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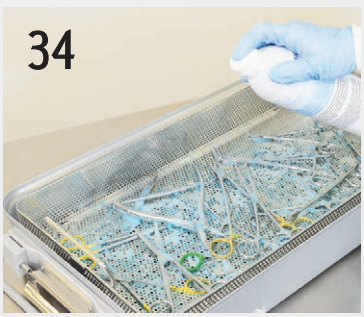
HEALTHCARE PURCHASING NEWS



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What not to do

We're all familiar with the debunked assurance, "If you like your doctor you can keep your doctor."

Political partisanship aside, the promise doesn't work with software.

Granted, it works with vehicles in an extended, but limited way. Why? Well, cars require ongoing routine maintenance and service – components and parts wear out and must be replaced and the body and frame rusts without the expensive coating. A well-maintained car should be able to last at least 20 years. For it to be regarded as an authentic classic (older than 25) or antique (50 years and older), according to the Antique Automobile Club of America (the Classic Car Club of America is a bit more generous in lowering the baselines by five years), you most likely have to let it undergo a pricey, full-on, frame-off restoration, sequester it in a temperature-controlled garage, drive it sporadically to shows and growl at misbehaving kids with sticky fingers not to touch it and wipe it down with a diaper every weekend.

Alas, you can't do that with software either.

In healthcare (but also everywhere else!), we all have to come to terms with this assurance that not only is a promise but a guarantee: "If you like Windows 7 you can't keep using Windows 7."

No matter how much we bristle, protest and whine, Microsoft simply decided to pull the plug on supporting its famously popular and well-regarded product. They can do that. General Motors killed Pontiac and Oldsmobile (tears and jeers), Chrysler killed the 1980s K-cars as well as the Neon and the Omni (cheers) and now Ford is killing its entire car line-up, save for the Mustang, crossover SUVs and SUVs (fears).

Organizations that continue to use software not backed up by its manufacturer (in terms of keeping security measures up-to-date) or some other authorized (or unauthorized? Careful…) third party leaves them vulnerable to cybersecurity crises and hacking disasters.

Boston-based BitSight (www.bitsight.com), a cybersecurity ratings company, monitors about 60,000 organizations across multiple industries. BitSight found that nearly 70 percent continue to use Windows 7 to some extent. In fact, roughly 90 percent of organizations employing more than 100,000 people continue to use Windows 7 on an unspecified number of computers. Further, and here's the kicker, BitSight found that more than 40 percent of large finance and healthcare institutions, as well as roughly 30 percent of large government and political firms have at least one in four employees using Windows 7.

Yikes.

For a healthcare industry concerned about the threat of cybersecurity – and the growing number of healthcare organizations falling victim to hackers poking around and electronically extracting what should be confidential information – this so-called "patch," as in upgrading to Windows 10, for instance seems like a no-brainer.

Yes, the nine-year-old Windows 7 software is so comfortable, convenient and user-friendly. But its manufacturer has decided it has outlived its useful life and like a venerable warship it must be decommissioned.

Give Microsoft plaudits and props, however, for continuing to offer paid support for professional and enterprise versions of the expiring (technically, expired) products for another three years.

Unfortunately, healthcare organizations frown on change; trying to modify organizational behavior is akin to executing successfully a three-point turn of an oil tanker trying to reverse its way through the Panama Canal.

Ironically, the one piece of technology we excitedly and faithfully demonstrate willingness to upgrade is our mobile smart-phones. When companies like Apple, Motorola, Samsung and the rest roll out new models sporting clever names or numerals we run right out to make the change, even if the only difference involves five more megapixels of camera lens clarity or Von Dutch-inspired pinstripes.

Maybe therein lays the solution: Microsoft merely needs to make upgrading to Windows 10 … "fashionable." TLC canceled the decade-long "What Not To Wear" nearly seven years ago; Microsoft should launch "What Not To Do" and highlight the organizational horror stories around retaining Windows 7.

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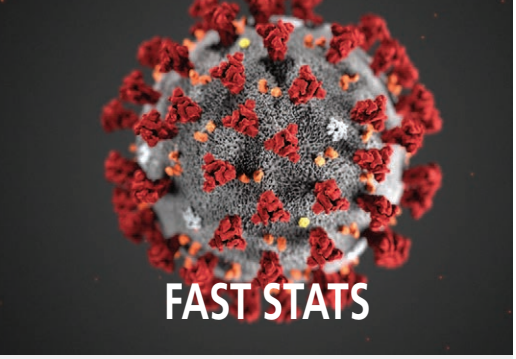

COVID-19*

Similar to MERS, SARS and the common cold, the novel coronavirus disease (COVID-19) was first detected in Wuhan, China, in December 2019, and has spread rapidly throughout China and the world.

3%

is the estimated mortality rate of COVID-19 infection

98%

of patients with COVID-19 infection presented with fever symptoms and later 55% of the patients developed dyspnea and 66% developed lymphopenia

76%

of patients presented with cough and 44% also had myalgia/fatigue with COVID-19 infection

2 DAYS TO 2 WEEKS

is the estimated incubation period after exposure according to the Centers for Disease Control and Prevention (CDC)

774

is the number of deaths across the world from SARS; COVID-19 deaths have now exceeded that number with over 1,800**

$675 MILLION

is the amount needed for new coronavirus preparedness and a global response plan covering the months of February through April 2020 according to World Health Organization (WHO) International

RRT-PCR

or reverse real-time transcription polymerase chain reaction assay is the CDC prescribed test for labs to use for COVID-19 detection

Sources:
https://www.who.int/news-room/detail/05-02-2020-us-675-million-needed-for-new-coronavirus-preparedness-and-response-global-plan
https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html
*Formerly 2019-nCoV
**As of February 16, 2020

NEWSWIRE

CDC updates recommendations for healthcare supply of PPE

The Centers for Disease Control and Prevention (CDC) continues to monitor the COVID-19 situation in the United States and around the world, and recently updated the information for healthcare providers for personal protective equipment (PPE).

The CDC has taken aggressive actions to prevent the spread of COVID-19 in the U.S., through a combination of proven public health actions. At the same time, CDC is preparing for the possibility that the COVID-19 situation in the U.S could become more serious, with sustained community transmission, and is taking steps to make sure there are enough supplies and appropriate guidance to prevent the spread of disease, especially among healthcare personnel caring for patients with COVID-19.

Healthcare personnel can protect themselves when caring for patients by adhering to infection prevention and control practices, which includes the appropriate use of engineering controls, administrative controls, and PPE. The CDC has issued guidance recommending the use of PPE for healthcare personnel caring for patients with confirmed or possible COVID-19 infection. Employers and healthcare personnel are reminded that PPE is only one aspect of safe care of patients with COVID-19. For the general public, CDC does not recommend the use of facemasks or respirators. CDC guidance is based on what is known about COVID-19 and what is known about similar coronaviruses, like SARS and MERS.

CDC also understands the importance of providing guidance that healthcare facilities can implement, given the supplies of PPE available. CDC communicates regularly with healthcare industry partners, as well as PPE manufacturers and distributors, to assess the availability of PPE. At this time, some partners are reporting higher than usual demand for select N95 respirators and facemasks.

Based on the current COVID-19 situation and availability of PPE, CDC has specific recommendations, summarized below.

Who needs PPE:

- Patients with a confirmed or possible COVID-19 infection should wear a facemask when being evaluated medically.
- Healthcare personnel should adhere to Standard, Contact, and Airborne Precautions, including the use of eye protection (e.g., goggles or a face shield) when caring for patients with COVID-19 infection. These precautions include the use of PPE, including NIOSH-approved N95 respirators, gowns, gloves, face shield/eye protection, etc. This includes, but is not limited to, surgical N95 respirators.

Who does not need PPE:

- CDC does NOT currently recommend the general public use facemasks. Instead, CDC recommends following everyday preventive actions, such as washing your hands, covering your cough, and staying home when you are sick.
- Manufacturers and Distributors:

Given decreases in exports from select countries (e.g., China, India, Taiwan) and increases in demand due to the outbreak, manufacturers of select types of PPE are reporting an increased volume of orders and challenges in meeting order demands. Plans to surge manufacturing globally are underway.

CDC offers strategies for healthcare settings on how to optimize supplies of N95 respirators in the face of decreasing supply. These strategies are organized using the occupational health and safety hierarchy of controls approach.

CDC link: https://www.cdc.gov/coronavirus/2019-ncov/hcp/healthcare-supply-ppe.html

COVID-19 and the supply chain

A concern for hospital officials is access to the supplies they need to test and treat infected patients while also protecting employees. Concerns about potential shortages of key supplies are driven, in part, by several recent developments.

The first issue is Cardinal Health's recent recall of more than nine million Level 3 gowns, which are used during surgical procedures or to provide barrier protection.

Cardinal Health decided to initiate the recall after learning in December 2019 that one of its Food and Drug Administration (FDA)-approved suppliers in China, Siyang Holymed, had shifted production of some gowns to unapproved sites, with uncontrolled environments, meaning that Cardinal Health could not be sure that the gowns are sterile. Since then, Cardinal Health has terminated its relationship with Siyang Holymed.

To help bridge the supply gap, Cardinal Health is increasing production of similar products, sourcing alternative suppliers of gowns for its customers, and offering customers protective Level 4 gowns.

Cardinal Health is certainly not the only organization manufacturing medical products in China. As the outbreak spreads and China places more locations into lockdown, disruptions to the global medical supply chain are becoming increasingly worrisome.

Resilinc, a vendor of supply chain risk and resiliency software, believes there is a high risk of disruptions to the supply chain, based on global containment measures. Bindiya Vakil, founder and CEO of Resilinc, noted during a webinar

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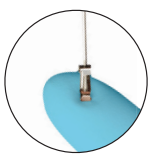

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presentation that businesses should expect supply chain disruptions for three to six months. Wuhan, the epicenter of the outbreak, is a manufacturing hub in China, including production of biotechnology products and the active ingredients, or APIs, used in pharmaceuticals, according to Resilinc. The city also is home to China's largest inland port, which handles ocean-going ships, Resilinc adds. Other product segments produced within the region include: high tech, auto, life sciences, medical device, healthcare, biotech, pharma, food, consumer goods, general manufacturing, aerospace, applied solutions, industrial printing, and consumer electronics.

This situation is an important reminder for supply chain professionals to track where their suppliers are located and where these suppliers get their materials.

To help head off potential shortages of PPE, the World Health Organization (WHO) in January launched a private-public collaboration called "The Pandemic Supply Chain Network," which is an effort to gather information about market capacity and risk assessment. It had hoped to complete the assessment by February.

Given the potential for supply chain issues, the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response has been "assessing the level of preparedness" of pharmaceuticals and medical supplies within the Strategic National Stockpile, which can be used in the diagnosis and treatment of people infected with the novel coronavirus, HHS Secretary Alex Azar said in a news briefing in January.

Vakil recommends that organizations develop supply-chain preparedness plans based on likely scenarios, set clear triggers for action, and communicate information widely. The planning process also should include collaborating with suppliers, she added.

Coronavirus becomes world's costliest epidemic at over $62 billion

The ravaging coronavirus has become the world's costliest epidemic in the last 20 years. According to an article by Justinas Baltrusaitis, from data collected by Learnbonds.com, the coronavirus, is projected to cost China about 2% of the GDP in the first quarter of 2020 – this is equivalent to $62 billion. Based on these calculations, the impact on the global GDP might be even bigger.

The outbreak might hamper Chinese growth as most operations have been halted. If the virus is not contained, a similar situation might be replicated in other parts of the world. China is prioritizing containing the virus with the government allocating $12.6 billion for medical treatment and equipment. Elsewhere, leading banks have lowered interest rates for small businesses and individuals in the worst-hit areas including Hubei.

The coronavirus is projected to be the costliest epidemic since 2000, when compared to other disease outbreaks including Ebola, Swine flu, among others. This is despite the fact that previous diseases such as Swine Flu and Ebola, had a much higher death toll.

Over the period under review, the Ebola virus was the second costliest epidemic. The virus, which hit most parts of Africa, led to a loss of $53 billion. Between 2000-2020, about 11,323 deaths and 28,646 infections as a result of Ebola were recorded. The most devastating Ebola epidemic of the last two decades occurred between 2014 and 2016, with Guinea, Liberia, and Sierra Leone becoming the worst-hit countries.

Swine flu has emerged as the third costliest epidemic. The zoonotic disease affected an unknown number of people over the last 20 years. The recorded number of deaths was 18,138, the highest figure for casualties during the period under review. The worst pandemic of Swine flu occurred between 2009 and 2010 where almost all regions of the globe were impacted.

Bird flu, which harbors some similarities to Swine flu, also caused global panic with a considerable impact on economies. In the period under review, the deadly flu accounted for 407 deaths globally while 701 people were infected. The flu resulted in a loss of $40 billion. The flu's major outbreak was in 2006 where cases were reported in at least 35 countries.

Severe acute respiratory syndrome (SARS) led to a loss of about $40 billion during diverse years between 2000-2020. The figure represents 0.5% of the GDP. The respiratory disease notable outbreak was between 2003 and 2002 in the Southern region of China. The virus resulted in 774 deaths across 17 countries with China accounting for most cases. The infected individuals stood at 8,098.

Lastly, the Middle East Respiratory Syndrome (MERS) accounted for a loss of $10 billion. The epidemic has affected 2,000 people leading to 720 deaths.

Report link: https://learnbonds.com/news/coronavirus-becomes-worlds-most-costliest-epidemic-new-report-reveals/

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SPECIAL REPORT

GPOs not allowing coronavirus outbreak to eclipse supply chain operations

Industry 'air traffic controllers' strive to stay ahead of tide

The outbreak of the coronavirus overseas and its emergence in the United States not only ignited clinical defenses but also engaged and continued to test the developing supply chain crisis/disaster response plans among healthcare providers and suppliers alike. As of February 14th, 2020, the coronavirus reportedly infected more than 65,000 persons in East Asia, and 15 in the U.S. mainland. The death toll exceeded 1,400. And the numbers keep rising.

To gauge how healthcare providers and suppliers are prepping their defenses with planned offenses, *Healthcare Purchasing News* Senior Editor Rick Dana Barlow reached out to six of the nation's largest group purchasing organizations (GPOs), representing the majority of healthcare providers and annual purchasing volume. Four responded to *HPN*'s three pointed questions designed to add historical context to the current event and evaluate progress with this latest challenge. Executives from Intalere, PDM Healthcare, Premier and Vizient shared their impressions and insights on what's happened and where the industry needs to go.

HPN: How is your organization working to calm/ease the supply chain fears of member healthcare facilities stemming from the coronavirus outbreak? What specifically are you doing in terms of recommended practices and operational strategies and tactics that reach beyond the C-suite and clinical realms deep into supply chain operations?

Steve Kiewiet, Chief Commercial Officer, Intalere: "Intalere is closely monitoring the coronavirus outbreak and potential impacts to the global healthcare supply chain. We use a robust platform to understand linkages and interdependencies across the healthcare supply chain and work with members and suppliers to understand how to mitigate potential impacts. While the majority of our clients are not currently experiencing disruptions, the outbreak at this time is rated as having a Potential Supply Chain Disruption score of MEDIUM, elevated from LOW at the start of the outbreak. While this outbreak has a potential impact on numerous industry sectors, there are companies in the healthcare supply chain that may be impacted.

"This continues to be an evolving situation, and Intalere is working with its partners and Intermountain Healthcare to actively assess the situation. In an effort to facilitate communication between Intalere's supplier community and Intalere's members, we are posting supplier updates, information and informational resources on the Intalere Member Resources website and coordinating efforts as requested."

Todd Larkin, Chief Operating Officer, Intalere: "The key issue is that we too often lack visibility to the multiple levels within an entire supply chain and fail to develop possible scenarios and then plans to mitigate potential impacts. Every single category plan should incorporate an action plan in the event of supply disruptions. In this way, we can proactively take action to address the first incident of potential disruption while at the same time review additional potential risks of another disruption – like the coronavirus in this instance. Intalere is working as part of an initiative with various stakeholders in the healthcare supply chain to drive improved visibility and accountability into the healthcare supply chain, as the products and services we rely on are critical for the care of our patients."

Ash Chawla, R.Ph., Chairman & CEO, PDM Healthcare: "It seems that coronavirus took many in the U.S. by surprise, especially some smaller or rural areas that may have not expected to encounter this type or epidemic. However, it is important to remember that the ease and increase of global travel has made the world more connected, including in terms of disease spread. Therefore, it is paramount that all healthcare facilities and links in the supply chain be prepared to mount a response to coronavirus, or a similar situation, with little to no notice and no interruption to their regular operations.

"In terms of coronavirus, as there is no cure or vaccine to date. The best practices to ease fears beyond the C-suite include ensuring that all providers and staff, from the top down, are well-versed and trained in hygiene and infection control. Operationally, purchasing and materials management departments need to verify that supplies like masks, isolation rooms/areas, gloves, respiratory supplies, etc., are fully stocked. Administrators should look at staffing to determine that they will be able to handle an outbreak in terms of patient care needs, but also in case staff is affected by the illness. Hospitals and emergency departments may need to change triage procedures for patients presenting with respiratory symptoms, including asking about recent international travel and setting up isolation/quarantine areas for patients who have been to affected areas.

"Finally, a situation like this coronavirus outbreak can serve as an important teachable moment to patients and the community which providers can use to reinforce the importance overall good health practices such as flu vaccines, travel vaccines and precautions, proper hygiene, wellness, and preventive care."

Chaun Powell, Group Vice President, Strategic Supplier Engagement, Premier: "Experience shows that the slightest suggestion of a possible disruption leads to proactive hoarding of products, which then intensifies the suppliers' burden to accurately predict demand. Part of Premier's role is to work with both our suppliers and serve as an extra set of hands and legs for our members. We are cautioning against any overreactions or unnecessary exaggerations of the current situation, and through Premier's Disaster Response team, we remain in constant contact with both members and suppliers to hear first of any potential product lapses. Our members have disaster and disruption

plans in place, and we are there to assist in executing those plans and smooth over any hiccups they can't resolve on their own. In our conversations with c-suite leaders and supply chain partners, we are helping to calm concerns and encouraging the judicious use of supplies."

David Gillan, Senior Vice President, Sourcing Operations, Vizient Inc.: "Vizient is closely monitoring the situation and working with suppliers to understand any supply limitations for the critical products based on guidance from the World Health Organization (WHO). In particular, we have seen a dramatic increase in demand for personal protective equipment (PPE). Suppliers of these products have almost universally implemented protective allocations meant to slow the surge in anticipatory purchasing and to help maintain availability of supply. Some suppliers are reporting temporary backorders on key PPE items, such as N95 disposable masks. Suppliers whose manufacturing sites are located outside of the affected regions in China, will likely be able to ramp up to meet demand, but we do expect a lag time where product may be difficult to obtain in some instances. This year's worse than average flu season had already placed some strain on the supply chain for many of these same products."

Not unlike prior outbreaks, the current coronavirus challenge emerges against the backdrop or alongside of a major supplier's product recall – in this case, kits and gowns – which can amplify and exacerbate problems in patient care delivery. In a way, situations like these represent a double-edged sword for supply chain operations – navigate through a problem that already experiences severe limitations on the products needed to manage and solve that problem. How can/should Supply Chain balance such a double-dose of crises?

KIEWIET: "It's mainly about being as proactive, prepared and transparent as we can be across the supply chain. We work closely with our partners to always have a backup plan or viable alternatives in any time of disruption. We also need to continue to get better at end-to-end transparency across the supply chain, in terms of supplier capabilities and resiliency and clients' true needs and expectations. Understanding that the supply chain is built around certain expectations and processes that can sometimes take some time to adjust, and that if one stakeholder along the way is impacted, we are all impacted, we must continue to be more collaborative and open, and be responsive without being too reactionary."

CHAWLA: "Flexibility in purchasing and supplier choice is one of the best ways to combat product shortages. It is in the best interest of a healthcare organization to maintain purchasing agreements with at least two or more suppliers of certain products rather than providing exclusivity to a single manufacturer. This flexibility allows them to 'ready' solutions in place when a shortage of their preferred products does come up rather than having to urgently seek a new supplier and create a new contracting supply chain structure. Most importantly, healthcare facilities should time monitor their inventory and place timely re-orders, specifically for products with a history of shortages or where shortages are anticipated due to market conditions or population health issues."

POWELL: "Research shows that poor demand planning accounts for roughly 68 percent of disruptions across all industries, and healthcare has its own set of nuances because in our industry, our commitments to suppliers do not guarantee demand over a given timeframe, which compounds the issue for manufacturers. On top of that, the medical device industry does not have industrywide protocols that prescribe how manufacturers should notify industry of a disruption; nor do we have measures for how healthcare providers should respond. These protocols exist for pharmaceuticals and are helpful in preventing hoarding, but are nonexistent in the device industry.

"Ambiguity surrounding device disruptions in healthcare is one of the reasons that it's imperative for providers, suppliers, and GPOs to work together. No two parties in isolation will solve the issue; proactivity by two of the three may lead to coverage for one patient population but put another at risk of not having product. GPOs have unique perspective on national ordering patterns and also gain insights into the patient needs of our members when these disruptions and disasters occur. As air traffic controllers of sorts, GPOs then have an opportunity to help mitigate against hoarding while guaranteeing that affected facilities are able to receive the products that they need to deliver uninterrupted patient care.

"Premier experienced this during the Ebola outbreak in which two states had confirmed cases but could not get ample product because other state-designated facilities had purchased their allocation, thereby reducing the available inventory. Through our GPO, Premier was able to identify where there was excess inventory and help get it to the specific providers that had confirmed needs, while assuring that the facilities that had excess would also be taken care of if their needs changed.

GILLAN: "Hospitals are turning to conservation strategies in order to mitigate supply challenges. In the case of gowns, hospitals are also investigating practices at their facilities to ensure that the right level of gown is being used in the correct circumstance so that the Level 3 and 4 gowns aren't being used when a Level 1 or 2 gown provides sufficient protection."

From SARS to MERS to Ebola to coronavirus, from terrorist attacks to tornadoes, hurricanes and earthquakes, from gloves to masks and respirators to IV solutions to kits and gowns, healthcare organizations – and certainly Supply Chain – has weathered a lot of crises and disasters since the late 1980s. What have we really learned from these disruptive patterns during the last few decades that should make preparations and responses more natural/second nature instead of panicked and rushed as they seem to be still?

KIEWIET: "Again, I do believe we have learned and gotten better at being more proactive and collaborative, rather than reactive and siloed. You can never prepare for every eventuality and there will always be some level of disruption, fear and misunderstanding when situations arise. But by being proactive, collaborative, transparent and realistic about real needs and expectations, without buying into the hype, we can mitigate difficulties and make sure that our customers have what they need, when they need it in order to better serve the healthcare needs of their communities."

LARKIN: "The healthcare supply chain is extremely complex, and over the last several decades, [it has] become global and introduced even more complexity. The challenge has been that historically the visibility to that complexity and corresponding interdependencies was not widely available or really sought. While other industries invested in these areas, healthcare lagged behind. I recall the Fukushima nuclear reactor disaster in 2011. At that time, many large supply chain organizations had visibility to which of their direct suppliers were impacted, but only a few had visibility to the tier 2, tier 3, and even tier 4 suppliers that were part of the upstream supply chain. The companies with that level of visibility were able to assist their supplier partners in finding alternative sources or even work with that tier 4 supplier to assist them in bringing their operations back online. The healthcare industry needs to make similar investments and drive to that level of visibility."

CHAWLA: "Advances in technology, from increasing ease of purchasing and product

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select, to transportation and even being able to more quickly identify disease causes, have made it easier in the past decades to deal with emergencies. A cause of the rush panic and rush to deal with emergencies may be that facilities on the first line of defense, especially public health facilities, may not have funding and supplies year round to be immediately prepared when disaster strikes. Ensuring that funding is available for these entities as well as a supply chain protocol to access needed products should work to provide a more seamless response to both natural disasters and disease outbreaks."

POWELL: "You've hit the nail on the head. The more we weather natural disasters, tariffs, economic policies, quality issues, viruses and other crises, the more it becomes apparent that the industry is in need of meaningful solutions that are proactive, long-term and sustainable. As it stands today, the U.S. healthcare supply chain is unable to confirm critical pieces of the upstream portion of the supply chain including raw material suppliers, third-party and contract manufacturers, sterilizers, and more. Suppliers are not obligated to share this information today and they will not be inclined to provide that information, unless and until it becomes an industry-wide expectation and best practice.

"The industry needs more transparency into where the individual components of products or pharmaceuticals are sourced. Absent true visibility into our suppliers, packagers and sterilization locations, we cannot predict or proactively address disruptions. This is why we have been advocating for this type of visibility, as well as working with manufacturers to broaden their sources into new and emerging markets.

"Luckily, we don't need to reinvent the wheel. We have an existing model that works – the drug shortage methodology – and can borrow from it heavily. When pharmaceuticals face a potential disruption, the industry and providers are notified and plan proactively because the FDA has formal regulation in place.

"As the industry makes progress toward similar regulations for medical devices, partnerships will be key. I believe the industry will be much happier to adopt a solution for product disruptions if it's created in collaboration with multiple stakeholders including suppliers, manufacturers, distributors, group purchasing organizations and associations. Under the leadership of the Health Industry Distributors Association, Premier has partnered with other GPOs, manufacturers and distributors to create a universal disruption notification template that went live this week (February 3). We are advocating for this tea plate to become standard industry process and adopted by all manufacturers and distributors."

GILLAN: "All hospitals have resiliency plans in place that are regularly stress tested by actual events – like outbreaks of SARS, MERS annual flu season – and through drills. They have learned to pre-qualify alternate suppliers and products commonly required in these situations through their value analysis processes. This enables them to quickly pivot to other suppliers in the event of a crisis or disruption in the supply chain.

"Hospitals also rely heavily on their GPOs and distribution partnerships, as well as on protective contractual terms, to help ensure continuity of supply. They have learned to change clinical practice and implement conservation strategies when necessary.

"Suppliers have also begun to further diversify manufacturing locations so that when disaster strikes, they have redundant capacity in order to be able to continue to meet demand. However, changing manufacturing site and modifying the required logistics takes time. When multiple crises overlap, the situation shifts from the foreseeable and manageable to the unforeseen and difficult to control." HPN

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Bar Coding vs. RFID: Win, Lose or Draw?

by Rick Dana Barlow

In the film *Ford v. Ferrari* the American and Italian automakers battled for supremacy in the boardrooms, development and engineering labs and on the racetracks – most notably during the celebrated 24 Hours of LeMans competition in France in 1966.

In the adoption and implementation race for tracking capabilities, bar coding and radiofrequency identification (RFID) continue to accelerate among providers and suppliers in the warehouses, storerooms, patient rooms, hallways and transport vehicles.

While both technologies have been available for decades – bar coding for at least twice as long as RFID – the healthcare industry still affords room for growth either in dedicated or specialized areas or across the enterprise.

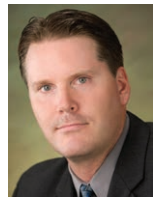
Short of committing all-in to one technology for every tracking need throughout an organization, how and where might an organization decide to pursue?

Healthcare Purchasing News reached out to nearly 20 suppliers of bar coding and RFID technology to assess and evaluate the roles and contributions of either technology in four key tracking areas: People (e.g., patients, staff, visitors), products in bulk (in the storeroom or warehouse), products in low units of measure (on the shelves in the storeroom, patient room or supply closet) and reusable devices and equipment (shared by clinicians and assigned to patients). *HPN* asked them to mull over which was more effective, efficient, popular and useful – four characteristics with varying applications, definitions and justifications.

Some might anticipate the newer technology, RFID, squeaking out in the lead position over the aging stalwart bar coding, but experts really lean toward balance and parity based on application and functionality, which should settle as good news to fans of either tracking modality.

Setting the stage

"To date, the use of bar codes for tracking in the healthcare industry is much more popular across all use cases because of its proven history, lower cost, variety of form factors and maturity," assured Chris Schaefer, Senior Director, Global Market Development, Data Capture Solutions, Zebra Technologies. "However, the adoption and use of RFID-enabled processes is rapidly growing thanks to the RFID's ability to read and track multiple items at one time. [This] can be extended and applied to automate and increase the efficiency of numerous processes across the healthcare value chain, reducing the overall return on investment (ROI) of RFID infrastructure and equipment.



Chris Schaefer

"Moving forward, we can expect that solutions will not necessarily be exclusively bar code or exclusively RFID, but rather a combination of various sensor and auto-ID technologies that best solve the business challenge," Schaefer continued. "As new RFID solutions and products come to market, they are generally backwards-compatible with bar codes, enabling the user to toggle between both data-capture formats."

Phil Sayles

Phil Sayles, President, Summate Technologies Inc., offers four decision points to consider when choosing either modality or both. He describes his company's technology as a "hybrid combo of RFID and bar codes [that] uses a radio signal but is very short range."

First is control/compliance. "Is the environment where scanning takes place conducive to scanning compliance? Digital supply chain management is only as strong as its weakest link," he indicated.

Next is operator ownership of the process. "Does the person scanning see their role in scanning at point of use to be an intrinsic part of their job - do they feel ownership of the process of accurate recording?"

Third is workflow integration. "Does the process of scanning fit easily into the current workflow process of the operator? Or is it a secondary procedure [that] adds extra work or takes extra time? [Does] application and subsequent use of RFID mark a secondary, extra procedure for the hospital and staff, adding time and cost?

Finally, determine the nature of the tagged item. "Is it a bulk item in a 'case' format, or an item that has been broken down into many distributed items located at many usage points?"

Dropping the green flag

When considering either modality for tracking people, products in bulk, products in low units of measure (LUM) and reusable devices and equipment, who clearly sides with Team Bar Coding vs. Team RFID or who diplomatically skates down the middle?

People (e.g., patients, staff, visitors, etc.)

Angela Fernandez, Vice President of Community Engagement, GS1 US, gives a thumbs-up to Team Bar Coding.

"Bar codes are already being used to verify a patient's identity at the point-of-care by providing a globally unique identifier that is printed on a bracelet label and scanned by the caregiver/staff member," she said. "Since an individual person's data does not need to be captured automatically (without a manual scan) or in bulk, there would be no advantage to using RFID instead of a bar code. A simple bar-code scan can be used to match a patient with the products being used in his or her care, and to upload that data into the patient's electronic health record (EHR)."

Bar coding generates credibility and popular support based on prominent regulatory agencies and clinical user convenience, according to Robert Christiansen, Pharm.D., Group Product Director, System Integration, B. Braun Medical Inc.

Robert Christiansen

Bar-code technology historically has a strong position in healthcare, driven by [The Joint Commission's] positive patient identification (PPID) requirement," Christensian said. "Bar-code medication administration (BCMA), lab specimen verification and blood bank product verification applications all provide PPID as a key component to their workflows. Employee ID badges also utilize bar codes for clinicians to quickly login and authenticate into clinical applications, providing a secondary accountability for witnessing narcotic shift counts, wasting controlled substances, and as a co-signature for administering high-risk medications that require a double check, or 'second set of eyes.'"

Still, Christiansen acknowledges the benefits of RFID for tracking human behaviors.

"RFID continues to emerge as an effective technology in healthcare for patient tracking, specifically infant tracking for security, and for Alzheimer and dementia patients with an elopement risk," he noted. "Hand-hygiene tracking practices and compliance

is another use that focuses on tracking clinician hand-washing patterns before and after patient contact. This is accomplished with an RFID reader positioned at the sink to detect hygiene events. From an employee-tracking perspective, proximity logon to the hospital network and clinical applications is another prevalent use of RFID."

Several others rally around Team RFID.

"Depending upon the application, RFID is generally better suited," Summate's Sayles indicated. "Patients and visitors have little ownership in the process, for obvious reasons."

Kapil Asher, Director of Sales, Asset Tracking/Management, CenTrak, concurs and leans toward RFID, which becomes more definitive for higher-end tracking demands.


Kapil Asher

"RFID is more effective than bar coding when it comes to actively locating patients, staff and visitors," Asher said. "Most of the utility of bar codes is in patient intake. They allow healthcare workers to share data and avoid the sort of human error that comes with manual data entry.

"However, when RFID technology is used as part of a Real-Time Location System (RTLS), its capabilities go well beyond data collection," he continued. "It enables healthcare organizations to analyze data to find opportunities for improvement, like shortening patient wait time and increasing hand-hygiene compliance, and drives automated workflows, like biomed reprocessing and nurse call response. RFID also allows healthcare facilities to keep visitors, patients and staff safe, with solutions like location detection tied to panic buttons and tags that help prevent infant abduction."

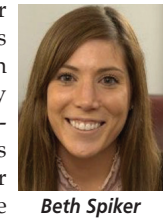
Still, Asher acknowledges bar coding retains certain merits.

"In general, bar coding is more widespread because it's an established technology that's been used by the industry for decades, it's less expensive, and universal standards have been in place for years," he noted. "That means almost any office printer can be configured to print bar codes with the right software, while RFID tags are largely proprietary. However, most customers find the benefits of an RFID system far outweigh the investment it takes to implement one."

Three others also favor RFID but highlight the notable distinctions for bar coding.

"Assuming the appropriate tag and reader infrastructure is in place, RFID is more efficient because it does not require human intervention," Zebra's Schaefer said. "In addition, RFID has the potential to read multiple people at one time, whereas bar codes require line-of-sight and can only be read one at a time. Of course, the solution that is most effective depends on the use case. In a situation where a patient needs to be uniquely identified and his/her medication validated and administered, a caregiver will always be involved and reading a bar code on a patient's ID tag might be the easiest and most cost-effective solution."

Beth Spiker, Sales Executive, Inventory Optimization Solutions (IOS), concurs.


Beth Spiker

"Often, patients wear bracelets with bar codes so that the bar code can be scanned to correctly identify the patient in Electronic Medical Records (EMR)," she said. "A bar code is cost effective because it does not require an RFID tag – resulting in cost savings – and it works well to track a patient based on a unique patient ID number. RFID-High Frequency (HF) is often used by hospital staff and personnel to gain entry into an area of the hospital. HF tags are passive, so they require the reader to be close so that they can be given enough power to provide a license plate or serial number. Based on this information, admission can be granted. Using an employee badge with RFID can give staff access to locked cabinets or store rooms quickly and seamlessly, with tracking of which team members accessed different areas and even what items they removed. In these instances, RFID can be useful for both staff and supply tracking."

Marek Dutkiewicz, Vice President, Technology & Product Strategy, GuardRFID, concentrates on the classification of people to determine modality application.


Marek Dutkiewicz

"Active RFID tags are the best and most widely deployed method for tracking 'at-risk' patients such as newborn babies to guard against abduction or mother-baby mismatch, elderly patients with 'wander risk' (e.g., suffering from Alzheimer's) and patients suffering from behavioral disorders," he indicated. "For these patients there is often a need to ensure that they cannot pass through certain exit points and security systems are integrated with an RTLS system to lock doors and sound alarms if the patient attempts to exit a protected doorway. For this class of patient bar codes cannot deliver the functionality offered by active RFID solutions.

"For 'low-risk' patients, bar-coded wrist bands are practical and cost effective for simple operations such as admitting/discharging and ensuring that the right medications are administered," Dutkiewicz continued. "In these cases, a bar-code scanning device can be used, and the benefits of real-time location (RTLS) are not as relevant as for the high-risk category. That said, there are hospitals that utilize RFID systems to track patient activity to help with facility design and optimization. Passive RFID tags are approaching cost levels where they are a viable replacement for bar-code patient wrist bands. The benefit of RFID is that the tag can be read even if it is obscured by clothing."

RFID also provides an expanded location span when a patient needs a critical medication to be administered and he or she is in the waiting area with family, watching TV or visiting with others, according to Dutkiewicz. At a workstation the nurse can locate the patient's ID tag if the facility is configured that way. Bar coding, on the other hand, remains "most useful" to match and confirm the right patient to the right medication, he added.

For staff considerations, RFID seems to be preferred, Dutkiewicz observes.

"Most hospitals deploy some type of Access Card system, which is often based on RFID to allow staff to access certain areas of a facility," he said. "For some situations where the staff might be at threat of attack from patients (e.g., behavioral health wards, emergency departments) or visitors active RFID-RTLS are often used to allow the staff member to press an alert button on the RFID tag to call for help. The RTLS solution will display the location of the staff member under threat to the security or to the nurse's station."

Bar codes, however, typically aren't used by staff members outside of selected functions, according to Dutkiewicz. "Keep in mind that bar codes are sometimes on the back of the employee ID badge so they can purchase food in the cafeteria (bar code is attached to a payroll account so money can be deducted from the paycheck) and, in some cases, to scan for use of a glucometer or other equipment."

The X factor applies to visitors as tracking capabilities vary greatly across organizations – from no tracking in place to using a visitor sign-in. "All of them do it differently," he said. "With some it's a manual process: Show your driver's license, tell them who you are visiting, they write it in a logbook and you get a visitor pass. Others have an electronic system on the computer. With some of these you get your picture taken (rather like a driver's license), your picture is on the ID and it states where you can visit. Sometimes you have a time in/time out – and some have a 'stop' sign embedded that as time progresses the ink bleeds through. In 24 hours the 'stop' sign is clearly visible and you'll be stopped for not having a current visitor pass."

Lana Makhanik, Chief Operations Officer and Co-Founder, VUEMED, attributes choosing either to the specific application.

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Lana Makhanik

"As with any technology, the effectiveness and efficiency of technology choice and its deployment really depend on the business problem it needs to solve and the ultimate value of solving that problem," she noted. "If it is sufficient to know, for example, that a patient checked into a particular area or was seen by a nurse, then bar coding would be a perfectly reasonable solution. If, on the other hand, it is critical for an organization to know the whereabouts of a patient moving around the facility, then RFID would be, by far, the more appropriate solution for managing this issue efficiently and effectively due to its automation and inherent tracking capabilities."

Products in bulk (in the storeroom or warehouse, etc.)

Most experts remain evenly dedicated to either modality for bulk-product tracking, depending on application and function.

"The relative usefulness of RFID vs. bar codes always depends on what you are trying to achieve," said GS1's Fernandez. "Fast, automated scanning of multiple units, even without a line of sight, can be achieved with RFID. Bar codes are printed on labels and are cheaper to generate than RFID tags. Two-dimensional (2-D) bar codes, especially, can carry all the necessary data and are more than sufficient for manual scanning. One thing to consider is that bar codes are already being used in healthcare so the infrastructure is currently in place."

Fernandez points to federal regulatory requirements as the impetus for bar-coding applications.

"The U.S. FDA's Drug Supply Chain Security Act (DSCSA) specifies that homogeneous cases of pharmaceutical products must be marked with a 2-D barcode, a linear barcode or a GS1-128 bar code containing four data elements: A National Drug Code (NDC) embedded in the GS1 Global Trade Item Number (GTIN), a serial number, a lot number and an expiration date. Eventually these bar codes will be used to support an interoperable, electronic system to identify and trace pharmaceutical products through the supply chain.

"For medical devices, the FDA's Unique Device Identification (UDI) Rule requires manufacturers to assign unique device identifiers (UDIs) to their products; to label those products with the UDIs in both human and machine readable formats, which could be either bar codes or RFID tags; and to publish the product information to the FDA's Global Unique Device Identification Database (GUDID)," Fernandez continued. "Medical devices are now being manufactured and labeled with bar codes containing the UDI to meet these regulatory requirements."

Still, RFID potentially offers improved efficiency for scanning bulk products in distribution, Fernandez indicates. "An RFID reader can scan entire shipments automatically and remotely in a fraction of the time that it takes to manually scan individual cases or packages," she said. "There are emerging use cases of RFID in highly specialized business scenarios, but to date, adoption and use of RFID is very limited. Industry would need to determine if there is a beneficial use case for RFID in the healthcare supply chain, and if so, work with GS1 US to leverage the appropriate standards for interoperability."

RFID benefits from its ability to read multiple, unique items at one time, according to Zebra's Schaefer, whereas bar codes, being a line of sight technology, are generally limited to reading one item at a time. In addition, RFID is designed around unique item identifier numbers such that each tag identifies a unique item, he added. "For these reasons, RFID is a much more efficient technology for reading bulk inventory in warehouses or storerooms," he said. "RFID can read items stacked in piles or rows without moving these items and require no human intervention, saving time and energy for workers. Additionally, the technology can prove more accurate, as those hard-to-read items are identified and tracked quickly and easily."

B. Braun's Christiansen zeroes in on cost-effectiveness considerations.

"Both RFID tags and bar codes are effective in tracking bulk items in the store room or warehouse," he indicated. "Although, bar coding is much more popular today, since it is more practical and cost effective to implement in the storeroom, especially with bulk items that only require 'one at a time.' Scanning RFID tags, readers and tracking software tend to be more cost prohibitive in the store room, and require an ROI to justify implementation."

Traditional 1-D bar codes are used on bulk-stored supplies to identify a category or family of good, but not the individual items in that group, Schaefer continued. "For these reasons, RFID can be both more efficient and effective because more information can be stored on an RFID tag, including specific information about each individual unit," he indicated. "It's more efficient because if RFID tags are applied to all the items typically managed in one of these locations, an inventory of that location could be completed in mere minutes with a handheld RFID reader, or even be tracked in real-time with fixed readers and antennas. The process of reading bar codes on those individual items would be time- and labor-intensive, requiring a person to aim a bar-code reader at each bar code on every single item one at a time. This process is also prone to human error as some bar codes may be missed or a defective label might not get read."

CenTrak's Asher sees bar coding as more prevalent for bulk items in high demand, such as bandages and gauzes that may be quickly used and discarded. Medications, however, seem to be a notable exception as passive RFID tags increasingly are being applied to medication carts and storage containers, due to the high cost and/or potential for abuse of some medications, he insists.

On the flip side, Summate's Sayles points to RFID as easier to use and less labor-intensive in this environment.

IOS' Spiker calls Ultra-High Frequency (UHF) RFID "probably the best bet" in a warehouse. "UHF does not require a tag to be close to a reader," she said. "Instead, it's an active tag that can be read from greater distance. Using a beacon or RFID reader to read products contained in central storage can save the warehouse a lot of time and money on cycle counts. In real time, the warehouse can know how much inventory is on hand. Although UHF technology can be read from a further distance, trying to find a particular product can be more challenging. UHF technology is best when trying to get the 'big picture' rather than unique items and location. Tagging within the organization is going to add some material and labor costs, but UHF tags are much more affordable than HF tags.

"The other advantage of RFID in the warehouse, particularly when it comes to higher cost items, is the ability to uniquely identify items," Spiker continued. "Warehouses often receive large shipments of products that are tracked based on lot number. RFID provides the ability to serialize products so that they can be tracked through their lifecycle. Product serialization can significantly help reduce write-offs."

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The value of an asset and the risk of its theft influence the bar code vs. RFID decision here, according to GuardRFID's Dutkiewicz.

For high-value assets that are easy to steal (e.g., computers, medical diagnostic equipment) an active RFID tag in conjunction with an RTLS system is most effective as it can lock doors, set off alarms if the equipment is taken close to an exit point," he said. "For equipment that is in short supply (and subject to hoarding/hiding by staff) an RFID system can be effectively used to locate equipment when it is needed. Many hospitals have reported big cost savings when such a system is used, which improves equipment utilization, saves employee time searching for equipment and avoids the need to rent equipment when it cannot be found.

"For low value equipment, such as stethoscopes, surgical equipment etc., the cost and size of active RFID devices is not practical," he added. "In these cases a passive RFID tag or bar-code label can be useful for inventory types of applications. Bar-coding is frequently used in storerooms (Central Supply, for example) to track boxes of supplies – for example, maybe a box of 24 suction catheters."

The business problem an organization wants to solve generally influences tracking technology choice, VUEMED's Makhanik agrees.

"RFID is great for the continuous tracking of any tagged items, and would be most valuable when items change locations frequently, and the business process and labor involved can be optimized from tracking and analyzing such movements," she said. "However, it is unlikely that bulk items will be individually RFID-tagged because of the cost-benefit ratio, and also because of the high velocity of such items. So only at the box-level does it make sense to use RFID. Similarly, bar-coding may be sufficient for indicating receipt of the items at the box level at the receiving dock. For any more granular tracking, such as the individual contents of the boxes dispatched to their relevant locations, either technology is perfectly adequate."

Products in LUM (on the shelves in the storeroom, patient room or supply closet)

Even though breaking bulk to point-of-use locations – including patients – may be an extension from the warehouse, similar tracking modality choices and justifications apply, sources stress. Clinicians seem to favor bar codes to link products to patients for consumption and billing.

GS1's Fernandez says federal regulations continue to support bar-code applications, and the UDI calls for identification at every packaging level and unit of use for medical devices. In fact, providers and suppliers have been building the infrastructure and processes to reinforce this. However, RFID is making some inroads, she adds, citing one manufacturer that produces and RFID-enabled trash receptacle that can automatically capture and report supply usage, case costs, and UDI details at the point of use. "Clinicians deposit used supplies into the receptacle without interrupting their focus on patient care," she said.

Summate's Set mapping solution enables scanning non-sterile implant usage directly from the sterile field.

"As the number of items that need to be counted decreases, the value proposition of RFID – counting many items at once – diminishes," Zebra's Schaefer said. "If there are less items to count, a manual bar-code process requires less work, and the primary advantage of RFID – reducing process time and effort – is minimized. Thus, bar codes may be more cost effective.

"However, an RFID-based process will always be more efficient," he continued. "It is just a matter of how much more efficient. If there are [fewer] items, the delta between efficiency of RFID versus bar-code processes decreases. RFID is always less error-prone and will always take less time than reading bar codes via line of sight. So while bar codes may not take much more effort in this scenario, the results of the effort may still be less accurate than RFID."

Once again, B. Braun's Christiansen centers on cost effectiveness and regulatory requirements, particularly for medications, as guiding factors.

"The FDA requires all unit dose medications to have a bar code on the label to support bar-code verification of medications at the patient's bedside, tracking meds stored in pharmacy-based carousels, robots [and] automated dispensing cabinets, as well as supporting the enterprise supply chain process with the drug wholesaler," he said. "Medical supplies stored on patient care units can also be tracked with bar coding to support the supply chain process using supply towers, or simply by maintaining PAR levels on shelves in dedicated supply areas."

IOS' Spiker relates bar coding vs. RFID to the consumer debate over Betamax vs. VHS for video-recording formats, arguing that not embracing a single solution may be costing the industry more time and money.

"This is the most evident on LUM, and the reason is because product information is not written to the RFID tags," she noted. "Therefore, every RFID system is proprietary. In addition, the cost of the tag and the labor associated with tagging products is eating into the margin of the problem we're all trying to solve."

Spiker likens issue to a domino effect. "If tracking low-unit-of-measure starts at the hospital, all efficiency of the technology has been lost upstream in the supply chain," she insisted. "The manufacturer is not registering the tag during production, the warehouse is not using it to efficiently capture inventory on the shelves, and the shipping department isn't using the technology to make sure the correct products were picked, packed and shipped. As a result, the hospital is bearing the cost to RFID tag and register the product – labor and cost of tags. On the other hand, if a manufacturer decides to use RFID and leverage warehouse efficiencies, and the hospital is not on the same platform, they will not be able to read the tag into their system, so no efficiency or savings results."

Process redundancies and disparate systems continue to create more work and drive higher costs, Spiker laments.

"Until a tag frequency (HF vs UHF) is determined to be best practice, and product is written to the tag so they can be universally read, RFID can cost the healthcare industry more time and money than it is saving," she estimated. "In the meantime, manufacturers should continue to standardize on GS1 bar codes [as] bar codes are the most effective and efficient way to track LUM."

Zebra's DS8178-HC bar-code scanner being used for medication administration applications.

RFID technology in recent years has evolved to being highly useful in some key hospital medication management processes, such as maintaining, and replenishing code carts and anesthesia medication trays and opioid kits, according to B. Braun's Christiansen.

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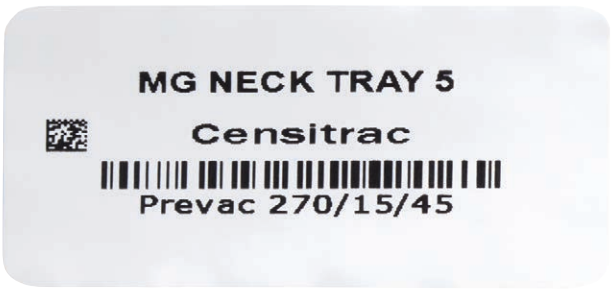
Hospitals stick with us.



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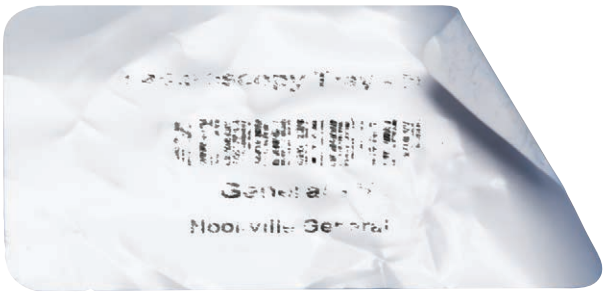

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"RFID solutions are available to provide medication inventory tracking, and automated tray processing to help pharmacies better manage these key processes," he noted. "The RFID tags are coded with the drug name, NDC number, lot number, manufacturer and expiration date. Many tags at once within a close proximity can be tracked with an RFID reader, which helps make tray and kit replenishment more efficient, and also supports hospitals' opioid diversion initiatives."

VUEMED's Makhanik supports RFID's application here.

"RFID can be cost-effectively deployed in Kanban-type environments for managing the replenishment of low-cost, high velocity items," she said. "In these kind of cases, it would be technically difficult and labor intensive to achieve the same level of efficiency with bar coding. RFID not only minimizes labor requirements, but also optimizes the real-time visibility of replenishment requirements."

CenTrak's Asher concurs.

"Products in low units of measure – like walkers, catheters and slings – tend to come with a higher price point, so it's often useful to invest in passive RFID tags to track them through the supply chain," he said. "Unlike active RFID tags, passive tags do not have a local power source or a built-in battery, so they're typically a better choice for items that are not used more than once and/or leave with the patient when he or she is discharged. While bar coding only offers a basic tally system, using a real-time location system equipped with RFID tags, healthcare organizations can analyze historical data to improve efficiency, utilization and workflows for products in LUM."

Reusable devices, equipment (shared by clinicians, assigned to patients, etc.)

Because this category involves the act of locating something, perhaps from longer distances and with less intervention of a human being, experts favor RFID.

"Reusable devices and equipment provide an ideal use case for RFID because unlike supplies in a warehouse, reusable devices are not as dependent on tagging or labeling at the point of manufacture," said Zebra's Schaefer. "In addition, these are often high-value items, which are costly to replace and can easily justify the higher cost of an RFID-enabled process. The absence of these items may impact patient care so the risk of being unable to find these devices often justifies investing in a more effective process to ensure that they are accurately tracked.

"An ideal scenario would involve creating an automated process in which RFID tags can be identified and tracked via fixed infrastructure (overhead readers) that can locate and identify items in real time," he continued. "Even a handheld RFID reader could leverage a locate function often available in order to minimize search time, locating an RFID-tagged item more quickly."

B. Braun's Christiansen agrees that RTLS using RFID tags are useful for tracking infusion pumps in clinical settings as they are often challenging to locate when needed.

"The RFID tag enables nurses to track the location of infusion pumps with RTLS software so they can quickly find the pump when the patient requires an infusion," he noted. "Biomedical staff can find the pumps easily for pump maintenance and cleaning, and for pumps that failed to upload the new library. Key data, including the infusion pump status and location data, are shared bi-directionally between the RTLS and the infusion pump software platform. In summary, RTLS systems essentially help to optimize asset utilization of the infusion pump fleet, improve staff efficiency, and help improve patient safety by having pumps readily available when needed."

But that doesn't diminish bar coding's useful applications, specifically involving "Barcode Medication Administration (BCMA) within most acute care hospitals and integrated delivery networks (IDNs) as it becomes part of the electronic health record (EHR) medication documentation process, he assures.

"Smart infusion pump integration is an extension of the current BCMA workflow, which provides auto-programming of the infusion pump and enables auto-documentation of medication infusion data to flow into the EHR until the infusion is documented as complete and the charge is captured appropriately," he said. "Bar-code verification is utilized within the BCMA/infusion pump integration process for scanning the patient wristband for positive patient identification (PPID), scanning the medication's patient specific barcode, and scanning the infusion pump to link the medication order to the pump."

VUEMED's Makhanik feels the advantage of RFID is its effectiveness at tracking location, "and thus very useful in automatically associating devices and equipment with a patient and managing compliance – or identifying non-compliance – particularly when the patient assignment or patient use indication didn't happen where it should have."

Experts home in on the sterile processing aspects of the equipment as a key concern affecting RFID application.

Much depends on the sterilization process itself, according to IOS' Spiker. "Currently tags are not able to withstand the sterilization process, especially with a product that requires frequent reserialization," she said. "HF RFID can help serialize equipment, and the serial number can be assigned to patients until it returns, a cleaning log can be kept by device, and knowing when to pull a device due to quantity of usages can be valuable. The same results can be made with serialized bar codes. The best technology for reusable devices and equipment really depends on the use case."

GS1's Fernandez highlights the UDI rule, which "specifies that product identifiers must be marked directly on reusable devices so that the code does not get separated from the product after it has been removed from its packaging. The special challenge of directly marking very small objects can often be addressed with the use of a 2-D DataMatrix bar code that is capable of carrying much more data in a smaller space than a linear bar code can.

Fernandez acknowledges that in some cases an RFID tag can be built directly into a product. "It stands to reason that for a high-value piece of equipment, this could make sense – especially if the product includes parts that are particularly difficult to mark, such as a specialty surgical device," she noted. "Since RFID can automatically read and record the presence of multiple items at once, a tray of RFID-tagged devices utilized in a procedure could be checked in and out of sterilization units within seconds before being placed back into inventory, saving considerable time and labor." HPN

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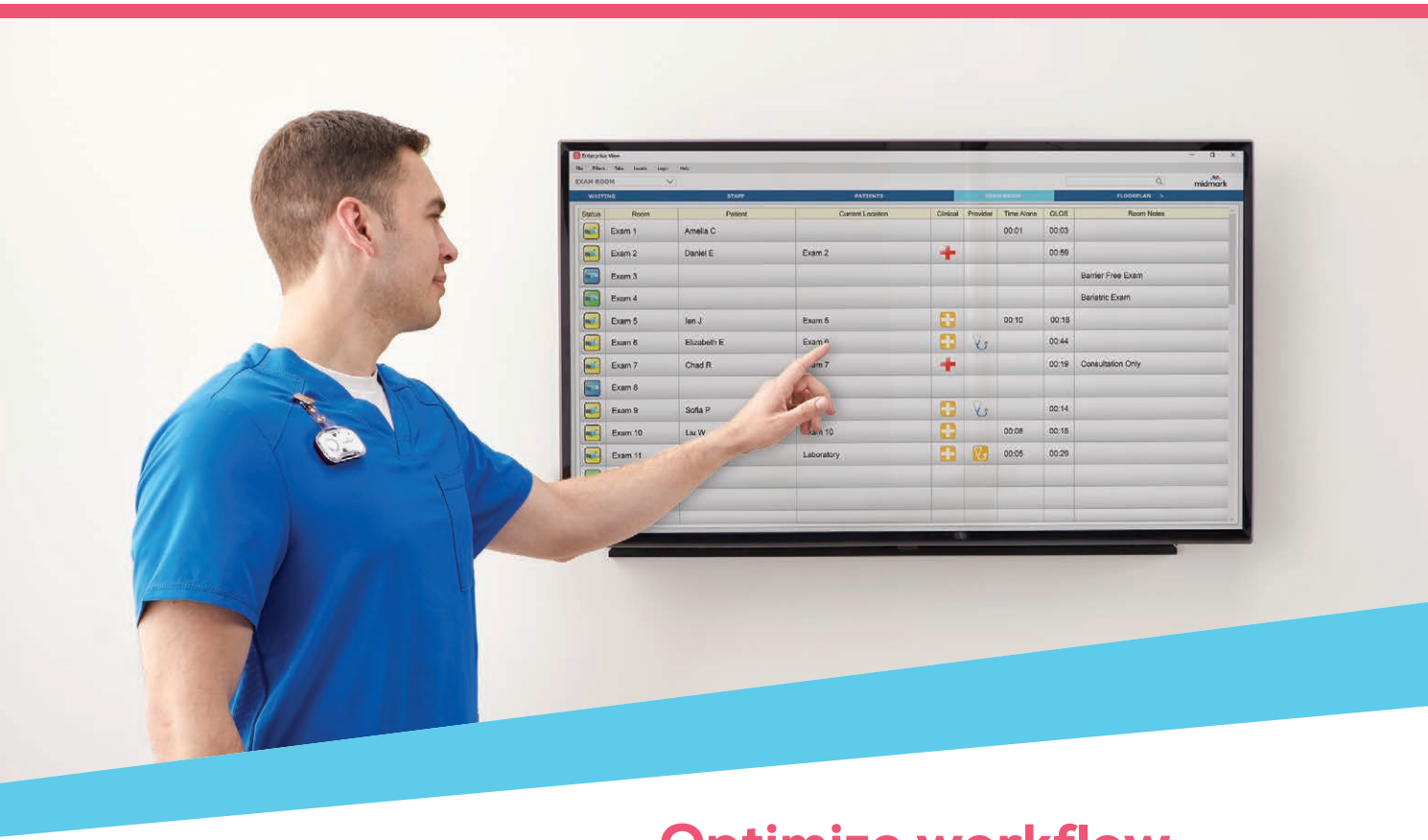

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To *air* is human

Monitoring patient breathing in healthcare settings

by Ebony Smith

With increasing respiratory diseases, 2019-nCoV (coronavirus)/other respiratory illness outbreaks and routine surgical, emergency room (ER) and intensive care unit (ICU) care, OR and hospital teams must concentrate on keeping their patients breathing steadily. This means the critical need to produce, learn and use the best respiratory monitoring and care technology to treat patients.

Rise of respiratory monitoring

MarketWatch points to the "Global Respiratory Care Devices Market Trends, Applications, Analysis, Growth, and Forecast to 2027" report stating, "Factors such as high prevalence of respiratory diseases such as chronic obstructive pulmonary disease (COPD), tuberculosis, asthma and pneumonia, rising urbanization and pollution levels, increasing incidence of pre-term births, increasing geriatric population, high prevalence of smokers, and changing lifestyle are fueling the growth of the global respiratory care devices market. In addition, rising demand for cutting-edge technologies, increasing per capita income and rising demand for respiratory devices in private sector hospitals and clinics are other factors attributed to market growth." [1]

Non-invasive, invasive or mechanical ventilation, sensors and other equipment help monitor and measure the ups and downs of patients' breathing, conditions and other vital functions while in the OR, hospital, home or other settings. These devices are continuously advancing on a global scale with automated, mobile-enabled, wearable, smaller-sized, portable and noncontact capabilities, according to the Transparency Market Research "Respiratory Monitoring Devices Market" report.[2] Among the report findings:

- "Companies in the respiratory monitoring devices market landscape are increasing R&D activities to develop wearable sensors that are capable of detecting respiration under various ambulatory conditions. These sensors are built on the technology of medical grade continuous spirometers. The spirometers product segment is expected to reach value of US $1.1 Bn by the end of 2027.
- Companies in the respiratory monitoring devices market are focusing on providing convenience of patients by increasing offerings in portable battery-powered capnometers to measure CO2. Since traditional capnometers in hospitals are bulky bedside machines, manufacturers are innovating in miniaturized capnometers that can be used as a patient's personal respiratory monitor.
- Manufacturers in the respiratory monitoring devices market are increasing their production capabilities to develop advanced pulse oximeters. The pulse oximeters product segment is estimated to reach a value of US $3.4 Bn by 2027. However, lack of training and resources has slowed down the adoption of pulse oximeters, especially in developing countries. Lack of training for healthcare professionals has led to increased death rates from anesthesia. Manufacturers are combining the technology of smartphones with pulse oximeters."

Ins and outs of technology and treatment

As respiratory treatment is essential, it also poses unique challenges – from complexity of equipment, patients' health status, lack of staff education and more. In this article, we asked industry professionals to weigh in with insights and latest products for respiratory monitoring and care.

One thing is that technology can be tricky. Capturing the right data on high-tech machines is not always easy, informs Tim O'Malley, President & Chief Growth Officer, EarlySense. "Respiratory rate is a difficult parameter to measure. Direct airway measurement is likely the most accurate, however, it can be challenging to deploy. Many times, these more complex technologies have migrated into the less acute care areas and have not been successful due to technology and staff interface capabilities."

Another factor is the shifting nature of health and the hospital. Differences in patients, revolving equipment and settings as well as insufficient staff training can complicate care, notes Lisa Rose, Chief Marketing & Innovation Officer, Vyaire Medical. "Respiratory care and monitoring in the OR and hospital can be especially challenging because every breath counts – yet everything is in a state of flux. At its most acute point, clinicians and doctors need to move patients through the hospital and make life and death decisions in real time. Yet, everybody's history and circumstances are unique. Added to that, hospital environments are continually changing and equipment continues to evolve. One particular challenge is that sometimes there are compatibility issues with equipment. Clinicians must have the right training and knowledge to ensure those challenges don't jeopardize the patient."

Rose cited differences in ventilation equipment and mask use as other potential issues. "Not all ventilators are created equal. Not all non-invasive ventilators can do invasive support well and not all invasive ventilators can do non-invasive support well. Additionally, non-invasive support requires a patient interface (mask) that must be appropriately sized and comfortable for the patient; if not, it can result in discomfort or skin breakdown and patient refusal to continue its use."

EarlySense Bedside unit and sensor

Ventilation support and obstacles

Ventilators are crucial for assisting patients with breathing during care, but may end up causing serious health complications. Conditions can include lung damage, oxy-

gen toxicity, blood clots, skin infections and vocal cord damage, addressed the National Heart, Lung and Blood Institute (NHLBI).[3]

Edwin Coombs, MA, RRT, NPS, ACCS, FAARC, Senior Director of Marketing, Portfolio Training Solutions, Clinical Affairs & Intensive Care, Draeger, Inc. explained, "The prolonged use of invasive ventilation can lead to VAE/VAP (ventilator-associated event/ventilator-associated pneumonia) and other pulmonary complications. A proactive and protective ventilation strategy must always be employed."

Coombs continued, "Postoperative pulmonary complications (PPC) can have significant consequences for high-risk surgical patients (abdominal, orthopedic, and neurologic) ultimately leading to poor outcomes and extended admissions into the ICU."

Further, "According to Zhan et al., postoperative respiratory failure (not including pulmonary embolism) added approximately 9 hospital days to hospital length of stay, greater than $53,000 to hospital costs, and an almost 22% increase in mortality. It is thus evident that postoperative respiratory complications have significant and widespread sequelae for both the patient and the health care system," reported in, "The Role of Capnography to Prevent Postoperative Respiratory Adverse Events" in the *Anesthesia Patient Safety Foundation Newsletter*.[4]

Evolution of ventilation machines

Healthcare providers can breathe easier knowing ventilation systems continue to become more sophisticated, automated, adaptable, integrated, visual, therapeutic and safety-driven in respiratory monitoring, data collection and care. Ventilation machines can help benefit patients in breathing through several stages of treatment as well as aim to prevent harmful health events in the OR, hospital and beyond.

Dräger's family of mechanical ventilators supports patients from emergency to post-acute care, highlights Coombs. "Our ventilators are manufactured to meet the need through their ventilation journey back to health. This includes all patient populations that a clinician would encounter in the ER, ICU, pediatric ICU, neonatal IC, and long-term acute care. The products integrate with many common electronic medical records for continuous documentation. When purchasing the V500 series ventilators or the mid-level Savina 300 ventilators, the devices can be configured with options to meet individual clinical requirements based on specific practice. Dräger has developed a customized value calculator to demonstrate potential savings for an institution for its anesthesia and ventilation products."

Dräger's Evita Infinity V500

He pointed to their Evita Infinity V500 for its automation, safety and comfort. "Our mechanical ventilator for post-op care and the ICU is the Evita Infinity V500. The V500 has a significant set of features to benefit a caregiver's workflow including the ability to provide invasive ventilation, non-invasive ventilation and high-flow 02 therapy with one device. Enhanced safety features are integrated into the user interface screen to support early decision making and facilitate corrective actions during alarm conditions. Additionally, a day/night screen and configurable alarm volume can support patient comfort. It offers a wide range of therapeutic tools for lung protection and monitoring of ventilation parameters. Automated weaning protocols and tools support clinicians when to liberate patients from mechanical ventilation."

Vyaire Medical's line of respiratory products caters to patients throughout critical care, shares Rose. "We have a broad portfolio of products and solutions that are very much a part of the OR and post-op care. Our sole focus is respiratory care and how it impacts the entire continuum of care."

She called out their bellavista 1000e ventilator (now available in the U.S.) for its adaptability, performance and ease. "The bellavista 1000e brings a truly versatile ventilation platform that was designed to be the one instrument that can meet all clinical needs, from high flow oxygen therapy to non-invasive ventilation to high performance invasive ventilation for patients of all sizes. Vyaire has a full-time team of clinical specialists to provide training on the devices, interfaces and accessories. By using a single device across care areas, complexities for clinicians are reduced, potential mistakes and errors are minimized and patient safety is enhanced. The bellavista is based on turbine technology. It also has an internal four-hour battery, which supports intra-hospital transport of the most critical patients for various procedures. Additionally, our Adaptive Ventilation Mode (AVM) is a closed-loop, fully automatic method of mechanical ventilation – it adjusts ventilation parameters according to patient weight and lung function and is designed to ventilate patients all the way from intubation throughout weaning to spontaneous breathing and extubation. Vyaire also incorporated a modern, ultra-high definition user interface that supports touchscreen and provides advanced graphics that help clinicians better visualize the patient's pulmonary status."

Vyaire Medical's bellavista 1000e ventilator

Growth of sensor devices

As earlier mentioned, respiratory monitoring devices are advancing, including portable, wearable, smaller and noncontact products like spirometers, capnometers and pulse oximeters. These sensors help benefit patients in breathing and strive to stop dangerous health events through automated data measurement and care in the hospital, other healthcare settings or at home.

The EarlySense sensor system is placed within a patient's furniture in acute or post-acute care, and measures heart rate, respiratory rate and motion, states O'Malley. "EarlySense has introduced a non-invasive and non-patient contact sensor, which is placed between the bedframe and the mattress. The contact-free sensor can also be used in a chair. This technology was designed for the non-acute care areas and provides continuous monitoring, with accuracy comparable to more complex critical care technology without the need to tether the patient. The respiratory cycle is analyzed through the sensor measurement and processing through our algorithms, accomplished twice per second. Our sensor captures waveshapes that the body produces, whether it is gross body motion, the cardiac cycle or the respiratory cycle. We then incorporate these signals into a processing device (monitor), which is built within an overall system, all designed to alert staff of a potential adverse event, which can be motion-related such as a potential unsupervised patient fall or a respiratory depression."

He emphasized the system's success in reducing hazardous circumstances. "The EarlySense system has been used with more

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than a million patients in hospitals as well as post-acute facilities. In addition, a version of our EarlySense sensor is being used in the Verily Baseline Study. The purpose of our sensor's use in this study is related to sleep. In hospitals and post-acute facilities, the EarlySense system is used to assist caregivers in avoiding adverse events, such as fall prevention, respiratory depression and other cardiac or respiratory events. Fall rates have been shown to reduce in the range of 40%, there has been a reduction of code blue events in the 60-80% range, and post-acute care facilities have shown to reduce admission rates by almost 20%."

Future of care

What more is in store for respiratory monitoring and care?

Coombs envisions continued automated monitoring, data and prevention in care. "The trend today and for the foreseeable future is the development of automated systems that are geared to minimize complications arising from mechanical ventilation. Early warning systems and data dashboards will be created to provide practical information to alert clinicians to acute changes and act preemptively to avoid further complications. Non-invasive applications for monitoring a patient's pulmonary status are being explored and show a promising horizon."

Rose forecasts expanded non-invasive monitoring and data among care providers. "We believe that non-invasive support is one of the fastest growing areas in respiratory care. Respiratory disease is a global issue and continues to grow every year. As we look to the future, there are opportunities across all segments to better equip care providers and improve patient outcomes. The more we understand the challenges, the more we will be able to successfully help care providers improve safety and predictability, leverage data, increase mobility and versatility and tailor care – regardless of the care environment."

She reported Vyaire Medical's ongoing product development in the industry, including pulmonary function tests (PFTs), which "measure lung volume, capacity, rates of flow, and gas exchange," defines Johns Hopkins Medicine.[5]

"Two of the latest Pulmonary Function Test technologies were introduced in the U.S.: Vyntus BODY and Vyntus ONE, both with SentrySuite software. Internationally, SuperNO_2VA, the exclusive nasal PAP ventilation mask was brought to market. And, we made two telemetry adaptors available for the U.S. market: ApexPrFH and MX40. We look forward to sharing other new products as they become available," Rose stated.

Non-contact monitoring and data will advance in care settings, predicts O'Malley. "We believe that every area across the healthcare continuum can benefit from contact-free sensing. I believe that sensor technology will continue to evolve allowing the ability to monitor more patients in more environments, with relative ease. Within hospitals, this may be expanding where we monitor and collect data from patients. Within post-acute facilities, it may be that we provide more analytics to organize information so that less overall interpretation may be needed. And in the home, we believe in simpler patient and family interfaces for the technologies still providing the advanced monitoring and data collection required." HPN

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PREVENTION UPDATE

Study: Diet makes a difference in fight against hospital-acquired infection

Popular diets low in carbs and high in fat and protein might be good for the waistline, but a new UNLV study shows that just the opposite may help to alleviate the hospital-acquired infection *Clostridioides difficile*.

In a study published in *mSystems*, an open access journal of the American Society for Microbiology, UNLV scientists found that an interaction between antibiotic use and a high-fat/high-protein diet exacerbate *C. diff* infections in mice. Conversely, they found that a high-carbohydrate diet – which was correspondingly low in fat and protein – nearly eliminated symptoms.

C. diff, an intestinal infection, is often acquired when antibiotics have wiped out the "good" bacteria in the gut.

Brian Hedlund, a UNLV microbiologist and study co-author said,"The gut microbiome is strongly affected by diet, but the *C. diff* research community hasn't come to a consensus yet on the effects of diet on its risk or severity. Our study helps address this by testing several diets with very different macronutrient content. That is, the balance of dietary carbohydrate, protein, and fat were very different."

Though studies suggest dietary protein exacerbates *C. diff*, there's little or no existing research exploring the interaction of a high-fat/high-protein diet with the infection. Recent studies suggest that because antibiotics kill bacterial species indiscriminately, the medications decimate populations of organisms that compete for amino acids, leaving *C. diff* free to propagate.

But Hedlund said the story is even more complex. "It's clear that it's not just a numbers game," he said. The new work suggests that diet may promote microbial groups that can be protective, even after antibiotics. For an infection to flourish, he said, "you might need this combination of wiping out *C. diff* competitors with antibiotics and then a diet that promotes overgrowth and disease."

The new study raised other questions as well. For example: The high-carb diet, which was protective against *C. diff* infection, gave rise to the least diverse community of microbes.

Though studies suggest dietary protein exacerbates *C. diff*, there's little or no existing research exploring the interaction of a high-fat/high-protein diet with the infection. Co-author Ernesto Abel-Santos, a UNLV biochemist, said "Lots of papers say that a lower microbial diversity is always a bad thing, but in this case, it had the best disease outcome," said Abel-Santos. The Abel-Santos lab has been working with *C. diff* for 12 years with the goal of developing compounds that could prevent infections from this bacterium. The Hedlund lab has been working with *C. diff* for five years, focusing on the role of diet in infection.

INFECTION PREVENTION

Infection Prevention Operations Worth Watching

Heroes pursuing "zero"

by Susan Cantrell, ELS

What makes a medical operation worth watching? Gains over infection, winning the battle. The gains don't have to be large to be significant. Even a small gain means someone did not suffer from or die of a hospital-acquired infection (HAI). Preservation of even one life is worth celebrating.

Below are stories of infection-prevention operations worth watching. Some of the facilities do not want to be identified, often because they feel it is bad press for it to be known that they needed to improve their infection rates. That is a shame, because they are in good company. Many hospitals need to improve their infection rates, but that does not mean they are not doing their job conscientiously. It often just means a tweak in best practice or a switch in product is needed. Whether the facility is named or not, hats off to their efforts to improve patient safety.

Maine General tackles SSIs

A report in JAMA[1] noted that, because the number of surgical procedures is rising in the U.S., it is critical to prevent surgical-site infections (SSIs). In addition to considering patient safety, the study stated, ". . . reporting of process, outcome, and other quality improvement measures is now required, and reimbursements for treating SSIs are being reduced or denied. It has been estimated that approximately half of SSIs are preventable by application of evidence-based strategies."

Tracey Shaw, MT (ASCP), CIC, Mölnlycke, nominated Maine General Medical Center as an operation worth watching. Shaw related, "Data analysis showed a spike in superficial SSIs among Cesarean-section patients between January and July 2017 at Maine General Medical Center. This spike was addressed with a focused postoperative infection-reduction strategy implementation." Shaw said the C-section SSI rates were lowered by an astounding 65 percent over eight months.

Shaw explains the steps that brought them to this result. "Strategies currently in place in the operating room and C-section delivery rooms for SSI prevention include pre-operative antibiotic administration, hair removal when appropriate, adherence to the Association of periOperative Registered Nurses (AORN) standard for surgical attire, intraoperative skin antisepsis with an alcohol/chlorhexidine product, maintaining traffic control during procedures, and monitoring hand hygiene. Multiple closure methods are used by surgeons. All surgeons routinely used sterile gauze for the dressing."

A vital step was to investigate possible causes of the spike in infection. "The root cause uncovered that, upon discharge, patients were instructed to remove the gauze dressing at home." Despite being discharged with written and verbal instructions on wound care and signs of infection, "surgeons noted that the wound-care instructions were not often followed, and the same dressing was still in place at the two-week post-op visit," said Shaw.

Outlining the plan of action decided upon, Shaw explained that a review of literature led them to adopt a standardized post-operative wound-cleansing strategy, following dressing removal, with a chlorhexidine gluconate (CHG) product. "The strategy was cost-effective and simple enough for patients to perform on their own. A decision was made to implement post-dressing

Hibiclens family of products, from Mölnlycke

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Dräger

The average cost of an SSI incident per US hospital is $11,874 - $34,670*

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*Scott R. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. US Centers for Disease Control, 2009. http://www.cdc.gov/HAI/pdfs/hai/Scott_CostPaper.pdf

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surgical-wound cleansing with CHG soap (Hibiclens, from Mölnlycke) in an attempt to decrease the number of superficial SSIs for patients undergoing C-section procedures."

Shaw concluded, "A multidisciplinary team, including infection prevention along with a surgeon champion, worked to update patient infection-reduction strategies and increase the post-operative education provided to patients. All protocol changes were incorporated into the electronic medical record, and staff were instructed to document that patient education was given and that a bottle of Hibiclens four-percent foam was provided."

It is amazing what a simple change in protocol and adoption of an inexpensive, easy-to-use product achieved in terms of infection reduction.

Ohio Hospital strives to rid sepsis

The Centers for Disease Control and Prevention (CDC) said that 1.7 million adults in America develop sepsis, with nearly 270,000 Americans dying as a result of sepsis. One in three patients who die in a hospital have sepsis.[2] Those are some serious numbers. The good news is that, with rapid diagnosis and treatment, about 80 percent of sepsis-related deaths can be prevented.[2]

Sepsis is also costly to treat. Todd Barnett, Director of Government and Strategic Accounts, EarlySense pointed out that sepsis has been named as the most expensive in-patient cost in American hospitals.[3] "More people die from sepsis than breast, prostate, and lung cancers combined," said Barnett.

In 2015, a hospital that prefers anonymity had a mortality rate of 27.1 percent, which is above the statewide average of 19.4 percent. Barnett said the hospital joined the Ohio Hospital Association's Institute for Health Innovation and the Sepsis Alliance to help reduce the number of sepsis-related deaths sharply, by 30 percent in two years. "The prevention focus is where we see our hospital partners really dig in," averred Barnett. "Just one year after the start of the campaign, the mortality rate from sepsis dropped to 8.9 percent, nearly a 70 percent decrease," stated Barnett. "EarlySense was one key component of their sepsis initiative."

Barnett described EarlySense as providing contact-free continuous monitoring of heart rate, respiratory rate, and motion. "When our customer strategically focused on reducing their mortality rate, they put a plan in place to help them identify the early warning signs," said Barnett. "EarlySense is part of this solution, as we can monitor heart rate and respiratory rate twice per second and notify care providers if these parameters meet their infection criteria. The sepsis dashboard also takes into account bloodwork, temperature, and other key parameters that may indicate early onset of infection. This initiative considers the whole patient, with a specific eye for sepsis, so they can assess and treat at the earliest signs versus trying to catch up to the infection."

CHOP fights CAUTIs

A critical concern in hospitals and care is preventing catheter-associated urinary tract infections (CAUTIs) with patients. An article in *Critical Care Nurses*, a peer-reviewed journal of the American Association of Critical-Care Nurses (AACN), examines the study and successes of Children's Hospital of Philadelphia (CHOP) in reducing CAUTIs in its 55-bed pediatric intensive care unit (PICU).[4]

"CAUTIs account for nearly a third of all healthcare-associated infections, with an estimated 45,000 events and 13,000 deaths each year. Despite initial success with lowering infection rates, hospitals have struggled to find long-term solutions to CAUTI prevention. CHOP took a proactive approach to identify and address barriers to CAUTI prevention. Daily targeted rounds and real-time training helped CHOP achieve a rate of zero CAUTI and sustain it for more than a year," according to the study.

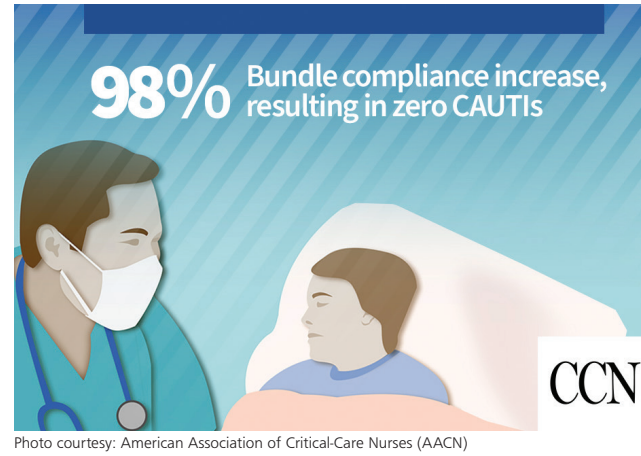

Photo courtesy: American Association of Critical-Care Nurses (AACN)

This initiative took a team effort. "The core of the approach was a multidisciplinary CAUTI work group consisting of an attending physician, nurse practitioner, unit-based clinical nurse specialist, unit-based safety quality specialist, clinical nurse leader, staff nurse, infection control specialist, executive sponsor and data analyst. The team met once or twice each month to track progress and make any needed modifications."

The team created a multi-tiered and integrated prevention program. "They developed a special data review dashboard with information from the electronic health record and other sources to more consistently track bundle compliance and access bedside review data. The dashboard allowed anyone in the facility to review compliance data, identify trends and see a clear snapshot of harm metrics in real time."

Their many efforts paid off. "Using a bundle of five specific CAUTI prevention elements, the PICU was able to achieve a compliance rate of 84% and an overall rate of 2.7 infections per 1,000 catheter-days. All patients in the PICU had appropriate indications for catheter placement. Between July 2014 and June 2017, bundle compliance in the PICU increased each year, from 77% starting in July 2015 to 84% to 93%. Among the individual bundle elements, compliance with avoiding dependent loops

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75,000 deaths occur annually in US hospitals due to HAIs

(It's time to take proven infection prevention further)

Figures released from the CDC make stark reading for Infection Preventionists. An estimated 722,000 healthcare-associated infections occur annually, resulting in 75,000 deaths and billions in additional costs.[1] More than half of these occurred outside of the intensive care unit.

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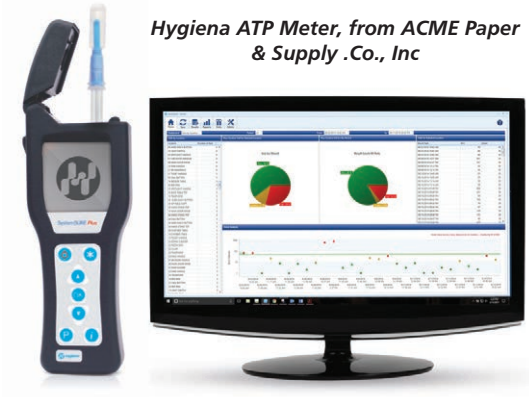
in the drainage tubing was consistently identified as an area for improvement. By significantly increasing compliance with that key element of the bundle, the unit was able to raise overall compliance rates. As bundle compliance improved, CAUTI rates decreased."

Maryland Patient Safety Center reduces HAIs

When the Maryland Patient Safety Center, a regional organization, focused on improving patient safety and healthcare quality, they selected ACME Paper & Supply Company as their exclusive distribution partner to assist in their efforts to reduce HAIs. Steve Attman, co-CEO, explained how the two worked together to develop Clean Collaborative, supporting seventeen acute-care hospitals, three long-term–care facilities, and four ambulatory surgical centers. "The collaborative was designed to improve environmental-surface cleaning, with the goal of reducing rates of *Clostridium difficile* infection, which the collaborative leadership selected as a proxy for HAIs. Together with ACME Paper, the collaborative helped participants identify and implement best practices for cleaning and disinfecting surface areas."

ACME Paper & Supply provided ATP (adenosine triphosphate) meters, which measure the adenosine molecule, present in all living tissue, and trained on its proper use to provide a baseline measurement for contaminated surfaces and to test surfaces throughout the program. Surfaces were swabbed and then tested by the ATP meter. Attman noted, "The program demonstrated that just the act of testing surfaces on a regular basis encouraged more thorough cleaning, a clear example of the Hawthorne Effect, a type of reactivity in which individuals modify an aspect of their behavior in response to their awareness of being observed."

Eighty-eight percent of the facilities that took part in the Clean Collaborative achieved the program goal of 10 percent reduction in relative light units from the baseline month to the final month of testing. "In addition, participating facilities achieved a 14.2-percent decrease in *C. difficile* rates compared to only a 5.9-percent decrease among non-participating facilities," stated Attman. (Note: these statistics were based on the second of two phases of testing).

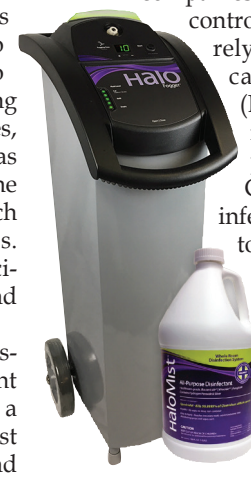


Hygiena ATP Meter, from ACME Paper & Supply .Co., Inc

"The Clean Collaborative demonstrated significant benefits to developing an ongoing program of testing surfaces for germs before and after cleaning, as it reduces contamination on surfaces across a wide range of healthcare facilities." Attman advised, "While hand hygiene remains the single most effective way to prevent the spread of bacteria, healthcare facilities need to be vigilant in developing new and more aggressive ways to fight the increasing prevalence of superbugs."

Regional service provides room disinfection

Room disinfection is a relative newcomer to the medical scene, but it has quickly proven to be an effective tool in reducing HAIs. Some medical facilities that do not have their own room-disinfecting units employ other companies to come in and disinfect their patient and operating rooms. Chris Truitt, PhD, Chief Science Officer, GermBlast, explained, "Regional disinfection service companies can play an important role in infection control. Many community and rural hospitals rely on service companies to augment the capabilities of environmental services (EVS) and infection-control staff. Also, a rural facility may not have an infection-prevention professional on staff, so GermBlast provides expert advice on infection-control methods and best practices to their customers."



HaloMist applied with the HaloFogger, from Halosil

Infection Control, Inc., dba GermBlast, headquartered in Lubbock, TX, services over fifty hospitals in rural Texas and New Mexico. The company routinely provides disinfection of operating-room suites, rooms that were occupied by patients with *C. difficile,* and contact isolation rooms. "GermBlast also has an on-call team to disinfect patient isolation rooms immediately after the facility's EVS staff has completed normal terminal discharge cleaning of the room," noted Truitt.

GermBlast uses the Halo Disinfection System from Halosil International as an arrow in its quiver of tools to disinfect against *C. difficile* spores and other HAI-causing pathogens. The system combines HaloMist, applied with the HaloFogger, and has a 99.9999 percent kill of *C. difficile* spores in a whole room.

According to Truitt, many rural hospitals do not have high HAI rates but want to reduce these low rates even further. "For example, a small, rural hospital in west Texas with four hospital-acquired *C. difficile* infections has lowered this rate to one per year."

Central Florida hospital works to prevent MRSA

The CDC estimated there were 119,247 methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections, with 19,832 associated deaths, in 2017. A report by Kourtis et al[5] noted, "Despite reductions in incidence of MRSA bloodstream infections since 2005, *S. aureus* infections account for significant morbidity and mortality in the United States. To reduce the incidence of these infections further, health care facilities should take steps to fully implement CDC recommendations for prevention of device- and procedure-associated infections and for interruption of transmission. New and novel prevention strategies are also needed." The rise in mupirocin resistance necessitates updated strategies.

"In one instance, a 136-bed facility implemented a Nozin daily nasal-decolonization protocol for all patients and achieved a 96 percent reduction of MRSA bacteremia hospital-wide and reached zero incidence of all Gram-positive and Gram-negative SSIs across all surgical procedures over a twelve-month period," noted Ernst W. Spannhake, PhD, Nozin Chief Science Officer.

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1. Deatherage N, AJIC, 2016: 44:6 (S101-S102). 2. Landis-Bogush K, Belani A, et al. AJIC, 2019: 47: 6 (S39). 3. Christie J, et al. AJIC, 2019: 47: 6 (S44 - S45) 4. Steed L, et al. AJIC, 2014: 42(8): 841-846. Made in USA. Nozin®, Nasal Sanitizer® are Global Life Technologies Corp. trademarks. Nozin Programs use nasal and body skin decolonization. Nozin® Nasal Sanitizer® antiseptic is for nasal decolonization. Nozin® Nasal Sanitizer® antiseptic is an OTC topical drug. No claim is made that it has effect on any specific disease. Savings estimates for example only.

Nozin nasal sanitizer family of products

According to Spannhake, hundreds of hospitals are replacing traditional MRSA surveillance strategies with universal (body and nasal) decolonization. "Research indicates that MRSA nasal colonization is the number-one risk factor for MRSA HAIs," observed Spannhake, "yet the nose is often left unaddressed in historic infection-prevention strategies, such as screen and isolate."

Spannhake said Nozin Nasal Sanitizer antiseptic solution enables hospitals to reduce risks of infection safely and decrease nasal screening, while supporting antibiotic-stewardship practices and avoiding bacterial resistance, shown to be associated with excessive use of mupirocin. Spannhake also stated that clinicians who adopted Nozin programs also noted higher patient and staff satisfaction as a result of reduced patient isolation and contact precautions.

Louisiana hospital prevents cross contaminants using SUDS

Cross-contamination in the patient environment, which may result in an HAI, is always a concern. Edwin Coombs, MA, RRT, NPS, ACCS, FAARC, Senior Director of Marketing, Portfolio Solutions Training, Clinical Affairs, and Intensive Care, North America, Draeger, Inc., cited the experience of an 800-bed hospital in Louisiana that has been utilizing the single patient use expiratory valve option with a high degree of satisfaction for several years. "Draeger worked with this hospital to provide this option, which over the long term has become cost-effective when comparing this disposable option to that of reusable components that require disinfection."

Ensuring that equipment is properly reprocessed should always be a priority throughout an institution. "Of primary concern," noted Coombs, "is the patient who must be protected and kept safe in the hospital environment. Secondly, Medicare and other health insurers will no longer reimburse providers for these types of infections, thereby adding to the operating cost per patient that the hospital must assume."

He referred to CDC recommendations for disinfection and sterilization. "The CDC has classified the reprocessing of medical devices based on the way in which devices are used and their risk. The three classifications are: 'non-critical,' devices that come into skin contact where the skin remains intact; 'semi-critical A/B,' components that come into contact with breathing gasses, mucous membranes, or pathologically altered skin; and 'critical A/B/C,' components that penetrate skin or mucous membranes or come into direct contact with blood."[6] The CDC also clarified that the use of a HEPA filter does not preclude the need for disinfection of components in between patients. "There are multiple concerns, including effectiveness of bacterial transmission cessation and the resultant expiratory resistance that a patient requiring mechanical ventilation endures."

To prevent cross-contamination when mechanical ventilation is in use, Draeger has created a disposable, single-use series of products, including disposable adult expiratory valves and CO2 monitoring cuvettes. Also, solutions to meet customer-specific requirements can be made. "Using this disposable line can eliminate the need to disinfect reusable components, while ensuring no risk of cross-contamination through use of single-patient components," said Coombs.

RWJ hospital decreases HAIs through mobile device disinfection

Robert Wood Johnson University Hospital Somerset's infection prevention efforts have resulted in lower infection rates, including catheter-associated urinary tract infections, central-line associated bloodstream infections, methicillin-resistant *Staphylococcus aureus* (MRSA), *C. difficile* infections, and SSIs. These reduced infection rates have led to national excellence recognitions, including a rare "A" Hospital Safety Score from the Leapfrog Group nine times. The facility has also been presented the 2019 Healthgrades Patient Safety Excellence Award, as a result of ranking among the top five percent in the country for patient safety.

ElectroClave, from Seal Shield

Recently, the hospital became the first in New Jersey to implement Seal Shield's latest breakthrough, UV-C disinfection technology, the ElectroClave, to protect patients better from cross-contamination hazards associated with mobile devices. Organizations that implement the ElectroClave can monitor the disinfection status of all mobile devices being used in the organization and send users a text or app reminder of when their device is next due for a disinfection cycle. According to Bradley Whitchurch, CEO, Seal Shield, "ElectroClave is the most comprehensive mobility-disinfection–management solution available today."

Most hospitals have very strict policies regarding staff maintaining good hand hygiene. However, in 2020, phones are like an extension of people's hands and are constantly negating efforts to maintain good hand hygiene if they are not being accounted for. Organizations that account for mobile devices when determining their hand-hygiene protocols are far better equipped to prevent the spread of infections than organizations that overlook them. **HPN**

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CS CONNECTION

Make time to take time for instrument pre-cleaning

by Kara Nadeau

Let's face it – healthcare is a dirty business. The clean and sterile devices and instruments that arrive in the operating room (OR) or other clinical areas for patient procedures typically leave post-procedure covered in residual bioburden, such as blood and tissue. This bioburden becomes harder to remove the longer it remains on an item. Not only can it damage them, if left long enough it can result in stubborn biofilm that can harbor dangerous microbes. Biofilm is challenging – if not impossible to remove. Bacteria within biofilms can be up to 1,000 times more resistant to a given agent (e.g. sterilants, disinfectants and antibiotics) than their counterparts that are not part of a biofilm colony.[1] When pieces of this biofilm detach from an instrument or device, they can potentially recolonize elsewhere, spreading infection.

While Central Sterile/Sterile Processing Department (CS/SPD) professionals are seen as those responsible for device and surgical instrument processing, the steps necessary to take dirty items and process them effectively for the next round of procedures start at the point of use (POU). Industry guidelines from the International Association of Healthcare Central Service Materiel Management (IAHCSMM), Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN), clearly state that POU pre-cleaning by clinicians or technicians post-procedure is critical to removing bioburden and helping to prevent the formation of biofilm.

"Preventing the formation of biofilm is one of the most important aspects of POU cleaning from a patient safety perspective because once it has formed we can't brush it, chemicals can't touch it and heat doesn't destroy it," said Casey Stanislaus Czarnowski, BA, CRCST, CSPDT, CIS, CER, Sterile Processing Educator, Stanford Health Care.

Casey Czarnowski

While the guidelines state that POU cleaning is a crucial step in effective and safe instrument processing, when speaking with CS/SPD professionals and others, it becomes clear that this step is often skipped, or performed inadequately, resulting in heavily contaminated instruments arriving in the CS/SPD.

In the case of Porter Adventist Hospital in Denver, failure of hospital staff to adequately pre-clean orthopedic and spine surgery tools contributed to inadequate processing and contaminated items being used in procedures, placing approximately 5,800 patients at risk for contracting HIV, hepatitis or surgical site infections (SSI). An investigation of the hospital by The Joint Commission found 129 instances of "incomplete removal of gross surgical contamination" over the course of 13 months.[2,3]

In a statement to the affected patients, Porter Adventist Hospital cited "a gap in the pre-cleaning process of surgical instruments, prior to manual washing, machine washing, and sterilization."[4]

Barry O'Brien Sr.

"Reprocessing - as we know - begins at the point of use," said Barry O'Brien Sr., BS-HCA, Sterile Processing Manager, Kaiser Permanente South San Francisco CA Medical Center. "The criticality of post-use pre-cleaning/pre-treatment steps – completed at the point of use prior to decontamination - cannot be overstated. Also, intra-operative wiping/wetting of instruments on the back table during cases to remove visible blood/bioburden prevents drying of debris on instrument surfaces during use and allows for easier post-use management."

In this article, *HPN* examines the importance of POU cleaning, why some healthcare staff members inadequately perform it (or neglect it all together) and best practices and products to boost POU cleaning compliance, efficiency and efficacy.

Stainless steel transportation cart from TBJ for holding and transportation of contaminated surgical instruments to SPD.

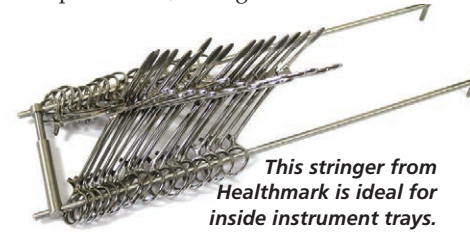
A pressing need and a growing concern

Both clinical areas and the CS/SPD face a tremendous challenge – how to effectively and safely process instruments and devices in the midst of growing case volumes, more complex and difficult to clean instrumentation, and pressures to streamline processes and increase efficiency.

While pre-cleaning at the POU may be viewed by some as an extra, time-consuming step, in reality the process paves the way for greater efficiency in the CS/SPD, which can mean faster turn-around times for instruments and devices back to the OR and other procedural areas.

"If instrumentation is prepped in the OR by OR personnel, it makes the cleaning process in the SPD easier, faster and more efficient," said Todd Campbell, President, TBJ.

Kevin Anderson, BSN, RN, CSSM, CRCST, CHL, CIS, CER, Clinical Education Coordinator, Healthmark, explains how POU cleaning has only grown in importance with today's more advanced devices and procedures, stating:



This stringer from Healthmark is ideal for inside instrument trays.

"The process of preparing soiled instruments for return to SPD becomes more important as surgical instrumentation becomes increasingly complex, and all members of the perioperative team feel the pressure to improve efficiency," said Anderson. "Proper preparation of soiled instruments in the OR can reduce processing time, preserve useful life of expensive instruments and endoscopic equipment, and improve staff safety and SPD quality."

Time is of the essence

The rationale for POU cleaning comes down to timing – and drying. Think of a dirty dish sitting after a meal. As the food matter remains on the dish and dries it typically becomes much harder to remove, which makes it more challenging to clean. It is a similar situation with an instrument or

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AAMI Guidance [1]

Point-of-use care and handling

"Gross soil should be removed as soon as possible…" ~ "Removing gross soil and moistening soil at the point of use improves the efficiency and effectiveness of decontamination…" **6.3.2**

"Prior to transport, instruments should be prepared in such a way as to prevent organic soils from drying by… c) applying a product designed for pretreatment." **6.3.5**

[1] ANSI/AAMI ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*

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device – if POU cleaning does not occur, bioburden remains, dries and hardens, presenting a significant challenge to the CS/SPD. Therefore, clinical staff must do their part to pre-clean instruments according to the manufacturer's instructions for use (IFU).

"OR treatment of instruments is safest for patients as the longer bioload sets on an instrument without any treatment, the more that bioload will dry, form biofilms and become extremely hard to decontaminate," said Alison Behn-Gartland, Customer Technical Sales Director, Micro-Scientific. "Dried bioload means that SPD will have a harder job and that there may be a greater risk of residual bioload that will stay on instruments and interfere with sterilization, in the end compromising the patient. Pretreatment is such a crucial part of the circle of processing that keeps instruments, patients and personnel safe."

Darren Dahlin, Director of Clinical Education for Cantel, stresses the need for prompt transport of instruments from clinical areas to the CS/SPD post-procedure, and the importance of keeping instruments moist during this journey, stating:

"After pretreatment is performed, the transport to the SPD should be quick and efficient to ensure that proper and timely cleaning can begin. Keeping the instruments moist during transport helps ensure that any remaining debris does not dry and harden. For endoscopes, if cleaning does not start within one hour of the end of the procedure, an extended soak is required, which can delay reprocessing by up to 10 hours."

INTERCEPT Foam from Cantel keeps endoscopes moist for up to 72 hours, helping prevent bioburden from drying and hardening.

John Kimsey, National Director, Professional Services, STERIS, has seen very high functioning healthcare facilities where instruments are decontaminated in the CS/SPD within 30 minutes of leaving the OR. But even in these cases, failure to pre-clean post-procedure still complicates the decontamination process. He states:

"Even at 30 minutes though, cement is hard as a rock and bioburden has begun to dry. I've also seen instruments sit in backlogs in decontamination for hours, which only increases the difficulty of cleaning. With the increased interest in offsite reprocessing, the delay from OR use to decontamination lengthens due to transportation time, reinforcing the need for POU cleaning."

Why isn't POU cleaning done?

Jamie Zarembinski, CCSVP, Clinical Educator, Sterile Processing, Key Surgical, says there is a wide range of compliance on POU cleaning across the U.S., and even those healthcare facilities that perform it have the opportunity "to be better and make process improvements at the departments and facility level."

According to Campbell, some OR areas are better equipped than others for prepping instruments prior to sending them to the CS/SPD, stating: "Some facilities do it as a standard procedure while others don't do any prepping prior to instruments going to the SPD."

The industry guidelines prescribe POU cleaning, and failure to perform it has been linked to infection outbreaks among patients. So why is this critical step being skipped?

"The biggest hurdle here is culture," said Kimsey. "Our culture has focused on turnaround times and shedding anything that inhibits a scrub tech or circulator from turning the room. The quote 'we don't have time for that' or 'that is SPD's job' shouldn't be an acceptable answer to a request that AORN and others support as best practice. We should be holding ourselves accountable to finding a process that allows for POU cleaning and efficient room turnovers."

Dr. Weigert PreStop from Key Surgical for pre-cleaning

While O'Brien acknowledges how time constraints in the OR force staff to be efficient and turn rooms quickly to satisfy the C-Suite, he adds that OR staff must play their part in instrument processing, stating:

"It's important to note that OR staff will push back when presented with the steps required post-use for instrument management due to existing time constraints and the like, but the role OR staff play in the overall instrument reprocessing spectrum is extremely critical. Attention to detail and removal of visible debris during and after cases is a minimum standard that should be in place and accountable. Coordinating the process as a collaborative between sterile processing and end users (OR, et. al.) is the key to developing a successful process."

"Keeping the soils moist using instrument pre-treatment products until manual cleaning can begin is a convenient and effective solution for point-of-use (POU) precleaning," said Ann Mangskau, Assistant Marketing Manager, Ecolab Healthcare. She offers the following considerations to help improve the process of pre-cleaning at the POU:

- Use pretreatment foams or gels, which are less prone to spill during transport and provide greater assurance that instruments remain moist during unexpected reprocessing delays.
- Use pre-treatment products packaged in a Bag-On-Valve canister to help reduce hand fatigue.

Lena Burgess, CRCST, CIS, CFER, CHL, Manager, Health Safety and Environment, Instrument Processing, STERIS Instrument Management Services (IMS), describes compliance with POU pre-cleaning as cyclic, stating:

"The process, when done consistently, works to decrease residual bioburden on instrumentation. The consistency with which the process is completed is cyclic. When there is a focus on point-of-use care of instrumentation, there is an increase in the process being completed. When the compliance improves and there is a shift in the focus to another area of improvement,

OptiPro Gel Instrument Pre-Cleaner from Ecolab: A ready-to-use, bag-on-valve surgical instrument pre-cleaner

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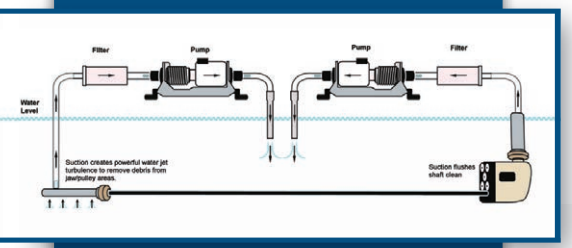

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the trend is for point of use instrument care compliance to wane."

Based on Kimsey's experience in multiple U.S. hospitals, he says POU cleaning is a "50/50 proposition" with orthopedics being the "worst offender of not cleaning or prepping their instruments." He adds, "other services are perhaps less invasive and thus their instruments are easier to accommodate."

The number of individuals in the OR and other clinical areas who handle instruments post-procedure during various shifts, and the lack of monitoring around POU cleaning are two factors that can result in low POU cleaning compliance, according to Anderson. He states:

"The incidence and quality of POU care is widely variable between institutions. Not enough facilities are monitoring this process closely. There are a lot of people handling instruments before they go to SPD. The typical facility has circulators, scrubs and first assistants (FA) on multiple shifts. Any of them could be responsible for preparing the instruments at the POU."

Certol ProEZ foam pre-treatment spray and bedside kit for cleaning scopes

"The most significant issues arise on weekends and after hours when staff is reduced or not available to handle the workload," said Dahlin.

"Instrument pre-treatment and compliance at point of use is one of the main focal points of Joint Commission surveyors and one of our most requested topics when we visit healthcare facilities," said Brett Norton, Marketing & Sales Manager, Certol International. "One of the biggest challenges is getting them to understand that everyone plays a critical role in the cleaning process. Pre-treatment is a team process. Everyone from the OR, ER, ICU, Pediatrics, Labor and Delivery, Med/Surg to the SPD plays an important role."

"When dirty instruments are left sitting for any amount of time, it's critical they're covered with a protective pre-treatment spray; preferably an enzymatic with corrosion inhibitors," Norton added. "Blood soils can start corrosion on some types of metals within 10 minutes and once instruments are compromised, they're difficult to clean adequately, putting patients at immediate risk." She adds:

- It is critical to routinely wipe off or flush soils DURING surgical and clinical procedures with sterile water and sponges.
- If transport delay is frequently over one hour, coverage with wet towels may not prevent corrosion. Select a point-of-use treatment spray tested and validated to provide anti-corrosives and effective enzyme action.
- Use OSHA biohazard compliant transport containers with solid sides, bottom and lids.

POU: Tips for making it happen

CS/SPD professionals and others recognize the importance of POU cleaning, so how do they work with the OR, other clinicians and healthcare facility leadership to drive greater compliance with industry guidance?

Establish a policy

Czarnowski says an effective way to drive POU cleaning compliance is to work with leadership to make it hospital policy that OR staff are required to perform.

"That way, when you are speaking to staff you can speak to the hospital's policy and say this is what we have decided must be done, based upon published standards," said Czarnowski. "When I joined one facility, POU cleaning was unknown to both the CS/SPD and OR staff. Through hard work and cooperation, we did a complete 180, achieving 100 percent buy-in and compliance."

Communicate and collaborate

Kimsey recommends creating an awareness of teamwork between the CS/SPD and OR and how "how each step in any process is really a supplier/customer relationship."

"Lean methodologies support ensuring each step of any process meets the quality output expectations of the next step so that the overall process becomes more efficient," said Kimsey. "In this sense, the OR is the supplier of a product to SPD as the customer. Expectations of how the OR is to supply the product 'dirty instruments' to the SPD is documented and agreed to and then measured for compliance."

Educate

Anderson says the most important factors of success for POU cleaning compliance are education and accountability. He states:

"Most healthcare institutions already have something like Healthstream in place, which is a program used to deploy mandatory educational materials across an entire institution, or system. This could easily be leveraged to educate staff on the importance of POU care of reusable medical devices (RMD), and the facility's policy and procedure regarding POU expectations."

While policy implementation got the ball rolling, it was OR staff education that truly made an impact on POU cleaning compliance in his facility, according to Czarnowski. He leveraged AORN guidelines and worked with front-line OR staff to develop a presentation to educate the OR on proper pre-cleaning.

"When we talk to the OR, a very useful resource is AORN, because it is an organization of their peers," said Czarnowski. "When you can point to AORN's perioperative guidelines that say POU cleaning is important than you are speaking from their group to their group. While we created the presentation, OR staff took the lead on educating their team. I felt this was important because I wanted the nurses and techs to hear from their own."

In 2019, the Association for Professionals in Infection Control and Epidemiology (APIC) published the results of an intensive "train-the-trainer" program emphasizing the importance of pre-cleaning, according to Lynn Burbank, DNP, RN, CRNP, Senior Manager, Infection Prevention, ENT, Gynecology, Surgical, Urology – Endoscopy, Reprocessing Strategy Office, Olympus Corporation of the Americas.

"Results were significant for implementing education as an intervention to facilitate the understanding of the importance of pre-cleaning as a means to prevent infection," said Burbank.

Implement new technologies and products

There is a wide range of solutions available to help in the pre-treatment of devices and instruments in procedural areas. For example, Zarembinski notes how there have been improvements in pre-treatment products that have increased material compatibility while providing superior performance.

When selecting a POU treatment, Marcia Frieze, CEO of Case Medical, offers the following advice: "Always review the safety data sheet (SDS) to ensure its safety, select pH neutral cleaners to avoid damage to surgical instruments and instrument containers, and ensure the cleaner is free rinsing to prevent residue that may interfere with sterilization or remain on instruments designated as ready for patient use."

PentaPrep Multi-Enzymatic Cleaner, Penta Wipes Multi-Enzymatic Wipes, or CasePrep Non-Enzymatic Cleaner for pre-treatment.

Campbell speaks to solutions available to aid in the transport of dirty instruments to the CS/SPD for processing. He states:

"Specialty transportation carts made specifically for transporting contaminated instruments from the OR to SPD enable the OR to, at the very least, help prevent soiled instrumentation from drying thus making the cleaning process in SPD less difficult."

Czarnowski offers his advice for POU treatment of flexible endoscopes, which are notoriously hard to clean, stating:

"If I were a super villain and wanted to design a device to transfer disease from one person to another, it would be a flexible endoscope, because it is complicated, hard to clean and delicate. The way we can combat that super villain is to employ conscientious POU cleaning, and a bedside flushing kit is a great place to start."

Czarnowski says there are a wide range of bedside kits available, which make it easy for technicians to perform the flushing step after use and before the endoscopes are sent to decontamination.

Take it off-site

When offering best practices for POU cleaning compliance, Czarnowski reminds those leading these efforts to incorporate sites using instruments and devices outside of the four walls of the hospital, including ambulatory sites and clinics.

"When it comes to POU cleaning, you have to reach out to ambulatory sites/clinics and make sure they are aware of it and perform it because the instruments may even sit longer than they do within a hospital setting, making bioburden even harder to remove," said Czarnowski. "The best practice is to travel to those doing the work and bring the information to them – someone has to step up and do that."

Document and track

As with any process, compliance can slip if a healthcare facility does not have in place a way to document POU cleaning and track it over time. Dahlin points to digital documentation systems that can track and monitor instruments and procedures to alert staff when a procedure is over, allowing the SPD staff to prep for the arrival of soiled instruments, as well as remind the OR staff to complete the pretreatment of the instruments prior to sending them to the processing area.

"Developing an audit tool and committing to auditing POU care compliance can be extremely effective when done correctly," said Anderson. "Audit results should be monitored, shared, and built into performance reviews to enhance awareness and compliance. It's important that this is not used to blame, but to drive quality." HPN

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Infection Control Summit on endoscope reprocessing

by Susan Klacik, BS, CRCST, CHL, CIS, ACE, FCS, IAHCSMM Clinical Educator

Recently, the American Society for Gastrointestinal Endoscopy (ASGE) held an Infection Control Summit outside Washington, D.C. to provide a state-of-the-art review of endoscope disinfection and reprocessing from regulatory, practice and training perspectives. The meeting also explored future avenues of technological advancement and research for endoscope disinfection and reprocessing.

The Summit provided presentations from key stakeholders and allowed for open discussion regarding next steps in the process of identifying recommendations and guidance for practitioners to ensure patient safety. The International Association of Healthcare Central Service Materiel Management was invited to attend and was represented by Executive Director Susan Adams and myself.

Key endoscope reprocessing experts and regulators provided insight into the current state of endoscope reprocessing. The overriding theme was that cleaning flexible endoscopes is the most important part of the process and that many challenges exist that must be overcome to ensure these devices can be effectively cleaned. Among the primary challenges is the design of flexible endoscopes. These devices feature long, narrow interior channels (lumens), including those with internal surfaces that are not smooth, have ridges or sharp angles, or are too small to permit a brush to pass through; hinges; sleeves that surround rods, blades, activators, inserters, etc.; adjacent device surfaces where debris can be forced or become caught during use; O-rings; valves that regulate the flow of fluid through a device (stopcocks), and other design features that cannot be disassembled for reprocessing.

Role of human factors

Human factors also present notable challenges for endoscope processing, a point that was addressed in a presentation by Cori Ofstead, MSPH, President and CEO of Ofstead & Associates Inc. She presented data that originated from audits she and her team performed during site visits to over 60 institutions, as well as from 2017 and 2018 surveys of IAHCSMM members. These studies established that personnel processing flexible endoscopes are often:

- Expected to memorize and perform complex tasks involving hundreds of steps from all of the instructions for use (IFU) involved;
- Subjected to a hostile work environment;
- Not provided with adequate training (some receive no training). Study findings showed, however, that certified technicians perform at a higher level;
- Unable to understand or follow the manufacturer's reprocessing IFU. A survey showed 84% of respondents had read the endoscope's IFU, but it could not be consistently understood or followed;
- Bothered by odors and pain during endoscope reprocessing (47% of survey respondents admitted this is a workplace issue);
- Pressured to move quickly. Up to 17% of survey respondents admitted skipping steps/cutting corners or doing steps faster due to time pressures; and
- Bullied by others in the workplace. A survey showed that 40% of endoscope reprocessing technicians either witnessed bullying or experienced it themselves – with bullying including both verbal and physical attacks.

The US Food and Drug Administration's (FDA's) Post-Market Surveillance Studies: Human Factors and Microbiological Sampling/Culturing Data was also presented during the Summit. The results from human factors studies indicate that reprocessing instructions in current user manuals should be strengthened because they are difficult for reprocessing staff to comprehend and follow. Many reprocessing professionals missed one or more steps in the process and needed additional training to complete the process properly. Also, it was noted that descriptions of some of the processing steps in the user manuals were unclear.

It was noted that drying is another critical part of the process because moisture facilitates proliferation of microorganisms and wet storage may promote formation of biofilm. Data presented supported that the duration of drying should be 10 minutes and that automated drying is more effective than manual drying. Training and education are also vital for improving the processing of flexible endoscopes, the presenters concluded, and many presenters suggested that certification of processing professionals should be required.

ASGE, the American Gastroenterological Association, the American College of Gastroenterology and the Society of Gastroenterology Nurses and Associates discussed actions they've taken to improve flexible endoscope processing:

- Improved communication with members, manufacturers, the FDA and Centers for Disease Control and Prevention (CDC)
- Monitoring of the FDA's Manufacturer and User Facility Device Experience database and other resources, setting up a website to track communications and inform members of issues and updates
- Joining the Association for the Advancement of Medical Instrumentation (AAMI) to participate in the revision of ANSI/AAMI ST91, Flexible and semi-rigid endoscope processing in healthcare facilities (this revision is nearly complete)

Other solutions included implementing the use of disposable duodenoscopes. There are many considerations regarding their use, such as cost, environmental impact and physician preference. Note: Since this meeting took place, the FDA cleared the first fully disposable duodenoscope. HPN

This article is a condensed version of one that will be published in the March/April 2020 issue of PROCESS, the publication of the International Association of Healthcare Central Service Materiel Management.

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Examining double peel pouch and ATP testing practices

by Ray Taurasi, Principal, Healthcare CS Solutions.

Q We recently began using self-seal peel pouches in our clinics. The OR supervisor insists that everything packaged in a peel pouch be double packaged. He claims this is required by the Association of periOperative Registered Nurses (AORN) and the Association for the Advancement of Medical Instrumentation (AAMI). Do you have any information regarding double packaging a self-seal pouch? I'm concerned that the paper on the pouch would face the plastic, preventing the steam from reaching all the contents in the inner pouch. Is it safe to double pouch these pouches?

A There are no AAMI or AORN recommendations that state you must double peel pouch items for use in the operating room (OR). Both AORN and AAMI state that you should follow the manufacturer's instructions for use (IFU) for any packaging materials you utilize. Their recommendations also advise that if a hospital chooses to double peel pouch, they must be sure that the manufacturer has validated their pouches for double pouching. Many peel pouches have not been validated for double pouching. I know of no peel pouch manufacturer that requires double peel pouching for the use of their products. As part of Food and Drug Administration (FDA) clearance, packaging manufacturers must provide validation that their product allows for sterilant permeation to achieve sterilization of the package contents. They must also provide validation of the product's ability to maintain sterility until the point of use.

Some ORs want certain items double pouched for sterile presentation. This might include multiple small items or instruments that might present a challenge in aseptic presentation, and thus may need to be held together or contained while being passed off to the sterile field. I find that many hospitals are unnecessarily double pouching all items as a force of habit while others claim it is necessary to prevent tears and punctures and to maintain sterile integrity. If you are double pouching due to tears and punctures, you may want to investigate your packaging techniques. Tearing is often associated with the following issues:

1. Packaging oversized or heavy objects in a peel pouch
2. Using the inappropriate size pouch for the item(s) being packaged
3. Failing to use packaging aids such as tip protectors on sharp tip instruments or devices with protrusions
4. Using lightweight, poor quality peel pouches for "perceived savings"

If you are double pouching all items to ensure sterility maintenance and using a less expensive and lower quality pouch, you might want to explore other peel pouches that provide a multi-layer of heavier polymer (plastic) and a heavier paper weight for added protection and superior performance. While the individual pouch cost might be slightly higher, use of such could, in the long run, cut your peel pouch inventory usage in half and result in real significant savings by reserving the practice of double pouching strictly for those items requiring such for aseptic presentation.

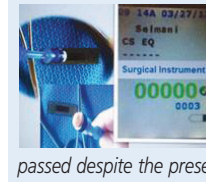
If you continue with double pouching, be certain that you obtain instructions from the pouch manufacturer. You will want to know what the acceptable sizing is for the inner and outer pouch. The inner pouch will need to be smaller, fitting freely within the outer pouch. Inner pouches must never be folded in order to fit in an outer pouch. Inappropriate sizing could impede the efficacy of the sterilization process and the performance of the packaging. Some peel pouch manufacturers provide a guide that specifies all acceptable inner and outer pouch size combinations.

Q We are evaluating adenosine triphosphate (ATP) monitoring systems to use for testing our surgical instruments and other medical devices to verify that they are clean. I am confused about what the passing number should be for an ATP detection test. Of the devices we have looked at, they each have different pass/fail levels. I consulted with our infection control officer and he said that while ATP testing is used in our Housekeeping and Food Service departments, she doesn't feel that ATP is necessarily a good test for monitoring surgical instruments. I know many of my colleagues in other hospitals are using ATP testing in their CS departments to monitor the cleaning of surgical instruments. I am a bit confused by the mixed information I am receiving on the use of ATP. What are your thoughts on this?

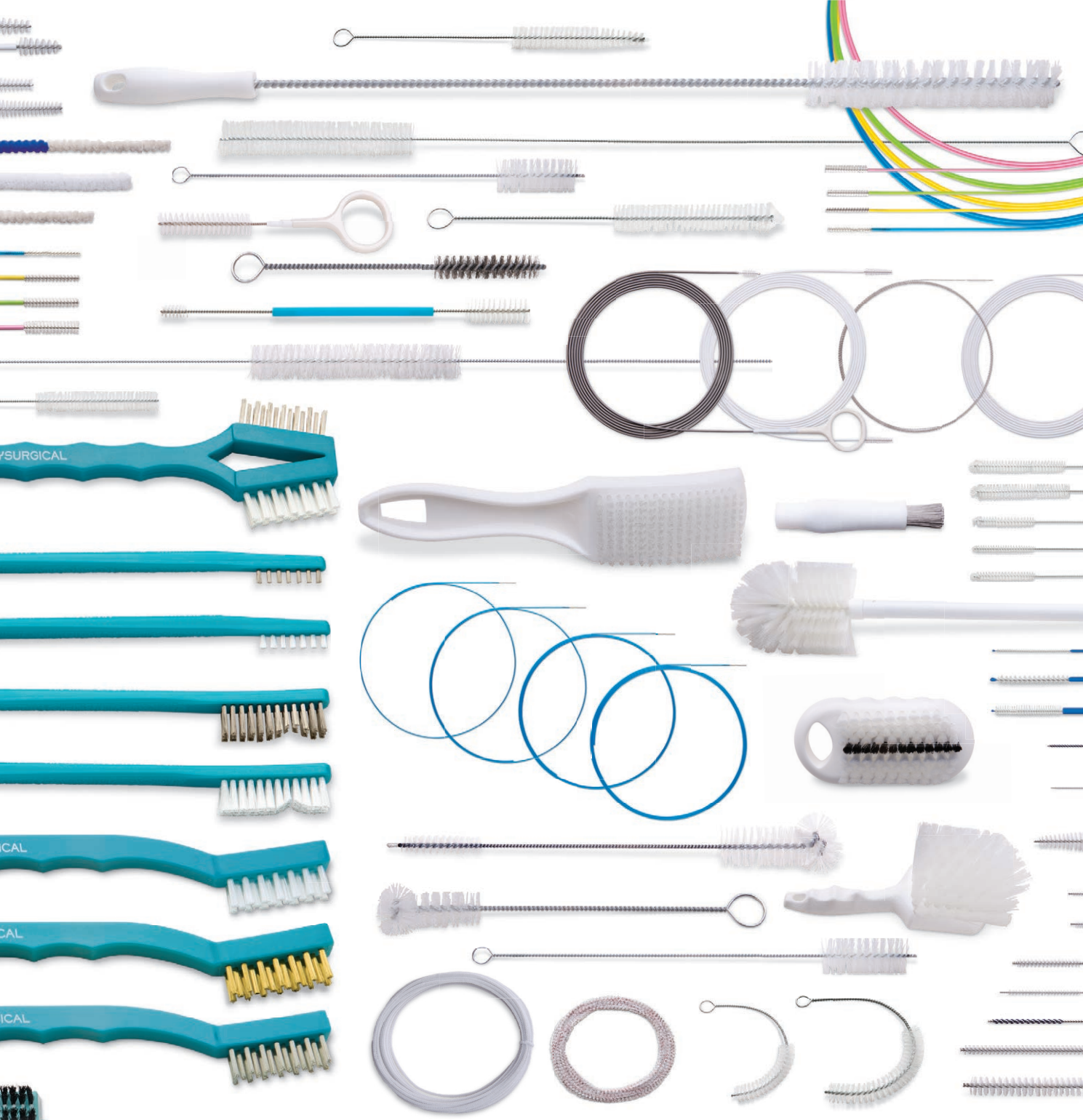
A Adenosine triphosphate (ATP) is a chemical that is produced in every living cell. So, its presence on an item tells us that there is something on that surface that is, or was recently, alive. An area or surface to be tested is swabbed, the swab is placed into a holder containing a chemical solution that prevents ATP degradation and is then placed into an illuminometer, which determines the detection of ATP residual in relative light units (RLUs), which are emitted from the swab. Acceptable RLU values vary from system-to-system and currently there is not a standard pass/fail unit of measurement across the various manufacturers' ATP testing systems. One manufacturer might say that a pass would be an RLU below 25 while another might claim a pass would be anything below 250 RLU.

ATP testing has been around for many years. It originated and is still used to effectively monitor equipment and surfaces in the food and environmental industries. In these industries, highly-invasive medical devices are not used or tested and the measure of "clean" does not have the same impact. ATP is not present in viruses nor is it present in components such as protein, carbohydrate, hemoglobin, lipids, and the like, which are the precise soils we confront in sterile processing when cleaning invasive medical devices and surgical instruments. ATP degrades over time and once it degrades it cannot be detected. This means it is possible to get a pass reading in ATP detection yet still have visible organic soil remaining on an object.

We obviously would not want to use a medical device in surgery with any residual soil remaining on it. I believe it would be more appropriate to use actual organic soil detection testing devices on invasive medical devices and surgical instruments – these devices are capable of detecting the most common organic soils found on medical and surgical devices such as protein, carbohydrate, hemoglobin, lipids and the like. HPN



A sample of dried sterile blood found on a stainless-steel plate was taken utilizing an ATP test swab. The ATP reader detected a zero RLU reading and the test passed despite the presence of blood.



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For more information, direct any questions to *Healthcare Purchasing News* (941) 927-9345, ext. 202.

LEARNING OBJECTIVES

1. *Identify the differences in IFU based upon a medical device's FDA classification*
2. *List the components necessary to meet FDA requirements for medical device IFU*
3. *Describe two IFU challenges that exist today*

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SELF-STUDY SERIES

Making sense of your medical device IFU

by Heide Ames and Delores O'Connell

The instructions for use (IFU) that are delivered with every new medical device by the manufacturer are intended to enable safe use of the item. They are a mandatory component for the sale and use of the device because of the product's impact on patient safety. Although IFU have been a longstanding source of confusion and contention for many sterile processing departments, great strides have been made in recent years to standardize content, expand reprocessing instructions and provide actionable processing steps. Sterile processing departments often focus on the reprocessing instructions for the reusable medical devices they clean and sterilize every day, but for many of the systems, sterilization chemistries and tests they use are also medical devices with IFU. Since patient safety is the ultimate focus of all the work done in the department, it is critical for sterile processing personnel to understand and include all medical device IFU appropriately when developing their processes and procedures.

Three types of IFU

IFU provide critical information on the application and preparation of a medical device for use. In the United States, the Food and Drug Administration (FDA) regulates all medical devices, including those used in sterile processing departments. Before it can be sold in the U.S., a medical device may need to be reviewed by the FDA to determine if it is safe and effective. The extent of review depends upon the class of medical device.

1. PMA IFU

The most stringent review occurs for Class 3 medical devices, which include any medical device that sustains or supports life, is implanted within the patient, or poses a high risk of harm to the patient should it be ineffective. Examples include pacemakers, implanted prosthetics, orthopedic screws and defibrillators.

Class 3 medical devices undergo the Premarket Approval (PMA) process. A PMA is the most thorough review process, requiring extensive testing and often, clinical trials. As part of the process, the IFU is reviewed and approved by the FDA. Approval indicates that FDA supports the IFU as sufficient for the safe use of the medical device.

2. Reviewed IFU

This type of IFU is supplied with Class 2 medical devices, which present a moderate risk of harm since they are often similar to another device already being used in healthcare facilities (a predicate device). Class 2 medical devices include such items as infusion pumps, some surgical instrumentation, and biological indicators. Some Class 2 medical devices are items used in the sterile processing department to process other medical devices.

Most Class 2 medical devices undergo the 510(k) review process. This process requires submission of testing to demonstrate that the new medical device is similar to, and as safe as a medical device currently being sold in the U.S. For example, consider a company that has developed a cranial drill for a specific procedure. When the manufacturer applies to the FDA for clearance to market the new cranial drill using the 510(k) process, they predicate their new cranial drill on the safety of other cranial drills currently on the market.

Class 2 510(k) testing is typically limited to a performance comparison, and clinical trials are not usually required. The FDA confirms that all required sections have been completed and that the device is substantially equivalent to comparable products. However, for the Class 2 review process, the FDA does not approve the IFU; it only reviews them. In the past, the FDA review focused on the intended use, indications for use, warning and precautions sections. Other sections of the IFU were not a focus in the review process, but going forward, FDA has stated that it expects manufacturers to provide reprocessing validation information for the IFU, including all cleaning and microbiocidal processes dictated by the instructions for certain reusable devices.

3. Manufacturer controlled IFU

This third type of IFU applies to Class 1 medical devices, which include items such as elastic bandages and exam gloves. Devices in this category are deemed to present minimal risk to the patient and are exempted from FDA review. They have the least regulatory oversight. Manufacturers are expected to perform appropriate testing and develop IFU based on the most current recommendations, but the FDA does not review the supporting testing or the IFU. It is up to the manufacturer to ensure that appropriate measures have been taken.

Regardless of the amount of oversight provided by the FDA, all medical device IFU have specific information that must be provided. These are detailed in the FDA document "Labeling: Regulatory Requirements for Medical Devices."

FDA-required IFU content

IFU arrive at medical and dental facilities in several forms. They can be an operator's manual, a separate instruction leaflet or a user guide. They may be a single document or may have additional documents such as wall charts and reference guides. Regardless of the format, the FDA requires specific information to be provided. This includes the *name and place of business,* the *intended use, warnings and precaution statements,* and the *directions for use*.

The *name and place of business* provides valuable information beyond the obvious. The term "manufactured by" indicates that the vendor owns the design and the manufacturing process. This type of vendor has ultimate control over the medical device for they have the design, research, testing and the know-how used to make the medical device.

An IFU stating "manufactured for" indicates the design is owned by the vendor but they do not make the device. Manufacturing is performed by a third party.

An IFU stating "distributed by" indicates that the vendor neither owns the design nor the manufacturing know-how. These are often referred to as "private-labeled" distributor devices. This vendor relies on the design owner to ensure the quality and compliance of the medical device.

The IFU must also identify the *intended use*, a broad, general description of the purpose of the device. "Monitoring steam sterilizers" and "For visualization and diagnostic/therapeutic access to the adult lower gastrointestinal tract" are examples of intended use statements.

The intended use can also include or be replaced by an *indications for use* section, which provides specific information that clarifies and limits the intended use. In the following example, the first sentence represents the intended use. The following paragraph details the indications for use.

> *The [redacted] cover and [redacted] pad are intended as a microbial barrier between the patient and medical imaging electronics.*
>
> *The [redacted] cover and [redacted] pad are used, without the need for ultrasound coupling gel, in adult and pediatric patients, for diagnostic ultrasound imaging, in sterile and non-sterile fields, that currently use an ultrasound coupling gel or fluid alone or in combination with a protective transducer cover, including ultrasound guided venous access, ultrasound imaging over surgical wounds, during transcutaneous biopsy; for intraoperative, endocavity, or transcutaneous imaging procedures; or to enhance acoustic coupling to difficult geometries.*

Every IFU must identify all necessary *warnings and precautions* when using or preparing the device for use. Warnings and precautions identify harm or potential harm that can arise with the patient, user or preparer. A typical precaution warns of conditions that might cause harm. "Protect the device from heat" is an example where heat may damage the device making it inoperable. A warning is a known harm that will occur. "Hot: Handle with thermal protective gloves" is a warning to protect sterile processing technicians from burns that can occur by handling hot items from a steam sterilizer.

Warnings and precautions can also be expressed as symbols. It is critical that users understand every symbol, so a key will be included in the IFU if symbols are used. Note that similar looking symbols can have very different meanings.

Examples of Warning and Precaution Symbols:

The FDA requires *directions for use* that are adequate to assure safe use and safe preparation of the device for use. Although this has been a requirement since 1989, manufacturers' interpretations of what "preparation of a device for use" means have been highly variable. Manufacturers' IFU have posed challenges for users, such as leaving out steps to effectively clean the device or requiring processes that are not available in the U.S. To address these challenges, a new guidance document was issued in 2015 and updated in 2017. "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" defined what is needed to ensure that adequate directions for use, including thorough processing instructions, were defined and usable by U.S. healthcare facilities.

This document states, among other requirements, that manufacturers must design reusable medical devices with cleaning in mind. The cleaning process included in the IFU must be validated. Proper microbiocidal treatments, as defined by the Spaulding Classification, must also be identified (see **Table 1)**. This guidance also requires manufacturers to verify that the instructions are clear and achievable by healthcare personnel with responsibility for the task at hand. In other words, vendors must demonstrate that sterile processing technicians can effectively clean and perform the appropri-

TABLE 1: Spaulding classifications and appropriate reprocessing processes.

Device Classification	Example	Microbicidal Process
Non-Critical		Low- or Intermediate-Level Disinfection
Semi-Critical		High-Level Disinfection or Sterilization
Critical		Sterilization

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

ate microbiocidal treatment using the IFU provided with the device.

Challenges still exist

The current FDA guidance has significantly helped sterile processing professionals as newer devices have entered the market. However, it has not solved all the challenges. The guidance is not retrospective, and older original 510 (k) clearances do not expire, so old devices that were cleared before implementation of this newer guidance document are not required to resubmit. Older devices may reference cleaning processes that are no longer available or sterilization processes that are not available to U.S. healthcare facilities.

The good news is, there may be ways to address these problems. Healthcare facilities with older devices may be able to get updated IFU or reprocessing instructions from the original device manufacturers, and old devices may meet the design and compatibility requirements for newer alternative processes. For example, devices requiring an extended steam sterilization cycle may be compatible with a standard vaporized hydrogen peroxide sterilization cycle.

However, old device IFU are not the only challenge. The *intended use or indications for use* of older 510(k) clearances and PMAs may be too general. Medical devices are typically grouped into categories. When a new category is first introduced, the intended use and indications for use tend to be broad and generalized. As the device becomes popular and new medical devices are cleared for similar uses, the indications for use for the newer devices become more specific. This gives the false impression that the older devices are more versatile than the newer devices.

Here's an example of how this can happen. In 1993, the first vaporized hydrogen peroxide gas plasma sterilizer was cleared for sale in the U.S., along with several monitoring accessories that were also considered to be Class 2 medical devices. These included items such as sterilization pouches, indicator tape and biological indicators. The indications for use of these accessories did not list specific sterilization cycles or sterilizer models; they simply stated, "vaporized hydrogen peroxide sterilization." Later, as new vaporized hydrogen peroxide sterilizers were cleared by the FDA, the monitoring accessories, cleared with the newer sterilizers, listed specific sterilization cycles and sterilizer models. The general intended use labeling of the older accessories cleared with the first units gave the impression that they could be used in all hydrogen peroxide sterilizers, which was not the case.

This can also be a problem even if indications for use have some specificity. In 1995, the first enzyme-based early-readout biological indicators were cleared. By 2012, the FDA had learned that healthcare facilities were using non-standard steam sterilization cycles and published new guidance around the clearance of non-standard steam sterilization cycles. In this guidance, references to non-standard sterilization cycles and the use of temperature and exposure time ranges were eliminated in favor of specific time and temperature conditions. This was reflected in the exposure time specificity change of the enzyme-based early-readout biological indicator cleared in 2012. **Table 2** illustrates the indications for use differences over time.

The increased specificity of newer clearances and approvals in product categories is a natural evolution. Healthcare facilities must be aware of this progression and ask critical questions when dealing with older product clearances and approvals. It can be helpful to include your supply chain professionals in conversations about the important role of IFU when selecting products and contracting for medical device and equipment purchases.

All IFU are important

Every day, sterile processing professionals use FDA-classified medical devices (washer-disinfectors, sterilizers, HLD systems, biological indicators, process monitoring devices) to reprocess other FDA-classified reusable medical devices. In a department with a mix of older and newer technologies, SPD managers who understand the bigger IFU picture can help ensure that their departments continue to appropriately select and safely use their medical devices. **HPN**

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Table 2: Example of increased intended use specificity

July 1995 Clearance First Enzyme-Based Early Readout-Biological Indicator	October 2012 Clearance After several enzyme-based early-readout products have been introduced
Indications for use: Use the [redacted] RRBI to monitor: 1. 250°F (121°C) gravity steam sterilization cycles 2. 270°F (132°C) vacuum-assisted steam sterilization cycles	Indications for Use: Use the [redacted] Biological Indicator [redacted] in conjunction with the [redacted] Auto-reader [redacted] to qualify or monitor dynamic-air-removal (prevacuum) steam sterilization cycles of 4 minutes at 270°F (1 32°C) and 3 minutes at 275°F (135°C). The [redacted] Biological Indicator [redacted] provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

CONTINUING EDUCATION TEST • MARCH 2020

Making sense of your medical device IFU

Circle the one correct answer:

1. **Which medical device classification requires approval of the instructions for use (IFU) by the Food and Drug Administration (FDA)?**
   A. Class 1
   B. Class 2
   C. Class 3
   D. Class 4

2. **Which is true of Class 1 medical devices?**
   A. Class 1 medical device IFU are reviewed by the FDA
   B. Class 1 medical devices require sterilization
   C. Class 1 medical devices include pacemakers and implantable devices
   D. Class 1 medical devices have the least amount of FDA oversight

3. **What is the difference in FDA oversight between a Class 3 and Class 2 medical device?**
   A. Class 3 devices require premarket approval whereas most Class 2 devices require 510(k) clearance
   B. Class 3 device IFU are not reviewed by the FDA but Class 2 device IFU are approved
   C. Class 3 devices have the most stringent FDA process whereas Class 2 have the easiest FDA process
   D. Class 3 devices never require clinical trials whereas Class 2 devices always require clinical trials

4. **"Manufactured for" indicates that the vendor _____.**
   A. Owns the medical device design and has a third party make the medical device
   B. Makes the product but does not own the medical device design
   C. Owns the medical device design and makes the product
   D. Does not own the medical device design nor make the product

5. **Which statement included in the IFU indicates the vendor with the most control of the medical device?**
   A. Distributed by
   B. Manufactured for
   C. Manufactured by

6. **What does the intended use provide?**
   A. Gives specific information for safe use of the medical device
   B. Provides a general description of the medical device's use
   C. Gives detailed cleaning instructions
   D. Identifies the microbiocidal process to use

7. **Why is an indication for use included with an intended use?**
   A. The intended use needs to be expanded to include other uses
   B. The device is the first in an FDA device category
   C. The device has additional warning or precautions
   D. The intended use must be clarified or limited

8. **A warning is provided when a known harm will occur.**
   A. True
   B. False

9. **Why are older device IFU challenging?**
   A. Older device IFU have very limited indications for use
   B. Older device IFU often list multiple sterilization processes
   C. Older device IFU can be missing cleaning steps or reference processes not available in the U.S.
   D. Older device IFU must be updated by the device manufacturer before they can be used

10. **The intended use or indications for use of older 510(k) clearances and PMAs may be too:**
    A. Specific
    B. Detailed
    C. General
    D. None of the above

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Shattering myths about clinical integration

by Rick Dana Barlow

Searching for quick results – in theory at least – a less experienced Supply Chain professional's perspective about clinical integration easily slips into the tactic of "showing docs the data because they're scientists" as if this is some mathematical equation on persuasive prowess.

Entrenched Supply Chain veterans, however, know that clinical integration instead calls for developing deep and meaningful business relationships with highly educated men and women who practice medicine and want to ensure their practices remain operational and reliable to care for patients. Certainly data remains a key component of those efforts.

Some contend that clinical integration extends beyond contract compliance, product evaluations and selections, value analysis and other supply chain-oriented functions. And yet it may involve all of these but not be limited to any or all.

From a top-tier Supply Chain perspective, clinical integration encompasses an acknowledgement and understanding of physician, surgeon and nursing needs, a fluid and seamless incorporation of their viewpoints in all discussions and decisions as standard operating procedure and a mutual aim to provide care services to patients.

The question lingers, however, on how deep and far does this philosophy burrow itself within Supply Chain mindsets, and if it remains shallow and near, how fast and long will forward momentum take?

Well, what is it?

Supply Chain seems to vacillate and waver on just what clinical integration means, let alone entails.

David Marcelletti, Vice Chair of Operational Excellence, Mayo Clinic, Rochester, MN, wonders whether the topical squishiness can be traced to a misunderstanding or an incorrect interpretation.

David Marcelletti

"I believe that it depends on who you ask (i.e., clinical leadership, physicians, nurses, supply chain staff, etc.) because you may get very different answers depending on their perspectives," Marcelletti told *Healthcare Purchasing News*. "It also depends on the supply chain maturity of the organization – are you embedded in the practice areas managing supplies with sophisticated processes and systems or are you a contracting and procurement organization [that] drops the supplies off at the department with little to no management at the point of use?"

Marcelletti questions physician involvement in an organization and the process.

"Are there physician leaders partnered with Supply Chain Management, Finance, and/or Revenue Cycle?" he asked. "Are business decisions made by committee, and if so, who's involved? Is Supply Chain involved in decision making recommending/partnering with the clinical practice or does Supply Chain only supply the data and the execution?"

Much hinges on credibility and the effort to achieve it, Marcelletti insists.

"As with any relationship, it takes a lot of work to establish credibility and maintain that credibility with the clinical practice," he indicated. "Clinical departments will watch and test the supply chain to see if they are truly serious about 'clinical integration' before the clinical department will go all in. A clinically integrated supply chain is not just contracting; it involves all functions across the entire end-to-end supply chain process. Clinical integration is not for the faint at heart and it does not happen overnight. Clinical integration will take years as the supply chain must establish credibility and continuously demonstrate they are a trusted partner with the clinical departments over time."

But it also could stem from differing perspectives, according to Jimmy Chung, M.D., Associate Vice President, Perioperative Portfolio, Providence St. Joseph Health, Renton, WA, and a member of *HPN*'s Editorial Advisory Board. The coin is double-sided.

Jimmy Chung

"Often, [Supply Chain Management] assumes that clinical integration means educating physicians about standardization and reduction of variation," Chung noted. "However, true clinical integration also means educating SCM professionals about meaningful clinical outcomes and how SCM/operational leaders and clinicians partner to achieve the best patient outcomes. Because SCM professionals don't have visibility or accountability for patient outcomes outside the hospital, they may not realize the total cost implications for each episode or patient."

Thankfully, Gary Fennessy, Vice President and Chief Supply Chain Executive, Northwestern Memorial HealthCare, Chicago, IL says he doesn't struggle with clinical integration at his organization.

Gary Fennessy

"For well over eight years we have had a physician adviser on our Supply Chain team to help support our initiatives," Fennessy said. "In my peer group of supply chain executives I never hear about short-changing clinical integration. Usually [I hear] more about how do we find the right individuals from the clinical side who want to support supply chain initiatives."

In fact, Fennessy fully endorses having a physician adviser integrated into supply chain initiatives. He promotes the physician as a "tremendous asset in terms of helping us understand what could the roadblocks be from the lens of the physician or caregiver," and "further provides clinical validation on assumptions and communications."

"Organizations should leverage clinical leadership whenever possible," he added.

John Cherf, M.D., MPH, MBA, Chief Medical Officer, Lumere Inc., a GHX company, Chicago, and former Chief of Orthopedics, Advocate Illinois Masonic Medical Center, Chicago, sees this as a developing work-in-progress.

John Cherf

"Health systems around the country are seeking physician leaders to support and improve clinical, operational and financial improvement initiatives," Cherf told *HPN*. "However, the industry as a whole still has a long way to go before we can declare that we are 'there yet' when it comes to operating as a truly clinically-integrated supply chain.

"I predict we will see much greater clinical involvement in supply chain activities over the next five to 10 years," he continued. "This will be driven by a heightened degree of integration between providers and pressure to act on value-based care market demands. We should expect to see physicians having a greater role in supply chain activities. This will be driven by new

payment models and the need to document value with optimal quality and cost to be competitive in an increasingly transparent marketplace."

Cherf earned 2019 P.U.R.E. designation by *HPN* for being a Supply Chain-Focused Physician. [Editor's Note: For details, visit https://www.hpnonline.com/21084729/].

Suzanne Smith, R.N., Value Analysis Solutions Advisor, Lumere Inc., remains optimistic, expressing that the two are drawing closer all the time. "From an awareness perspective, healthcare supply chain professionals have known for a long time that incorporating clinical stakeholders into their workflows is essential," Smith indicated. "There are excellent role models out there who are willing to share their learnings, but greater industrywide networking and outreach is crucial to getting hospitals even closer to this new paradigm."


Suzanne Smith

Shaun Clinton, Senior Vice President, Supply Chain Management, Texas Health Resources, Arlington, TX, bristles at the perceived hullabaloo over clinical integration's role in supply chain operations.

"The healthcare supply chain at its core is clinically integrated and to suggest otherwise or attach a term to it feels wrong," Clinton asserted. "I'm not 100 percent sure where the [point of view] comes from that says the healthcare supply chain is not clinically integrated. I don't know of a single supply chain that exists in a vacuum. Demand comes from somewhere. It is some sort of integration with this 'demand' that produces a supply chain to begin with. The question for me has always been 'what level of (and type of) integration is necessary to get the right thing to my customers?" Again — a core tenet of any supply chain."


Shaun Clinton

Clinton recalls a hospital Lean project he helped lead many years ago. "When all was said and done and we had mapped out the process from the procurement of an item to its eventual use, it became clear to everyone involved that the only real value-add step in the process was when the item was used in the provision of care. That, more than anything else, convinced me that clinical integration exists as a fact, not a goal, of the healthcare supply chain."

The clinical integration practices of Mayo and Northwestern as described by Marcelletti and Fennessy, respectively, and the assertions by THR's Clinton apparently remain well above the norm, however.

"Commonly, we see organizations that believe they are clinically integrated, yet, by our assessment, they are falling short of a truly comprehensive clinically integrated supply chain," said Daria Byrne, EdD, R.N., Vice President, Clinical and MedSurg Solutions Consulting, Intalere.


Daria Byrne

"Value Analysis, while a great step towards clinical integration, is not all encompassing," Byrne continued. "Healthcare organizations have an immense opportunity to place a strategic emphasis on a clinically integrated supply chain. So much of that simply begins with the belief that 'we can do better,' 'we should do better' and 'we can do things differently than we've done before.' Healthcare is evolving, and we need to acknowledge that the supply chain function and the clinical function are better with strategic collaboration and a mutual understanding of how both critical areas have the same goal in mind – to drive quality care."

Much depends on Supply Chain's influence within a healthcare organization and its focus on issues beyond pricing, according to Erik Axter, Managing Principal, Vizient Inc., Irving, TX.


Erik Axter

"It's easy for supply chain professionals to short-change the idea of formal clinical integration when they aren't in a position to challenge organizational precedent and inertia in the effort to reduce non-value added variation in goods and services," Axter said. "They understand that price reduction on their current mix of supplies and services will only take an organization so far, and the key to unlocking value beyond price is through clinical integration. Thus far, few health systems have truly moved beyond giving Supply Chain a savings target as opposed to setting cost and performance improvement goals at the service-line level where Supply Chain is one of many contributors. Until there is a true push to align the incentives of the physicians with that of the overall organization, they have a right to be skeptical."

Axter also acknowledges the difficulty of Supply Chain integrating itself within clinical and top-tier administration issues.

"Transforming a supply chain into a trusted partner entity within an organization is a complex and multi-step process that needs an executive-supported strategy," he noted. "It also requires an organizational investment in creating a physician decision-making body, having credible informatics for physicians that show opportunity beyond price, setting expectations for all involved so they are collectively accountable to drive performance improvement as well as a measurement platform."

With healthcare providers aiming to deliver higher-quality care at lower costs to remain financially solvent, along with value analysis and clinical integration both essential to optimizing care delivery, Supply Chain's roles during the last decade have had to evolve, observed Shannon Candio Hunt, Vice President of Academic Initiatives, Premier, Charlotte, NC. In fact, their roles and responsibilities have shifted from contract management and the logistics of ensuring adequate supplies to focusing on total cost of ownership and outcomes, she added.


Shannon Candio Hunt

"While clinical integration once called for a primary focus on negotiating the lowest-acquisition cost, today it is imperative that Supply Chain professionals broaden their roles to incorporate the total cost of ownership and outcomes, including elements such as: reimbursements, patient experience, trusting physician partnerships, organizational improvements, outcomes-driven data, key performance indicators, safety, infrastructure to manage risk, patient outcomes, and disposable and capital equipment costs," Candio Hunt said. "Healthcare providers are recognizing that unless clinical integration is prioritized, mounting market pressures may force them to act differently or close."

Further, she indicates from her research that recent information points to industry reimbursement cuts that exceed $250 billion during the next decade as inpatient revenues continue to decline.

Lumere's Cherf believes supply chain professionals see the value in clinical integration, but they often don't know where to begin to bring about the shift.

"It's highly likely they have been burned in the past when trying to institute change among physicians, do not have access to or an understanding of data that physicians need to properly engage, lack a physician champion or lack institutional incentives for collaboration," Cherf listed. "The framework for clinical integration simply has not been developed in many systems. Developing an operational process is one of the biggest stumbling blocks supply chain professionals face and must be cleared before true improvement can be achieved. The most important thing to remember is that physicians care most about improving patient outcomes – demonstrating how this can be improved through a greater degree

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of collaboration between supply chain and clinicians is key to establishing a healthy partnership."

Lumere's Smith concurs, citing "previous failures, lack of executive support, competing priorities, fear of upsetting physicians, and belief that suppliers have the stronger relationships with physicians all contribute to a lack of forward momentum," as culprits clotting process improvement.

Cutting through clutter

Clinically integrating the supply chain need not be so complicated operationally beyond personality clashes. Some teams – such as Fennessy's at Northwestern – incorporate physician advisers for active decision making. Other teams – such as Chung's at Providence St. Joseph – have physicians on staff. Still others rely on their group purchasing organizations (GPOs) that employ physicians and clinicians as consultants or other external, third-party expertise from independent consulting firms and even suppliers that have physicians and clinicians either on staff or on call.

But they shouldn't be rubber stampers, turf builders or window dressing.

"Adding clinical advisers or leaders on the Supply Chain staff is one solution but it must be done with a definite purpose, and the clinician must be aligned with organizational goals," Chung urged. "Developing an internal structure that is accountable for total value of care that includes both clinicians and SCM leaders would be more successful."

Mayo Clinic's Marcelletti recognizes that incorporating physicians in any of these ways at least advances clinical integration. After all, his organization is physician-led.

"SCM executives should seek to partner with physician leadership to do just that – partner and be seen as a trusted business adviser to the practice," he noted. "When picking a physician to partner with, it is important to select one that has the time and interest in working with Supply Chain. Mayo Clinic has experienced very positive progress by engaging physicians in a formal leadership role within Supply Chain as well as developing strong physician relationships in the practice areas that we rely on as part of the decision making process along with supply chain professionals. We have also found a big benefit to clinical integration is to move SCM staff out of the back office and reside in the clinical practice. Physical presence goes a long way to build relationships."

Intalere generally offers four initial recommendations to drive clinical integration in the supply chain, according to Byrne.

First, is to simply establish a shared purpose and common vision with key stakeholders from both functions. "Champion buy-in from all constituents and allow them to witness the strategic emphasis that has been placed on supply chain-clinical collaboration," she said.

Second, allow clinicians (physicians and nurses) to have a seat at the Supply Chain table. "Clinical subject matter experts, specifically clinicians at the bedside who are still caring for patients, should have a voice in supply chain decision making, es-

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Playing long-ball with clinical integration

What strategies and tactics can generate long-term vs. short-term improvements within an organization? Eight experts share their tips.

"Developing an internal structure that is accountable for the total value of care will establish long-term goals and accountability that includes not just supply chain but clinical quality, revenue improvement and growth. Clinical integration is a core concept that supports this strategy. A dyad consisting of a value executive and physician adviser/medical director to lead this program is essential."

Jimmy Chung, Providence St. Joseph Health

"Moving towards digital where process and systems are automated and enables content management through data capture allows an organization to advance through knowledge and information sharing. Since you can't manage what you can't measure, a tactical first step may be to focus on low-hanging fruit found in the systems/data and leverage that to gain trust with the practice. If physicians are not engaged with supply chain activity it is important to start fostering relationships with key physicians and being transparent with them. Include physicians in business decisions and educate key physicians on supply chain processes and strategies. As relationships evolve and expand these key physician contacts will become critically important in advancing key initiatives."

David Marcelletti, Mayo Clinic

"We made a decision over eight years ago to recruit caregivers into Supply Chain in the sourcing and value analysis work streams. Clinicians talking to clinicians. I often talk in terms of how many years of bedside experience we have working in supply chain. It creates a different dynamic in terms of how we approach initiatives, etc. Further, it provides a level playing field in terms of discussion with the decision makers or our customers. When we talk about standardizing a particular class of spend we have our value analysis clinician talking with another clinician. It eliminates one conversation right off of the top: 'You are not a caregiver and you do not know what you are talking about.' We still have some of the same challenges that are typical of any standardization initiative, but we advance things faster from my perspective and gain a lot of credibility with the process from the start."

Gary Fennessy, Northwestern Memorial HealthCare

- "Align products and services that will improve your organization's key performance indicators such as mortality, length of stay and EBITA.
- "Have a defined project management process to enable success with clinical integration. Value analysis committees that follow these steps for all initiatives tend to have the most success: Identification, Gathering Information, Analysis, Implementation, and Monitoring.
- "Create a fluid pipeline of project opportunities to identify opportunities to standardize, starting with low-hanging fruit and building toward items that require clinical evaluation such as physician preference items. Leverage your GPO data to create this pipeline and prioritize opportunities by initiative status using categories such as contracts and new technology, building toward standardization to improve continuity of care.
- "Set up decision-making meetings with defined roles and responsibilities that help track progress in product evaluation. Key groups include the Executive Steering Council, Enterprise Value Analysis Committees and Value Analysis Sub-Committees. Without a structure and defined roles, providers risk that key product decisions that will not be made in the short- or long-term, resulting in a product or process change that is ultimately not sustained.
- "Identify key champions by department and include them in the decision-making process. Empowering them to own the education of their peers is extremely helpful in the adoption of new items.
- "Leverage manufacturer relationships and evaluate a manufacturer's full line of products. Bringing in a suite of products from one manufacturer often results in a better price, which bolsters the organization's financial health.
- "Communicate and collaborate. Constant communication keeps information top-of-mind, while a consistent meeting cadence enables clinical integration success with prompt review of the pipeline. My recommendation is that executives meet at the high-level Executive Steering Council monthly; the supply chain value analysis team meets weekly; and the Enterprise Value Analysis Committee, which includes department champions, supply chain, distributors, GPO and quality, meet biweekly."

Shannon Candio Hunt, Premier

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pecially when decisions impact the delivery of care," she recommended.

Third, both functions need a solid foundational understanding of the other. "When onboarding new employees, especially clinicians not familiar with the supply chain function, they need to be introduced to the inextricable link between supply chain and clinicians," she said.

Finally, [facilities] need to acknowledge that novice clinicians who comprise a significant population of the clinical staff may not be familiar with the supply chain function at all. "We need to emphasize a clinically integrated supply chain culture as we onboard and discuss processes on clinical units allowing these impressionable minds to understand that without one another, we cannot provide safe, quality care," she added.

Vizient's Axter acknowledges that each organization remains unique in how its clinicians interact with supply chain but the path toward mutual visibility and support can be closely tied. "It's an effort that requires diligent planning with the long-term objective clearly defined, broadly communicated and supported by senior leadership," he indicated.

Still, a typical pathway, according to Axter, starts with developing a thoughtful supply chain transformation strategic plan that often includes the following critical elements:

- Internal assessment of supply chain talent, operations, data capabilities and foundational elements to support a paradigm shift
- Crisp alignment with an organization's overall strategy
- Visibility and support from the executive team
- Scalable data capabilities to provide comprehensive total cost, outcome and economic informatics to support informed decision making
- Consideration for incentive alignment from the clinical enterprise
- Diagnostic clarity on what's currently in place and how to re-shape, re-structure or re-build entirely

Axter recommends demonstrating to the organization that a sound plan exists as the first step. Next, ensuring credible informatics to fuel the performance improvement conversations beyond price should be second. Finally, it's imperative that the organization is told and knows that these efforts are designed to achieve "non-value-added variation reduction," he advised.

"Establishing the right structure, data, process and expertise for your organization is essential, and this is where assistance from clinical integration experts outside of your organization can be helpful," he said. "They have seen what works and what doesn't based on a unique environment or culture and can help facilitate and expedite results. They can also help craft the messages, set unbiased goals and targets and drive sustainable performance improvement measures."

Hospitals needing to reduce costs safely while improving outcomes is quickly becoming standard operating procedure, according to Premier's Candio Hunt. That's why clinical integration efforts must extend beyond products.

"Supply chain purchases typically account for 15-30 percent of hospitals' operating expense," she noted. "According to market research, more than 10 percent of this spend could be cut through a successful value analysis program focused on improving standardization and utilization management. Premier is seeing clinical integration yield cost-savings and stronger organizational alignment when these multidisciplinary value analysis teams, which include physicians, expand their scope outside of just products and services, focusing on overarching improvement opportunities." HPN

***Playing long-ball with clinical integration**, continues...*

"For short-term improvements, it's important to be transparent about what the change is, why it's necessary and what the expectations are. C-suite leaders must set the tone across the organization and acknowledge that there will be some initial growing pains in order to unlock dramatic improvement over the long-term.

"Everyone must understand that just focusing on pricing within the supply chain is no longer where the big savings can be achieved. To be successful the organization must now focus on standardization, utilization and the elimination of unnecessary clinical variation in care.

"Short term and long term, it's important to make this about the patient. If everything you do is with the focus on quality and safety and what's best for the patient, and you truly embrace that as an organization, improvements will come and everyone can be aligned behind the goals of improved patient care.

"It is also important to remember that change-management principles are at play with this process and publicizing 'quick wins' is essential, along with recognizing those individuals who are demonstrating the new organizational strategy in action. Doing that will help sustain momentum."

Erik Axter, Vizient Inc.

"Modification of culture and change management principles reinforce long-term adoption of behaviors. Reinforcing the importance of a relationship between the supply chain and the clinical staff will withstand staff attrition and time. If healthcare organizations embed collaborative processes within care delivery with all reinforcing a culture of teamwork across functions, then behaviors and processes are carried down and exhibited by all members of the organization. In essence, the culture becomes rooted deep within the organization. From a leadership perspective, it begins at the top and trickles down.

"Creating a standard operating procedure or a new policy and educating the team on that policy one time will reinforce a culture of short-term acceptance. Having a nurse or physician serve as an adviser to the supply chain staff, but not allowing them to garner feedback from the bedside or educate their peers on the importance of collaboration will result in less than desirable results. The appearance will be there, but the results will not."

Daria Byrne, Intalere

"In the short-term, supply chain leaders should develop a system that meets the needs of both supply chain and clinicians. Putting processes in place will provide a foundation to tackling future supply chain challenges. I firmly believe that 'if you build it, they will come.' However, the evolution of this system will be an ongoing work in progress.

"For long-term success, it's imperative to embrace collaboration between supply chain and clinicians. Building a strong foundational partnership will take time. In order to do this, both parties must recognize that each one has something to learn from the other. Physicians are long on clinical expertise but often do not understand the supply chain space whereas supply chain professionals are strong in supply chain knowledge but short on clinical expertise. Both parties need to educate the other to optimize supply chain management. This won't happen overnight."

John Cherf, Lumere Inc.

"For long-term success, it is all about building relationships – not just with physicians. It is essential to partner with suppliers, executives and other key clinicians in order to sustain the desired outcomes. Cementing yourself as a trusted resource who understands the importance of being reliable and accountable will go a long way with these partners. The best approach in the short-term is not to change everything at once. Leverage key relationships, develop a plan using a repeatable process and build on success."

Suzanne Smith, Lumere Inc.

Charting supply chain success with clinical integration

Healthcare organizations that have progressed with clinical integration have generated notable success stories. Eight experts recount their wins.

"We initiated a project to provide high-quality and efficient anesthesia care while reducing the greenhouse effect of anesthesia gas agents. We did this by using cost and usage data that showed significant variation across our system, and reducing the use of desflurane, which is more expensive and worse for the environment without any proven added benefit to the patient. Achieving this integration required both education of physicians on the cost and harmful effects of desflurane and working with [Supply Chain Management] to renegotiate with the vendor to avoid the initial penalty of not meeting contract obligations. Essentially, reducing the use of desflurane was better for the planet but worse for contracting because of the terms under renting the vaporizers and gas purchasing commitments. Bringing the clinicians and SCM to the conversation together helped achieve our goals of doing the right thing and recalculating the true total cost of care."

Jimmy Chung,
Providence St. Joseph Health

"We have proven success in utilizing a clinically integrated approach across several contracting categories. We have physicians participate as subject matter experts during the early contracting stages, which brings in the clinical perspective and expertise. Following contract launches we utilize our physician partners through implementations. Peer-to-peer discussions are very effective when discussing outcomes and removing barriers. Through a clinically integrated approach we have expertise on the business side as well as the clinical/provider side. This model has allowed us to move market share across various categories where in the past these changes have proven to be very difficult. Actively engaging champion physicians and other clinicians into the decision making and implementation processes has expedited the change management required to ensure success across all our campuses. Lastly, having physicians and nurses employed within Supply Chain bridges the clinical/business language gap and ensures key stakeholders' voices are heard."

David Marcelletti, Mayo Clinic

"Over the past 18 months we have changed our structure for value analysis in a very rapid manner. We handed decision making to our clinical leadership through seven value analysis committees that act on behalf of the entire system: Cardiac, Vascular, & Thoracic; General Medical Products; Orthopedics; Interventional Labs and Diagnostic Imaging; Surgery and Subspecialties; Neurosurgery and Spine; and Lab.

"Achievements include:

- Program launched in March 2018
- Committees have the autonomy to drive decisions for the Northwestern Memorial System
- Transformed from a regional model to a system model within one year
- 73 percent of committee members are actively practicing physicians or clinicians
- [Established] enhanced decision making efficiency through reduction in approving bodies from multiple committees to a single system
- Provide timely feedback within 25 days from request for a new product introduction, resulting in continued physician engagement
- Achieved significant savings that exceeded the budget and funded new product introductions
- Improved supply portfolio standardization to 35 percent from 7 percent."

Gary Fennessy,
Northwestern Memorial HealthCare

"Premier worked with one if its member health systems, a multi-hospital, fully integrated academic center, [which] had more than 500 projects in its pipeline, including commodity items, purchased services, pharmacy and financial services, among others. [The system] reviewed the total cost of ownership for neuromodulation products and services in its value analysis committee and discovered improper coding for this procedure. By utilizing its value analysis committee not only to analyze products, but also reimbursement, the hospital was able to save $1.2 million. By helping the system prioritize opportunity areas, Premier enabled the provider to save $35 million in a year with a strategic focus on non-labor expense reductions."

Shannon Candio Hunt, Premier

"As a performance improvement partner to our membership, we are routinely involved in working with organizations as a trusted adviser helping to establish the appropriate integration of data, physician/clinical alignment, infrastructure, strategic planning and supply chain's role in the effort. One example that comes to mind is an academic medical center in the West. Its supply chain leaders understood the financial and market trends as well as insight into the unique and specific objectives of their C-suite. The CFO was looking for savings to meet looming payer-mix changes, the CMO and CNO wanted a meaningful way to engage clinicians in organizational transformation, and the COO was seeking a programmatic and sustainable approach that could evolve over time as the central platform for performance improvement. In this example, the Supply Chain leader was able to build a plan that aligned with the organization's executives and engaged mid management and front line employees in the organizational performance improvement program. The model incorporated all of the critical elements of talent, data, accountability and clinical integration and started generating results immediately. Success has bred expectations and greater involvement, and the organization continues to leverage and expand the platform going into their third year."

Erik Axter, Vizient Inc.

"We have consulted for organizations [that] have immense supply chain waste. Missing charges, lost inventory (i.e., things going home with nurses in scrub jacket pockets), and products wasted due to unfamiliarity resulting in potential patient harm, etc. After obtaining an initial understanding of the existing supply chain-clinical collaboration, we made recommendations to improve processes and provide education to close the knowledge gap for clinicians on supply chain, and for supply chain personnel on clinical workflow. Through education and exposure to supply chain principles and clinical workflow, we see a greater appreciation for the complexity of the roles by the other. For the clinician, a greater understanding of the selection, obtainment, purchasing, and logistics of medical supplies necessary to provide the utmost care for patients. For the supply chain, an appreciation of the clinician's workflow, and the impact, for example, on how one small supply chain can disrupt care delivery. Both functions begin to view the other through a more appreciative lens. As collaboration ensues, compliance increases."

Daria Byrne, Intalere

"In 2003, I helped found the orthopedic department at a private orthopedic surgery/neurosurgery specialty hospital in Chicago. As a startup, we were very sensitive to cost but also needed to provide physician preference items (PPI) to encourage orthopedic surgeons and neurosurgeons to work at our institute. I frequently worked with administration and purchasing to control supply costs for both outpatient and inpatient neuromuscular care. We ensured over-communication to our clinical staff about our decision-making, and this helped ensure physician buy-in. Much of our success was based on respectful collaboration between strong clinical leaders. In this situation, [an] R.N. director was invaluable in bridging the gap between traditional supply chain and clinicians."

John Cherf, Lumere Inc.

"In my previous role as a Value Analysis Director, I was responsible for working directly with physician leaders on large PPI sourcing initiatives. We had a process that was transparent and engaged physicians from day one. A successful project that comes to mind was for GI Lab products. I developed an excellent working relationship with the service line medical director, and he partnered with us every step of the way from reviewing spend data and clinical cross references to establishing rules of engagement with our suppliers and gaining the support of his peers. The result was an 85 percent conversion to the awarded supplier and more than $300,000 in savings in year one. His leadership not only helped pave the way for a smooth conversion, but this contract is still supporting product standardization four years later."

Suzanne Smith, Lumere Inc.

From regulation to recalls: Why implant informatics matter

by Karen Conway

One of the primary purposes of the Food and Drug Administration's (FDA) unique device identification (UDI) rule was to improve recall management, especially for implantable devices. But confusion over how implants are defined, classified, used and documented could result in hospitals being unable to effectively identify patients who may have been adversely impacted by a recalled device. That despite regulations from both the Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare and Medicaid Services (CMS) that require capture, storage and sharing of UDI-related data for implants in electronic health records (EHRs) and other technology.

In this month's column, we will review the various issues and challenges, many of which have come to light as the result of continued work by members of various Association for Healthcare Resource & Materials Management (AHRMM) Learning UDI Community (LUC) work groups.

Supply vs. Implant documentation

For most healthcare systems, the item master (on premise or cloud-based) serves as the primary source of product data for EHRs. Products that are flagged as implants trigger those responsible for clinical documentation to include not only the UDI-DI (device identifier) but also the UDI-PI (production identifier) such as lot, serial number, expiration data in the patient record. Supplies not flagged as implants do not have this additional information recorded, and sometimes are not documented at all.

Once a determination is made and implant status is noted in the item master and made available to the EHR, it can be difficult for hospitals to change the status. Some systems allow an override, but that can also create further variation in how implants and associated data are managed.

Identifying implants

There is not a specific implant flag in the FDA's Global UDI Database (GUDID) that indicates if a product is an implant, but there is a field for a procode, which manufacturers assign to their products during the regulatory approval process according to an FDA classification system. Those codes determine which pathway a product goes through to receive market clearance. You can download the procodes from the FDA website and see additional attributes including implant flags. An API on the accessgudid.nlm.nih.gov website also enables you to download a list of products with implant flags based on the procodes, although there are some inaccuracies in the data.

Problems arise when an assigned procode incorrectly identifies whether a product is an implant or not. For example, former Shock Trauma Implant Coordinator Trent Pierce found a product that contained no drugs had been assigned a procode for a medication vs. an implant. Some LUC members have convinced the FDA to correct such errors, while others have been unsuccessful, suggesting inconsistencies in FDA processes to report and request corrections.

Classification counts

The Device Classification and High Risk Implant LUC work groups recommend use of the Global Medical Device Nomenclature (GMDN) as a better taxonomy for implant identification. A required field in the GUDID, the GMDN code is assigned by manufacturers based primarily on the approved use of a device but it can also reflect actual use; unlike procodes, GMDN codes can be changed by the manufacturer without regulatory implications.

A common, but mistaken practice in many hospitals is to use the United Nations Standard Products and Services Code (UNSPSC) to designate if a product is a supply or implant. While there are codes for various medical implants, e.g., surgical, cosmetic, orthopedic, UNSPSC was designed to support spend analysis in e-commerce and not designations of clinical use.

Variation in product use

One of the biggest challenges in determining whether a product is an implant has to do with variations in how products are used, e.g., if they stay in the body and for how long. The U.S. FDA definition of an implant is as follows:

"A device is regarded as an implantable device for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner of Food and Drugs determines otherwise in order to protect human health."

In practice, some devices that are *intended* (by the manufacturer) to remain implanted for 30 days or more are removed sooner. As an example, K-wires are used to stabilize bone fragments. While often removed after the bone has healed, they are intended to stay in the body for 30 days or longer. Other times they are used only temporarily during surgery. In such cases, the K-wire, while originally intended for longer implantation, may be documented as a supply and not recorded with UDI-PI or at all, in the patient record.

In other cases, implanted products are designed to be absorbed by the body, often faster than 30 days, but they may remain intact in the body longer than anticipated, sometimes causing complications.

Combination products create further confusion. For example, there are separate procodes for bowel staplers (classified as supplies) and the staples that remain in the body (and classified as implants). But what about a stapler that is preloaded with staples? As noted above, how products are flagged – implant or not – designates the level of downstream documentation and the ability to follow up with patients if there is an adverse event or recall.

Recommendations

Despite these challenges, the promise of using structured and standardized product identifiers to improve patient safety remains. With the highest risk recalls on the rise in recent years (more than a 64 percent increase from 2016 to 2017), overcoming these challenges should be a priority.

The Recall LUC work group is tackling some of these issues, and several LUC members offer these unofficial recommendations:

STANDARD PRACTICES

1. If in doubt as to whether an implantable product will be in the body longer than 30 days, err on the side of caution and document it as an implant. In the event of a recall, it is easier to rule out patient exposure than to potentially miss identifying an impacted patient.
2. Help clinical staff understand the value of fully documenting implants to increase patient safety.
3. Promote the use of scanning to reduce the time clinicians spend on supply documentation. Scanning takes as little as eight seconds compared to up to nine minutes for manual documentation.
4. Create mechanisms for front line staff to report problems with implant designation, and request the FDA provide guidance on how best to resolve such issues.
5. Join the AHRMM Learning UDI Community (www.ahrmm.org/luc) to learn about best practices and offer your own input to accelerate UDI and value. **HPN**

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

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Managing medical device security risk starts with Supply Chain

Make it 2020 vision before it becomes 2020 hindsight

by Clyde Hewitt

Over the past decade, many technological advances have improved how we deliver healthcare. Technology now automates many previously manual processes and connects information directly from the bedside into caregivers' hands. Medical devices can integrate into the electronic health record (EHR) and can move critical patient information quickly. Radiology systems make images available on many different devices, including mobile phones and tablet computers. This rapid acceleration of information sharing has improved efficiency and care, all while reducing medical errors. This technology also has enabled better care with leaner staffing.

That same technology – especially medical devices – has introduced serious security risks. These unique security challenges cannot be solved by the Information Technology (IT) department alone. They require a team approach, and the first steps on building a solid security foundation is the responsibility of the procurement team.

What are the risks?

It is easy to assign medical device security risks to the hospital's Information Security Officer (ISO). After all, IT manages the computers, and medical devices are just another computer. These assumptions can lead to a disaster for several reasons. First, many hospitals have not assigned responsibility for medical devices to the Chief Information Officer (CIO). This leaves a management gap that often leaves critical tasks undone. Second, some hospitals have outsourced the management of their medical equipment or departments like radiology, laboratory and pharmacy to third parties, leaving an accountability gap between what the hospital is responsible for and the vendor/third party.

These are challenges, but the ultimate barrier to good medical device security is the inherent nature of the devices. For example, IT departments typically have a technology refreshment program with workstations being replaced every four years (give or take) and servers/network components every five to seven years. Medical devices are kept much longer, with some in excess of 15 years as not uncommon. The operating systems in these devices are many years past end of life. By comparison, on January 14, 2020, there was a shock wave across the sector, as an estimated 71 percent of medical devices still run on Windows 7 and Windows Server 2008, both of which reached their end-of-life support. Future software updates will not be available.[1]

While this disturbing revelation generated a lot of media attention, medical devices actually have been running with obsolete and unsecure software for decades. Manufacturers are not forthcoming to disclose their software bill of materials (SBOM) so new equipment is still being shipped with Windows 7 embedded, even though the software won't be patched.

Supply Chain's reaction?

The impacts of unpatched devices can be devastating to providers. In November 2019, Roosevelt General Hospital discovered ransomware on their radiology devices.[2] Reacting to these incidents should have begun before the contract award, during the request for proposal (RFP) process. It is only then can healthcare entities outline the security responsibilities with which each vendor must comply.

Please note that language like "industry best practice" in the security section is meaningless, especially when you consider that 13 out of 14 organizations failed the government's HIPAA desk audit. The average "best" just isn't good enough as 30 percent of all healthcare breaches have been traced to a vendor's weak security controls.

Diving into the specifics

So how can the procurement community support the medical device security challenge? First, all RFPs should include a requirement that vendors provide a SBOM for every device sold, as well as the date for the software's end of life. It would also help to obtain a commitment that future software versions will be supported. As Microsoft typically provides support for 10 years post-launch, there is no reason medical device manufacturers could not eventually meet this same threshold. Decision makers can use this information to select the product with the best chance of being supported long-term, indirectly supporting a secure environment.

Second, vendors that require internet access to their devices for remote diagnostics, management and even operations should be held to the same security standards as other critical cloud providers – perhaps those that host the EHR. These persistent connections into a hospital's networks are prime targets for hackers. We have seen multiple instances now where attackers first compromise a third-party vendor, then leverage the direct connections to infect providers. The December 2019 attack on Complete Technology Solutions[3] impacted 100 providers. Further, healthcare providers saw a 60 percent increase in attacks in 2019.[4]

Finally, procurement executives need to actively participate in the security and privacy governance committees. The best defense starts before the contract is signed. HPN

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