of pre-cleaning's importance to patient safety," said Burbank. "Pre-cleaning at the point-of-use is recommended by the U.S. Food and Drug Administration (FDA) to 'prevent drying of soil and contaminants in and on the device' and to 'facilitate subsequent cleaning steps.' Immediate removal of microorganisms on the surface of a device prevents development of bioburden, which cannot be eliminated through high-level disinfection or sterilization."

Because devices are so varied in design and complexity, Schultz says point-of-use pre-cleaning can be compromised by lack of staff knowledge around how to clean various items used in patient procedures.

"Medical devices range from simple-to-clean such as hemostats and scissors, where operating room personnel are taught to separate the rings and wipe with a moist sponge, (preferably not saline) to difficult



Photos courtesy: Specialty Care

Photos taken in a decontamination area of dirty instruments where no pre-cleaning was performed.

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laparoscopic instruments that need to be disassembled, wiped and flushed," he stated. "A challenging instrument to effectively pre-clean is a Kerrison Rongeur. Some of these instruments have the ability to be taken apart and others do not come apart, but all need to be pre-cleaned just the same. The overall solution to this challenge is education."

Schultz recommends his "*The World of Surgical Instruments: A Definitive Inspection Textbook,*" along with its complementary Instrument Coaching Cards, as great resources to help with the education and training of both OR and CS/SPD personnel.

Proper training in the OR and CS/SPD is particularly critical during the pandemic when facilities experiencing staff shortages are having to bring new employees up to speed, explains Pate.

"The orientation of new employees to the processes of pre-cleaning instruments is vital," she said. "If there is a new employee or an employee that is working in the reprocessing area for the first time, the facility must ensure they receive extensive education and training prior to beginning work. Although it takes increased time to properly educate and train employees, the benefits outweigh the risk."

During the pandemic, and times of "business as usual," a strategic training strategy is the foundation of all successful processes and policy adherence, says VanHee. When implementing improved pre-cleaning policies, he recommends that CS/SPD and OR leaders work together to communicate the value and benefit of the new policies, host training sessions with *all* the staff that is involved in the process, and schedule follow-up training and communication.

"It is especially important to include everyone that is affected by the new policy or procedure in all communication and training provided during process implementation," said VanHee. "Great plans fail too often because only a portion of the staff involved in the process were trained, not only on the process itself, but on the benefits to the team and patients that they serve."

Steps to safe and effective pre-cleaning

Pre-cleaning can start during the procedure, should take place immediately after the case ends, and steps should be taken to keep instruments and devices moist during transport to decontamination, which eases CS/SPD staff removal of remaining bioburden.

"Doing something as opposed to nothing at the point-of-use to aid in effective pre-cleaning in the CS/SPD area is always a huge benefit," said Todd Campbell, President of TBJ. "Anything that can be done at the point-of-use to keep instruments wet is a major benefit in subsequent pre-cleaning processes. Options such as keeping instruments moist with a wet towel to soaking instruments in a tray or container with an enzymatic on the way to SPD are very helpful."

Here are some best practices from industry experts on pre-cleaning success at each stage of the process:

During the procedure

- Clean each instrument of gross debris after each use.
- This can be done by wiping the surfaces with a lint-free cloth or sterile surgical towel moistened with sterile water (not saline).

"Ensuring that the OR is stocked with the correct supplies for pre-cleaning is critical," said Agoston. "Sterile water and a sterile towel or sponge should be used during the procedure to remove gross debris. Saline should not be used as it can cause corrosion to metal. If enzymatic solutions or foams are to be used at the end of the surgical procedure, these must be stocked in the OR. If the instruments require suctioning or priming with enzymatic solution (e.g., flexible endoscopes/Da Vinci Instruments), the solutions and accessory items must also be stocked in the room. It is important to verify in the IFU the correct volume of enzymatic solution to suction or prime the lumens."

Burbank says staff understanding of pre-cleaning detergents and cleaning product mechanics supports best practice. She explains how appropriate detergent selection should be based on the device manufacturer's IFU, noting how neutral pH, enzymatic detergents are a common choice when cleaning devices instead of detergents with high pH (alkaline), which can cause damage to the items.

"Another recommendation is the use of lint-free clothes or wipes," said Burbank. "Use of a cotton-based product, such as a gauze pad, can leave small fibers (lint) that can potentially attract microbial growth. Providing robust education on products used during reprocessing helps users understand how their actions are critical in preventing infections and possible damage to equipment."

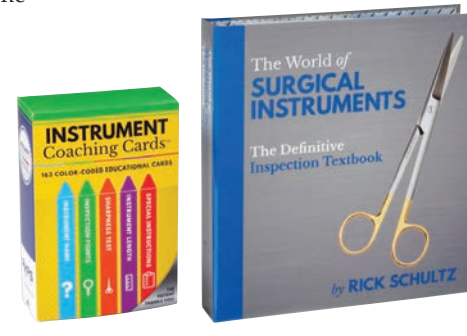
Immediately following the procedure

- Apply pretreatment solution to all instruments immediately following the procedure or as the patient exits the procedure room, according to the manufacturers' IFUs.
- Place all devices back in their original containers or trays to prevent damage during transport and support process efficiency in the CS/SPD.
- Heavier, more durable instruments should be placed on the bottom of the tray and lighter, more delicate instruments on top to minimize the risk for damage.

"The devices should be opened during pre-cleaning and complex instruments should be disassembled according to the manufacturer's IFU," said Ramos. "Post procedure, clinical staff should latch sharp instruments on the first box lock notch and remove and discard all sharps in the designated biohazard containers to help ensure safe handling."

Agoston explains how many hospitals use a spray foam or liquid enzymatic solution to pre-treat the instruments prior to transporting to the decontamination area. He says in order for these products to be effective, the person applying them must ensure the instruments are thoroughly coated with the product following the manufacturer's IFU.

Healthmark Post-Procedure Pretreatment Kit



"The World of Surgical Instruments: A Definitive Inspection Textbook" and Instrument Coaching Cards from RMPS Publishing

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"The biggest challenge we see in hospitals is ineffective spraying," said Agoston. "To be effective, the instruments must be thoroughly coated with the pre-treatment. Lumens are a particularly difficult area to clean. Da Vinci instruments require that the lumens be primed with enzymatic solution and flexible endoscopes require that enzymatic solution be suctioned through the instrument lumens in the OR prior to transporting."

During transport

- Instruments should be transported to the decontamination area in a closed, rigid container or enclosed transport cart.
- Instruments should be kept moist according to their manufacturers' IFUs.

"The container or cart should be leak-proof and labeled with a red biohazard sticker," said Ramos. "Biohazard labels should be affixed to the transport device to prevent separation from the contents. Contaminated instruments and other items should be separated from clean and sterile supplies before transport to the processing area."

Arrival in decontamination

By the time instruments arrive in decontamination, the pre-cleaning process should have been well underway due to the efforts of OR staff at the point-of-use. To improve productivity among CS/SPD staff members, Pietura recommends that hospitals focus on both personnel and process.

"Productivity and employee satisfaction are improved when the CS/SPD has the proper tools to ease labor efforts and address safety considerations, such as ergonomics," she said. "That alone helps with the high turnover rates in sterile processing departments that lead to even more bottlenecks in productivity."

Agoston notes how some hospitals separate instruments that have been "used" from those that were "unused" in the procedure, explaining the drawbacks of this approach:

"All instruments should treated as if they are contaminated when returned from the OR. The cleaning processes should be identical for all instruments, regardless if they were used or not used during the surgical procedure. Additionally, separating instruments from their original set can make the assembly process more difficult, increasing the chance of errors."

Tips for compliance and continuous improvement

In the busy OR environment, it is easy for staff members to overlook the importance of instrument pre-cleaning when faced with the pressures of patient care. Hospitals must take steps to reinforce education and training, drive policy compliance and hold staff members accountable for their actions (or lack of action).

Lane stresses the importance of communication and support from leadership to drive compliance with pre-cleaning protocols.

"When support is gleaned, staff are typically held accountable and the lack of pre-cleaning is reduced greatly," she stated. "Submitting safety reports or completing audits on the case carts or instrumentation sent to SPD is a great method to track compliance. Of course, this requires additional work initially on SPD staff in the decontamination area and the SPD leadership as it relates to the documenting, but typically it subsides quickly as the staff responsible for improper pre-cleaning are held responsible by their leadership."

Lane adds that buy-in and support from infection prevention is also critical to long-term success.

"Obtaining their support has gotten much easier over the past several years as The Joint Commission has placed a great deal of focus in this area and has issued many findings as it relates to improper or lack of pre-cleaning of medical devices," she elaborated.

With all of the variety of instruments and devices that flow in and out of the OR, staff members can benefit from ongoing educational tools on proper pre-cleaning and equipment to help them have what they need at hand in terms of cleaning supplies, explains Mangskau.

"Using tools like a process wall card provides reminders on the proper procedure. In addition, tailoring the pre-cleaning process to fit the existing OR workflow and making sure pre-treatment products are available at the point-of-use can also drive process improvement and help ensure pre-cleaning processes are followed. Products can 'walk away' from their location, so installing a wall rack to hold the bottle can help keep it in the right location, ready for use."

Agoston recommends hospitals have an established formal error reporting system that tracks errors in instrument reprocessing both in the OR and CS/SPD.

"Management must closely monitor this information and implement corrective action as needed," he said. "Notification to the OR team that returned improperly prepared surgical instruments is just as critical as reporting errors made by the SPD. Education to both the OR and SPD staff is critical to ensure that instruments are available, functional and safe to use for each surgical procedure. SpecialtyCare has a trained and experience LEAN Six Sigma trained staff that can help hospitals identify the root cause of SPD/OR problems and develop effective solutions." HPN

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1. ProClean white paper, "ProClean Adds Value to Any Powered Equipment Account." Stryker Instruments, 2012.

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SUBMIT YOUR QUESTIONS:
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Heat sealers: How to test and verify the sealing process

by Stephen Kovach

Q Our facility got a new heat sealer because our old one was delivering bad seals. What are the requirements for testing this new piece of equipment?

A As we know, all medical equipment can fail. Ensuring every piece of equipment within a medical device reprocessing department is working properly is vital to reducing patient infections. A properly functioning heat seal is essential because a proper seal will allow the peel pouch to provide a sterile barrier for the items placed in that pouch.

There are two major types of heat sealers used in a medical device reprocessing department: (See Figure 1)

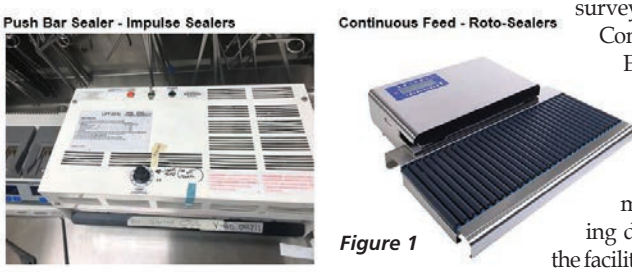

Figure 1

- Push Bar Sealer - Impulse Sealers
- Continuous Feed - Roto-Sealers

To achieve a proper seal, both types of sealers require three critical parameters to take place during the sealing process:

- Temperature
- Pressure
- Dwell time

Thus, checking that these critical parameters are happening each time is essential and should be tested (monitored) to ensure a proper seal. Newer models of heat sealers display the temperature and some even have alarms if the temperature varies a few degrees from the set temperature to help ensure a proper seal every time.

ANSI/AAMI has a few documents that we need to examine on verifying the seal on peel pouches. These documents are ISO/TS16775 and ISO 11607.

In ANSI/AAMI ST79, there is support for risk assessment if any failures occur within the sterilization process. Failed seals on peel pouches are a significant concern, and a way to decrease this is to verify the heat sealer is properly functioning. Thus, having a process in place with a verification test for the sealing function would be part of the department's Quality Management System (QMS) and help reduce sealing failures caused by an improperly working heat sealer.

ANS/AAMI ST90 outlines the QMS process and the requirements for Performance Qualification (PQ). This process is what the user performs on all their equipment to verify that equipment is working correctly (in this case, a heat sealer). PQ is also concerned with obtaining and documenting that the equipment, as installed and operated per procedures, consistently performs following predetermined criteria and yields product meeting its specifications (a proper seal).

Next, we need to look at the standards of survey agencies, like The Joint Commission (TJC) standard E.C.06.2, which states that medical equipment is maintained, tested and inspected. All equipment within a medical device reprocessing department is tagged by the facility's biomedical engineering department, which puts those pieces of equipment into the facility's medical device inventory. The inventory would then include heat sealers within the reprocessing department because they have been tagged.

Within the TJC standard is Infection Control (IC) standard IC.02.02.01, which requires hospitals to reduce the risk of infections associated with medical equipment, devices, and supplies. Therefore, making sure a heat sealer works properly (providing a proper seal) fulfills this requirement. Remember that this process must be documented.

To determine if a heat sealer is working correctly, a medical device reprocessing department should institute a QMS for their heat sealer:

IQ

- Check-in process when the heat sealer arrives.

OQ

- Preventive maintenance program to ensure it is properly functioning and all work should be documented.
- Clinically relevant, evidence-based products for testing and verification of the seal:
  - Seal tests
  - Electrical testing
  - Other tests

PQ

- Independent testing and verification of the heat-sealing process using clinically relevant, evidence-based products is key to reducing unsterile surgical instruments and hospital infections.
  - Daily testing of equipment
  - If a poor seal exists, then no sterile barrier is provided by the peel pouch (i.e., ensuring proper sealing).
  - Staff training on use and testing of the heat sealer.
  - Documentation of training and test results.

The method discussed in the standards for seal verification testing is an Ink Pouch test or the Dye leak penetration test for the routine testing of peel pouch sealing seams as per ISO 11607-1 and ASTM F1929. This Ink Pouch test or the Dye leak penetration test will show any irregularities that occur (e.g., channels of ink in the seal are a sign of a poor sealing process) and become visible immediately after the single-use dye test pack. It is easy to use, and the process can be documented. (See Figure 2). There are specific dye tests for TYVEK and paper plastic pouches.

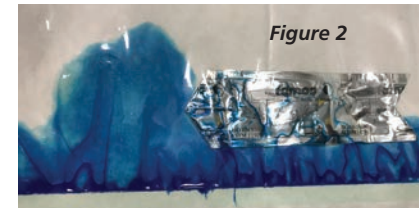

Figure 2

Heat sealers do fail. Verifying your heat-sealing process with daily testing should be performed to help ensure a proper seal on peel pouches.

Many companies sell a dye test for heat sealers. Partner with a company that supports the idea of a QMS for testing your peel pouches and heat sealers. Ensuring your heat sealer provides the proper seal by simple daily verification tests fulfills the requirements outlined in the various standards presented and helps reduce the chance of a poorly sealed pouch and the possible risk of an unsterile medical device being used on a patient. HPN

Stephen M. Kovach, BS, CFER, is Clinical Educator Emeritus at Healthmark Industries.

Processes improve when SPD, surgeons engage directly

by David L. Taylor III, MSN, RN, CNOR

Today's Sterile Processing (SP) leaders and their staff members practice in very complex, high-stress environments. The constant pressure to do more with less as a result of staffing shortages, budget cuts, limited resources and, at times, increasing procedure volume, can create moral conflict — sometimes, making employees feel they must choose between doing what is right or doing what it takes to meet surgeon and scheduling demands, even if that means cutting corners.

Although no employee ever wants to jeopardize patient safety, it is nonetheless a potential outcome because high-pressure, high-stress situations often lead to high-risk SP environments. Ensuring and preserving our commitment to patients requires significant moral courage, exceptional preparation and dedication. It also involves interdisciplinary teamwork and effective communication — and, at times, some difficult conversations with SP's most demanding customers.

Meet with surgeons

Too often, surgeons experience issues with the instruments used in the operating room (OR). When something goes wrong, it's often the SP professionals who are blamed. What the surgeon may not know, however, is that every instrument they use goes through many hands, and everyone who touches that instrument holds some level of responsibility for its care, handling and functionality.

It's important to educate surgeons and others in the surgical suite (and end users in other patient care areas) about the proper care and handling of instruments and the time it takes to properly clean, disinfect and render instruments and equipment safe for reuse. They may also need to be reminded of the many standards, guidelines, regulations and internal policies and procedures that must be followed in the name of compliance, quality care and patient safety.

Of course, when it comes to building better interdisciplinary relationships, SP professionals also share the responsibility. They must commit to visiting with surgeons and other customers who rely on their services, and listening to their challenges, needs and concerns. Having honest discussions about what customers' experiences have been as a result of the work from the SPD is key to better outcomes. Communication can be as simple as meeting at the scrub sink to engage and understand the surgeon's perspective.

As the relationship grows, SP leaders can take their commitment further by meeting surgeons in their offices. Surgeons may share valuable insight into changes their practice may be going through, new procedures they may be adding to the surgical schedule or, perhaps, their decision to take on new partners who will be performing surgery at the facility. Paying attention to these subtleties will allow SP leaders and their teams to manage changing demands proactively. Having close contact with surgeons can also help SP leaders determine who the physician leaders are within the specialties—and who may be able help champion initiatives that will support the SPD's efforts.

When working to improve relationships with surgeons and other end users, it's imperative for SP leaders to educate them on SP-related workflows, processes and pain points. This is an opportunity to be transparent, so both parties understand what is at stake. Consider inviting surgeons to the SPD to review their instrument sets — and while they are there, invite them to take a quick tour of the department. When they see firsthand the sheer number of instrument sets returned to the decontamination area (and the condition of the instrumentation when it arrives), they will gain powerful perspective. *Note: Be sure to share with surgeons the various processes needed to reprocess an instrument set and the length of time it takes to properly clean, disinfect and reprocess those items.*

Instrument set review

When reviewing surgeons' instrument sets, explain how unnecessary items in those sets increase reprocessing time (even instruments that are not used during a procedure require meticulous attention and thorough reprocessing). If SP professionals could remove those often unnecessary items, reprocessing becomes more efficient, and instrument inventory levels could potentially be increased by creating new sets from the excess instruments. Adding to the inventory also allows the SPD to take sets out of the rotation to properly inspect, sharpen and repair them, which adds value for the surgeon.

If a surgeon is reluctant to reduce their set size, that is an opportunity to explain the task and average time requirement of turning over instruments. If the average is three hours, what impact would that have on a surgeon's practice? If the surgeon understood how reducing set size of unused items could save time, resulting in faster turnarounds and more set inventory, they may be more apt to agree. Also, be sure to share with the surgeon how reducing set size will save time in the OR (less inventory equals faster set-up times, counting procedures, and turnovers).

Beyond reviewing set size and contents, it's beneficial to explain to surgeons the inventory on hand for their specialty. For example, they may routinely schedule the same five procedures every Monday. What they may not know is the hospital only has three instrument sets for that procedure and one set may be out for repair. When surgeons have the full picture, they can make calculated decisions that will not only help themselves but also the processes.

Building bridges

Collaborating directly with the end users gives SP leaders the opportunity to develop a professional relationship with their surgeons and help those surgeons better understand the work that goes on in the SPD. Most surgeons do not realize how hard SP professionals work every day or the time needed to safely reprocess instrumentation and other reusable items. When SP leaders build a bridge from their department to the surgeons, they begin to see ways to enhance the relationships and build processes that will streamline their jobs and create a safer environment. HPN

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March 2021

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LEARNING OBJECTIVES

1. *Explain the potential consequences of improper ophthalmic instrument reprocessing*
2. *List three IFU changes that may impact ophthalmic instrument reprocessing*
3. *Identify common pitfalls when reprocessing ophthalmic instruments*

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SELF-STUDY SERIES

Eye spy: Changes in ophthalmic reprocessing

by Delores O'Connell

When sterile processing managers request information about best practices, evidence-based procedures, or the location of specific reprocessing information within standards, I always ask them, "Do you perform eye cases?" The most frequent answer: "We don't do cataract cases, so eye instrumentation isn't a concern for us." While cataract surgery is the bulk of eye surgeries performed in the U.S., it is not the only surgery performed on those beautiful windows to the soul, so I revise my question; "Do you perform eye trauma, glaucoma, macular degeneration or pediatric corrective surgeries?" The answer is typically a resounding "yes!" and a look of surprise.

Managers now realize that they must identify the instruments used in their facility for both routine and uncommon eye surgeries they perform. Why? Because ophthalmic instrumentation may require special handling, may have new recommendations, or may require sterile processing managers to rethink their ophthalmic instrument reprocessing protocols.

Why all the concern for eye instruments?

While the ANSI/AAMI ST79:2017 "*Comprehensive guide to steam sterilization and sterility assurance in health care facilities*" is the universal guidance for all surgical instrument reprocessing, eye instruments require additional special considerations. Improperly processed eye instruments have led to a condition called Toxic Anterior Segment Syndrome (TASS), a preventable acute inflammation of the eye that if not caught quickly may result in diminished eyesight or blindness in the affected eye.

While often attributed to cataract surgeries, TASS can occur from any ocular surgery where the anterior segment is exposed. TASS is not an infection but a reaction to foreign material carried into the eye. Incomplete cleaning processes that leave residual cleaning chemistries, mineral deposits from steam sterilizers, and/or powder from sterile gloves have contributed to cases of TASS. Though ophthalmic instruments have the same materials of construction and require similar reprocessing steps (point-of-use treatment, cleaning, rinsing and sterilization), vigilance against the causative elements of TASS requires enhanced methods that are key for any ocular program.

Furthermore, TASS is not the only concern. Surgical site infections can cause complications that can also lead to impaired vision or blindness. Considering these serious risks, it's easy to understand the critical importance of thoroughly cleaning, rinsing and sterilizing ophthalmic instruments.

The specifics of ophthalmic instrument reprocessing

Technicians need an eye for detail when reviewing their ophthalmic instrument reprocessing procedures. Every step, whether it's during point-of-use pretreatment, cleaning, rinsing, or sterilization, requires exact implementation of the instrument manufacturer's instructions for use (IFU). It's also important to be aware of recent changes in the IFU that may have a large impact on the sterile processing department's handling of ophthalmic instruments.

Attention to reprocessing needs starts in the procedure room. Point-of-use treatment to remove bioburden is a continuous part of every procedure, not just ophthalmic surgeries. Following best practices and guidelines for pre-treatment will ensure that soils do not dry on the instruments or within the lumens. Typically, this is accomplished with sterile water and a lint-free surgical sponge. Eye tissue is very delicate and is easily torn or damaged, but ironically, when eye tissue dries on or in the instruments ,it can be very difficult to remove and can result in instrument damage.

Post-procedure, the instruments should be transported as instructed by relevant IFU and following facility policy and OSHA recommendations. If using a commercial pre-treatment product, it's important to use a non-enzymatic wetting agent. This product must also be free-rinsing and must align with the instrument IFU.

A gentler cycle

If an instrument is not clean, it cannot be successfully sterilized. However, many ophthalmic instruments are very delicate and easily damaged, so they require special handling during cleaning. Recent revisions to ophthalmic instrument IFU include added details about mechanical washing, with some going so far as to specify exact processing parameters. The standard cycles of mechanical washers may not be safe for delicate ophthalmic instruments.

Not all washers are created equal. Managers should assure that they are using a cycle specifically designed to handle ophthalmic instrumentation. They should verify that the department's mechanical washer can meet their ocular instruments' IFU parameters. This is as important as any other step in reprocessing. A call to the original equipment manufacturer of the mechanical washer can determine if and how specific cycle requirements can be added to a unit. If the recommended cycle parameters can't be added, manual processing instructions should be followed.

Changing ultrasonic requirements

Ultrasonic cleaning systems are equally integral to the successful cleaning of eye instruments. In years past, ophthalmic IFU required that an ultrasonic system be dedicated solely to a department's ophthalmic instruments; now instructions may require *two* ultrasonic cleaners. The first dedicated unit provides static soaking and ultrasonic cleaning, and the second unit delivers critical water ultrasonic rinsing. This is an example of why it's important to review an instrument's IFU periodically for updates; they may have changed significantly.

Disinfection dilemma

Disinfection makes instruments safe to handle on the clean side of SPD. However, since residual disinfectant chemicals can injure eyes, many ophthalmic instrument IFU caution against chemical disinfectants. So, how can you disinfect without chemical disinfectants? Thermal disinfection solves this dilemma. This process uses heat and not chemicals to kill microorganisms. Consider using washers and ultrasonic units capable of thermal disinfection temperatures ≥180°F in their final rinse.

Focus on details and big picture

The days of departments having only one or two instrument sets for a potential eye case may be over. As they become more aware of specific processing needs for each ophthalmic instrument, sterile processing managers are grouping instruments into sets identified for their special processing requirements. In addition, some departments are choosing to have a specific location within the decontamination area that's devoted strictly to eye instrumentation.

Providing readily accessible key information, tools and supplies for technicians and not comingling with other specialties increases control of the ophthalmic reprocessing function. It is also helpful to review the quality system in place for ophthalmic reprocessing protocols and apply Lean principles to optimize these procedures in all settings, including the hospital central sterile department, the outpatient surgery department, and the reprocessing areas in freestanding surgery centers.

Sterile processing departments often focus on big changes and lose sight of specific processes and procedures they should already have implemented. It's crucial to review all instruments' IFU regularly, including but not limited to instructions for ophthalmic instruments, other procedural instruments, washers, ultrasonic units, brushes, cleaning chemistries, sterilizers, and supporting tools and accessories, to assure up-to-date compliance. In addition, watching the sterile processing department in action may help managers identify some common processing problems.

Don't be shortsighted about mats

While silicone instrument mats are ideal for protecting delicate tools inside an automated system, mats can also inhibit cleaning. For example, mats can over-absorb the cavitation action of ultrasonic systems and decrease the cleaning ability of their cycles. Developing an ultrasonic process for ophthalmic instruments without mats will help ensure effective cleaning the first time and eliminate the need for rework.

Watch out for water contaminants

Water quality is vital in all phases of reprocessing and is especially important when reprocessing ophthalmic instruments. Utility/tap water is not of the same quality in all areas of the country, and some regions may have additional issues with heavy mineral deposits and pH levels that are not conducive to instrument reprocessing. The Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force noted in 2018 that utility/tap water may contain heat-stable endotoxins and gram-negative bacteria in municipal water supplies and recommended critical water for the final rinse.

Help is available to tackle any water quality questions that may arise, first from the AAMI Technical Bulletin TIR 34:2014 *Water for the reprocessing of medical devices*, and then from the washer and ultrasonic manufacturers. They can typically direct sterile processing departments to water testing resources. These professionals understand the needs specific to instrument reprocessing. Proper water quality will ensure a long life for the surgical instruments and for the mechanical washers and ultrasonic cleaners.

Avoid cleaning chemistry blind spots

The proper selection and use of cleaning chemistries is very important for effective reprocessing. Poor cleaning chemistry choices can lead to damaged instruments, incomplete soil removal, and interference with mechanical cleaning equipment. Inappropriate rinsing of chemistries may also leave residues that can lead to TASS.

The chosen cleaning chemistry must be compatible with each instrument. For example, if an instrument's IFU calls for a neutral pH detergent, this is a strong indication that high pH solutions will damage the instrument finish. Therefore, alkaline cleaning chemistries would not be appropriate for this device. The cleaning chemistry must also be compatible with the equipment or process. Ultrasonic cleaners have different requirements from automated washers, for example.

It is critical to review all cleaning chemistry claims. If doubt or confusion exists, contact the product's manufacturer to request a technical data monograph (TDM). TDMs provide detailed

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

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information about the product itself and frequently include results of product testing that illustrate how the manufacturer arrived at the claims for the cleaning chemistry.

Getting soap in your eye may sting but getting residual enzymes in your eye from a poorly processed instrument may blind you. Many ophthalmic instrument IFU have limited or discontinued the use of enzymatic chemistries for this reason.

One more caution: selecting a chemistry based on cost, convenience, or a shorter cycle or soak time, rather than choosing one that complies with your instrument's IFU, is shortsighted. Not aligning with the IFU may represent an off-label use of the chemistry, which could put a facility in the difficult position of defending their practice to a reviewer during a survey.

Another change: single-use brushes

Ophthalmic instrument IFU revised in the last three years may now include a restriction to single-use brushes for cleaning. Departments must define what 'single use' means. Additionally, departments with mixed inventory (some instruments' IFUs that allow brush reuse and some that don't) must have a means to segregate instruments to ensure proper brush use. These requirements may impact brush inventories (and waste management procedures) to account for increased disposal of some reusable brushes.

Optimize inspection

While lighted and magnified visual inspection is now a standard, it may not be enough for today's intricate instruments. Lumens, cracks, and fine details make enhanced magnification tools a necessity. Using a borescope or video enlarger allows a full assessment of the entire instrument, including the internal surfaces of lumens.

Burrs, cracks, or breaks trap foreign material and residual soils and chemistries that may be transferred to the eye during the procedure. If any of these flaws are identified at any time, follow facility protocols for repair or return to the manufacturer for further evaluation.

Instrument staining is more than cosmetic – it's a serious concern. Staining has many causes. The most troublesome are stains from residual chemical, hard water or other foreign substances that can cause TASS if transferred to the eye. If instrument staining is noted, a full review of the entire reprocessing workflow from decontamination through sterilization should be done to determine the exact cause of the staining and how to resolve it.

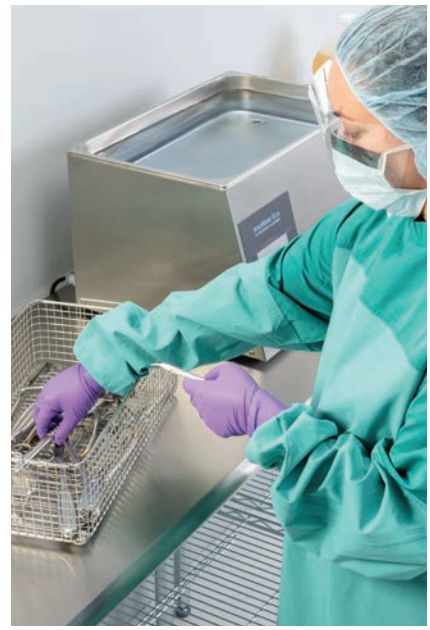
Making the invisible visible

Eyes are sensitive organs, but they can't see everything, even with magnification. Yet even a microscopic amount of powder from a glove or residual debris can induce catastrophic reactions in the eye. Using powderless gloves solves one problem, but how can reprocessing technicians see other contaminants that can't be seen?

A quality procedure for soil testing needs to be in place before the instruments are prepared for sterilization, to verify that instruments are clean beyond what can be visualized. ANSI/AAMI ST79:2017, Annex D lists eight soil markers that are appropriate for use to identify residual soils. Protein is listed first because protein is present in all human soils. Checking for protein-based residuals will reliably identify instruments that are not clean and that need to be returned to the decontamination area to restart the process.

Appropriate streamlining

Reducing unnecessary complexity in reprocessing is valuable. It helps to reduce errors and makes work easier for staff members. However, some streamlining efforts may be detrimental. For example, special cycles may be required to sterilize some ophthalmic instruments, but not all. One set of instructions may call for a 10-minute 270°F prevacuum steam sterilization cycle, while other IFU call for a four-minute exposure. Standardizing on the 10-minute exposure cycle streamlines the process, but then the four-minute instruments are not being processed per their IFU. Moreover, the extra exposure may have a negative effect on these delicate instruments. Longer exposures could increase repair/sharpening frequency and shorten the useful life of the instruments. Always consult the relevant instrument manufacturers before determining whether or not to standardize a cycle and consider all potential consequences of a streamlining change before it is made.



Set your sights on the future

Because of documented patient injury risks, reusable ophthalmic instruments must be processed with great attention to detail and to each instrument's IFU. The increasing complexity of ophthalmic instruments and their reprocessing requirements will require ongoing attention by everyone involved in their handling. As they continue to evolve, so will their IFU, so it's important to check periodically for updated requirements. Any workflow improvements should also take the IFU into account, including automated equipment needs, the appropriate use of cleaning chemistries, single-use accessory requirements, and proper inspection tools. By keeping an eye on ophthalmic reprocessing in your facility, you will help prevent TASS and infections and thereby improve patient safety. HPN

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CONTINUING EDUCATION TEST • MARCH 2021

Eye spy: Changes in ophthalmic reprocessing

Circle the one correct answer:

1. **What can cause Toxic Anterior Segment Syndrome?**
   a. Bacteria
   b. Foreign material
   c. Dry eye
   d. Infection
2. **Which set might have ophthalmic instruments?**
   a. Labor and Delivery set
   b. Trauma sets
   c. Total hip replacement set
   d. Bronchoscopy set
3. **Why do ophthalmic instruments require special washer cycle parameters?**
   a. They are harder to clean
   b. They are delicate and easily damaged
   c. They can only be cleaned one at a time
   d. They do not require manual cleaning
4. **Silicone mats should not be included with instruments in the ultrasonic cleaner because they can inhibit cleaning.**
   a. True
   b. False
5. **When selecting a type of cleaning chemistry, it should be approved for use per the _____.**
   a. Instrument IFU
   b. Washer or ultrasonic IFU
   c. A and B
   d. None of the above
6. **If water is safe to drink it is guaranteed safe for instrument reprocessing.**
   a. True
   b. False
7. **Soil tests help to find residual soils that may be invisible to the naked eye.**
   a. True
   b. False
8. **Why is instrument staining a concern?**
   a. Staining is cosmetic and nothing to worry about
   b. Doctors don't like it
   c. It shows instrument color tape is bleeding
   d. It could be foreign material that could transfer to the eye
9. **Residual soils that are not visible to the unaided eye are of no concern since the item will be sterilized.**
   a. True
   b. False
10. **What should be done when several instruments within a single set have different sterilization exposure times?**
    a. Sterilize at the longest exposure time of the instruments in the set
    b. Sterilize at the shortest exposure time of the instruments in the set
    c. Create separate sets based on sterilization needs
    d. Standardize on one sterilization time

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Skating from behind the eight-ball

Bar codes, RFID chips and tags can help supply chain with its breakaways and forward strides through COVID-19 vaccine logistics

by Rick Dana Barlow

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At the close of January about a year after COVID-19 emerged in the United States, media provided a curious public with a range of data highlighting the number of vaccine doses administered to citizens. Depending on the source, more than 26 million to nearly 32 million doses were given, representing a miniscule slice of the American population.

No matter how the statistics were explained, the spread of about six million might give enthusiasts of DraftKings and FanDuel pause.

While the numbers draw quizzical looks about the state of public-sector vaccine supply logistics that *Healthcare Purchasing News* currently is exploring, they also pose a serious question: How might the extensive use of track-and-trace technology involving bar coding and radio frequency identification (RFID) down to the "eaches" have contributed to the accuracy and precision of product movement from raw materials to manufacturing to distribution to administration or consumption?

Where to begin?

In theory and on paper at least, affixing bar-code labels or RFID chips on products may seem like a simple "no-duh" solution. But it may be a bit more complex than such perceived simplicity, according to Jessica Bernardo, Senior Product Marketing Manager, Label and Receipt Printer Solutions, Toshiba America Business Solutions.

Deploying the latest technology to improve efficiency and effectiveness indeed may help manage the complexity of distributing COVID-19 vaccines, Bernardo acknowledges.

"By facilitating data transparency, bar-code and RFID labeling enables vaccine operation professionals to make better decisions," she told *HPN*. "From improving shipping and storage space utilization to where, when and who should receive vaccines. Most important, delivering this degree of accuracy saves lives."

Federal, state and local agencies must weigh their options before finalizing an information technology solution to facilitate this process, Bernardo recommends, whether that be RFID or bar coding, both of which can reduce misidentification of medical assets.

"RFID technology saves time and money with real-time data capture by identifying the vaccine, its location and physical attributes, such as size, temperature and placement in a container or warehouse," she said. "This data is available without human intervention, requires no line-of-sight to the container while simultaneously recording multiple data points.

"RFID technology also provides a wealth of data for later analysis," Bernardo continued. "And automating this process greatly increases medical staff productivity. Eliminating manual data entry exponentially enhances accuracy while increasing the opportunity for patient interaction. Vaccine tracking also improves operations and staff efficiency. For example, RFID tags may create alerts helping ensure vaccines maintain temperature and use thresholds."

Bernardo emphasizes the convenience and flexibility of bar coding as a relevant and useful choice, too, as the labels can be adapted to specific needs that may include tracking assets or fulfilling shipments.

"Bar-code printing is also affordable," she noted, "in many instances only requiring the addition of specialized labels to accommodate medical applications. Print and apply systems furthermore automate multi-container labeling specific to medical applications (i.e., vials, tubes, bags). This automated process labels in a fraction of the time in comparison to manually affixing tags."

Any track-and-trace effort applied to such an overwhelming logistics operation must begin at the source, urges Tony Cecchin, Vice President and General Manager, Global Supplies, Zebra Technologies, and President, Temptime.

Tony Cecchin

"The key COVID-19 vaccine manufacturing and distribution services to date have focused on bulk container-based supply chain tracking and tracing along with temperature monitoring," Cecchin said. "The federal government's goal of accelerating vaccination throughput via a network of mass vaccination sites should require a vial-based focus to support the distribution efforts of the vaccine supply chain."

This translates to automating the myriad vaccination locations, Cecchin deduces.

"The workflows at local vaccination sites will necessitate vial-level information that

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lends itself to 2-D barcoding and scanning as an alternative to manual data entry," Cecchin insisted. "These vaccination sites include onsite vial management, patient injection recordation, second-dose administration tracking and wastage rate data collection. Moreover, the data needed to fight counterfeiting or support product recalls will require vial-level detail. In the short term, 2-D bar code and scanning technology can help accomplish this goal and is consistent with the policy set forth in the Drug Supply Chain Security Act of 2013."

Compassion, understanding

Jason Rosemurgy, Senior Vice President, Sales and Marketing, Terso Solutions, cautions against criticizing the current logistics process too quickly due to the demand for product and service, the expediency of desired results and the depth of planning and preparation.

Jason Rosemurgy

"The logistics related to the COVID-19 vaccine deployment are unlike anything we've ever experienced in the healthcare – or any other – supply chain," he said. "One of the fundamental pieces being that the right levels of vaccine must make it to the desired location, and to date, many of the big [third-party logistics companies] have done an outstanding job in designing and deploying solutions to handle broader logistical needs."

Once the vaccine stock arrives on site, it's up to the healthcare workers at those locations who are handling and administering the vaccine to run with the baton handed to them by the distributors, according to Rosemurgy.

"From what we've heard, this can be challenging and supported by many manual processes, including spreadsheets and handwritten logs," he noted.

Rosemurgy acknowledges that RFID certainly can help track critical inventory in a more automated way and provide important data that is essential to the efficacy and safety of this inventory.

"Some vaccines need to be stored at ultra-low temperatures (-80 degrees C), which is crucial to a vaccine's efficacy," he indicated. "If a vaccine isn't kept at these critical temperatures it is rendered ineffective. Terso offers an RFID-enabled ULT [product] that we have deployed at several hospitals throughout the U.S. to help them store COVID-19 vaccine safely. All these devices are secure (badge-access) as well, so no vaccine could be removed from its cold storage without the system knowing who accessed it and when. If a case, box or individual vaccine were RFID-tagged, all of this information would be captured as well, ensuring chain of custody for the healthcare provider. With the features of a fully automated RFID system, such as proactive temperature monitoring, hospitals can help mitigate issues, such as having to throw away spoiled vaccine if a freezer or fridge fails, which recently happened at a hospital on the East Coast."

Rosemurgy briefly highlights several projects around tagging individual vials at the manufacturer level to help ensure complete traceability. "Because of the flexible nature and performance aspects of RAIN (UHF) RFID, product can be tracked throughout its journey along the healthcare supply chain from both close range and further distances," he added.

Bar codes applied to the cases, boxes and vials of COVID-19 vaccines encode electronic information about the product, such as its [National Drug Code], lot number, expiration date and in some cases — a unique serial number, according to Kim Elmore, Senior Director, Pharmacy Contracting, Premier Inc. But electronically tracking vial to patient may be challenging right now.

Kim Elmore

"While it is likely that the bar codes on the cases and boxes will be scanned to populate devices and inventory management systems, there is currently no harmonized and widely adopted data system that relies on either the bar code or RFID to track inventory at a national level across all stewards," Elmore pointed out. "The most predominantly used bar code will be the one printed on the vials. Most vaccinators use an [electronic medical record] system that is capable of associating the product information to a specific patient, and scanning a bar code on the vial to capture this information is much more efficient and more accurate than hand keying the information for every patient and dose."

Eye end game

John Freund, President and CEO, Jump Technologies Inc., expresses concern more for function over form.

John Freund

"Bar coding and RFID technologies are both ways to capture data," he said. "It is what you do with that data that is important. Standard supply chain data about shipments of the vaccine from manufacturer to distributor to hospital to patient is probably available today. However, being able to provide real-time, virtual inventory management is a significant value-add."

Freund encourages the use of bar coding beyond just the product.

"Most states are asking people to make appointments for the vaccine," he said. "There could be a bar code that is generated by the facility that would integrate basic patient information, such as age, race, gender, ZIP code. This would help officials understand what percentage of a given population has been vaccinated, making it easier to understand the progress towards reducing the COVID threat."

From the idealistic to the practical and pragmatic, the COVID-19 vaccine logistics process throughout the nation has experienced fits and spurts akin to bumper cars in a demolition derby.

Since the first doses were administered in mid-December 2020, "members of the media, government and the public quickly began to criticize the implementation and pace of this effort, calling for faster, more efficient distribution," observed Carl Gustafson, Senior Consulting Director, Supply Chain Operations Services, Vizient. "Several global studies on the effectiveness of the cold chain supply of vaccines have concluded that the transport systems were not up to standard to ensure the quality and stability of the vaccine, according to the National Institutes of Health in a report published online in January 2020," he added.

Carl Gustafson

Gustafson recognizes the ideal end game that includes the interoperability of multiple technologies.

"By deploying RFID, bar codes, mobile computers, GPS and cloud-based blockchain technology solutions, the distribution of the COVID-19 vaccine can have complete transparency, surface problems or potential problems and improve process," Gustafson forecast. "Every step in the chain of custody — from the manufacturer to the transporter to the healthcare provider — can be accomplished more efficiently and effectively than ever before. Traceability of the vaccine can begin with the initial shipment and through the transit process, continue to the medical facility, the healthcare worker and finally, to the patient."

GPS-enabled RFID can smooth out the rough spots and speed bumps that may delay transport.

"Deploying GPS-enabled RFID tags to verify delivery and receipt and obtain reporting will support identifying weak links in the supply chain," he predicted. "At the time of manufacturing, a GPS-enabled

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RFID chip should be placed within the pallet/package. The chip can provide information such as lot number, expiration date, cold-chain tracking, time, locations and who the vaccine was handed off to. Once en-route, the tags can then track cold-chain stability and if a temperature excursion occurs, send an alert in real time so that the situation can be remedied."

Gustafson outlines that once the vaccine has been delivered and stored at the destination facility, [real-time location systems] can monitor staff involved in the dispensing of the vaccine, and bar-code scanners can track patient, lot number and expiration dating along with ensuring that the cold chain was not compromised onsite.

"Blockchain, tracking and monitoring sensors, hand-held bar-code technology and cloud-based solutions provide transparency, reporting and visibility into all supply chain attributes for distribution," he noted. "GPS-enabled RFID tags have the capability to provide notification for any fluctuations in the cold chain, and that can help prevent loss and compromised storage requirements of COVID vaccines, thereby increasing supply chain resilience."

Peter Sturtevant, Senior Director, Community Engagement, GS1 US, recognizes that the supply chain has operated behind the eight ball for the bulk of 2020.

Peter Sturtevant

"Supply-chain and product transparency are foundational to establishing public trust in the vaccine supply," he said. "The healthcare supply chain came under great scrutiny in the early stages of the COVID-19 pandemic when supplies of personal protective equipment and other products were disrupted by unanticipated and unprecedented demand."

Now in 2021, the supply chain must navigate through the pitfalls and pratfalls of vaccine manufacturing, distribution and administration.

"Hospitals and other dispensers need to know when the vaccine will arrive and how many doses they will receive," Sturtevant indicated. "Caregivers and patients alike will be more confident in the vaccine knowing that it has been tracked and traced through the supply chain, that it is legitimate – not a counterfeit – and it can be traced back if anything goes wrong. "

Two key elements compound the process, Sturtevant insists.

"Traceability is crucial to monitor shipping conditions and events, keeping in mind all the vaccines have differing cold chain requirements, among other things," he said. "Distribution planning is further complicated by the need to deliver a second dose of the same vaccine for the same patients within a specified period of time, 21 or 28 days from administration of the first dose."

The pharmaceutical industry already has been moving to full implementation of bar codes on its regulated products using GS1 Standards to meet the requirements of the Food and Drug Administration's Drug Supply Chain Security Act (DSCSA), according to Sturtevant.

"Standardized data, encoded in a bar code, makes it possible for supply chain partners to accurately pinpoint the details of the vaccine's manufacture, including lot/batch number, expiration date and unique product identifier, [such as] a Global Trade Item Number or GTIN," he continued. "In the COVID-19 vaccine rollout, supplychain visibility afforded by the use of bar codes, using GS1 Standards, will help improve efficient distribution and traceability to benefit patient safety. Throughout distribution, these bar codes can be scanned to capture all the relevant data so that the product can be tracked and traced quickly and accurately. The key to traceability in the healthcare supply chain is exchangeable data, made possible through the use of the GS1 System of Standards."

Sturtevant cites World Health Organization (WHO) recommendations of affixing a 2-D (DataMatrix) bar code on secondary packaging (cartons), and if possible, also on the primary packaging (vial or prefilled syringe), according to a Deloitte report, which also notes that UNICEF recently announced it will utilize GS1 bar codes on packaging beyond the primary level to improve traceability of vaccines.

In the U.S. specifically, according to Sturtevant, drug identification and labeling requirements for the COVID-19 vaccines will require:

- a 2-D bar code containing the National Drug Code (NDC) embedded in the GTIN
- lot number
- a placeholder expiration date of 12/31/2069 on secondary level packaging

"Global alignment on the use of global standards for identification and bar coding of the vaccines will enable traceability across borders to reduce falsification, enable precise product identification in patient health records and facilitate recalls or adverse event reports," he added.

Examples abound

The public agencies managing the vaccine logistics and administration process perhaps should tap into the knowledge and experience of the private sector for recommendations, advises Cory Turner, CMRP, Senior Director, Healthcare Strategy, Tecsys Inc. Turner formerly has served as Director of Regional Distribution Center at Greenville (SC) Health System, which *HPN* named its 2013 Supply Chain Department of the Year.

Cory Turner

"It's not the time to reinvent the wheel," he said. "It's time to draw from some of the greatest healthcare supply chain strategists in the world running some of the largest healthcare delivery networks in the world. These healthcare organizations are proving that they have the technology, processes and staff in place to be able to scale up their vaccination operations. While some may need to add software or technology along the way, health systems are, by and large, engineered to manage lumpy patient throughput in a safe and secure manner. Proven tech like bar coding and RFID are well-incorporated into how they run their business already, so while this effort flexes their capacity, the tools they use to track and trace likely do not veer too far from existing best practice."

Turner acknowledges that many players involved in the vaccination process may not be as well-versed in the particulars of the healthcare supply chain. "This means a sharp learning curve with any medical distribution processes, so familiar and intuitive technologies are the most reasonable option," he observed.

Bar coding implementation may be the most logical first step, according to Turner.

"Pragmatically, bar coding is the lowest common denominator," he said. "The tech to read them is inexpensive and mainstream, and the manufacturer already prints them on the packages. Scanning at receiving, lot tracking, and track and trace at the vial and patient level are all then just a quick scan of a bar-code gun. The same technology can be used to track assets, supplies, users and any other regulatory data point that may arise.

"As the rollout continues to scale, it will be important to identify chain-of-custody blind spots for when the vaccine shipments are broken down and distributed to makeshift locations like arenas and civic centers. We should know by now that the answer is not on a clipboard. These visibility gaps in the transportation leg of the journey are great candidates to leverage bar-code technology to preserve end-to-end traceability." HPN

Visit https://hpnonline.com/21210505 for the full story and related content.

Future care: There's no place like home

by Jimmy Chung, M.D.

Meet Donna, a 42-year-old dental hygienist who lives in Portland, OR with her family of three children and husband. She recently received bad news: Her mother, who lives near Los Angeles, has fallen ill, and Donna needs to see her as soon as possible.

Donna immediately begins her internet search for a good pilot. Her local airport has links to airlines and a "Find a Pilot" link, so it seems straight forward, but Donna hasn't flown for years, as she usually prefers driving to California. Donna is in a hurry, so she picks the one with the highest "star-reviews." Unfortunately, that pilot is not taking new passengers. The next highest rated pilot isn't available for three months.

Donna knows flying is risky; she just read recently that one in every 100 flights has a safety issue. She looks at the next five pilots' profiles, but their safety records are not public, so she needs to take a guess based on years of experience and the schools they attended. She picks one named Jane, who has a flight available in two days, and quickly reserves a seat.

Soon after, Donna receives an email from the airline giving her instructions on how to prepare for the flight and payment options. Fortunately, her family has good transportation insurance, so most of her travel costs will be covered, but she still needs to pay a sizeable portion of the aircraft fuel to meet her deductible. Donna calls the insurance company to make sure she is preauthorized for the flight.

The day before the flight, the airport sends Donna an email with instructions on how to get to the airport, where to park, and how to get to the gate. Some of the procedures conflict with the instructions from the airline, so Donna calls the airline to clarify them.

The airport is preparing for the flight, as per its usual protocols. The airport pulls the preference card for Pilot Jane and makes sure the ground crew and flight attendants are informed of her specific requests. Pilot Jane, with a typical East Coast training, likes to use a short runway and demands the northern takeoff approach, so the airport makes the necessary adjustments in the flight schedule.

Donna finds her seat on the plane, and feeling a bit nervous, she asks the passenger seated next to her, "Hi, have you ever flown with Pilot Jane before?" The elderly man replies, "Oh yes, I've flown with her several times. She's a little slow, but I do like her better than the pilot she replaced who retired a few years ago."

It's a month later, and Donna has been back home for about two weeks. She receives several pieces of mail related to the trip, including a bill from the airport, another from the airline, and something from the insurance company. Fortunately, she is familiar with dental office billings, so she is able to sift through the paperwork and figure out how much she owes out of pocket to which party. She is surprised that the airline charged for two packets of sugar for her coffee, when she never even used sugar, and the airport charged a fee for parking when she already paid on the way out. She also received another bill that she thought was junk mail but turned out to be an invoice from the vendor who runs the motorized jetways; she never even knew that was an outsourced service.

Not surprisingly, this tale is an allegory that may seem familiar. In fact, if you replace "pilot" with "surgeon," "airport" with "hospital," "airline" with "clinic," and other analogous terms, you might recognize a very typical experience for almost every person who has undergone a clinical/medical/surgical procedure in the United States.

From air care to healthcare

Comparisons between the airline industries and healthcare systems have been made for years, and many articles and books have been written on the topic. The premise is that both industries involve highly regulated services where consumers are literally putting their lives in the hands of trained professionals. Both require the practice of high reliability to reduce errors with a focus on safety, which over many years, the airline industry has been able to achieve within Six Sigma standards. However, one key difference is that the airline industry achieved a very high level of safety while developing a consumer-centered business model.

Sad to say, the healthcare industry has achieved neither the same level of safety nor a consumer (patient) centric model of service.

What could a patient-centered model look like for a perioperative experience?

Patient-centricism

Meet Todd, a 58-year-old man recently diagnosed with a tumor in his colon. His doctor referred him to a surgeon who recommended surgery. Now Todd must navigate through how to get this done.

The surgeon's office gives him a referral to the local perioperative clinic. Before Todd gets home, he already receives a text from the clinic. The text includes a link to a scheduling site that allows him to pick an appointment date within the next three days. Todd enters initial information through the secure site and receives instructions for his appointment. At the appointment, he meets a perioperative medicine clinician who goes through his entire medical history and standardized, evidence-based risk assessment tools. Todd receives a customized plan and is assigned a personal navigator.

Todd is assured that an appropriate preoperative optimization will maximize his chances of a good experience without affecting his chances of a cure. In fact, standardized preoperative optimization of his overall health will improve his risk of complications and his chances of a good surgical outcome. At the clinic, he undergoes standardized programs for smoking cessation, treatment for anemia, and prehabilitation to increase his exercise tolerance. A personal navigator reviews Todd's progress and helps him schedule the surgery within the following six weeks, giving enough time for him to get physically and mentally prepared as well as get his life in order for the post-operative period.

The clinic communicates the plan seamlessly to the hospital through a common electronic health record system, and all information is readily accessible to Todd

via his patient portal. All costs related to the surgery are listed clearly, including Todd's share, based on his health plan. There will be no surprise billings, and later, after the perioperative experience is over, he will receive all results and invoices via his portal.

As Todd prepares for his surgery, he receives a single set of instructions from the clinic so that there is no confusion. He arrives at the hospital as instructed, and there are no glitches – no missing paperwork, no missed labs, no conflicting instructions that were not followed. Safety checks are performed using standardized checklists. All staff is focused on the comfort and safety of the patient. The operating room feels welcoming with all staff working as a team to focus on the patient experience. The anesthesia professional, whom Todd met earlier, follows standard enhanced recovery protocols (ERP) to ensure all safety risks are double-checked.

Todd recovers from surgery predictably without problems and is discharged home in three days without the need for prescription pain medications, thanks to the ERP. The clinic remains the primary resource for the next three months to make sure Todd follows up with the right doctors and addresses any postoperative issues.

Homeward unbound

Todd's experience may seem too good to be true, but some hospital organizations have already begun implementing these concepts. One such concept is known as the Perioperative Surgical Home (PSH).

According to the American Society of Anesthesiologists (ASA), the PSH is "a system for organizing and coordinating care that is patient-centered, physician-led and team-based. PSH care extends from the decision for surgery until completion of recovery." Much work has been done in the past years to demonstrate that implementing PSH protocols result in improvements in:

- Quality of care
- Patient safety and medical errors
- Opioid use
- Hospital length of stay
- Readmissions and returns to the emergency department
- Postoperative complications, both medical and surgical
- Total cost of care
- Patient satisfaction
- Provider satisfaction
- Hospital revenue
- Reduction of waste and unnecessary variation

Establishing a PSH includes giving the patient the sense of a "home" for all surgical needs, which could be in the form of a physical clinic or virtual platform. Even more critical, however, is the coordinated multidisciplinary team that is led by a clinician who is responsible for overseeing perioperative medical care. While not yet a formally designated specialty, Perioperative Medicine is fast becoming recognized as a much-needed practice that encompasses the care of the whole person centered around a procedural episode.

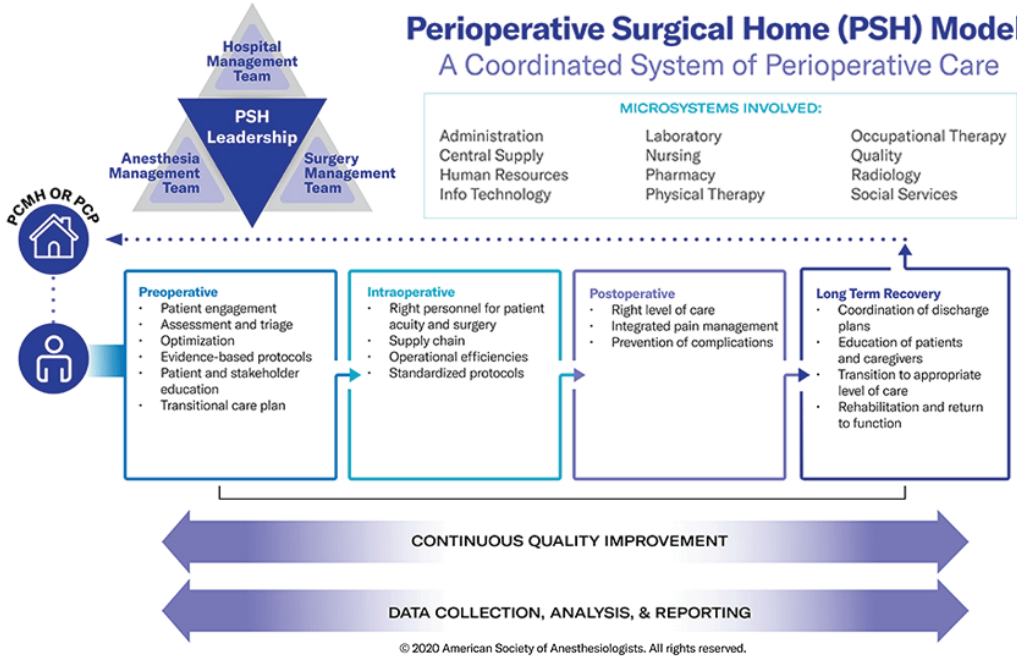
Common barriers that hospital organizations encounter when attempting to establish a PSH include:

- Lack of financial modeling
- Lack of leadership
- Lack of care coordination resources
- Information technology challenges
- Cultural resistance against change or standardization
- Lack of clinical champions
- Competing interests between specialties

None of these barriers are insurmountable, and in fact, much can be gained by implementing even a small piece of the PSH (e.g., a single specialty ERP) to begin with, and small successes will often catalyze rapid expansion of the program. A nationwide PSH Learning Collaborative of the ASA was able to demonstrate that an initial investment into a well-supported PSH program uniformly resulted in strong clinical and/or financial returns.

Providence, a 51-hospital integrated delivery network (IDN) in seven western states, adopted the PSH as the best-practice model for optimizing the patient experience. One major regional medical center saw significant improvements just six months after implementation, including a reduction in length of stay to 4.1 days from 4.9, readmissions to 9.9 percent from 12.4 percent, reoperations to zero from 2.1 percent and patient-controlled opioid use to 18.7 percent from 24.7 percent.

Dramatic improvements in patient satisfaction were demonstrated by improvements in Press-Ganey scores and consistent patient feedback. For example, scores improved for "speed of discharge" to 92.3 from 52.4, for "overall care" to 92.3 from 81.8, and for "likely to recommend" to 92.3 from 76.2. Based on these and other successes, a maturity model was developed as a template for guiding other hospitals to achieve high-level patient experiences and outcomes using evidence-based tools.



Healthcare is undergoing rapid changes as it tries to keep up with consumerism trends and demands for digital solutions. The COVID-19 pandemic has added even greater urgency to these changes, and as healthcare provider organizations struggle to identify more opportunities to innovate, the PSH is an ideal example of a patient-centered model of optimizing cost, quality and outcomes. HPN

Jimmy Chung, M.D. serves as Associate Vice President, Perioperative Portfolio, Providence St. Joseph Health, Renton, WA, and is a member of HPN's Editorial Advisory Board.

Eying Supply Chain IT in 3-V: visibility, vaccinations, variation

by Karen Conway, Vice President, Healthcare Value, GHX

In recent *Standard Practices* columns, I have referenced how variation (and lack of standardization) reduces visibility needed to improve the quality and safety of patient care. This month, I would like to add some additional thoughts related to our ability to effectively vaccinate the nation and monitor the performance of medical products, from personal protective equipment (PPE) to implantable devices.

Vaccine distribution varies

In February, we saw measurable improvement in the rate of vaccination, but visibility remained a problem. The new director of the Centers for Disease Control and Prevention (CDC), Rachel Walensky, MD, said in late January that she did not know how many vaccine doses the nation had, which makes it hard for the states to plan effectively for vaccine distribution.

This is the first break in the chain as the federal government is the primary distributor to the states. Speaking at an IDN Summit Executive Exchange, Maj. Gen. Vinny Boles said the metric given to Gen. Gustave Perna, Chief Operating Officer for Operation Warp Speed, was to deliver the vaccine to the states, which he did. Had the metric been to deliver doses into arms, Boles is confident Gen. Perna would have figured that out. The problem currently is that national visibility is lost once the vaccine is delivered to the states.

At the state level, variation is widespread by design. Early in the pandemic, then-President Donald Trump told governors, who had requested more federal intervention, that they needed to take responsibility, famously saying the federal government "is not a shipping clerk." Director Walensky has a different opinion, noting the need for more harmonization, as least as to how we are prioritizing specific populations for vaccination.

Penn State Health Chief Supply Chain Officer Richard Bagley said during the Executive Exchange that many states have further delegated the last mile, if not the last inch, to local health departments, which are staffed with qualified clinicians, not supply chain experts. In other states, vaccinations are being handled by retail pharmacies, which conceivably have more supply chain expertise. It will be interesting to watch and see if there are notable differences.

Maj. Gen. Boles still believes in more federal involvement, noting that this is a war against the virus: "When you go to war, we send in the federal troops, not state or local forces." He adds that two of the states with the most success to date both leveraged the resources of the national guard, which have both the medical and logistics expertise. To me, it also seems a missed opportunity that the government (at any level) did not call upon the supply chain expertise within our nation's hospitals.

Device performance clearance eases

Last month, I wrote about how the federal government had created roadblocks to achieving its own vision for how unique device identifiers (UDIs) can provide earlier visibility to poor if not deadly device performance, while generating evidence to accelerate the market approval for new devices or expanded use of existing devices. But the federal government may be once again undermining its own intentions.

In the waning days of the Trump Administration, the Department of Health and Human Services proposed permanently exempting 84 Class II devices – including infusion pumps, fetal monitors and certain kinds of PPE – from having to undergo typical 510K clearance review, the process by which the U.S. Food and Drug Administration (FDA) approves a device (or expanded use of the device) based on the fact that it is substantially equivalent to a device already approved on the market. The rationale behind the move was to make it easier and cheaper for manufacturers to bring them to market. The problem, according to critics of the move, is that some of the devices on the list have been associated with 46 deaths according to the FDA's MAUDE database.

UDI data storage separation

Finally, here's a note about the AHRMM Learning UDI Community (LUC) efforts to convince the Office of the National Coordinator for Health IT (ONC) to require that the UDI be parsed into its two components – the UDI device identifier (UDI-DI) and the production data (UDI-PI) – with each part stored in discreet fields in electronic health records and other systems. Without such a requirement, the UDI could be stored as a single number in an open text field, making it hard for health systems, researchers and regulators to find critical production data, such as lot or serial numbers and expiration dates. Storing such data separately allows easier access to the data for a variety of purposes, such as:

- Identifying when a particular batch of products, not the product itself, is faulty.
- Managing expiration dates to use the products expiring the soonest first and making sure not to use an expired product in patient care.
- More quickly removing unused recalled products from the supply chain and identifying if recalled products were used in patient care, and specifically on which patients, in order to take corrective, and potentially life-saving, action.

As noted last month, the FDA's original vision for UDIs was to help capture more data on device performance in routine clinical practice, to not only have visibility to adverse events faster, but also to generate evidence that could help bring new and especially life-saving/sustaining technology to market sooner. The problem is, use of the data requires the right data to be in the right place for easy analysis.

Hospitals across the country have made significant investments in health information technology (IT) to be able

to share data with patients and with other providers caring for patients. This data has the potential to help us understand what delivers value (best outcomes at the best cost) to patients and to minimize the still high levels of medical error. Let's not make the error of failing to capture data in a manner that makes that vision a reality. **HPN**

Karen Conway works to advance the role of the supply chain as a critical enabler in the pursuit of a value-based healthcare system. As Vice President, Healthcare Value for Global Healthcare Exchange (GHX), Conway explores how the supply chain and improved data quality and visibility can support understanding of what increases value for patients and to those organizations that develop and deliver healthcare products and services.

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Supply Chain must use healthcare business data effectively

by Nancy LeMaster, principal, Nancy J. LeMaster Consulting

Many times during the COVID-19 pandemic, healthcare supply chain professionals could be heard exclaiming, "we can't let a good crisis go to waste," or "we will come out of this stronger and wiser." They verbalized an unwavering commitment to go beyond surviving the onslaught of the moment and making systemic changes that would strengthen the industry going forward.

The global nature of the pandemic revealed supply chain vulnerabilities and over-reliance on foreign production. It also highlighted how little most healthcare providers knew about exactly where their products were manufactured, let alone where second- and third-tier manufacturers were located and key raw materials were sourced.

It became apparent that to build stronger, more resilient operations, supply chain professionals must gain a deeper understanding of the interconnectedness of the global supply chain and the economic factors that influenced these connections. Additionally, more expertise in demand planning, risk mitigation strategies and complex data analytics will be required.

Where to start

Healthcare supply chain professionals are no strangers to benchmarking and data analytics. They are experienced in evaluating and comparing supply spend and inventory turns with their peers. They have made great progress in understanding and educating physicians and clinicians on supply costs and their related quality outcomes per procedure. However, when it comes to gaining a deeper understanding of the global supply chain functionality, additional data sources are helpful.

Three key resources are available to provide healthcare supply chain professionals with insights that can inform their planning and decision making: *The Hospital ISM Report on Business*, the *Services ISM Report On Business*, and the *Manufacturing ISM Report on Business*, all of which are registered trademarks of Institute for Supply Management (ISM).

A leader in supply chain education, certification, leadership development and research, ISM was founded in 1915 as the National Association of Purchasing Agents (NAPA), which became the National Association of Purchasing Management (NAPM) in 1968 before adopting its current name in 2002. In 1931, the organization began publishing the *ISM Report on Business*, which is considered one of the most reliable economic indicators available. Today, it is widely referenced by financial publications such as T*he Wall Street Journal* and is used to inform government policy.

The Hospital ISM Report on Business was developed in conjunction with the Association for Healthcare Resource and Materials Management (AHRMM) and Strategic Marketplace Initiative (SMI). These organizations collaborated to tailor a survey for the hospital industry and to identify survey participants. Data collection and validation began in April 2018 and the first report was released to the public in August 2020. The validation period was extensive to make sure the Hospital report had the same degree of reliability as the Services and Manufacturing reports. The mathematical models were validated by the arrival of COVID-19 when the Hospital report accurately reflected the associated market trends.

All three reports have been shown to be reliable economic indicators and very timely information available to supply management practitioners. The data are provided by a dedicated panel of supply chain executives standing at the nexus of supply and demand. The indexes measured in both include: Business Activity, New Orders, Employment, Supplier Deliveries, Inventories, Prices, Backlog of Orders, New Export Orders, Imports, and Inventory Sentiment. The Hospital report breaks down prices into supplies and pharmaceuticals and includes information on Case Mix, Days Payable Outstanding, Technology Spend and Touchless Orders. The indexes are supplemented with informative comments from the panelists.

Hospital inventory planning

The Hospital report provides supply chain leaders the opportunity to compare their current situation and trends with others across the country. Insight into demand patterns, inventory and pricing trends and supplier performance can help organizations with their internal planning and assist in determining strategies for engaging suppliers and distributors. For example, if a hospital were having problems with backorders and knew from the report that supplier deliveries had improved steadily for the past three months, they could approach their distributor to find out why they were an exception to this trend. Additionally, having information that showed an increase in industry wide demand and escalating prices could be the additional information needed to convince a CFO to fund increased inventory levels.

Managing logistics, transportation

The Services and Manufacturing reports are full of information providing insight into the overall health of the supply chain all industries. Medical device manufacturing information is captured within the Miscellaneous Manufacturing sub-sector. Some of the report's most helpful information pertains to transportation and raw materials issues and examples of the interdependencies across the various industry segments. For example, port delays and the inability to quickly offload ships in California have ripple effects across industries. An early awareness of this issue would allow hospital supply chain leaders to talk with their suppliers about specific port(s) of entry for their products and strategies for managing the situation. An awareness of commodities, such as plastics and resins, that are in short supply or experiencing price increases could impact inventory planning.

Effective use of business data, such as the *ISM Report on Business*, is a critical tool that enables healthcare supply chain professionals to continuously improve operations and better collaborate with their suppliers and distributors to develop transparency and resiliency throughout the entire supply chain. HPN

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Redfern et al Pain Manag Nurs 2019 Apr;20(2):164-169.

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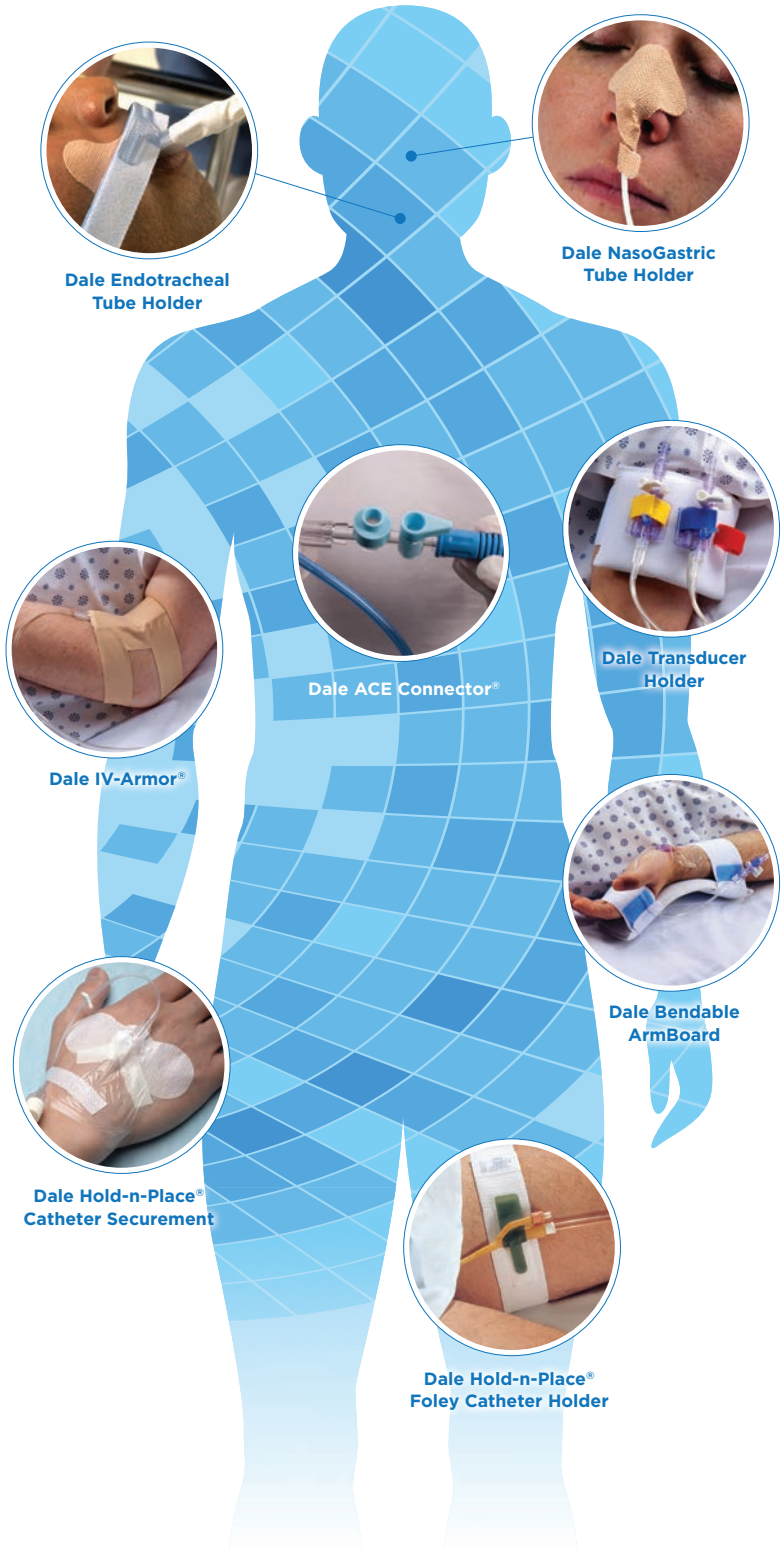

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