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HEALTHCARE PURCHASING NEWS®

CLINICAL INTELLIGENCE FOR SUPPLY CHAIN LEADERSHIP

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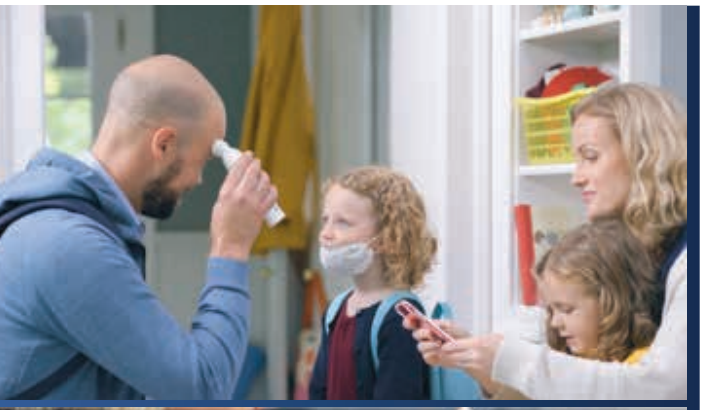
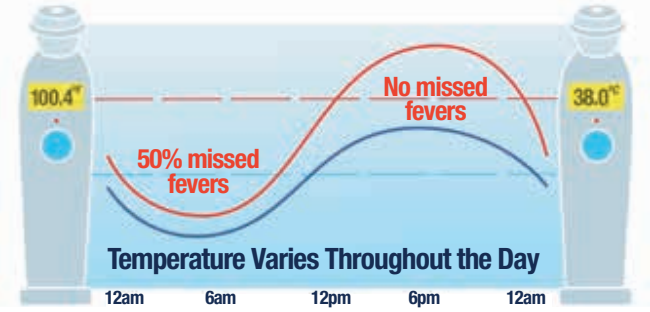


Supporting At Risk Nurses & Families

Exergen Corporation Launches Nurse Support Program to Ensure Every Nurse Has Access to an Accurate Thermometer at Home to Protect Themselves and Their Families.

A series of new studies underscores the alarming toll that COVID-19 takes on frontline nurses and, ultimately, their families. The studies show that patient-facing nurses and their households have a three- and two-fold increased risk of COVID-19 hospitalization, respectively.

- Patient facing nursing 3x the risk of hospitalization
- Nurses are disproportionately affected among healthcare personnel
- Checking temperature only once is not sufficient



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Q&A's on Temperature Screening

Q: What are the recommendations for back-to-school and back-to work temperature screenings?

A: Back to school and back to work recommendations from authorities direct temperature screenings to be done at home.

- American Academy of Pediatrics Interim Guidance for School Re-entry
- Centers for Disease Control and Prevention (CDC)
- Occupational Safety and Health Administration (OSHA)

Q: How do circadian rhythms impact temperatures and assessments of temperatures?

A: Our internal biological clocks produce circadian cycles that vary throughout the 24 hours of each day. This causes body temperature to vary about 1.6°F (0.9°C) between lowest temperatures in the morning and highest temperatures in the evening. With fever, the circadian variation still occurs, but at higher temperatures. Accordingly, temperature assessments in the morning are low and will miss about half of the fevers. Temperature assessments in the evening are high and will detect all the fevers.

Q: When should temperatures be taken?

A: Twice Daily. Before leaving for school or work in the morning, and at dinner time in the evening. If a fever is detected at either time, a medical care professional should be contacted immediately. Even if school or work is done on-line, it is important to check temperature twice daily for the health of the family.

Q: What makes thermometers accurate? What should we know about thermometer accuracy? How about No Touch Thermometers?

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. No Touch thermometers are well known to be inaccurate, with unavoidable errors of +/- 4 deg F. They have no published peer-reviewed clinical studies supporting their accuracy.

Q: What types of thermometers are recommended for use in schools and workplaces? For use by families?

A: Only those thermometers that are clinically accurate as demonstrated by published peer-reviewed clinical studies.

Q: Can you explain how a thermometer margin of error might guide the choice for a cut-off of fever?

A: Some attempts to use a lower cut-off for Covid-19 screening have been made due to the low readings of the no touch thermometers from their inaccuracies. These attempts have been unsuccessful in "improving" the no touch devices' accuracies. A thermometer with accuracy backed by more that 80 published peer reviewed studies requires no adjustment to the medical standard cut-off for fevers.

Exergen Corporation
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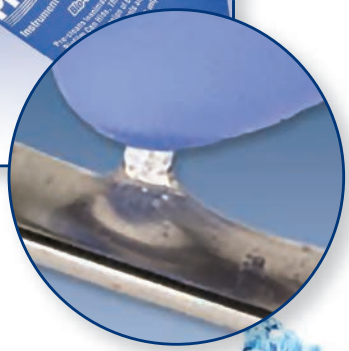

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HEALTHCARE PURCHASING NEWS

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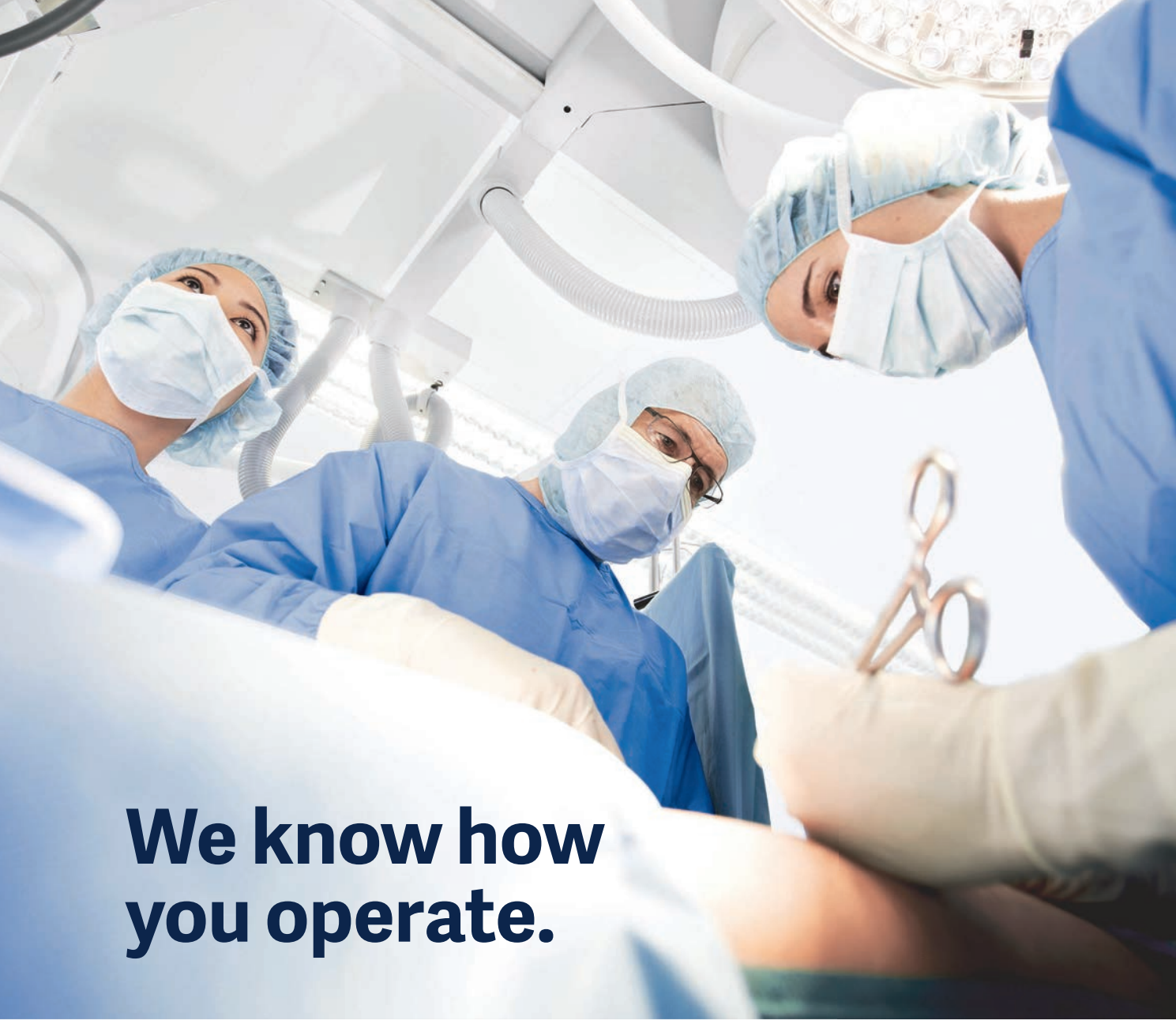

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Tool time

Supply Chain isn't about just buying, storing and moving stuff anymore. It's about the process that links all of it – the glue that binds it all together.

Last year, Healthcare Purchasing News asked readers about the products and services Supply Chain professionals need to succeed and cannot succeed without having.

What's noteworthy from what they told us? Of the 25 top responses, 15 concentrated on technology (primarily for analytics and communication), five on professional management relationships, four on data and one on the dominant product concern of 2020 – PPE. Here they are in random order.

1. Electronic/online exchange for sourcing, transactions
2. Accurate/clean, consistent, standardized Item Master
3. Motivated staff supported by the C-suite
4. Clinical analyst on staff
5. A robust ERP suite
6. An efficient MMIS
7. EDI (electronic data interchange)
8. A backorder notification system
9. Accurate and trustworthy benchmarking sources
10. Expense and usage analytics
11. WMS (warehouse management system)
12. Bar-code scanning
13. Accurate and reliable metrics
14. GPO dashboard
15. An EMR
16. Microsoft Excel
17. Smart phone
18. Mobile device (e.g., iPad, bar-code scanners, etc.)
19. Communication tools
20. Contract management tool
21. Empowerment to manage clinical relationships, product/service conversions and workflow
22. PPE
23. Data analytics and visibility into supplier sourcing and delivery locations
24. Clinical partnerships and relationships
25. Ability to network easily with professional colleagues and peers – including competitors

Next month, we show what technology-oriented processes, products or projects they would like to implement in 2021 if provided the necessary resources. No. 1 may surprise you.

DATABANK

How involved is Supply Chain in the bid process?

Check out this five-year trend.

	2020	2019	2018	2017	2016
Materials/purchasing leads the entire process including: Sourcing, negotiating, purchase.	56%	50%	54%	60%	57%
Materials/purchasing handles the sourcing, but selection is led by the requesting department. Purchasing then takes over.	27%	36%	35%	32%	24%
Materials/purchasing gets involved after vendors are selected.	8%	9%	5%	5%	7%
Materials/purchasing is brought in after the deal is complete and a PO is needed.	9%	5%	5%	4%	6%

Source: 2020-2016 *Healthcare Purchasing News* Supply Chain Surveys

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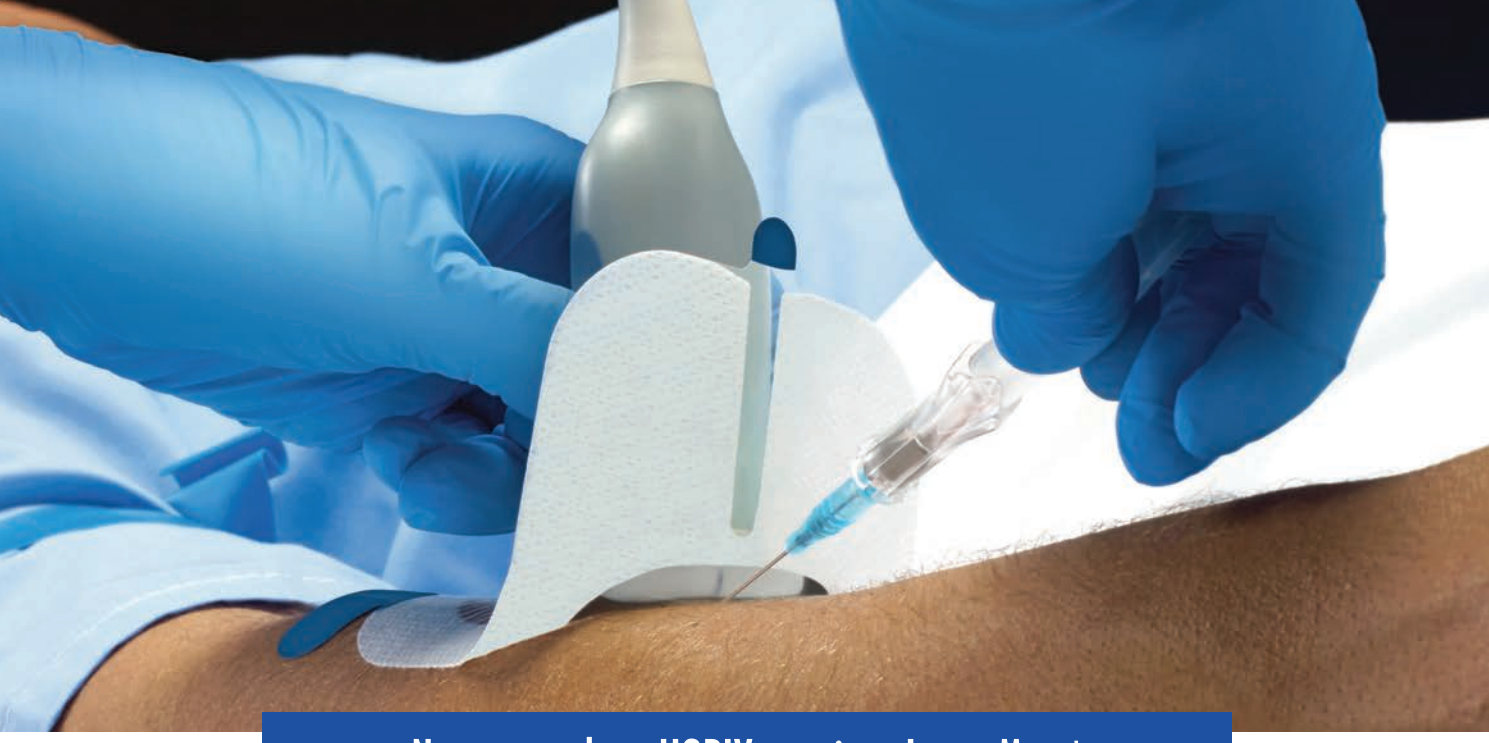

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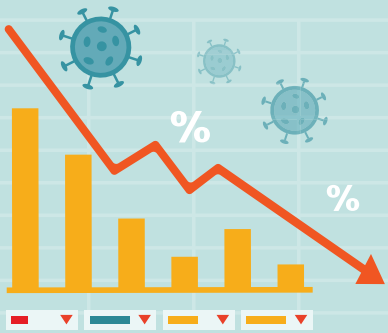

FAST STATS

7%

overall decrease in CLABSIs between 2018 and 2019 with the largest decrease in NICUs (13%).

8%

overall decrease in CAUTIs between 2018 and 2019 with the largest decrease in ICUs (12%).

2%

overall increase in VAEs between 2018 and 2019 with an increase observed in ICUs.

18%

approximate decrease in hospital onset *C. difficile* infections between 2018 and 2019.

3%

overall decrease in central line device utilization between 2018 and 2019 with the largest decrease in ICUs (3%).

7%

overall decrease in urinary catheter device utilization between 2018 and 2019 with the largest decrease in wards (7%).

3%

overall increase in ventilator utilization between 2018 and 2019 with increase observed in ICUs.

1

in 31 patients approximately each day has at least one infection in association with his or her hospital care, underscoring the need for improvements in patient care practices in U.S. healthcare facilities.

Citation: 2019 National and State Healthcare-Associated Infections Progress Report, Executive Summary, https://www.cdc.gov/hai/data/portal/progress-report.html#2018

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NEWSWIRE

WHO reveals leading causes of death and disability worldwide from 2000 to 2019

Noncommunicable diseases now make up seven of the world's top 10 causes of death, according to the World Health Organization's (WHO's) 2019 Global Health Estimates, announced the organization.

This is an increase from four of the 10 leading causes in 2000. The new data cover the period from 2000 to 2019 inclusive.

The estimates reveal trends over the last two decades in mortality and morbidity caused by diseases and injuries. They clearly highlight the need for an intensified global focus on preventing and treating cardiovascular diseases, cancer, diabetes and chronic respiratory diseases, as well as tackling injuries, in all regions of the world, as set out in the agenda for the UN Sustainable Development Goals.

As of Dec. 9, 2020, COVID-19 has tragically claimed more than 1.5 million lives. People living with pre-existing health conditions (such as heart disease, diabetes and respiratory conditions) are at higher risk of complications and death due to COVID-19.

Health authorities worldwide depend on timely, reliable and actionable data to make informed decisions – this is especially true during a global pandemic. The next update to these estimates will include an assessment of the direct and indirect impact of the COVID-19 pandemic on mortality and morbidity.

"These new estimates are another reminder that we need to rapidly step up prevention, diagnosis and treatment of noncommunicable diseases," said Dr. Tedros Adhanom Ghebreyesus, Director-General of WHO. "They highlight the urgency of drastically improving primary health care equitably and holistically. Strong primary health care is clearly the foundation on which everything rests, from combatting noncommunicable diseases to managing a global pandemic."

Heart disease remains the number one killer; diabetes and dementia enter the top 10.

Heart disease has remained the leading cause of death at the global level for the last 20 years. However, it is now killing more people than ever before. The number of deaths from heart disease increased by more than two million since 2000, to nearly nine million in 2019. Heart disease now represents 16 percent of total deaths from all causes.

Alzheimer's disease and other forms of dementia are now among the top 10 causes of death worldwide, ranking 3rd in both the Americas and Europe in 2019. Women are disproportionally affected: globally, 65 percent of deaths from Alzheimer's and other forms of dementia are women.

Deaths from diabetes increased by 70 percent globally between 2000 and 2019, with an 80 percent rise in deaths among males. In the Eastern Mediterranean, deaths from diabetes have more than doubled and represent the greatest percentage increase of all WHO regions.

In 2019, pneumonia and other lower respiratory infections were the deadliest group of communicable diseases and together ranked as the fourth leading cause of death. However, compared to 2000, lower respiratory infections were claiming fewer lives than in the past, with the global number of deaths decreasing by nearly half a million.

HIV/AIDS dropped from the 8th leading cause of death in 2000 to the 19th in 2019, reflecting the success of efforts to prevent infection, test for the virus and treat the disease over the last two decades. While it remains the fourth leading cause of death in Africa, the number of deaths has dropped by more than half, falling from over one million in 2000 to 435,000 in 2019 in Africa.

Tuberculosis is also no longer in the global top 10, falling from 7th place in 2000 to thirteenth in 2019, with a 30 percent reduction in global deaths. Yet, it remains among the top 10 causes of deaths in the African and South-East Asian regions, where it is the 8th and 5th leading cause respectively. Africa saw an increase in tuberculosis mortality after 2000, though this has started to decline in the last few years.

The new estimates also emphasize the toll that communicable diseases still take in low-income countries: six of the top 10 causes of death in low-income countries are still communicable diseases, including malaria (6th), tuberculosis (8th) and HIV/AIDS (9th). Meanwhile, in recent years, WHO reports highlight an overall concerning slow-down or plateauing of progress against infectious diseases like HIV, tuberculosis and malaria.

The estimates further confirm the growing trend for longevity: in 2019, people were living more than six years longer than in 2000, with a global average of more than 73 years in 2019 compared to nearly 67 in 2000. But on average, only five of those additional years were lived in good health.

Injuries are another major cause of disability and death: there has been a significant rise in road traffic injuries in the African region since 2000, with an almost 50 percent increase in both death and healthy life-years lost. Similar but slightly smaller increases (at around 40 percent) were also observed for the Eastern Mediterranean

Page 8

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region. Globally, deaths from road traffic injuries are 75 percent male.

In the Americas, drug use has emerged as a significant contributor to both disability and death. There was a nearly threefold increase in deaths from drug use disorders in the Americas between 2000 and 2019. This region is also the only one for which drug use disorder is a top 10 contributor to healthy life-years lost due to premature deaths and disability, while in all other regions, drug use does not make the top 25.

CMS proposes new rules to address prior authorization and reduce burden

The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would improve the electronic exchange of healthcare data among payers, providers, and patients, and streamline processes related to prior authorization to reduce burden on providers and patients.

By both increasing data flow, and reducing burden, this proposed rule would give providers more time to focus on their patients and provide better quality care. The proposed rule aims to improve this for patients navigating care. The proposed rule would build on the Interoperability and Patient Access final rule published by the CMS in May.

The rule would require payers in Medicaid, CHIP and QHP programs to build application programming interfaces (APIs) to support data exchange and prior authorization. APIs allow two systems, or a payer's system and a third-party app, to communicate and share data electronically. Payers would be required to implement and maintain these APIs using the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) standard. The FHIR standard is an innovative technology solution that helps bridge the gaps between systems so both systems can understand and use the data they exchange.

Prior authorization is an administrative process used in healthcare for providers to request approval from payers to provide a medical service, prescription, or supply. This process takes place before a service is rendered. The rule proposes significant changes to improve the patient experience and alleviate some of the administrative burden prior authorization causes healthcare providers. Medicaid, CHIP and QHP payers would be required to build and implement FHIR-enabled APIs that could allow providers to know in advance what documentation would be needed for each different health insurance payer, streamline the documentation process, and enable providers to send prior authorization requests and receive responses electronically, directly from the provider's EHR or other practice management system. While Medicare Advantage plans are not included in today's proposals, CMS is considering whether to do so in future rulemaking.

The proposed rule would also reduce the amount of time providers wait to receive prior authorization decisions from payers—the rule proposes a maximum of 72 hours for payers, with the exception of QHP issuers on the FFEs, to issue decisions on urgent requests and seven calendar days for non-urgent requests. Payers would also be required to provide a specific reason for any denial, which will allow providers some transparency into the process. To promote accountability for plans, the rule also requires them to make public certain metrics that demonstrate how many procedures they are authorizing. **HPN**

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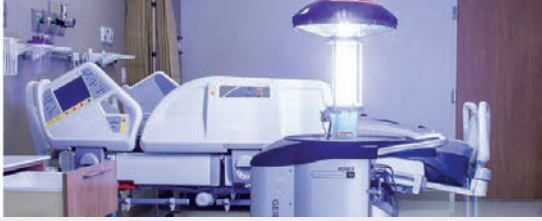

2020-2021 HEALTHCARE PRODUCT ALL-STARS

Stellar product MVPs notable for their essentialness amid pandemic response

by Rick Dana Barlow

To achieve "All-Star" status in anything business- or sports-related, one likely is judged on his or her performance during a specified time frame, whether that's a calendar year, fiscal year or playing season. In addition, the All-Star executive or athlete most likely earned "Most Valuable Player (MVP)" status during a series of projects or games where he or she achieved stellar results or satisfied a need.

Healthcare products are no different.

Last month, *Healthcare Purchasing News* unveiled its Healthcare Product Hall of Fame, spotlighting the 10 members of the inaugural Class of 2020, highlighting each's lifetime industry contributions and recognizing the companies that brought them to market.

This month, *HPN* debuts its Healthcare Product All-Stars, briefly profiling seven relevant products and services that within the last year – and most likely throughout this year – excelled at meeting and exceeding clinical and public demand, driving into the end zone for the benefit of patient care. Over time, any of these seven All-Stars could qualify for Hall of Fame recognition once they've recorded a long and solid "career" of contributions.

Not surprisingly, the vast majority (six of seven) can trace their All-Star determination and status to the coronavirus pandemic as their utility to fight the spread of COVID-19 remains essential. The seventh concentrates on convenience and pain reduction to monitor a chronic disease.

Without further delay, following are *HPN*'s seven Healthcare Product All-Stars with an approving nod to the companies that bring them to market.

Hand-held external temperature scanner

KEY SUPPLIER: Exergen

FIELD PERFORMANCE: Measuring a person's temperature, a necessary step for diagnosing illness and determining treatment, used to involve an invasive procedure that relied on a contained but hazardous liquid metal that reacted to heat. Then Francesco Pompei, Ph.D., engineer, inventor, physicist and scientist, decided to think outside the body cavity. Such ingenuity propelled the art and science of thermometry into heretofore unseen noninvasive territory. His company, Exergen Corp., launched the "temporal artery scanner" that uses infrared sensors to detect a person's temperature by swiping the device softly across the skin.

"Exergen TemporalScanner thermometers have changed the way the world takes temperature," said Marybeth Pompei, Ph.D., Exergen's Senior Vice President and Chief Clinical Scientist, also a nurse and bioethicist. "Patients no longer need to be subjected to invasive, uncomfortable, and sometimes harmful temperature probes in order to obtain accurate temperatures. With the Exergen TemporalScanner, just a gentle scan of the forehead produces a medically accurate temperature, with accuracy backed by more than 80 peer-reviewed published studies."

Pompei points to the accuracy, convenience and pain-free nature of noninvasive thermometry.

"We remember when a nurse approaching a patient with a thermometer produced anxiety, fear and physical resistance on the part of the patient," she indicated. "It is very satisfying to hear nurses report that their patients smile when they approach with an Exergen TemporalScanner to take their temperature. We also see nurses smile when they tell this story, reflecting that they find the use of the Exergen TemporalScanner a very pleasant experience for them as well."

Her husband Francesco Pompei, Ph.D., is Exergen's Founder, CEO and President.

Exergen's invention of noninvasive thermometry motivated some to try to push the concept even further. If you can take someone's temperature outside of the body on the surface of the skin, why can't you take someone's temperature outside of the body and away from the surface of the skin? These companies created a niche of "non-contact" thermometry as a potential extension of the concept.

While Exergen's noninvasive temporal artery thermometer remains popular in clinical settings and, by and large, the gold standard in medical and surgical circles, non-contact thermometers are gaining in popularity and widespread use outside of the healthcare arena in such places as schools, universities, stadia, restaurants and retail stores. Supporters attribute demand for these devices to the additional distance between a person taking the temperature of another.

However, a recent observational study reported in a respected infection control publication found that the farther removed the thermometer was from the patient's skin the less accurate its temperature reading was above 99.5 degrees. Pompei indicates the non-contact devices used for mass screening for fever gives a "false sense of security." This also leads to accuracy questions about "smart helmet scanners" used in some European airports for non-contact thermometry.

PPE duo (face shields and N95 respirators only)

KEY SUPPLIERS: 3M Health Care, CleanSpace Technology, Dräger, **Healthmark, Key Surgical,** Medline, **O&M/Halyard,** Precept Medical, **Ruhof,** Viscot




2020-2021 HEALTHCARE PRODUCT ALL-STARS

FIELD PERFORMANCE: When an easily and rapidly transmissible respiratory virus spreads around the globe, clinicians and other healthcare workers delivering patient care in confined but exposure-laden spaces require something a bit more protective than standard hand-sewn, homemade cloth covers, masks and woven surgical masks. They need much more durable products that can filter out and repel most, if not all, airborne, liquid and solid contaminants. One option (face shields), made of clear, protective plastic, migrated to healthcare from other industries, such as construction and maintenance, repair and operations (MRO). The other option (N95 respirators) can trace its roots back to Peter Tsai, an inventor and materials scientist who patented the N95 respirator and its synthetic filtration material in 1995.

The explosion of COVID-19 in early 2020 spiked consumer demand for these higher-end clinical products, leading initially to stockouts and shortages for clinicians and healthcare workers on the front lines until federal and state authorities redirected mass consumption to standard cloth and surgical masks. This, combined with the 3-D print production of face shields by a growing number of charitable and social responsibility-minded companies, helped to replenish supply.

3M Health Care certainly recognizes and understands the supply-and-demand pressures on N95 products wrought by the pandemic, according to a statement the company issued to HPN.

"With the COVID-19 global pandemic, healthcare workers around the globe face extraordinary challenges every day. 3M is committed to supplying our healthcare heroes with N95 respirators so they can continue to treat their patients," 3M Health Care stated.. "As a leading manufacturer of N95 respirators in the U.S., 3M is making more respirators than ever before. We will produce 2 billion respirators globally by the end of 2020, supporting the public health and government response to the pandemic, while helping businesses return to work as economies reopen."

Owens & Minor/Halyard weathers the supply-and-demand pressures, too.

"The COVID-19 pandemic has reinforced the fundamental role personal protective equipment (PPE) plays in the delivery of safe, effective healthcare," said Alex Hodges, Vice President of Marketing & Global Strategy, Owens & Minor/Halyard. "So much so that PPE is a now a widely understood acronym among policymakers and the public, in particular N95 respirators that have become a household name.

Hodges notes that while some N95s approved for emergency use are industrial grade, the Halyard N95s are cleared by the Food and Drug Administration as medical devices for use in healthcare settings. Further, the Fluidshield Surgical N95s are manufactured domestically. The duckbill breathing chamber is more than twice as large as the leading surgical N95, and exceeds NIOSH standards for breathability, according to Hodges. Because proper snug fit is critical, Owens & Minor/Halyard's N95s come in a range of sizes, with malleable nose wire to adjust fit and have strong elastic straps that are securely bonded — not stapled — to the mask.

The need for face shields in certain areas pre-dates the demand COVID-19 brought on.

"Face masks and face shields have long been critical tools in protecting healthcare workers from airborne contaminants," said Ralph Basile, Vice President, Healthmark Industries. "At Healthmark, our focus is the processing professional responsible for cleaning clinically used medical devices. Generally referred to as the 'dirty-side' as the name implies, this is the area where heavily soiled medical devices arrive to be cleaned. While COVID-19 has brought sharp focus on PPE, and particularly face masks and face shields, the fact of the matter is, those working on the 'dirty side' have always been working in a very hazardous environment.

"The act of manual cleaning, for instance, inevitably aerosolizes contaminants on the medical device," Basile continued. "The source of most of those contaminants comes from patients, often patients with compromised immune systems and/or infections. When airborne, these contaminants represent a significant risk to the worker. Splashing can lead to contaminants reaching the eyes, mouth, nose and attire of the worker. Aerosolized contaminants can be breathed in by mouth or nose. Without protection tools, such as face shields, and face masks, as well as other engineering controls (splash screens, for instance), staff are at very high risk of being infected with serious, life-threatening, contaminants."

The challenge healthcare – and Healthmark – faced is that the virus originated and moved from the same geographical location as where many PPE items are manufactured. Essentially, shortages followed the spreading virus, according to Basile.

"To address this, we pivoted to find domestic sources for face shields, and also developed our own capabilities to make our very popular style of face shield – the face shield with a drape," Basile noted. "The drape material (which is SMS) is attached to the bottom of the face shield and is then tucked into the protective gown, providing protection of the neck area from splashing. It took us a couple of months to find a suitable source and develop our production line. But I am happy to say we are now able to reliably supply face shields to the sterile processing professionals who need them."

Designed by biomedical engineers, CleanSpace Technology's CleanSpace HALO is a Powered Air Purifying Respirator (PAPR) that eliminates the need to stockpile disposable N95 respirators and solves the problem of supply chain disruptions experienced during the pandemic, according to Alex Birrell, Ph.D., CEO.

"For those wearing CleanSpace HALO, the benefits include a higher level of protection and increased comfort," Birrell indicated. "CleanSpace HALO overcomes a lot of the discomfort issues that healthcare workers commonly experience when wearing disposable N95s, such as heat stress, fogging, moisture and facial scarring. When compared to traditional PAPRs, CleanSpace HALO is a game changer in that it has none of the belts and hoses usually associated with PAPRs and it's really lightweight, simple to use and deploy."

Clinicians can treat COVID-19 patients while comfortably wearing CleanSpace HALO for up to nine hours, and they can communicate easily with colleagues and patients while wearing the respirator, Birrell added.

IF BENCHED: Not only would clinicians and other healthcare workers risk exposure to bacterial and viral microbes but they'd also fail to recognize and avert health-compromising habits.

"Ruhof's Anti-Fog Face Shields are vital to the welfare and safety of healthcare providers especially in light of the current COVID-19 pandemic," said Noreen Costelloe, Director of Marketing, Ruhof Healthcare Corp. "The face shields are designed

Page 12

to provide face and eye protection from the splattering/splashing of hazardous or infectious substances, while also delivering added protection against airborne droplets. The blue forehead latex-free band is cushioned and offers a snug fit, while the chin-length guard allows cool air flow to the face, ensuring comfortable protection during long shifts. The lightweight anti-fog shield provides continuous, clear visibility and can be worn comfortably with surgical face masks, eyeglasses or safety goggles. When paired with a mask, Ruhof's Face Shields truly help keep clinicians safe by preventing absent-minded face touching and providing an additional barrier against viral infection."

If anything, the pandemic caused clinicians and healthcare workers to redefine and expand their roles and potential risk, according to Alana Suomela, Director, Corporate Marketing, Key Surgical.

"As a global provider for protective products such as face masks, face shields, barrier gowns, gloves, etc., our priority is to ensure our customers have what they need in order to perform their duties," Suomela said. "Of course, the definition of 'duties' has now taken on a different form due to the unexpected outbreak of COVID-19. In addition to performing their vital roles in healthcare, clinicians, techs, surgeons, nurses, etc., are now also being called upon to help with COVID cases. Without masks and supplies, our healthcare professionals, ancillary staff, patients, and families would have increased risk of spreading or being exposed to the virus. The need for sufficient supply of PPE is ever present."

Suomela acknowledges the "creativity" shown by clinicians and other healthcare workers in dealing with shortages, but remains concerned about the risk exposure.

"The unprecedented increase in demand caused PPE availability shortage on a global scale and facilities were requiring their workers to reuse single-use face masks and shields, rationing available PPE, and even creating makeshift masks made of cloth or surgical wrap," she said. "While the creativity is commendable, protection levels – particle filtration, bacterial filtration, etc. – can't be guaranteed, which puts our front-line workers at contamination risk. Our ability to quickly pivot to design new masks and shields and add them to our product line for our customers helped relieve this shortage, providing proper protective equipment specifically designed for use in hospitals, [for] surgery, etc."

Key Surgical's OR Clinical Education Manager Michelle Lemmons emphasizes the "need" over the "want," expressing satisfaction that "we were able to provide vital supplies to those who needed them when they needed them."

UV disinfecting/sanitizing light technology

KEY SUPPLIERS: Diversey, Far UV, Far-UV Sterilray, Steriliz, Tru-D, UV Angel, UVDI, UV Ninja, **Vystar, Xenex**

FIELD PERFORMANCE: While "germ-zapping robots" may have debuted as a novel way to disinfect rooms with a degree of automated efficiency, they now are taking on COVID-19 in even more novel ways. Not only are healthcare facilities using pulsed ultraviolet light emitted from these portable units to disinfect surfaces in rooms, but they're increasingly using them to disinfect face shields and N95 respirators for reuse. Meanwhile, other companies are using UV technology to disinfect and sanitize the air of viral particles before they have a chance to fall to a surface. In addition, some companies are adapting the technology for hand-held wands, pocket-worn badges and even wireless smartphone-charging stations that sanitize the germ-riddled communication devices.

Executives at Xenex Disinfection Services marvel at the ingenuity of healthcare facilities.

"Every day we hear from healthcare facilities about the extreme stress and pressure they are under because of the pandemic," said Irene Hahn, Xenex's Senior Vice President of Sales & Marketing. "It's been our honor to provide them with a technology to assist in their battle against SARS-CoV-2, the virus that causes COVID-19, and the innovation we have seen from the hospitals in their use of our Germ-Zapping Robots to quickly disinfect rooms and areas is inspiring."

Hospital-acquired infections and manual cleaning remain ongoing challenges, according to Hahn.

"Before the pandemic, nearly 300 people died in the U.S. every day from an infection they contracted during their hospital stay," she indicated. "Very little has changed in manual hospital cleaning techniques in the past 20 years, although the superbugs are becoming resistant to antibiotics and some cleaning chemicals. Hospital Infection Preventionists and [Environmental Services] Directors have been asking for new technologies in their battle against pathogens, and now that preventing disease transmission is a global priority, they are getting the attention they have long deserved. Investing in LightStrike robots is helping them battle not just SARS-CoV-2, but other pathogens that pose a risk to patient safety – for example, MRSA, *C.diff* and VRE.

"When we began hearing reports from overseas about the spread of [COVID-19], one of the first things we did was to test LightStrike against SARS-CoV-2" Hahn continued, "and the robot achieved a 99.99 percent level of disinfection in two minutes. As an evidence-based company, it was very important to us that we confirm efficacy against the actual virus."

Hahn highlights LightStrike's speed at deactivating SARS-CoV-2 in two minutes with no warm-up or cool-down time.

"Some hospitals have stationed a robot in the ED so they can disinfect every room and area where coronavirus patients are treated," Hahn noted. "Others have a robot follow the patient from the ED to radiology, and to their COVID-19 unit, disinfecting rooms against SARS-CoV-2 along the way. The robots are being operated in healthcare facilities around the world around the clock, and it's humbling for us to be part of their pandemic response plan. Post-pandemic, without question, there will continue to be a need for enhanced room disinfection to battle all of the pathogens that pose a risk to patient safety – MRSA, *C.diff*, and VRE for examples – as well as emerging pathogens. The investment that hospitals are making in disinfection technology will continue to help them fight this battle well into the foreseeable future."

Diversey Inc.'s MoomBean3 offers added assurance for disinfection, according to Carolyn Cooke, Diversey's Vice President of Healthcare Sales, North America.

"Facilities are taking extra measures to ensure that staff, patients and visitors are protected," she said. "MoonBeam3 has demonstrated efficacy in seconds against SARS-CoV-2, and other common healthcare pathogens. The system is portable, weighs 39 pounds, and can easily be transported and operated by any associates in the facility. It has multiple safety features, and is very easy to use. During COVID-19, many of our operators have used it prior to manual cleaning to ensure staff members feel safe when cleaning."

Several companies insist that disinfecting surfaces is useful and necessary but they don't stop there. They focus their UV technology on the air, zapping germs before gravity pulls them down to surfaces – even COVID-19.

John Neister, President, Far-UV Sterilray, refers to numerous published studies showing that 222nm UV technology effectively kills coronavirus and is safe for humans. One of those studies appeared in *JAMA Internal Medicine* in October 2015. In fact, his company has been making excimer lamps that produce the Far-UV wavelength since 2007 and holds the patent for 222nm disinfection technology. Further, Far-UV Sterilray's devices can disinfect the air in real time with people present, according to Neister.

Page 14

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Unfortunately, the pandemic represents a missed prevention opportunity, Neister laments.

"If this technology [were] in place before the pandemic we could have saved thousands of people's lives," he said. "We could have protected first responders and healthcare workers by providing them with Far-UV Sterilray lamps to disinfect their PPE, the air in the room and their equipment, while taking off their gear. One study found that over 46 percent of subjects self-contaminated their skin and clothes during their PPE removal. 222nm technology could have made a tremendous difference in flattening the curve."

The butterfly effect remains significant, Neister insists.

"If this technology [were] already in place before the pandemic, we would not have had to shut down our schools, our companies, or small businesses," he noted. "Families would have been together at hospitals with their loved ones for major surgeries, births and doctors' appointments. Production facilities could have been fully staffed. Public transpiration would have been safer. Restaurants could have full capacity again and public events like high school and college graduations wouldn't have been cancelled.

Disinfecting the air to protect against the airborne coronavirus makes a great deal of sense, according to Bryan Stone, M.D., Internal Medicine & Nephrology, Chief of Medicine Emeritus for Desert Regional Medical Center, Palm Beach, CA, and member of the Board of Directors for Vystar Corp., which makes the RxAir UV light air purification system.

"Healthcare professionals as well as the general public are well aware of the usual hygiene protocols such as washing your hands, [wearing] face masks and controlling where you sneeze," Stone said. "We all were told that this would curb airborne disease transmission. However, none of us were entirely satisfied with the results. Now we are faced with the airborne coronavirus pandemic that raises the odds and results in high rates of illness and death."

Healthcare has been slow to adopt an approach for airborne coronavirus because healthcare experts initially linked transmission to contact, according to Stone.

"SARS CoV-2 traveled from Wuhan, China around the entire planet in 60 days, Stone said. "Clearly, this involved air and droplet transmission as hundreds of scientists stated. The transmission from surface exposure is far less important, yet millions of dollars are spent on surface disinfection that is compromised the moment an infected individual breathes, talks or coughs, leaving a cloud of pathogens waiting to be inhaled by or land in the eyes of others. Too many clinicians are forced to rely solely on PPE and surface disinfection to protect themselves from coronavirus and other airborne pathogens."

Clinicians, patients and consumers in general must take air disinfection more seriously, according to Stone.

"People are now paying more attention to the air in the 26,000 breaths they take each day," he noted. "We as healthcare professionals have to understand and appropriately address the airborne problem that has been in front of us. It is important to select FDA-cleared Class II medical devices that have been independently tested in FDA- and EPA-certified labs to be effective at inactivating or killing viruses and other pathogens. Untested units will not only waste money but create a false sense of security that can put people at risk. Air purifiers work in concert with traditional hygiene protocols rather than replace them."

Stone reinforces the importance of air disinfection in professional and personal spaces. He shared several anecdotal testimonials from customers as examples of utility.

IF BENCHED: Healthcare facilities would need to redeploy human disinfection teams that may not be able to reach the hard-to-reach nooks and crannies requiring cleaning and disinfection. Without air disinfection devices, healthcare facilities would be left with air "purifiers" not cleared by FDA as Class II medical devices but something purchased at a local retail store.

It's technology like this that helps clinicians and administrators to do their jobs and fight healthcare-acquired infections (HAIs), according to Peter Veloz, CEO, UltraViolet Devices Inc. (UVDI).

"The brave men and women preventing Infections everyday on healthcare's front lines rely on science and evidence to inform critical decisions," Veloz indicated. "It is for them – and ultimately, the patients we all aim to protect – that we at UVDI are dedicated to the highest levels of evidence-based support for device efficacy, including: Pathogen inactivation claims validated by independent third-party testing; testing conducted at time and distances – five-minute inactivation at eight feet – indicative of efficient whole room disinfection; proven 360-degree surface coverage confirmation; and peer-reviewed published clinical studies demonstrating HAI reduction.

Companies like UVDI strive for such results ahead of any governmental or regulatory body standards, Veloz insists.

"We take these important measures not out of regulatory compliance – as there are no consolidated EPA standards as there are for manual disinfectants – but because it is the right thing to do," he continued. "Healthcare professionals deserve credible, proven solutions to the day-to-day challenges they face. Without these voluntary initiatives to prove performance, the onus would be on healthcare professionals to spend precious time and resources to investigate claims or to experiment with unproven or ineffective solutions – none of which is a suitable alternative in this or any time. We will continue to push in 2021 to raise the bar for UV device standards in science and evidence, in service of better patient outcomes."

Far UV Technologies Inc. manufactures the Krypton air and surface disinfection lighting system that serves as a countermeasure to infectious disease in occupied spaces where transmission is most likely to occur, according to P.J. Piper, President and CEO.

Piper emphasizes that the Krypton disinfection ceiling lights are gaining traction in the U.S. military, medical and dental facilities, airports, airplanes and buses and in schools and commercial real estate.

"Hospitals and clinics are increasingly using Krypton disinfection lighting in entrances, lobbies, waiting rooms, exam rooms, operating rooms, patient rooms and ambulances to continuously reduce the viral load in those spaces, whether they have been exposed to SARS-CoV-2, the common cold or flu or hospital acquired infectious diseases such as MRSA or C difficile," Piper noted. "Social distancing, wearing masks and better hand hygiene have proven to be useful in combating the spread of COVID-19, but they apparently are not good enough alone as the disease is continuing to spread either due to human error or equipment failure. Adding Krypton Disinfection Lighting as a fourth layer of active protection can help mitigate the remaining risks."

Wearable glucose monitor

KEY SUPPLIERS: Abbott Laboratories

FIELD PERFORMANCE: Being able to test your own blood glucose levels at home without having to see a doctor was considered revolutionary at the time of change for the convenience and control it gave persons managing diabetes. A fingerstick, while fleetingly painful, seemed to some a small price to pay to avoid going to the physician unless absolutely necessary.

Then Abbott Laboratories developed a new wrinkle that could be classified as revolutionary at best but certainly evolutionary at minimum: The FreeStyle Libre. The television commercials appear regularly with the woman nonchalantly holding her mobile phone for a second over the circular sensor explant affixed to her skin to obtain a noninvasive readout in real time. Patients also can customize the system to sound an alarm if blood glucose readings are too low or high or if the reader and sensor experience signal loss for any reason.

In-demand infection prevention trio (disinfectant wipes, hand sanitizers, high-level disinfectants)

KEY SUPPLIERS: 3M Health Care, Best Sanitizers, Clorox, **Diversey**, **Ecolab,** ESSITY/TORK, Georgia-Pacific Professional, Gojo, Henkel/Dial, Kimberly-Clark Professional, Mölnlycke, **PDI**

FIELD PERFORMANCE: Aside from cash and coins, gems, precious metals and stock shares in 2020, this trio of in-demand infection prevention products may be the closest ever to reach for legitimate currency status this side of bitcoin. Because of rampant demand detonated by COVID-19 fears, disinfectant wipes, hand sanitizers and high-level disinfectants vanished so quickly and routinely from retail store shelves and healthcare facility storeroom shelves, respectively, you'd swear they were the 21st century successor to the Cabbage Patch Dolls of the 1980s and Beanie Babies of the 1990s.

For clinicians and other healthcare workers, the importance of these products – before, during and after a pandemic – remains blatantly obvious.

"Disinfection of healthcare surfaces and non-critical patient care equipment is one of the cornerstones in the foundation for infection prevention practices," said Debra Hagberg, MT (ASCP), CIC, Director, Clinical Affairs, PDI Healthcare. "PDI created the first pre-moistened germicidal wipe product for healthcare use in 1988. Healthcare providers, including clinicians, would not be able to contribute efficiently and effectively to providing a sanitary patient care environment without PDI Germicidal Disposable Wipes. The ability to have pre-moistened disinfectant wipes at point of use has changed the concept that disinfection is for environmental services only."

Ecolab Healthcare credits timing as the company launched its Disposable Wipe System near the close of 2019 just as COVID-19 was emerging, according to Chris Paradise, Senior Marketing Manager, Environmental Hygiene for Ecolab Healthcare.

Paradise describes the system as consisting of a low-count roll of disposable dry wipes and a reusable canister, which the user saturates with liquid disinfectant to create a convenient disposable wipe option for disinfection.

"The low-count wipe roll reduces waste associated with the product not being used in a timely manner, product being left open to dry out, or as was the case in some facilities during the pandemic, theft of product," Paradise said. "Further, the wipe substrate is qualified for compatibility with OxyCide Daily Disinfectant Cleaner, which is widely used by hospitals across the country. OxyCide is based on a peracetic acid and hydrogen peroxide and has not been impacted by quat raw material shortages that limited availability of many disinfectants early in the pandemic."

Diversey aims for speed to augment safety with its Oxivir product, according to Larinda Becker, Executive Director of Infection Prevention Platform, North America.

"During this time, it has been paramount for providers to have a product that is fast for turnover, and is effective against this pathogen and others, as quickly as possible," she said. "Being tough on pathogens, and not on people is a key benefit of Oxivir, and having a product that has the best possible safety rating in all six toxicity categories has made it available at the point of care. Many products take more time, or dry prior to the pathogens [dying]. Oxivir makes it possible to kill pathogens and enable fast turnover for the next patient."

As traditional supply dwindled in 2020, hospitals had to pivot, Paradise recalls.

"Numerous hospitals across the country supplemented, and in some cases fully replaced, their depleted stock of pre-saturated wipes with OxyCide paired with the

Page 16

Disposable Wipe System, enabling efficient disinfection by clinical teams at a time when it was needed most," he noted. "Additionally, since OxyCide has efficacy against *C. difficile* spores, in most cases hospitals were getting a higher level of antimicrobial efficacy than they were from their prior, non-sporicidal disinfectant wipe. Ecolab has been able to keep these products in stock throughout 2020, helping to ensure hospitals could continue to operate safely."

IF BENCHED: Without these products healthcare facilities would have to retreat to a "back-to-basics" approach with copious calls for handwashing as well as extensive and arduous use of a variety of soap, disinfectant and bleach products.

"The practice of environmental disinfection would look very different without access to PDI Germicidal Disposable Wipes," Hagberg indicated. "Cleaning and disinfection would purely fall on the shoulders of environmental service staff who would not be able to perform disinfection as frequently as needed in today's busy healthcare environment. The COVID-19 pandemic has certainly highlighted this reality. It takes a coordinated effort from all healthcare workers to stunt the spread of highly communicable diseases."

But Hagberg cites human behavior as the X factor.

"The alternative to PDI Germicidal Disposable Wipes is typically a liquid disinfectant solution in a bucket that is applied by a cloth or mop," she noted. "This technique can introduce several issues prone to human error, particularly if protocols are performed quickly and more often. Dilutable liquid disinfectants increase the chance of concentration errors during the dilution process and increase potential safety issues regarding splashing to the user. Strict protocols also need to be monitored when using mops/rags to avoid cross contamination between areas of use. Disposable germicidal wipes eliminate these issues by providing ready-to-use pre-moistened wipes, no dilution or mixing required. The convenience of PDI products provides compliance and control for all healthcare workers to use."

3-D printing/additive manufacturing

KEY SUPPLIERS: 3D Systems, HP, Proto Labs, Stratasys

FIELD PERFORMANCE: Using 3-D printing a k a "additive manufacturing" excited and intrigued consumer and business markets alike because just about anyone could obtain this technology to reproduce a variety of products. On the flip side, however, were those expressing concern about intellectual property (e.g., formulas, ingredients, etc.), reliability and risk (e.g., liability) stemming from reproducing such items as medical/surgical device components, orthopedic implants or any fibrous/plastic/synthetic products used throughout a healthcare facility. One popular newspaper even published a story about a guy who 3-D printed a spaghetti dinner that he reviewed as tasting about as good as you might expect or imagine from a 3-D printer versus actual kitchen.

But when the pandemic spurred demand for selected products last year, 3-D printing capabilities alleviated some of the pressure. How and why? Healthcare organizations relied on smaller businesses and local colleges and high schools to produce face shields and other components for PPE products in a pinch that were allowed by federal, state and local authorities to be used for clinical purposes. In fact, a number of hospitals and integrated delivery networks (IDNs) performed their own 3-D printing operations for member/participating facilities to cope with COVID-19 supply chain backorders and shortages. Search HPN Online for examples and for the complete story. HPN

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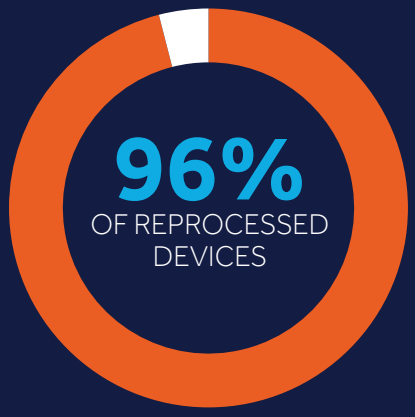
Study published in *Surgical Endoscopy* raises questions about the ability to effectively clean and sterilize with reprocessed vessel-sealing devices[1]



1 OUT OF 165 REPROCESSED DEVICES **GREW BACTERIA IN CULTURE.** AND THE LEVEL WAS **166X FDA GUIDELINES.**[1,†]

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Read the full study here.

†Sterility assurance level of 10-6 accepted by the FDA as laid out in the Association for the Advancement of Medical Instrumentation (AAMI) standards ST67 and TIR 12 for devices contacting normally sterile tissue.

‡The combination of failed tests included visual inspection, optical and scanning electron microscopy, hemoglobin detection, and sterility testing.

§Medtronic will not perform complaint investigations on competitive devices.

ΩOptional risk-sharing and indemnification programs include the LigaSure™ Technology Performance Pledge and Project Zero collections programs.

1. Chivukula, S.R., Lammers, S. & Wagner, J. Assessing organic material on single-use vessel sealing devices: a comparative study of reprocessed and new LigaSure™ devices. *Surg Endosc* (2020). https://doi.org/10.1007/s00464-020-07969-8.

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OPERATING ROOM

Pressure on patient positioning

Suitable practices, equipment help prevent infection, injury

by Ebony Smith

Patient care requires many measures in the effort to achieve safety and comfort for every patient. One primary concern, no matter the healthcare setting, is preventing healthcare-associated infections (HAIs), injuries or other complications that can be harmful, or even worse, fatal for those in care.

Addressing staff challenges

Staff must give special attention to patient positioning in order to prevent pressure injuries or other negative outcomes for patients treated in the operating room, an intensive care unit (ICU), or other hospital or medical facility. Several barriers, however, may make the processes of turning or moving patients difficult, points out Brittany Hahn, Marketing Communications Specialist, HoverTech International, Allentown, PA.

"Challenges facilities face include not having the appropriate safe patient positioning devices readily available when needed, insufficient policies and procedures in place, and a lack of adequate training and support for staff on patient positioning," Hahn indicated. "It's no secret that healthcare workers are extremely busy, and as a result of that, the use of proper equipment and techniques can be overlooked. The best patient positioning equipment in the world has no value unless it's being used."

Caring for COVID-19-infected patients presents unique positioning complications, she added.

"Shortly after the virus spread across the US, it was discovered that proning can be used to optimize oxygenation. Although it can be beneficial for patients, the task of proning poses a high risk of injuries to healthcare workers. In order to perform the task safely, it requires proper technique, equipment, and additional staff to keep everyone safe. The burden for this task is especially heavy given the current need to limit the number of staff in ICU rooms to reduce virus exposure."

Caroline Marchionda, BSN, RN, a clinical specialist at LINET Americas, Inc., Charlotte, NC, states, "One of the biggest problems we as nurses encounter is that the nurse is usually in the isolation room with no other staff. That makes repositioning more stressful for the patient and nurse. We have found the assistance from the Multicare bed helps to turn patients with its frame-based lateral turn technology. Less staff is needed to care for each patient at a time, which reduces PPE, makes more consistent Q2 hour turns, and makes offloading easier."

Advancing patient safety

Obstacles with care-acquired conditions

Several national agencies and organizations provide oversight, standards, education and support regarding patient safety, as it remains a high priority in care.

The Agency for Healthcare Research and Quality (AHRQ), part of the U.S. Department of Health and Human Services (HHS), last March released a report that "reviews 47 practices that target patient safety improvement in hospitals, primary care practices, long-term care facilities and other healthcare settings." [1]

Some main topics in the report include:

- "Medication management
- Healthcare-associated infections (HAIs)
- Nursing-sensitive practices
- Procedural events
- Diagnostic errors
- Crosscutting factors"[1]

The report went on to highlight the persistence and impact of hazards with patients, noting, "Despite sustained national attention and notable successful interventions in recent years, patient safety remains a significant problem in the United States. Harms such as adverse drug events, HAIs, falls and obstetric adverse events are blamed for thousands of deaths and hundreds of thousands of injuries each year. AHRQ statistics estimate that in 2017, there were 86 hospital-acquired conditions per 1,000 hospital discharges – a figure that has fallen steadily in recent years but remains alarmingly high."[1]

Successes with pressure injuries

Leading progress in decreasing patient pressure injuries in hospital care is the Joint Commission Center for Transforming Healthcare, which last October announced that, "A collaborative project to address hospital-acquired pressure injuries (HAPI) has resulted in more than a 60 percent reduction in a common but preventable issue that claims over 60,000 U.S. lives each year. Led by the Joint Commission Center for Transforming Healthcare, the improvement initiative — including The Johns Hopkins Hospital, Kaiser Permanente South Sacramento Hospital and Memorial Hermann Southeast Hospital — saw these significant reductions sustained even as the COVID-19 pandemic accelerated in the United States."[2]

Pressure injuries pose a detrimental threat to patient health and life as well as costs of care, growing into an even greater challenge during the COVID-19 pandemic, indicated the commission.

"The project launched to identify solutions to prevent and reduce the rate of pressure injuries, also known as decubitus ulcers or bedsores, in healthcare facilities after seeing that HAPI were rising nationally. Experts estimate more than 2.5 million patients in U.S. acute-care centers experience pressure ulcers and injuries each year. Because pressure injuries are a significant risk for immobile patients, the country is experiencing a jump in this condition as COVID-19 patients require long hospitalizations."[2]

The commission shared that the three hospitals accomplished not only less pressure injuries, but more savings of costs in care.

"Organizations achieved an average 55 percent relative reduction in intensive care unit pressure injuries from May 2018 to December 2019. They continued building on that momentum from January to April

2020, experiencing a 62 percent average relative reduction and preventing 78 pressure injuries annually. This outcome resulted in a cost savings in aggregate of $15.3 million for the length of the project by reducing an expensive condition that costs the healthcare industry $11 billion a year."[2]

Adding prophylactic dressing standards

Bringing to the forefront prophylactic measures are the National Pressure Injury Advisory Panel (NPIAP) and the European Pressure Ulcer Advisory Panel (EPUAP), which last November announced, "the launch of the joint NPIAP-EPUAP Prophylactic Dressing Standards Initiative (PDSI) and the establishment of a dedicated international Task Force to lead and develop this initiative." [3]

The panels stated, "No known standards exist anywhere in the world for prophylactic dressings, despite their international widespread and growing use. Performance standards based on bioengineering laboratory testing generate critical information, which is needed to guide effective medical product selection and practice. Testing standards and consistent manufacturing are established for all types of medical devices and serve different stakeholders in multiple ways, including the industry itself by providing benchmarks for development purposes or instructions for use. Testing standards further serve regulatory bodies and reimbursement policy makers in evaluating safety and efficacy and in qualification of existing and new products for use with patients who have specific needs."[3]

Proning and positioning patients

Healthcare teams should work together to use a proning technique to position patients with respiratory ailments, remarked the American Association of Critical-Care Nurses (AACN) last January.

"When research and new clinical guidelines strongly recommend that critically ill patients with severe acute respiratory distress syndrome (ARDS) be face-down for most of the day, the change requires a team approach to integrate the logistically challenging, multifaceted repositioning procedure into clinical practice."[4]

The association continued, "ARDS is estimated to be responsible for 10 percent of all admissions to ICUs worldwide and occurs in nearly a quarter of patients undergoing mechanical ventilation. The mortality rate for ARDS remains high, even though patient outcomes have improved significantly in the last decade, from an estimated hospital mortality of 90 percent to a reported 46 percent. Prone positioning is now considered first-line therapy for patients with severe ARDS to reduce lung trauma and improve outcomes. Recent studies show that lying face-down for up to 16 hours a day can improve oxygenation and decrease mortality."[4]

As many COVID-19-infected patients experience respiratory conditions and treatment, proning and specialized positioning equipment may be effective in their care.

HoverMatt Single-Patient Use Air Transfer Mattress

"COVID-19 patients often need to be in prone position for long periods of time," Marchionda explained. "Special care must be given to prevent skin breakdown since critical patients are possibly not turned as frequently due to being hemodynamically unstable. Micro-shifting a patient while in prone position, such as laterally tilting one degree at a time with the Multicare critical care bed by LINET, provides pressure redistribution and pressure relief with minimal hemodynamic impact. The Multicare has frame-based lateral turn technology that assists caregivers with daily care, helps with pressure injury prevention, and assists in preventing ventilator-associated pneumonia."

Proper patient positioning equipment and practice provide dual protection for patients and staff.

"For patient length of stay, the HoverMatt Single-Patient Use (SPU) Air Transfer Mattress and HoverSling Transfer and Lift System, in combination with HoverTech Positioning Wedges, provide a well-rounded solution to protect nurses from musculoskeletal injuries, and patients from friction and shear while supporting pressure injury prevention initiatives," Hahn indicated. "The HoverMatt SPU and Positioning Wedges comply with NPIAP guidelines for the prevention and treatment of pressure injuries. HoverTech offers the HELP Program, which assists hospitals in assessing and creating a robust Safe Patient Handling and Mobility (SPHM) program."

"Looking for a solution to prone their patients, a one-thousand bed Magnet Certified hospital in the Southeast turned to the HoverMatt SPU," Hahn shared. "This resulted in a better approach for patient safety while reducing the risk of muskuloskeltal injuries in healthcare workers."

Page 20

Multicare critical care bed by LINET Americas, Inc.

Rehabbing at home

After returning home from critical care in the hospital or another setting, patients must maintain movement and continue rehabilitation in their daily activities. This better ensures they will recover well and avoid harmful situations.

The Society of Critical Care Medicine last February reported that, "Home health rehabilitation can help seniors get stronger and resume activities after an ICU stay, yet one in three Medicare patients don't receive this care, according to a first-of-its-kind study presented at the Society of Critical Care Medicine's 49th Critical Care Congress."[5]

Such care can be vital to preventing patient infections or other serious complications.

The society continued, "People who spend time in the ICU are at risk for post-intensive care syndrome (PICS) or problems that remain after critical illness. One of those problems is ICU-acquired muscle weakness, and people who were admitted for sepsis (a severe infection) or spent a week or longer in the ICU are at increased risk. Rehabilitation is an important part of post-discharge care, which improves the chance of recovery. There are no established guidelines for the number of visits these patients should receive. Most of the patients in the study were homebound, meaning they could not leave the house without significant effort."[5]

Other findings from the society include:

- "One in three Medicare patients referred for home health rehabilitation after the ICU don't receive any services, and those who do get very few visits.
- It can take up to six months for many of these patients to recover function after an ICU stay if they recover at all.
- Those who lived alone or in rural areas were least likely to receive home rehabilitation.
- All patients who spend time in the ICU should be screened for rehabilitation needs, as many will be at risk for post-intensive care syndrome."

Expanding transfer devices

So, what does the future hold for patient positioning? Lateral transfer is one possible area, as evidenced with Arjo's last December announcement of its "acquisition of AirPal, a privately owned US-based company specializing in Air-Assisted Lateral Patient Transfer solutions." [6]

Such equipment can be critical to preventing staff injuries and adverse patient care outcomes.

The company continued, "Healthcare has the highest proportion of work-related injuries of all professional groups (of nonfatal accidents). Fifty to 60 percent of all global healthcare professionals are affected by muscular skeletal disorders. Lateral transfers and repositioning are the most commonly cited patient handling tasks reported in healthcare, and when performed manually, jeopardizes both staff and patient health. Using an air-assisted system, such as AirPal, provides a more effective solution to mitigate the physical efforts and injury risks associated with performing lateral transfers, in addition enabling reduced caregiver injuries and healthcare costs. AirPal's technology releases low-pressure air through perforated chambers in its TransferPad, which is placed under the patient in the same manner as a bed sheet."[6]

This market, projected by Arjo, will continue to grow nationally and beyond.

"Today, the US market size for air assisted lateral transfers is estimated at approximately 160 M USD, with an estimated annual growth of five percent. The initial focus is on the US market, followed by UK and Australia." HPN

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INFECTION PREVENTION

Pandemic boosts infusion demands

Securing supplies, adapting treatment and training, and elevating patient and staff safety and outcomes remain critical elements

by Ebony Smith

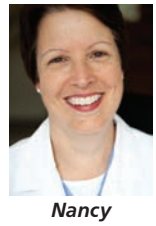
Doctors, nurses and healthcare teams make a pledge to "do no harm" to patients. Whether practicing emergency, surgical or routine care, the goals remain the same – to perform the most effective and safe treatment and improve health, comfort and satisfaction for every patient.

Catheter placement and infusion therapy typically require the use of invasive devices. These, of course, pose health risks in care, including potentially dangerous or deadly infections. The ongoing COVID-19 pandemic also creates additional hurdles in acquiring vital supplies and equipment needed for patients.

So, what kinds of situations may arise when delivering this care? And what are the most useful products and best practices recommended to achieve safe and successful outcomes?

Preventing complications

Education and compliance



Nancy Moureau

Nancy Moureau, RN, PhD, CRNI, CPUI, VA-BC, Chief Executive Officer, PICC Excellence, Inc, Hartwell, GA, USA, first points to considerable intravenous (IV) device use and issues during care in COVID-19 times.

"COVID-19 has increased the number of intravenous devices used during this pandemic surge," Moureau indicated. "The increasing need for intravenous device insertions and crisis management has negatively affected outcomes and the ability to purchase better products or apply performance improvement initiatives. Overall, we have seen an increase in device-related complications as a result of COVID-19."

Other circumstances, Moreau observes, are patient choices around treatment and the risk of COVID-19 infection.

"Patients have all been scared, especially those with chronic or genetic disorders, while receiving treatment in or out of the hospital," she explained. "Two patients of mine receive long-term intravenous treatments and are at higher risk for COVID-19. One of these patients is very careful and compliant with distancing and day-to-day activities resulting in more stability, while the other is noncompliant. The noncompliant patient has experienced multiple hospitalizations and is exposed to greater risk to his health status. Using all the best products to ensure safety and positive outcomes still requires constant education of the patient and caregivers with a goal of optimal health."

Staff should receive adequate education on tools and processes in order to benefit care and patients, Moreau continues.

"We know from the published research that using reflux-limiting needleless connectors reduces catheter failure and other complications," she noted. "Education focused on using effective flushing techniques and correct clamping sequences for needleless connectors helps to minimize thrombotic occlusions, but what we have found is that education does not reach everyone and needs to be reinforced over and over. As technology increases in healthcare, it is necessary to provide evidence-based education to clinicians on how to safely and efficiently perform management and care of devices used for treatment."

Specialty teams and technology

At Hartford Hospital, part of the Hartford Healthcare system in Hartford, CT, they concentrate on techniques that help lower the risk of complications, maintain devices, and manage costs in care, expresses Lee Steere, RN, CRNI, VA-BC, Unit Leader IV Therapy Services.

"Our goal is to increase first-time insertion success and reduce preventable complications in order to make vascular access devices last longer," Steere said. "Part of this involves centralizing IV therapy services – including catheter selection, insertion and management – within a vascular access specialty team (VAST) of experts. As a result, we have decreased our catheter consumption, which can help avoid any sourcing or supply issues that may arise. In addition, our experience has shown this approach can increase patient satisfaction, improve clinical outcomes and reduce costs associated with infusion therapy."

One problem that can occur and be prevented is a catheter occlusion, addresses Steere.

"Catheter occlusions are a frequent complication when it comes to central vascular access devices (CVADs), which unfortunately can lead to delays in therapy and a possible need for line replacement," he added. "More recently, there has been an identified correlation between patients who receive alteplase for intraluminal blood occlusions and development of central line-associated bloodstream infections (CLABSIs). We use the Nexus TKO-6P anti-reflux technology, which helped us reduce CVAD occlusions by 69 percent – a reduction we've been able to maintain for five years. In addition, by using the needleless connector as part of our evidence-based technology bundle for peripheral IV catheter (PIVC) insertions, we managed to reduce PIV occlusions to zero."

Both technology and practices have improved the hospital's care and bottom line, continues Steere.

"A study of this model found higher IV success rates, longer dwell times and fewer complications, which translated to an 80 percent reduction in catheter consumption and a projected annual savings of $2.9 million," he indicated.[1] "For CVADs, the

Nexus TKO-6P anti-reflux technology used by Hartford Hospital

Page 24

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References: 1. PDI *in vivo* Study PDI-0113-CTEV01
2. PDI user acceptance study *Surgical site infections
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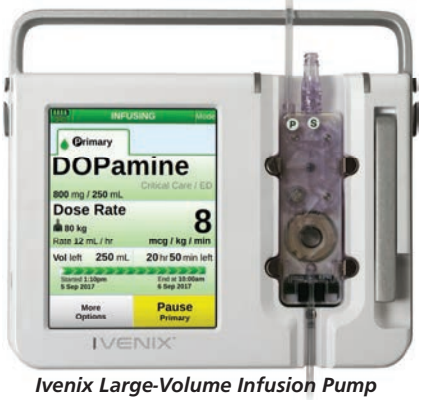
anti-reflux device helped reduce occlusions by 69 percent, while also lowering needleless connector consumption by 51 percent. Overall, we estimate an annual savings of more than $250,000 by reducing occlusions and CLABSIs, as well as the use of alteplase, heparin and other supplies." [2]

Device maintenance and disinfection

Another focus for hospitals and healthcare facilities is keeping medical supplies and equipment in working order, clean and sterilized for use on patients.

"Even before COVID, today's infusion pump market was already strained due to FDA recalls and warnings for hardware and software errors, cybersecurity gaps, and issues relating to more stringent cleaning practices," emphasized Susan Niemeier, MHA, BSN, RN, Chief Nursing Officer, Ivenix, Inc., North Andover, MA. "The pandemic also has emphasized an important element of medical device products: the materials in which the devices are made of matters. To prevent infection, devices that withstand frequent, harsh chemicals used to disinfect between patients are key. Devices with ingress protection and few crevices to trap contaminants are equally important to prevent transmission of infectious pathogens."



Ivenix Large-Volume Infusion Pump

Michele Padovan, Clinical Nurse Specialist, Angelini Pharma, Inc., Rockville, MD, addresses the importance of catheter disinfection with dialysis treatment.

"Tunneled, central venous catheters are meant for long-term use in the hemodialysis patient (months to years), making them high-risk implantable items in an immune-suppressed patient," Padovan stressed. "It is critical that the catheter is accessed aseptically for dialysis and that the exit site is kept clean and dry. For some dialysis patients, this CVC will remain their sole access for treatment if they have exhausted all peripheral means for phlebotomy. Alcavis 50 is a high-level disinfectant with a broad and rapid kill and ExSept Plus is an isotonic catheter exit site cleanser; both products are safe and effective

Alcavis 50 and ExSept Plus from Angelini Pharma

with a long history of use on catheters. The Alcavis Bleach Wipes are chlorine-based surface disinfectants in three dilutions for a variety of hard surfaces, including infusion pumps and poles."

Further, the company provides cleaning and sanitizing products for other items in healthcare environments, expresses Padovan.

"Over the past eight months, Angelini Pharma has seen a remarkable increased interest from customers requesting products that facilitate antisepsis and disinfection in their facilities," she continued. "This includes products for catheters, skin, hands and surfaces. A dialysis facility relayed to us that the addition of the Alcavis Bleach Wipes to disinfect frequently touched surfaces, such as countertops, waiting room furniture, and doorknobs, has given their patients a sense of comfort while they are in the facility. The nurse stated that her patients are less concerned coming in for their treatments, seeing that staff have implemented this procedure with regularity."

Protecting patients and staff

Rapid care

Controlling the transmission of COVID-19 among patients, staff and visitors remains top of mind in medical settings. The crisis, however, has taken a major toll on necessary medical and personal protective equipment (PPE) items, emphasizes Karoline Draper, RN, MSN, VA-BC, Smiths Medical, Minneapolis, MN.

"Our healthcare customers are currently struggling under the weight of extremely sick and contagious patients," Draper shared. "They are overwhelmed and under financial strain, making it more difficult to allocate resources to much needed supplies."

The company's POWERWAND family of products offers up to 90 percent completion of therapy for medication delivery, diagnostics and blood sampling, resulting in more efficient care [3], notes Draper.

"We have seen a lack of PPE for healthcare workers during COVID-19," Draper said. "To keep nurses safe and prevent spread, clinicians are leaning on products like our POWERWAND midlines and extended dwell catheters to decrease utilization of PPE, by helping achieve one-stick hospitalization, and less time spent in COVID-19 rooms. [3-4] The POWERWAND midline catheters can be placed in patients upon admission to the hospital and/or COVID-19-specific units. This practice has been implemented in facilities with the intent to decrease delays of care, improve patient outcomes, [4] protect staff from unnecessary exposure with restarts [1] and reduce PPE usage."

Managing supplies and care

Increased inventory needs

As the COVID-19 global public health emergency carries on, so does the pressure on healthcare supply chain and critical care operations, observes Matthew Hutchings, VP Global Marketing and Innovation, Infusion Systems, ICU Medical, San Clemente, CA.

"Hospitals around the world have not only experienced unprecedented surges of critically ill COVID-19 patients, but this uncertainty and variability in patient volumes have also put significant stress on the healthcare supply network," Hutchings addressed. "At the onset of the pandemic, a rapid increase in patient volumes, coupled with the stockpiling of essential infusion consumables, created back orders and supply shortages — from PPE to core infusion sets and infusion pumps. In contrast, the volumes of elective surgeries are still far below pre-pandemic levels, placing additional financial burdens on hospitals and healthcare facilities."

The change in seasons and viruses, Hutchings indicates, will heighten tension on healthcare systems, supply availability, and capacity for treatment.

"The fall and winter months are traditionally very busy for healthcare suppliers, as hospitals and healthcare facilities stock up on essential supplies for treating seasonal flu patients," he emphasized. "As COVID-19 continues to draw much of the supply from

ICU Medical's Human Connections IV pump

Page 26

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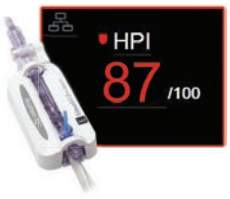

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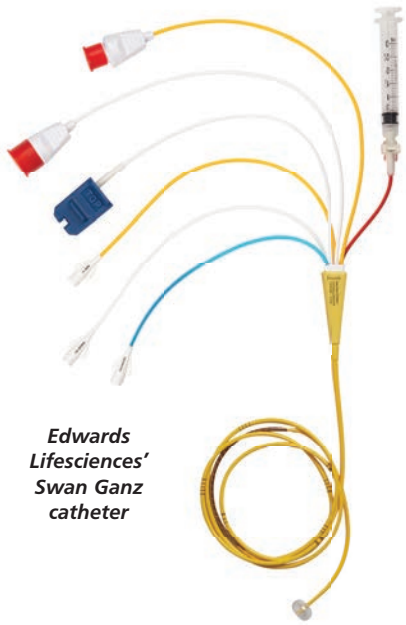
the healthcare supply chain network, already-stretched manufacturers may face additional challenges. It's clear that healthcare suppliers will continue to fare differently as those that built additional supply early on may have an advantage in maintaining a consistent, reliable supply of essential infusion products to help healthcare providers weather this evolving storm. Also, the increased pressure to stockpile supplies has left many with limited space. As a result, many now rely on manufacturers and vendors, like ICU Medical, to be more of a warehouse, supplying them timely as massive spikes in COVID-19 patients increase demand."

Katie Syzman, Corporate Vice President, Critical Care, Edwards Lifesciences, Irvine, CA, suggests that medical manufacturers must shift production accordingly in order to meet needs during the continuing crisis.

"Early in the COVID-19 pandemic, our manufacturing sites were operating with 20 percent less employees while demand increased significantly," she said. "At the same time, the resources of even the most well-funded hospitals were, and still are, being strained as a result of the pandemic, limiting capital spending for the ICU. And, as the COVID case numbers go in 'waves,' so does a hospital's ability to perform non-emergent procedures and the demand for the products needed to support them. It's important for manufacturers to have a strong supply chain and field team that is flexible enough to support these rapidly changing needs."

For example, Syzman, added, "We saw that the COVID-19 pandemic caused hospitals to expand ICUs, which in turn created a high demand for critical care equipment, including products such as our HemoSphere advanced hemodynamic monitor, Swan Ganz catheter, pressure transducers, etc. In a normal year, according to the CDC, the flu season alone can impact up to 11 percent of the U.S. population. As hospitals work to treat patients with these two diseases, which both impact the respiratory system, we may see an even higher need for medical technologies. This could lead to hospitals being once again overwhelmed and having to manage ICU space to care for critically ill patients."



Edwards Lifesciences' Swan Ganz catheter

AI and data

Technology, like artificial intelligence (AI), may become a greater resource in care, observes Syzman.

"AI has been a buzzword for a while now, but I think we're really starting to see some technologies come to market that are using AI wisely in a way that rapidly analyzes a lot of data to quickly give clinicians valuable information," she explained. "A big focus for us is advancing our hemodynamic monitoring platforms with predictive software, and we are also evolving these systems to support remote monitoring, giving clinicians even more access to patient data beyond the bedside. The move to less-invasive and noninvasive devices is another area that isn't new, but the need is heightened by COVID-19."

Adapting processes, settings

Versatile care

As intensive care has risen during the COVID-19 pandemic, many hospitals have reallocated supplies and adjusted protocols and practices, addresses Niemeier.

"One such practice change was to move infusion pumps away from the bedside and into the hallway, enabling clinicians to limit contact frequency and conserve critical PPE while treating COVID patients," she indicated. "This also allows clinicians to easily manage multiple IV lines and infusions, especially those that contain life-sustaining medications for which even a brief pause in delivery could be tragic. To increase the length of IV tubing, multiple extra-long extension sets are connected together to reach the patient, which has resulted in skyrocketing demand for extension sets for this modified workflow. In addition, the increased demand for additional IV accessories – fluids and dedicated IV tubing, for example – has also increased."

She points to several examples of what has been valuable for safe and effective care in this era, including:

- Accurate infusion drug delivery under changing clinical conditions – regardless of extension sets, position to the pump-to-patient, and viscosity of the medication;
- Remote clinical viewers that allow clinicians to see their patient's status, if alarm conditions exist, and help ensure life-sustaining infusions are not interrupted due to a low IV bag;
- The latest drug library updates – automatically delivered within minutes and without disruption to care; and
- The availability of clinical resources and educational materials on the pump, reinforcing COVID safety guidelines and drug regimens, reducing confusion and providing safer care.

With regard to patient procedures, various supplies, equipment and modes may be used to support safety and infection prevention, explains Harrison Richards, Director of Marketing, IV Consumables, ICU Medical, San Clemente, CA.

"One option is using gravity IV sets with integrated manual flow controller devices," Richards expressed. "These devices allow healthcare providers to administer medications safely when access to IV pumps may be limited. While IV therapy is essential to COVID-19 patient care, accessing these patients' bloodstreams may increase infection risk. Consequently, minimizing entry points for bacteria with needlefree connectors, such as our Clave needlefree IV connector technology, can be an essential to helping reduce the risk of bloodstream infections. Additionally, the FDA recently authorized monoclonal antibody treatments for emergency use to treat mild-to-moderate COVID-19 in adult and pediatric patients. The recommendation is to administer these treatments through polyvinyl chloride (PVC) infusion sets containing 0.20/0.22 micron in-line polyethersulfone (PES) filters." [5-6]

Virtual training

Going virtual has become an essential part of healthcare and manufacturing training and business during the crisis.

"We are adapting product training and education to a virtual environment, which has become crucial for our customers in today's healthcare setting," Draper shared.

Online platforms can help improve time and efficiency in service, addresses Niemeier.

"From a vendor's perspective, we are changing the way we market and deploy our products," she explained. "In one recent experience, we virtualized our whole model of implementation. Our project kick-offs, design and build sessions for the infusion management system, the drug library and configurations, and testing were all done via a virtual conference platform. We utilized computer-based training to replace the majority of what is done in a classroom and were able to reduce the amount of on-site time to less than 10 percent." HPN

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LEARNING OBJECTIVES

1. *List the standards and guidance documents for container care*
2. *Explain the importance of cleaning and decontaminating rigid containers after every use*
3. *Describe the rigid container quality inspection process*

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SELF-STUDY SERIES

Are you reprocessing your instrument containers correctly?

by Pamela Carter

While conducting a processing assessment at a healthcare facility, I noticed a steady flow of OR personnel arriving with used rigid containers. Instead of placing them in the queue for cleaning, they inverted the containers, smacked their sides, wiped them with a dry towel and placed new filters in them. After this process, the containers and their lids were stacked on a wire shelf in the assembly area. The SPD technician then retrieved these rigid containers to place newly cleaned instruments for sterilization in them.

When asked about the process, the technician stated, "If the container leaves the surgical suite before the patient comes into the suite, we don't send the containment devices back to the SPD decontamination area for cleaning. Instead, we bring the containers directly to the clean side for instrumentation assembly and packaging. We don't have the time or space to clean them and they're not dirty anyway. We have been handling our containers this way for years!"

Stunned, I turned to the sterile processing manager, who immediately recognized the problem and knew corrective action was required to achieve best practices. Not only were the containers' instructions for use (IFU) not being followed, but it was clear that staff didn't realize they were jeopardizing patients, colleagues and the facility.

Why clean all containers every time?

Container systems, which are medical devices, protect instrumentation during and after sterilization. In the course of their use, containers may be exposed to environmental and procedural contamination. Without proper cleaning and decontamination, those contaminants can be passed on to sterile processing staff who work with the containers, potentially causing injury or illness.

Those same residual contaminants could contact instruments and shield microbes from the disinfection or sterilization process. This could result in patient exposure in the OR, which could lead to an infection. In addition, residual procedural chemicals or disinfectants transferred to instruments can injure patient tissue during the procedure, which can complicate recovery and, in some cases, cause permanent disabilities like blindness.

Injuring patients and staff can have large ramifications for the facility. For example, in addition to the personal consequences to patients and staff, both the facility and the patient can incur increased costs due to required additional treatment. Facility reputations can also suffer, which can reduce the number of elective patients and ultimately reduce revenue. Ultimately, the failure to properly follow the IFU can lead to accreditation citings and the potential of losing reimbursement status.

Instrument containers serve a critical function in the surgical department. Staff must take the time needed to properly care for them.

Guidance for manufacturers

A number of organizations provide guidance to packaging manufacturers and to users. The sources most commonly used in the U.S. are the Association for the Advancement of Medical Instrumentation (AAMI), Association of peri-Operative Registered Nurses (AORN), and International Association of Healthcare Central Service Materiel Management (IAHCSMM).

There are several different types of packaging used to maintain the integrity of sterilized medical devices. These include peel pouches, woven fabric (muslin, which is rarely used now), non-woven disposable wrap, and rigid containers. Packaging manufacturers must validate that the packaging/containers they offer ensure sterilant penetration into the contained medical devices, and that they prevent ingress of microbial contaminants and maintain instrument sterility throughout handling, storage, transport and aseptic presentation in the OR.

Manufacturers of rigid container systems turn for guidance to ANSI/AAMI ST77 *Containment devices for reusable medical device sterilization*. ST77 covers minimum labeling and performance requirements for rigid sterilization container systems and for instrument organizers. Rigid container manufacturers are responsible for providing thorough IFU that include safety and effective use, routine maintenance and inspections, generalized information on their medical device validation testing, weight limitations and design characteristics, and the proper cleaning and decontamination modalities to use. For example, *Section 4.3.2 – Decontamination* states that containment devices and their reusable accessories need to be properly cleaned and decontaminated after each use via manual or automated processes per the manufacturer's IFU. *Section 4.5.2 – Instructions for use* discusses several components needed by the end users to assist with the use of the manufacturer's containment devices.

Guidance for container users

Users of rigid sterilization container systems typically defer to the appropriate guidance document for each sterilization method used at the facility. These include:

- ANSI/AAMI ST79: 2017. Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.
- ANSI/AAMI ST41: 2008/(R)2012 Ethylene oxide sterilization in healthcare facilities: safety and effectiveness.
- ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in healthcare facilities
- AORN Guideline: Packaging Systems

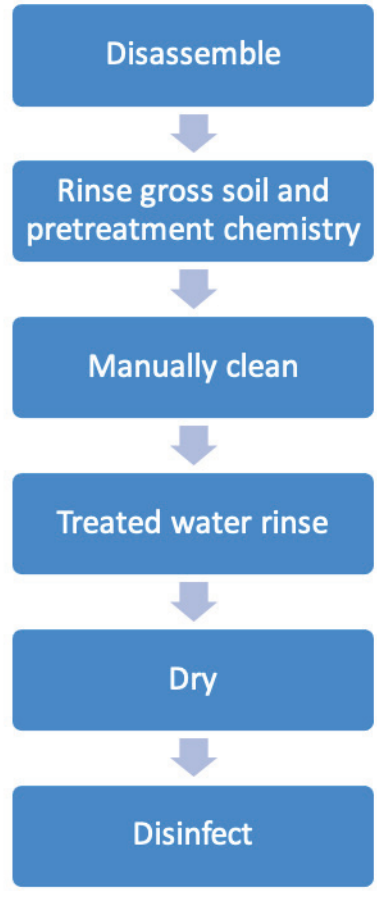
These guidance documents help SPD managers establish standard policies and procedures for workflow instructions in their departments. The container manufacturers' IFU also play a vital role in establishing care and use instructions. Before purchasing a new container system, sterile processing management should conduct a pre-purchase evaluation and request written manufacturer's IFU to ensure that their department can follow the validated cleaning and decontamination steps required for that containment system. The validated method of cleaning containers can be very detailed and can include the required cleaning agent, manual cleaning steps, mechanical cleaning steps, and disinfection process to use before loading instrument sets for sterilization.

Both AAMI and AORN state that containers should be cleaned and disinfected as soon as possible after each use. They also advise to:

a. Follow the manufacturer's written IFU
b. Include instructions for manual cleaning, mechanical cleaning or both
c. Use cleaning agents that don't damage the container or its components (seals, filter retention plates)
d. Follow accepted practices for decontamination and employee safety, including wearing of PPE

Cleaning and decontamination processes

Container systems follow the same cleaning and disinfection processes as other reusable medical devices. First, used containers must be disassembled, and all disposable components discarded. External process indicators and locks, single-use filters and retention plates, silicone mats and liners are removed, and accessory devices are disassembled per IFU.



Next, all surfaces and accessories must be thoroughly pre-cleaned using a proper brush or sponge as directed by the container manufacturer. Remove and rinse out any excess debris, soil, and pretreatment cleaning product with the sponge or brush before the manual or mechanical cleaning process.

Manual cleaning may involve several steps, and every step must be completed. The cleaning methods and chemistries must be compatible with the rigid container system. Abrasive cleaning agents can cause corrosion or damage external surfaces of the container, which could cause cracking or degradation. For aluminum and plastic containers, a neutral pH detergent is often recommended to avoid the adverse effects of harsher chemistries.

Following manual cleaning, all components of the container system must be rinsed with critical water to remove detergent and soil residuals. After rinsing, they are dried with a soft, clean, lint-free cloth. If any residual soils or cleaning chemistry are found during visual inspection, the cleaning process must be repeated.

The disinfection step is necessary to make the containers safe to handle. To assure an effective process, it's important to use compatible disinfectants formulated specifically for disinfecting medical devices and thoroughly removing cleaning chemistries.

Automated cleaning

Container cleaning can also be automated. Mechanical cleaning equipment cleans, rinses and thermally disinfects the containers. When using mechanical equipment to clean containers, end users must follow the system's IFU and must use the required washer accessories to avoid negative outcomes or a lapse in the processing cycle. It's also important to note that even if an automated process is being used, containers must still be disassembled and rinsed thoroughly per container IFU before they are placed in the automated system for processing. It may also be necessary to perform some manual pre-cleaning.

When loading containers into a washer-disinfector, it's important to use the racks and other accessories designed specifically for processing containers in that system. Special racks are often needed to assure thorough cleaning of container systems and their accessories. Some washer-disinfectors use a single rack or basket, while others can have multiple shelves or baskets. Knowing how to load a rack is essential. Detergent can only clean what it reaches. Shadowing, stacking and other improper loading techniques block proper distribution of water and cleaning chemistries within the equipment, which prevents cleaning and thorough rinsing.

Automated systems often have impingement technology that disperses water and cleaning chemistries to all surfaces of the containers. Spray arms and nozzles

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

Page 30

increase the water pressure to apply force that dislodges residual soils. The programmed cycle used for containers is typically labeled "container" or "utensil," but may vary depending on the equipment's cycle names.

Cart washers come in an array of sizes to accommodate the needs of various sized facilities, from small ambulatory surgery centers to large hospitals. Using a cart washer to reprocess containers enables the department to improve its reprocessing workflows by not tying up smaller washer disinfectors with bulky containers. This frees up the washer disinfectors to be used for medical device sets and surgical accessories, which assures greater efficiency and throughput overall.

Quality inspections

Inspecting rigid containers after cleaning and disinfection is as important as the cleaning itself. Inspection checks for residual soils and cleaning chemistry, wear and tear, and mechanical disfunction that could potentially interfere with sterilization or could fail to maintain sterility of the contents. If inspection identifies damaged containers or accessories, they need to be repaired or replaced. Items to inspect include (but are not limited to) gaskets, valves, interior baskets, mating surfaces, reusable filters, filter retainers and latches. Damaged containers and accessories must be removed from the use inventory and the manufacturer needs to be consulted.

As part of a thorough quality system for containers, a routine preventive maintenance schedule should be established and documented; this assures that tools are in place to detect and/or avoid potential problems. Containers are not meant to last forever, so the container vendor can provide information about the expected useful life of each type of container. The department or purchasing manager should then budget accordingly for timely replacement of compromised or aging rigid containers.

Automated Equipment Items to Know

- Maximum load weights
- Dissasembly and loading instructions
- Openings face down
- Place lids and retainer plates in loading slots
- Correct cycle choice

Space constraints

Regulatory inspectors will not allow space constraints as an excuse for skipping reprocessing steps or not fully following manufacturers' IFU. They will expect departments to maximize the space they have by performing proper planning that includes workflow, case demands and calculated expected throughputs. It's worthwhile to consider automating the container cleaning process. Automation allows consistent proper practice while freeing staff to focus on case sets and other instrumentation.

Tight reprocessing spaces, like those in ambulatory surgical centers, require equipment with small footprints. In addition to the washer, it's important to have the correct number and types of racks needed to process the containers in use at the facility. Depending on the case load, it may also be wise to invest in a small cart washer, which would allow the washer disinfector to be dedicated to instrumentation and the larger cart washer to case carts. This would enable a better use of space and equipment, and would support a continuous, more efficient workflow and throughput for both instruments and container systems.

Avoid container woes

No one wants to be the person standing in front of the auditor explaining why containers are not being properly processed. Rigid sterilization container systems are Class II medical devices and are cleared by the U.S. Food and Drug Administration (FDA) for use. Per FDA and other regulatory guidance, facilities must adhere to the container manufacturers' IFU, which provide all the necessary information for correct use, care, cleaning, inspections, routine maintenance, sterilization methods, and storage. Facilities must develop policies and a standardized workflow that support these instructions, and confirm staff competency through training, education and regular evaluation of staff performance. Be the one who finds and corrects any problems in container processing, before the auditor does. HPN

Container System Inspection Item Examples	
GASKET	• No fraying, cuts or missing pieces
BASKET	• Broken or missing handles • Sharp edges or broken wires
MATING SURFACES	• No dents, chips, cracks • Filter retainer fits with no gaps
REUSABLE FILTERS	• Within its use limit
LATCHES	• No missing components • Securely attached • Lid secures with even latch pressure

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CONTINUING EDUCATION TEST • JANUARY 2021

Are you reprocessing your instrument containers correctly?

Circle the one correct answer:

1. **Which is a quality standard that provides guidance to manufacturers for rigid container systems?**
   A. ANSI/AAMI ST79
   B. ANSI/AAMI ST58
   C. ANSI/AAMI ST77
   D. SGNA
2. **Which is a quality standard that provides guidance for users of rigid container systems?**
   A. ANSI/AAMI ST91
   B. ANSI/AAMI TIR31
   C. ANSI/AAMI ST90
   D. ANSI/AAMI ST79
3. **Which is a method used to clean containers?**
   A. Mechanical cleaning equipment
   B. Paper towels
   C. Metal brush
   D. Detergent
4. **Why do all containers need to be cleaned?**
   A. Container manufacturer requirement
   B. Standards and guidance requirement
   C. Contamination can occur at any time
   D. All of the above
5. **What is removed from containers during the initial rinse?**
   A. Gross soil and residual pretreatment chemistry
   B. Bioburden and cleaning chemistries
   C. Saline and disinfectants
   D. Bone cement and sterilants
6. **Improper container loading techniques can:**
   A. Block proper distribution of water and cleaning chemistries
   B. Enhance cleaning
   C. Impede thorough rinsing
   D. a and c
7. **Cart washers cannot clean and thermally disinfect containers.**
   A. True
   B. False
8. **Using a cart washer to reprocess containers enables a department to:**
   A. Eliminate the need for thermal disinfection
   B. Allow smaller washer disinfectors to be used specifically for surgical instruments
   C. Help achieve greater efficiency and throughput for containers and instruments
   D. b and c
9. **Why is inspection important?**
   A. It finds residual soils
   B. It identifies containers needing repair or replacement
   C. It discovers mechanical disfunction that could potentially interfere with sterilization
   D. All of the above
10. **Rigid sterilization container systems are Class II medical devices cleared by the FDA for use, so facilities must adhere to the container manufacturers' IFU.**
    A. True
    B. False

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Assess and assure quality in every step of sterilization process

by Kara Nadeau

Maintaining a high level of quality in a healthcare setting is always a challenge given the many factors that can disrupt standard processes and sometime require staff members to divert from established protocols. While nobody wants to admit it, an emergency case might require operating room (OR) and central sterile/sterile processing department (CS/SPD) staff members to streamline processes in order to provide immediate care to the patient on the table.

This has been especially true during the COVID-19 pandemic, where a sudden surge in SARS-CoV-2 virus cases and depletion of personal protective equipment (PPE) have forced healthcare staff members to engage in practices that would be considered taboo in times of "business as usual." In the CS/SPD, staff have found themselves using equipment normally intended for the reprocessing of surgical instruments to reprocess disposable N95 respiratory masks for reuse.

The pandemic is by no means over, but surgical cases have resumed out of necessity to care for non-virus patients. Healthcare staff members have been challenged with maintaining high quality levels in care delivery during these unprecedented times. In the CS/SPD, some professionals have taken the opportunity to evaluate the processes they have in place for quality and sterility assurance and make improvements to increase efficacy and safety. In many cases, quality/sterility assurance best practices can boost process efficiency as well, enabling the CS/SPD to deliver safer and more effective instruments to customers faster.

The big picture

While improvements to the processes of instrument delivery to the OR, use on the patient, delivery of instruments back to the CS/SPD, and reprocessing of those instruments can make a difference, Barbara Ann Harmer, MHA, BSN, RN, Vice President of Clinical Services, IST, urges healthcare facilities to take a step back, evaluate these processes as a whole and implement an overarching continuous quality improvement program.

Barbara Ann Harmer

"A continuous quality improvement program takes into consideration the entire process pathway, which would include decontamination, cleaning, preparation, packaging, sterilization, quality control (monitors), storage and distribution," said Harmer. "Your organization should be conducting an ongoing risk analysis for all aspects of your processing. The identification of any risk is integral to prevent any risk that could occur to staff or personnel. Risk stratification is integral to the identification of risk areas, quantifying the risk and the identification of any actions that could be taken to prevent or resolve the risk."

Harmer says education and training will assist staff in understanding how to identify a risk, provide a plan, prevent the risk or resolve the risk. Therefore, those conducting the risk assessment should communicate to staff members whether the risk has been prevented or resolved.

"Typically, risk analysis is performed at least annually," said Harmer. "With COVID-19, there was the necessity to look immediately at risks for the department's processing activities. For example, supply chain management issues were overwhelming for CS/SPD; to name a few, the lack of PPE, detergent solutions and wipes, processing supplies; with lockdowns, the inability for service representatives and sales representatives to offer maintenance and information onsite. Staffing is a daily consideration in CS/SPD but inadequate staffing was evidenced by staff or a staff member's family becoming positive and the staff member could not come to work."

An ounce of prevention

Addressing quality issues before they impact care is critical. That's why CS/SPD professionals should take the time to inspect instruments and perform preventative maintenance to avoid issues down the road. But pressures from the OR to turn around sets faster for a growing number of procedures makes it extremely challenging for CS/SPD staff to find the time to perform these proactive tasks.

"Thorough inspection of instruments during tray assembly and careful documentation of instrument set contents are essential for quality tray assembly," said Lawrence Zelner, President, RST Automation. "All too often technicians shortcut the inspection process because of time pressure due to labor shortages and large swings in workload. Missing instruments and incorrect instruments are other problems that result from shortcutting the instrument verification process required by contemporary computerized instrument management systems."

"Increasing complexity of surgical instrumentation, unclear, incomplete or missing instructions for use (IFU), overloaded surgical sets and overburdened SPD staff are just some of the contributing factors that lead to inadequate cleaning and inspection of surgical instruments, resulting in increased bioburden risks," said J Schrader, Marketing Director, SPD Products and Services, Aesculap.

"The COVID-19 pandemic has made it more important than ever to carefully inspect instrumentation for bioburden," Zelner added. "At some hospitals, the pressure of the pandemic has also led to increased labor shortages. Therefore, it is more important than ever before to implement new processes that promote improved quality while assisting technicians to work more efficiently."

"By proactively inspecting these vital tools, customers can greatly decrease their risk of broken/damaged instruments and potentially damaged containers that can lead to compromised sterility issues," said Schrader. "It is imperative that the SPD department partner with a repair vendor who offers training, on-site service and a preventative maintenance plan that focuses on all sets, particularly the high-turn trays."

Manufacturers in the CS/SPD space have introduced new innovations to make it easier for department professionals to perform proactive inspections and preventative maintenance. For example, Aesculap offers Surgical Asset Management programs,

Page 34

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including its QuickScan baseline assessment and Process Ready Analysis. This combines tray utilization data with workflow and process observation to develop solutions that streamline inventory and optimize surgical trays, helping to reduce complexity, assembly and inspection errors, and decreased bioburden and contamination risks.

"These best practices are easy to implement and can save the SPD time and money in the long run," said Schrader. "They can also greatly decrease the risk of sending a set to the OR that has a quality or sterility issue."

To help CS/SPD technicians assemble surgical instrument sets and packages of individual instruments in a safer, more consistent and more efficient manner, RST Automation has developed its Assisted Instrument Management (AIM) line of products. This includes the AIM Tray Assembly solution, which uses machine vision (MV) technology and artificial intelligence (AI) to automatically identify and verify instruments on the count sheet; and the AIM Peel Pack tool, which uses MV technology and AI to automatically generate sterilization pouches and labels simultaneously.

RST Automation AIM Peel Pack tool and AIM Tray Assembly solution

Tracking and reporting errors

Gregg Agoston, M.B.A., Vice President, Business Development, SPD Transformation Services, says his number one recommendation for quality and sterility assurance is to view the CS/SPD as a manufacturing process. This means that quality assurances and quality control measures must be integral to CS/SPD operations. Agoston explains how each CS/SPD must determine an acceptable level of inspections of assembled sets prior to sterilization. The department must also put in place a formal system to track and report on errors discovered.

Gregg Agoston

"Based on assessment findings from hospitals across the country, there is significant need for improvement in QA/QC practices," said Agoston. "The goal should always be that 100 percent of the instruments assembled and sterilized are available when needed, functional and safe to use on the patient. To accomplish 100 percent accuracy on these three critical factors, SPD management must determine the number of inspections that are necessary. These inspections must be conducted by a competent person who was not the person assembling the peel pack or tray. The number of inspected items can change as findings increase/decrease. Findings should be documented so that trends can be identified. Both the SPD and OR must accurately report events for the data to be meaningful. Trend data must then be used as a control tool. Training and process adjustments must be applied to prevent errors from occurring."

Proper protection

Schrader points out the need for hospitals and other healthcare facilities to properly protect their surgical assets during sterilization and transportation to extend instrument life and optimize reprocessing.

"A tray instrument organization system reduces instrument damage and reduces case delays by making it easy to identify missing and/or wrong instruments during preparation," said Schrader. "During surgery, the staff is able to more easily locate the proper instrument. Placing these organized sets in rigid sterile containers helps eliminate case delays related to holes in blue wrap and helps reduce overall sterile packaging processing costs and reprocessing time."

The Aesculap JS Series SterilContainer S2 is U.S. Food and Drug Administration (FDA) cleared for low temperature (STERRAD, STERIS V-PRO, STERIZONE), PreVac Steam and EtO sterilization modalities. It features an anodized finish, and it is easily identified by its gold container handles and lid latches. Aesculap has a wide variety of baskets, racks and Instrument Organization System (IOS) holders to organize and protect instrument sets. It can be used to sterilize pre-configured orthopaedic, spine and specialty medical instrument sets.

Aesculap JS Series SterilContainers

Point of use (POU) cleaning

While quality and sterility assurance of surgical instruments is typically placed in the hands of the CS/SPD, OR staff must also do their part to keep instruments safe and effective. As Ron Banach, Director of Clinical Training for Ruhof Healthcare, explains, point of use (POU) cleaning of instruments and scopes by clinical staff in procedural areas paves the way for effective cleaning and sterilization in the CS/SPD.

"Keeping instruments moist helps prevent soil (e.g., blood, body fluids) from drying and adhering to the instruments," said Banach. "Dried soil can make instruments more difficult to clean and potentially lead to the formation of dry-surface biofilm. Treating instruments with an enzymatic pretreatment at the point of use can help prevent rusting and corrosion; prevent blood, organic materials and debris from drying on the instruments; and inhibit dry-surface biofilm formation."

Ruhof's Prepzyme Forever Wet

Banach says it is recommended that perioperative personnel use enzymatic pre-cleaning humectants and sprays to keep instruments and rigid scopes moist, especially those that sit for extended periods of time. One such enzymatic humectant spray is Ruhof's Prepzyme Forever Wet with moisture retention properties lasting up to 72 hours, making cleaning easier and more effective.

Sterilization success

"With the onset of the COVID 19 pandemic, one of the biggest challenges facing supply chain and SPD professionals was the unpredictable demand for personal protective equipment (PPE), mostly notably the supply of N95s," said Julie Gorog, RN, BSN, CNOR, Clinical Education Consultant/Clinical Trainer, Advanced Sterilization Products. "Due to unpredictability of the impact on hospitalization admissions, healthcare facilities had to temporarily modify some of their practices that were inconsistent with professional standards and guidelines prior to the COVID-19 pandemic."

Gorog points specifically to the FDA's Emergency Use Authorization (EUA) for Sterilization Systems.[1, 2, 3] This is intended for decontamination of compatible N95 respirators for single-user reuse by healthcare personnel in healthcare facilities to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

"This temporary authorization was outside the recommended practices of the

Page 36

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Association of periOperative Registered Nurses' (AORN) guidelines on proper use of surgical N95 respirators in the perioperative setting," Gorog continued. "Hospitals were tasked with developing new protocols that outlined steps to reprocess single use N95s that met the criteria of the FDA, mask manufacturer and sterilization manufacturer authorization."

"As a result of the pandemic, the U.S. Centers for Disease Control and Prevention (CDC) and AORN have developed optimization strategies that provide predictive analytic tools that facilities can use to anticipate their potential supply demands with the evolving pandemic and readily respond to ensure that they can protect both their staff and patients," Gorog added.

Biological indicators

Regarding best practices for quality and sterility assurance, Gorog says one of the most important practices to implement within the CS/SPD is to monitor every load with a biological indicator (BI). She points to a number of industry guidelines in support of this practice.

For example, the CDC states in its Sterilizing Practices chapter, "Biological Indicators are the only process indicators that directly monitor the lethality of a given sterilization process."[1] The AORN 2020 Guidelines on Sterilization[2] and Association for the Advancement of Medical Instrumentation (AAMI) ST 58[3] recommend sterilizer efficacy monitoring, preferably with each load.

"By monitoring every sterilization load, the SPD can ensure sterilization conditions were achieved prior to releasing surgical instruments for use on patients and reduces the recall time needed to identify and recall instrumentation in the event of a positive BI," said Gorog. "As part of a quality management strategy with sterilization monitoring, every load monitoring can identify facility process failures earlier compared to daily monitoring practice."

The human factor

"The number one root cause of errors in SPD is related to the technician(s) who processed the instrument(s)," said Agoston. "Factors such as amount of time, competency, standard work, distractions, motivation, work environment, complexity of the instrument, etc. all enter into the equation and impact the quality of the work. Staff shortages and limited experience exacerbate the problem. In most hospitals 30 to 50 percent of the SPD staff have less than one year experience."

"Automated washers and sterilizers do fail periodically but there are automated verifications and indicators to warn of a problem," Agoston added. "Instruments wear out and fail, and the well trained SPD technician can, through inspection, weed out these before they threaten the patient. But the biggest issue in every OR is quality errors either caused or not discovered by the technicians who processed the instrument. These errors are recorded as a missing instrument, broken instrument, improper packaging and contamination due to a dirty instrument or contaminate in the package."

According to Agoston, staff members working in decontamination play a critical role as they can examine instruments for missing parts and perform quality assurance checks, such as leak testing a flexible endoscope. When a quality issue is discovered, he says it is the technician's obligation to report this information to the OR.

"The physician should be notified when a flexible endoscope is found to leak post use. This knowledge can help the physician effectively monitor or treat the patient to reduce the risk of infection," said Agoston. "Unfortunately, the current practice in most hospitals is to focus on the cleaning process so that the endoscope is not flooded and then to return it for repair. What is lost is the fact that there is a potential that the endoscope was in use when the leak developed. No competent SPD professional would allow it to be used on a patient because a leaking endoscope cannot be effectively sterilized or high level disinfected (HLD)."

Agoston points out that when the CS/SPD does not have adequate quality assurance/quality control (QA/QC) processes in place, the quality burden falls on the OR.

"It is never a good idea to have your nurses and surgeons be your QA person," said Agoston. "This wastes time in the OR and potentially places patients at risk if the errors are not found or if the error is found during use. Having the nurse or surgeon be the QA person is equivalent to a manufacturer of a product having the customer evaluate it for form, fit and function. Many customers would be lost if this was the industry's accepted practice. The QA/ QC process must take place in SPD to prevent wasting time in the OR and increasing risks to patients."

Gaining support for quality/ sterility assurance investments

While CS/SPD professionals want to improve the quality of their processes in order to enhance patient care and safety, many face challenges in securing leadership support for resource allocation to the department. How do you convince the C-suite to make investments in the CS/SPD?

The power of data

"With data," said Eddie Conklin, CRCST, CHL, Central Processing Manager, Peninsula Regional Medical Center, Salisbury, MD. "For requests of full-time employees (FTE), new processes, new equipment and materials, you must provide your data." He offers the following examples:

- **FTEs**: "A FTE request starts with understanding customer service levels: Is the expectation that everything is processed the same day, 24/7/365? Then calculate your demand takt time, resources and workflow."
- **Additional instruments**: "Measure your flips (EZ Passes) and calculate the waste from the OR and central sterile processing (CSP). If you need new containers for ridged scopes, then gather your repair data."

"To queue up your future requests and to gain momentum, show the results to the senior staff again using data," Conklin added. "For example, make the case for new workbenches by explaining to senior staff that this will help reduce cycle times in assembly and enable the movement of third-shift employees to peak times, which in turn provides additional benefits, such as the ability to provide immediate missing instrument information to the OR. I'm sure there are hundreds of examples. By providing data to your senior staff you are providing them a choice and direction to improve and hopefully elevating CSP to become their priority."

Conklin's team at Peninsula Regional earned *Healthcare Purchasing News*' 2013 SPD Department of the Year award.

Communication is critical

Kevin Anderson BSN, RN, CNOR, CSSM, CRCST, CHL, CIS, CER, Clinical Education Coordinator, Healthmark, agrees that using the right data to support resource requests is key to securing leadership buy-in for them. He adds that communication is also critical, stating:

"If you are not getting what you need, then chances are you have to find a better way to communicate. Data certainly speaks to most administrators, but it could also be a story of a near miss that could have been avoided. So the short and simple answer is to communicate whatever is necessary to get what you need, albeit while being ethical and not making things up to manipulate the situation. Hopefully, that part goes without saying." HPN

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IAHCSMM VIEWPOINT

Power of competency checklists for Sterile Processing

by Tony Thurmond, CRCST, CIS, CHL

It's important to assess how competencies are used in the Sterile Processing (SP) profession. Are they viewed as a necessary evil or do SP professionals embrace the opportunities competencies can provide? ANSI/AAMI ST79, Section 4.2.2, states that "the responsibility of sterile processing should be assigned to qualified individuals who have demonstrated competence in all aspects of sterile processing."

Document learned skills

Qualifications of SP professionals include demonstrated knowledge of and documented competencies in the tasks they perform as well as working knowledge of the SP environment. "Documented" is an important distinction because if it is not documented, there is no evidence that proper training and demonstration of that training occurred. Undoubtedly, surveyors will ask to see the orientation checklist for an employee as well as further documented competencies for each employee.

A competency checklist must be developed and maintained in each of the following SP areas:

1. **Decontamination:** Competency must be shown in sorting, disassembling/reassembling, manual and mechanical cleaning methods, microbicidal processes, equipment operation, standard- and transmission-based precautions, and engineering and work practice controls.
2. **Instrumentation:** SP professionals must know the names and descriptions of instrumentation, and the inspection points of each instrument. Other competencies include proper preparation and packaging methods for sterilization.
3. **Sterilization/High-level disinfection (HLD):** Competencies should cover all sterilization practices and principles, including steam, low temperature, ethylene oxide, and HLD processes.
4. **Worker safety and environmental safety:** SP professionals should be able to demonstrate how to properly handle emergent situations, environmental hazards and other patient safety scenarios.

More competencies can be developed for specific equipment and instrumentation and can include proper cleaning techniques, sterilization and maintenance of each. It's important to recognize that a completed competency does not ensure a technician is competent. The proper skills learned and used effectively in day-to-day operations are what make for a competent technician. During the competency review, some technicians may correctly demonstrate how to perform a task, but then return to their bad habits after the review.

Start with new employees

Competency checklists may vary for each department and equipment. Department design will dictate processes and workflow necessary for competencies to be completed. An orientation checklist, used for new hires in the department, should come first. The new employee should work with a competent technician who is willing to train and has the necessary skills to properly onboard the new team member. The orientation checklist is typically completed after 90 days of employment to help verify the skills learned.

If the employee has demonstrated they have retained the training information provided and demonstrates a willingness to continue building upon their skills, this should be documented during the 90-day period. If areas of weakness or areas where the information was not retained are noted, the supervisor should review the training process. The supervisor may need to review the preceptor or trainer to determine whether the proper information was given and whether there is an area in the training process that could use some improvement.

If no areas of improvement are needed in the training process and the preceptor is providing proper, effective training, it must then be determined whether the new hire can be successfully trained and prepared for their role. Every employee learns at their own pace, but they must demonstrate the desire to learn and do their best if they are to move past their 90-day review and continue to grow in the role. It is recommended that the employee both verbalize and demonstrate the task(s) being evaluated. Upon completion of the onboarding process and 90-day review, if the employee fails to grasp the information and shows little sign of succeeding in the role, it is best to reconsider their employment.

Review and repeat

An effective competency checklist is thorough and written in the order of the process or workflow of the desired skill being reviewed. Each item to be reviewed must be well understood and/or demonstrated. The checklist should indicate whether the demonstration is verbal or physically carried out, and the task must be marked as satisfactory or unsatisfactory (with each task initialed by the person reviewing it). Competency checklists should also include an area for comments that can highlight suggested training or positive feedback for employees who demonstrated aptitude with a particular task. Competency reviews of each technician must be reviewed by a competent technician, educator or manager who also has demonstrated working knowledge and expertise of the area being reviewed/assessed. The checklist must be signed by both the evaluator and the individual being evaluated. After the review, the competency must be placed in the employee's file where it can be accessed for review as needed.

At minimum, the checklists should be reviewed every six months to determine areas in need of improvement, and managers should ensure the checklist is current and factors in any equipment changes or standards updates that could impact current practices. Actual completion of competency checklists should be done at least once a year (more often if a process is complex). If an increase in errors occurs, it is prudent to perform a competency and checklist review to help identify areas in need of attention. *Note: Competency checklists may be developed from instructions for use of SP-related products or equipment, or from published standards such as those from the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN) and others. IAHCSMM provides some examples of competency checklists for its members on its website that can be tailored to individual SP departments. Visit: https://www.iahcsmm.org/resource-documents/cs-sample-documents.html.* HPN

Competency checklists and reviews provide opportunities for improvement within the department and can help standardize how tasks and processes are performed – both of which can spur performance improvement and error reduction that benefits the department, its customers and, most importantly, the patients.

Tony Thurmond, CRCST, CIS, CHL, is IAHCSMM's immediate Past-President and serves as Central Service Manager for Dayton Children's Hospital.

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Erasing instrument errors

by Stephen M. Kovach

From the Author: *As this is my first column, I would like to thank my friend and mentor, Ray Taurasi, and HPN for allowing me to carry the torch of answering your questions. Ray wrote this column for 19 years, and I will do my best to follow in his footsteps to bring you evidence-based answers that are clinically relevant. We know that many of the processes we perform are "sacred cows" that have been passed down to us and therefore, we may not have data or information to back up the practice. I will do my best to answer your questions, never-the-less.*

Q I saw an employee use an eraser on an instrument. Why would they have one at their workstation?

A Your question has taken me back to the start of my career in healthcare in 1975 as a sterilization orderly. When I was inspecting and assembling floor trays between sterilization cycles, if I saw a certain color, spot, or stain on the instrument, I would use an eraser to check it out. But why was I allowed to use an eraser? My manager shared that staff think surgical instruments do not "stain" because the instruments are made from stainless steel, but stainless steel is only corrosion resistant. It can still rust or stain if handled improperly.

We were taught that if we saw a brown-orange discoloration, we could check to see if it was rust by using a standard pencil eraser. We would rub the eraser on the stain/spot and take note of what we saw[1] (see Fig. 1 & 2). If the discoloration was removed and the metal underneath shined with a smooth, clean look, the mark was not corrosion/rust. If a pit mark appeared under the discoloration, the spot/stain was corrosion/rust and needed to be pulled from usage and sent out for repair.

Using an eraser is a time-proven test. In the American V. Mueller Care and Handling of Surgical Instruments, it is stated that a simple and easy way to test for corrosion on an instrument is to take an ordinary rubber eraser and try to erase the spot or stain.[2] In the book "The Basics of Sterile Processing," they remind staff when using a pencil eraser, it is important to wash the instrument afterwards to remove eraser marks and residues.[3]

The practice of using an eraser on stainless steel is not a new idea. Wm. H. Kellogg noted (1907) that a very convenient way of removing rust and brightening surfaces of tools, such as steel, brass, or silver, is to rub the surface with a common ink eraser. It does not scratch the surface as emery cloth does, and it is always available.

But is using an eraser a verifiable process in your workplace today? My answer is yes, based on the information I have just shared. You need to work with your management team to put in place a practice guideline to check instruments, including stains/spots, addressing the various ways you check instruments when these stains are present. One way may be using an eraser. Other ways might be using products that detect protein, or hemoglobin, or using enhanced visual inspection.

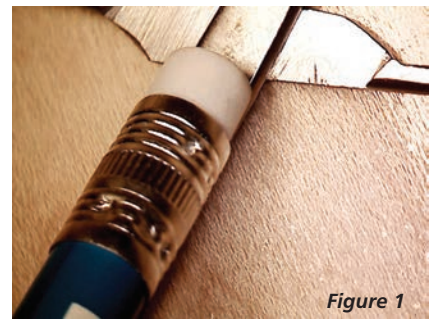

Figure 1

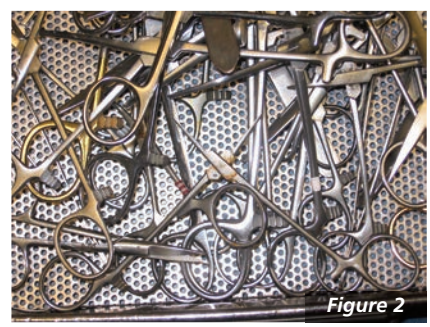

Figure 2

I cannot complete this response without addressing some basic facts about corrosion/rust on instruments. According to AKI Red Book, rust is defined as the product of corrosion on iron, steel, and steel alloys as a result of oxidation, a reaction with oxygen in an atmosphere containing water.[4] Finding the source of rust on your instruments is paramount for every medical device reprocessing department. Surgical instruments are a major asset for every facility, and it is, therefore, important to ensure they last a long time.

My general suggestions are to work with your instrument manufacturer and repair company to review data on how many instruments could not be repaired because of rust/corrosion concerns. Then, use that data to explore potential causes, starting with the list of issues that can cause corrosion/rusting of your instruments. The list of causes below will get you started in solving this concern.

- Sterilizing instruments of different metals in the same cycle will cause rusting. An electrolytic action carries the carbon particles from the exposed metal and deposits them on the stainless-steel instruments.[5]
- Exposure of instruments for a prolonged time to saline solution or blood can result in pitting and rusting.[6]
- If any moisture remains on instruments, they may rust in storage.[7]
- Insufficient rinsing of operating room linens after the laundry service has used caustic chemicals. When instruments are wrapped or placed on towels, the chemicals may be absorbed by the instruments.[8]
- Reduction of the passivation layer on instruments by etching of instruments, poor water quality, poor steam quality, or improper cleaning chemistries.[9]
- Excess amounts of iron or other minerals from the local water supply may cause the rust deposits.[10]
- The rust film on the surface of stainless-steel instruments can be caused by chemicals in the detergent.[11]
- Ensuring instruments are dry is important – if water is left on the instruments it can form water spots.[12]

In closing, if you are using an eraser and find rust, you need to start a process to find out why and "erase this concern" before it spreads out of control. HPN

Stephen M. Kovach, BS, CFER, started in the medical field in 1975 as a sterilization orderly and has worked in many positions within the Healthcare Industry. He presently is Clinical Educator Emeritus at Healthmark Industries.

Some say knowledge is power, but I believe real power comes when we share our knowledge with each other. This column is how we will share our knowledge with each other.

Visit https://hpnonline.com/21164222 for references

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Ace in the hole or race to a goal?

Supply Chain ponders the promise, reward from purchased services

by Rick Dana Barlow

Imagine the following scenario: As healthcare continues to navigate, meander and languish through the pandemic, Supply Chain faces C-suite requirements to cut a minimum of 30 percent of its operational costs by mid-year. Squeezing contract pricing won't even put a dent in the hard-dollar savings the team needs to book. Those within the department feel that much of the identifiable fat has been stripped to the bone so that only meat seemingly remains.

Seeing how Surgical Services embraced service line management (SLM) in the previous year, cutting services that either were not profitable or that consumed too many resources, the Supply Chain leader applies the SLM framework to the department's functions and turns to purchased services as a viable option.

The next monumental hurdle? Deciding which functions to flip externally to a contracted third party from having his or her own internal team tackling them.

Regardless of facility type, size or location, Supply Chain leaders may choose from a litany of prospects within their realm alone, hinging on their long-term goals. Supply Chain also may advise the C-suite to consider other areas as well where they may only have dotted-line influence or oversight.

The overarching strategy proffered by purchased services experts? Gather and analyze your data, evaluate third-party references and think holistically rather than incrementally.

Start by asking the right fundamental questions about your organization, according to Blaine Douglas, Managing Principal, Vizient.

"Regardless of a hospital system's size, location and facility type, before tackling new savings initiatives, it is important to delve into your spend analytics, understand your data and prioritize your approach based on what the data is telling you," Douglas indicated. "Where do the opportunities exist? Do you possess the expertise internally to drive satisfactory results or do you need help in certain categories? Are your purchased services contracts procured through a centralized process? Have you leveraged standardization across your system to the extent possible? Have you taken a lean approach to the number of vendors you utilize across a category?"

Blaine Douglas

Then delve a bit more deeply.

"Once meaningful purchasing processes are put in place that leverage best practices and reflect your system's culture, it is time to look deeper into your operation," Douglas continued. "Based on historical success, Vizient has identified some top areas to look into, including food and nutrition services, health care technology management, human resources benefits, pharmacy benefit management and information technology. Typically, these are high-spend areas with a five-percent-to-30-percent savings opportunity within these categories. Any savings strategy developed should align with your system's values and streamlined purchasing process to ensure that captured savings is long-standing."

Taking the plunge

Jeffrey Ashkenase, MPA, Group Vice President, End-to-End Supply Chain, Nexera (a Premier company) asserts that third-party contracts for large operational areas can offer the best possible transparency, cost structure and quality. In fact, the three areas Ashkenase recommends purchased services to "support significant multi-year savings" includes supply chain, environmental and facilities services and information technology (IT).

While he doesn't consider this "true outsourcing," Ashkenase further urges providers to leverage an E-Payables vendor, such as AMEX, for example, to support discounts on vendor purchases, improved cash flow and revenue enhancement on existing volumes.

Jeffrey Ashkenase

"Today, however, we're advising providers to think broadly and holistically review spend categories — employing data-driven technology to benchmark against peers and identify the greatest areas of opportunity," he noted. "By tracking and measuring spend by category, supplier and facility, an integrated spend management platform helps providers overcome the siloed nature of various contract, set and manage specific savings targets and oversee contract compliance once new agreements take effect."

When evaluating purchased services opportunities, providers should concentrate on four key questions, according to Ashkenase.

Is the service "core" to your mission and competitive position?

Can you perform the service at a lower cost and/or higher quality than a third-party vendor?

Can your organization keep up with technical requirements, labor laws, personnel sourcing or operational improvements at the same level as vendors that have potentially larger scale and investments?

What is the opportunity cost of insourcing versus outsourcing? In other words, what else could you be doing with the funds, talent and attention that you are devoting to operating and managing an in-house operation?

Angie Haggard, COO, Ron Denton & Associates LLC (RDA) claims health systems can identify several areas that consistently generate hard-dollar savings, but those areas require collaboration and willingness to challenge the status quo objectively. Granted, savings may not be the overriding goal, she added. "Quality and patient satisfaction scores must also be weighed into the decision to outsource or insource as well as the long-term strategic and community impact," she noted. "Most of the time, the quality and patient satisfaction gain outweigh the benefit of the cost reduction."

Haggard pinpoints four primary targets for purchased service consideration, along with three additional prospects.

- **Dietary/Food:** Most organizations already have this as a purchased service, however, they are not managing the relationship, so there are opportunities for enhancement," she indicated. Utilizing a purchased service for dietary/food will provide a foundation for continual improvement and enhancements in the type of food, food quality and efficient methods for preparing food onsite. It can also provide a revenue generating opportunities via coffee shops on-campus (without the burden of managing the detail daily operations).

Page 44

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- **Environmental Services/Linen:** This is an area that can have a significant impact on an organization's quality and patient satisfaction scores, she noted. Utilizing a purchased service company to manage EVS/linen benefits hospitals with streamlined processes, a consistent training program for its employees and utilization ideas that could financially benefit the hospital.
- **Copiers/Printers:** Utilizing a team of experts that stay up to date on the latest/greatest copier/printer technology can benefit an organization, she insisted. Similar to the other two top categories, this is historically already a purchased service. However, we consistently find that the contract is not managed, nor are there quarterly business reviews conducted with the supplier.
- **IT:** There are multiple categories within this department to evaluate (e.g., hardware, software, telecom, cyber security, etc.). There is so much competition in this field, evaluating providers for various IT services can result in large dollar savings for a health system. In addition, evaluating lease versus buy options for employee laptops/tech is important.
- Freight/Shipping, Invoice Audit Services and Laboratory remain candidates, too, she added.

Two executives at TractManager, which announced in November it was being acquired by symplr, point to three areas that may be low-hanging fruit. They are staffing/recruiting, revenue cycle management and vending services, according to Michael Costantini, Vice President of Sales, and Eric Slimp, Purchased Services Director.

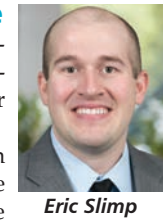
- **Staffing/Recruiting:** Recruiting for healthcare, both clinical and non-clinical requires a degree of expertise and network of connections to properly source and vet qualified candidates, Costantini and Slimp agreed. If you have recruiters on staff, you are likely paying them commissions and salaries, but third-party recruiters commonly work on commissions alone.
- **Revenue Cycle Management (RCM):** Outsourcing some or all the revenue cycle management function almost always results in a savings, they indicated. This can be anything from Billing & Collections to Claims Management or Medical Coding. This is due to the complexity of the billing processes and processes for securing reimbursement that a health system simply cannot staff the expertise required to perform end-to-end RCM processes at scale.
- **Vending Services:** This is one that is often overlooked because it doesn't show up as a high spend, both insist. Why? That is because vending services should be a profit center rather than an expense. Companies like Coca-Cola and Pepsi will pay incentives and commissions to the hospital while providing the products and vending machines at no direct cost to the hospital so that they can secure exclusive rights to sell their products in a health system, they added.

"The typical process for identifying high-impact purchased services involves identifying categories of high spend and forming initiatives around those purchased services," Slimp said. "Although vending is a purchased service, the spend is offset by the revenue that is generated. The vendors charge for the products and services, but they 'credit' the hospital for their commissions on anything they sell. Therefore, it will not show up as a high-spend category even if it is an area of opportunity."

Michael Costantini

Expanding the base

But Costantini acknowledges Supply Chain's limited influence – if any – over these areas.



Eric Slimp

"Supply chain has an indirect influence on these categories, but ultimate influence is driven by the primary decision makers in those departments," he said. "Food Services is driven by Support Services, typically [led] by a Dietary Director or [Vice President]. Revenue Cycle Management is driven by the Finance/Accounting group, typically [led] by the CFO. Staffing by HR Services and depending upon department, driven by the HR Director, CIO, CMO and CNO depending upon area of staffing.

"Traditionally, the department heads drive control, but the pandemic has aligned hospitals, and aligned the C-suite organizationally around profitability of the hospital," he continued. "The focus [is] to drive EBITDA [Earnings Before Interest, Taxes, Depreciation, and Amortization], especially since the downturn of elective surgeries. Purchased Services is the last bastion of significant savings [and] is providing increased influence toward Supply Chain to drive savings."

Weighing purchased services is like balancing scales, observes Fred Crans, Healthcare Business Development Executive, St. Onge Co.

"The premise behind purchased services is that an expert in a given area will do a better job and do it more cost-effectively than an amateur," Crans told *Healthcare Purchasing News*. "Healthcare organizations are experts in rendering care, not in providing support services. There are scores of services that can be bought instead of made." Crans lists such examples as elevator maintenance, biomedical service, transport services, copy and print management, record retention and storage, waste management of all types, legal services, translation services and transcription services.

"The three that I think would win anywhere, anytime and in any size organization are Environmental Services, Food Services and Laundry/Linen Management," he continued. "The large management companies are simply too experienced compared to self-ops. They have people, processes, technologies, data, aggregate purchasing capabilities and a willingness to go 'at risk' to guarantee savings. Laundry/Linen Management is extremely capital intense, and while some organizations have – and are – building their own operations, most realize very quickly that the numbers they ran in the planning process do not hold up in real life."

Against the backdrop of the pandemic makes for an intriguing time to consider purchased services as an opportunity, advises Barbara Strain, CVAHP, a veteran value management consultant with years of experience in hospital and healthcare systems.

"Holistically, it's a good time for every health system to take stock of 2020 to determine what worked well and why," Strain insisted. "Did you miss the voices of staff you may have furloughed? What operational departments were not heavily relied on or what layer of administration seemed frivolous in hindsight? Could you have used outside help to fill in the gaps where needed and felt empowered to stop their services when they were not?"

Strain encourages health systems to consider "trimming the fat" that may exist in non-core business services such as Food, Environmental Housekeeping, Courier, Valet, IT or PC maintenance, Waste Management, Sharps Disposal, Recycling, Security, Parking Lot/Garage Management, Shuttles and others.

Accentuate the positive

RDA's Haggard cautions against spreading the stereotypical stigma typically associated with purchased services.

"Some view outsourcing or purchased services as negative," she said. "However, that is not always the case. Most of the healthcare functions that are outsourced require on-site resources that live locally. The only difference in outsourcing versus insourcing for these functions is the outsourced team gets their check from another company (aka purchased services). However, they are working side-by-side the hospital employees. In addition, outsourcing doesn't have to be 100 percent outsourcing of a department or function.

It could also include outsourcing expertise or getting a [subject matter expert's] input on a specific project or initiative. Outsourcing or transitioning to a purchased service should be selective and should be viewed as a way for healthcare facilities to focus on their core competency – taking care of patients."

When an organization identifies services that are not part of their area of expertise, thereby making them viable candidates for purchased service consideration, challenges can emerge, according to Haggard.

"It's hard to have an unbiased view when you have been at one or two organizations your entire career," she said. "Sometimes you need an outside perspective to gain insights into best practices and a different way of thinking."

Supply Chain easily can determine what the organization values, Haggard hints.

"A good way to evaluate what should be transitioned to a purchased service is to look at your organization's website," she said. "What is showcased on the website as the predominant service? Taking care of patients…The most innovative IT company…Full-service dietary/EVS/linen company…Supply Chain Optimization company?

"If your organization's website doesn't list your function or service in your department as being the best in the industry or providing that function or service to others as a revenue source, a purchased service should be considered – even if it is only in the sense of getting outside expertise/support," Haggard continued. "The intent is not to have all functions/roles in a hospital that are not patient care-focused transitioned to a purchased service, however. If a function/service is not part of the organization's strategic plan, outside expertise and/or a purchased service should be evaluated."

By and large, purchased services can benefit healthcare operations in two ways, Haggard advises. Skills and specialization represent the first.

"The companies that provide these services do nothing else but these services, so it is their core competency," she said. "They lead their industry in creating and defining best practices. They research and identify how to continually improve the services they provide. If they do not excel in their service, they would cease to exist. Therefore, they are motivated and aligned to excel in their field and continually differentiate themselves from their competition."

Aligned incentives represent the second.

"The purchased service company can be held accountable for their performance via service level [key performance indicators] and financial incentives for exceeding measurable goals," she said. "In addition, a purchased service typically results in additional value-adds that the healthcare system would not have achieved on its own – i.e., training, SME support, innovation, etc. These value-adds could be incorporated into the contract, which would not be available with an employer/employee relationship."

Purchased Services Pick List

Supply Chain executives and observers generally agree on the following as 30 notable functions for outsourcing to a third party as a purchased service.

- Biomedical Engineering
- Contract Management/Optimization and Spend Analytics
- Copy and Print Management
- Courier
- Dietary/Food and Nutrition Services
- Elevator Maintenance
- Environmental Services
- Equipment Distribution
- Freight/Shipping
- Garage/Parking Lot Management
- Healthcare Technology Management
- Human Resources Benefits
- Information Technology
- Invoice Audit Services
- Laboratory
- Laundry and Linen Management
- Legal Services
- Mail Services
- Pharmacy Benefit Management
- Record Retention and Storage
- Recruiting and Staffing
- Recycling
- Revenue Cycle Management
- Security
- Transcription Services
- Translation Services
- Transport Services
- Valet Services
- Vending Services
- Waste Management

Keeping ops close

A strategy worth embracing stems from Strain's personal experience.

"The best executive decision-making structure I worked within was to make sure there were no more than three levels before you connect to the top of the organization," she recalled. "The closer to the work the better the communication, buy-in, loyalty, trust and productivity. This means you are working at the core of your business and not creating so many layers that when faced with a short- or long- lived emergency, you don't have to look far to get into meaningful action mode. Those organizations that rolled up their sleeves, knew what to do and took early action are functioning better today and may not go back to 'business as usual.'"

That's why Strain believes it makes so much sense to shift non-core competency business needs out to purchased services.

"As a previous director of supply chain operations it became clear that unless we hired professional drivers, leased, purchased and maintained our own fleet of trucks, assured regulations were followed and licensing fees and liability and other insurance premiums were up to date, then we needed to outsource these services," she said. "This can be to and from warehouses to various entities in and out of your system, experience in logistics with dropping off trailers, exchanging cabs, drivers, hauling equipment, etc. Leave it to the experts and take these expenses off the organization books. Operating costs at a purchased service level are easier to manage than what to do when the truck you need is stuck with a load on the road to your critical care hospital, and you don't have a back-up."

All too often Supply Chain is asked to manage a variety of ancillary departments, including mail services, linen services, equipment distribution and copy services, to name a few, according to Strain. All can be outsourced to a purchased service for one clear benefit, she suggests.

"It keeps your core supply chain to become more fully clinically integrated managing patient care needs," she noted. "This may allow Supply Chain to do custom stocking projects for niche clinical care areas, streamline real time inventory management and storage solutions while understanding the diversity of each service type that would raise clinicians, technicians and physicians to reach levels allowing them to function at the top of their licenses."

Strain suggests three primary factors when transferring control to a third party offering purchased services.

1. Do your homework contacting user references, both those who converted from one service to the one you are considering, and if you can find those willing to talk to you, those who converted away from the one you are considering.
2. Develop contracts with clear expectations of both parties. If it's not documented it's not important and include clear remediation and out clauses.
3. Monitor performance based on mutually agreed upon metrics and hold regular check-ins and business meetings to assure all is on track. **HPN**

See sidebar, "Fire one, fire all and fire up every cost-containment cylinder" at: https://hpnonline.com/21165735

EXECUTIVE BRIEF

Integrating dynamic sourcing in hospital supply chain purchasing

Technology and data provide greater pricing visibility, contract negotiation, and cost savings

Photo credit: Alex | stock.adobe.com

In the ever-changing world of healthcare, the costs of medical supplies and equipment fluctuate, impacting business and financial operations. In order to best keep pace with the marketplace, hospitals and health systems, consequently, should look toward creating greater flexibility, transparency, and decision making around supply chain pricing, sourcing, and purchasing.

Nearly all other industries view their supply chains to be mission critical to the financial success of their organizations. Hospitals, however, have proven this to be contrary to their operational strategies, which is reflected in their inherent lack of resources and their decision to outsource many supply chain functions, especially sourcing.

For hospitals and health systems to most effectively and efficiently address this spend, they need to take control of their supply chains by deploying sourcing technologies and analytics as part of a dynamic sourcing model. Shifting from a traditional static contracting model, which many systems use today, to a dynamic sourcing model that facilitates periodical pricing negotiation, could result in securing best available market pricing from contracted and non-contracted suppliers and improving budget goals and financial outcomes.

Pandemic supply chain plight and opportunities

The COVID-19 pandemic has brought transparency to the adverse effects of not viewing supply chain as a mission-critical element to financial success. In many cases, hospital supply chains failed to provide adequate support from the onset of the pandemic, including their outsourced partners, such as distributors and group purchasing organizations (GPOs). And to make matters even more challenging, many hospitals decided to double down on this strategy by furloughing supply chain resources.

COVID-19 has shined a bright light on the critical importance of hospital supply chains, which likely has leadership strongly desiring to change their current supply chain landscape and is causing a degree of uncertainty as to an appropriate and a viable solution.

How the dynamic sourcing model works

First and foremost, hospitals need technologies in place that provide real-time visibility into current market pricing for supply purchases made across GPOs and peer organizations. This visibility is vital to ensuring that hospitals are paying the lowest possible price available based on their spend volume and market share. Transitioning to a dynamic sourcing model is the most logical and stable method for hospitals and health systems to instill continuity within their supply chains.

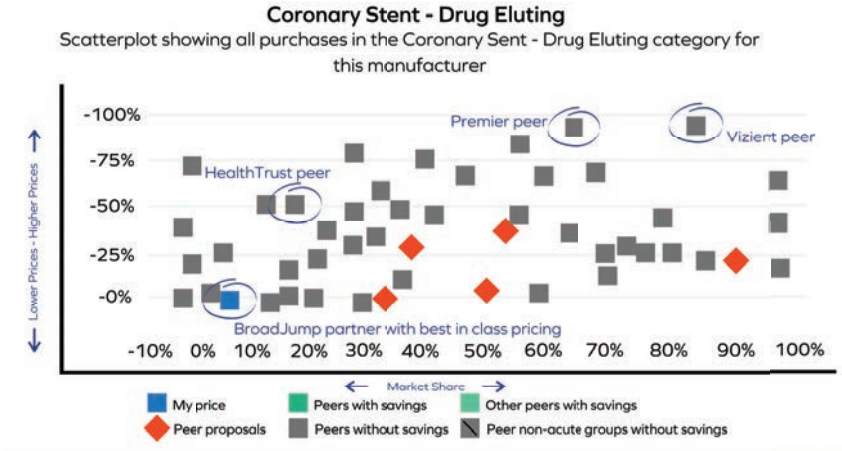
Technologies that capture last price paid from closed receipt invoices, representing thousands of hospitals across every GPO and self-contracting integrated delivery network (IDN), provide full pricing transparency. The fastest way to cost savings is to pay the appropriate market price from incumbent suppliers. Paying current competitive market pricing for medical, surgical, and pharmaceutical supplies leads to greater procedure margin and sustainable cost control. The best of the best likely have access to five to eight percent in cost savings through simply paying the lowest available qualified price, where most hospitals likely have access to north of 12 percent available cost savings.

VIP products in hospital care

Hospitals buy millions of products to take care of patients. Similar to the auto industry, hospitals need to give greater scrutiny with regard to purchasing supplies. They need to become more competitive and engaged in their supply chain operations, as well as pursue fair market pricing.

The slowest way to cost savings is to convince medical staff members to use products they do not want to use. Physician preference items (PPI), purchased services, and specialty drugs, respectively, continue to be the three largest non-labor operating expenses. These three areas also offer the greatest opportunity for cost savings, mostly due to the fact of how these items are being procured and managed.

More often than not, especially with PPI, suppliers do not provide their most competitive pricing to GPOs, since they believe they will need to provide lower



BroadJump System shows 95% price variation across the market, with pricing NOT reflective of market share or volume

pricing to hospitals to receive market share and volume commitment. This market pricing strategy, deployed by most suppliers, creates market pricing variation in many product categories, and therefore requires constant monitorization of current market pricing provided in numerous categories.

Five Myths

1. Suppliers provide most competitive market pricing to GPOs.
2. Long-term, committed contracts deliver the most competitive market pricing.
3. Available benchmark pricing data and technology offered by GPOs and third-party vendors ensures alignment with most competitive market pricing.
4. Suppliers ensure pricing parity throughout a health system.
5. Focusing on product utilization versus product pricing is the fastest way to cost savings.

Data drives pricing comparison, competitive negotiation and costs savings for healthcare organization

Mosaic Life Care[1], for example, is one healthcare organization that has integrated technology to help monitor current marketing pricing and keep costs down in their supply chain operations. Mosaic is nationally recognized for quality, value and patient experience in traditional healthcare and wellness support for residents in the St. Joseph, MO region. Their services include family care, urgent care, emergency care and a large variety of specialty care, therefore their staff must always have access to standard and specialty medical equipment.

As PPI typically account for a high percentage of supply chain expense, Mosaic wanted an easy, efficient way to monitor medical-surgical product pricing in order to ensure that their pricing was competitive across all vendors and to speed up the negotiation process for new product contracts.

Mosaic employed BroadJump's AutoPricer and PriceChecker solutions to better understand their supply chain expenses. They were able to track current medical-surgical pricing to discover savings opportunities through pricing of peer facilities with similar spend, volume and market share, as well as analyze quotes and proposals to negotiate lower pricing. In the first month using these solutions, Mosaic realized more than $400,000 in savings without changing one SKU or affecting current clinical practice. Using BroadJump's real-time repository of expense data from facilities across the nation, they were able to determine realistic opportunities with pricelist-to-pricelist comparisons. The supply chain team was able to reduce costs across several PPI, resulting in significant savings.

"I have personally used BroadJump at two different health systems now, and both times the results were outstanding," said Sean Poellnitz, BS, CHRM, Vice President of Supply Chain, Mosaic Life Care. "As a Supply Chain Executive, BroadJump gives us the ability to forecast and bring home the real savings that we promised our CFO."

GPO contract and spending

The traditional hospital sourcing model uses long-term GPO contracts for high dollar purchase volumes and multi-source contracts for PPI. This model, in turn, creates a pricing disadvantage and reduced operating margins since non-labor expenses represent nearly fifty percent of a hospital's operating budget.

GPO contracts typically apply to about 35 percent of a hospital's non-labor expenses. These contracts generally carry a three- to five-year term with fixed tier-level pricing, which often do not offer best market pricing from the onset of the contract. These lengthy contracts unintentionally trap hospitals into unfavorable product pricing positions, with very limited resources to negotiate better pricing, thereby causing one to miss out on years of savings opportunities. It is quite possible for a newly negotiated GPO contract to have out-of-market pricing as early as 90 days after the contract start date.

The remaining 65 percent of non-labor expenses commonly are purchased outside of GPO contracts and ideally need to be locally negotiated contracts in order to secure competitive pricing. The larger portion of this spend, representing as much as fifty percent, falls within the following three areas: PPI, purchased services, and specialty drugs, respectively. Unfortunately, most hospitals and health systems do not have adequate technological, analytical, or human resources to be able to most effectively address this spend.

Sourcing strategy, efficiencies and savings

The dynamic sourcing model, used by Mosaic Life Care and other organizations, is a best practice for hospital supply chain management. This model, ultimately, opens the door for numerous potential benefits and efficiencies in business operations and financial outcomes, including:

1. Promotes periodical pricing negotiation with suppliers.
2. Ensures one is paying the best available market pricing at the point of purchase.
3. Virtually eliminates the need for requests for proposals (RFPs).
4. Reduces supplier negotiation time by as much as 70 percent.
5. Delivers seven to 10 percent in annual supply savings year over year.
6. Reduces annual supply spend by as much as 15 percent.

The healthcare landscape and marketplace will continue to evolve and affect hospitals and healthcare systems. Now is the time for them to take the next step and adopt the dynamic sourcing model as part of their mission-critical supply chains. Their sourcing teams, undoubtedly, need more tools, insights and resources in order to be operationally and financially successful. This can be realized through implementing technology, data and transparency into supply chain management. HPN

References:

1. Mosaic Life Care saves $400,000 in less than one month with BroadJump's solutions without changing one SKU or affecting clinical practice, https://www.broadjumpllc.com/insights/success-stories-and-papers/mosaic-life-care-saves-400000-in-less-than-one-month-with-broadjumps-solutions-without-changing-one-sku-or-affecting-clinical-practice/?utm_source=hpn&utm_medium=link&utm_campaign=successstory&utm_content=mosaiclifecare

"BroadJump simply represents a game-changing sourcing intelligence platform that enables us to craft creditable sourcing strategies for medical-surgical product negotiations."

—Mosaic Life Care's Vice President of Supply Chain, Sean Poellnitz, BS, CHRM

WORTH REPEATING

"Hospitals around the world have not only experienced unprecedented surges of critically ill COVID-19 patients, but this uncertainty and variability in patient volumes have also put significant stress on the healthcare supply network. At the onset of the pandemic, a rapid increase in patient volumes, coupled with the stockpiling of essential infusion consumables, created back orders and supply shortages — from PPE to core infusion sets and infusion pumps. In contrast, the volumes of elective surgeries are still far below pre-pandemic levels, placing additional financial burdens on hospitals and healthcare facilities."

Matthew Hutchings, VP Global Marketing and Innovation, Infusion Systems, ICU Medical

"Based on assessment findings from hospitals across the country, there is significant need for improvement in QA/QC practices. The goal should always be that 100 percent of the instruments assembled and sterilized are available when needed, functional and safe to use on the patient. To accomplish 100 percent accuracy on these three critical factors, SPD management must determine the number of inspections that are necessary. These inspections must be conducted by a competent person who was not the person assembling the peel pack or tray. The number of inspected items can change as findings increase/decrease. Findings should be documented so that trends can be identified. Both the SPD and OR must accurately report events for the data to be meaningful. "

Gregg Agoston, M.B.A., Vice President, Business Development, SpecialtyCare/SPD Transformation Proper protection

"Challenges facilities face include not having the appropriate safe patient positioning devices readily available when needed, insufficient policies and procedures in place, and a lack of adequate training and support for staff on patient positioning. It's no secret that healthcare workers are extremely busy, and as a result of that, the use of proper equipment and techniques can be overlooked. The best patient positioning equipment in the world has no value unless it's being used."

Brittany Hahn, Marketing Communications Specialist, HoverTech International

PEOPLE & OPINIONS

SMI Executive briefing on demand planning

by SMI members

In an ideal state, providers across the industry would be able to forecast accurately the supplies that they need for clinical care with great precision and adequate lead time. Suppliers would use these demand signals from across the marketplace to fine tune production and distribution. By minimizing the risk of disruption to the supply chain, sophisticated demand planning can support uninterrupted clinical care delivery at the front lines.

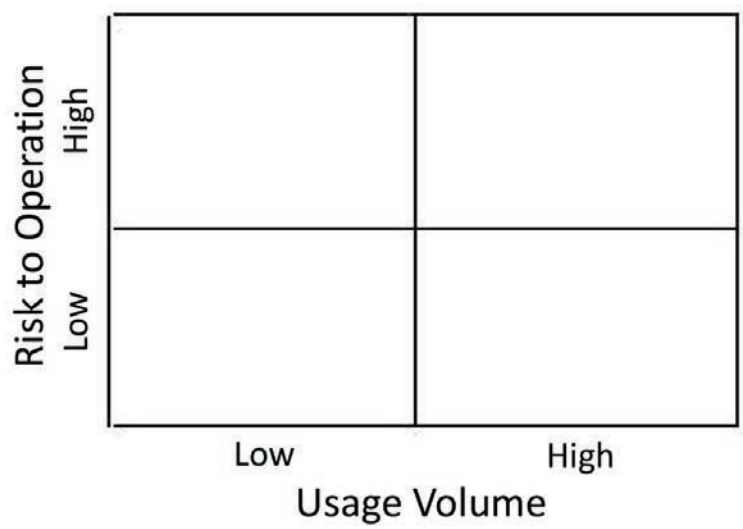
In aspiring toward this state, healthcare must mature as an industry and broadly establish competencies in the fundamentals of demand planning. These industry "must haves" include product category prioritization, data standards, and information sharing between trading partners. While there are pockets of such expertise and activity today, as a whole, the industry has yet to meet the milestones necessary to engage in demand planning at the same level as other industries.

Planning to address spikes in demand starts by determining what are typical purchasing and utilization levels during normal times. With this as a baseline, suppliers can better identify when purchasing or utilization patterns are out of the ordinary. Providers should also attempt to advise suppliers when they anticipate or are experiencing true changes in demand, given that actual need can be obscured when providers place orders with multiple vendors in an attempt to aggregate necessary volumes in the face of allocation.

This executive briefing outlines, in four stages, the fundamentals that healthcare must achieve in order to advance our ability to engage in more advanced demand planning.

Stage 1 – Defining the most critical products

- Purpose: Provides focus to providers and suppliers by defining the most critical products with clear understanding of reason behind criticality.
- Provider Organizations: Plot your 100 most critical items in a grid, such as the one below, based on the volume of the product you use and the risk to your organization. Each organization may develop its own definition of risk, but for the purposes of this exercise, consider multi-dimensional risk including



threats to clinical care, revenue, operations, clinical quality, patient and staff experience, etc. The items in the "high volume, high risk" top right box are the highest priority and should command focus in the next 3 stages.
- Supplier Organizations: Gain insight into your customer's critical products and priorities.

Stage 2 – Speaking a common language across the industry

- Purpose: Enables data synchronization, aggregation, and communication across the industry. Demand data from a single customer is not enough to provide direction for suppliers; they need data from a critical mass of the marketplace to respond effectively.
- Provider Organizations: While item masters today may assign unique local or proprietary product codes, it is imperative to transact data on products using identifiers that are common across the industry. SMI recommends use of the GS1 global trade item number (GTIN), although use of any of the industry standard codes that are compliant with the U.S. FDA's unique device identification rule will suffice, i.e., the GTIN, HIBCC-LIC or the ICCBBA ISBT-128.
- Supplier Organizations: Assist your customer by helping them gain access to the GTINs for your products.

Stage 3 – Understanding inventory and consumption in real time

- **Purpose:** Line of sight into inventory levels and consumption rates directly translates into understanding how much you need to order and provides critical information for manufacturing production schedules.
- **Provider Organizations:** Create real-time visibility into your inventory. Inventory should be digital, and consumption should be real time. This may be a significant shift for some organizations, so focus efforts on your top priority products defined in Stage 1.
- **Supplier Organizations:** Prepare to receive data from provider organizations and set up systems and processes to review and react to the data.

Stage 4 – Sharing information using data and metrics

- Purpose: Data shared between trading partners will allow demands signals to be identified and used to enable business continuity for both providers and suppliers.
- Provider Organizations: Share data on inventory and consumption via electronic channels with your suppliers on a regular and continuous basis.
- Supplier Organizations: As you aggregate and interpret demand signals across your customer base, provide feedback to the providers regarding your efforts and ability to meet their demand.

Demand shapers

Beyond addressing the fundamental steps above, we recognize that multiple factors exist that shape demand. While these factors cannot stand alone, they can improve the precision of the demand signals generated by provider organizations. As we consider, as an industry, how to best incorporate these into our demand planning rubric, we should also build capabilities for trading partners to share this information.

Internal data sources

- Service Line Planning & Projections
  - Anticipated or budgeted volume
  - Anticipated consumables associated with capital equipment purchase
  - Physician recruitment or departure
  - Strategic decisions – what's being marketed
- Clinical use/Clinician behavior
  - Clinical volume - inpatient census and outpatient clinic volume
  - Clinical protocols that dictate how product is being used
  - Staff behavior relating to use
  - Procedural schedule
  - Workforce data

External data sources

- School schedules
- Payer/benefits trends
- Population-level claims data
- Search engine data
- Seasonal variation: flu, weather, pollen count, etc.
- Population growth or shrinkage by age group
- Shared inventory at the state and national levels

To accomplish this important change, providers must take positive control of consumption data and forecasts, and then establish methods to communicate information to suppliers for use in improving production schedules and inventory in channel. To do this, we must all speak a common language by utilizing data standards that support aggregation of information to provide critical mass sufficient to support meaningful action by supplier in production planning and channel partners for inventory visibility.

This work will start small but needs to advance to scale into advance planning systems that are capable of managing thousands of SKUs. These advance planning systems will provide data for skilled inventory/demand planners to use in managing the end-to-end supply chain with distribution and manufacturing supply chains. HPN

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Vaccine safety: Modern medicine meets the manual supply chain

by Karen Conway, Vice President, Healthcare Value, GHX

President Franklin D. Roosevelt described Dec. 7, 1941, to an emergency Joint Session of Congress as "a date which will live on in infamy" following the horrendous attack on Pearl Harbor. Seventy-nine years and one day later, Dec. 8, 2020, made its mark in the history books as a 90-year-old grandmother in the United Kingdom (U.K.) became the first person in the world to receive the Pfizer/BioNTech vaccine to fight off COVID-19. Up to four million of her country men and women are expected to receive similar inoculations by the end of January. Meanwhile, on the same day, the U.S. Food and Drug Administration announced it determined the same vaccine has "met the prescribed success criteria," a necessary precursor for the Pfizer/BioNTech vaccine to receive emergency use authorization in the U.S.

U.K. Secretary of of State for Health and Social Care Matt Hancock heralded the start of the vaccination program as "the start of the fightback against our common enemy, the coronavirus." In many ways, it also marks the start of one of the supply chain's greatest logistical challenges as a multitude of stakeholders work to ensure the safe and effective delivery of the vaccine to billions of people around the world.

You've heard the stories about the challenges of keeping some of the vaccines, including the Pfizer/BioNTech, at ultra-cold temperatures. The Pfizer/BioNTech must be stored long-term at minus 94 degrees Fahrenheit or below, a capability that even many of the most sophisticated health systems do not have. Another promising vaccine from Moderna also needs to be kept cold, but at less extreme temperatures, while others in the pipeline have even fewer requirements. None of this overcomes the fact that the different vaccines come with different requirements, from cold chain to the number of doses required, all of which introduces more variation into the system. And as readers of "Standard Practices" appreciate, variation is the enemy of quality.

Further, within days in November, we received two ominous warnings about cyber criminals attempting to disrupt the cold chain and render the vaccines ineffective, and the likelihood of organized crime stealing the highly valuable vaccines and/or selling fake doses.

Image by Willfried Wende from Pixabay

The good news is we have the technology to overcome these challenges. The bad news is the use of that technology (e.g., bar codes and scanners) is limited, and the ability to share data across multiple parties, i.e., interoperability, remains a struggle. Couple that with the fact that the ability to secure vaccines through the system, whether to monitor the cold chain or to prevent counterfeit products, depends on the actions of a multitude of players, from manufacturers and distributors to hospitals and state and local health departments.

Let's start with interoperability. We are making progress on the regulatory front, with new rules going into effect Jan. 1, 2021 that require hospitals and payers to share data across organizations and with patients. But hospitals, even before facing the challenges of COVID-19, have argued that compliance is difficult due to cost and technological capabilities.

The U.S. Drug Supply Chain Security Act (DSCSA) was passed in 2013 to help address the counterfeit issue, but all medicines are not required to be tracked at the unit level until 2023. The global standards organization, GS1, also has developed a data matrix configuration that can integrate the use of sensors to monitor temperature with bar codes, which would make it possible to address both the cold chain and counterfeit issues. At this point, there are no requirements to include bar codes at the primary (or vial) level. Instead, bar codes will be on the secondary packaging, which could hold hundreds of vaccines.

According to the World Health Organization, some manufacturers have argued that requiring bar codes at the primary packaging level would be both time consuming and costly, especially given that many sites where the vaccines will be given do not have the scanning capability in place. Others have countered that traceability of the vaccines will be much more difficult if those secondary packages need to be opened for distribution to rural and remote locations where there simply are not enough people to warrant sending the larger quantity packages. Instead, the ability to comply with cold chain requirements and to track which patients received which vaccine will be up to the individual players in the vaccine supply chain. The vials will have information that can be recorded manually, but as we all know, manual documentation is error prone.

How then can we be confident that we are capturing information accurately to ensure the effectiveness of the vaccines by complying with cold chain requirements; monitor for potential adverse effects of any of the vaccines or specific batches or lots; and guarantee that patients who require a second dose do indeed get the second dose of the same vaccine? These are all critical issues to achieve the promise of what has been nothing short of a modern medical miracle around the speed of vaccine development. As a friend of mine in the vaccine manufacturing space asked: If we can create effective vaccines in less than a year, why can't we take the time to ensure the integrity of the vaccines by applying barcodes to support traceability? HPN

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Building resilience from chasing a moving target

By Ed Hardin, FACHE, CMRP

Looking back to October, I am feeling somewhat vindicated by the performance of my hometown baseball team that was the subject of my previous two Periscope columns in January and July 2020. Retention and development of talent was the topic of those articles, and these remain critical areas of talent management consideration for Supply Chain leaders.

Nevertheless, in this environment with new terms like social distancing, work from home, quarantine and contagious to name a few, it is likely that we have ignored the growing problem of isolation to our staff. After all, isolation, by its very nature, makes it exceedingly difficult for team members to engage, and a less engaged team member ultimately translates to challenges to retention and development efforts. While the verdict is still out on the long-term effects of such isolation, here are just three recent mental health studies that provide insight worth noting:

- A survey conducted by the Cleveland Clinic found that 77 percent of respondents said their stress levels increased during the pandemic, about 45 percent said their emotional and mental health declined during this difficult period, and most troubling was that 59 percent said the pandemic had a greater negative impact on their mental health than the 2008 economic recession.
- The Kaiser Family Foundation Health Tracking Poll identified similarly disappointing results, including 53 percent reporting that their mental health has been negatively impacted due to worry and stress over the pandemic, which represented a nearly 21 percent increase since March 2020 when the question was first asked. Once more, many respondents also reported specific negative impacts on their mental health and well-being, such as difficulty sleeping (36 percent) or eating (32 percent), increases in alcohol consumption or substance use (12 percent) and worsening chronic conditions (12 percent).
- And if the Centers for Disease Control and Prevention (CDC) was not busy enough, they managed a survey that showed 40.9 percent of respondents reported at least one adverse mental or behavioral health condition, including symptoms of anxiety/depressive disorder (30.9 percent), symptoms of a trauma- and stress-related disorder (26.3 percent), and having started or increased substance use to cope with stress or emotions related to COVID-19 (13.3 percent). Most disturbing was the result that more than 10 percent of respondents had seriously considered suicide, including a rate of 25.5 percent among 18-to-24-year-olds and 21.7 percent among essential workers.

We can only pray that the arrival of several promising vaccine alternatives over the next several months coupled with sheer human resiliency will stem the tide of any lasting effects of this mental health crisis. That said, if there is anything that we have learned from this pandemic, it is that we have still much to learn as we chase a moving target.

Three tactics for engagement

Here are three tactics that we have deployed in my organization that we believe are working to keep team members engaged. These are relatively easy to deploy but do require a commitment of time and disciplined effort on the part of leaders.

1. Actively round with staff.
Every leader in my organization is expected to meet one-on-one with each staff member each month over video conference. While meeting over a video conference is not the ideal, all of us have become more adept to this technology, coming very close to the effectiveness of an in-person meeting. Our standard for these sessions is simple: Come prepared with questions and feedback, dress professionally, use both video and voice, and be present by turning off distractions, including people, animals and cell phones. Leaders should come to these meetings with three to five standard questions, documenting staff responses and feedback, and then allow for an equal amount of time for less formal discussions. Most importantly, we strive to listen rather than talk with the goal of giving staff at least 20 minutes of a 30-minute video conference. The collective responses to these rounding sessions are shared with leaders and our Staff Council to, in turn, identify and develop ways to make our department a workplace of choice.

2. Assure a stable work environment.
The first months of the spring pandemic were a struggle in terms of workload. Unfortunately, what many organizations had to offer was instability in the form of furloughs and layoffs come the summer. Not at my organization. Anticipating an eventual return to normal but with a long road to recovery, we quickly identified and implemented approaches to reducing our cost structure without adversely affecting job security. Most importantly, we actively communicated these efforts and their results. As a result, team members' trust in leadership grew knowing that leaders were making the decisions necessary to retain jobs.

3. Retain your normal work day.
Here is where individual tactics vary. The recommendation is to evaluate your regular activities to determine their efficacy towards promoting engagement while meeting appropriate safety requirements. For us, this meant a commitment to several long-standing traditions, including the continuation of our aforementioned Staff Council, a non-managerial board of staff charged to make recommendations that make our department a workplace of choice. Keeping this group active meant that senior leaders could be assured of keeping an honest pulse on staff issues. Additionally, all work groups of eight or fewer were required to meet monthly and in-person using appropriate social distancing and other CDC guidelines. Larger work groups, including department-wide and leader-only meetings, would simply have remaining personnel join these team meetings via video conference. Finally, our biggest success in this area was maintaining the awarding of a bi-weekly employee recognition trophy. HPN

Ed Hardin, FACHE, CMRP, serves as Vice President & Chief Supply Chain Officer for Froedtert Health, a Milwaukee-based integrated delivery system. In October 2020 Hardin was inducted into Bellwether League Foundation's Hall of Fame for Healthcare Supply Chain Leadership. He can be reached via email at edmond.hardin@froedtert.com.

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