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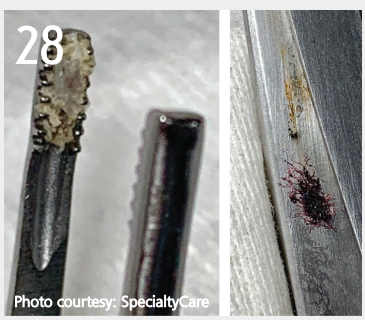

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Stepping stones, stumbling blocks

As the post-holiday bills come due this month we should enter the New Year with some levity and "clarity of vision." Okay, enough with the feeble 20/20 references. In healthcare organizations, here are 20(+) of the best and worst things to hear from alternating perspectives…the first being the setup example.

1. On an airplane: "We'll be on the ground shortly."
2. In the OR/ICU: "We're finished!"
3. In SPD: "Is this clean?"
4. In the C-suite: "Doctor who?"
5. In Supply Chain's storeroom/warehouse: "If it's in stock, we have it!"
   a. Runner-up: "They'll never find it here."
6. During the Value Analysis meeting: "It's going to cost how much?"
7. In Infection Prevention: "The Joint Commission is here."
8. In Environmental Services: "It's clean!"
   a. Runner-up: "The Joint Commission is here."
9. During the P&T committee meeting: "We use what?"
10. In Information Technology: "Did you turn it on?"
11. In Dietary: "Cook, then chill."
12. In Facilities Management: "Did you plug it in?"
13. In Quality/Risk Management: "Don't bring problems, just solutions, so do you really have to contact us?"
14. In Accounts Payable/Billing: "People complain about having to prove who they are to pay by phone as if we'll allow complete strangers to do it."
15. In Finance: "Strive for balance, don't go negative."
16. In Operations: "My supervisor told me to have a great day … so I left."
17. In HR: "Being late does not shorten your day!"
18. In Nursing: "Red Sharpies are not for drawing blood."
19. In Laboratory: "We're the only ones who can prove division equals multiplication."
20. In Radiology: "Don't lie to me because I can see right through you!"
    a. Runner-up: "You're positive you lost an electron?"

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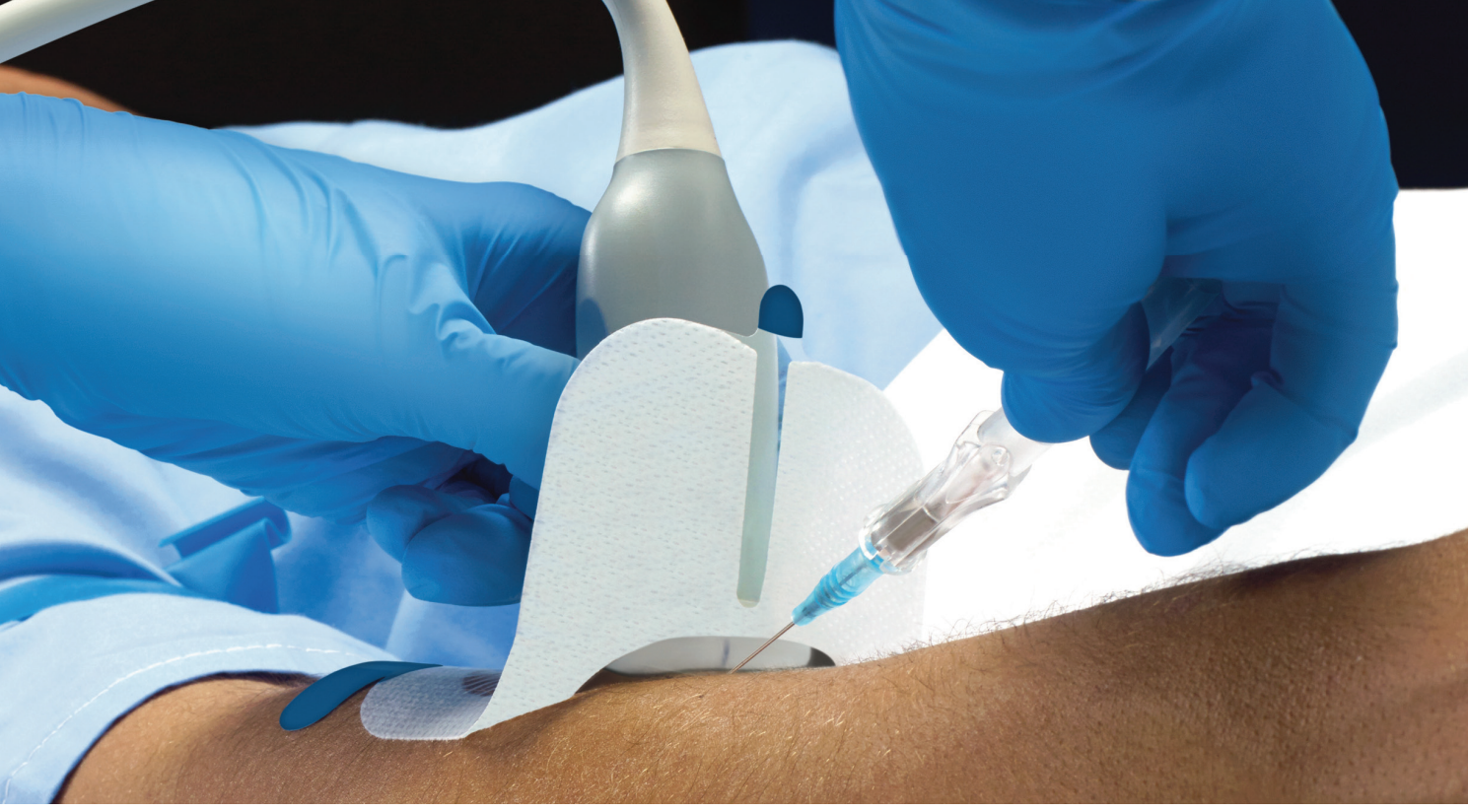

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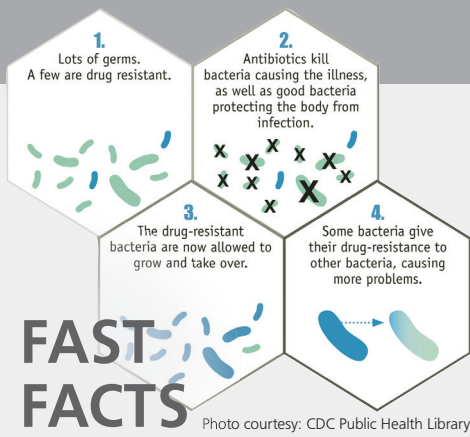

FAST FACTS

Photo courtesy: CDC Public Health Library

In the report, The Antibiotic Resistance Threats in the United States, 2019, the continuing impact of antibiotic-resistant (AR) germs on people and communities is highlighted. Last published in 2013, it now features 18 germs of concern; a watch list with three threats; the latest numbers of AR infections and deaths; and actions to prevent, treat and stop the spread of AR infections. Findings:

2.8 MILLION+

antibiotic-resistant infections occur in the U.S. each year, and more than 35,000 people die as a result.

2,868,700

infections or at least 35,900 deaths are estimated to be caused by antibiotic-resistant bacteria and fungi each year.

223,900 CASES

or 12,800 deaths of *Clostridioides difficile (C. diff)* are related to antibiotic use and antibiotic resistance.

30,000 CASES

of invasive pneumococcal disease and 3,000 deaths were prevented by the PCV13 vaccine from 2010 to 2013 alone.

47 MILLION

antibiotic courses are estimated to be prescribed each year for infections that don't need antibiotics.

$300 MILLION+

is invested in 59 state and local health departments to detect and prevent resistant threats.

350+

partners are engaged globally through the Antimicrobial Resistance Challenge.

550,000

drug-resistant infections are estimated to occur each year.

2 MILLION+

pneumococcal infections occur each year in the U.S., resulting in more than 6,000 deaths and $4 billion in total costs.

Source: CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.

NEWSWIRE

AHVAP announces their new Board of Directors for 2020

AHVAP, the Association of Healthcare Value Analysis Professionals, has announced the 2020 Board of Directors. A huge congratulations to the incoming leadership.

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The Association of Healthcare Value Analysis Professionals (AHVAP) is an organization of professionals whose expertise bridges the gap between clinical and supply chain process. Through the use of evidence, clinical and financial expertise value analysis facilitators play a pivotal role to ensure effective decision making that positively impacts clinical, operational and financial outcomes. For more information, visit AHVAP.org.

CMS Office of the Actuary releases 2018 National Health Expenditures

Total national healthcare spending in 2018 grew 4.6 percent, which was slower than the 5.4 percent overall economic growth as measured by Gross Domestic Product (GDP), according to a study conducted by the Office of the Actuary at the Centers for Medicare & Medicaid Services (CMS) and published by *Health Affairs*.

As a result, the share of the economy devoted to health spending decreased from 17.9 percent in 2017 to 17.7 percent in 2018. Growth in overall healthcare spending has averaged 4.5 percent for 2016-2018, slower than the 5.5 percent average growth for 2014-2015, that was affected by expanded Medicaid and private insurance coverage and increased spending for prescription drugs, particularly for drugs used to treat hepatitis C. The growth in total national healthcare expenditures was approximately 0.4 percentage point higher than the rate in 2017 and reached $3.6 trillion in 2018, or $11,172 per person.

According to the report, private health insurance, Medicare, and Medicaid experienced faster growth in 2018. The faster growth for these payers was influenced by the reinstatement of the health insurance tax, which was applied to private health insurance, Medicare Advantage, and Medicaid Managed care plans. The health insurance tax was a fee imposed on all health insurance providers beginning in 2014 as a part of the funding for the Affordable Care Act (ACA) and was subsequently amended to institute a one-year moratorium on the fee for 2017.

- Private health insurance spending (34 percent of total healthcare spending) increased 5.8 percent to $1.2 trillion in 2018, which was faster than the 4.9 percent growth in 2017. The acceleration was driven in part by an increase in the net cost of private health insurance, which was a result of the reinstatement of the health insurance tax in 2018 following a one-year moratorium in 2017.
- Medicare spending (21 percent of total healthcare spending) grew 6.4 percent to $750.2 billion in 2018, which was faster than the 4.2 percent growth in 2017. The faster growth in Medicare spending in 2018 was influenced by faster growth in the net cost of insurance of Medicare private health plans (mostly Medicare Advantage plans) due to the reinstatement of the health insurance tax in 2018, faster growth in Medicare spending for medical goods and services, and an increase in government administration spending after a reduction in 2017.
- Medicaid spending (16 percent of total healthcare spending) increased 3 percent to $597.4 billion in 2018. This was faster than the rate of growth in 2017 of 2.6 percent. The faster rate of growth in 2018 was driven by faster growth in the net cost of insurance for Medicaid managed care plans, also due in part to the reinstatement of the health insurance tax.
- Out-of-pocket spending (10 percent of total healthcare spending) includes direct consumer payments such as copayments, deductibles, and spending not covered by insurance. Out-of-pocket spending grew 2.8 percent to $375.6 billion in 2018, which was faster than the 2.2 percent growth in 2017. Faster out-of-pocket spending growth for retail prescription drugs, durable medical equipment, and dental

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services more than offset a slowdown in out-of-pocket spending for hospital care.

Healthcare spending growth was mixed in 2018 for the three largest goods and service categories – hospital care, physician and clinical services, and retail prescription drugs.

- Hospital spending (33 percent of total healthcare spending) increased at about the same rate in 2018 as in 2017, growing 4.5 percent and 4.7 percent, respectively, to reach $1.2 trillion in 2018. The steady growth in 2018 was driven by an acceleration in hospital price growth that was offset by slower growth in the use and intensity of hospital services.
- Physician and clinical services spending (20 percent of total healthcare spending) increased 4.1 percent to reach $725.6 billion in 2018. This was slower than the rate of growth in 2017 of 4.7 percent. The deceleration in 2018 was driven by slower growth in the use and intensity of physician and clinical services, as physician and clinical price growth accelerated in 2018.
- Retail prescription drug spending (9 percent of total healthcare spending) grew 2.5 percent in 2018 to $335.0 billion following slower growth of 1.4 percent in 2017. This faster rate of growth was driven by non-price factors, such as the use and mix of drugs consumed, which more than offset a decline of 1 percent in prices for retail prescription drugs.

FDA updates on EtO sterilization of medical devices

The U.S. Food and Drug Administration (FDA) is providing information on recent actions responding to ongoing concerns about ethylene oxide (EtO) in commercial operations and encouraging innovative approaches to medical device sterilization.

On June 15, 2019, the FDA announced two Innovation Challenges to identify sterilization alternatives and reduce EtO emissions. The FDA received 46 applications from companies large and small. After careful review using an established set of criteria, 12 challenge applicants have been selected to participate.

The FDA announced its Ethylene Oxide Sterilization Master File Pilot Program (EtO Pilot Program). This voluntary program is intended to streamline the submission process, so that sterilization providers that sterilize single-use medical devices using fixed chamber sterilization processes may submit a Master File to the FDA when making certain changes between sterilization sites, or when making certain changes to sterilization processes that utilize reduced ethylene oxide concentrations, and premarket approval application (PMA) holders can reference such a Master File in a post-approval report instead of submitting a traditional PMA supplement.

On Nov. 6 and 7, 2019, the FDA held an advisory committee meeting to discuss EtO sterilization of medical devices and its role in maintaining public health. Based on panel discussions, the FDA is encouraging device manufacturers to move to electronic labeling and instructions for use in the near term.

1 in 5 adolescents and 1 in 4 young adults now living with prediabetes

Nearly 1 in 5 adolescents aged 12-18 years, and 1 in 4 young adults aged 19-34 years, are living with prediabetes, according to a new Centers for Disease Control and Prevention (CDC) study published in *JAMA Pediatrics*.

Prediabetes is a health condition in which blood sugar levels are higher than normal, but not yet high enough to be diagnosed as type 2 diabetes. The condition also increases the risk of developing type 2 diabetes, chronic kidney disease, heart disease, and stroke.

Monitoring the percentage of adolescents and young adults with prediabetes can help determine the future risk of type 2 diabetes. To do this, CDC researchers used data from the National Health and Nutrition Examination Survey covering the years 2005-2016.

"The prevalence of prediabetes in adolescents and young adults reinforces the critical need for effective public health strategies that promote healthy eating habits, physical activity, and stress management," said CDC Director Robert R. Redfield, M.D. "These lifestyle behaviors can begin early in a child's life and should continue through adolescence and adulthood to reduce onset of type 2 diabetes."

Key study findings:

- Nearly 1 in 5 (18%) adolescents (those aged 12-18) and 1 in 4 (24%) young adults (aged 19-34 years) were living with prediabetes.
- The percentage of adolescents and young adults living with prediabetes was higher in males and participants with obesity.
- Hispanic young adults had higher rates of prediabetes compared to white young adults.
- Adolescents and young adults with prediabetes had significantly higher cholesterol levels, systolic blood pressure, abdominal fat and lower insulin sensitivity than those with normal glucose tolerance, which increased their risk of type 2 diabetes and other cardiovascular diseases. HPN

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SPECIAL FOCUS

Smart storerooms, wireless warehouses

From blank check to budget crunch, updates may be fundamental but not infinite

by Rick Dana Barlow

Photo courtesy Intermountain Healthcare Supply Chain

Hiking through the canyons of a logistics trade show floor, flush with vendors exhibiting the latest material handling devices, equipment and technology, you'll get a sense that contemporary storerooms and warehouses seem like an amusement park full of workflow-oriented operational rides.

You'll spot colorful horizontal and vertical conveyor units, roving automated guided vehicles (AGVs), airborne and wheeled drones, motorized lifts, robotic arms with synchronized movements, electronic head-worn and wrist-worn gear programmed with augmented reality capabilities to ensure accurate replenishment and shelving position and a host of additional options sure to populate any busy Supply Chain professional's wish list.

For high-end, high-tech and high-volume manufacturing and distribution operations, these tools buttress functionality and reinforce fundamental issues related to performance, productivity and workflow. For hospital and healthcare organization storerooms and warehouses, these tools represent a stroll through a logistical FAO Schwartz.

From First in, first out (FIFO) to Last in, first out (LIFO) to inventory turns and the vaunted "Golden Zone," hospital and healthcare facility storerooms and warehouses may not have to be equipped with dancing robotic arms and Star Wars-like droids scooting around to get the work done.

But how do you design or redesign a storage footprint that can pivot adroitly when demand soars and when supply swells but keep the traffic patterns running flexibly and smoothly?

For more information on storeroom-warehouse design, read "Pinpointing storeroom, warehouse design slips, slides" at www.hpnonline.com/13000938, "Thinking outside the moving of boxes" at www.hpnonline.com/13001320, and "Super storage design may call for up, up and awaaaay!" at www.hpnonline.com/13001544.

Blank check booyah

Imagine having access to virtually limitless resources (challenging to do post-holiday, for sure, but could be therapeutic) to design or redesign a storeroom or warehouse with a keen eye on effective but efficient product flow and fast and seamless performance improvement.

Sound too good to be true? Well, for many, it very well may be. However, some strategists might advise you to envision the end game and work your way back. In terms of equipping a facility, this translates into picking your technology tools and then figuring out how to pay for them or scaling back.

Updating or upgrading a storeroom or warehouse this decade centers on effective data management, sources almost unanimously agree.

For supply chain professionals, storerooms and warehouses typically involve a significant amount of energy to receive, restock and pick inventory on a daily basis, observed Thomas Redding, Senior Managing Director, Healthcare Services, St. Onge Co.

Thomas Redding

"Streamlining operations requires considerable effort on data standardization and synchronization with suppliers to allow for information to easily flow to ensure a properly designed operation can leverage its assets appropriately," Redding said. *To read Redding's list of useful tools, read "Dear Santa Storage, this is what I want…" at https://hpnonline.com/21117592.*

Application and implementation of tools already reflect the cost shifting of human to machine labor that will emerge in the coming decade within this "dynamic and customer service-focused business," according to Jim Richardson, Portfolio Executive, Senior Consultant, Vizient Inc.

Jim Richardson

"As markets grow tighter and more expensive, technology is replacing labor in warehousing and distribution," Richardson noted. "Distributors and manufacturers are already using several of these advanced technologies to reduce labor costs, increase throughput and maximize customer service." *To read Richardson's list of useful tools, read "Dear Santa Storage, this is what I want…" at https://hpnonline.com/21117592.*

Yet Gordon Slade, Logistics Director, Intermountain Healthcare Supply Chain, cautions against giddiness and greed when faced with even virtually unlimited resources to make improvements. Why? Available space (that tends to be ceded to revenue-generating enterprises) and product demand.

Gordon Slade

"Even with a limitless budget and resources, the focus of design and application technology in a medical supply warehouse/storeroom must consider the reality of limited physical space constraints within acute and non-acute healthcare settings," Slade told *Healthcare Purchasing News*. "While healthcare facilities should always maintain a finite level of critical supplies for patient [surgical] and emergency/disaster events, supply storage space continues to receive pressure in support of increased utilization

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of space for patient services. This reality will continue the need for more creative, reliable and timely supply logistics solutions. Keeping this in mind, the future of warehouse storeroom physical location, design and technology must ultimately focus on meeting the changing needs and environment of the end user – regardless of available resources and technology."

Still, Slade encourages automating existing manual process flows, storage, picking, transportation and replenishment activities, but with a few caveats.

"Automating manual processes should ideally reduce labor dependence and physical inventory space, while increasing service levels to user locations," he added.

Slade foresees a central warehouse/storeroom as utilizing "robotic and automated solutions to receive, put away, store, replenish and pick items in defined units of measure with little to no direct labor involvement." That also involves the ability to order cycle times reduced to minutes/seconds for urgently needed critical to life items. "Large or multi-site central storerooms could be served from a larger offsite central warehouse and/or local micro fulfillment center established on or near campus," he observed. *To read Slade's list of useful tools, read "Dear Santa Storage, this is what I want…" at https://hpnonline.com/21117592.*

Slade acknowledges that automation and other new tech carries a high initial capital cost and may not yield significant improvement over traditional tech.

"Automation technologies that are stand alone in nature, and do not communicate via a standard protocol, should be avoided," Slade insisted. "Many suppliers have products and solutions that require custom programming to interface. Managing these complex and variable environments, coupled with every changing operating system versions and different cloud databases can lead to unexpected downtime, poor reliability and system incapability issues. Successful automation system should be fully integrated under a common platform that can manage, monitor, report and adjust to desired performance outcomes."

Fred Landgraf, Senior Vice President, Supply Chain Solutions, Intalere, delineates between scaled-down, smaller hospital-centric storerooms topping off at 1,000 square feet and large warehouse space as storeroom space exceeding 1,000 square feet typically are repurposed for revenue-generating services. As a result, redesign efforts probably should focus on the warehouse.

"Technology in a warehouse is the primary backbone of the management of the inventory, both from internal management of storage locations and inventory levels as well as external placement of orders to vendors/manufacturers," Landgraf indicated. That's why he recommends healthcare organizations invest in a solid warehouse management system (WMS) that will provide "adequate capability to manage inventory at the level of detail required than a materials management information system (MMIS) or enterprise resource planning (ERP) system.

"The appropriate level of WMS will give the system the capability to manage the inventory and operate in a paperless environment with the use of radio frequency technology and hand-held scanners," he continued. Such technology will enable high-volume picking in case quantities and in less-than-case quantities with storage and material handling equipment spanning from pallet racking through carton flow rack and even potential pick modules with some level of conveyors, he added. While Landgraf sees conveyors as beneficial, he expresses concern that they "can minimize efficiency in high density picking."

Unless space constraints warrant the use of high-density storage solutions, Landgraf expresses concern that the expense of such technology may outweigh expected benefits gleaned from it.

Landgraf favors a more open-concept approach.

"High-density storage generally requires designated pods or position for picking and give minimal flexibility in flexing to high or low volumes," he indicated. "Handheld scanners in an open architecture environment give significant flexibility for scaling to high-volume output while minimizing expense when the physical infrastructure is designed appropriately." He further notes that open architectural storage design enables inventory access even during power/system breakdowns and outages.

The economics of designing or redesigning storage space extends beyond making expense management more efficient and pushes into revenue areas, asserts Beth Riggio, Director, Solutions Management, Swisslog Healthcare.

"The warehouse of the future is designed to maximize usable space at hospital for revenue-generating patient care areas," Riggio told *HPN*. "In many metropolitan areas, the per-square-foot cost of hospital space is at a premium. That makes storing products there relatively expensive. In addition to this direct cost there is an opportunity cost. In-hospital storage takes up precious space that could be better used by repurposing it to offer new or expanded, high-margin services. Consequently, in-facility storage has a double impact on a hospital's budget."


Beth Riggio

By contrast Riggio notes that centralizing storage and distribution of med/surg and pharmacy items at a Consolidated Service Center (CSC) liberates healthcare facility space for better use. "Moreover, administrators can drive down the per-square-foot cost of storage by purchasing or leasing space in less-costly areas," she added.

Such realization fuels expansion and growth in the CSC distribution model, according to results of a Swisslog Healthcare survey of hospital supply chain executives last year. Survey results showed that 43 percent of respondents report currently distributing from a CSC and another 43 percent are considering it, Riggio noted.

As larger distribution centers, CSCs can consider different types of technology, such as comprehensive WMS, automated guided vehicles, pick-to-voice technology and even robotic goods-to-person storage systems, she indicated.

Riggio cited Indiana University Health as a particular success story that supports 17 hospitals and picks 7,500 lines per day. *[See the September 2018 HPN for details or search for IU Health on HPN online.]* "In a traditional manual picking model, hospital distribution centers target 60 picks per hour. However, the robotic [low-unit-of-measure] picking system at the IUH Integrated Service Center enables three people to pick 500 lines per hour at 99 percent accuracy," she added.

CSCs also provide additional avenues for service line growth, such as pharmacy, according to Riggio. She cites a recent Swisslog Healthcare survey of pharmacy executives as finding that 75 percent of health systems currently using a CSC model report an ROI in less than 12 months.

"When pharmacy can share an existing warehouse space with supply chain,

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it significantly reduces the investment required to centralize operations and strengthens the case for consolidation," she said. "When you think about all the possibilities for centralization and consolidation of distribution and management of shared services, the question is no longer simply, 'What does the warehouse of the future look like?' The question becomes, 'What can the hospital of the future accomplish thanks to innovation in supply chain management?'"

Shakedown breakdowns

In cases of backorders, breakdowns, outages and shortages, Tessa Natterer, Director, Supplier Performance, PartsSource Inc., recommends looking outside the box.


Tessa Natterer

"Healthcare supply chain leaders fear critical item shortages and back orders, an increasingly common problem with clinical supplies," she said. "Clinical engineers face the same challenge as it relates to back-ordered and slow-to-ship parts and service that takes months to schedule. These challenges lead to delays in equipment repair, lost revenue, waiting patients and idle CE staff. Instead, if resources were limitless, building the artificial intelligence to predict and automate your ordering would dictate warehouse size and design specific to your facility's patient requirements."

And if a healthcare organization cannot achieve such AI service itself it can look to a third party serving as a warehouse extension, Natterer continued. "Based on millions of transactions made by hundreds of hospitals, we leveraged aggregate data from CE teams to determine which mission-critical replacement parts are often out of stock or have long lead times to ship," she noted. "The identified critical products are now guaranteed in-stock at our warehouse, ready for prompt shipment to members of the PartsSource Pro community, saving hospitals significant stock out or backorder days, but not adding to their warehouse requirements."

Because operating rooms, no matter how technologically advanced they may be, require sterile storage support, they should consider automated vertical storage equipment to help them "make maximum use of minimal space" and "to protect sterile supplies from the possibility of contamination," insisted Amy Flynn, OR/CS Market Manager, Hänel Storage Systems.


Amy Flynn

Hänel's sterile storage inventory management systems not only improve accuracy to more than 99 percent, but also reduce the likelihood of shortages, expired items, having to spend valuable time to correct errors, and having to spend time searching for items urgently needed in the OR, Flynn noted. "The Hänel Rotomat has been proven to boost productivity due to increased efficiencies in supply retrieval, streamline operations by lowering the need for a large staff, increase inventory security by storing expensive implants and supplies within a secure six-sided unit, provide additional security by requiring password access or keycard swipe in order to obtain supplies, improve ergonomics by keeping movement within the OSHA-suggested 'golden zone' between the waist and mid-chest height, and mitigate infection rates by keeping sterilized supplies within a closed environment."

Flynn doesn't recommend hospitals adding a roomful of individual compartment racks as their storage solution. "These racks allow sterile supplies to be organized into removable plastic compartments, but the baskets often fall out of their tracks," she said. "The bottom of one compartment often drops into the open top of the one below it, or a bin may have multiple types of items in it, so organization can very easily give way to chaos. Even though these racks have wheels, the combined weight of all the items on board makes it difficult to roll, and someone still needs to access items by moving outside the golden zone to do so."

Minding maturity

Deep pockets should take a back seat to efficient and intelligent use of resources, advises Carlo Malaguti, M.Arch., Senior Supply Chain Applications Specialist, Warehouse Design, TECSYS.


Carlo Malaguti

"Every warehouse and storeroom should be viewed as a queuing system where products received join a queue (stored) and are waiting to be serviced (shipped or used)," Malaguti observed. "The holy grail of that queue is when technology, time (labor) and space (storage) are synchronized so perfectly that inbound and outbound flow at a constant rate. No matter how deep your pockets, that fundamental concept should guide you.

"It is certainly an interesting thought exercise to imagine intelligent sortation, image-based dimensioning equipment, automatic de-stacking and sortation, automated storage and retrieval systems, robotized order picking, automated AGV loading, routing and stocking — the list goes on," he continued. "Ultimately, though, we ought to think about diminishing returns on the technology we implement, both financially and logistically."

Malaguti recommends investing in Auto-ID technology that connects a facility's inventory to its storage facility. This strategy extends beyond what he calls a "well-oiled software platform and appropriate use of data capture technologies" to create a "network of datapoints to tap into the purest form of continuous improvement.

Malaguti further emphasizes the need for standards-based tracking and tracing processes.

"Devices, equipment and products need to be tracked using supply data standards, and a new generation of disposable, wireless microchip can satisfy that requirement and then some," he said. "Other than [identifying] every single item/[unit of measure] and carrying a huge volume of data, these microchips can also communicate temperature, 'smell' the surrounding, register shocks and unwanted movements, or confirm location within the supply chain when interacting with wireless locators. The microchip can be inserted by the manufacturer, programmed based on requirements of the customer, and have the capacity to capture and transmit information until it reaches its final consumption point, including recycling or waste disposal data for statistical purposes." HPN

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[1]http://www.acc.org/latest-in-cardiology/articles/2017/11/08/11/47/mon-5pm-bp-guideline-aha-2017

Positioning patients for success

Clinicians under pressure to detect, prevent injuries

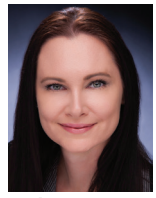
by Ebony Smith

Pressure injuries (PIs), also known as pressure ulcers or pressure wounds, continue to rise and harm patients throughout the U.S. PIs are difficult to detect, cause pain and infections, prolong hospital stays, are costly to treat and can become deadly.

The National Pressure Injury Advisory Panel (NPIAP) defines pressure injury as "localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device." [1]

The NIAP, renamed last November from the National Pressure Ulcer Advisory Panel (NPUAP) in line with the internationally preferred pressure injury term[2], added, "The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue." [1]

PI costs and causes



Kristy Warren

Kristy Warren, MSN-Ed, RN, BA, CLLM, Director, Clinical Resources, Encompass Group, LLC, affirms a heavy human and financial toll of PIs on people and healthcare providers. "While the newly published AHRQ report data for 2014-2017 shows an overall decrease in Hospital Acquired Conditions (HACs), this doesn't extend to pressure injuries (PIs). The rate of PIs rose by 6% over the study period. This represents an increase of 119,000 pressure wounds, resulting in close to 5,000 deaths. In addition, the average lengths of hospital stay more than doubles for patients who acquire PIs during their care. PIs increase healthcare utilization and medical management, costing the U.S. healthcare system around $11 billion per year."

Healthcare staff, leadership and operations all play a part in PIs, said Erica Thibault, MS, RN, CNS, APN, CWON, Sizewise Clinical Manager, and Suzanne Worden, PT, MS, CSPHA, Sizewise Clinical Liaison. "Staffing ratios, lack of staff education, and lack of support from leadership all contribute to the growth of pressure injury incidence. There are also problems with assessment documentation, complete lack of written processes, or the failure of processes in place."

Assessment and late-stage detection of PIs are other concerns, add Thibault and Worden. "PIs present differently in darker skin, and are often missed until they advance into higher, more dangerous stages. This is one of the most challenging areas in pressure injury (PI) prevention and treatment."

Certain patients and their circumstances are more prone to PIs. For example, Warren points to older age and surgical procedures as factors. "As our population ages, the risks associated with developing a pressure injury increase. Additionally, surgical patients that may not have presented at-risk prior to surgery have an increased risk during and post operatively of developing a pressure injury."

Mark Lazzeri, TransMotion Product Marketing Manager, on behalf of Winco Mfg, LLC, identifies patients' health as another issue. "Patients are getting larger and staff is getting smaller. Obesity and diabetes are on the rise, increasing risk in a patient population in which pressure ulcer incidences are higher."

Having cared for her own mom, Lauren Somma, President of Life Solutions, sees quality of care in the home as another concern. "Individual circumstances would be the first contributor, and secondly, the quality of the care a patient is receiving will play a role in pressure injuries. Caregiver fatigue and not having proper support will also contribute to the quality of care she/he is able to provide."

Somma added, "The biggest challenge I see is that home caregivers and small companies are not sensitive to the challenges of positioning patients. This will lead to a lack of quality care, injuries, caregiver burnout and compromised patients. Think about the one simple fact that each person needing this level of care, if being cared for properly, needs to be changed two to three times per night. That's huge! When this does not happen, bed sores, infections and UTIs are just some of the problems that can occur."

Even more factors may be of influence, according to Mölnlycke Health Care. "The aetiology of pressure injuries is still being uncovered; for example, until recently it was not recognized that pressure injuries can occur in the OR in as little as two hours. As this knowledge base continues to grow, we can expect to see more effective prevention strategies become widespread across the continuum of care."

Challenges and opportunities in care

Healthcare facilities face several challenges and opportunities when it comes to patient care, PI prevention and costs of workplace injuries, explain Thibault and Worden. "Cost is always a challenge, as many facilities are unable or unwilling to allocate funds for repositioning processes. In addition, obesity rates continue to rise and nursing staff levels continue to shrink. However, facilities are open to the chance to lower workers' compensation claims and of course to improve patient satisfaction, so the opportunities rise just as much if not more than the challenges."

Pete Nelson, Marketing Manager, Prevalon, on behalf of Stryker Medical Sage business unit, also calls staff injuries a challenge. "When healthcare workers lack proper tools for repositioning, the risk for injury increases. According to OSHA, the average cost of a patient handling claim is $15,800. [3] There's also the factor of time away from work. When healthcare workers are unable to work or afraid of getting injured, it has a direct impact on patient care."

Additionally, he raises finding the right patient positioning products as an opportunity. "Decreasing staff injuries due to patient handling and repositioning is an ongoing challenge for hospitals. There are several different types of repositioning products on the market, but many don't work as intended because they don't fit into the workflow of patient care or they aren't readily available when needed. As a result, patients may be missing out on interventions to prevent pressure and skin

injuries. This presents a huge opportunity to improve patient care."

Patient positioning growth

According to "The Global Patient Positioning System Market" report by Data Bridge Market Research, the patient positioning product industry is revolutionizing and expanding. The market "accounted to USD 987.5 million in 2016 growing at a CAGR of 4.7% during the forecast period of 2017 to 2024." [4]

Further, the report found that, "The growth is due to a great extent of the developing needs of current medicinal services. The entire medical equipment market is facing and confronting different new challenges. The patient positioning market is specifically connected with the modernization drives, which are directly flooding the healthcare canvas. Few modest modernization drives have started great innovation, standards creation and streamlined the entire post and pre-surgery care for whole diagnostic industry, which is evolving faster around the world. It creates an advantage point for both patients and doctors."

Looking ahead, the market is positioned for enhanced products and patient care, says Mölnlycke Health Care. "With increasing focus on the importance of pressure injury prevention and safe patient handling, the right patient positioning products will continue to gain awareness among clinicians and healthcare providers dedicated to improving standard of care. This increased focus will promote the elevation of the current standard of care like foam wedges, pillows or gels with limited clinical outcomes and will pave the way forward for advanced products."

In-hospital solutions

From beds, chairs and pillows to boot protectors, positioners and turning systems, a wide scope of products is available to aid in safe patient positioning during medical procedures, hospital stays and other settings, and reduce the risk of PIs.

One area of focus for Innovative Medical Products (IMP) is surgical and post-op positioning, notes Jim Bailey, President, IMP. "One source of frustration for administrators in regard to pressure injuries is tissue injuries that can occur when the patient's arm is tucked at his or her side with bedsheets. "Tucking" provides no real flexibility or pressure relief, creating unnecessary strain on the nerves and can lead to tissue injuries on the patient's tucked arms. In addition to injuries and ischemia, tucking can also interfere with physiologic monitoring (i.e., blood pressure monitoring, arterial catheter monitoring, checking of electrical leads). Without clear access to the tucked arm, staff may be unable to examine a patient during an emergency. There is also an increased risk for the patient to develop compartment syndrome in the upper extremity."

For surgeries, Bailey highlighted, "LapWrap, a positioning pad system ideal for any surgery that properly secures a patient's arm to the OR table side rail while evenly distributing pressure across its soft foam lining. LapWrap also protects against shoulder injuries that could occur as a result of a patient's arm falling off the side of an OR table. The soft material also protects neurological structures by preventing hyperextension at the elbow, while allowing anesthesiologists easy access for IV tubes and leads.

"We manufacture the most recognized knee positioner in the industry, the IMP De Mayo Knee Positioner. The device works by securely holding a patient's leg so that OR staff doesn't have to. The additional space grants surgeons unobstructed surgical access. An optional off-table version helps reduce lower back strain during procedures by allowing the surgeon to stand between the patient's legs during surgery," he continued.

For post-op recovery, Bailey added, "One product often recommended by surgeons for post-op care, a Hip Abduction Pillow, which helps to prevent the patient's hip from moving out of the joint. The pillow is placed between the patient's thighs and attached to their legs with straps. IMP's post-op Hip Abduction Pillows provide greater comfort and more accessible nursing care by utilizing soft straps that help evenly distribute pressure."

Stryker Medical Sage business unit supports in-bed patient positioning, says Nelson. "Boosting and repositioning patients in bed is a high-frequency task. The Sage Prevalon AirTAP Patient Repositioning System uses air-assisted technology to reduce the amount of exertion needed to turn patients. Unlike plastic slide sheets, it stays under the patient at all times, so it's always ready to assist with turning, repositioning, and boosting the patient. AirTAP helps address sacral pressure injury risk factors by offloading the sacrum. It also helps maintain an optimal microclimate to protect skin."

Air-assisted systems also are offered by HoverTech International, states Katie Kramer, Marketing Communication Manager. "The air technology used to reduce the physical effort for caregivers also benefits patients, who glide over surfaces on a cushion of air that eliminates friction and significantly reduces shear. Patients feel comfortable and secure, while families benefit from knowing their loved ones are not in pain during routine patient handling tasks."

Kramer spotlights, "The HoverMatt Single-Patient Use (SPU) air transfer system uses air technology to reduce the force needed to move a patient by 80-90%. This reduces the physical strain on nurses, as well as the number of caregivers needed to perform patient handling tasks for improved staff safety and efficiency. The HoverMatt SPU is constructed of advanced breathable fabric that has been tested according to the latest standards approved by the National Pressure Injury Advisory Panel's S3I Committee. This means caregivers can be confident leaving the HoverMatt SPU under their patients for all-day care, including lateral transfers, boosting, turning and positioning.

"The Q2Roller Lateral Turning Device is another tool that facilitates pressure injury prevention. Left under the patient for easy access, the Q2Roller can improve compliance to q2h protocol by eliminating manual handling for turning and positioning patients. Caregivers can quickly and easily inflate the chambers of the Q2Roller to gently turn the patient for pressure relief and improved access to the patient's back and sacrum for hygiene and wound care," she continued.

HoverMatt SPU by HoverTech

Winco Mfg, LLC concentrates on positioning and transporting patients, declares Lazzeri. "TransMotion by Winco offers TMM3; TMM4 and TMM5 stretcher chairs that are intended for use in patient treatment, transport and/or recovery within a hospital, clinic, same day/ambulatory surgery center, or similar environment. The TMM is a procedure chair, transport device and stretcher all in one! The powered position adjustments include table height, leg angulation, back angulation, Trendelenburg, ReverseTrendelenburg and Seat Tilt. These independent positions have been shown to reduce pressure points under the patient. [5] TransMotion Pad Cushions have a multi-layer foam that has also been shown to reduce pressure when compared to single layer devices."

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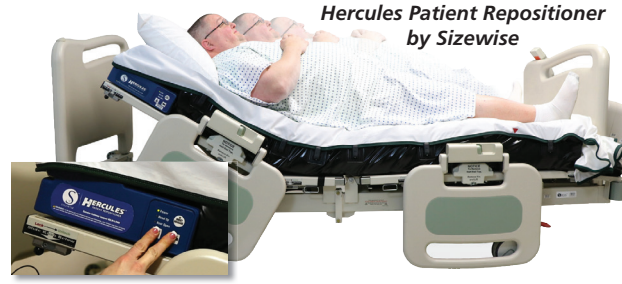
He points to Bascom Palmer Eye Institute's use and improved safety, reporting, "Their goal was creating a no-lift, no-transfer environment in the OR, addressing three high-profile operational and safety issues: (1) patient fall hazards, (2) risk of injury to staff, and efficient patient flow. A zero-transfer solution was implemented utilizing the TransMotion TMM5 Surgical Eye Stretcher Chair. Patients remained in the same chair through all phases of their procedure, thus eliminating transfers that could be hazardous to patients and staff members. The goal was reached, as there were no patient falls and no worker's compensation cases relating to back pain from transferring patients and increased patient flow."[6]

TransMotion Medical's TMM4X Plus Medical chairs

Supporting patient positioning throughout care is Sizewise, express Thibault and Worden. "Our Hercules Patient Repositioner is best for patient positioning during hospital stays. Hercules helps a single caregiver reposition a patient up to 750 lbs. with the touch of a button.

"Hercules features a synthetic, moisture-wicking sheet, which sits on a low air loss mattress or pressure redistribution foam mattress. Clips help the sheet slide along with the patient, which reduces friction and shear. Hercules sheets can be removed and washed in the washer, and then tumble-dried. The mattress can be cleaned and disinfected according to a facility's regular mattress cleaning procedure. We've recently started offering disposable sheets for facilities not wanting to manage laundry. Only one caregiver is needed to reposition, which saves patient dignity by reducing the number of people in the room. Hercules lowers pressure injury (PI) rates, allows for boosting often and painlessly, and helps reduce caregiver injury (and therefore lost workdays). Our customers absolutely love it. They say it's easy to use and a time saver, and that back injuries have virtually disappeared," they added.

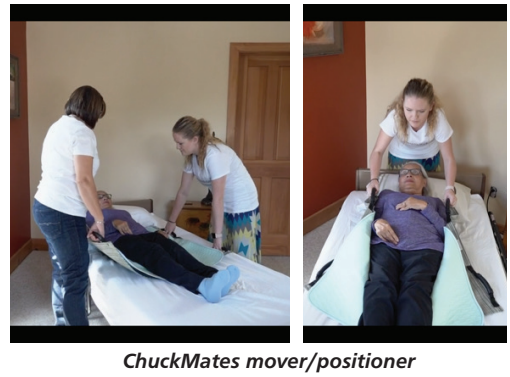


Hercules Patient Repositioner by Sizewise

At-home solutions

ChuckMates helps caregivers accomplish the task of positioning and changing their loved ones at home, shared Somma. "This product (ChuckMates) was developed solely for the assistance with my own mom. It is weight bearing so it helps the caregiver and the patient with positioning, maneuvering, and bed changing. It can be used with one or two caregivers, and the handles are ergonomically placed. The goal is to help prevent caregiver fatigue and back strain as well as allow the patient to maintain dignity while being cared for in this way. The material is strong, breathable and Microban protected. ChuckMates can be washed as often as needed with bleach or detergent and air dried."

She adds about her 2019 National Caregiving Product Innovation Award winning product, "Caregivers say that their backs are not hurting, they are not as fatigued, and they love the varied use for the product. They use it to pull the patient to the top of the bed, rotate the patient for bed changing, and it also helps patients get out of bed by pulling it and helping the patient rotate to bring their legs to the side of the bed. Patients are not being pushed and pulled and compromised in any way. It's a win/win for all."



ChuckMates mover/positioner

Multi-setting solutions

Assisting patient positioning across a range of healthcare and residential settings is Mölnlycke Health Care. Their Z-Flo Fluidized Positioners, Tortoise Turning and Positioning System and Z-Flex heel boots are designed for single-patient use. However, these pressure injury prevention tools can accompany a patient across the continuum of care – from OR to ICU to hospital to long-term care to home, according to the company.

Mölnlycke's Z-Flo Fluidized Positioners are used to redistribute pressure over a greater surface area or to help offload bony prominences. They are easy to mold and will conform to virtually any shape, allowing them to adapt to multiple anatomical sites, including occiput, sacrum and extremities. Their unique structure also allows areas in the positioner to be depressed, or hollowed out, for medical lines, tubes or existing wounds. At North Shore University Hospital, Brennan et al reported that there were no moisture concerns with the use of the Z-Flo Fluidized Positioner, and that patients were more comfortable and less likely to move, potentially reducing the effects of friction and shearing. The hospital experienced a 54% overall reduction in pressure injuries.[7]

Tortoise Turning and Positioning System

Mölnlycke Tortoise Turning and Positioning System is a support surface that has been clinically shown to help prevent pressure injuries by providing continuous pressure redistribution.[8] The Tortoise positioning mat helps redistribute pressure over the patient's sacrum and buttocks with a low pressure air chamber designed to envelop the patient through positive air displacement. If the Tortoise travels home with the patient, it makes it easier for family caregivers to boost and move the patient while adding a layer of pressure-relieving comfort to any bed. At Sharp Coronado, the use of the Tortoise system reduced caregiver injuries by 89% and resulted in a direct cost savings of $108,948 on claims in just one year.[9]

The Z-Flex Fluidized Heel Boot Protector was designed by Mölnlycke to offload the heel and maintain an anatomically neutral foot position. The boot incorporates a Z-Flo

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••

Zero PIs for two years – what one hospital achieved after adopting a perioperative prevention program that includes Z-Flo™ Fluidized Positioners.[4]

Get the complete story at **www2.molnlycke.us/zflopositioners**

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Fluidized Positioner to mold and contour around the vulnerable Achilles tendon. A built-in foot gate allows heel skin assessment without boot removal. During a recent study at Ethica Health, 100% of the study patients reported comfort and ability to comply with the plan of care versus those with the prior heel suspension boot, which was reported as hot, heavy and uncomfortable. Staff compliance with protocol also improved due to ease of application and resident satisfaction.[10]

Industry future

As the patient positioning market and needs continue to grow, Lazzeri predicts, "Enhanced pressure reduction surfaces and additional design improvements to enhance patient and caregiver satisfaction."

Encompass Group, LLC is focusing on surfaces, reports Warren. "In addition to a full line of support surfaces that are made in the U.S., Encompass Group LLC recently launched the innovative, engineer and clinician designed Airisana. Airisana features the first of its kind, five support surfaces in one. This surface offers low air loss with targeted air flow, pressure redistribution, alternating pressure on a randomized cycle to prevent acclimation, microclimate management, immersion and envelopment, and lateral rotation to assist with caregiver turn assist, pulmonary health and early mobility."

Lifts and education are in development with Stryker Medical Sage business unit, says Nelson. "The new Sage AirTAP Lift Compatible (LC) was introduced to the market in November. AirTAP LC provides 3-in-1 patient mobility by helping staff achieve compliance to protocol for in bed repositioning, lateral transfer, and vertical transfer from bed to chair using overhead and portable lift equipment. We also partner with hospitals to provide the education and tools necessary to ensure proper use and drive better patient care."

Prevalon AirTap from Stryker Medical Sage

While IMP looks to increased Ambulatory Surgical Centers (ACSs) and a hip positioning device. "One positive healthcare trend is the rise of ASCs. Recently, ASCs have been approved to do more types of joint replacement surgeries. IMP is committed to helping ASCs enhance profitability by offering many space-conscious solutions, attractive product bundling options and access to on-site in-service training for ASC staff. In 2020, we're planning a release of an all-new hip positioning system that will significantly reduce setup times in the OR. The product requires very little training to set up and features a unified, unfolding design that simplifies setup and saves time." HPN

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Virtual reality could help flu vaccination rates

Using a virtual reality (VR) simulation to show how flu spreads and its impact on others could be a way to encourage more people to get a flu vaccination, according to a study by researchers at the University of Georgia and the Oak Ridge Associated Universities in Oak Ridge, TN. This is the first published study to look at immersive virtual reality as a communication tool for improving flu vaccination rates among "flu vaccine avoidant" 18- to 49-year-old adults.

"When it comes to health issues, including flu, virtual reality holds promise because it can help people see the possible effects of their decisions, such as not getting a flu vaccine," said Glen Nowak, the principal investigator and director of the Center for Health and Risk Communication headquartered at Grady College. "In this study, we used immersive virtual reality to show people three outcomes—how if infected, they can pass flu along to others; what can happen when young children or older people get flu; and how being vaccinated helps protect the person who is vaccinated as well as others. Immersive VR increases our ability to give people a sense of what can happen if they do or don't take a recommended action."

The research, "Using Immersive Virtual Reality to Improve the Beliefs and Intentions of Influenza Vaccine Avoidant 18- to 49-year-olds," was published by the journal *Vaccine*.

According to the Centers for Disease Control and Prevention (CDC) during the 2017-18 flu season, only 26.9% of 18- to 49-year-olds in the U.S. received a recommended annual influenza vaccination even though it is recommended for all 18- to 49-year-olds. The low current acceptance of flu vaccination makes it important to identify more persuasive ways to educate these adults about flu vaccination. The findings from this study suggest one-way VR can be more effective as it can create a sense of presence or feeling like one is a part of what is happening.

In the VR condition, participants were provided headsets, which enabled them to vividly experience the information and events being shown as if they were in the story, and video game controllers, which enabled them to actively participate at points in the story. Compared to video or the e-pamphlet, the VR condition created a stronger perception of presence – that is, a feeling of "being there" in the story, which, in turn, increased participants' concern about transmitting flu to others. This increased concern was associated with greater confidence that one's flu vaccination would protect others, more positive beliefs about flu vaccine and increased intention to get a flu vaccination. Neither the e-pamphlet nor the video was able to elicit a sense of presence nor were they able to improve the impact of the CDC's Vaccination Information Statemet on the confidence, belief and intention measures.

INFECTION PREVENTION

Smart for safety & savings

Don't try to outsmart your infusion pumps, catheters and related devices

by Susan Cantrell, ELS

Seventeenth-century English physician Thomas Sydenham is credited with the axiom "first, do no harm." This advice on patient safety still stands today, a few centuries later, but possibly now there are myriad more opportunities for patient harm, however unintended. Two medical devices that are commonly recognized as sources of medical errors are infusion pumps and catheters of all sorts.

Infusion pumps

Intravenous (IV) infusion pumps deliver medication to the patient, and therein lies the potential for an adverse drug event (ADE). An ADE is injury due to a medical intervention related to a drug, including but not limited to medication errors and overdoses. Inpatient settings account for approximately one in three of all hospital ADEs, affect about 2 million hospital stays each year, and prolong hospital stays by 1.7 to 4.6 days, according to the Office of Disease Prevention and Health Promotion.[1]

Infusions cause 54 percent of ADEs, 56 percent of medication errors, and 61 percent of serious and life-threatening errors.[2] *AAMI News,* referring to articles published in the fall 2015 issue of AAMI's *Horizons,* stated that misuse, "overriding and manually bypassing key safety features of IV smart pumps often is to blame. Smart pumps are programmed with a built-in drug library and dose error reduction system to protect patients from programming errors by checking inputted information against approved safe dosing ranges."[2]

Thomas Utech, PharmD, Worldwide Vice President, Global Solution Management & Marketing, Medication Management Solutions, BD, advised, "Minimizing medication errors while improving clinical efficiency is a top concern across the healthcare landscape. Healthcare executives are constantly looking for ways to leverage technology to support this outcome."

Because the healthcare industry is under pressure to improve patient safety and care, Utech recommends a holistic approach for infusion-medication management.

Utech explained that BD's smart-pump infusion system, Alaris System with Guardrails software, helps protect against infusion-pump medication errors in four ways. "First, infusion devices and modalities are standardized at the bedside and compounding equipment in the pharmacy. Then, the hardware is wirelessly connected with software and data on one platform, BD HealthSight." He advised that those tasked with making a decision on choosing a smart pump should determine beforehand how

BD Alaris System with Guardrails software smart-pump infusion system

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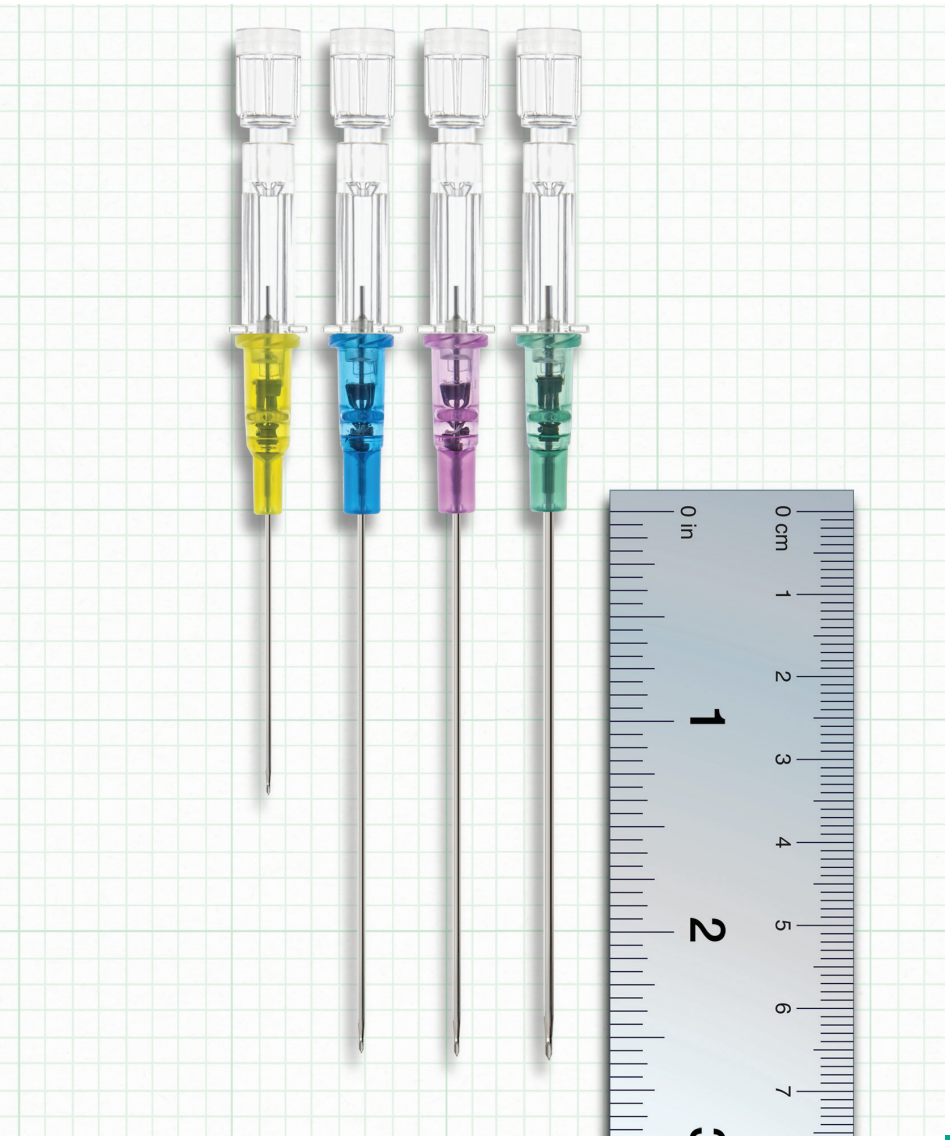
B BRAUN
SHARING EXPERTISE



Longer length peripheral catheters help facilitate IV procedures involving:

- Ultrasound guidance [1]
- Access to deeper veins [1]
- Patients with difficult access [2]
- Overweight/obese patients [2]

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1 Stone, Phillip, RN, and Britt Meyer, MSN. "Ultrasound-guided Peripheral I.V. Access: Guidelines for Practice." American Nurse Today. N.p., Aug. 2013. Web. 05 June 2014.

2 Elia, Fabrizio, M.D., Ferrari, Giovanni, M.D., Molino, Paola, M.D., Converso, Marcella, M.D., De Filippi, Giovanna, M.D., Milan, Alberto, M.D., Apra, Fanco, M.D. "Standard-length catheters vs long catheters in ultrasound-guided peripheral vein cannulation." The American Journal of Emergency Medicine. 2012. Vol. 30.

3 Data on file (B. Braun ETR NPAK-AKRJQV)

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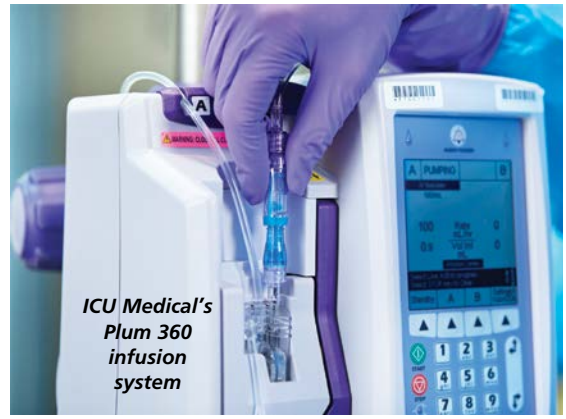
the technology fits into the hospital's future wireless and interoperability goals. "Next, the BD Alaris System and BD HealthSight solutions capture infusion data, for continuous quality improvement. Finally, the addition of the new BD HealthSight Clinical Advisor functionality aggregates disparate data from hospital systems to identify if a medication order is no longer clinically appropriate for a patient. The hosted software application enables robust medication-stewardship alerts, advanced analytics, and dashboards designed to improve patient outcomes.

"To gain a holistic view of infusion-administration processes," continued Utech, "the BD Knowledge Portal for Infusion Technologies is an intuitive, web-based reporting tool that quickly translates BD Alaris System data into actionable intelligence that helps drive clinical education, drug-library standardization, alarms management, and dose-error–reduction software compliance. Together with the BD HealthSight platform and its suite of advanced analytics solutions, actionable data can be accessed to help reduce variation and improve the practice. Device alarm data includes alarm types, counts, duration, care area, drug/fluid name, and the time associated with each infusion modality alarm, to help comply with The Joint Commission National Patient Safety Goals on Alarms Management."

ICU Medical's aim also is to improve patient safety through a more effectively designed infusion system. Matthew Hutchings, Vice President Global Marketing & Innovation, Infusion Systems, described ICU Medical's Plum 360 infusion system as having a unique, proprietary, cassette delivery system that provides a direct connection for the secondary line, which helps to eliminate secondary set-up errors shown to occur in 48 percent of secondary infusions. "This includes eliminating the need for bag-height differential and alerting clinicians when a secondary clamp is left closed," said Hutchings.

Hutchings referred to the Institute for Safe Medication Practices' (ISMP) draft guidelines, which include a recommendation (item 1.7) for secondary delivery.[3] "Use an automated secondary IV infusion management system that is not dependent on head height differential and has the ability to assure secondary flow." Hutchings averred, "The Plum 360 infusion system meets this guideline for secondary delivery with the cassette-based delivery system."



ICU Medical's Plum 360 infusion system

Talking about the high cost of sepsis and the role of an infusion system in its prevention, Hutchings noted that sepsis is the leading cause of death in hospitals and is the most expensive condition to treat, with U.S. total annual hospital costs of more than $24 billion.[4] He also referred to a white paper from Premier Inc, "Creating a Culture of Optimal Care Delivery," published in October 2018, that stated the average cost per case for hospital-associated sepsis has jumped more than 20 percent since 2015, in excess of $70,000.

"Research shows that poor sepsis outcomes occur when diagnosis and treatment are delayed,"[5] said Hutchings. "The 'sepsis bundle' is the cornerstone of sepsis quality improvement. Two key elements of the bundle are the administration of broad-spectrum IV antibiotics and fluid resuscitation with an IV crystalloid fluid. The bundle should be started immediately upon diagnosis. The Plum 360 smart pump has the unique ability to guarantee secondary delivery, ensuring a secondary delivery of antibiotic is not missed."

Hutchings cited a study by Prusch et al[6] in support of IV interoperability as a patient-safety measure. The study aimed to develop, implement, and evaluate an IV interoperability program to improve medication safety at the bedside. The study concluded, "By integrating two stand-alone technologies, IV interoperability was implemented to improve medication administration. Medication errors were reduced, nursing workflow was simplified, and pharmacists became involved in checking infusion rates of IV medications."[6]

Catheters and related devices

Most hospital patients have one or more catheters inserted during their stay. Patients, particularly the immunocompromised, are at risk of infection due to a catheter, because it is invasive and provides ingress to pathogens.

Doug Shook, Vice President of Marketing, Access Scientific, highlighted the attributes of POWERWAND midline and long peripheral intravenous catheters, made of ChronoFlex C with Bioguard technology in preventing potential infection. Infections become established on the catheter through the production of biofilm.[7] He said they are the only noncoated catheter shown to inhibit bacterial attachment, even during extreme exposures. It also is FDA-cleared for thromboresistance. "These catheter characteristics help explain why only the POWERWAND has over 36,000 published catheter-days without a reported infection," said Shook.

Access Scientific feels confident that users can achieve these results because of outcomes reported by current users. Furthermore, "If hospitals do not reach their targets, we provide meaningful reimbursement," offered Shook.

POWERWAND midline catheters enable clinicians to remove central-venous–access devices sooner, according to Shook, which can help reduce the rate of infection. An outstanding example is found in a published scientific study focusing on Richmond Medical Center in Staten Island, which reduced CLABSI in one ventilator intensive-care unit by 100 percent using POWERWAND. The result was nearly $500k savings as compared with the previous year.[8]

Access Scientific has such confidence in their product that they offer a guaranteed reduction in total central-line–associated (CL) bloodstream infections (BSI; CLABSIs) and central-line usage. "We guarantee, by using POWERWAND, hospitals can reduce their total CLABSIs by 10 percent and central line usage by 25 percent." That may represent a substantial savings, as Shook noted that the cost of a CLABSI is estimated at $48,000 per incident.

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Vascular-access expert and consultant to Parker Laboratories, Inc, Nancy Moureau, RN, PhD, CRNI, CPUI, VA-BC, and CEO of PICC Excellence, told *Healthcare Purchasing News* that UltraDrape (Parker Laboratories) is designed specifically for ultrasound-guided (UG) peripheral intravenous (PIV; UGPIV) procedures. Its value lies in separation of the ultrasound probe and gel from the insertion site, enabling clinicians to maintain a sterile insertion site, thereby reducing the risk of infection associated with peripheral catheters.

Explaining that contamination during UGPIV procedures is a major concern, Moureau said, "Separating gel from the skin with a sterile barrier dressing promotes an aseptic UGPIV procedure by reducing contamination risk during and after insertion. It also eliminates post-insertion clean up."

Moureau emphasized the importance of standardization and consistency in procedure. "While the Centers for Disease Control and Prevention require clinicians to maintain aseptic procedure for the insertion and care of intravascular catheters to prevent infections, inconsistent UGPIV practices minimize the effectiveness of aseptic techniques."

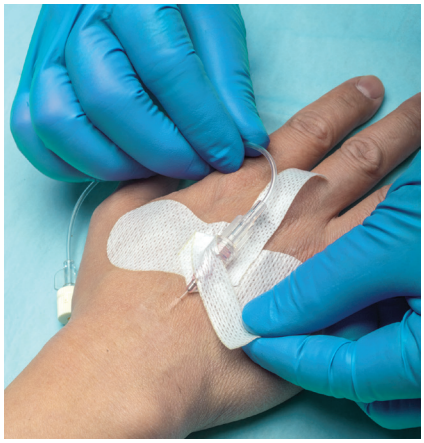
UltraDrape UGPIV Barrier and Securement, from Parker Laboratories, Inc.

Standardization of the insertion procedure with UltraDrape reduces touch contamination, improves visualization of the insertion site, and minimizes contamination that commonly occurs with cleaning gel off the skin. "It also provides a sterile barrier between the probe and insertion site, consistent with the Association for Vascular Access (AVA) Transducer Disinfection Guidance Document,[9] which requires the probe to be covered or separated from the insertion site," said Moureau.

An added value, according to Moureau, is that UltraDrape eliminates the need for supplies such as sterile gels, probe covers, adhesive films, and other cleaning items. Because it is an all-in-one barrier, it may also reduce labor costs.

She cited a scientific published study that found one hospital system reduced the cost of supplies used for UGPIV insertions by 55 percent with UltraDrape.[10] "As reported at the 2019 AVA conference, a multi-center prospective study evaluated the UltraDrape standardized UGPIV procedure across three hospitals within the Sharp HealthCare system in San Diego, CA.[10] Overall, 99 percent of clinicians in the study recommended adopting the standardized procedure, and a majority strongly agreed/agreed that UltraDrape improved patient safety by facilitating better aseptic technique."

Vascular catheter-stabilization devices can help to prevent pistoning, accidental dislodgement, and needlestick injuries. Kurt T. Kyvik, Senior Product Manager, Dale Medical Products, described their catheter-securement devices' attributes. "Dale Medical's Hold-n-Place engineered stabilization devices 850 for PIV, arterial, and mid-line



Dale Medical Products' vascular-access stabilization device

catheters and the Hold-n-Place 852 for central venous catheter, peripherally inserted central catheter, and arterial sheath devices are built on a history of hypoallergenic skin-safe products." The devices are made of a soft, flexible, low-profile material, with no hard plastic to irritate the skin or attract patients' attention. "In most applications, no skin prep is required, and no alcohol is required for removal," added Kyvik.

The clinically familiar chevron securement technique is adaptable to many different single- and multi-lumen catheter configurations. Kyvik said that the chevron securement method prevents the rigid catheter hub and connectors from irritating the patient's skin, reducing pistoning, twisting, and side-to-side movement of the catheter, keeping it secure from all directions, top, bottom, and sides."

Kyvik explained that the Dale Hold-n-Place securement device separates the functions of securement and transparent dressing to maximize catheter security and purchasing flexibility. "Dale Hold-n-Place product numbers 848 and 854 feature a separate PrevahexCHX antimicrobial, transparent-film dressing, for added protection against CRBSI. Dale has the first and only securement kits to feature PrevahexCHX. Product numbers 849 and 853 feature a separate, regular, transparent dressing."

Figuring it out

Whatever sort of infusion pump, catheter, or catheter-related device you are seeking to replace or upgrade, do your due diligence. Ask the vendor for the scientific evidence of efficacy in the form of independent studies published in respected medical journals. Multiple studies confirm claims of efficacy, because if the product works, results from these studies can be duplicated in other independent tests. That is the evidence you are looking for, and the vendors will be delighted to make it available to you. **HPN**

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The quandary of assuring quality

by Kara Nadeau

In the fast-paced, demanding and often under-resourced central sterile/sterile processing department (CS/SPD) environment, it can be extremely challenging to ensure process quality and the delivery of effective, safe and sterilized instruments and devices to clinical care areas. This article explores the spectrum of quality/sterility assurance best practices – from the easiest and most expedient to implement to the most difficult but highly valuable – and presents some new products and service offerings designed to help enhance the quality and safety of CS/SPD operations.

IFUs and Industry Standards

Manufacturer instructions for use (IFU) and industry standards are there to guide CS/SPD professionals at each stage of the process.

Ryan Lewis, MD, MHA, MPH, Senior Director Medical Affairs and Medical Safety at ASP, explains how, for hydrogen peroxide sterilization, a combination of validation testing documented in IFUs and routine monitoring to verify quality/sterility assurance are generally part of a quality assurance program.[1] He references the American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) ST58:2013 (R) 2018, "Chemical sterilization and high-level disinfection in health care facilities."

"Best practices strive to achieve the highest standard of care," said Lewis.

Jeremy Yarwood, PhD Microbiology, Immunology & Molecular Pathology, Vice President of R&D at ASP, references AAMI ST58 section 9.5, which recommends a combination of parametric monitoring, chemical indicators and biological indicators/process challenge devices.

"This combination provides the most complete picture for process monitoring of sterilizers," said Yarwood. "Of these monitors, a process challenge device (PCD) provides the best indication of sterility assurance by providing a challenge greater than or equal to the most difficult items routinely processed (AAMI ST58, section 9.5.4.1). As such, we reference the AAMI ST58, section 9.5.4.3 recommendation to use a PCD at least daily, but preferably in every sterilization cycle."[1]

Focus on the people

When asked for best practices related to quality/sterility assurance in the CS/SPD, many of those interviewed for this article cited factors related to the CS/SPD professionals themselves, including the need for executive-level recognition and training, and the team's ability to communicate and collaborate with other healthcare organization stakeholders.

Barbara Ann Harmer, MHA, BSN, RN, Vice President of Clinical Services, Innovative Sterilization Technologies (IST), describes how a CS/SPD staff member becomes a best performer in his or her department:

"From a best practice model, personnel who work in a CS/SPD should be oriented to their department's policies/procedures and processes," said Harmer. "Each staff member should be competent to perform the tasks that he/she is asked to carry out. Competency can be observed and witnessed in many different ways but one of the best methods to use is unannounced direct observation. Inservicing should be ongoing with staff having the ability to review the material and then ask questions after they have had an opportunity to digest the material. And lastly, the performance evaluation is used as a tool to assist with recognizing achievements and areas for improvement while setting future goals and targets."

Supervisor engagement

"The most value-added quality assurance best practice I recommend is both the easiest and the hardest – supervisor engagement in employee performance," said John Kimsey, National Director, Professional Services, STERIS. "We readily use the term 'Leadership Routines' to describe the routine tasks and activities an SPD leader should do on a regular basis to ensure quality products and services are being

Examples of dirty/damaged instruments Photos courtesy: SpecialtyCare

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*AAMI ST58 2013/(R) 2018 (9.5.4.1) states "A PCD is used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed."

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delivered. Creating 'Supervisor Routines' that allow them the time to observe their staff and work processes, ensure compliance to standard work, and identify opportunities for improvement can make a tremendous impact on quality. Supervisors must be actively engaged on the floor. This is simultaneously easy and hard. Easy because it doesn't cost anything and only requires the supervisor to become involved and hard because it requires time and the potential for confrontation."

Relationship building

"Of the best practices I employ number one is building relationships," said Andrea M. Harris, B.A., CSPDT, Central Service Manager for AdventHealth Apopka and Winter Garden. "I consider building relationships as a best practice because when you have a good relationship with your vendors, the operating room (OR), the environmental services (EVS) team, knowledgeable members of the industry, etc., it makes it easier to get things done the correct way."

"With our vendors, expectations are stated at the door," Harris explained. "Our OR team usually coordinates the delivery of vendor trays, but they know to request instructions for use (IFU) from the vendors if we have not previously processed the tray. Our department must be kept clean; therefore, building a relationship with EVS is important, so that our work environment begins in the state we need it to be in. Finally, we build relationships with others in the industry. Networking is one of the best practices that one can have. This allows you to have a group of people who can help you identify better practices and how to improve your processes that are currently in place."

Personal technology

When it comes to potential sources of contamination in the CS/SPD, an important but sometimes overlooked area is the mobile devices used by department professionals.

"It is well established that mobile devices harbor dangerous pathogens, including multidrug-resistant microbes," said Andrew McCarthy, President of Seal Shield. "It is therefore critical for the professionals who work in the CS/SPD to follow the CDC's recommendation to disinfect their mobile devices at least daily, and to clean those devices at least five times between disinfections. The constant handling of mobile devices - the typical cellphone user touches their device more than 2,500 times daily - means that they can serve as a primary vehicle for the spread of nosocomial infections. UV-C disinfection, accomplished through devices like the ElectroClave, is an easy way to disinfect mobile devices in seconds without the utilization of harsh cleaners, which damage those devices over time. Regular cleanings are thereafter best performed using a microfiber cloth."

Seal Shield's ElectroClave

Processes and workflow

At each stage of the sterile processing workflow, CS/SPD professionals have the opportunity to improve quality, whether it is through adherence to manufacturer IFUs, process automation and/or standardization, enhanced product selection, or monitoring, testing and validation of their equipment and work.

HALYARD and BELINTRA SMART-FOLD STERISYSTEM

A holistic approach

According to Joseph Hannibal, Marketing Director for Sterilization, Surgical and Infection Prevention, Halyard, a holistic approach to sterile processing is an effective way to not only improve quality but also boost efficiency.

"Given that space is often a factor for sterile processing departments, an ideal solution maintains sterility while saving on space and creating a more efficient workflow," said

Detergent considerations

Marc Esquenet, Vice President of Ruhof Corporation, says one key area that product committees and CS/SPD professionals must address as part of their quality assurance plan for sterilization is the use of an optimized, quality detergent, stating:

"Quality assurance starts with knowing you're using quality detergents. Not all detergents are created equal. If you don't select the right one, your likelihood of success is compromised."

He explains how enzymatic detergents designed specifically for cleaning reusable medical devices have been proven to improve performance over non-enzymatic detergents for cleaning soiled devices, therefore, choosing an enzymatic detergent that conforms to the new 2019 ASTM:D8179 Standard Guide For Characterizing Detergents For The Cleaning Of Clinically-Used Medical Devices guideline can assure positive results.

"According to the guideline, detergents are made up of a collection of cleaning agents with no one component exclusively responsible for its performance," said Esquenet. "There are appropriate test methods to determine if a detergent has all of the required components. The tests set out to determine rinseability, biodegradability, cleaning efficacy, material compatibility and toxicity."

Esquenet points to Ruhof's new enzymatic detergent, ELEMENTUM, as an example of advanced product innovation that conforms to ASTM:D8179. He says the product consists of the first new protease enzyme created in the healthcare field in 40 years.

"Passing all of the required tests, Elementum consists of powerful dispersing agents, tough solubilizing agents, advanced builders, four enzymes and produces astonishing results," said Esquenet. "At an extremely low dilution rate, 1/8th oz per gallon, this best-in-class solution rapidly breaks down organic, protein rich soils and breaks down the multi layers of bioburden."

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Hannibal. "Therefore, it's best for SPD professionals to think about the sterilization process holistically and consider a vendor whose solution addresses packaging, storage and transportation. A holistic system can decrease the number of touch points, which is always beneficial for sterility maintenance. If your facility uses a sterilization wrap for packaging, make sure to choose one that is designed to easily identify breaches. Also, consider a solution that allows you to store your wrapped trays without stacking and enables easy transport to and from ORs."

Cleaning is critical

"An instrument can be clean without being sterile, but it can't be sterile without being clean," said Marc Esquenet, Vice President of Ruhof Corporation. "This statement supports the fact that cleaning is the most critical step in the reprocessing cycle and should precede all disinfection and sterilization processes. Failure to do so can inhibit microbial inactivation and compromise the disinfection or sterilization process. Improperly cleaned surgical instruments and complex reusable devices, such as endoscopes, place patients at serious risk of healthcare acquired infections."

Don Rotter, Lead Technical Account Specialist, Ecolab Healthcare, notes how automated cleaning processes are superior to manual cleaning because they minimize variation. He states:

"Adequate cleaning of devices being the prerequisite to successful sterilization means sterile processing departments must eliminate variation in cleaning processes. Automated washers and ultrasonics provide less variation compared to manual cleaning processes, yet this equipment is still susceptible to component failure and its function challenged by human factors."

Ecolab Central Sterile Program combines washer cleaning verification and monitoring

Tray assembly

Tray assembly is another area at risk for quality failures in the CS/SPD. According to Braun C. Kiess, Director of Sales/Chief Financial Officer, RST Automation, the quality of surgical instrument tray assembly is often affected by the absence of a uniform structured assembly process.

"Missing instruments, inadequate inspection and technician distraction when they need to leave their workstations once or multiple times to hunt for missing instruments are all factors which affect set quality," said Kiess. "Inaccurate instrument counts are another qualitative factor which results from technicians checking off count sheets in instrument management systems from memory because it is too time consuming to check them off one at a time."

RST Automation has created an Assisted Instrument Management (AIM) suite of vision technology products, which utilize a structured process that helps overcome the weaknesses of current tray assembly methods.

RST Automation's AIM products

Monitoring, testing and validation

Another quality/sterility assurance best practice is the monitoring of processes, testing and validation of successful results, particularly related to sterilization.

"As the adage goes, you can't manage what you don't measure," said Erin Manning, Vice President Marketing, Verrix. "When it comes to sterility assurance, monitoring is important not only for compliance but also for problem solving and process improvement. The more frequently a process is monitored, the more tightly it can be controlled. Monitoring every sterilization load the same way ensures consistency in the standard of care provided to all patients and minimizes risk in the event that a sterilization failure occurs. Frequent monitoring empowers sterile processing professionals with the valuable data they need to make informed decisions and help protect patient safety."

David Jagrosse, CHL CRCST and consultant to oneSOURCE, recommends the use of ELM to enhance quality and patient safety. Jagrosse references AAMI ST79 2017, which guides users to perform biological indicator testing, specifically section 13.5.3.2, which states that users should monitor (test) "at least weekly but preferably everyday and with loads containing implants."[2]

"It does not prohibit users from going above the recommendation," said Jagrosse. "I highly recommend increasing the frequency of biological indicator testing through every load monitoring (ELM). A financial and ethical case can be made to do so."

"A deficiency in automated cleaning processes detected promptly through daily testing is ideal over delayed discovery through testing less frequently," said Rotter. "Sterile processing staff not only need to understand how to use commercially available indicators as intended by the manufacturer, but correct interpretation, documentation and storage of the results are also imperative for quality control purposes."

The STERRAD VELOCITY BI/PCD rapid read process challenge device for STERRAD Systems meets AAMI recommended guidelines

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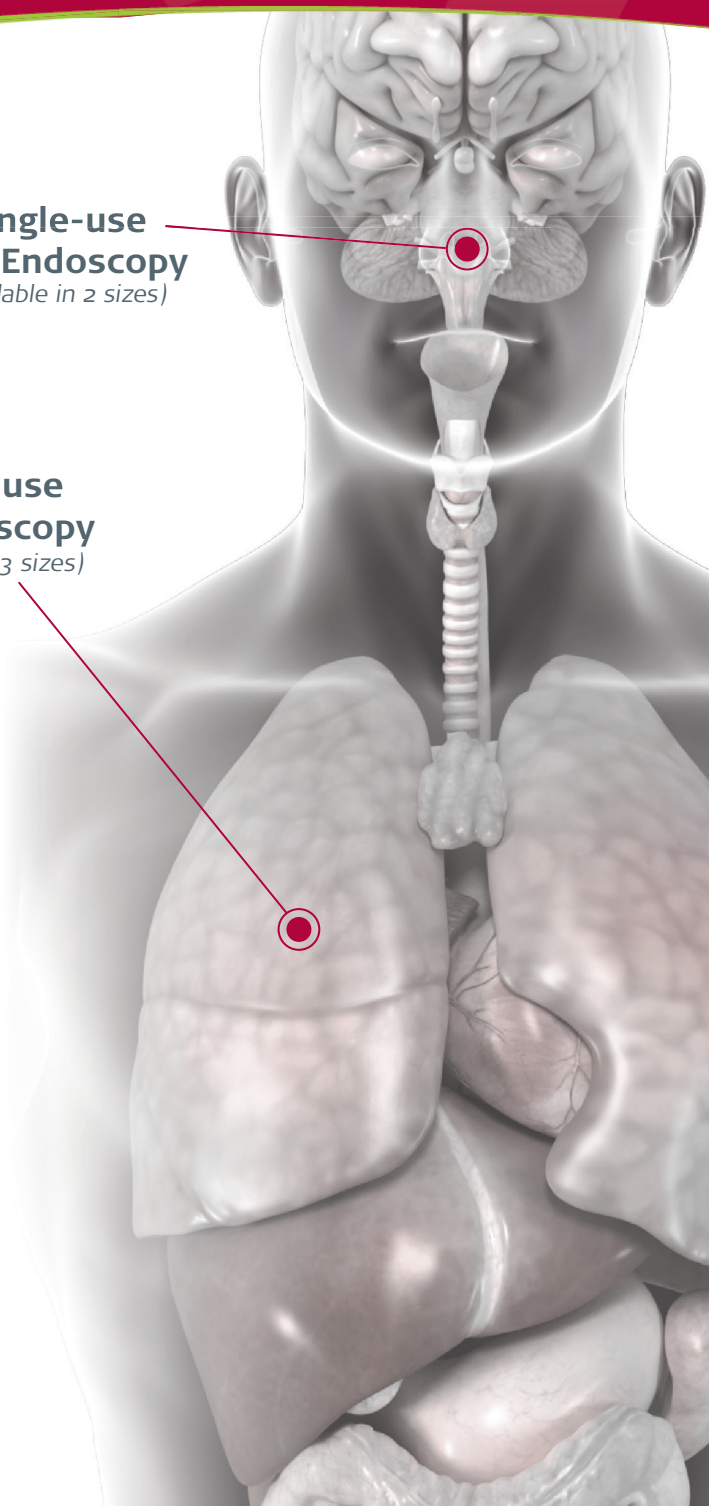

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Jagrosse points out how AAMI gives guidance (13.7.5.1 section C) on how to handle a recall when sterilization failures occur.[3]

"It tells us that when there is a failure we are to recall all goods to the last known negative BI test," said Jagrosse. "This can mean hundreds of items and potentially dozens of patients - I refer to this as a 'window of liability.' To eliminate or close this window of liability, facilities can practice ELM with biological tests. From an ethical standpoint, why should some patients have biological testing done on their instruments and some not? What would you want for your loved ones or yourself? ELM provides the safest patient care possible while ensuring an equal continuum of care."

According to Esquenet, visual verification following cleaning is a great way to examine results, as noted in ANSI/AAMI ST91: Comprehensive guide to flexible and semi-rigid endoscope processing in healthcare facilities: "Careful visual inspection should be conducted to detect the presence of any residual soil."[4]

The Ruhof Corporation's Visual Inspection Borescope (VIB) allows for instant visual detection of internal debris and damage inside the channels of an endoscope, reducing the risk of device related infections. The Ruhof VIB's advanced visual inspection system includes a state-of-the-art camera system and intuitive software providing high resolution, knowledge-based images to help quickly determine the condition of medical devices and instruments.

It all comes down to patient safety

"When we talk about quality and sterility assurance, we are really talking about patient safety and the impact CS/SPD has on the ultimate quality measurement; surgical site infections (SSI)," said Gregg Agoston, MBA, VP Minimally Invasive Surgical Support, SpecialtyCare.

Agoston explains how the CS/SPD directly affects patients' risk of SSI in two ways, as defined by American College of Surgeons and Surgical Infection Society's Surgical Site Infection Guidelines: Operative time and sterilization of surgical equipment.[2] The CS/SPD can extend operative times if instruments are not available or functional, and can impact patient safety if instruments are not properly cleaned and sterilized or high-level disinfected (per the manufacturer's IFU).

"Unfortunately these goals are often not met as there is a silent epidemic of non-sterile and/or non-functional instruments that make their way to the OR every day across the country," said Agoston. "If it were not for antibiotics and other steps to minimize SSI, we would likely see this epidemic in the news daily. The reality is that our population is aging and more people will require surgery, bacteria are becoming more virulent and time to antibiotic resistance now is being measured in weeks and months versus years. This equates to a perfect storm that could result in many more SSI and patient deaths from them. For these reasons, CS/SPD must do all it can to meet its goals of instrument availability, functionality and safety for every patient." HPN

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January 2020

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LEARNING OBJECTIVES

1. *Identify the key elements assessed by change committees*
2. *Define the contents required for a change proposal*
3. *Calculate the return on investment*

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SELF-STUDY SERIES

Writing a winning process change proposal

by Heide Ames and Karen Owens

As we all know, change is constant in the workplace. In healthcare environments, regulatory guidelines change, inspections and audits happen, and new infectious outbreaks raise questions about existing policies and procedures. These events provide opportunities to make changes that achieve optimal processes. However, gaining the approval to implement changes can be challenging, even if those changes could result in a higher standard of care. Process improvement requires formal written proposals. To gain approval, it's important to include all the necessary elements.

Change approval elements

Any change in device processing, no matter how necessary, must be reviewed and approved before being implemented. Each facility's policies and procedures dictate the approval process. While some changes may only require manager approval, others require approval from a change control committee.

Change control committees can consist of cross-departmental representatives from within the healthcare facility. Members may include infection control, risk management, finance, surgery, device processing, facilities, and strategic planning representation. Though each functional group reviews the proposal from its specific perspective, the committee as a whole looks for three key elements: necessity, benefit and cost.

Necessity

The higher the necessity for change to assure the function and wellbeing of the patients and healthcare facility, the more likely the proposal will be approved. High necessity changes are driven by federal or state law, results of credentialing inspections, or actions to stop current facility healthcare-acquired infection (HAI) outbreaks. Low necessity changes typically include proposals offering small improvements. For example, proposals that provide a minor process improvement or waste reduction may have a low necessity.

Benefit

Changes can be beneficial in many ways. Some changes directly improve patient care. Other changes reduce spend. Some changes may improve quality while others increase productivity. Each type of benefit carries a different weight based on the healthcare facility's needs and goals. Those with the most importance to the facility carry the highest weight and will be approved over those that don't align with their goals. Typically, the highest weighted changes include those that directly impact patient care. This is normally followed in importance by cost savings. Changes that indirectly improve patient care or increase department productivity usually fall into third place. Finally, changes that prevent minor inconveniences, such as having to reclean a device found dirty during inspection, would have the lowest weight.

It's also important to note that a benefit may not be a tangible improvement in performance. Some benefits involve the prevention/avoidance of a possible event that could negatively impact a patient or the facility. Changes that may prevent medical errors, unseen contamination and outbreaks can be highly desirable even when none of these events have been documented at the healthcare facility.

Cost

Cost is divided into two buckets; short-term and long-term. Short-term costs include one-time spends associated with implementing the change. Short-term costs may include such things as new equipment, installation, room modification and associated labor. Long-term costs are those costs that reoccur after installation is complete, such as disposables, service, maintenance, and limited reuse items associated with the new process.

Deciding what to work on

The change control committee receives more proposals than the facility can implement. They are responsible for reviewing all proposals and selecting the ones to implement. Although each facility has its own set of requirements, the decision process is similar for all.

The first projects to be reviewed and approved are those that are legally necessary. These include state mandates, national rulings, and proposals that are intended to

address audit findings. Although the facility can continue operating without addressing audit findings from credentialing agencies and The Center for Medicare and Medicaid Services, failure to meet these organizations' mandates can impact payment for a specific set of patients. Depending on the facility's typical patient mix, this can severely impede the facility's revenue stream.

The remaining proposals are then reviewed with the healthcare facility's strategic goals in mind. Healthcare facilities have short-term and long-term strategies. Short-term strategic goals are actionable within 6 to 12 months. They typically focus on actions that help the facility now. An example of a short-term strategy is "decrease missing instruments in OR sets by 5% by the end of the year."

Long-term strategies tend to be larger business goals that take two to five years to complete. "Gain recognition as a national leading heart care center" is an example of a long-term goal. Typically, long-term goals have several planned stages. Each stage would have several short-term strategic goals that lead to achieving the long-term goal. Proposals that align with strategic goals are given a higher priority.

Problem statement example:

Several studies published in the past 12 months indicate that duodenoscopes present a challenge to cleaning and have been traced back to several outbreaks including Carbapenem-resistant Enterobacteriaceae (CRE) outbreaks. Most recently, a published study has indicated that double high-level disinfection is not effective at reducing the contamination rate of duodenoscopes.[1] Additionally, the US Food and Drug Administration has issued a Safety Communication dated 08/29/2019 in which they recommend that facilities consider reprocessing with supplemental measures such as sterilization or use of a liquid chemical sterilant processing system consistent with the device's labeling.[2]

The offsite endoscopy center currently has five duodenoscopes that undergo cleaning followed by high-level disinfection using ortho-phthalaldehyde and no other supplemental treatment. A risk assessment team consisting of infection prevention, endoscopy, endoscopy reprocessing, risk control and sterile processing professionals determined that reprocessing errors similar to those identified in the published studies may happen at this facility, which could expose this facility to a CRE outbreak.

The potential impact from one outbreak with three affected patients includes additional treatment costs of $15,126; indemnity costs of $418,014 and reputational costs from resulting negative publicity. The proposed project will decrease the probability of a CRE outbreak, increase compliance to recommended practices for difficult-to-clean duodenoscopes and reduce the risk of reputational consequences.

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Writing for approval

If a proposal isn't approved, it may be because of how the material was presented rather than about the idea itself. Change proposals can be presented as PowerPoint presentations, as free-form written documents, or in standardized facility forms. Regardless of the format, proposals that provide relevant and succinct information, contain the three critical elements, and show alignment with the facility's strategic goals will have a higher probability of success.

Establish the problem

The proposal starts with the *problem statement*, which defines the current productivity, financial and/or patient issues that require improvement. The statement is factual and, whenever possible, supported by facility data. It should also indicate the strategic goals that this project will meet. The problem statement should reference guidelines, research information and potential financial impact if the proposal is not approved. All data, whether internal or external, should be provided in a list of references.

The problem statement sets the stage and focuses the reviewers on the specific challenge that the proposal will address. In the example shown, the reviewers immediately know that a documented challenge exists for duodenoscopes, a cross-functional team has determined that patients are at risk, and that the proposal will decrease the probability of a Carbapenem-resistant Enterobacteriaceae (CRE) outbreak. The next section of the proposal will describe solutions.

Set up the ultimate solution

Many proposal originators will jump right into the *proposed solution*. This can be a mistake because committee reviewers may have less direct experience with the issue. Presenting only the proposed solution creates reviewer tension because they must completely trust the originator. As a result, they often act conservatively by delaying the review or rejecting the proposal.

To give committee members confidence in the proposal, a few potential solutions should be offered that were considered but ultimately rejected. This demonstrates that the originator performed due diligence and that the decision to move forward with the proposed solution is sound. For each of the rejected solutions, the proposer should include the potential benefits of the solution, the cost of implementing that solution and the reason it was rejected.

Lay out the benefits and value

Once this groundwork is set, committee members are ready for the proposed solution. The benefits and cost to implement should be discussed for the proposed solution just as they are for the rejected solutions. Then, the value of the proposed solution can be laid out by discussing the return on investment (ROI). This should be followed by the implementation plan and the defined metrics that will measure the success of the change.

Benefits should be listed with corroborating evidence, which may include white papers, gray literature, Food and Drug Administration clearances, documented practices from other healthcare facilities, and technical product and industry literature. Every data source should be scientifically sound and relate to the facility or patient population affected by the solution.

The benefit assessment should tie back to every issue in the problem statement, linking benefit(s) to each specific issue identified in the document. If a solution is not available for an issue, either remove the issue from the problem statement or indicate that it will require further investigation.

List additional benefits, but only if they reflect known concerns of the healthcare facility or its strategic plan. Do not list benefits that are not valued by the committee members or the healthcare facility. To determine whether or not to add a benefit, ask these questions:

- Does the change provide better compliance to recommended practices or other legal requirements not stated in the problem statement?

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

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- Are there other short-term strategic goals or performance standards that the solution will assist with?
- Does the change give the healthcare facility a better competitive advantage?
- Does the change improve or prevent tarnishing of the facility's image or reputation?
- Does the change assist in achieving any of the long-term strategic initiatives?

Assess the costs

After the benefits have been discussed, the associated costs for the proposed change should be explained. Costs should be reported in two buckets: capital and operational. Capital costs include all items that are purchased once, plus any consumables or services used to implement the change. Items such as equipment, reusable medical devices, room modifications, contractor charges and required software fall into this category. Typically, capital costs are considered short-term expenses.

Operational costs include ongoing consumables and limited reuse items. Printer paper, water filters, sterilant, bandages and utilities all fall within the operational budget.

Consumables can fall under capital or operational costs. Capital consumables are necessary for installation but are not used again. This can include special tests used to qualify equipment. Consumables that fall under operational costs are periodically used after implementation and during normal use.

The final cost consideration is labor. Labor is typically associated with operational costs, though some process changes may require allocation of personnel during installation or implementation of a change. Labor is reported as full time employee (FTE) costs. FTE costs are more than the hourly wage payed to the employee. It includes all benefits and is often referred to as fully burdened. Typically, an average rate is used in the calculation based upon employee title. The finance team within the facility will be able to provide the value to use for FTE and guidance on its allocation within capital costs.

After all the costs have been identified, the ROI is calculated. ROI provides a means to compare the cost of the project against the potential savings and avoidance of cost. Savings is the difference between what was previously spent for a given period of time and what will be spent for the same amount of time after the change is made. Savings may seem like a straightforward calculation, but there are some nuances to it. The evaluation must be focused on the *total before and after costs*. Typically, the previous 12 months of spending are used to calculate the costs associated with the current practice. This is then multiplied for the desired time period for the ROI assessment. The operational costs reported on the ROI include consumables, service and labor. It does not include the cost of the equipment itself or any of the installation charges or other capital costs. The future spend is then calculated in the same manner, using the projected operational cost of the new process and not including installation costs.

When cost savings can also be realized by reducing unplanned costs derived from current HAI rates it should be included as cost savings. The amount saved is based on the estimated number of HAIs that will be avoided and the average cost to the facility of each HAI. Remember to only include the HAI costs that will not be reimbursed.

Showing the ROI

Once the total costs and total savings are known, the ROI can be calculated. ROI is typically calculated over a 5-year period, but some financial groups may request a 3- or 7-year analysis. Consult with the finance department to determine the calculation to apply. The basic formula is:

$$\text{ROI} = \frac{\text{Total Savings over 5 years + Cost Avoidance over 5 years – Capital Cost} \times 100}{\text{Implementation Cost}}$$

In some cases, the ROI will be positive. Positive numbers indicate that more money will be available for the hospital to use after the change is made. In other cases, the ROI may be negative. A negative ROI indicates that the facility will need to spend additional money each year following the change.

A negative ROI does not cause immediate rejection of a proposal. In some cases, the healthcare facility will have to spend more in order to resolve a problem or stay compliant with legal agencies. Knowing the amount of additional money required will allow healthcare facilities to plan and budget for the expense.

The ROI is only based on actual events and known spends. In some situations, an event has not yet happened but could have a significant impact if it did. In the example previously discussed, the healthcare facility has not experienced a CRE outbreak from its offsite endoscopy facility. If it were to happen, the increased cost to the facility would be substantial. In this situation, the cost avoidance would be described in the benefits and not included in the ROI since no dollars have been spent on this type of event in the past.

The proposal should close with a *call to action*. The call to action provides a timeline with all important implementation milestones and timeframes to complete. It should reiterate the most critical benefits and include the expected timeframe in which those benefits will be realized.

Help move your hospital forward

Gaining approval for a change in practice can be challenging. For your proposal to succeed, it must address a recognized issue, synchronize with the facility's goals, and be thoroughly and thoughtfully presented. Knowing what to write and how to present the material can improve your chances of gaining approval, which ultimately can contribute to optimal healthcare delivery at your facility. HPN

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CONTINUING EDUCATION TEST • JANUARY 2020

Writing a winning process change proposal

Circle the one correct answer:

1. **Who would be a member of a change control committee?**
   A. Sterile processing department manager
   B. Member of risk management team
   C. Sterilizer vendor
   D. A and B only

2. **Which is an example of a high necessity change?**
   A. Implementing cleaning tests of endoscopes to address a Joint Commission audit finding
   B. Installing an automated soap dispenser at the sink to enhance dispensing accuracy thereby reducing soap waste
   C. Installing an electronic documentation system to increase form completion rates
   D. Switching from a disposable biological indicator test pack to a reusable biological indicator test pack to reduce waste

3. **All benefits are equal when being assessed by the change committee.**
   A. True
   B. False

4. **What does the problem statement define?**
   A. The benefits of the proposed change
   B. A listing of all the equipment that will be required
   C. Current productivity, financial and/or patient outcomes that require improvement
   D. The timeline to complete the proposed change

5. **The Proposed Solution section should include other possible solutions and the reasons for their rejection.**
   A. True
   B. False

6. **How are costs reported in a change proposal?**
   A. Costs are not addressed in a change proposal
   B. Capital costs are discussed but operational costs are not
   C. Capital and operational costs are discussed as part of an ROI
   D. Only potential savings are reported

7. **Which types of cost are used to calculate savings?**
   A. Calculated prior 12-month cost and future estimated costs
   B. Calculated prior 12-month cost and installation costs
   C. Calculated prior 12-month cost and equipment costs
   D. Calculated prior 12-month cost and implementation costs

8. **What does a negative return on investment (ROI) mean?**
   A. The proposal must be rejected
   B. The change will save the healthcare facility money
   C. The change will cost the healthcare facility more money
   D. The calculation was done wrong

9. **Which goal is a long-term strategic goal?**
   A. Reduction of urinary tract infections by 2% by the end of the year
   B. Reduce spend in sterile processing by 3% this calendar year
   C. Implement duodenoscope sterilization process to comply with FDA recommendations
   D. Expand neurological specialties to become the number 1 neurological facility in the Northeast

10. **What elements should be in the call to action?**
    A. Implementation timeline
    B. Key benefits that will be achieved
    C. Timeframe in which the benefits will be realized
    D. All of the above

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The approval number for this lesson is **STERIS-HPN 192611**.

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IAHCSMM VIEWPOINT

Active chapter involvement drives quality outcomes, opportunity

by Julie E. Williamson

New and veteran Sterile Processing (SP) professionals who aren't currently a member of an IAHCSMM chapter – or belong to a chapter but don't participate to the fullest – should consider stepping up their involvement in the new year. As many chapter members can attest, the efforts can pay big dividends by providing valuable networking and educational opportunities, allowing best practice sharing, and building a stronger sense of pride in the profession.

Currently, there are more than 60 IAHCSMM chapters across 42 states and five countries, a far-reaching presence that provides an overwhelming majority of SP professionals with more direct access to meetings and educational events. Chapter meetings and other educational and social events held throughout the year typically feature well-respected speakers who address a range of pertinent topics impacting the profession. Vendor sponsors and exhibitors are also often available to educate attendees and share their latest product and service offerings. Collectively, chapter involvement affords an opportunity for SP professionals to build enduring relationships with their peers while engaging in satisfying professional development programs that advance the profession and promote continued chapter growth and success.

"Chapters are a great place to share our knowledge and learn from others, but you need to do more than become a member if you want to reap the benefits – you need to participate as much as possible," said IAHCSMM President Tony Thurmond, CRCST, CIS, CHL, who also serves as SP manager at The Christ Hospital and Health Network in Cincinnati, OH. Thurmond is a Past-President of the Buckeye Central Service Association and has long advocated for improved chapter reach and visibility, and knowledge sharing between chapters to boost member recruitment, participation and education.

Pride and participation

No question, SP professionals are busy and often face tremendous workplace pressure; therefore, it's no surprise that some individuals might avoid joining chapters and actively participating in their meetings because they don't want to take time out of their already hectic schedules. But the benefits far outweigh any perceived drawbacks, chapter representatives stress.

Participating in chapter meetings and events provides a golden opportunity for members to learn about hot topics from expert speakers and earn continuing education credits, which can be applied toward IAHCSMM recertification. Additionally, active chapter participation can help members develop valuable new skill sets. This is especially true for those who serve on chapter committees because their various roles can include developing programming and managing resources, enhancing engagement, and gaining more confident in public speaking – all skills that can serve professionals well in their quest to climb the career ladder.

"Being active with my local professional organization has given me many opportunities that, in turn, gave me the desire to become a leader and expand my education in my professional career," said Larry Guittard, CRCST, Past-President and current Secretary of the Long Island Association of Central Service. Belonging to the chapter provided a sense of belonging that he said placed him in an arena with successful leaders in the field.

"I was able to build up my contacts with professionals who set the standards and recommended practices in my profession, which is the backbone for patient safety. If you want to be a leader, surround yourself by leaders. It's a win-win situation," he stressed.

Guittard's many years with LIACS (and also in his time serving on the IAHCSMM Board of Directors) led to some unexpected advantages, not the least of which included being able to lean on friends and colleagues he'd met over the years -- and in many places throughout the U.S. -- for sound advice and best practices. That benefit was especially valuable during surveys, he noted.

Above all, he said the chapter-level education expanded his skills, knowledge and career, and gave him the confidence to become a role model and mentor. "Education leads to success and is the key to patient safety. Lead by example and reach out to your network of professional friends," he said. "Those were the tools I brought with me, along with my resume, on every interview as I climbed the career ladder."

Although education, networking and professional advancement rank high on the list of chapter involvement benefits, there's another perk that's no less important: being part of a group of individuals that understands the value of the profession and all who comprise it, and truly takes pride in the discipline.

"To grow, it takes people getting involved with others who have the same passion for this profession," said IAHCSMM Board of Directors member Patty Taylor, CRCST, CIS, CHL, CFER, who also serves as Clinical Supervisor of Central Sterile at MHP Medical Center in Shelbyville, IN.

Those who currently have no chapter locally or within their state and wish to start their own will find plenty of information on IAHCSMM's website. Existing chapters can also offer some valuable assistance – a point that further underscores the upside of networking with professional peers, regardless of their location. The Western Wisconsin Chapter of IAHCSMM, for example, is one large and active group whose members have stated their willingness to share how their chapter got started and how the group provides meetings and educational events that always keep quality and patient safety at the forefront. Many other chapters are willing to assist as well. HPN

For more about the IAHCSMM chapters in your area, visit www.iahcsmm.org/chapters/chapter-listing.html. The chapter section (www.iahcsmm.org/chapters) also offers information on chapter policies and guidelines, resources for forming, managing and rechartering a chapter, as well as a Frequently Asked Questions section, and more.

SUBMIT YOUR QUESTIONS: **editor@hpnonline.com**

Breaking down reprocessing process; blood cells role; instrument pack weight

by Ray Taurasi, Principal, Healthcare CS Solutions.

Q Is it essential to sanitize all soiled items returned to CS or are decontamination and disinfection sufficient prior to sterilization?

A It is important to realize that decontamination (cleaning), sanitization, disinfection and sterilization are different and unique processes. The first step in reprocessing involves thorough cleaning, which is the removal of soil from used materials. The second step involves a microbicidal process such as sanitization, disinfection or sterilization.

The objective of decontamination is to protect individuals from disease caused by contact with pathogenic organisms on soiled medical devices. Thorough cleaning, while an essential first step, may not always be sufficient to assure an item is safe to handle. Currently there is no standard to measure just how clean or safe to handle an object may be, therefore, to ensure that harmful microorganisms are destroyed a microbicidal process may be employed. Medical devices that have been contaminated by blood, body fluids or large microbial populations must always be subjected to a microbicidal process after cleaning. Deciding which process to use is a risk-versus-benefit decision for each item you process. Therefore, a clear understanding of these processes is imperative.

Sanitization is suitable for easily killed microorganisms and it can reduce the number of microbial contaminants on an inanimate surface to a relatively safe level. Following thorough cleaning, the objects are rinsed by hot water or steam purged for a designated period of time, depending on the method used. Some examples of sanitizing equipment include cart washes, steam guns and utility washers. Sanitization is adequate for items that only come in contact with the surface of unbroken skin.

Disinfection provides a higher level of safety and can be used on work surfaces, medical devices and equipment that have come in contact with highly contaminated substances, body fluids and blood. The disinfection process may be accomplished by thermal, chemical or UV exposure. Most instrument washers today provide a thermal disinfection process during a final rinse with elevated water temperatures. Pasteurization is another example of a thermal disinfection process, which involves exposing an object to a hot water bath at 150 to 170 degrees Fahrenheit for 30 minutes.

It is essential to always consult and adhere to the medical device and processing equipment manufacturer's instructions for use (IFU). Policies and procedures for the processing of medical devices should be developed in compliance with relative IFUs.

Q I always thought that the body's immune system produced white blood cells to defend and rid the system of infections. I recently was reading an article that referred to T cells as the body's major defense against infectious agents, can you clarify this?

A You are correct. The body's immune system, in a healthy person, will produce more white blood cells to combat pathogenic organisms that have invaded the body. There are many types of white blood cells. Lymphocytes are one type of white blood cell, and two major classes of lymphocytes are T cells and B cells. T cells are critical immune system cells that help destroy infected cells and coordinate the overall immune response. The T cell has a molecule on its surface called the T-cell receptor. This receptor interacts with molecules called major histocompatibility complex (MHC). The MHC molecules are on the surfaces of most other cells of the body and help T cells recognize antigen fragments. B cells are best known for making antibodies. An antibody binds to an antigen and marks the antigen for destruction by other immune system cells.

Other types of white blood cells include macrophages and neutrophils. Macrophages and neutrophils circulate in the blood and survey the body for foreign substances. When they find foreign antigens, such as bacteria, they engulf and destroy them. Macrophages and neutrophils destroy foreign antigens by making toxic molecules, such as reactive oxygen intermediate molecules. If production of these toxic molecules continues unchecked, not only are the foreign antigens destroyed, but tissues surrounding the macrophages and neutrophils are also destroyed. This results in diseases known as autoimmune diseases.

Q How can one be certain that an instrument pack doesn't exceed the maximum density of 7.2 pounds?

A The 7.2-pound density ceiling applies to linen packs only. It is not used as a parameter for instrument sets. Recommendations for instrument sets are focused on weight limits and metal mass. AAMI St79 standards state instrument sets should not exceed 25 pounds. Excessive weights can present ergonomic concerns associated with employee injury. Excessive metal mass and weights can impede drying and result in wet packs. **HPN**

Ray Taurasi is Principal, Healthcare CS Solutions. His healthcare career spans over three decades as an Administrator, Educator, Technologist and Consultant. He is a member of AORN, AHA, SGNA, AAMI and a past president of IAHCSMM.

Future-proofing product alerts and recalls

by *Rick Dana Barlow*

With access to all of the resources and technology available now or in the very near future, one might argue convincingly that healthcare organizations have what they need to effectively monitor and manage product alerts and recalls.

From wired or wireless, cloud-based software to subscription-based notification services (via pull- or push-based communications) to artificial intelligence to online programmable search bots to dedicated staffers or teams with information technology skills, Supply Chain's product alert and recall process toolbox seems rife with options.

And yet, product alerts and recalls consistently continue to evoke panic (however mild) and pressure to do more or the painful realization that not enough is being done. Of course, the question remains, how can or do you predict an alert or recall? Without precognition or any kind of prognostication, perhaps proactivity has its limitations.

Short of shoring up your offense, the focus must then shift to strengthening your defense and streamlining your reaction.

Equipped with a team of IT-savvy Supply Chain professionals (or even fluid connections to IT pros) operating within a well-documented process, online access to a notification database service that includes links to government resources, and an expedient way to track and remove a product from circulation as well as notify affected patients quickly, healthcare organizations should be set, right?

Not so fast.

Because product alerts and recalls *should* happen so infrequently, healthcare organizations may not give the issue a high-enough priority (despite the considerable liabilities), which dovetails into a lack of budget for necessary talent and technologies, including tracking tools and software connections to electronic health records (EHRs). They also may not realize the impact on product warranties and how that ties into Medicare regulations and private payer reimbursement.

For more information on setting up processes for product alerts and recalls, visit *HPN*'s online archive at https://cdn.hpnonline.com/inside/2011-03/1103-PS-Recalls.html, https://cdn.hpnonline.com/inside/2012-09/1209-PS-Recalls.html and https://cdn.hpnonline.com/inside/2013-09/PS-Recalls.html.

Alerts and recalls occur for a variety of reasons. Many tend to involve manufacturer issues – either functions or components were found to malfunction in some way or quality measures in the manufacturing process weren't followed or documented properly; others may involve products damaged via distribution or in transit; products damaged in the cleaning, disinfection or sterilization process as component materials reacted negatively to chemical or gas exposure; or patients' physiology reacting negatively to product exposure or implantation.

Whatever the case, product alerts and recalls remain a reality, no matter how frequent, and must be addressed in terms of tracking, tracing, notification, retrieval and all of the communications and record-keeping along the way.

Future looping

One of the strategies behind designing a new product or process or even redesigning an existing product or process involves thinking big, looking at the end game or desired outcome and working your way backward. It's essentially akin to reverse-engineering effectiveness for efficiency's sake.

For seasoned experts in product recalls and alerts, the underlying premise resides in convenience through automation and quick communication. Think smart notification and response. While we may not be there yet, forward thinking just may have the industry on its way.

"The 'end game' is always to prevent bad products from reaching consumers," Herb Wong, Vice President, Marketing & Strategic Initiatives, rfxcel, told *Healthcare Purchasing News*. "However, if a bad product does get dispensed, then the No. 1 priority is to stop it from being consumed. The United States and other countries are assigning unique serial numbers to prescription drugs, which allows systems to precisely track a product. If money were no object and resources were virtually limitless, then we could also apply smart Internet of Things (IoT) technology to individual units (e.g., bottles) so each can provide a real-time notification to consumers that the medicine has been recalled. This solution benefits not only the end of the supply chain — patients and consumers — but can enable faster, more precise recall processing further up the supply chain for dispensers and distributors."

Herb Wong

Chaun Powell, Group Vice President of Strategic Supplier Engagement, Premier Inc., ideates about an emerging option that pushes into curiously creative territory but then scales it back to something more practical.

Chaun Powell

"If money were no object, we would supplant manufacturing sites altogether and place 3-D printers, capable of printing real-time sterile product and implants, in every OR and patient treatment area across the country," Powell envisioned. "Inventory would be tracked in terms of raw materials for printing, rather than physical product, helping alleviate the nearly endless shelf space that healthcare organizations today must dedicate to millions of SKUs that we may use on a daily basis.

"Absent of that happening, an ideal solution to this would be a WiFi- or Bluetooth-enabled sticker that automatically turned red in the event that a recall on that specific lot was activated," Powell continued. "This sticker could also turn red upon expiration of the sterile shelf life or the half-life of a drug. This would prevent accidental use of incorrectly tracked product at the site of patient care."

Sources point to the Food and Drug Administration (FDA) and data standards via the Unique Device Identification (UDI) initiative as the most practical and realistic option.

"The key to a truly efficient alert and recall process is enabling track and trace capability back to the manufacturer, similar to what we are seeing in the food industry," observed Keith Lohkamp, Senior Director, Industry Strategy, Workday. "We currently have limited visibility to an item as it moves through the supply chain to the hospital. Using UDI as a foundation for product identification, if the manufacturer could share details electronically

Keith Lohkamp

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Who's managing your product recalls?

Due to grants recently received by the non-profit National Recall Alert Center, recall services are now available at no cost to qualified facilities. To inquire, call 1- 888-537-8376 or visit www.recallalert.org.

How would you rate your organization's ability to handle product recalls? Are you able to process them seamlessly, as soon as they happen? Can your various departments (e.g., pharmacy, surgical, dietary, lab, etc.) immediately identify the products in question, determine their exact location and remove them from inventory as quickly as possible? Does your facility sail through unexpected audits because the necessary compliance data is current, organized and immediately accessible? Does your facility have a track record of never missing a recall, not one? The answer to those questions should be yes. But considering that more than a million Class 1 recalls remain on the shelves at healthcare facilities across the nation every year, for some, the answer is a sobering no.

Defective medical products that fall into the Class 1 category are the most harmful because they have the potential to cause serious injury and/or death to patients. And while rapid growth in the medical device industry has led to improved surgical outcomes for patients it has also led to an exponential increase in Class 1 recalls. The Food and Drug Administration (FDA) receives more than one million adverse event reports from device manufacturers every year. In fact, medical device recalls have increased 126 percent during the first quarter in 2018 alone — more than twice the number reported just a few months prior. This trend is expected to continue, and it's not just medical devices under the radar. Recalls for food, drugs and other products are on the rise as well. Is your facility prepared? If not, now is the time to be proactive because sticking with a poor, inefficient recall management strategy can lead to painful consequences.

Protect your patients, protect your organization

The key to successful recall management is having a reliable, user-friendly, closed-loop system in place 24/7 that prepares every department in a healthcare system to handle recalls as they happen. But that can be tough for any healthcare facility to achieve alone. The process is complicated and time-consuming. It demands constant surveillance, full cooperation and awareness across all departments, a swift, appropriate response when recalls are discovered, and meticulous record-keeping. Anything less and recalled products are at risk of being overlooked, forgotten or poorly processed.

That's why four out of five hospitals have subscribed to the National Recall Alert Center (NRAC), a nonprofit product recall management organization established in 1973 that offers a level of expertise and service unmatched by any other service provider. Made by hospitals for hospitals, NRAC is on the job 24/7/365 collecting the critical information hospitals need on active recalls and delivering it in real-time.

"We've tried to juggle the FDA's websites and keep up with our recalls and we just couldn't find a system that worked," said Cindy Lang, Risk Management Director at Denton Regional Medical Center, a 13-hospital health system in North Texas and Oklahoma. "NRAC is one that works. It's easy to use, it's in real time, and if we have any concerns at all I send an email and I get a response within minutes."

Proven track record

Having established long-term relationships with thousands of manufacturers around the globe enables NRAC's proprietary network to collect and share recall information faster and more accurately than others. Alerts are automatically prioritized and the data is filtered several ways so only the pertinent details are delivered via NRAC's unique triple-alert system — and only to departments that are affected by the recall. Therefore, this streamlined system assures that a health system located in the Northeast will never have to spend valuable time sorting through pages of recall data on defective products in the Midwest.

"NRAC sends alerts to me every day and we're able to manage those without much worry of not having one come through that we're going to miss," said Charmaine Thomas, Risk Manager at Floyd Medical Center in Georgia. "It has a tiered system that lets you know if a recall has not been handled and really helps us to be able to keep a pulse on our recall alerts."

That's because once a facility receives the information, NRAC continues to track and trace the recall until the disposition is complete. If a department doesn't respond to an alert, follow-up alerts are escalated up the line in order to secure a final disposition. You can also download your item master and NRAC will match recalls to your organization's inventory so that the data you receive is precise and geared to your GPO contracts and purchasing patterns.

"It just makes all of our lives so much easier," said NRAC member Teri Reinhertson, Director of Risk Management at Carepoint Health, a three-hospital health system in New Jersey. "We don't have to wait for a piece of paper or wait for [the recall information] to come from three different places, and at different times and then go through it thinking did we do this, did we do that? We just look on the dashboard. The best part is that it's not just one person doing the work because when you use the dashboard the different departments get the recalls and then we follow up to make sure that it's done. When the FDA comes, I can just push a button, run a report and show them what we had, what we did, and it's done. It's been such a lifesaver."

All day, every day

Whether it be a weekend, holiday, or 2 a.m. on a Tuesday, the system never stops working because recalls don't follow a schedule, they happen when they happen, and NRAC is there to catch them when they do. In 46 years, NRAC has never missed an active recall, not one. Clients also receive personal, one-on-one account management whenever it's needed and are protected under NRAC's $5 million insurance policy. Importantly, there are no contracts to sign — ever — so you won't be locked into a three- or five-year agreement.

Compared to other service vendors, not only is NRAC the most complete recall management system available, it's also the least expensive (grants are also available to help facilities offset the system's already low cost). For little more than $10 a day — less than the cost of a single movie ticket — NRAC has you covered 24/7. Why not give it try? A live, 15-minute immersive demonstration is available risk-free, and you can use and evaluate the system free of charge for as long as you need before making a final decision. With Class 1 recalls at an all-time high, now is the time to do something about it. Contact NRAC for a free demonstration and trial period at 1-800-NRAC-NOW (1-800-672-2669).

on every item shipped, the recipient could cost effectively track items, lots and serial numbers. If the items go through distribution, the distributor could then share when the items are sent to a provider. And the provider then tracks when items are used and for which patient. With near complete traceability, a recall could be sent through the same chain to quickly locate a recalled item."

Lohkamp posits that interoperability and even blockchain could facilitate and streamline information transfer.

"Enabling this will require adoption of interoperable technology that could be used to share this information," he continued. "Blockchain is a promising technology to support track and trace. With blockchain, the manufacturer could initially place the item on blockchain and each party could potentially reference that item and add transactions to the 'ledger'. This could provide the quick visibility required. Of course, core ERP, point-of-use and EMR systems would need to be able to update or view data from the network. And to scale up, product auto-id processes, computer vision, RFID and other automatic sensing technologies would be needed to remove heavy human intervention to capture details on each individual product as it is picked or consumed."

Digitizing the din


Michael Hardin

Michael Hardin, BMET, Senior Solutions Consultant, TractManager, identifies one key challenge about this issue – the cacophony of content.

"With respect to recall and safety notices, there's a lot of noise out there," Hardin determined. "There are official FDA notices, preliminary vendor recalls (not yet FDA validated), MAUDE reports, vendor notices, incident reports, and more. Ultimately, I'd want a process that makes the management of safety notices and recalls more efficient, that considers all recall related documentation and that's gives visibility to all related stakeholders. I envision a single technology repository (i.e., a blockchain structure) for Food, Pharmacy and Medical Devices that would be the clearinghouse and source of truth for all related transactions."

Hardin points to integration as a necessity and validated information.

"With clear visibility to all recalls and the like we'd then have the ability to materially redesign the human and technology-related aspects of recall and safety notice management," he continued. "For example, we'd be able to easily identify those notices that are preliminary in nature, and contrast and compare those notices with their corresponding validated FDA notices. Integrating with CRM and ERP systems would allow quick identification of provider exposure to risk – whether those materials are in house or in-patient. Such integration would also allow providers to assess the actual cost of recall mitigation based upon the time required to remediate, as well as the resource types required to execute each recall action. With this information, I can envision more informed capital equipment negotiations, including limits on how much expense the provider is willing to accept to remediate defects. Accordingly, any costs above the negotiated limit could then be passed on to the supplier."

Suppliers would benefit because they ideally would also be able to track the remediation progress in real time, according to Hardin.

Hardin envisions nearly endless opportunities. "A chronologic single source of truth for all recalls and safety notices is the foundation from which many good things can build," he said. "Cost is also a critical factor, and probably the primary reason why we haven't already seen major technological advancements in this area. But the technology to make revolutionary changes already exists, and over time will become more affordable. So, I don't think a next generation solution is very far off."

Dr. Mark Cohen, Founder and President, National Recall Alert Center, which has been consistently active since 1973, minces few words as he describes a simple three-step process most healthcare organizations can activate and implement right now.


Mark Cohen

"I would require (1) that every end-user provider scan all items into their inventory, (2) the scan must be 3-D so that all data can be on the barcode, and (3) UDI numbers would be on all products produced by and sent from manufacturers and their distributors to the providers so that they, too, are part of the 3-D scan," Cohen recommended.

Flag the FDA, UDI


Peter Casady

Peter Casady, Founder, Champion Healthcare Technologies, acknowledges the burdensome and complicated nature of current processes such that providers and suppliers would welcome improvement. He suggests the FDA should assume more of a prominent role.

"Today, medical device recalls are reported to hospitals primarily by manufacturers," Casady noted. "Information may be shared in spreadsheets, emails or other diverse formats that require hospital staff to interpret them. The FDA reports device recalls as well, but it can take several months before they are distributed. With the emergence of the FDA's UDI on device packages, the time has come for the FDA to be the primary source of all recall data for hospitals across the country.

"The most efficient way for the FDA to report recalls would be through an API that is accessible by all healthcare stakeholders," Casady continued. "The recall data would not only include legacy product codes or model numbers but also new UDI data. The matching of recalled devices to products stored by manufacturers, distributors and hospitals could be accomplished through barcode scanning or RFID sensors by all stakeholders prior to transfer/shipment and prior to patient use. Recall data should be uploaded in real-time, via the proposed FDA API, to software used to monitor storage, transfer and use of these devices [in order] to provide instant notification to all stakeholders when a device is scanned."

Siobhan O'Bara, Senior Vice President, Community Engagement, GS1 US, remains upbeat about progress toward real-time product recalls and alerts.


Siobhan O'Bara

"Leveraging new and developing technologies, data capture and exchange about patients' and physicians' use of medical products could one day become automated, linked to individual records and facilities, and located for remediation quickly and efficiently," O'Bara noted. "Providers and patients could then be notified of recalls and alerts in real time." At that time healthcare organizations and patients alike will recognize the "power of comprehensive, standardized and interoperable data across the entire healthcare ecosystem," eliminating information gaps and reinforcing safer, quality and more efficient care, she added.

O'Bara acknowledges the ongoing debate between information sharing and personal privacy creates friction with the need to automate information recording. Achieving balance among these hot-button issues will lead to transparency, she indicated. "While we already have the technology to associate specific products with patient electronic health records

(EHRs), the use of that information is often limited by concerns about privacy," she continued. "Scanning medical device or pharmaceutical barcodes into patients' EHRs at point of care as they are administered provides data that is crucial not only in a product recall or alert, but also for tracking the product's effects."

Artificial Intelligence (AI) should play a vital role as it provides "unprecedented computing power" for data gathered from millions of patients across many geographical locations "to enable proactive and predictive analytics that can be used to quantify occurrences of side effects, product performance issues and adverse events, O'Bara noted.

"The 'machine learning' of AI can detect and identify links between co-occurring and seemingly unrelated conditions or outcomes, drastically multiplying the power of data analytics to inform and educate the medical community and advance the practice of medicine," she said. "In addition, automated information sharing has the potential to help reduce clinicians' role in data collection and assimilation, freeing them to focus on patient care."

O'Bara sees the capabilities of computing power hamstrung by privacy measures, and hampering efforts to analyze data around product use and effects on individual patients. Still, cybersecurity must be an "increasingly important prerequisite for locking down patient information without losing its value," she added.

The end game represents the continuous and seamless validation of inventory at each touchpoint across the healthcare supply chain, according to Mike Schiller, Vice President, Healthcare Engagement, SteriTrack. In this scenario, Schiller highlights "at each of these touchpoints a product can be scanned and the end-user alerted, in real-time, if the product is affected by a recall."

Mike Schiller

Schiller credits Mike Nolan, President of Automatic Identification Systems (AIS), for this vision, which, he further argues that "baseline infrastructure and technology already exist to make this vision a reality.

"There are applications available today that have the ability to access recall and adverse event databases where a scan of the UDI Device Identifier (UDI-DI) and Production Identifier (UDI-PI) would confirm whether a product is affected by a recall," Schiller said. Touchpoints include order fulfilment activities at the manufacturer or distributor level where scan technology is typically incorporated, receiving activities, subsequent stocking activities and point-of-care consumption within the healthcare organization setting where scan technology may or may not be deployed, he added.

Schiller describes a potential scenario: The first validation touchpoint would occur during the product pick activity at the manufacturer or distributor warehouse. For the second validation touchpoint, prior to shipping the order, the manufacturer or distributor would include the UDI-DI and the UDI-PI into a "license plate-type" barcode for all of the product that has been packaged in the box or carton. For the third and fourth validation touchpoints, this barcode license plate would be scanned at the receiving location, and the individual product would be scanned at the stock location, capturing both the stocked quantity and the stock location. Validation touchpoints five and six occur when the product is picked for consumption and consumed at the point of care.

He also believes this model could be carried downstream into the home health setting where consumers would have the ability to scan products ensuring their safety prior to use.

Horizon scanning

Beyond capabilities and technology currently available, sources point to several options to reach the next level of development. Those options center on real-time access to information.

Artificial intelligence (AI) capabilities seem the most attainable.

"We at National Recall Alert Center are happy to report that Artificial Intelligence (AI) is already a major part of every recall we transmit to our member facilities and we use it in our four-phase data filtering system," NRAC's Cohen said. He further added that they would like to incorporate RFID technology in the future.

Rfxcel's Wong calls for IoT technology to provide real-time, one-way and two-way notifications to consumers during a recall. For example, an IoT-enabled bottle can monitor storage conditions (e.g., temperature, light, humidity) and send alerts if pre-set parameters are exceeded and the integrity of the product is at risk.

"This two-way feedback introduces enormous amounts of complex data into the supply chain, which can be difficult for traditional systems to process," Wong indicated. "Artificial intelligence (AI) can deal with these large volumes of data, enabling smarter monitoring of the drug supply chain to not only manage recalls but provide proactive warnings about products that may need to be recalled due to incorrect handling or storage."

Because the recall process is so complex, multiple stakeholders need to be aware right away when specific devices are affected, such as implants, according to Champion's Casady. Electronic scanning facilitates preventive measures and may portend predictive capabilities.

"Utilizing scanning and/or RFID technology can play a major role in preventing hospital administration from ever picking up and using recalled implants," Casady said. "Further, as passive identification technologies become more commonplace, patients and their primary care physicians should also be able to be made aware of concerns."

Casady forecasts a day when regular annual check-ups involve a scan of implants to ensure none is negatively impacted. "The specificity of UDI provides tremendous potential for artificial intelligence (AI) to help predict and identify early trends with recalls," he noted. "Today, recalls tend to be highly reactionary with providers attempting to catch up with communications as they are released. I envision a day where data is mined to help manufacturers figure out additional related implants that are at risk. This type of predictive information could also help hospitals prepare and understand how widespread or impactful a recall might become. Eventually, past trends may also help providers navigate and determine which implants are safest to use based on prior recall data available at their fingertips."

Workday's Lohkamp believes that absent of a "perfect process," providers should have enough available technology to improve their recall process. Just follow the paper-to-digital trail.

"Ideally, recall notices would come in electronically, using modern webservice technology, and actions could be quickly initiated," Lohkamp noted. "Unfortunately, since many recall notices come in on paper or via PDF, many health systems struggle to pull the notice into an electronic format so it can be easily searched and matched. Artificial intelligence, and specifically machine learning, can be leveraged first to capture data off the document and then to go through the data to identify things like GTIN, lots, serial numbers and more. Once in electronic form, that data can be used to automatically search your ERP to determine if that item was ever purchased and if it is still on-site." HPN

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Product recalls, alerts: What did you miss?

Managing and rectifying product recalls and alerts not only represent a complex and necessary process, but also a stress-inducing one. It simply cannot be ignored from a trifecta of standpoints – patient, liability and financial.

Still, it's easy to understand how something – no matter how esoteric or granular – can fall through the proverbial cracks. Whether overt or hidden, these issues must be identified and addressed.

Healthcare Purchasing News asked five executives who deal with recalls and alerts what healthcare providers and suppliers should monitor.

Peter Casady, Founder, Champion Healthcare Technologies

"An area in the product recall process that is often overlooked, or could be done better, is medical device warranty claims and credit resolution. A 2018 Office of Inspector General (OIG) **report demonstrates how this is a pervasive issue.** The report cites that 210 hospitals under review did not comply with Medicare requirements for reporting recalled cardiac device manufacturer credits. See the full report here (https://oig.hhs.gov/oas/reports/region5/51600059.asp). Hospital compliance leaders are generally aware of CMS requirements and the detrimental fines issues by the OIG for noncompliance (we've found the average OIG fine to be [approximately] $400,000), but managing device warranty claims may not be prioritized because it is a challenging process that requires the efforts of multiple stakeholders to accomplish successfully.

"Beyond the need for multiple departments to contribute, challenges include a lack of clarity on whether a device is eligible for warranty credit, manufacturers are not transparent and timely about communication around the status of warranty claims, and hospitals may not even know how to match a credit with a specific device due to vague information from vendors.

"I believe that hospitals need to prioritize investing in an electronic platform to automate and centralize warranty claims management. This type of platform would enable streamlined and transparent collaboration between clinicians, pathologists, supply chain and finance/revenue cycle to coordinate all activities and touchpoints to ensure warranty processing in a compliant manner. When investing in an electronic platform, it's also imperative to ensure integration with manufacturers so they can provide automatic updates on the real-time status of each device claim. Without this ability, hospitals must manually compile this information from monthly reports or by directly contacting each vendor for specific claims."

Dr. Mark Cohen, President, National Recall Alert Center

"Overlooked: The completion of the disposition on every single product that is under recall at any facility.

Solution: We are the only organization that incorporates a five-level escalation system to assure that no recalled product "falls through the cracks." For that reason, National Recall Alert Center has never missed a bona fide recall since its founding in 1973.

"Overlooked: Class I recalls – those that can lead to the deaths of patients.

Solution: We've developed a highly sophisticated triple alerting procedure and system that assures Class I products are treated with extreme alacrity at both levels – at our office when transmitting and at the provider end when receiving.

"Overlooked: Litigation control.

Solution: We are the only organization that maintains a $5-million E&O insurance policy with Lloyds of London for such events."

Chaun Powell, Group Vice President of Strategic Supplier Engagement, Premier Inc.

"One pressing topic that is being considered globally, and specifically by the Food and Drug Administration, is to reevaluate the degree of sterilization called upon for particular items. As an example, is sterile water needed for colonoscopies? As we continue to face challenges with ethylene oxide sterilization plants, there is a decent probability that we will see a day in the not-so-distant future where sterilization of products that score 10 to -6 on the sterility assurance level (which measures the probability of a viable microorganism being present on a product after sterilization) is no longer necessary. As sterilization of devices expires at that range, it will be interesting to see if there is a subsequent test that could be run to revalidate what currently constitutes expired product, thereby increasing the shelf life.

"There are also more formal product alerts that are tied less to patient safety and more to manufacturing documentation protocols, with the intent to monitor these processes explicitly to the letter of the regulations and registrations with the FDA. We see this frequently with distributors as well. Manufacturers and distributors could examine whether these alerts are indicative of a breach of patient safety protocols, and then determine whether they are necessary or if other solutions exist to account for process regulation."

Herb Wong, Vice President, Marketing & Strategic Initiatives, rfxcel

"The safety of products can be compromised after they leave the manufacturer. I'd use individual IoT-enabled packages (e.g., bottles) to improve safety in the supply chain because they'd provide optimal traceability at the unit level. Today, IoT-based sensors can still be cost-prohibitive, so they're attached to shipments or pallets, not individual units. As along as everything stays together, this is not a problem: The IoT device provides proper monitoring of the aggregated items. However, if an individual case or collection of products is removed from a shipment/pallet and is not handled correctly, the mistake could go undetected. This wouldn't occur with unit-level IoT monitoring, as individual products that were compromised would be detected early (in real time, actually). A proactive, targeted recall of the case or bottles can be issued, protecting consumers and resulting in significant cost savings and brand protection for the manufacturer."

Michael Hardin, BMET, Senior Solutions Consultant, TractManager

"It's easy to overlook the life of a recall. The issue is that preliminary recalls are often confused as being functionally equivalent to official FDA recalls. Recalls can be initiated in a variety of ways, like an observation of a defect, or a problem on the supplier's manufacturing floor. They can also be identified as a result of a complaint from a provider/patient. Once the supplier is notified of a potential defect, they must conduct an investigation to validate the problem, scope and severity, as well as develop a corrective action plan. For FDA-approved medical devices, the supplier must also notify the FDA of the complaint and the ensuing investigation. Once the supplier has completed its investigation and corrective action plan, they are required to provide that information to the FDA — who will in turn conduct their own investigation and review of the supplier's corrective action plan. It is only then that the FDA will publish an official FDA notice (if warranted).

"Suppliers will often notify providers when they've completed their internal investigations. These notification typically happen well before the FDA has completed its process. Every provider receives such notices

on a regular basis, either by hard copy or email, and must act upon them appropriately.

"Here's where things can get overlooked: The recall notice sent by the supplier is technically a preliminary one, meaning that the FDA has not completed its investigation. And, during the FDA's investigation, the scope of the problem may well be redefined. There could be more products involved, different affected lot codes, or the action plan could change, for example.

"This is where things get tricky. Because I've seen numerous examples of providers receiving the official FDA notice, and assuming they've already completed the corrective action work based upon the notice from the vendor. Given that the scope may well have changed, one must really compare the preliminary notice with the official FDA notice. Leveraging the product history can resolve this, as well as reconciling preliminary notices from the supplier with actual FDA notices."

Denise Maxwell-Downing, Vice President, Clinical Quality and Patient Safety, SteriTrack

"Omission of a recalled or warranty step can result in millions of dollars in fines or back payments for a healthcare organization. Healthcare organizations not reporting partial or full medical device credits, or replacements not charged to the healthcare organization for recalled medical devices from the manufacturers, is one area of the recall or warranty process that has been overlooked and has recently been unveiled by the Office of Inspector General (OIG). In March 2018, 210 hospitals were found to not have complied with reporting manufacturer credits to Medicare. This resulted in $4.4 million of overpayments to healthcare organizations that must be returned from the healthcare organization to Medicare.

"Disparate systems with separate workflows set the stage for a lack of availability or poor-quality data, which contributes to medical device recall or warranty processes being overlooked or ignored. Financial and revenue cycle systems assist healthcare organizations to increase accuracy and simplify claim submission and payment management processes, but due to information privacy and security rules the entire clinical record may not be accessible to obtain important information needed for financial decisions. Or if the clinical record is accessible it may contain phrases that result in imperfect matching when the biller is trying to code the procedure. Scheduling practices vary among healthcare organizations and even throughout one healthcare organization. This lack of standardization contributes to coding and billing difficulties especially when a recalled or warrantied medical device was replaced.

"To capture recalled or warrantied medical devices the process should start when a surgical or invasive procedure is scheduled as a revision or replacement. An automated, electronic scheduling form that includes the necessary, minimum data set, for the appropriate condition, value, or modifier codes for a revision or replacement procedure would identify the procedure as having a medical device that is within the warranty or recall period. Collection of only key information assists with managing privacy concerns when the data is needed by diverse professionals. If additional data is needed then communication across the diverse professionals (e.g., surgeon, perioperative supply chain, manufacturer representative, perioperative leadership) can occur. From the scheduled procedure, supply chain staff or the department's materials manager is notified of the medical device's recall or warranty status to ensure proper purchase order (PO) pricing occurs. The procedure is flagged for the financial system to notify the biller and accounts payable individual to ensure proper management for billing of the procedure, the device supplier and claims submission.

"This data flow supports appropriate informatics strategies for interoperability. The data will serve 'dual purposes' from a single workflow. The system architecture anticipates the need for data linkages and aggregation of data across multiple disparate sources. Also, employing the medical device's unique device identifier (UDI) in the data collection and exchange assists with verification of the device against available regulatory databases, FDA GUDID and MDR, and against previous procedure claims. The association of UDI data to patients and procedures will ensure the exchange of a recalled or warrantied medical device has occurred. Close collaboration with stakeholders internal to (e.g., supply chain, billing, scheduling, risk management, IT) and external to the healthcare organization (e.g., Medicare and other payer organizations, the FDA, manufacturers) is essential for designing bi-directional data flow and maintenance of this type of process. Input from all the stakeholders ensures the process does not ignore or miss needed steps in the recall or warranty process.

"The other step of the recall and warranty process that is frequently overlooked is adverse event reporting. This step is frequently missed or ignored because the patient and surgeon are already aware of the medical device's recall status and the medical device is returned directly to the manufacturer once removed during the surgical or invasive procedure. Flagging the procedure when scheduled as a procedure that requires an adverse event report will ensure timely reporting of the event to the registry sponsor to enable further investigation and analysis of the medical device. Registries use this data to compare costs of medical devices to current devices therapies, to establish medical device best practices, especially when off-label use of the device is the norm, and for regulatory post-market surveillance. Healthcare organizations who participate in registry data collection generally receive regular reports containing quality measure information. This information is used to benchmark their performance, to identify areas of potential quality and process improvement and for reporting purposes to governmental and accrediting organizations. The utility of medical device adverse event data to and from a registry is critical for the healthcare organization and the registry.

"Instead of working under the one task one-person paradigm, groups of individuals in the complex network need to perform related tasks together. The culture that values teamwork as a structural foundation for cooperation and synergy, instead of individual performance, is fundamental."

Siobhan O'Bara, Senior Vice President, Community Engagement, GS1 US

"Today, manual processes are still commonly used to locate and pull recalled products from inventory. As these products are being marked with standardized data encoded in barcodes, as required by both the Drug Supply Chain Security Act (DSCSA) and Unique Device Identification (UDI) rule, those barcodes will be scanned at the point of care so that providers will be able to track identify and notify patients that received the product. In a fully standardized system, products still in inventory will be quickly and accurately located – down to a specific closet on a particular floor within a facility – by matching the barcode scans to Global Location Numbers (GLNs). Providers looking to upgrade their processes and take advantage of these improved capabilities can refer to the GS1 Healthcare US Point-of-Care Scanning Implementation Guidance (https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=1583&language=en-US&PortalId=0&TabId=134) for help.

"According to Stericycle Expert Solutions' 2019 Recall Index (http://www.stericycleexpertsolutions.com/wp-content/uploads/2019/04/StericycleExpertSolutions-RecallIndex-Q12019.pdf), in the first quarter of 2019, 164 medical devices and 94 pharmaceutical products were recalled, including almost 135 million and 13 million units, respectively.

"The ability to marry patient records with product identification and tracking (by uploading the information to EHRs and using AI and blockchain, for example, to amalgamate that data) could be the key to a more proactive healthcare paradigm. We could prevent adverse events by checking the database to verify a product is still good – it has not expired or been recalled, and specific reactions have not been recorded, for example – before it is even put into use. Leveraging data and technology to proactively track product results could improve effectiveness of recalls, minimize the occurrence of negative consequences and improve the quality of care."

WORTH REPEATING

"As markets grow tighter and more expensive, technology is replacing labor in warehousing and distribution. Distributors and manufacturers are already using several of these advanced technologies to reduce labor costs, increase throughput and maximize customer service."

Jim Richardson, Portfolio Executive, Senior Consultant, Vizient Inc.

"Staffing ratios, lack of staff education, and lack of support from leadership all contribute to the growth of pressure injury incidence. There are also problems with assessment documentation, complete lack of written processes, or the failure of processes in place."

Erica Thibault, MS, RN, CNS, APN, CWON, Clinical Manager, and Suzanne Worden, PT, MS, CSPHA, Clinical Manager, Sizewise

"Minimizing medication errors while improving clinical efficiency is a top concern across the healthcare landscape. Healthcare executives are constantly looking for ways to leverage technology to support this outcome."

Thomas Utech, PharmD, Worldwide Vice President, Global Solution Management & Marketing, Medication Management Solutions, BD.

"With respect to recall and safety notices, there's a lot of noise out there. There are official FDA notices, preliminary vendor recalls (not yet FDA validated), MAUDE reports, vendor notices, incident reports, and more. Ultimately, I'd want a process that makes the management of safety notices and recalls more efficient, that considers all recall-related documentation and that gives visibility to all related stakeholders. I envision a single technology repository (i.e., a blockchain structure) for Food, Pharmacy and Medical Devices that would be the clearinghouse and source of truth for all related transactions."

Michael Hardin, BMET, Senior Solutions Consultant, TractManager

"... a process challenge device (PCD) provides the best indication of sterility assurance by providing a challenge greater than or equal to the most difficult items routinely processed (AAMI ST58, section 9.5.4.1). As such, we reference the AAMI ST58, section 9.5.4.3 recommendation to use a PCD at least daily, but preferably in every sterilization cycle."

Jeremy Yarwood, PhD Microbiology, Immunology & Molecular Pathology, Vice President of R&D, ASP

PEOPLE & OPINIONS

Preoperative skin antisepsis

Is it time to expand the playing field?

by Helen Johnson

When it comes to choosing a topical antiseptic for preoperative skin preparation that complies with SSI prevention guidelines, the options are limited. Current guidelines from the Centers for Disease Control and Prevention, Society for Healthcare Epidemiology of America, and Infectious Diseases Society of America call for an alcohol-containing preparation, based on alcohol's highly bactericidal and rapid onset of action, along with an additive antiseptic that provides more persistent antisepsis.[1-2] In the US, the only commercially available preparations combining alcohol with an antiseptic for preoperative skin antisepsis include those with povidone iodine (PVI) or chlorhexidine gluconate (CHG). A study published in August 2019 by researchers from the University of Wisconsin and the University of Texas Southwestern, however, is poised to 'expand the playing field' and proponents of antiseptic stewardship are likely to think the timing could not be better.

The study, published in the journal *Infection Control and Hospital Epidemiology*, reports the results of two phase 2 trials assessing a novel topical skin antiseptic combining isopropyl alcohol with citrate, alkyl para-hydroxybenzoates, methylene blue (as a colorant), and purified water.[3] In both trials, the novel formulation matched the efficacy of the widely-used 2% CHG/70% isopropyl alcohol formulation in achieving target post-application microbial reductions. Additionally, the formulation was effective even when suboptimal (shorter) application times were employed—a finding with practical implications for surgical practitioners given that compliance with application and dry-times have been reported to be as low as 24.6%.[4]

What makes this development noteworthy is the context of the current antiseptic landscape, particularly as it relates to CHG. CHG is a potent antiseptic with a broad spectrum of activity and a robust body of evidence supports its efficacy in reducing certain healthcare-associated infection risk.[5-8] CHG made its commercial debut in the 1950s in the UK and its use has grown exponentially ever since.[9] Case in point: in 2013, a single regional hospital in Massachusetts reported 17 different applications of CHG, excluding the long-standing application of gingival and periodontal antisepsis.[10] While none of the SSI guidelines preferentially recommend an additive antiseptic agent, market reports indicate 2% CHG/70% isopropyl alcohol products are among the most widely used topical skin preparations in the United States.[11] There is growing concern, however, surrounding the widespread use of CHG-containing products within the healthcare industry for two reasons:

1. reports of resistance/reduced susceptibility among clinical isolates in high-use settings, and
2. an up-tick in accounts of adverse events and allergic reactions.

CHG resistance on the rise

Over the past eight to ten years, there has been increased detection of CHG resistance/reduced susceptibility within the acute care setting that appears to be associated with increased CHG exposure.[12-17] One of the first studies to demonstrate this came from a Taiwanese hospital in which CHG had been in use for hand hygiene for over 20 years.[12] The study, published in 2008, found that between 1990 and 2005, the percentage of MRSA isolates with reduced susceptibility to CHG rose from 1.7% to 46.7%.[12] Two years later, British researchers reported that use of CHG for MRSA decolonization in the ICU led to selection of a strain with CHG susceptibility three times lower than the other MRSA strains in the facility.[13] Zhang et al reported that the prevalence of CHG-resistant genes in the skin commensal coagulase-negative staphylococci was significantly higher in nurses than in the general population (57% vs 14%, $p<0.001$), which they attributed to repeated exposure to CHG in the hospital environment.[14]

More recently, researchers from Johns Hopkins University studied CHG susceptibility in organisms causing central line-associated bloodstream infections (CLABSI) and found a 69% prevalence of reduced susceptibility.[15] In units where CHG bathing was performed, organisms causing CLABSI were significantly more

likely to have reduced susceptibility than in units without CHG bathing protocols (86% vs 64%, p=0.028).[15] In a 2017 study, scientists identified a high prevalence of CHG-resistant genes (67% *qac*, 18% *smr*) in organisms recovered from the skin of patients with central venous catheters who wore CHG-impregnated dressings.[16] The proportion of specimens with the *qac* resistance genes was significantly higher from patients who had worn the dressing for >72 hours compared with those with shorter exposure (p=0.04).[16]

Alarmingly, reports of cross resistance between CHG and certain antibiotics, including the last-resort antibiotic colistin, have also been published.[18-19] Taken together, these findings have led to a number of cautionary statements from experts in the field regarding judicious use of CHG and the need to champion "antiseptic stewardship."[19-20]

Adverse events/allergies

In 2017 the FDA issued a warning about allergic reactions with use of CHG based on a growing number of cases of CHG-induced anaphylaxis (FDA).[21] Although the total number of cases is relatively small, it is widely acknowledged that they are on the rise—in fact, half of the reported anaphylaxis cases occurred since 2010 despite the fact that CHG has been available in the US since 1969.[21]

CHG can elicit other allergic reactions, including mild contact dermatitis and delayed or immediate hypersensitivity reactions, and sensitization appears to play a role.[22-23] A review of CHG allergy found that the majority of patients who experienced a serious allergic reaction to CHG reported minor symptoms upon previous exposure to the antiseptic.[23] Just how prevalent these allergies are remains unclear—a review of adverse events with CHG published in the journal *Dermatitis* reported that studies of CHG allergen series patch testing yield positive results in anywhere from 0.5 to 13.1% of the studied population.[10] Most experts agree, however, that cases are likely underreported and are likely to increase in frequency given the extensive use of CHG in a variety of healthcare products and applications [10,22]

The perioperative setting is no exception to this trend.[22-24] One Danish study found that 9.6% of perioperative anaphylaxis cases were attributable to CHG allergy.[25] A 2015 literature review of chlorhexidine-induced anaphylaxis in surgical patients published in the journal of the Royal Australasian College of Surgeons found that 39.71% of affected patients had to have their procedures canceled and 27.94% resulted in unplanned ICU admissions.[26] The authors conclude that "rationalization" of CHG-containing products is needed to avoid the morbidity and mortality associated with CHG-induced anaphylaxis.[26]

Looking to alternatives

Preoperative skin antisepsis—or "skin prep"—is a well-established surgical site infection (SSI) prevention measure. Multiple studies have demonstrated that antisepsis with an alcohol-based agent reduces the concentration of bacteria residing on the skin at the surgical site and results in significantly fewer SSIs,[1,27-28] but the spectrum of alcohol-based agents available in the US is small. Formulations combining alcohol with PVI are currently the only alternative to CHG-alcohol products. Though CHG may have longer residual activity than PVI,[29] to date there is insufficient high-quality evidence to support the superiority of either formulation in preventing SSI.[1-2]

The authors of the ICHE article argue that "continued diversification of [the] topical antiseptic armamentarium" is imperative to mitigating the upward trend in both CHG resistance and allergy.[3] Champions of antiseptic stewardship similarly argue that the healthcare community must be cautious with such a valuable weapon in order to preserve its efficacy.[20] With as many as 48 million surgical procedures performed in the US each year[30] and the average American undergoing 9.2 surgical procedures in their lifetime, according to a study published by the Massachusetts Chapter of the American College of Surgeons,[31] it may indeed be time to grow the 'team' of topical antiseptics used for preoperative skin prep in an effort to steward existing topical antiseptics. **HPN**

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Getting it right the first time: The power of standardization

by Karen Conway, Vice President, Healthcare Value, GHX

As discussed many times in this column, one of the primary benefits of standardization – be it in process or in products - is the ability to reduce "uncontrolled" variation that can impact quality. When it comes to patient care, there is an added dimension in the pursuit of quality – the reduction of "unwarranted" variation. In this month's column, we explore a program in the UK that is demonstrating the value of this approach, from both a clinical and financial perspective.

First, let's explore the differences between uncontrolled and unwarranted variation. Those trained in the Six Sigma methodology seek near perfection in the form of no more than 3.4 defects per million opportunities (which translates to six standard deviations between the mean and the nearest specification limit). Anything outside those specification limits is considered uncontrolled variation. Within those limits, there will always be some degree of controlled variation, the result of normal causes that will always exist in nature. In the pursuit of quality, the key is to determine if the variation is uncontrolled (the result of special causes) and can and should be addressed. Failure to recognize the difference and misdirected improvement efforts can result in actions that can worsen, not improve, quality.

When it comes to patient care, there is a further consideration: whether variation is warranted or unwarranted. Let me explain. In contrast to building a product to certain specifications, such as a car, patients are unique. There is still tremendous value in standardizing clinical protocols based on evidence of what works best for specific patient populations. But individual patients also present with their own unique anatomical characteristics, genetics, lifestyles, even personal opinions as to what they consider to be favorable outcomes. As a result, as we seek to standardize care on what works best, we should also create mechanisms for clinicians to vary care – including the choice of devices or drugs – to meet the unique needs of their patients.

A program in the UK – Getting it Right the First Time (GIRFT) – is performing groundbreaking work in this area at the system level, seeking to reduce variation in how care is delivered across the National Health Service (NHS). The program was started by orthopedic surgeon and professor Tim Briggs, who was provoked by the case of a 73-year-old woman who, after undergoing spine surgery, was unable to raise her head to look forward. He wants to ensure that no patient, let alone someone at her age, has to undergo corrective surgery because it wasn't done right the first time.

GIRFT's first workstream was in orthopedics, laying the foundation for a methodology now being deployed across 40 medical and surgical specialties in the NHS. By identifying the practices that lead to the best outcomes, GIRFT clinical leaders seek to standardize those practices in their respective areas of expertise across the NHS.

Some of GIRFT's early groundbreaking work focused on the appropriate use of cemented vs. uncemented orthopedic implants in patients over and above the age of 55. Despite evidence of better outcomes (from a patient satisfaction and clinical perspective) for total hip arthroplasty (THR) patients over 55 with less expensive cemented implants, and no evidence of a difference between cemented and uncemented implants in younger patients, GIRFT identified a substantial increase in the use of uncemented implants for patients of all ages. With an aging population, rising rates of obesity, and nearly 20 percent annual increases in referrals for THR, GIRFT warned of a substantial financial drain on the NHS and recommended standardizing care based on clinical evidence and cost considerations.

In its research, GIRFT identified significant variation in practice and outcomes in terms of device and procedure selection, clinical costs, infection rates, readmission rates, and litigation rates. With predictions of lower revision rates with cemented implants (especially for patients over 65), studies estimated the NHS could save £18.5 million within five years, and likely more, if it were to standardize care more on cemented implants. Even taking into account faster surgery times with uncemented implants, research found trusts would not be more profitable even if they doubled the number of procedures with uncemented devices due to their higher costs.

GIRFT research across numerous medical specialties is generating important research on the value of standardization of care to reduce unwarranted variation. At the same time, researchers also recognize the continued need for warranted variation based on specific patient needs. As one study noted: "The use of cemented components in routine primary THR in the NHS as a whole can be justified on a financial level but we recognize individual patient factors must be considered when deciding which components to use." HPN

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

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A call to ... [f]arms!

by Ed Hardin, FACHE, CMRP

Looking back at the past three years, having experienced leadership time in resurgent rust-belt states, I've had a running list of top three concerns that have managed to shift but always remain in the top spots: *Meeting Ever Increasing Demands for Supply Chain Savings, Integrating Supply Chain Data with Clinical Data to Inform and Enhance Decision Making*, and *Retaining and Developing Talent*.

As I scoured what *Healthcare Purchasing News* had to say on these topics in recent articles, I found myself gravitating towards the topic of talent management, a subject I'm passionate about and have put time in to studying. I was struck by the fact that in July 2018 two of the most respected leaders in our field managed to produce articles for *HPN* that had seemingly different things to say on this topic: One for its admitted absence as a trending concern from an annual survey of providers and suppliers; the other for highlighting 17 "skills" required of a successful supply chain professional. I hazard to guess the disconnect, but suspect the survey represents the most contemporary of concerns and the latter a more fundamental and arguably timeless view of talent. Let's reconcile these, but first let's draw on a metaphor about baseball, one that puts my beloved hometown team between the pages of this magazine for likely the very first time.

Sabermetrics

Generally recognized as one of the greatest Major League Baseball turnaround stories in the 2000s, the Houston Astros accumulated a miserable six-season (2009-2014) winning percentage of .393, then managed to follow the next five seasons (2015-2019), including their most recent one, with a winning percentage of .594 and two trips to the World Series. Their accomplishment seems all the more unlikely when one considers that they moved from the National League to the American League in 2013 after reports of their impending demise ran the gauntlet of the national press. Foundational to their success is their widely known reliance on data, taking a page from the Athletics' 2002 season, to assemble a competitive team at a fraction of the cost that teams like the New York Yankees and Boston Red Sox were spending.

Less known is that their rigorous application of sabermetrics, the empirical analysis of baseball statistics, was not focused on the Astros themselves but instead on their Triple-A farm system to develop talent, a move to fewer farm system teams to concentrate their talent and trainers, and the hiring of Jose Fernandez, co-founder of FC Barcelona's – yes, the world-renowned soccer team – La Masia farm system. And if I can be so bold, the Astros' new ownership – the transition that took place in conjunction with their move to the American League – was highly competitive and held a great sense of urgency.

Talent and retention

Perhaps the balance of supplier respondents to the 2018 survey skewed the results, but I believe strongly that the world of the provider, particularly amongst supply chain professionals, is highly competitive as evidenced by the time I spend with my industry peers as well as my own experience. Just in the last six months, our organization lost three, relatively short-term, highly competent and young supply chain personnel to Harley Davidson, Milwaukee Tool and Briggs & Stratton. If you're operating in a manufacturing or Fortune 500 hub, the competition for talent is real. Couple this competition with the following:

- Very limited empirical data to guide the industry to what are required, needed and nice-to-have skills
- Declining member engagement in some of our industry's anchor organizations largely responsible for professional development and advancement
- Shrinking budgets for training and education for perceived non-essential staff
- Inability for supply chain leaders to seriously develop succession planning
- Migration of non-healthcare personnel into leadership ranks

What you're left with is a critical gap to retaining and developing talent that will widen. As leaders, we must view this time as a clarion call to put aside our paradigms and radically rethink how we address talent management. A call to farms (as in farm teams), if you will.

Space limitations require a quick wrap-up but in my follow-up later this summer – two years to the date of the 2018 aforementioned articles – I want you to ask yourselves these important questions and email me back your perspectives, which I'll explore further and incorporate into a strategic list of critical and timely to-do's for the industry:

- Who are our anchor organizations and what obligation do they have to ensure that talent management remains a top priority?
- How does higher education play a role and what linkages might supply chain leaders create with their local universities, colleges and vocational schools?
- What specific groups/individuals must collaborate to form a multi-disciplinary panel of thought leaders to accurately identify the educational, training and networking requirements of entry, mid-level and leadership personnel?
- How do we help organizational development and education departments to best re-prioritize resources to support our efforts in talent management, inclusive of education as well as succession planning?
- What can we do to turn the tables on our non-healthcare rivals for talent and become more competitive for entry-level personnel that haven't given healthcare serious consideration to launch their careers? **HPN**

Ed Hardin, FACHE, CMRP, serves as Vice President & Chief Supply Chain Officer for Froedtert Health, a Milwaukee-based integrated delivery system. Hardin is an educator and mentor, passionate about creating work environments that cause people "to wake up every day loving what they do and loving who they're doing it with." He previously served as Vice President, Supply Chain Management, for Irving, TX-based CHRISTUS Health, which earned the 2016 Supply Chain Department of the Year Award from Healthcare Purchasing News. He recently was diagnosed with Stage 4 colon cancer and is ever mindful of prioritizing what is most important about life: Faith, family and others. He can be reached via email at edmond.hardin@froedtert.com.

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