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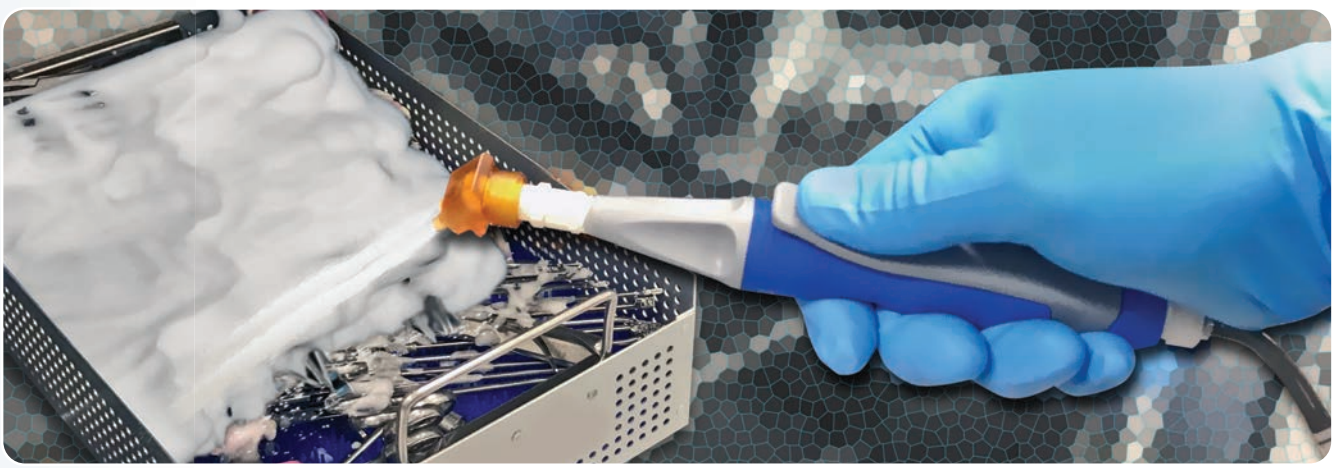

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Supply Chain: Endgame

In the Healthcare Cinematic Universe, the evil despot Covidicus the 19th snaps his fingers, and half the industry's labor force disappears. How? He possesses the six Logisticity Stones in his trusty Logisticity Gauntlet: Sourcing, Purchasing, Contracting, Distributing, Storing and Demand Planning.

Chaos reigns. Cargo ships get clogged in canals. They meander around oceans like Billy wandering home to dinner in the comic strip "Family Circus" because few to no available spaces exist in America's cluttered coastal ports. Meanwhile, stacks upon stacks of multicolored cargo containers pepper the ports and warehouses near airfields, resembling rainbow-hued small high-rise buildings populated by tons of stuff that don't lease or pay rent. Semitrucks with heavy laden trailers, box trucks and vans poke out from warehouse docking bays, unable to move.

There's no need to fear! The JIT League is here!

Healthcare supply chain executives and professionals around the nation mobilize into rapid response resource teams to retrieve and control each of the six Logisticity Stones to restore access, availability and order among product flow in the HCU.

While clinicians battle Covidicus the 19th head-on with calls for masking, physical distancing during social events and vaccinations, the JIT League fights his sidekick, Stockpylon, to prevent panicked healthcare organizations – out of perceived desperation (and irate clinicians) – from hoarding, buying more stuff and paying too much for it from vendors, a small fraction of which are wily, opportunistic, less-than reputable and unscrupulous.

Under duress, they strive for durability, flexibility, reliability and visibility, the quixotic quartet of loosely definable aims best left to the educated pep talks of the alternately heroic Consulting Collective.

Ultimately, what do they seek for their administrative and clinical customers in the HCU? They seek to hear those magic words of 2022: "Yes! It's in stock and ready to ship!"

Plagued by bad data, incomplete data, no data, siloed data, devoid of standards for data and processes, devoid of transparency and authority, devoid of respect and cooperation, devoid of facilitation and collaboration and saddled with simple C-suite ambivalence and indifference about the value of effective Supply Chain Management in the HCU, the JIT League throws down the Logisticity Gauntlet! No more!

They agree to adjust their masks, pull up their boots, throw back their flowing capes with six degrees of amalgamation, consecration, veneration, vindication. The Post-Pandemic Supply Chain Protocols.

1. Supply chain executives and professionals will be degreed, certified and accredited by notable colleges, universities, commissions and professional organizations.
2. Because Supply Chain touches everyone and everything, all hospital spending on products and services will go through Supply Chain for review, evaluation and approval, applying decency and common-sense collaboration, communication and cooperation with clinical and administrative experts.
3. Through careful facilitation and due diligence, Supply Chain decisions are recognized, acknowledged, supported and reinforced by C-suite executives for the good of the organization and its mission to serve patients – not pocketbooks.
4. Supply Chain will maintain healthy professional relationships with local, regional, national and global suppliers that are reputable, honorable and focused on customer service with the understanding of providers delivering high-quality patient care within communities and populations.
5. Supply Chain will create, develop, manage and oversee an active provision network of first-responding manufacturers, distributors and service companies, along with a flotilla of backup, secondary responders, primed and ready-to-deliver within a 24-hour period.
6. Supply Chain will maintain healthy professional relationships with direct and indirect provider competitors within a 100-mile diameter to buttress and reinforce supply access and availability if and when needed under the notion of "First focus on the patient anywhere; then treat the balance sheet with care."

Wait for the end credit sequence showing federal government officials heaving sighs of relief knowing that the private sector now seems to have everything under control … until you see a young Covidicus the 20th peering into the Capitol chamber …

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U.S.: $17.60 **Canada/Mexico/Foreign A/O:** $22.00

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Healthcare Purchasing News (ISSN: 1098-3716) is published monthly by Endeavor Business Media, 2477 Stickney Point Road, Suite 315B, Sarasota, FL 34231, Phone: (941) 927-9345, Fax: (941) 927-9588, *www.hpnonline.com*, Business hours: 8:00 a.m.-5:00 p.m. EST.

Office of publication: Periodicals Postage Paid at Nashville, TN 37209 and at additional mailing offices.

Postmaster: Send address changes to: *Omeda (Healthcare Purchasing News)*, PO Box 3257, Northbrook, IL 60065-3257.

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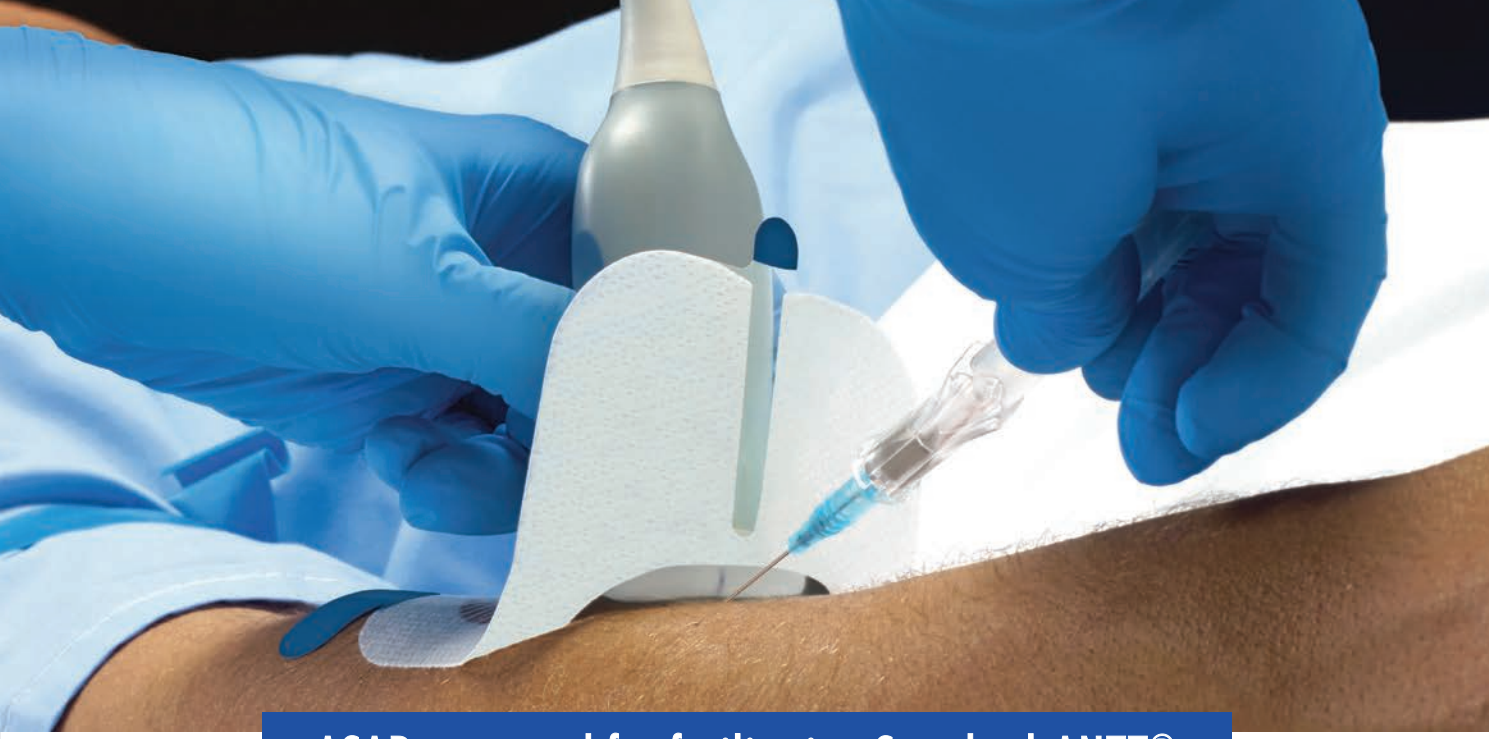

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FAST STATS

New data from the World Health Organization reveal that the COVID-19 pandemic has disrupted malaria services, leading to a marked increase in cases and deaths.

241 MILLION

malaria cases worldwide in 2020, about 14 million more cases compared to 2019.

627,000

malaria deaths worldwide in 2020, an increase of 69,000 since 2019.

66%

of these additional deaths (47,000) were linked to disruptions in the provision of malaria prevention, diagnosis and treatment during the pandemic.

95%

of malaria cases came from Sub-Saharan Africa in 2020.

96%

of malaria deaths in 2020 came from Sub-Saharan Africa.

80%

of deaths in Sub-Saharan Africa are children under 5.

72%

of insecticide-treated mosquito nets had been distributed in malaria-endemic countries as planned by the end of 2020.

15

countries with a high burden of malaria reported reductions in malaria testing of more than 20% in April-June 2020 compared to the same period in 2019.

https://www.who.int/news/item/06-12-2021-more-malaria-cases-and-deaths-in-2020-linked-to-covid-19-disruptions

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NEWSWIRE

HHS study shows 63-fold increase in Medicare telehealth utilization during the pandemic

A new report from the U.S. Department of Health and Human Services (HHS) found that massive increases in the use of telehealth helped maintain some healthcare access during the COVID-19 pandemic, with specialists like behavioral health providers seeing the highest telehealth utilization relative to other providers.

The report, which was produced by researchers in HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) and analyzes Medicare fee for service (FFS) data in 2019 and 2020, also highlights that telehealth services were accessed more in urban areas than rural communities, and Black Medicare beneficiaries were less likely than White beneficiaries to utilize telehealth.

To help beneficiaries maintain some access to care amid stay-at-home orders to reduce COVID-19 related exposure, CMS used emergency waiver authorities enacted by Congress, as well as existing regulatory authorities to implement policies expanding access to telehealth services during the pandemic. These included waiving several statutory limitations such as geographic restrictions and allowing beneficiaries to receive telehealth in their home.

Outside of the public health emergency (PHE), Medicare is generally restricted to payment for telehealth services in certain, mostly rural areas, and when beneficiaries leave their home and go to a clinic, hospital, or other type of medical facility for the service. There were some exceptions for beneficiaries with end-stage renal disease, stroke and other specific conditions. Additionally, in response to the pandemic, the HHS Office for Civil Rights relaxed enforcement of Health Insurance Portability and Accountability Act (HIPAA) of 1996 privacy requirements for videoconferencing.

Taken as a whole, the ASPE report found that the share of Medicare visits conducted through telehealth in 2020 increased 63-fold, from approximately 840,000 in 2019 to 52.7 million. States with the highest use of telehealth in 2020 included Massachusetts, Vermont, Rhode Island, New Hampshire and Connecticut. States with the lowest use of telehealth in 2020 included Tennessee, Nebraska, Kansas, North Dakota and Wyoming.

The report also found insightful trends on the kinds of services Medicare beneficiaries sought through telehealth. While overall healthcare visits for Medicare beneficiaries declined in 2020 as compared to 2019, telehealth was particularly helpful in offsetting potential foregone behavioral healthcare. In 2020, telehealth visits comprised a third of total visits to behavioral health specialists, compared to 8 percent of visits to primary care providers and 3 percent of visits to other specialists. These findings prominently show an increased interest in seeking behavioral healthcare through telehealth.

To help protect access to care as informed by data, CMS recently announced that for the first time outside of the COVID-19 PHE, Medicare will pay for mental health visits furnished by Rural Health Clinics and Federally Qualified Health Centers via interactive video-based telehealth, including audio-only telephone calls.

Additionally, CMS is permanently eliminating geographic barriers and allowing patients in their homes to access telehealth services for diagnosis, evaluation, and treatment of mental health disorders, including via audio-only communications technology. These provisions were included in the Consolidated Appropriations Act of 2021.

Other Medicare services added to the telehealth services list temporarily during the PHE will remain in place through December 31, 2023, while CMS continues to evaluate whether these services should be permanently added to the Medicare telehealth services list. And to provide more transparency and visibility into telemedicine usage, CMS is also releasing a new snapshot showing the number of people with Medicare who utilized telemedicine services between March 1, 2020 and February 28, 2021. The snapshot includes Medicare FFS claims data, Medicare Advantage (MA) encounter data, and Medicare enrollment information.

2022 McKenna Health Policy Lecture with Raquel Bono on Lessons in Readiness

The McKenna Health Policy Lecture Advisory Committee is pleased to announce that Raquel Bono, MD., MBA, FACS and Vice Admiral of the United States Navy Medical Corps (Ret.) will deliver the 2022 McKenna Health Policy Lecture, In this era of COVID-19, readiness, across all sectors, especially healthcare, is critical.

With another pandemic anticipated within the next decade, going back to the "old normal" is not an option. Dr. Bono successfully consolidated the respective military health services under the Defense Health Agency (DHA) and led its readiness work. Anyone involved or interested in healthcare and emergency preparedness, especially involving collaboration by competitive providers of care, will find her remarks informative and fascinating, as Dr. Bono illuminates opportunities for the civilian healthcare system, grounded in

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1. Power, Jan. Two Methods for Turning and Positioning and the Effect on Pressure Ulcer Development A Comparison Cohort Study. J Wound Ostomy Continence Nurs. 2016;43(1):46-50.
2. https://www.cdc.gov/nora/councils/hcsa/pdfs/17-Zheng-508.pdf

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the success of the military, for the civilian healthcare sector.

The title of Dr. Bono's presentation is "The Last Mile: Strategic Leadership Development - Lessons in Readiness".

She'll discuss how effective medical preparedness requires end-to-end planning for services in hospitals. Readiness needs to be considered through an aperture of public-private partnership that strategically-savvy leaders must understand how to navigate and facilitate.

For more information and to register for this free event visit https://www.capsresearch.org/events/2022-mckenna-lecture/

30% of American adults skipping medical treatment due to cost poll finds

Nearly one-third of Americans skipped needed medical care in the past three months due to cost, the highest reported number since the COVID-19 pandemic began and a threefold increase from March to October, according to the latest survey from the nonprofit, nonpartisan organization West Health and Gallup, the global analytics and advice firm and their press release.

Even about 20% of the nation's highest-income households — those earning more than $120,000 per year — blame cost as the reason for not seeking care, up from 3% over the same timeframe.

The survey also found that the COVID-19 experience has significantly shaped public opinion of the U.S. healthcare system, which an estimated 100 million Americans would self-describe as either "expensive" or "broken."

Nearly half (48%) of Americans say their view of healthcare in America has decidedly worsened due to the pandemic. An estimated 150 million Americans (59%) say they are now more worried about the cost of healthcare services and 45% are more worried about the cost of prescription drugs. It is no wonder more than half the country reports that the high cost of healthcare contributes some (36%) or a lot (15%) of stress to their daily lives.

Another 60% report higher concern over growing healthcare inequities, a concern that rises to nearly 75% of Black Americans and more than two-thirds of Hispanic Americans. An estimated 12.7 million people, or one in 20 American adults, report that a friend or family member died this year after not receiving treatment because they could not afford it, with Black Americans twice as likely to know someone who died as White Americans.

This nationally representative survey of more than 6,600 American adults (18+) comes as a new COVID-19 variant emerges and the death toll from COVID-19 nears 800,000.

The full findings of this latest survey and comparative findings from a series of previous surveys conducted over the last year were published in the West Health-Gallup 2021 Healthcare in America Report.

Despite attempts in Washington to address high healthcare prices through Build Back Better legislation, more than two-thirds of Americans, regardless of party affiliation, are pessimistic that policies that reduce costs will emerge. In fact, nine in 10 expect their costs to continue to rise and 42% are concerned they will be unable to pay for healthcare services in the coming year.

$9 billion in provider relief funds released to support healthcare providers

The U.S. Department of Health and Human Services (HHS,) through the Health Resources and Services Administration (HRSA), announced the distribution of approximately $9 billion in Provider Relief Fund (PRF) Phase 4 payments to healthcare providers who have experienced revenue losses and expenses related to the COVID-19 pandemic. The average payment being announced for small providers is $58,000, for medium providers is $289,000, and for large providers is $1.7 million.

More than 69,000 providers in all 50 states, Washington, D.C., and eight territories will receive Phase 4 payments. Payments will start to be made later this week.

The PRF Phase 4 payments, in addition to the $8.5 billion in American Rescue Plan (ARP) Rural payments to providers and suppliers who serve rural Medicaid, Children's Health Insurance Program (CHIP), and Medicare beneficiaries, are part of the $25.5 billion the Biden-Harris Administration is releasing to healthcare providers to recruit and retain staff, purchase masks and other supplies, modernize facilities, or other activities needed to respond to COVID-19.

HRSA publicly released the Phase 4 payment methodology in September, making it available to providers during the application period. Approximately 75% of Phase 4 funding is being distributed based on expenses and decreased revenues from July 1, 2020 to March 31, 2021. HRSA is reimbursing a higher percentage of losses and expenses for smaller providers – which generally entered into the COVID-19 pandemic on worse financial footing, have historically operated on slimmer financial margins, and typically care for vulnerable populations – as compared to larger providers.

HRSA is distributing 25% of Phase 4 funding as "bonus" payments based on the amount and type of services provided to Medicare, Medicaid, or CHIP patients. Similar to the American Rescue Plan (ARP) Rural payments, HRSA is using Medicare reimbursement rates in calculating these payments to mitigate disparities due to varying Medicaid reimbursement rates.

Additionally, HHS has updated the Terms and Conditions for Phase 4 and ARP Rural payments to ensure relief funds are being used to address the financial impact of COVID-19. Recipients whose payment(s) exceed $10,000 are required to notify HHS of a merger with or acquisition of any other healthcare provider. Providers who report a merger or acquisition may be more likely to be audited to ensure compliant use of funds.

HRSA is currently reviewing the remaining Phase 4 applications and will make the remainder of Phase 4 payments in 2022.

Investing 1 dollar per person per year could save 7 million lives

A new World Health Organization (WHO) report shows that close to seven million deaths could be prevented by 2030, if low and lower-middle income countries were to make an additional investment of less than a dollar per person per year in the prevention and treatment of noncommunicable diseases (NCDs).

NCDs – which include heart disease, diabetes, cancer, and respiratory disease – currently cause seven out of every ten deaths around the world.

Yet their impact on lower income countries is often underestimated, despite the fact that 85% of premature deaths (between ages 30-69) from NCDs occur in low- and middle-income countries, making them a huge health and socioeconomic burden.

The vast majority of those deaths can be prevented using WHO's tried and tested NCD 'Best Buy' interventions. These include cost effective measures to reduce tobacco use and harmful use of alcohol, improve diets, increase physical activity, reduce risks from cardiovascular diseases and diabetes, and prevent cervical cancer.

Keeping people healthy reduces health costs, increases productivity and leads to longer and healthier lives.

Saving lives, spending less: the case for investing in noncommunicable diseases, focuses on 76 low- and lower-middle-income countries. The report explains the NCD Best Buys and shows how every dollar invested in scaling up Best Buy actions in these countries could generate a return of up to USD 7 - potentially USD 230 billion by 2030. **HPN**


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Test Faster, Treat Faster

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The patient presents with cough, body aches, nasal congestion, fever, etc. It's the standard list of symptoms for the flu.

It's also the standard list of symptoms for a patient infected with COVID-19.

Without rapid, point-of-care (POC) testing, it may be difficult to diagnose a respiratory illness, and to recommend the most effective and expedient course of treatment.

This winter, the stakes are especially high.

Hospitals continue to see new COVID-19 cases, and with flu season coming on, healthcare facilities are gearing up for a tough round of both.

One of the clearest routes of prevention, according to Jeff Andrews, MD, FRCSC, and Vice President of Medical Affairs at global medical technology company BD, is early detection and correct diagnosis.

"We now have oral antiviral treatments available by prescription for both COVID and the flu, but those work best when prescribed early in the course of illness," Andrews says.

Getting a late jump on treatment can mean the difference between a patient's quick recovery, and prolonged illness. Amplified across a community, this can mean the difference between containment and outbreak.

The BD Veritor™ Plus System now features a new 3-in-1 SARS-CoV-2 and Flu A+B assay. The BD Veritor™ Plus System can produce positive-negative results for all three viruses from a patient's single nasal swab sample, in just 15 minutes.

"The whole system is a little bit bigger than a cell phone, and easily fits in your palm. It has one-button functionality, and you can use it one test at a time, or in batch testing," Andrews says. The device is fitted with a rechargeable battery and is simple to use.

Among the testing system's other unique features is real-time-reporting capability that can automatically send data to health authorities.

The BD Veritor™ Plus System was granted approval by the U.S. Food and Drug Administration in March for Emergency Use Authorization (EUA). Other versions of the testing system are currently in use at more than 70,000 healthcare facilities.

In addition to COVID-19 and influenza, the system can test separately for respiratory syncytial virus (RSV) and Group A Strep.

The BD Veritor™ Plus System could not have been developed at a better time, says Andrews.

"We know there are good vaccines, so that will certainly help. But overall, there's less mask wearing going into this winter than there was last winter," Andrews says. "We're concerned about having both COVID and flu, co-circulating."

In addition, international travel bans have recently been lifted, and pent-up demand is bringing in visitors from abroad in high numbers.

"If we look back at previous seasons and epidemiological work reported by the CDC, it appears that typically the flu comes to North America from other parts of the world. When you open up air flights, you're likely replicating what happened before COVID, with travelers unwittingly bringing in the flu," Andrews said.

In light of these potentialities, the BD Veritor™ Plus System promises to be an important tool in combatting serious respiratory illness in the coming months, he says. "The ability to use one sample swab and test for three viruses is going to make a very big difference."

*Disclaimer: This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner. HPN

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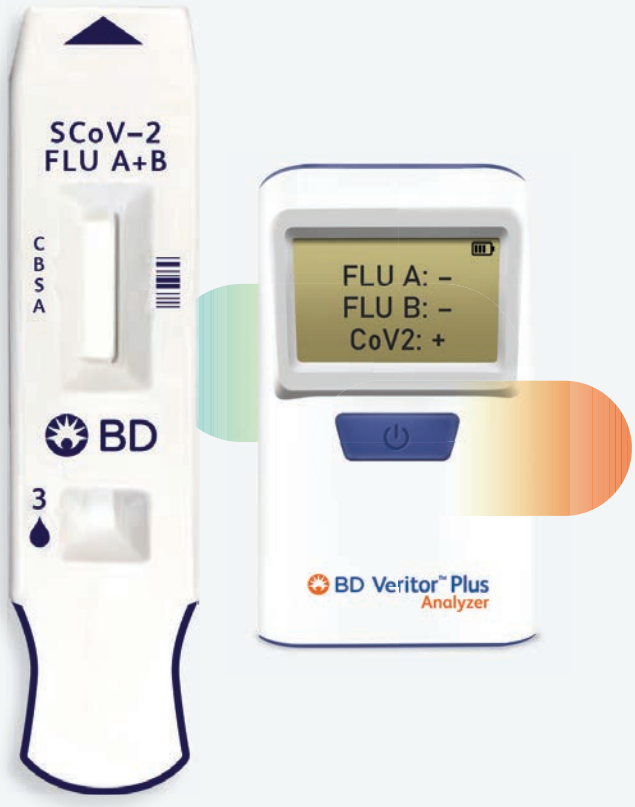

†Centers for Disease Control and Prevention Weekly U.S. Influenza Surveillance Report

*The BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2 & Flu A+B is intended for the qualitative detection of SARS-CoV-2 and/or influenza A and B nucleocapsid antigens directly from anterior nasal swab samples taken from individuals who are suspected of a viral respiratory infection consistent with COVID-19 by a healthcare provider, within the first six days of symptom onset

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BD

Next-generation distribution models must embrace that syncing feeling

by Rick Dana Barlow

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Almost two years into the COVID-19 pandemic (and its variant offspring) and people seem even more fed-up and irritated with the supply chain around the most fundamental of issues – primarily not having stuff accessible when they want it and secondarily, paying way more for what is available.

If the supply chain were a pickup truck the public would want to see a gleaming, fresh-off-the-lot, bells-and-whistles-laden luxury model. Instead, they rely on a beat-up old rust bucket, well-worn with six-digit mileage after toiling for years on the farm or work site. Further, these days, more people envision that patinaed work truck on cement blocks minus the tires.

During his keynote address at the Association of Healthcare Resource and Materials Management (AHRMM) conference last August in Nashville, award-winning professor and consultant Randy Bradley, Ph.D., tried to set the record straight with a more realistic and reasonable portrait of the supply chain in peril. He countered those who continued to lament that it was broken.

"We found out it wasn't broken, but fragile," Bradley, CPHIMS, FHIMSS, Associate Professor of Supply Chain Management and Information Systems, University of Tennessee Knoxville, Haslam College of Business, Department of Supply Chain Management, told several hundred attendees in a scaled-down convention center hall at one of the few in-person industry events slowly re-emerging from a sea of online virtual conferences. "It did what it was supposed to do. It did what it did but nothing more. It's performing as designed and not designed to perform. It wasn't ready for the mess we were thrust into.

"The global supply network is like a basket of eggs," he observed. "We need to handle it with care. Irrational buying creates waves. We were never out of toilet paper. We just bought more than we needed for two years. The supply chain was not broken. We are."

Catching the wave

As the supply chain has weathered a host of challenges and disruptions that span access to raw materials; labor shortages at docks, ports and warehouses; fuel cost increases for airplanes, cargo ships and trucks; government intervention; questionable demand planning and data reliability; and the human reactionary behavior of panic buying, supply chain executives and professionals have faced a brunt of criticism, whipsawing between the widening gap that separates realistic accomplishments from reasonable expectations.

Might a single linchpin be driving this? What might it be? Or is each merely chipping away and poking holes in an otherwise solid structure?

The global supply chain (of which healthcare represents a component) has been something of a powder keg and perceived by the public as the poster child for inefficiency. Deserved? Earned? Debatable, sources told *Healthcare Purchasing News*.

"The human behavior of panic buying, which we have seen in retail during the pandemic, is not new to healthcare," observed Cory Turner, CMRP, Senior Director, Healthcare Strategy, Tecsys Inc. "It is something supply chain leaders have struggled with for a long time."

Cory Turner

Turner knows quite a bit about that struggle as a former supply chain executive within Greenville (SC) Healthcare System, *HPN*'s 2013 Supply Chain Department of the Year.

"Clinicians who have come up against supply shortages in the past tend to be distrustful of supply chain's ability to get what they need when they need it," he continued. "They also don't trust the old, disjointed inventory management systems used in procedural areas for supply replenishment.

"All of this drives a hoarding mentality among clinicians with the idea that 'I've run out of products before [and] I'm not going to let it happen again.' Throw a pandemic on top of these long-held beliefs and behaviors, where clinicians are experiencing real supply shortages and problems that impact patient care, and the panic buying has only become worse," he added.

Tom Redding, Senior Managing Director, Healthcare Services, St. Onge Co., echoes the irrationality of decisions under duress.

"We all know that humans are predictably unpredictable, yet we continue to think of ways to change human behavior to allow for better control of supply chains," he said. "Successful supply chains have a clear understanding of their customer's needs, wants and demands, and organize activities to create end-to-end alignment. The issues around raw material sourcing, to shipping, to labor shortages is becoming the norm. The only way to manage through the various constraints is to better understand the demand side of the equation, including variability and customer lead time sensitivities. If we have a clearer picture on the expected demand, then supply chain leaders will be able to assess where changes are needed to substitute products, consolidate products to meet the needs of their customer."


Tom Redding

The pandemic not only has challenged supply chain among hospitals but also the companies that provide products and technology services to those hospitals, according to Michael DeLuca, Executive Vice President, Operations, Prodigo Solutions Inc.


Michael DeLuca

"The past 18 months have put Prodigo's technology to the test," DeLuca noted. "As we faced COVID-19 head on, our main priority was supporting our clients' hospitals behind the scenes while they were unusually strained, just trying to execute on their day-to-day tasks. Our strategic partnership with our healthcare clients shed light on the hurdles that clinical staff, physicians and administration face every day when making the best decision, in that moment, for their specific organization."

DeLuca sees supply chain's reliability as integral to healthcare service delivery and essential patient care.

"Healthcare supply chain has grown by leaps and bounds and now has an increasingly crucial role in enhancing patient care and supply preparedness as the industry charges forward," he said. "[It's] what Prodigo sees as the linchpin in creating a long-term solution is resilience. It's a resilient – flexible, adaptable, reactive – supply chain that will in turn resolve this host of challenges and disruptions. Forming resilience into the healthcare supply chain is critical in predicting disruptions, not reacting to them. A resilient supply chain will lessen the burden of external challenges and sort out those existing. Healthcare supply chain isn't an easy egg to crack, so the first step towards resiliency is to surround yourself with technology leaders and industry experts. We need to act right, and act now."

Balancing risk for reward

Whether anyone agrees or likes it, supply chain represents a risky business due in part to a global reach motivated by economic advantage and should be managed as such, according to Steve Kiewiet, FAHRMM, FACHE, Chief Operations Officer (COO), CCS Medical, and Immediate Past Chair, AHRMM.


Steve Kiewiet

"The linchpin here is the need to re-think how we evaluate supply chain risk and how the C-Suite evaluated the success of the supply chain organization," Kiewiet said. "We are in our current situation because supply chains and organizations became obsessed with lowering invoice cost of goods and services. Every contract renewal came with pressure to reduce the price and still maintain service and quality. This unrelenting pressure forced manufacturers to find lower and lower costs for production and raw materials. The result being that the supply became more and more extended to China and other remote countries with the elimination of redundant sources for goods."

Kiewiet is familiar with the push and pull of supply and demand with a decade-long service record as a Navy Hospital Corpsman who then served as a paramedic, then spent a number of a years in sales and operations for a variety of companies that included PSS World Medical Inc. and Cardinal Health before leading Supply Chain operations at BJC HealthCare and then Chief Commercial Officer at Intalere, which was acquired by Vizient last year.

"It is time to re-educate and re-orient ourselves and our C-Suites around the virtues of balancing cost and risk," he continued. "We need to find other ways to make healthcare more affordable without simply asking suppliers to charge less. Focus on the total cost of care and the total cost of supplies and services. For example, in a total cost, balanced scorecard equation, it is better to pay more for some goods and services that are produced in your community? Maybe. The point being that supply chain need to be measured by more than one metric and not every metric should be cost-focused."

Peter Saviola, Vice President, Logistics and Supply Chain Optimization, Medline Industries, hesitates to attribute current supply chain woes to a single cause.

"There isn't necessarily one linchpin that needs to be solved first, but rather multiple weak links that should be addressed simultaneously," Saviola insisted. "Things like fuel cost fluctuation, government intervention and panic buying are common reoccurring challenges in the supply chain, and the supply chain typically can account for these issues. However, what the industry is experiencing now is a supply chain that is completely out of balance, components of the supply chain are out of sync – for example not enough empty shipping containers to load goods to, and once goods are loaded there's not enough empty trailer chassis to place the full containers on, and so on. On top of all of this is an overall industry labor shortage that expands across all components of the supply chain. This may be the most pressing issue when it comes to course correcting the overall supply chain."


Peter Saviola

Jim Mullins, Senior Vice President, Global Supply Chain, Henry Schein Inc., homes in on the labor shortage as having the greatest impact to the supply chain.

"Labor impacts every part of the supply chain from manufacturing, warehouse workers, truck drivers and port employees," he said. "The labor participation rate has declined since the beginning of the pandemic, and this has worsened the supply chain shortages. Contributing factors to the labor shortage include, mismatch in skills and openings, wages, COVID-19 health concerns, general healthcare needs, early retirement and other sources of friction in the market."


Jim Mullins

And where that labor crunch is most acute should be the target to tackle, according to James Sembrot, Senior Vice President, U.S. Supply Chain, Cardinal Health Inc.


James Sembrot

"Our priority should be on the ports and related issues with trucking," Sembrot urged. "We must improve the scheduling software, and we need support

via the National Guard, or other entities, to help fill labor holes. The ports require more attention and oversight and should not be managed independently. The current backlog is so significant that without cleaning it up, the other initiatives really don't make sense."

Margaret Steele, Senior Vice President, Med/Surg, Vizient Inc., labels the supply chain's panoramic view as "all problematic" and connects the dots from one hiccup to the next in a butterfly effect that starts with raw materials.


Margaret Steele

"Raw materials are stressed due to global demand," she observed. "The cost has increased significantly. By way of example, resin has increased considerably and that impacts a number of products. The suction canisters category is really struggling — the two main suppliers of these products both are experiencing production constraints leading to backorders. Additionally, the cost of the resin is such that they must focus on how to continue production without operating at a loss."

Transportation challenges quickly follow, exacerbating costs, according to Steele.

"The increase in raw materials is exacerbated by the cost of getting the product to the U.S.," she continued. "With so many ships sitting idle for weeks, the strain on these materials continues to increase. Once they are offloaded, the transportation container costs have increased from $2,500 per container to reports of $30,000 per container and higher. In turn, transportation from the ports has increased in cost as well. Wages and labor shortages continue to add to that strain on the supply chain. The challenges are real. Yes, there are instances of some panic buying, which adds to the strain, but the raw materials, transportation and labor issues are the problems to be addressed. Economic indicators project the raw materials issue will see some relief in the coming months. However, transportation, labor shortages and increased wages will last much longer. The possibility of expired tariff relief on many healthcare products will only add to the increased costs."

At press time during seasonal shopping in December, Steele expresses concern about compounding problems.

"With providers stockpiling key products to protect from future constraints, you have a real bottleneck," she added. "We believe proven redundancies in production, e.g., in the form of manufacturers setting up a secondary plant or buying from secondary sources, combined with sourcing alternatives will help ease the impact of these challenges."

Managing the bullwhip

Other supply chain experts point to demand planning and data reliability as key issues where providers and supply chain professionals need to improve as these are within their control. Mike Henry, Managing Partner, Ron Denton & Associates LLC, is one of those proponents.

"Providers did a good job with things like burn-rate calculators for PPE during the height of the pandemic, but now we're seeing shortages that cut across all product categories," Henry told *HPN*. "Improved coordination and data sharing across the supply chain from raw materials to supplier to provider is critical to improve demand planning and to reduce the bullwhip effect.


Mike Henry

Better demand planning between the provider and supplier would be a good start," he continued. "At the provider site there continues to be limited visibility into what supplies/devices are on hand, let alone have the ability to monitor usage and consumption in real time. Systems and processes need to be put in place to more dynamically track and forecast demand. and to respond to fluctuations. Descriptive analytics are helpful, but they are a rear-view mirror. There needs to more focus on prescriptive analytics – what do we need to do moving forward – and predictive analytics – understanding the impact of taking various actions."

James Ludwig, Vice President, Partnerships, Premier Inc., advocates strongly for demand planning and data reliability improvements.

"COVID-19 forced more of an emphasis on end-to-end supply chain visibility and reinforced the urgent need to better understand demand surge and product availability," Ludwig indicated. "With most product disruptions occurring as a result of poor demand signaling, effective demand management and supply network mapping are foundational components of supply chain preparedness."


James Ludwig

Expanded supplier mapping, risk scoring and AI-enabled data intelligence enables organizations to accurately identify the intersection of demand and supply, more effectively secure product and better ascertain potential risks, according to Ludwig. He cites Premier's October decision to expand its partnership with Resilinc for a supply chain mapping footprint to encompass more than 1,300 suppliers and 15,000 sites with visibility down to the site, product and ingredient/part levels for the leading contracted suppliers.

"Today, more providers are also leveraging innovative models and partnerships that aggregate demand via committed 'buyers' club' purchasing strategies – giving manufacturers proper demand signaling, predictable revenue and the surety needed to ramp up production or enter new markets," he noted. "Suppliers get more accurate demand forecasting and committed purchases. Health systems get a guaranteed supply of critical products at a fair price."

Alex Wakefield, CEO, Longbow Advantage, however, cautions against concentrating on demand planning and forecasting at the expense of overall fulfillment and nimble operations.


Alex Wakefield

"The real challenge with supply chains today is that there is an over-reliance on the accuracy of planning and forecasting during a time that's proven on multiple different occasions that we need to be able to be more agile in our operations and fulfillment," Wakefield said. "Planning is important, but it's only half of the equation. What happens when trucks are jammed or warehouses are – quite literally – frozen? Logistics teams have to be constantly looking at their operations within the day, really within the hour, and have the kind of constant real-time visibility into intra-shift data that will allow them to pivot and communicate quickly and easily."

Amazon Business envisions a more holistic approach fueled by creative applications of automation, data and demand planning capabilities.

"Since supply chains are inherently interconnected, and each link has breaking points that can cause disruption, prioritizing one over the other is not the best approach," insisted Sandhya Dhir, Head of Healthcare Strategy and Development, Amazon Business. "Rather, to mitigate the impact of disruption, each link of the chain needs improved technology for real-time access to data, so organizations can make quicker decisions. For example, by adding AI and machine learning models

to enhance data reliability and demand planning, leaders can gain insights and make quick decisions to pivot purchasing decisions. Accessing real time analytics into buying patterns allows organizations to turn insights into actions including modifying forecasts to accommodate seasonality and building contingency plans to ensure access to critical supplies when need is unpredictable."

Rosy, but thorny, outlook

Other supply chain experts fully see the current performance uncertainties being addressed somewhat organically and slowly.

"From a category management perspective, the medical/surgical supply chain challenges continue to be a dynamic and evolving situation," said Jack Slagle, Vice President, Category Management, McKesson Medical-Surgical. "Many industries are experiencing domestic and global transportation disruptions. These disruptions are largely due to congestion at ports of discharge and labor shortages resulting in product backorders, delays in transportation and increased freight and materials costs. I would expect to see these challenges remain steady over the next few months but hope to see improvement in early 2022 as we all learn how to better navigate."

Slagle maintains optimism.

"The good news is that many of the manufacturers are producing and making product. Manufacturing lines are up and running, and production is overall healthy," he noted. "It's just a slow and murky supply chain right now and it will take time to dig out of those transportation challenges. The transparency, collaboration and frequent communications between distributors and suppliers is at an all-time-high, and we are continuing to see a lot of organizations, across the supply chain, working together to expedite production and improve the supply chain experience for our customers and their patients."

Jake Crampton, Founder and CEO, MedSpeed, acknowledges that providers and suppliers alike have "lived in a near-constant state of crisis mode for the past two years" that is and must be manageable.

Jake Crampton

"While the pandemic shined a spotlight on the very important role that the healthcare supply chain has on patient care delivery, cyber security challenges and, most recently, labor shortages have created new obstacles hindering the return to normal. Harnessing and advancing technology has the opportunity to elevate the supply chain and accelerate progress. But the truth is, this industry will always be reliant on dedicated people who work hard to support care delivery. For that reason, labor shortages and the associated downstream impacts to the supply chain, such as the inability to manufacture and receive shipments, is the greatest challenge we face today.

"In MedSpeed's world of same-day healthcare logistics, we have seen the impact of the current environment on healthcare operations," Crampton continued. "While we do not have a silver bullet to address this complex issue, our employee-based model and our emphasis on company culture have played a significant part in helping us weather the storm so far." HPN

Editor's Note: For an in-depth examination of leading strategies and tactics going forward, visit https://hpnonline.com/21249247.

STRATEGIC SOURCING & LOGISTICS

Having had enough of the pandemic, hospitals simply want just enough supplies

by Rick Dana Barlow

Photo credit: FrankBoston | stock.adobe.com

Back in the go-go 1980s, low-unit-of-measure (LUM) distribution concepts such as just-in-time (JIT) and stockless were emerging as quite the rage among forward-thinking, progressive materials management leaders.

For many, these "new" – at least in healthcare – methods were seen as perhaps the greatest process improvement since sliced bread. These days with supply chains strafed by pandemic-induced backlogs and shortages, more seem to view sliced bread as an expensive novelty and likely prefer sticky buns.

During his keynote address at the Association of Healthcare Resource and Materials Management (AHRMM) conference last August in Nashville, award-winning professor and consultant Randy Bradley, Ph.D., CPHIMS, FHIMSS, Associate Professor of Supply Chain Management and Information Systems, University of Tennessee Knoxville, Haslam College of Business, Department of Supply Chain Management, highlighted three distinct Achilles heels that threaten faith in – and perhaps viability of – JIT distribution.

Those three elements? They form an equation. 1. When you have a supply shock. 2. When you have a demand shock. 3. When you have a price shock from the supply and demand shock.

"We got all three – not just one," Bradley said. "And when demand outpaces supply we try to overcorrect." The resulting focus on stockpiling he billed as "JIC" for "just-in-case" as one end of a seesawing trend back-and-forth. "We will see more of this," he predicted. "When things get good, you'll swing back."

What the industry needs is a new philosophy, according to Bradley, called "JE" for "Just Enough." This "requires you to do demand planning, demand sensing and demand shaking," he added.

Where do we go now?

Supply Chain experts believe the healthcare industry still has miles to travel before that becomes standard operating procedure but remain mixed on JIT's future demand.

"No organization wants a repeat from the pandemic, so returning to the same practices from two years ago would be short-sighted," said Sandhya Dhir, Head of Healthcare Strategy and Development, Amazon Business. "Now is the time to embrace new technologies and new supply chain models to build more resiliency. While some of the shortcomings of the JIT model were exposed during the pandemic, managing backorders and stockouts has always been a concern for healthcare providers, to the point that industry almost turned their back on recognizing this is a problem that can have better solutions. A way to create a balance and still be able to rely on a JIT model is to ensure an organization is already set up to access multiple sources of supply as soon as fluctuations, especially when not predictable, occur. In addition, leveraging newer e-commerce technologies including ERP API integrations, approval workflows, auto-reorder tools, and real time analytics builds efficiencies during times of supply uncertainty."

What's clearly recognized is that the pandemic shook healthcare supply chain's faith in and reliability on JIT to the core.

"Over the years, the healthcare industry became overly reliant on a just-in-time (JIT) delivery model and other approaches, like 'stockless,' that helped cash-strapped healthcare systems trim costs," noted Michael DeLuca, Executive Vice President, Operations, Prodigo Solutions Inc. "The method had its benefits: It kept operating costs low, while still allowing hospitals to operate efficiently and order medical supplies when needed, and it placed a priority on driving down inventory-related expenses. This approach was applied across health systems for all medical supplies and mirrored best-in-class inventory and fulfillment practices of Fortune 100 manufacturers.

"In 2020, many hospitals had to re-evaluate this model in real time as they adjusted purchasing models," DeLuca continued. "The grim reality of the pandemic proved that the healthcare industry no longer has any choice but to apply the painful lessons we have learned and pivot to a more thoughtful and strategic approach to supply chain management and demand planning. As our nation emerges from the COVID-19 crisis, it is critical for the industry to step back and re-evaluate past practices so that the industry is better prepared for the future."

Everyone's going to have to work together on this, according to DeLuca.

"Maintaining a more strategic level of preparedness will require a long-term commitment from healthcare systems, medical supply distributors, manufacturers, and the federal government. And most importantly, health systems need to work together and support one another in creative solutions – this collaborative spirit is what will unite the industry for whatever is in our future," he added.

It's a control thing

What the COVID-19 pandemic cast in doubt really is who had – and has – control over product.

"Hospitals want and need to control supplies for patient care. But with just in time

or stockless methods, they are putting all reliance on a distributor or manufacturer," indicated Cory Turner, CMRP, Senior Director, Healthcare Strategy, Tecsys Inc. "It takes control away from the hospital's supply chain and puts it into the hands of these third parties.

"Supply chain teams are the experts in what their facilities and clinicians need in terms of products to care for patients, so supplies must be in a place where they can manage them effectively. More and more hospitals are looking at consolidated service centers (CSC) as more of a need than a want. They are increasingly leveraging CSCs to put supply chain squarely in control over supply management as opposed to relying on distributors or manufacturers."

Still, Supply Chain experts agree, by and large, that JIT isn't dead and done – not by a longshot.

"I think the industry has learned that just-in-time has its place, but it should not be adopted across the board," said Tom Redding, Senior Managing Director, Healthcare Services, St. Onge Co. "When considering the use of a CSC, an organization can continue a just-in-time model, which is based on their ability to carry a larger subset of inventory to handle the larger variation in demand.

"There is some hesitation in the market to actively pursue a stockless program with a distributor, versus considering the option to do it themselves," Redding continued. "As the market changes, the distributors will further bolster their [third-party logistics] services to assist their clients with running a CSC. The easy answer is to do it yourself but having the knowledge, experience and systems to run a distribution center should be taken seriously."

Alex Wakefield, CEO, Longbow Advantage, concurs.

"We aren't seeing just-in-time necessarily go away as a strategy, but supply chain teams are definitely revisiting how they approach these types of strategies," he observed. "For some, this has come in the form of stocking up. However, the reality is warehouses or [distribution centers] can only hold so much product. For supply chains that are looking to restructure their just-in-time strategies, they'll need to be hyper-vigilant about efficiency when it comes to storage, throughput and things like cross-docking for more immediate shipments in order to maximize the space they have. Visibility into – and maximizing – warehouse capacity and order fulfillment across the network will be more important than ever before for companies that need to increase contingency-order storage."

Finding balance

JIT among other LUM models certainly has its limitations, which should encourage supply chain professionals to expand their toolsets, according to Steve Kiewiet, FAHRMM, FACHE, COO, CCS Medical, and Immediate Past Chair, AHRMM.

"I don't think the concepts shattered," he reassured. "They have been effective tools for decades. However, they are not the only tools, and it means we need to be more proactive in understanding the balance of supply chain cost and risk. This allows us to deploy the correct inventory management and supply chain tools to fit the risk and cost situation. The breakdown we all experienced here is because many supply chains became highly focused on one tool and had too strong of a focus on removing cost, etc.

"JIT was built specifically for a single-piece flow assembly line environment while operating with well-known demand and little-to-no variation," Kiewiet continued. "Healthcare is not that environment. We

still don't have good demand signals, we don't reliably share information freely across all links of the chain and we have a lot of variability. There are places where JIT and stockless can and will work but it won't work everywhere. Just like healthcare is moving more and more to precision medicine and patient-focused outcomes and treatments, we need to bring in a variety of tools and methods to manage our supply chains that support this delivery of care."

Rather than why JIT may no longer work, the real discussion centers on for what it specifically does and does not work. Some have a few ideas.

"While just-in-time inventories can be cost savers and conveniences on typical days, they are very problematic in a pandemic or another scenario that sees massive demand surge," noted James Ludwig, Vice President, Partnerships, Premier Inc. "Experience shows that for products needed in an emergency, a hybrid approach is probably necessary: Buyers carry in-house inventory on a just-in-time basis, while manufacturers and direct sourcing companies take a just-in-case approach, reserving capacity for surge, retaining safety stock, and building rapid replenishment channels for restock."

Ludwig cites Premier's ProvideGx generic sourcing program as one example where Premier requires manufacturers of critical products to source from multiple, diverse locations and carry adequate amounts of safety stock in exchange for long-term, committed-volume contracts. "In the case of COVID-19, ProvideGx validated that suppliers had four-to-six months of active pharmaceutical ingredients on hand, as well as four-to-six months of finished dose form products," he said. "With safety stock on hand, it was possible to weather surge demand of more than 150 percent, even as health systems continued ordering just-in-time. This model works for low-margin generic drugs, suggesting it could work equally well for other critical, low-margin items."

He also indicates that "greater intelligence and improved technology can help providers estimate case load surge and automate the prediction of future supply needs. In this way, ordering is more evidence-based, data-driven and rationalized to align with anticipated caseloads. Such systems exist today and will be crucial for rationalized buying in future emergency events," he added.

"[JIT] can work for certain items like drugs and other medical products, but pandemic-related items should have more safety stock," said James Sembrot, Senior Vice President, U.S. Supply Chain, Cardinal Health. "At Cardinal Health, we're also increasing safety stock of our raw materials and components used in manufacturing. This deviates from Kanban relationships we normally would have with suppliers and helps insulates us from significant disruptions if there are raw material issues."

Medline Industries isn't necessarily seeing a shift away from or unwinding from JIT or stockless distribution methods, according to Peter Saviola, Vice President, Logistics and Supply Chain Optimization, but they do see the move to low-unit-of-measure from bulk deliveries continuing as "more of a hybrid approach that complements JIT with a small cache of on-site inventory," he added.

"Most health systems are now maintaining a 30- to 60-day stockpile, and looking to their distribution partners, like Medline, to have inventory available to compensate if, and when, needed. We are seeing this approach being taken across healthcare systems of all sizes – from small to large," he said.

Mike Henry, Managing Partner, Ron Denton & Associates LLC, calls for considerable dedicated supply chain soul searching among healthcare organizations to determine JIT's prospects and relevance.

"There's a risk of conflating different and largely unrelated issues here," he indicated. "JIT, stockless and logical unit of measure programs should be viewed as a means of efficiently moving routine supplies to end use locations while reducing process redundancies and friction. These programs in no way preclude the provision for providers to plan for and maintain strategic contingency inventory. In fact, these programs can enhance those capabilities by freeing up space and other resources to focus on contingency inventory and related processes. Supply Chain professionals should ask themselves: Are there routine tasks that we do every day that could be moved upstream in the supply chain that would free up our resources to focus on higher value activity?"

For JIT to experience a renaissance will require deeper and more intense collaboration between provider and supplier, according to Jake Crampton, Founder and CEO, MedSpeed.

"Even before the pandemic, there were trust issues on supply availability and workarounds – desk/ceiling stock, for example," Crampton said. "But acute safety issues like N95 shortages during the early days of COVID-19 touched a nerve, so establishing enough trust to move back to even a new and better JIT model may take some time. Supply chain teams left no stone unturned in their search for PPE for their clinical counterparts and learned many lessons about the need for previously unheard-of contingency planning protocols. To return to a JIT model, the supply chain will need to have full transparency with the clinical staff around the rationale for the change and the playbook if another COVID-like event challenges the supply chain in the future."

Margaret Steele, Senior Vice President, Med/Surg, Vizient Inc., admits that pre-COVID, she heard speculation that up to 70% or hospitals engaged in some degree of just-in-time or low-unit-of-measure ordering.

"Throughout COVID, we heard comments that supported the saying, 'the only trusted inventory was a facility's owned inventory,'" she said. "While we don't envision these practices as dead, we do anticipate them evolving. Sequestered or protected inventory creates some additional assurance to those facilities looking to source in this manner. We've seen increased requests for dedicated space within a traditional distributor's warehouse to ensure protections and accurate inventory visibility. Additionally, providers are seeking to secure secondary distribution partners to provide additional avenues in case of stockouts." HPN

Just-In-Time's popularity fades in struggle between other, emerging models

As healthcare supply chain professionals debate, discuss and even joke about "Just-In-Case" versus "Just Enough" versus "Just-In-Stock" as potential successors to the beleaguered "Just-In-Time" hyphenated model of low-unit-of-measure (LUM) distribution, Healthcare Purchasing News asked more than a dozen supply chain experts to pontificate about future models and potential solutions.

"With the adoption of analytics and the [consolidated service center] model, hospital supply chains are becoming stronger. I like to think we are moving to a 'just what is needed' approach. With demand planning and forecasting, it gives us the power to be proactive versus retroactive.

"More hospitals are getting to that point, but that is a process too. It takes a culture shift to move from physicians and clinicians driving supply levels based on gut instincts and the fear of running out, to where supply chain can leverage data and analytics to stock what is truly needed."

Cory Turner, CMRP, Senior Director, Healthcare Strategy, Tecsys Inc.

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Preparing for the healthcare supply chain 'new normal' in 2022

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In early November, the White House released key performance indicators measuring progress in clearing bottlenecks throughout the U.S. supply chain. The metrics showed an "abnormally high" number of container ships awaiting berth at the ports of Los Angeles and Long Beach, which together handle 40% of containerized imports entering the country.[1]

Congestion at major ports of discharge translates to product backorders and delays further down the supply chain across industries. Increased freight, transportation and materials costs – along with labor shortages – also factor into this.

However, if we narrow the focus to the healthcare supply chain, the short-term outlook materializes as a steady state through the end of 2021, with relief just over the horizon. "We hope to see improvement in 2022 as we all learn how to better navigate the landscape," says Jack Slagle, vice president of category management at McKesson Medical- Surgical.

"It's just a slow and murky supply chain right now, and it will take time to dig out of transportation challenges," adds Slagle. "The good news is that manufacturing lines are up and running, and overall production is healthy."

Healthcare-specific products

Amid current supply chain uncertainty, McKesson monitors more than 41,000 critical care products and communicates areas of concern to customers. Proactive oversight reveals that most suppliers' production levels are at full capacity for goods needed by primary care providers, according to Slagle. For instance, after periods of widespread shortages, personal protective equipment and infection-prevention items (for example, gowns, N95 masks and gloves) are readily available.

"This is largely attributable to McKesson's due diligence to diversify and expand our domestic and global supplier base to ensure that we are providing our customers with quality products from socially responsible manufacturers," Slagle explains.

At-risk categories include durable medical equipment, exam tables and other exam room items that have extended lead times. Other challenges vary by manufacturer. "Suppliers that produce full truckload shipments of large, bulky products are typically in a tougher situation than a supplier that produces sutures," Slagle points out.

Moving forward, enhanced healthcare supply chain management is going to require transparency, collaboration and frequent communication between distributors and suppliers. Organizations across the medical supply chain must work together to help improve production and smooth out problem areas in order to achieve a "new normal."

McKesson's recent action items include running backhauls to suppliers, expanding ordering lead times and providing more accurate forecasting to customers. Additionally, some suppliers have agreed to cut back production in low-demand categories to help increase and expedite production in high-demand categories.

Assistance and advice for providers

Just as suppliers and distributors need to collaborate, healthcare providers should maintain an open dialogue with distribution teams regarding supply chain requirements. According to Scott McDade, general manager for health systems at McKesson Medical-Surgical, the company relentlessly strives to improve customer service levels and can help in the following areas:

- Working with manufacturers to ship products directly to customers
- Utilizing technology and data analytics to view current inventory levels and cross-reference for alternative products
- Requesting formulary adjustments and/or identifying conservation strategies for critical and high-demand categories
- Expanding customers' networks to include neighboring systems, local manufacturers and suppliers

Further, as the cold/flu season approaches its peak, primary care practices must make sure that they have enough vital supplies. "Plan, prepare and perform," advises John Harris, vice president of strategic accounts, laboratory at McKesson. "Proactively work with your distributor to assess market conditions and stay up to date with your product needs and availability. This includes monitoring disease prevalence in your area and understanding trending patient care needs and acuity levels. [And] have flexible protocols in place to accept alternative options and methods if you can."

Expect to see more physician offices and retail pharmacy chains setting up clinical services, including rapid COVID tests and other lab offerings. Harris noted that McKesson plans on being ready with respiratory testing solutions it can administer to patients at the point of care.

Managing day-to-day inventory concerns

It takes a resourceful collaborator to work through the unique medical and pharmaceutical supply chain issues that have cropped up at health systems and provider practices across the country. McKesson Medical- Surgical's experience includes these recent examples:

- When a customer needed 100 wheelchairs to support a vaccine center, only 40 were available at the time. McKesson searched for alternatives through its SupplyManager℠ online ordering tool, which enables product comparisons, and located 60 transport chairs as acceptable substitutes.
- Another customer requested a specific type of hand sanitizer for wall-mounted dispensers at their facility. Although the exact sanitizer was not available, McKesson worked with three different manufacturers to ship alternative options from their existing inventories of ready-to-sell products.
- When a health system needed a large order of traditional crutches, which were unavailable, McKesson supplied forearm crutches as a viable alternative.
- Nurses at another health system needed an out-of-stock size of surgical masks. McKesson located a supply of children's masks that successfully completed the order and fit the nurses who needed them.

Staying ahead of the curve

As we look toward the first half of 2022, healthcare supply chain stakeholders – public and private – are going to prioritize medical supply movement through the U.S. transportation system.

Consequently, flexibility, teamwork and planning are going to prove key components of effective supply chain management in the months ahead.

Customers should keep in mind that distributors and their representatives can "do the heavy lifting for you," comments Slagle. "McKesson specializes in the non-acute, alternative-site distribution business and can provide the solutions and strategies that support getting customers through some of the recent challenges." Nonetheless, he recommends, "If you have significant product needs or are working on an expansion project that will require new equipment, large supply or pharmaceutical orders, let your distributor(s) know as soon as possible. The more time you allow for order planning, the better the outcome will be for you and your patients."

Concurrently, healthcare providers can do their part to help avoid potential supply chain concerns. "Stay in close contact with your distributor to understand the measures they are taking and categories that may present challenges in the near future," suggests McDade. "Take action now to build alternative product formularies so you can make decisions before an issue arises." Finally, "Make sure your teams exercise conservation efforts in at-risk categories," he adds.

In an environment of across-the-board collaboration, organizations of all types are committing resources to help improve the medical supply chain. McKesson plans on continuing to advocate for providers in non- acute, alternate care site facilities "to make sure we have the appropriate processes in place to get products to physician offices, surgery centers and even patients' homes," observes McDade.

"With time and patience, we are confident that things will continue to improve, and we are working hard to make this a better supply chain overall," Slagle concludes. HPN

Source:

1. https://www.whitehouse.gov/briefing-room/blog/2021/11/03/improving-andtracking-supply-chains-link-by-link/#content

McKESSON

"Providers cannot apply a 'one size fits all' approach to inventory management. Each product category must be evaluated on a number of different attributes. The pandemic taught supply chain practitioners that having stock on hand in some categories does make financial sense – especially if not having it results in operational impacts. And a strategic approach requires a strategic vision. Procurement and inventory technologies must be flexible and allow for multiple business processes simultaneously."

Michael DeLuca, Executive Vice President, Operations, Prodigo Solutions Inc.

"The ongoing consideration is: Where in the supply chain does it make the most sense for various activity to occur from the standpoint of efficiency and data visibility? It's not the same answer for everyone. Whether bulk or LUM, more opportunity exists to blur the lines between distributed and direct purchase products. Distributors should expand their efforts in the [third-party logistics] space in pursuit of moving product through the most efficient channel and away from manual requisitioning and a very cumbersome order to pay cycle. As we think about the future, we need to challenge ourselves as participants in healthcare supply chain to think about how traditional practices need to change. If we don't disrupt the industry ourselves outside players will."

Mike Henry, Managing Partner, Ron Denton & Associates LLC

"Teams are looking at every possible solution right now, as they should be. With the massive labor shortage distribution teams are facing, they're being asked to do more with less — more than ever before. Supply chain executives should be looking at where just-in-case, just-enough, or just-in-stock strategies make sense. The reality is that our warehouses only have so much space. Creating a multi-pronged strategy that relies on real-time, actionable data is the wave of the future. Executives need to know where they can find additional space for the products they need to increase capacity for—and they need to know how and where they can employ just-in-time or other strategies effectively across their networks. If they aren't looking to proactively react and adjust in real-time intra-shift, then they're going to be left behind."

Alex Wakefield, CEO, Longbow Advantage

"There are many tools and methodologies for effective supply chain management to meet the needs of our stakeholders. I feel like we got lazy as an industry and relied too heavily on just one or two of these methods, and life was great until a global pandemic blew all the wheels of the truck. We knew there were flaws in these methods before the pandemic. Like you, I have listened to hundreds of stories at conferences about how some health system rose to the occasion and were superheroes amid some disruption brought on by disaster. I've heard these stories for over 25 years now. Everyone applauded and adjusted their own plans and went about business as usual.

"As an industry we never forced ourselves to fully address the flaws so that we don't need heroics. We did not do the work to build the healthcare supply chain equivalent of a highly reliable organization. Once that is built to manage cost, quality, outcomes and risk. We all survived the previous events because they were local or regional and could get help from unaffected areas. The pandemic fully exposed all the fatal flaws that we must now address. Going back to the way it was cannot happen. We must tackle these wicked problems as an industry – not as individual businesses and health systems. For me, this is truly one of the most exciting times in history because we have the chance to fundamentally improve and revolutionize supply chain for generations to come."

Steve Kiewiet, FAHRMM, FACHE, COO, CCS Medical, and Immediate Past Chair, AHRMM

"Future distribution model will start to consider the impact on patient home deliveries and create a more holistic experience for the patient, which could include delivery of supplies, equipment, pharmaceuticals, food and other materials.

"In today's B2B model, it works well but it will need to evolve to consider the benefits of product kitting to more robustly support the surgical operations as well as patient specific needs. As deliveries expand beyond the patient care facilities, the ability to properly handle patient returns will require additional expertise and knowledge to manage effectively and efficiently. The decision to outsource will become more relevant as the number of touchpoints in the network increases and patient expectations are considered for home deliveries."

Tom Redding, Senior Managing Director, Healthcare Services, St. Onge Co.

"It will be a combination of:

- More onshoring and right-shoring
- More diversification of supply chain by item and country
- More inventory carried by distributors and customers
- Safety stocks that are paid for by customers, but allow rotation."

James Sembrot, Senior Vice President, U.S. Supply Chain, Cardinal Health

"Whether bulk or low unit of measure, we expect the current methodology of delivery to become irrelevant and distribution to depend more on the end destination or end user usage. In the past there was not solid actionable data on usage, so the idea was to have more stock to cover for mistakes. Now the industry is moving toward a centralized dashboard approach with healthcare organizations having greater visibility into their own product inventory levels as well as what their distribution partner, like Medline, has currently available and on order. This will make it easier to predict and prevent a potential inventory problem weeks down the road, rather than only addressing what the healthcare provider needs today."

Peter Saviola, Vice President, Logistics and Supply Chain Optimization, Medline Industries

"Forever we've heard, 'If you've seen one health system…you've only seen one health system.' Each system is unique, and decisions about future program models will be driven by a number of complex factors, including real estate availability, geographic scope, patient volume and inventory turn times. No matter which model is adopted, agility is essential. We saw it during COVID when PPE and ventilators needed to be shared rapidly between facilities as they dealt with spikes. We are seeing it elsewhere with non-Covid related (but still vital) products needing to be repositioned. Optimizing every element of the supply chain to adapt to the future challenges and needs of the system is paramount. This end-to-end supply chain optimization must include vendors, suppliers, distributors and the supply chain working together in support of care, wherever it is taking place."

Jake Crampton, Founder and CEO, MedSpeed

"We believe that the supply chain of the future will consider cost and service, as well as the following when building a supply chain model:

- Data and technology
- Automation and future labor skills needs
- Service level agreements (SLAs)
- Environmental and social impacts
- Diversification of suppliers
- Rationalization of product offerings."

Jim Mullins, Senior Vice President, Global Supply Chain, Henry Schein Inc.

"At Amazon we innovate on behalf of our customers, creating a hands-off experience so organizations have the supply they need, in the right specifications and quantity, without overly complicated management. While Amazon continues to improve our bulk capabilities, we see opportunities for organization to do less bulk ordering, given the inflexibility and costs to manage, and transition to smaller orders that gets shipped directly to the end user, wherever they are. Combining our parcel delivery strengths with Amazon's world class fulfillment network, organization are finding they can create efficiency and costs savings by bypassing intermediaries and eliminating multiple steps to get supplies directly and quickly to the final user. This model reduces cash tied up in inventory and improves operations by having fewer personnel assigned to managing and breaking down bulk deliveries. Creating future distribution models are something we obsess over on behalf of our customers at Amazon." HPN

Sandhya Dhir, Head of Healthcare Strategy and Development, Amazon Business

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Inserting best practices with every catheter

by Nancy Pasternack

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Two years ago, Ben Galvan, an Infection Preventionist, worked in relative obscurity at Tampa General Hospital (TGH) in Florida. He audited quality care practices for central venous catheters (CVCs) and other medical devices, conducted surveillance for healthcare-associated infections (HAIs), developed procedures and trained staff to prevent infection transmission, and generally spread the good word of good hygiene throughout the hospital.

But after helping fight against HAIs through month after month of the pandemic, his job is now center stage, and Galvan's team of eight (plus a director and manager) — are considered heroes.

In June, 2021, they received the 2021 Heroes of Infection Prevention Award from the Association for Professionals in Infection Control and Epidemiology (APIC). The award specifically honored the team's Outstanding COVID-19 response.

Prior to COVID-19, "A lot of people might not have realized who we were," Galvan said of the team's role.

But during a time that has seen ICU beds filled, and unprecedented hospital staffing shortages, HAIs have been difficult to prevent. Patient-facing departments looked to Galvan's work, and that of his colleagues, for information and recommendations.

Nationally, the Centers for Disease Control and Prevention (CDC) reported significant increases of HAI cases from 2019 to 2020.[1] The usual suspects, including central line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI), ventilator-associated events (VAE), each left its mark.

CLABSI in intensive care units (ICUs) saw a 50% increase in CLABSI cases in 2020 over 2019. During the especially hard-hit fourth quarter of 2020, cases increased by 65% over the fourth quarter of 2019. The same fourth quarter-to-fourth-quarter ICU comparison for CAUTI revealed a 30% increase. For VAE, ICU infection rates increased by 44%.

"We were in crisis mode for a long time," Galvan said of COVID-19's widespread impact. "Lots of patients had lots of (IV) lines and were incredibly sick."

Ben Galvan

It was difficult for hospitals everywhere to prevent HAIs when they were packed with seriously ill patients requiring a high level of care, Galvan says. Staffing shortages left lower nurse-to-bed ratios than normal, and immunity-suppressing factors such as high steroid and antibiotic use raised the likelihood of infections.

The staff at TGH got a brief mid-fall respite when the volume of COVID-19 patients tapered off. But before the next big surge, a full-blown COVID-influenza "twindemic," or another virulent mutant strain shows up, Galvan says it's time, "to get back to the nuts and bolts," of infection prevention.

He lists some of the most likely and dangerous places where bacteria lurk.

"IV pumps themselves can be a source of infection if not cleaned properly," he said. "Central line care — the catheter itself — has to be secured, not tugging on the skin, which can cause microtears. We want to make sure our IV tubing is not expired and that it's labeled properly. The dressing right around the (catheter) insertion site must be clean, and changed as needed."

Preventing contamination of the insertion site is key, he says, and using anti-microbial dressings can help.

Pathogen-fighting products

Products designed to help prevent HAIs play an important role in infection prevention. Choosing them wisely can make a difference.

Teleflex makes antimicrobial vascular products that include the catheter itself. Chlorhexidine and silver sulfadiazine,

"impregnate the entire indwelling surface length of the catheter," according to the company's description.

Arrowg+ard Blue Plus Protection, the line of CVC products offered by Teleflex, includes citations and summaries for research that has found the technology to be effective. Those include studies published in Association for Vascular Access (AVA), *Intensive Care Medicine*, and the *American Journal of Infection Control*.

Scott Schneider, Vice President of Sales for Teleflex, "are making the biggest impact on patient care and hospital performance." The real benefits, he said, "are that they protect the patient while providing procedural efficiency for our clinicians."

Becton, Dickinson and Company (BD) announced early last year (2021) results of a clinical trial, now published in *The Lancet Infectious Diseases*, which found that the risk of peripheral IV catheter (PIVC) failure can be reduced by 27% — resulting in longer catheter dwell times without complications — with four BD products, used in tandem.

"The problem with PIVC lines is that they often fail prematurely," said Dr. Klaus Hoerauf, Vice President of Global Medical Affairs at BD.

PIVC re-insertions can be painful, and may raise the probability that additional complications will develop.

CDC guidelines recommend that PIVCs be replaced no more frequently than every 72 to 96 hours.[2]

The CLEAN3[3] study, funded by BD but designed and conducted independently, included about 1,000 participants in a French university hospital. Both comparative dwell times and antiseptic solution effectiveness were examined.

Use of the BD "integrated solution" resulted in fewer peripheral intravenous catheter (PIVC) failures compared with the standard group (34.8% vs. 47.5%. respectively) and extended median times between catheter insertion and failure (50.4 hours vs 30.0 hours, respectively), according to the study's findings.

"The whole goal of the study was to compare two peripheral vascular care approaches — an integrated product solution versus the hospital's standard approach — in preventing complications that lead to peripheral IV catheter failure," Hoerauf said.

CLEAN3 included the use of some of BD's own products as part of that control group. They were used independent of a prescribed product combination.

The trial found the use of 2% chlorhexidine-gluconate (CHG) 70 % isopropyl alcohol (IPA) single use, sterile applicator skin, antiseptic reduced the risk of infectious complications by 92% compared with 5% povidone iodine (PVI) 69% ethanol.

The four-product regimen tested as part of the CLEAN3 trial includes PIVC (BD Nexiva), needle-free connector (BD MaxZero), disinfecting cap (BD PureHub) and a sterile prefilled flush syringe (BD Posiflush).

According to the trial summary, use of the integrated solution — or care bundle — is the best practice standard when peripheral IV catheter dwell time is expected to last more than 24 hours.

More than a billion PIVCs are inserted each year in hospitalized patients worldwide, according to the *Journal of Hospital Medicine*.[3]

Leadership is key

Not long after the TGH team was honored by APIC, Galvan was named as the organization's inaugural "Emerging Leader in Infection Prevention."

According to the commendation, Galvan, "managed performance improvement projects that have reduced the risk of patient harm and resulted in impressive outcomes such as a significant reduction in catheter-associated urinary tract infections, a reinvigorated hand hygiene compliance program, and a culture shift toward shared accountability with hospital cleanliness."

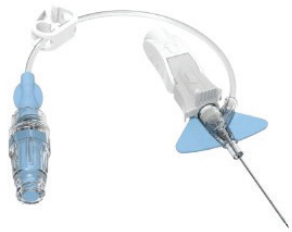
Galvan shrugs off the accolade. After all, pathogen patrol is never done.

He's sanguine about the future. People after all, may be wiser from having endured nearly two years of pandemic crises.

"Everyone is more savvy now in their understanding about healthcare," he said. HPN

BD integrated solution:

- ***Establish patient IV line using BD Nexiva catheter***
- ***Attach BD MaxZero needle-free connector***
- ***Flush IV line***
- ***Inject patient medication***
- ***Flush line again***
- ***Place disinfecting cap onto needle-free connector***



An integrated peripheral IV catheter (BD Nexiva™)

A positive needle-free connector (BD MaxZero™)

A disinfecting cap (BD PureHub™)

A sterile pre-filled flush syringe (BD Posiflush™)

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3	$570	$273	$298
4	$761	$363	$397
5	$951	$454	$497
6	$1,141	$545	$596
7	$1,331	$636	$695
8	$1,521	$727	$795
9	$1,711	$818	$894
10	$1,902	$908	$993
*16	$3,042	$1,453	$1,589
50	$9,508	$4,542	$4,966
*62	11,789	$5,631	$6,158
99	$18,825	$8,992	$9,832
100	$19,015	$9,083	$9,932
101	$19,205	$9,174	$10,031
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Keeping pressure off the patient

Photo courtesy AliMed

Repositioning a patient sometimes requires a shift of mere inches. But making sure a patient is repositioned frequently and precisely enough to prevent pressure injuries demands time, consistency, and a lot of physical strength on the part of nurses and other healthcare workers.

A patient may weigh several hundred pounds, yet be very fragile medically. And repositioning a patient, even one of average size, poses risks of injury to both patient and nurse.

Fortunately, there are options available. A wide spectrum of devices and small-to-medium tools can help adjust a patient's weight to prevent pressure ulcers, or keep the body stationary while the patient is under anesthesia. Innovation in these medical products has continued to flourish through the COVID-19 pandemic. In 2020 the global patient positioning market was valued at $1 billion, and is expected to see modest growth over the next decade, according to a market research report by Fact.MR.

Given an increase in Intensive Care Unit (ICU) patients due to COVID-19-related hospitalizations, a national upward-trending Body Mass Index (BMI), pent-up demand for postponed surgeries, and many other moving parts to our healthcare picture and economy, the need for such innovation is clear.

"While many hospital-acquired conditions (HACs) have decreased, pressure injuries remain a stubborn exception," says Michelle Daniels, Encompass Group Vice President of Product Strategy, Development and Administration.

An Agency for Healthcare Research and Quality (AHRQ) study from 2019, states that the rate of pressure injuries in 2017 was 23 for every 1,000 patient discharges.

The Joint Commission Center for Transforming Healthcare, reported in October 2020, a collaborative project to address hospital-acquired pressure injuries (HAPI) has resulted in more than a 60% reduction in a common but preventable issue that claims over 60,000 U.S. lives each year.[3] The report also mentioned that AHRQ information estimated 2.5 million patients suffer from hospital-acquired infections each year.

Customized by technology

The prevention of pressure injuries has evolved in recent years and technology has led the way. Encompass recently announced the issuance of a patent for its Airisana Therapeutic Support Surface.

Airisana, Daniels says "does five therapies, all in one surface."

The device was developed by a wound management advisory team made up of clinicians, Wound, Ostomy, and Continence (WOC) nurses, physical therapists, respiratory therapists and chief financial officers (CFOs).

The group set out three years ago to develop a device based on what patients and healthcare workers actually need, Daniels says, "not what the market was telling them they need."

Airisana, according to promotional literature, uses, "pressure redistribution, alternating pressure, low air loss, immersion/envelopment and lateral rotation," in order to adjust the placement of pressure against the patient's body. It does this by way of an algorithm that randomizes patterns of pressure applied by the device.

A repeating pressure therapy pattern will stop working after a while, Daniels explains. Clinicians have found that a patient's body, over time, will begin to adapt (involuntarily) to the pattern. Eventually, it fails to respond to the therapy.

The introduction of a random sequence, she says, is effective and unique.

"We really started this at the bedside," she says. "We didn't want to just create something

Airisana theraputic support surface from Encompass

that was the same as — but slightly different from —what already existed."

Airisana is produced domestically, she said, and was designed specifically to be compatible with equipment made by other companies.

"Many surface systems require bed frame integration. With Airisana, you can use the current frame," Daniels said. "We're not trying to reinvent a hospital's entire existing systems.

Weighty challenges

As the resident population in the U.S. continues to grow heavier, so, on average, do hospital and longer-term-care facility patients.

According to the Centers for Disease Control and Prevention (CDC), the prevalence of obesity in U.S. residents was 30.5% in the years 1999-2000 and had risen to 42.4% in 2017-2018. During the same span of time, the prevalence of severe obesity increased from 4.7% to 9.2%.[4]

Models and designs of many patient positioning devices have had to be created or adjusted accordingly.

Encompass, for instance, offers a bariatric patient option Airisana product with a weight capacity of up to 750 lbs, according to Daniels.

"Growing patient size means having to reposition more and more," says Daniels. Airisana's features help prevent staff injury. "It means three clinicians aren't required to move a patient," she said.

AliMed's product portfolio of both reusable and disposable positioners includes some that are specially made to assist extra-heavy patients, including positioning straps for bariatric surgery, and a medical bariatric table-width extender.

Senior Product Manager Christian Baker says AliMed's new AliBlue Gel positioners were designed, "to offer the same premium pressure relief as other comparable products on the market, while offering a more cost-competitive price point."

AliBlue Gel Positioners are made of 100% polyurethane-based viscoelastic gel, aid in pressure redistribution and include an 18-month warranty against manufacturing defects.

AliBlue Gel Positioners from AliMed

Baker said the company has heard from a lot of happy customers about the gel line.

"They have been thrilled with the feel, along with the crisp clear blue appearance of the positioners and have appreciated that AliMed has these in stock during a time of increased supply disruptions," he said.

A lighter alternative, AliLite Positioners, are up to 50% lighter than comparable gel-only positioners, according to the company's website. The hybrid material in those products are easier to carry and maneuver, a feature that helps prevent staff injuries.

"These are aimed, Baker said, "at helping healthcare facilities decrease their overall spend on surgical procedure supplies."

COVID impact

The respiratory distress suffered by COVID-19 patients has placed a new spotlight on the use of prone positioning and small positioning readjustments to prevent pooling of lung secretions, and encourage circulation.

"Pulmonary hygiene," says Daniels of Encompass Group, "is a very hot topic right now."

Katherine Gunn, Senior Director of Clinical Operations at Wellsense, has found this to be the case, as well.

"COVID-19 exposed and highlighted the biggest gap in the pressure injury prevention spectrum— the inability to see pressure," said Gunn. That guesswork, she says, made the business of treating hospitalized COVID-19 patients harder.

"Hospitals were contacting us for a solution because their prone patients were acquiring pressure injuries," she said. "Proning became a critical adjuvant therapy for improving ventilation in COVID patients."

"Proning already increases the risk of acquiring a pressure injury by greater than 29%, and these patients were often in this position for longer than Q2," Gunn said. "Many staff members were not familiar with placing patients in this position."

The Wellsense solution was an advanced pressure visualization system called VŪ.

"With the VŪ, caregivers can see the effect that head-of-bed (HOB) and foot-of-bed (FOB) adjustments have on pressure and they can adjust inflation settings based on what is appropriate for each patient," Gunn said.

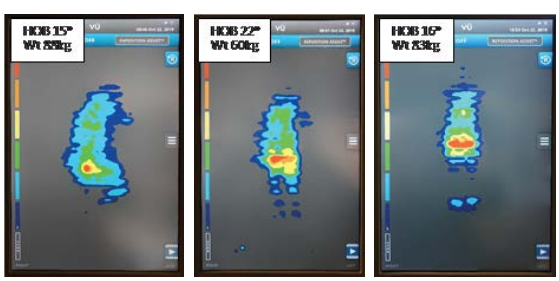
The device provides visual feedback on the effectiveness — or ineffectiveness — of the pressure-reducing interventions being employed, she explained. A healthcare provider (HCP) can see, for instance, "when a pillow is appropriate for offloading or when a wedge is required."

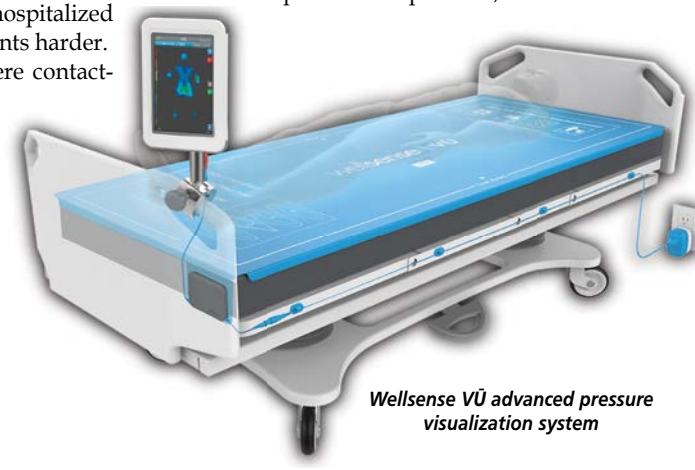
"Once the VŪ was implemented, there was no guessing where the high pressure was located or wondering if positioning devices were correctly placed," Gunn said. "Staff could leave the bedside, confident in their actions, knowing the patient was in a position of low pressure. They could continuously monitor this pressure from outside the room and conserve PPE, as well."

Historical pressure reports also are available for each VŪ patient, which facilities use, Gunn says, "for education, goal setting and root cause analysis."

Patients too can access the information, which can improve health outcomes and reduce costs.

"PI reductions achieved with our customers during COVID-19, with the highest-risk patients is a testament to the necessity of pressure visualization in the PI prevention spectrum," Gunn said.





Wellsense VŪ advanced pressure visualization system

Secured for surgery

During surgery, even healthy patients are at risk for pressure injuries and falls.

Dan Allen, founder of D.A. Surgical, has made it his business to track emerging trends in surgery, and create products for those surgeries. Most devices the medical products entrepreneur creates are meant to keep anesthetized patients safely positioned on the surgical table, even when placed at a steep angle.

Perhaps best known as creator of the surgical stirrup that bears his name and for a boot-style stirrup now ubiquitous in operating rooms, anatomy and gravity, he says, are two intractable realities that drive most of his work.

Early in his 40-plus years of observing surgery, Allen says he saw just how vulnerable surgery patients are when they are under sedation.

If not well-secured, he says, "They could slide off the (surgery) table and suffer horrible injuries."

Sliding, Allen says, is the primary problem his inventions are designed to prevent.

"Sliding should be a 'never' event," Allen said.

Allen's chief interest these days is in positioning products related to robotic-assisted laparascopy procedures.

TrenGuard 450 positioner from D.A. Surgical

"The unique technology used by the surgical robot creates unintended consequences in regard to patient positioning," according to D.A. Surgical.

The flagship product, called TrenGuard, restrains a patient during surgeries performed in Trendelenburg positions, "as extreme as 40-degrees," according to the company description.

Another of the products in the series protects a patient's face from swinging robotic arms.

In addition to potentially being struck in the face, there is risk of a "meat hook" restraint.

"When patients slide even 'just a little bit,' while in Trendelenburg position, it is the (fixed) trocars that end up restraining the patient on the table," Allen says.

"Fixed robotic trocars," his website warns, "create a serious potential for patient risk as it can cause incisional tear, post-operative hernia formation, and increased post-operative pain secondary to over-stretching of the anterior abdominal wall."

Along with these restraints Allen has developed numerous disposable foam pillows to keep every part of the patient's body positioned safely for surgery.

Some call Allen's products "innovative," or "inventive," but Allen takes more of a tinkerers view." I make lots of little problem solvers," he says. HPN

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Quality in, quality out

Assurance of sterility takes best tools and best practices

by Kara Nadeau

The Central Service/Sterile Processing & Distribution (CS/SPD) department is known for its fast-paced environment burdened by high employee turnover and intense pressure to reprocess instrument sets quickly but also in accordance with manufacturers' instructions for use (IFU). All of this impacts the quality of processes and instrumentation, as Sharon Hadley, BSN, RN, CNOR, CSPDM, CHL, CFER, Principal Consultant, STERIS Instrument Processing Solutions, explains.

"Quality suffers due to lack of training for staff, increased complexity of instrumentation, time crunches (e.g., ORs pushing staff in both departments to perform turnovers faster), and lack of staff – both qualified and entry-level. Effective processes have given way to chaos in many SPDs. Leaders may attempt to perform process improvement, but in reality, they are just trying to keep up with demand in whatever way possible."

Sharon Hadley

Quality and sterility assurance in the CS/SPD department is only becoming more important as healthcare industry agencies and associations, health systems and hospitals themselves demand greater quality from all areas that impact patient care.

"More focus will be put on quality/sterility assurance and I believe that our Joint Commission surveyors, the Association for the Advancement of Medical Instrumentation (AAMI); as well as, our internal surveyors from areas like infection prevention will require higher levels of quality/sterility assurance standards be implemented," said Mary K. Lane, MHA, CSPDM, CSPDS, CSPDT, MK Lane SPD Consulting.

Mary K. Lane

Hadley, Lane and others offer myriad recommendations on assuring CS/SPD quality and sterility, from quick wins to longer-term strategies and approaches, and share their thoughts on the future state of sterile processing.

Staff education and training

The often "chaotic" nature of the CS/SPD environment, where technicians are forced to balance quality and safety with OR staff demands for quick instrument turnaround, can leave little time and resources for educational efforts, SPD experts say. Those in the field note how this can lead to technicians being thrown into the fire of the job without adequate training.

"SPD staff get rushed to meet quantity quotas that come from finance measures, some staff are still in the learning stage and are afraid to ask questions, others don't have a good understanding/appreciation as to why quality/sterility assurance is critical to successful patient outcomes, and others lack attention to detail that is so very critical," said Lane. "In addition, there is no consistency in color of the chemical indicators in SPD and this causes additional confusion for both SPD and the operating room (OR) staff."

The development of a well-trained team with a high level of knowledge and skill and commitment to patient safety is absolutely necessary to improving CS/SPD quality and sterility, according to Seth Hendee, CRCST, CIS, CHL, CER, CSPDT, CFER, IAHCSMM Approved Instructor, Clinical Education Coordinator, SPD, Healthmark Industries. He points to current quality gaps between what technicians need to know and what many training programs teach them.

Seth Hendee

"In too many processing departments, trainees are routinely 'trained' while also being part of daily production," Hendee noted. "The model is easy to understand considering the limited staff and space many SPD are restricted by, but this style of training rarely allows time for a key piece of information, the 'why' behind the process. Without this essential piece of the puzzle, techs may not understand the repercussions of taking short cuts or deviating from facility policy. Any long-lasting solution to this problem will have departments separating training from production and adding clinical knowledge of not only how but why we do what we do."

Hadley says standardized training, using standard work instructions, is becoming a focus for CS/SPD departments.

"Leaders responsible for this department are reorganizing staff structure to allow for SPD-certified educators to be added to ensure staff are trained in an organized

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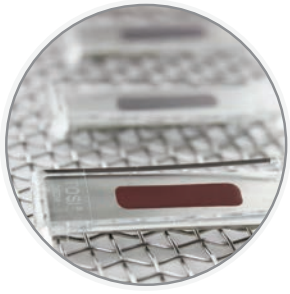

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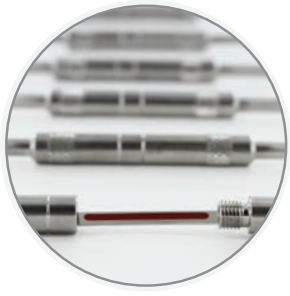

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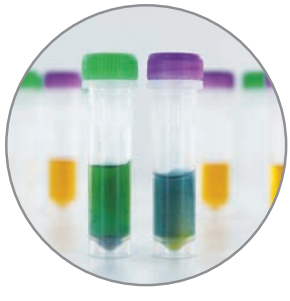

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and standard manner as well as sustain what has been taught," she commented.

Beyond the CS/SPD

It's not just CS/SPD professionals who can benefit from enhanced education and training, explains Leslie Kronstedt, CRCST, CHL, CIS, President Elect of the Western Wisconsin Chapter of the International Association of Healthcare Central Service Materiel Management (IAHCSMM).

Leslie Kronstedt

"Knowledge is a powerful tool; it becomes apparent that there are gaps when some don't know what quality/sterility assurance means or how to establish it within their departments," said Kronstedt. "It becomes necessary to recognize that you may need to educate infection control, perioperative services, and risk management on handling different quality and sterility assurance events."

Kronstedt notes how each department owns its own piece of the quality/sterility assurance continuum, thinking about it in their own way. It ranges from the mechanical/ temperature gauges used during sterilization to measure time, temperature and pressure to chemical indicators (CI) and biological indicators (BI). With regards to sterile storage, quality/sterility assurance for perioperative means looking for holes, tears and moisture in wrapped sets, she explains.

"Many SPDs are using process improvement events to create effective and positive change," said Hadley. "Working collaboratively with the OR and other customer departments to refine or completely revise existing processes can greatly impact efficiency and improve quality and customer and staff satisfaction."

Detailed documentation

With internal and external surveyors applying more stringent quality/sterility assurance standards to their inspections of CS/SPD operations, Lane says CS/SPD professionals have to be more meticulous in their data collection to prove compliance at each stage of reprocessing.

"This will likely require additional documenting from SPD staff and retention of additional record keeping," she stated.

Kronstedt says data collection is required to manage both simple and complex processes in the CS/SPD. She notes how maintenance records must be kept from the time instruments arrive in the department to the time they are sterilized and stored.

"Every sterilization load will have data detailing the sterilization process if parameters have been met and accountability for who has handled the processes in place," she said. "In the event of a recall, there must be a system in place for finding and reprocessing the items in question and who needs to be notified when such an event occurs. Even the room maintenance records must be maintained and recorded to ensure that temperature or humidity within the room doesn't compromise sterility."

According to Kronstedt, gaps in quality/sterility assurance occur when each hospital's CS/SPD has its own unique methods of documenting this critical information.

"There is a lack of comprehensive national quality programming that makes policies and procedures universally handled identically," she explains. "This allows gaps to infiltrate the system leading to a breakdown in patient safety. If anything has been identified in the healthcare system, the best way to prevent errors is to have continuity across the board. This removes doubts and creates standardization that is not going to vary from organization to organization."

Don't skip the basics

When educating CS/SPD staff and other stakeholders on ways to improve quality and safety and achieve and maintain the sterility of instrumentation, leaders shouldn't skip the basics: Hand and instrument cleanliness. Both factors can help minimize the risk for healthcare acquired infections (HAIs), while maximizing the opportunity for high quality patient outcomes.

"Hand hygiene plays a critical role in all infection prevention efforts and is an important indicator of a facility's commitment to patient safety and quality healthcare," said Jaimee Rosenthal, Acute Healthcare Market Director, GOJO Industries. "In departments like CS/SPD, where there is a strong focus on safety, quality and risk-reduction, basic protocols for infection prevention can play an out-sized role. Ensuring staff are performing hand hygiene, with products that are designed for healthcare environments, prior to the start and at the completion of any task is important to reducing the potential for germs that may cause illness."

Jaimee Rosenthal

When it comes to the quality and sterility of instruments, the following has often been referenced and is worth repeating: "An instrument can be clean without being sterile, but it can't be sterile without being clean," commented Noreen Costelloe, Director of Marketing, Ruhof Corporation.

"This statement supports the well-known fact that cleaning—the removal of organic and inorganic debris from an instrument or device should precede all disinfection and sterilization processes," she said. "Failure to do so can interfere with microbial inactivation and can compromise the disinfection or sterilization process, placing patients at serious risk. Therefore, one key area that CS/SPD professionals must address as part of their quality assurance plan for sterilization is the monitoring of/and verification that instruments and devices have been properly cleaned."

Costelloe points to how leading industry associations recommend verification testing of instrumentation, medical devices and endoscopes to ensure cleanliness has been achieved prior to sterilization.

"The Association of periOperative Registered Nurses (AORN) recommends ATP as one of the valid qualitative tests that can be used to assess cleaning efficacy, stating further that such testing will allow the tracking and trending of performance as part of a quality program. The Association for Advancement of Medical Instruments (AAMI) also recommends rapid, easy to perform and sensitive verification testing such as ATP for the detection of organic residues on instrumentation while the Centers for Disease Control and Prevention (CDC) endorse the use of ATP testing as a method for evaluating environmental hygiene," Costelloe cited.

As Costelloe explains, an ATP Contamination System is a quick, easy to use and a reliable monitoring tool used to detect Adenosine Triphosphate (ATP), the universal energy molecule found in all animal, plant, bacterial, yeast and mold cells. In addition to its use in the CS/SPD, ATP can also be used to test non-critical surfaces throughout a healthcare facility.

"Product residues, particularly blood and bio burden, contain large amounts of ATP while microbial contamination contains ATP, but in smaller amounts," she added. "An ATP Contamination Monitoring System measures the amount of contaminants present after cleaning and with integrated software enables data tracking to focus on process improvement efforts where they're needed most."

CS/SPD: 2022 and beyond

The COVID-19 pandemic has driven significant change in healthcare delivery over the past two years. The CS/SPD has

not been immune to the impacts, as evidenced by the International Association of Healthcare Central Service Materiel Management's (IAHCSMM) efforts to help enact hazard pay for sterile processors for their work during COVID-19 in 2020 and 2021.[1]

The fight continues for CS/SPD professionals to prove their critical role in patient care and safety to their health system and hospital leaders, on par with other clinical areas. Moving forward, Hadley says CS/SPD must become a focus to leadership in order for departments to secure the resources they need for quality and sterility assurance improvements, stating:

"Technology in SPD must match the technology in the OR. Facilities spend millions of dollars for the latest surgical technology but do not match that for managing the care of those instruments."

"The spotlight is finally shining on the sterile processing department," Hadley added. "Senior leaders are realizing the critical importance of this department and are willing to invest for success as never before. Technology in SPD must mirror that of the OR it makes little sense to invest millions on the latest surgical innovation if one can't adequately care for the instruments used in those innovative procedures."

Hendee envisions a future where CS/SPD technician training will be on par with the full classroom experience provided to other clinical professionals. He says this model has already begun, with stand-alone and interdepartmental tech training classes "popping up" around the country.

For example, the CS/SPD tech training program at Northside Hospital in Atlanta requires new CS/SPD technicians to attend several weeks of classes along with hands-on training. Hendee notes how this model of class time blended with hands-on experience is creating techs with a greater depth of knowledge and a high rate of passing the certification exam.

"For decades SPD staff have been seeking recognition for how technically challenging the role is," Hendee said. "Unfortunately, with so many onboarding programs solely based in on-the-job training, the profession is often equated to a factory production line. If classes teaching the basics of asepsis, microbiology and other clinically relevant topics were part of every technician's training, the tech would not only possess a greater understanding of their job, but others within the facility would see the true depth of skill needed to do the job well.

Kronstedt foresees a future where there is greater continuity in how CS/SPD quality/sterility assurance is documented, recorded and monitored, stating:

"With the advancements of technology, paper tracking will disappear and be replaced with digital," she said. I hope technology will be so advanced that the sterilizers will detect wet loads. Our computer software will track room parameters and notify us when sterility has been compromised in sterile storage."

"What will be the driving force behind all these advancements? Standardization," Kronstedt added. "Much like the structure and repetition that creates patient safety in the rest of the healthcare setting, quality/sterility assurance will also receive its own overhaul of structure that will be the same no matter what facility you walk into, continuing the continuity of care that we have all come to depend." **HPN**

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

LEARNING OBJECTIVES

1. *Define five types of obsolescence in sterile processing departments*
2. *Discuss the potential benefits that can be derived from obsoleting equipment*
3. *Understand how to develop a department obsolescence plan*

SELF-STUDY SERIES

Can you afford to ignore obsolescence?

by Heide Ames

If you say "obsolescence" to sterile processing managers, the first thought that comes to their minds is "major expenditure to replace equipment." Many managers have been heard to say, "I'm going to use that sterilizer until it stops running!" This may seem the thrifty thing to do – after all, sterilizers can be an expensive proposition for any sterile processing department – but it's not always the right choice. Obsolescence has many hidden costs, but depending on the type, obsolescence can also yield benefits.

Types of obsolescence

Sterile processing departments face five forms of obsolescence: the most common being functional. Adam Hayes defined ***functional obsolescence*** as "the reduction of an object's usefulness or desirability because of an outdated design feature that cannot be easily changed or updated."[1] In the SPD, this translates to aging sterile processing equipment that can't perform with the processing parameters necessary for today's complex instrumentation or can't keep up with the processing pace of the department.

Functional obsolescence also includes products and services that are no longer desirable because of increased cost of ownership, which can be defined as the cost to use and support that equipment. Older equipment typically needs more service, requires more repairs, and uses more utilities. It is less desirable to use this equipment as the overall cost of ownership increases. Sterilizers, washers, and other major reprocessing equipment can fall into this category, but surgical instruments can also become functionally obsolete.

Sometimes, manufacturers of a given model of equipment or instrument may discontinue the model along with related service and parts. This is a form of functional obsolescence since the unavailability of service and parts may prevent the use of the equipment.

Technological obsolescence occurs "when a product or service is no longer needed or wanted even though it could still be in good working order."[2] Systems with software features are often the victims of this type of obsolescence. Each new model brings new features, connectivity or processing capabilities preferred over the older model. Though the old models still function, they may sit idle. Washers, sterilizers, and ultrasonic cleaners can become technologically obsolete as newer models provide greater productivity or meet the needs of specialized instrumentation like robotic arms. With the current pace of technological development, advancements have outpaced the useful life of many types of equipment. Today, equipment using software or connecting with computer services are expected to be obsolete in as little as two years from initial introduction.

The simple definition for ***legal obsolescence*** is "a forced retirement of assets."[3] Equipment becomes obsolete due to the actions of an authority such as a local, state or governmental agency that dictates the discontinuation of use. For example, the SPD experiences legal obsolescence when FDA issues a recall or EPA decrees the discontinuation of a specific chemical, like ethylene oxide. Legal obsolescence can be immediate or may be phased out over several years.

Legal obsolescence can be direct, such as a recall, or indirect through pressures of regulation. For example, ethylene oxide has been around as a sterilant since the 1950s. However, in recent years changes to the hazards classifications of ethylene oxide have led to strict regulation of emissions, requirements for personnel monitoring, and restricted application in healthcare facilities. This increased regulation has raised the cost of ethylene oxide sterilizer operation and restricted its use, resulting in the discontinuation of ethylene oxide sterilization in many healthcare facilities.

Style/aesthetic obsolescence can be most easily defined as a product or service that is no longer "fashionable." Clothing is not the only thing that goes out of style – equipment and instruments do too. How many


Photo courtesy STERIS Corporation

Favoring the use of a washer-disinfector with green and red status lights over a traditional washer-disinfector without lights is and example of a style/aesthetic obsolescence

instruments or specialty sets were hot commodities last year but are barely requested today? As procedures change and new instrumentation becomes available, doctors may prefer one type of instrument or set over another. This change in preference results in effectively obsoleted instruments and sets left unused in inventory.

Finally, we have ***economic obsolescence***, which is "the loss of value resulting from external economic factors to an asset or group of assets."[4] Simply stated, economic obsolescence occurs when an asset is at an economic disadvantage due to events outside the control of the facility. Regulatory changes, scarcity of necessary resources to run the machine, and equipment valuation by the market are a few factors that create an economic disadvantage. All sterile processing equipment experiences economic obsolescence simply by getting old. Just like a car, the value of equipment goes down as the equipment gets older and the number of procedures or processing cycles it has experienced increases.

The benefits of replacing obsolete equipment

Obsolescence is often perceived as a negative event: expensive equipment that can't perform the desired reprocessing parameters or is forced to retire through recall and regulation turns into a useless hunk of metal. However, if you look closer, there are meaningful benefits connected to obsolescence.

Productivity and recruitment gains

Obsolete equipment provides an opportunity to upgrade to newer models with increased efficiency and more useful features. Newer equipment may have faster processing times or meet the processing requirements for new instrumentation, for example. Departments benefit from high efficiency systems that improve department workflow and productivity. Replacing obsolete equipment with newer models also allows facilities to expand their surgical or procedural options and attract physicians who use more modern instrumentation that could not be processed in the obsolete systems.

Utility and sustainability improvements

Obsolescence supplies an opportunity to improve department spend and reputation. Utilities such as water and electricity are part of every department's budget. Newer equipment is typically designed to reduce utility usage. This can save departments thousands of dollars over the life span of the equipment. By reducing the use of resources, newer equipment can also help reduce the department's carbon footprint and environmental impact.


Photo courtesy STERIS Corporation

Some newer cart washers offer reduced utility consumption and include specific cycles for instruments and rigid sterilization containers.

Reduced maintenance and repair costs

The financial benefits go beyond utility savings. Older equipment costs the department more to use. Higher service contract costs and increased repair costs coupled with more downtime results in higher department spend and possible lost surgical revenue. Downtime has the additional effect of reducing department productivity and causing backlogs and potential overtime expense. Comparing these costs to the cost of purchasing and using the newer equipment can show a benefit from obsoleting the older equipment and investing in new equipment.

The subtle benefit of depreciation

Depreciation is a factor applied to capital purchases that shows the loss of value that an item incurs over time. A familiar example of depreciation occurs when you purchase a car. The resale value of the car steadily decreases each year you own the car, based on the car's age, mileage, and condition. At some point in the future, the car will have negligible value. The difference between the purchase price and the market value is its depreciation.

Depreciation is calculated and used in accounting to represent the declining value of an individual's or organization's major assets over time, which is counted against its income. Applying depreciation will reduce the overall income reported, which in turn means less taxes paid.

However, there is a finite time during which depreciation can be used. The method of calculating depreciation is decided by the accounting team but is typically spaced over a specified useful lifetime for the equipment. Once the useful lifespan is reached the equipment can no longer be depreciated and will no longer count against the income. Obsoleting equipment and purchasing new systems creates a new opportunity for depreciation. Although this is the weakest benefit of obsolescence, it is a crucial consideration when discussing obsolescence planning for department equipment.

Develop an obsolescence plan

Obsolescence planning is a proactive approach that manages the timing and impact of equipment obsolescence. Ideally, the planning should start before any equipment is installed in the department, but this is unrealistic in most cases. For most departments, planning starts by assessing the current situation.

Assess what you currently have

Assessment identifies the current condition of existing equipment and the risk of this condition to the department. For example, newer equipment has less chance of breaking down or becoming technologically obsolete, so it has a low risk of obsolescence. However, older sterilizers, washers and other system models may no longer be manufactured and are more likely to be made obsolete by the manu-

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

Table 1: Questions to ask during an obsolescence risk assessment

Obsolescence Type	Questions to consider
Functional Obsolescence	• Has the cost of service, repairs, parts, and/or necessary consumables significantly increased? What is the annual cost? • Has a manufacturer discontinuation notice been issued for it or its necessary parts or consumables? • Does the equipment meet the needs of current or anticipated instrument processing parameters/instructions for use? • Does the equipment meet the productivity needs of the department?
Technological Obsolescence	• Can the equipment's software and hardware communicate with necessary devices? • Does the device meet the facility's carbon footprint or green initiatives? Is there a need to improve upon these? • Can the system meet the processing parameters necessary for new instrument models? • Is the equipment's software supported?
Legal Obsolescence	• Have legal or regulatory changes impacted the cost to operate the equipment? • Is there an increased safety risk when using the equipment? • Have components or consumables used in conjunction with the equipment been reclassified as hazardous? • Is there a recall notice for this device model? • Is there security risk if the equipment's software is no longer supported?
Style/Aesthetic Obsolescence	• How often is the equipment used? • Do technicians favor the use of other equipment?
Economic Obsolescence	• Has the equipment reached its depreciation limit?

facturer, which presents a high risk to the department.

When assessing equipment obsolescence risk, consider each type of obsolescence (see Table 1). Include an accounting department member as part of the risk assessment team because they can provide insight on the economic obsolescence risks associated with each piece of equipment. The combination of *impact to the department* and *probability of obsolescence* will help you determine low-risk and high-risk obsolescence conditions for each system.

Work with the depreciation schedule

Once the current equipment conditions have been assessed, it's time to determine the depreciation timeframe for all equipment. In general, it is better to maintain equipment that provides depreciation. Equipment that is obsolete for whatever reason can provide a depreciation advantage when it's replaced. When planning equipment replacements, try to optimize the depreciation schedule for the department.

Build a technology roadmap

The final consideration when planning for obsolescence is the technology road map. As mentioned earlier, today's rapid technological advances often outpace the useful life of equipment. To prepare for this, department supervisors should have a technology map that anticipates the department's needs for software, hardware, equipment connectivity, and higher productivity, each of which may require more advanced equipment. It's also important to keep track of manufacturers' newest useful features, capacities and capabilities, in case they can fulfill a need for your department.

Establish the plan

The planning process identifies solutions for high-risk and obsolete equipment. In the case of high-risk equipment, this may include sourcing consumables, repair organizations, and replacement parts. Manufacturers often supply a timeline for discontinuation of services and parts, so SPD managers should plan to stock up before the deadline. If it's not possible to obtain new equipment within this timeframe, buying key components and a large quantity of consumables near the deadline as a "last time buy" can help extend the use of the department's equipment until a new system is purchased.

Department managers should plan a replacement schedule that considers the risk assessment, equipment depreciation schedules, and technology plan for the department. This plan may cover many years and becomes the basis for justifying and budgeting for replacement equipment. As with any plan, situations can change and affect the plan, so the equipment assessment, depreciation schedules and technology road map should be maintained and updated periodically. The frequency depends on an individual department's situation. At a minimum, these planning elements should be reviewed prior to the facility's strategic and budgetary planning events. However, it's also important to review them whenever new equipment is installed, significant technology advancement occurs in the industry, and whenever new legal or regulatory requirements affect the status of equipment in the department.

Prepare for obsolescence

Sterile processing equipment will become obsolete – that is inevitable. However, the negative impact to a sterile processing department and its surgical "clients" can be minimized if department leaders plan proactively to anticipate the risks, breakdowns, avoidable financial consequences, and potential downtime that obsolescence can cause. Planning for equipment replacement also has the potential to provide direct and indirect benefits to the department and the healthcare system's finances. In the end, it's well worth the effort. HPN

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CONTINUING EDUCATION TEST • JANUARY 2022

Can you afford to ignore obsolescence?

Circle the one correct answer:

1. **Which is the most common type of obsolescence in sterile processing departments?**
   A. Functional obsolescence
   B. Technological obsolescence
   C. Style obsolescence
   D. Economic obsolescence
2. **A recall is a type of legal obsolescence.**
   A. True
   B. False
3. **Depreciation is a factor in**
   A. Technological obsolescence
   B. Style obsolescence
   C. Economic obsolescence
   D. Depreciation obsolescence
4. **How can replacing obsolete equipment help sterile processing departments save money?**
   A. New equipment can't process complex instruments
   B. New equipment has lower productivity
   C. New equipment does not meet regulatory needs
   D. New equipment costs less to use and maintain
5. **Which part of obsolescence planning looks at the probability that current equipment will become obsolete?**
   A. Risk assessment
   B. Technology road map
   C. Depreciation timeline
   D. Process flow map
6. **A technology road map tracks the depreciation timelines of department equipment.**
   A. True
   B. False
7. **Which consideration is part of assessing equipment for technological obsolescence?**
   A. Cost of service, repairs, parts, and consumables
   B. Discontinuation notices received from manufacturers
   C. Staff use preferences
   D. Equipment's ability to communicate with other devices
8. **Which of the following is the highest obsolescence risk?**
   A. Equipment installed within the last year
   B. Equipment that has reached the end of depreciation
   C. Equipment with high maintenance and repair cost
   D. Equipment that is only used during peak operation times
9. **How often should the obsolescence plan be reviewed?**
   A. Prior to strategic planning and budgeting
   B. Every 2-5 years
   C. Every 10 years
   D. Never
10. **Which event should trigger a review of the obsolescence plan?**
    A. New employee joins the team
    B. The finance person retires
    C. New equipment is installed
    D. Consumables are changed

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The approval number for this lesson is **STERIS-HPN 210812**.

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Lighten instrument set loads for processing success, staff safety

by David Taylor III, MSN, RN, CNOR

The density of items placed in an instrument set matters. Imagine 25 pounds of surgical instrumentation evenly spread out across the work surface in the Sterile Processing (SP) assembly area. Now, imagine that instrumentation inside a tray. Because instruments are tightly packed together, there is less surface area in an instrument tray, which creates more mass (density) that can impede successful sterilization.

Association for the Advancement of Medical Instrumentation (AAMI) standards recommend that instrumentation be evenly distributed; however, achieving even distribution can be difficult in the confines of an instrument tray—and there's the added challenge of having SP staff know how those items should be best arranged in trays/containers.

Historical perspective

In 2006, AAMI recognized that heavier sets could compromise sterilization (rendering the sets unsafe to use) and pose an ergonomic strain for employees. That same year, the association recommended limiting instrument sets' maximum weight to 25 pounds (this weight limit includes the combined weight of the pan, packaging and the instruments). The following year, AORN's 2007 Guidance Statement: Safe Patient Handling and Movement in the Perioperative Setting was released with an ergonomic tool that outlined the risks associated with lifting and carrying heavy items such as instrument trays. The guidance was developed in collaboration with ergonomics experts, which included the National Institute for Occupational Safety and Health (NIOSH). NIOSH developed a tool for occupational health and safety professionals to assess the risks associated with lifting and lowering objects within the workplace. A Lifting Index value of 1.0 or less indicates a nominal risk to healthy employees; however, a Lifting Index greater than 1.0 represents indicates a task is high risk for some individuals and can place workers at risk for low-back pain. For that reason, AORN advises caution with lifting tasks that have an index of 1.0 or greater. Many SP leaders and their staff members know of this standard and can articulate the reasoning behind it. Unfortunately, all over the country, instrument sets continue to exceed 25 pounds (sometimes, significantly). Failing to manage instrument set weights places not only the SP and operating room (OR) staff at risk for a work-related injury, but also places patients at greater risk for a surgical site infection (SSI) or other negative outcomes due to the impact heavy sets can have on the sterilization process.

Note from the Healthcare Sterile Processing Association (formerly known as the International Association of Healthcare Sterile Processing Materiel Management): Auditing sets to determine weights and standardizing instrument sets per specialty can help lower set weights by reducing or eliminating instruments that may go unused during the procedure (or allowing extra or frequently unused devices to be placed in a separate container). Loaned instrument sets can also pose a challenge regarding weight; orthopedic sets, for example, can contain dozens of instruments and easily tip the scales at 40 pounds or more. SP professionals should work with their vendors to review set contents and weights and determine how those sets can be broken down into more than one container to make them easier for employees to handle. HPN

David Taylor III, MSN, RN, CNOR, is an independent hospital and ambulatory surgery center consultant and the principal of Resolute Advisory Group LLC, in San Antonio, Texas. He has served as a contributing columnist for the Healthcare Sterile Processing Association (formerly known as the International Association of Healthcare Central Service Materiel Management) since 2019.

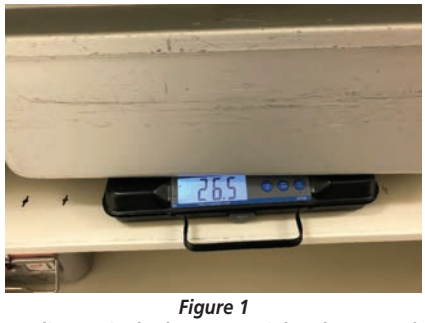
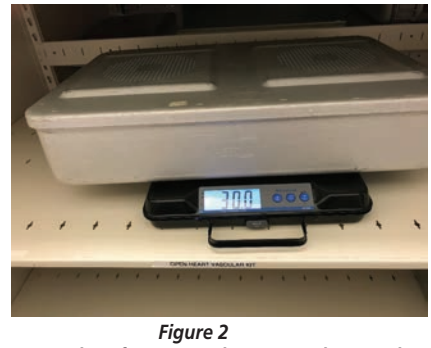


Figure 1
Audits routinely show set weights that exceed the 25-pound limit. Even a pound or two can increase risk for wet packs/sterilization failures and employee injury.



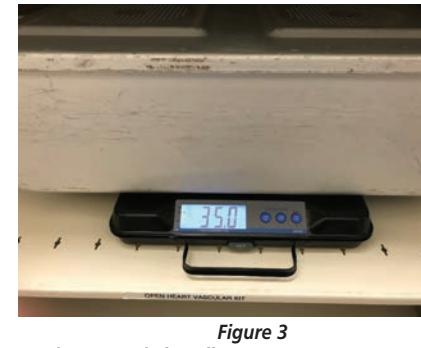


Figure 2

Figure 3

Examples of two open heart vascular sets that topped 30 pounds (an all-too-common occurrence in healthcare facilities across the country). Standardizing sets by specialty and working with vendors can help keep set weights at 25 pounds or less.

What's new in ANSI/AAMI ST91 latest update?

by Stephen M. Kovach

Q "I have heard that ANSI/AAMI ST91 has been approved. If that is true, what are some of the major changes we should be aware of?"

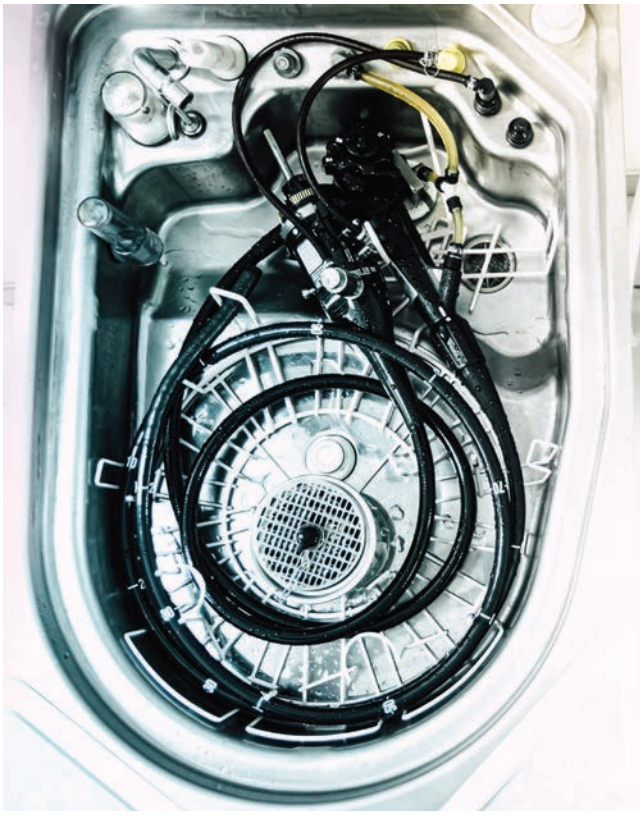
A I have been told it is ready for distribution sometime this month. As you know, there are hundreds of changes to the commentary. Some are just editorial, while others are technical. Here's my Top 10 list of things to know about the new ST91.

1. **Precleaning renamed "Point of Use Treatment":** There is also now a recommendation to note the time when point of use treatment is conducted and convey that information to the processing staff so that they know whether or not to follow the delayed reprocessing procedure.
2. **Leak testing procedure has been changed to 60 seconds of observation instead of 30 seconds:** There is now a recommendation to test the leak test units for pressure output every day the unit is used.
3. **Added a designation of "high-risk" endoscopes:** The standard contains different guidance for processing high-risk versus non-high-risk endoscopes.
4. **Cleaning verification testing intervals have changed:** ST91 now requires cleaning verification on all high-risk endoscopes and a statistically significant portion of non-high-risk endoscopes. The document walks you through how to figure that out in an annex.
5. **Strengthened guidelines around enhanced visual inspection:** The standard now recommends the use of lighted magnification.
6. **Borescope inspection is now recommended at a periodic interval determined by the facility.**
7. **Manual disinfection is no longer recommended due to the variability/inconsistency personnel responsible for the process:** That's a big one!
8. **ST91 strengthened wording on which scopes should be sterilized and which may be high-level disinfected:** All endoscopes should be sterilized (if possible), but if not possible, then we resort to high-level disinfection. Endoscopes used in a critical application—meaning used in a sterile area of the body—must be sterilized.
9. **All endoscopes are now required to be completely dried (both externally and internally) before reuse, even though they were run through an AER:** This does not matter whether the endoscope is going into the storage cabinet or back to immediate reuse; all scopes should be subjected to a compressed air-drying cycle of 10 minutes or placed into a drying cabinet to dry internally. This will add time to the processing cycle.
10. **Endoscopes should be handled with new, clean gloves (at all times):** Perform hand hygiene before donning and after doffing gloves.

ST91 is a document that involved and reflects the collective expertise of a committee of healthcare professionals and industrial representatives.

I want to thank the AAMI co-chairs: user co-chairs Nancy Chopin and her successor Garland Grisby and industry co-chair Mary Ann Drosnock (whose term just ended upon ST91's completion). Thank you for your hard work and dedication through the development of the new ST91 document.

As with any standard document (especially this one), my suggestion is to order your own copy from AAMI at www.aami.org to read the complete document. You asked for my thoughts about the changes in ANSI/AAMI ST91. If you want an official interpretation of any AAMI standards and recommended practices, you must make it in writing to the AAMI Vice President, Standards Policy and Programs. Good luck in implementing ANSI/AAMI ST91 at your facility. HPN



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Screenshots courtesy LeanTaaS

Scheduling systems sourcing, selection shouldn't be satisfied in a vacuum

by Rick Dana Barlow

Ponder this for a moment: How enticing (let alone efficient) would it be to have a single computer system in your healthcare organization to track and trace persons (patients, staff and visitors), processes (practices and workflow) and products interoperably? Think of it as HAL without the spurious attitude from "2001: A Space Odyssey" or the MacGuffin-like Starfleet computer on the U.S. Enterprise in "Star Trek."

Short of a hospital-wide enterprise-resource planning (ERP) system, industry experts acknowledge that we're not there yet but perhaps enroute. Healthcare organizations, by and large, allow their departments to invest in their own software and systems with the Information Technology (IT) department assisting in some ways to get them all to interact.

On the surface, healthcare-oriented scheduling systems may conjure up images of an electronic clipboard for patients to get on a list to visit a doctor or to reserve an operating room for an elective surgical procedure or for clinicians to determine on the fly where to send a patient who needs emergency surgery – stat!

But effective and efficient scheduling systems encompass so much more than that. They may record and track where a patient, staffer (clinician and administrator) or visitor goes but they also can do the same thing for product consumption and use or even how frequently hands are washed.

After all, if Supply Chain sources, tracks and traces what's brought in, then the clinical departments, such as laboratory, radiology and surgical services, for example, should track and trace what's done to patient and the products used for and on them.

Ideally, scheduling systems should be easy-to-learn and user-friendly, intuitive to a degree, enable customization and mobility, comply with regulations and rules, generate accurate and reliable records and reports, come with helpful customer support and be cost effective. In a spirited interview with *Healthcare Purchasing News* Senior Editor Rick Dana Barlow, six scheduling system experts share their thoughts on integrating administrative, clinical, financial and operational multifunctionality within healthcare systems on the way toward authentic interoperability.

HPN. What are some of the key factors that should be considered when sourcing, evaluating and choosing scheduling systems for the OR and why?

Matthew Rechin, Chief Commercial Officer, ReadySet Surgical: There are several important factors which should be considered when evaluating potential scheduling systems:

1. **Ease of implementation is pretty critical.** Hospitals have a number of competing priorities, many of them involve IT support. Scheduling systems that require significant IT resources during the implementation process delay the hospital's ability to

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begin recognizing the value the scheduling system can create.

2. **Ease of use is also important.** The Scheduling System should be easy to access and easy to utilize by all users…from the OR to the SPD to Supply Chain to suppliers and more.
3. **Adaptability is also important.** Looking at a scheduling system which cannot interface with the hospital's legacy systems just creates one other system that has limited reach…and impact. The system should be able to communicate with all needed users from the OR, SPD, Suppliers and Supply Chain.
4. **The system should be able to demonstrate measurable impact, otherwise, it is just a calendar.** Metrics such as on-time deliveries, on-time case starts, volume/# of trays, contract compliance, etc. are critically important to the success of the system. Scheduling systems do a great job in creating efficiencies. However, the scheduling systems that are most unique and create the most value are the ones that not only drive efficiencies, but also have the ability to generate measurable hard dollar savings.
5. **The robustness of the system is also important.** How far ahead can the SPD professionals assess inventory status for an upcoming case? Do the vendors have access to see their upcoming cases? Can the system handle all kinds of inventory (e.g., owned, consigned and loaners), etc.
6. **And of course, price and value are critically important.** When looking at value, consider the hospital should take some time to identify exactly what they hope to gain from the scheduling system. If the scheduling system of choice merely an electronic calendar that provides greater visibility/transparency, it will do very little in creating measurable value. From a pricing point of view, hospital should understand exactly how the scheduling system supplier is priced. Some scheduling systems reduce the charge to the hospital and will in turn, charge vendors to utilize their system. Others price relative to surgical case volume. The point is pricing such as that rarely creates a win-win for the hospital. Best to work with scheduling system suppliers who have very clear, easy-to-understand pricing, along with the benefits and dollar savings they will generate.

AI-based tools from LeanTaaS optimize hospital operations and unlock capacity."

Niloy Sanyal, Chief Marketing Officer, LeanTaaS: Look for tools and capabilities that drive prescriptive action and not those that just admire the problem.

- Real ROI from past system-wide implementations. LeanTaaS has executed OR scheduling optimization across 43 health systems and 2,400 ORs with a history of strong ROI execution. LeanTaaS differentiation also stems from a unique commercial offer of zero financial risk to our customers.
- A surgeon-centric solution is key to success.
- Measure the right metric to make sure you are making the right impact. Example, collectible time is a better metric than block utilization.
- Know that your EHR is not designed for predictive decision support.
- Your in-house IT team will not be able to create an AI-powered, end-to-end digital solution that has been tested and scaled across 100+ health systems.

Rosanne Zagone, Associate Principal, Clinical Operations and Quality Consulting, Vizient Inc.: A strong implementation and training process provided by the supplier must be considered when choosing a scheduling system. Although many companies say this is provided, what they provide is not always what is needed by the organization. Organizations should seek references and talk to colleagues who use the system. Organizations must consider the compatibility of any new system with existing systems that are going to remain in service. Ease of use for staff must be top of mind. You don't want to bring in a system that will require more work! Although a new system will require more work upfront and during the initial learning curve, in the long run, the new system should help rather than hinder your staff. A key requirement, in addition to ease of usability, are the reporting capabilities of the system.

Unfortunately, there is no one perfect scheduling system on the market right now that also has all of the additional interfacing programs needed: EHR, billing, scheduling, materials. There are suppliers that can provide all the IT systems needed, but few healthcare systems can afford to convert all IT systems at the same time, both financially and resources required for such a conversion.

So it is very important to define your organization's needs, both short term and long term. Your organization may need a scheduling system that is usable across multiple locations, such as the [ambulatory surgery center] (ASC) and acute care operating rooms settings. But even if the organization doesn't have an ASC today, there may be plans for one in the future, and organizations would want to be able to use their existing scheduling system once the ASC is built.

When it comes to evaluating scheduling systems, what's the leading factor on the minds of the OR that should be kept in mind when sourcing prospects and why?

RECHIN: The OR is highly interested in driving surgeon satisfaction, so a leading factor should be on-time case starts and ensuring the surgeon's requested inventory is where it is supposed to be, on-time and ready-to-go. Another issue should be to consider the scheduling system supplier's install base.

SANYAL: Real ROI from system-wide implementations. LeanTaaS' iQueue for Operating Rooms solution has consistently delivered $500K per OR per year across 43 health systems and over 2400 ORs. This is a result of 7% improvement in Staffed room utilization, 6% increase in case volumes and 5% increase in block utilization.

Kelly Matwiejczyk, Senior Consulting Director, PPI Advisory, Vizient Inc.: The OR must define its needs and what its top problems are. For example, an OR might be using a

system that is not able to define equipment very well, causing conflicts to arise on the day of surgery with equipment double booked or unlocatable. Sometimes these mishaps are caused by human error, but that may mean the system is not user friendly enough.

What else is important?

- A system that increases the reliability of accurate scheduling
- Electronic scheduling to eliminate paper processes that are prone to additional errors
- Having a system that not only provides reports, but enables users to look deeper into the data beyond the reports to identify the issues behind the data report
- Seamless connectivity with other systems: billing system, charge data master, EHR, and materials management supply chain item master. This will allow for accurate clinical, supply and charge documentation, as well as ensure the right products will be at the right place at the right time
- Networking between all systems will also provide improved tracking of supply and implant utilization, cost-per-case actual and projections, revenue projections and provide improved budgetary planning.

Technology is only as good as the policies and procedures put in place for the system, so organizations will need to ensure the strength of those policies and procedures. In addition, they should consider how much support and intelligence they are going to receive from the scheduling system company.

Finally, with the staffing shortage, organizations need to look at staff retention and satisfaction. Redundancy in work is a major frustration for staff, so the system needs to be useful for them as well. Leadership oftentimes makes these types of decisions, but staff need to be involved in the review of system and have input into the final decision-making.

How much sense does it make to invest in a surgical scheduling system with built-in capabilities to interface/integrate with the billing system and charge data master, EHR/EMR system and supply chain's item master as well as mobile devices – all securely – and why?

RECHIN: The one reality everyone can count on with the OR schedule is that it changes. If the system cannot interface with the EHR/EMR system, it is virtually impossible to provide communication on scheduled case changes or updates. Some systems, such as ReadySet Surgical, works with/interfaces with the hospital scheduling system to ensure that all updates and communications occur in real-time.

Hospitals should consider scheduling systems that can create end-to-end value; meaning from the moment the case is scheduled, until the moment the case is completed, billed and the loaned inventory has been picked up from the hospital. To invest in a scheduling system that can only provide daily updates on planned inventory misses the point.

It is not only important to interface with the hospital's EHR/EMR system, but also the hospital's ERP. This provides a complete and seamless flow of information without the need for human intervention on the hospital side. ReadySet Surgical (RSS), as an example, provides a comprehensive management system which interfaces with the hospital's ERP, the EHR/EMR system and supply chain's item master, so they not only can provide real-time alerts on schedule changes, but they also can track vendor delivery performance, alert supply chain and OR leadership to any planned/requested off-contract inventory requests, verify the submitted charge sheet's pricing is accurate, and if it is not, update it to the contracted rate, etc.

Accessibility is critically important to the success of the scheduling system. ReadySet Surgical's system is easily accessible thru any hand-held device, the ReadySet Surgical app, or via the web/the user's laptop. Scheduling systems need to be able to provide benefit for all users, not just the hospital, so a system that cannot allow a vendor rep to check in inventory without being on-site, creates a lot of inefficiency. ReadySet's system allows a rep to check in their onsite inventory with the touch of a button, on their mobile device, saving valuable time and money.

SANYAL: It makes no sense to invest in a 'surgical scheduling system' above and beyond the EHR. But it makes all the sense in the world to invest in a 'surgery schedule optimization system.' It is important to make a clear distinction between scheduling and optimization. Scheduling is the act of putting down a specific appointment onto a calendar, regardless of whether the calendar is on paper, on a spreadsheet, or on an online calendar of some sort. Optimization is the underlying intelligence that determines the best option for scheduling a particular type of appointment or allocating a specific type of asset based on the sophisticated consideration of dozens of factors that influence both the supply side as well as the demand side of that decision.

Technology that embeds optimization into online scheduling tools is ubiquitous in today's sophisticated business environment, where profitability depends upon executing a high volume of transactions while maintaining a high level of asset utilization.

A good analog would be if you open an account on Charles Schwab. Sure, you can trade stock and bonds, but you don't get any real guidance on how best to allocate your portfolio to maximize returns given your level of risk. Similarly, EHRs in themselves give you the ability to schedule cases and bill for them. However, that is nearly not enough to actually maximize utilization of block, staffed rooms and prime time. There are a few fundamental issues EHRs do not address:

- Predicting which blocks will not be well used way before day of surgery and nudging clinics to release that time. Meanwhile the way blocks are allocated leads to a culture of 'scarcity' with there being no incentives to release time early even when block owners know they won't be using the time. This leads to a situation where surgeons can find a table for 4 on OpenTable for dinner a lot easier than finding time in the OR.
- Metrics like 'Block Utilization' that are used to right-size blocks are fundamentally, mathematically broken and lead to bad decisions and ones surgeons can find all kinds of issues with.
- Reporting and data are often not believed/not shared as broadly as is needed to create a culture of transparency and accountability.
- Many community clinics don't have access to the EHR and end up capturing their backlog on paper and sending case information by fax and phone.
- The right time to invest in new equipment like robots. Are the current set of robots actually being used to mostly do robotic cases?

These are some of the issues that scheduling optimization systems, like iQueue for Operating Rooms, solve.

Keith Lohkamp, Senior Director, Industry Strategy, Workday: The industry has rightly put significant emphasis on Interoperability among systems for patient data. But interoperability among systems for master data is also vital to supporting efficient and effective delivery of care.

As customers move to our cloud-based supply chain management system, we've seen them put an emphasis on using a system like Workday as the source of truth for their item master. From this item master, Workday then sends that data out to all the other systems that need it, like the surgical system and the charge master. Updates, deletions, and adds are all controlled through the item master, meaning that the organization has one process for managing. By centrally managing, the supply chain team is better able to track the supplies and implants being used, encouraging standardization and effective cost management.

On the OR side, having up-to-date, accurate product and cost information from the item master helps ensure that item data on procedure cards is current, accurate, and ready to use, enabling quick documentation via barcode scanning or mobile. Post-surgery, downstream processes like billing or payment for consigned items can flow automatically with no or limited intervention leading to faster, more accurate billing and quicker payments to suppliers.

By having integrated systems, healthcare providers will be able streamline and automate processes, increase revenue capture, control costs, and improve safety through accurate and up-to-date product and price data.

With the increase in supply disruptions and backorders over the past year, it is more critical than ever for health systems to have visibility into planned and anticipated demand. Unfortunately, when it comes to the OR, many supply chain teams don't get visibility into detailed demand from scheduled cases until orders come in to be picked for the case the next day. But, with the right level of interoperability in a scheduling system, this doesn't have to be. Since many cases are scheduled 6, 8 , or 12 weeks out, we believe there is great opportunity to leverage advanced planning tools to pull scheduled procedures from the scheduling system along with detailed procedure cards and to forecast out anticipated demand for implants and other items. We're working with early adopters today to use forecasted demand to compare with expected inventory and anticipate potential shortfalls, allowing plenty of time to adjust ahead of the scheduled case.

ZAGONE: Built-in capabilities to interface with other systems and mobile compatibility are a must, as well as the ability to integrate with ambulatory electronic medical records, lab and radiology as well as physician offices. Surgeon clinic/physician office systems are often overlooked when planning for integration of systems.

In order to provide optimal patient care, organizations must aim for ease of communication between caregivers and the different departments required to coordinate care and plan for the care of surgical patients. The scheduling system is the initial point of entry. From there, the other computer platforms need to be able to bring together everything else required for the day of surgery: Lab work, radiology reports, history and physicals, consent forms and anesthesia plan of care. Once the scheduling is completed, it takes a lot of time, and energy is wasted tracking down these requirements — time and energy better spent caring for patients.

Finally, and often overlooked, is that supply chain needs a line of site for upcoming cases so that supplies and equipment can be made available in a timely, efficient manner. Integrated systems also allow organizations to trace any recalls back to patients more effectively. They also improve accuracy of billing.

[Further] mobile device access is important for surgeons and anesthesiologists for accessing patient documentation.

How might artificial intelligence (AI), machine learning (ML) and/or robotic process administration (RPA) play a role in scheduling systems when it comes to workflow, performance improvement and process efficiency, among other factors?

RECHIN: Some scheduling systems, like ReadySet, are already using AI to help hospitals with things such as identifying non-compliant inventory requests well in advance of the case. AI also drives the unique advanced scheduling algorithms and predictive alerts ReadySet provides. Through these benefits, RSS has helped hospitals as well as device manufacturers by creating benchmarks for forecasting required inventory levels for orthopedic cases, helping hospitals reduce their opened-but-unused tray volume, and also helping device manufacturers limit or reduce inventory levels that just sits in a rep›s garage.

However, there are other AI applications being used in the OR, such as predicting unused block time in ample time to schedule cases. This feature improves a hospital's OR utilization and is a huge driver of surgeon satisfaction.

SANYAL: AI/ML/RPA in healthcare is in an early stage, but the early results are promising in a few areas:

- Prediction of case length and case volumes, cancelations and no-shows: Helping Operating Rooms predict expected case lengths far more accurately than 'averages' of past case lengths can help schedule cases better. Also predicting significant dips or swings in case volumes can both help with 'over-booking' and staffing shifts as needed.
- Prediction of the volume and mix of patients and the patient mix in infusion chairs, and clinic exam rooms to be able to optimize patient flow and 'level load' the day and staff appropriately.
- Image recognition: Machine-assisted diagnostics that help radiologists and physicians interpret images are showing good results. However, since the biology of each patient is unique, each provider practices medicine in a unique manner and each disease progresses in a unique manner. These technologies will likely need time before they can completely take over a meaningful share of the intelligent decisions that need to be made thousands of times each day in any health system.

In the coming years, healthcare will see what we have seen in other industries – for instance, Uber uses AI and machine learning to ensure they have the right number of drivers in the right locations available for any given city or time of day. We should expect to see intelligent assistants that can construct appointment schedules that utilize the existing scarce resources (e.g., providers, ORs, machines, beds, chairs, etc.) much more efficiently while giving the patients more choices in selecting an appointment slot.

We should also expect to see vastly improved patient flows throughout the health system, manifested by the emptiness of

the waiting rooms scattered throughout. These intelligence assistants will be pervasive and yet mostly invisible — they will operate behind the scenes on the application pages used by schedulers to make appointments and will use AI and machine learning to gently and persistently guide schedulers into making better decisions in a timely manner. These assistants will also be prescient -- they will anticipate delays and cancelations and will automatically reroute patients and providers and issue quiet, unobtrusive push notifications to the affected parties while giving them an opportunity to override. Patient flow will resemble a crowded freeway of autonomous vehicles with fully networked communications moving quickly and confidently, adapting as needed without colliding into each other.

These are just a few examples of 'predictive and prescriptive analytics' and not just 'descriptive' and 'diagnostic' analytics that are about 'see a number, show a number.' Data science done right can significantly enhance outcomes, increase utilization and access – all while transforming the patient experience.

Kevin Lewis, Consulting Director, Supply Chain Services, Vizient Inc.: Robotic process automation (RPA), also known as "bots," can help reduce the time staff spend on highly manual and redundant tasks such as compiling data for scheduling and workflow. RPA can do anything a person can do on a computer, such as pulling data from different systems into a dashboard or report, offering real-time performance improvement reporting and constant monitoring for opportunities to improve efficiency.

Where RPA acts like a virtual person, clicking and compiling data as a human would do, artificial intelligence software uses techniques such as machine learning and pattern recognition to help supplement human reasoning on identifying the best or most appropriate workflow, as well as conduct root cause analysis on performance failures and process inefficiencies. RPA and AI can be used to provide more actionable analytics, such as descriptive (i.e., 'What's happening now?'), predictive (i.e., 'What's the forecast?'), and prescriptive (i.e.., 'What should we do?') analytics.

In addition, AI helps to weave in emergency procedures more efficiently into an organization's schedule. Charge nurses do a great job, but AI can provide additional decision-making support, including historical acuity level data that provides more insight into pre-operative and intra-operative requirements for the case, and relies less on the charge nurse's 'experience' and 'best guesstimate.'

When considering scheduling systems, ease of use for staff as well as reducing workload is key to improving staff satisfaction and retention. Organizations should be looking at systems that will make staffs' lives easier. HPN

Taking AIM on UDI: progress, problems and possibilities

by Karen Conway, Vice President, Healthcare Value, GHX

Last month, AIM North America held a masterclass on the evolution of UDI. Despite having worked on UDI for nearly 15 years, I learned even more about not only the challenges, but also how and why we must continue to work together for its adoption.

I would like to recap some of the key messages from the two-hour program and offer some commentary on where we go from here. For those not yet familiar with UDI, regulators around the world, beginning with the U.S. FDA, are issuing regulations requiring manufacturers to assign and label their devices with unique device identifiers (UDIs) and to publish data about those products in designated databases. The UDI itself contains two parts: the UDI-DI that identifies a product, e.g., a manufacturer labelled suture or implant, at a particular packaging level, while the second part, the UDI-PI includes the production data, such as lot or serial number, expiration date, for specific products.

A primary regulatory driver has been to "identify devices through distribution and use," which the first speaker, Steven Luxenberg, MD, with the U.S. FDA said includes documenting UDIs in "electronic health records, clinical information systems, claims data sources and registries." The International Medical Device Regulators Forum, which provides guidelines on UDI regulation to support more global harmonization, recently added materials management systems as another key place where UDI should be documented to maximize its value.

Progress and problems on the regulatory front

In his comments, Dr. Luxenberg noted that more than 3.1 million UDI records have now been published by more than 6300 companies in the U.S. FDA's Global UDI Database (GUDID). That data has broad interest, with an average of 4600 daily log ins to AccessGUDID (https://accessgudid.nlm.nih.gov/), where most of the GUDID data is publicly available for search and download.

Dr. Luxenberg said that new forms used for X12 administrative (claims) transactions enables the inclusion of the UDI-PI, although it is not yet required. X12 plans to recommend these new forms supporting UDI information exchange be federally mandated, which would then initiate a multi-year federal process to make the recommendation a requirement. Even without a mandate, many have argued for voluntary use, noting that the inability to specifically identify in claims data the brand of a device used in patient care increases healthcare costs while jeopardizing patient care in the event of recalls.

Other speakers spoke to some of the regulatory challenges to both compliance and use of UDI. Jay Crowley, who wrote much of the U.S. UDI regulation and now serves as vice president, medical device solutions and services for USDM Life Sciences, says despite the IMDRF's call for harmonization, there is increasing variation in the requirements published or proposed in different countries. BD UDI program lead Dennis Black added that such variation increases the compliance cost and complexity for medical device manufacturers. This, in turn, can create challenges for providers. For example, manufacturers may publish different "clinically relevant" information about the same products given the variation in requirements across countries. Different regulatory triggers as to when a product's UDI needs to change could also lead to a proliferation of multiple UDI-DIs for the same product globally. The IMDRF notes how this proliferation of different device identifiers and the lack of harmonization makes it difficult to ensure access to products during emergencies such as the recent pandemic.

UDI and the clinically integrated supply chain

James Tcheng, MD, a practicing interventional cardiologist at Duke Health, shared both the challenges and benefits of UDI adoption in the healthcare delivery environment. Dr. Tcheng noted the importance of integration of UDI into clinical and supply chain processes to enable the "clinically integrated supply chain," in which clinicians, supply chain and other healthcare leaders collaborate on decisions to improve both the cost and quality of patient care. As he put it simply: "it's about getting everyone working in concert vs. doing their own thing independently."

Data, like UDI, according to Dr. Tcheng is key to collaborative decision-making. Dr. Tcheng outlined the steps that Duke Health has taken to incorporate UDI in the Cardiac Cath and electrophysiology labs, including use of the standard identifiers for procurement and inventory, clinical supply documentation at the point of use, and charge capture and billing. The results have been impressive, reducing manual documentation and associated errors, shortening procedural time, and improving both inventory and recall management, all of which he says have contributed more than half a million dollars in financial benefits.

Such improvements and savings did not come easy, says Dr. Tcheng, noting that it took more than 300 hours just to enable the various technology systems to be able to share UDIs. But he added the ongoing benefits are worth it. Just because it is hard, doesn't mean it won't work, said Dr. Tcheng, citing a similar journey taken by the aviation industry. In the late 1990s, following a series of mass casualty plane crashes, representatives from regulatory authorities, pilot unions, air carriers, and eventually air traffic controllers began a quest to create a unified, data-driven approach to aviation safety. It wasn't easy, with many initially fearing that sharing information on safety incidents, even near misses, would result in retaliation. Advocates of the new, and notably voluntary, approach did not give up, ultimately leading to a new era of data capture, sharing and analysis, and resulting in zero fatal crashes among U.S. commercial airlines since 2009. It gives cause to question those who insist that UDIs will only be fully adopted across healthcare if they are mandated. My question is: If we can collectively improve the cost and quality of care, while reducing the clerical burden for clinicians and healthcare workers, why aren't we rallying together to make it happen? HPN

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HAVING MY SAY

4 reasons to rethink disposable ECGs lead wires

by Kathleen Fallon, RRT, Senior Marketing Manager, Hospital Accessories and Consumables, Dräger

Photos courtesy Draeger

Infection prevention (IP) has been top of mind for clinicians as they have worked to stem the spread of SARS-CoV-2 (COVID-19) among their patient populations. While developing and implementing infection prevention (IP) protocols specifically aimed at COVID-19, many clinicians have taken a step back to examine their facility's overall approach to combatting healthcare acquired infections (HAI).

In light of research showing high levels of bacterial contamination of certain reusable patient interfaces,[1,2] U.S. hospitals have increasingly switched to single-patient use monitoring accessories such as non-invasive blood pressure (NIBP) cuffs, pulse oximetry probes, and disposable ECG wires.[3,4] Nonetheless many hospitals continue to utilize reusable versions of many other high volume, low cost consumables.

For example, few have converted from reusable to single patient use electrocardiogram (ECG) electrodes.[5] This is despite the fact that it has been shown that reusable ECGs can harbor dangerous microbes, including vancomycin-resistant enterococci (VRE). For example, in one study, researchers found 77% of "supposedly clean" wires were contaminated with antibiotic-resistant bacteria.[6]

The cost to treat a single patient with an HAI can be as high as nearly $50,000[7] and is no longer reimbursed by CMS. As they rethink their IP strategies, a growing number of hospitals are reevaluating this risk area.

Here are four reasons to rethink disposable ECGs beyond infection risk alone:

1. Patient care and satisfaction

The trend of consumer driven healthcare and the role of the patient in deciding where he or she will be treated has increased competition among healthcare provider organizations. Research from Accenture found, "U.S. hospitals that deliver 'superior' customer experience achieve net margins that are 50 percent higher, on average, than those of hospitals providing 'average' customer experience."-

Healthcare institutions want the best for their patients and strive to be considered high-quality in their communities. Therefore, these institutions put patient care and safety first in every choice that they make. This includes using the best quality capital equipment along with the best quality accessories.

High-quality, disposable ECG lead wires free of wear and tear can reinforce to the patient the quality and safety of a healthcare institution's care delivery. As patients increasingly research hospital infection rates and complications, it is even more important to avoid HAIs related to reusable devices.

2. Clinical efficacy and staff satisfaction

Another downside of reusable ECGs compared with disposable is durability and reliability. The internal wires fray over time, leading to artifact on the electrocardiogram tracing.[9] Clinicians can become frustrated as they look to find fault with the monitor when in reality a deteriorating ECG lead wire set is the cause.

When an ECG fails, the clinician has to take off the lead wires and put on new ones, which can prolong care delivery and cause additional patient discomfort. It's important to note that less "patient touches" can drive higher patient satisfaction rates and decrease the opportunity of nosocomial infections.

A study performed in cardiac telemetry units found significantly fewer false-alarms with disposable ECG versus reusable, with the researchers concluding that disposable ECG "may save nurses time, decrease alarm fatigue and improve patient safety."[10]

3. Patient care continuity

Today, technology is available where you can secure for your patient a disposable ECG set and a disposable NIBP cuff that can be used from admission to discharge. Adapters enable these disposable items to be used across various brand monitors and have been tested and validated with these manufacturers' devices.

Therefore, if a patient moves from one brand of monitor in the ER to a different brand in the ICU, the same disposable cuff and ECG set can move with him or her. This approach supports continuity of care, with clinical staff not having to switch lead wires each time the patient is moved. There are also potential cost savings benefits from using a single ECG lead set throughout the patient's stay, rather than having to use multiple forms of this item due to monitor incompatibility.

4. Supply standardization and savings

Health systems and hospitals are increasingly working to standardize on supplies in an effort to reduce complexity and costs. Those that use ECG lead wires from various companies must engage in the procure-to-pay (P2P) process with each manufacturer, manage each brand's inventory and find adequate storage space to house the variety of items.

By standardizing on one brand of disposable ECG lead wires, you can streamline your P2P and inventory management processes, while reducing storage requirements. Supplier consolidation can also enable you to capitalize on bulk buy discounts for this particular item.

To further reduce complexity and generate greater savings, consider standardizing on one manufacturer that has capital equipment and consumables/accessories for multiple areas of the hospital (e.g., anesthesia, ventilation, monitoring, etc.) and the service to support these items.

Conclusion

Supply costs, care quality and financial outcomes are always top of mind for healthcare organizations. While it may be a rather small, inexpensive item compared with many of the other items you procure and use in your organization today, an ECG lead set can have a big impact in many different areas. Taking the time to rethink disposable ECGs lead wires could result in far reaching benefits for your organization, staff and patients. HPN

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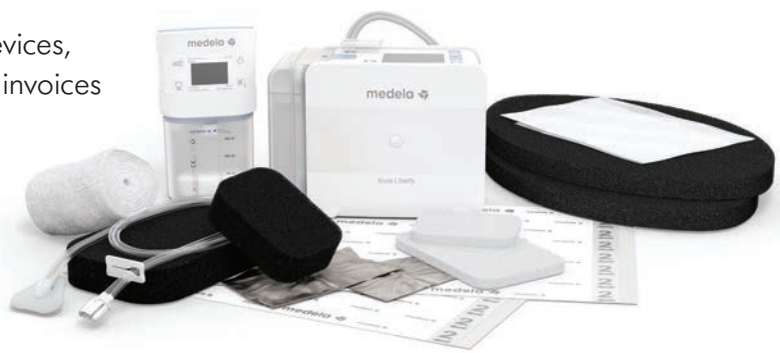

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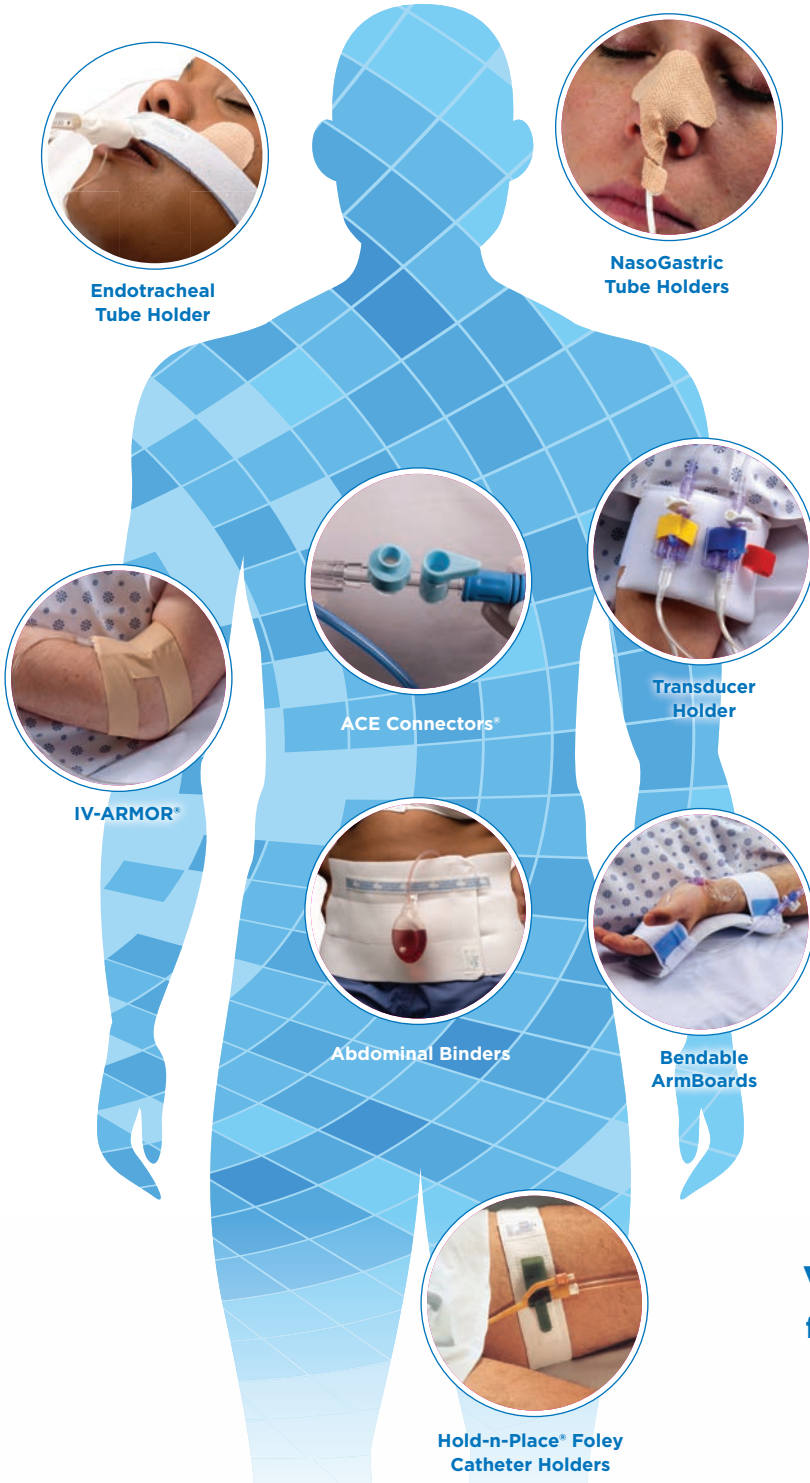

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