A HEALTHTRUST PUBLICATION

The Source

FIRST QUARTER 2019
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SAFETY FIRST

HealthTrust and many of its members champion a vendor credentialing standard that addresses safety and regulatory issues

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MAKING SURGERIES SAFER

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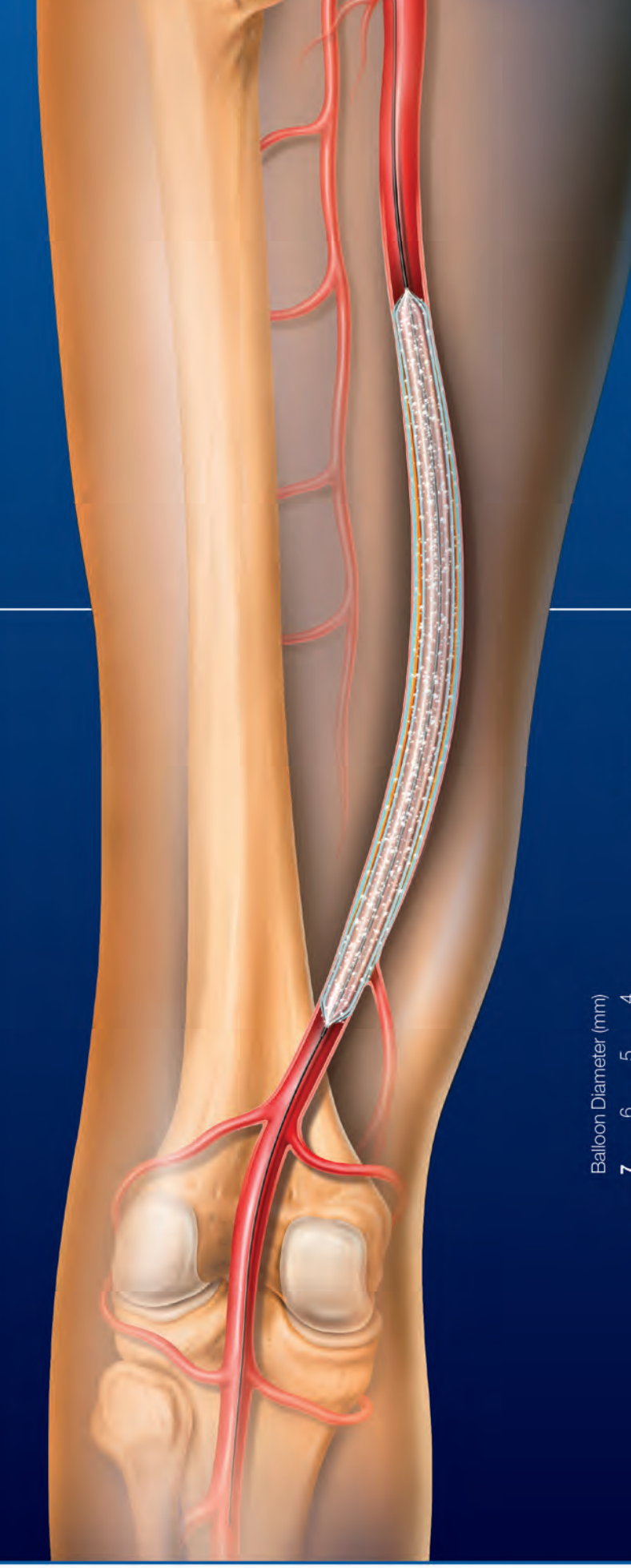

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On the Cover:
Tracy Cleveland

Photography by
Jeff Kowalsky

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HealthTrust is committed to strengthening provider performance and clinical excellence through an aligned membership model, and the delivery of total spend management advisory solutions that leverage our operator experience, scale and innovation. Headquartered in Nashville, Tennessee, HealthTrust (www.healthtrustpg.com) serves approximately 1,500 acute care facilities and members in more than 32,500 other locations, including ambulatory surgery centers, physician practices, long-term care and alternate care sites.

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Flashback to 1999

Reflecting on 20 years of foundational history & business growth

Rewind to 1999 and what do you remember most? Notably, Bill Clinton was halfway through his second term as U.S. president, Columbine became a name forever etched in our hearts, and technology experts were warning us about the Y2K bug and its perceived impending doom on computer systems as we transitioned from the 20th to the 21st century. Personally, I was the father of one small daughter with a second one on the way. I was also preparing to move my family from Richmond to Nashville after assuming a role as one of HCA's vice presidents of supply chain.

BUILDING THE BUSINESS

The last year of the 1990s also marked the creation of HealthTrust. While the healthcare GPO industry already existed, founding CEO Jim Fitzgerald put a stake in the ground from the beginning that one of the organization's founding principles would be member participation in advisory boards. Not only was that decision industry-differentiating, but my predecessor recognized it as one of the most important factors in our long-running success.

At the time, HCA made the decision to spin off LifePoint and Triad. As the senior executive of supply chain, Jim and his team were exploring ways to continue to aggregate the purchasing power of all three IDNs, which historically delivered the industry-best pricing they had obtained as an HCA collective. This was a very important component because it laid the foundation to successfully transform the supply chain from a sourcing function to a total spend management organization.

In addition to supporting the three founding healthcare providers (HCA, LifePoint and Triad), a longer-term goal became expanding the GPO with other organizations that shared a vision and culture of improving both patient care and operations. We are proud to have expanded HealthTrust's membership to now include more than 1,500 of the most dynamic and esteemed healthcare organizations that still share that vision.

The other signature feature that remains inherent to our DNA is the model for committed purchasing. While competitors have tried to emulate our aggregation strategy over the past 20 years, none has the track record of successfully and consistently delivering significant speed to value. Fast forward to 2019, and the success of that business model has stood the test of time. (Last year, HealthTrust exceeded $40 billion in aligned spend.)

EXPANDING TO MEET MEMBER NEEDS

I was honored to join HealthTrust in 2008, first as its chief operating officer, and then as its CEO when Jim retired in 2012. In more recent years, our business model has expanded beyond group purchasing to assist providers in meeting the requirements of an increasingly complex healthcare environment. HealthTrust's total spend management solutions now also include consulting and data and analytics capabilities to positively impact provider supply chain, clinical integration and workforce initiatives.

Our daily accountability to the nation's leading health systems provides us with industry-leading benchmarks and best practices in service line leadership, shared services management, physician engagement and innovative pilots. This "operator advantage" informs every assessment and recommendation we make to help providers achieve improvements in costs, quality and outcomes. It also affords our members access to a rich community of colleagues for learning and knowledge sharing opportunities.

CELEBRATING 20 YEARS

The official acknowledgment of our 20-year milestone will commence in the first quarter with the publication of an inaugural annual report. We look forward to commemorating our platinum achievement throughout 2019, including an in-person celebration with member attendees during the HealthTrust University Conference, Aug. 12–14, in Nashville.

As we envision the future, I look forward to hearing your thoughts on advancing our collaboration to meet the needs of your progressive organization over the next 20 years!

Ed Jones
President/CEO, HealthTrust

Share your success stories throughout the year. Contact the executive editor of *The Source* (**faye.porter@healthtrustpg.com**) and let us know how HealthTrust is helping your organization meet its cost, quality, outcomes and initiatives.

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HealthTrust contract #6629

My First Year in Retrospect

I suppose the grace period for saying "I'm new" is drawing to a close, considering I will have completed my first year as HealthTrust CMO by the time you receive this Q1 edition. It has been a privilege to meet so many of you in person and collaborate on strategies to advance your organization's clinical agenda.

The holy grail of a clinical integration strategy is the ability to obtain evidence regarding safety and product effectiveness combined with an analysis of clinical, financial and operational impacts. In many contract categories, we are providing members with that information so their discussions can evolve from preference dialog to fact-based conversations that can be aligned with their organization's clinical and economic objectives.

Paramount to my team's commitment to helping members achieve a clinically integrated supply chain is data. As I mentioned previously in this column, internal clinical data and analytics capabilities are in the process of review and restructure. This will enable us to leverage the collaboration of both personnel and data sources as we continue developing an integrated and aligned clinical services team and data solution. While there are many miles to go, I'm proud to report our first major deliverable was realized the third week of January when we provided our equity members with analytic dashboards for 18 clinically relevant patient population groups for facility comparison around national and regional benchmarks.

5 AREAS OF INFLUENCE

As I travel with the leadership team for member and prospect meetings, rather than focus on the individual groups within Physician Services, I've found it helpful to summarize the work of my team in terms of how we support the HealthTrust membership.

1. Informed Purchasing | Aggregate clinical evidence and outcomes research in partnership with respected physician feedback, obtained from HealthTrust Physician Advisors, to make recommendations to advisory boards for adding clinical products to HealthTrust contract portfolios, enabling members to transform product discussions from preference-based to fact-based

2. Knowledge Building | Develop education, publications and other resources to keep members on top of relevant healthcare issues as well as create awareness of new technologies and important FDA product updates

3. Access to Innovation | Vet new technologies for presentation during HealthTrust's Innovation Summit. Member clinical, supply chain and operational advancements and ingenuity are recognized annually with a Member Innovation grant

4. Share Successes, Fill Knowledge Gaps, Improve Efficiencies | Sponsor live summit events, webinars, courses and *The Source* magazine to encourage member information- and best practice-sharing as providers develop strategic and systematic approaches to key clinical, supply chain and operational challenges

5. Positively Impact Cost, Quality & Outcomes Initiatives | Combine best-in-class consulting, evidence-based solutions, clinical analytics and technology to enhance provider service line performance. Improve outcomes and lower service line costs with targeted forensic analysis to ensure providers reduce practice variation and enhance utilization and standardization

I look forward to providing additional updates on these areas of influence as I embark on year-two of my tenure and the deliverables mature. Members are welcome to contact me with feedback regarding their clinical agenda and how my team can assist via thesource@healthtrustpg.com.

PROGRAM RESULTS

Physician Advisors – HealthTrust's Physician Advisors program was restructured over the last year to include four inaugural councils—Surgery, CV, Ortho/Spine, Wound Care—in addition to ongoing ad hoc groups on topics related to upcoming contract renewals. Building on the work of my predecessor, we have grown the program to 160 physician advisors in more than 30 specialties/subspecialties, representing 31 health systems. One of the areas of focus in the next few months will be in establishing a steering committee, made up of chief medical officers from across the HealthTrust membership. This committee will determine priorities and uncover alignment opportunities with the Physician Advisor program. Such expertise might be directed toward expanding our clinical research agenda or providing input for Clinical Evidence Reviews and contract sourcing projects for categories outside of physician preference items.

Clinical Evidence & New Technology Reviews – I hope you are utilizing the Clinical Evidence Reviews (CERs) and New Technology Reviews available

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Continued from page 6

through our member portal to assist in physician alignment on key product categories within your facility or healthcare system. These reviews cover multiple service lines and 33 product categories. They are part of a library that also includes a summary of FDA activities related to new or updated product and technology approvals and recalls that is updated monthly.

CE-based Education – Clinicians and colleagues throughout HealthTrust member organizations are invited to regularly take advantage of the continuing education-based, live webinars in various disciplines sponsored by HealthTrust throughout the year. These are promoted through **www.healthtrustpg.com/education** and *The Response* and *Education Update* newsletters. Last year, more than 4,100 continuing education credits were provided free to HealthTrust members through live webinars, summits and the HealthTrust University Conference.

Consulting Services – A number of members engaged our inSight Advisory cardiovascular service line consultants for process improvement work where we overhauled and implemented sustainable processes to review complications and mortality; applied processes for adequate risk assessment of patients; addressed root causes around high RN turnover rates in critical care units; developed protocols to ensure consistent use of evidence-based, standardized order sets; and, established training and processes for hospitalists to have sufficient knowledge of care paths and patient flows.

More than 40 facilities took advantage of our "Total Joint and Performance" dashboards. Healthcare systems involved in those consulting engagements observed the following impactful decreases in length of stay:

- Total Knee Replacement – 5.7%
- Total Hip Replacement – 8.9%
- Lumbar Spinal Fusion – 1.4%

insight Advisory consulting:

- $21M in savings realized through medical device custom sourcing engagements across 10 IDNs in 2018
- $8.5M in potential savings identified through medical device management consultative engagements across 3 IDNs in 2018

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HealthTrust Contract #7738

EXTENDING CAPITAL INVESTMENTS

How HealthTrust Helps Hospitals Reduce Equipment Expenses & Increase Value for Capital Purchases

Hospital leaders have a mounting list of priorities on which to focus—from navigating changing regulatory demands and reimbursement models to managing razor-thin budgets. These time-strapped leaders often put facility issues on the back burner until they reach a crisis level or start negatively impacting patients or staff.

With equipment costs rising and tariffs increasing the price of devices imported from China, hospitals can no longer afford a reactionary approach. The sooner they can plan for purchases as well as the repair and replacement of equipment as it reaches the end of its life, the better value they can find.

"If we encourage hospitals to be more proactive, HealthTrust can help make their investment go a lot further," says **Jeff Woodyard**, vice president of capital equipment services at HealthTrust.

Jeff Woodyard

Hospitals can benefit from a dedicated team of HealthTrust experts who understand the life cycle of equipment and how to maximize their capital investments at each stage. Below are six ways HealthTrust assists hospitals in getting equipment expenses under control.

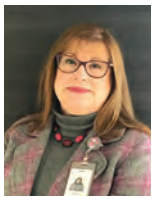
1. Provide visibility. HealthTrust helps hospitals evaluate their most immediate needs, assess their inventory and determine the best route for financing. For example, one hospital saved thousands of dollars after the capital equipment services team advised buying rather than renting expensive equipment.

"The facility was spending $300,000 a year to rent a piece of equipment, but they were able to purchase it for $150,000—and it paid for itself in six months," says **Dan Schweinhart**, a capital equipment services director at HealthTrust.

Dan Schweinhart

The team also works to uncover the total cost of ownership, including additional fees for equipment-related needs such as utilities or preventive maintenance, and budget accordingly.

"We want hospitals to spend capital dollars on capital equipment, not on extended warranties or service agreements," says **Paula Branson**, a capital equipment services director at HealthTrust. "We can help them put the right items on their capital budget and designate the rest as part of their operations budget."



Paula Branson

2. Strengthen the input of stakeholders. Typically, capital planning falls on one or two people who may have a limited view of needs across the organization or lack the clinical or technical insight to make the best decisions for all stakeholders. HealthTrust works with hospitals to bring clinicians to the table when choosing medical equipment to purchase. "We try to right-size the buy and bring some clinical intelligence into these conversations," Schweinhart says.

The team also helps hospitals gather input from stakeholders across departments, from finance directors and biomedical engineers to IT personnel. "We make sure the right people within the health system are talking to each other," says **David Heider**, a capital equipment services director at HealthTrust. "If we can coordinate those conversations on the front end, we can help them feel more confident in their purchasing decisions."

David Heider

3. Facilitate group discounts. Hospitals base equipment purchasing decisions not only on cost and clinician preference, but also on their own organizational standards and habits, Branson adds. A facility in California may make capital decisions very differently from a hospital in Florida, for instance. HealthTrust has the advantage of working with health systems across the country, giving its team a bird's-eye view of what works best where, what suppliers are quoting and how to negotiate the best deals for different types of equipment.

"There are many opportunities to both aggregate spend and discover savings on clinical equipment that hospitals may not be aware of," Schweinhart explains. Through its Capital Equipment Group Buy Program, HealthTrust helps members maximize these opportunities. "If we know what members are buying or thinking about buying in 2019 (and beyond), we can make adjustments to our annual group buy calendar to accommodate their needs," Woodyard adds.

4. Prepare for technology challenges. With the growth of connected medical devices and remote patient monitoring systems, hospitals must be vigilant about cybersecurity and take the right steps to protect patient data from hackers. HealthTrust has its own team devoted to discussing these issues with manufacturers and negotiating cybersecurity and data integrity standards on behalf of members. (*See related story on page 20.*) HealthTrust also has IT experts on hand to help hospitals sift through the massive amount of new technologies and devices on the market

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[1]Safdar N. Maki D.G. The pathogenesis of catheter-related bloodstream infection with noncuffed short-term central venous catheters Intensive Care Med. 2004; 30:62-67

PATIENT CARE ENVIRONMENT OF CARE **INTERVENTIONAL CARE**

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to find the most interoperable platforms. "We vet this kind of equipment so hospital leaders don't have to," Schweinhart says.

5. Find creative alternatives. When equipment breaks, most hospitals rush to draft a budget for new capital. But HealthTrust can help brainstorm options for solving these issues without breaking the bank.

For example, if a hospital has an IV pump with a door that keeps breaking off, "maybe they can provide some training for those using it or put some procedures in place to make it last longer and reduce the cost of the damage," Schweinhart says.

Training is much cheaper than investing in new equipment, and hospitals can often find workarounds that meet their needs just as effectively. If an OR director requests a new $100,000 sterilizer, for instance, the hospital may instead be able to save $75,000 by investing in a new decontamination sink and extra carts.

"Sometimes a hospital doesn't need more equipment—they need something to help them improve the process and build in efficiencies," Branson says.

6. Redeploy capital assets. The majority of hospitals have a closet or a corner of a warehouse where they take equipment when it reaches the end of its life, and it usually sits there for years. "We're working on getting more suppliers on contract who will come in and write a check for those kinds of items," Branson says.

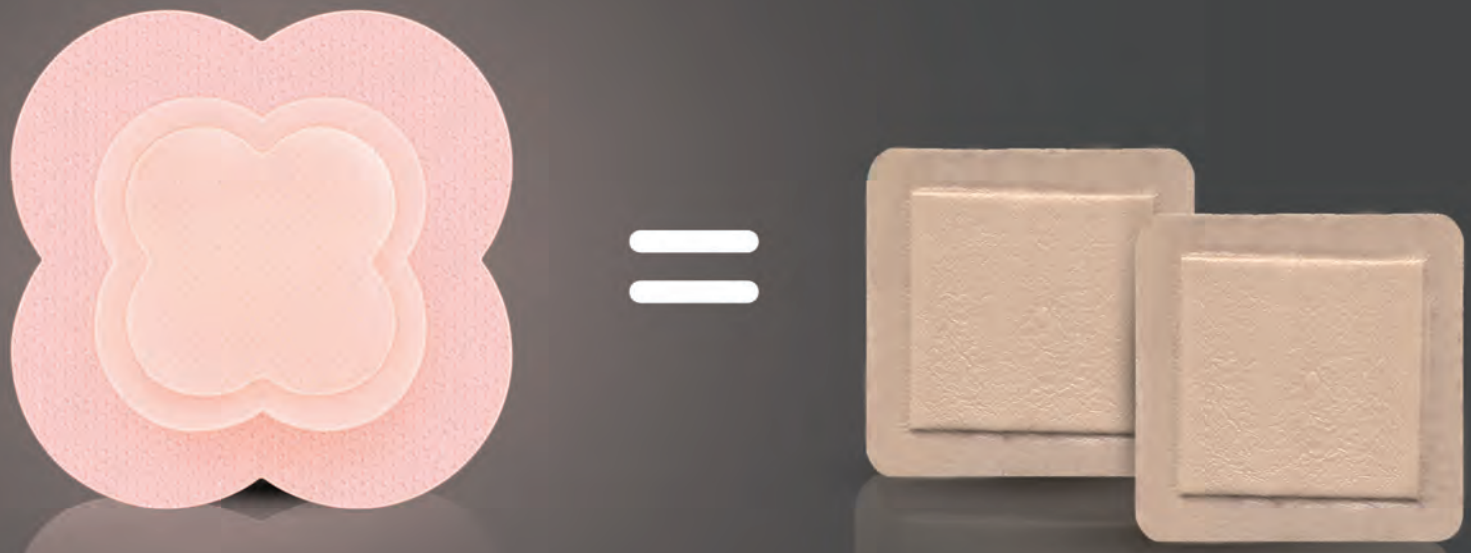
According to Woodyard, some third-party suppliers are willing to offer a much higher trade-in value for used equipment than the original manufacturer. "Hospitals don't realize there's an aftermarket for this equipment, but a team like ours can bring that expertise to the equipment life cycle conversation," Woodyard adds.

HealthTrust helps hospitals set a fair price for used inventory and negotiate the best deals. When one manufacturer refused to give a hospital more than $500 for a trade-in on an old microscope, the HealthTrust team found an outside supplier willing to match that. The manufacturer responded by raising its offer to $2,000. The team also connects hospitals throughout the membership that might be interested in swapping assets with one another.

Having a go-to team of subject matter experts in capital planning and budgeting can ease some of the operational burden hospitals face and help them discover new opportunities for savings. ●

For more information on HealthTrust capital planning services, contact Jeff Woodyard at **jeffery.woodyard@healthtrustpg.com**.

HealthTrust contract #24201



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References: 1. Joy H et al. A collaborative project to enhance efficiency through dressing change practice. Journal of Wound Care. Vol 24. No 7. July 2015 P3-4. 2. Clarke R. Positive patient outcomes: The use of a new silicone adhesive foam dressing for pressure ulcer prevention and treatment.

COMPOUNDING SAFETY

3 Things to Know About 503B Outsourcing Facilities

In the spring of 2012, a compounding pharmacy in Massachusetts shipped a batch of steroid drugs to medical facilities around the country. Within a few months, 800 patients became ill and 76 died.

Investigations revealed that the drug became tainted with mold due to unsanitary conditions at the compounding facility, leading to a fungal meningitis outbreak. This tragedy, which could have been avoided had the facility observed appropriate standards, led Congress to pass the Drug Quality and Security Act. The act was signed into law in November 2013 and added a new section to the Federal Food, Drug and Cosmetic Act (FD&C) Act. Titled 503B, the section established the regulation of "outsourcing facilities" that provide patient-specific medications.

Today pharmacy compounding facilities are required to demonstrate compliance with the FDA standards for sanitary conditions and quality as outlined in 503B. Here are three things to know about section 503B and the regulations governing outsourcing facilities.

1 Outsourcing facilities solve problems. Outsourcing facilities are FDA-registered locations where sterile drugs are compounded. Rather than issuing medicine pursuant to patient prescriptions, outsourcing facilities produce compounded drugs in bulk for institutions to address workflow constraints, become more operationally efficient and assist with drug supply during shortages. To qualify as an outsourcing facility, compounders must follow current good manufacturing practice (CGMP) requirements, submit to FDA inspections and comply with the requirements set forth by section 503B.

These facilities create pharmaceutical products to meet needs that traditional FDA-approved drug manufacturers and commercially available drugs cannot. For example, outsourcing facilities might offer unique sizes or dosages, or make drugs without the preservatives found in their commercial counterparts.

Mark Walsh, PharmD

These facilities are also helpful during drug shortages, explains **Mark Walsh**, PharmD, HealthTrust's director of Clinical Pharmacy Strategy. "When a drug shortage occurs, the FDA allows 503B facilities to compound products that would not otherwise be allowed during normal market conditions."

Walsh explains that 503B outsourcing facilities are typically prohibited from making products that are essentially copies of FDA-approved drugs available on the market. However, in the case of a drug shortage, when traditional FDA-approved drug manufacturers are unable to meet the demands of patients, hospitals and providers, these prohibitions are lifted. "During this period, the FDA allows 503B facilities to assist in alleviating market demand challenges," he says.

Walsh provides regulatory and clinical input to help inform HealthTrust's 503B contracting process. He says one of the benefits of 503B facilities is that they help diversify the supply chain, adding to the choices available. "This increase in supply chain diversification creates additional flexibility in the market to allow for more rapid means of addressing drug shortages when they occur."

Small healthcare providers rely on outsourcing facilities for another reason. For places like physician offices and dialysis centers, complying with the extensive regulations around compounding is nearly impossible.

"There are regulations governing sterile compounding at any practice site—what the beyond-use date should be, what engineering and environmental factors need to be accounted for, etc.," Walsh explains. "For some facilities to become compliant with those standards, it could be cost-prohibitive. 503B facilities offer ready-to-use products, removing the need for compliance with the costly engineering standards that would have been required if the product was compounded in-house. This allows smaller facilities to remain compliant with the regulations."

2 503B provides accountability and assurance. To become a verified outsourcing facility, Section 503B requires compounders to register with the FDA and report all compounded drug products. The FDA then inspects all registered facilities according to a risk-based schedule.

Since the 2012 meningitis outbreak, the FDA has inspected hundreds of outsourcing facilities and reports that, without regulation, unsanitary conditions will continue. Initial inspections have revealed everything from dead insects to microbial growth at compounding sites. Thanks to 503B requirements, outsourcing facilities are held accountable to best practices. These requirements

Continued on page 16

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Continued from page 14

and inspections mean that, while drugs at outsourcing facilities are not FDA-approved, a registered and inspected outsourcing facility meets CGMP standards.

Other requirements set forth by 503B include ingredient compliance with the United States Pharmacopeia (a compendium of drug information) and the labeling of drugs with the required information. The section also prohibits outsourcing facilities from making drugs removed from the market due to safety or lack of efficacy, as well as the replication of approved drugs.

"Previous to the 503B regulations there wasn't really any guidance that addressed how to deal with these type of entities," Walsh says. "Compounding facilities existed in this gray area of pharmacy, but they shipped interstate. It was undefined who was in charge of regulating them. 503B allowed for federal oversight and tried to create the standards that organizations needed to adhere to."

As a newer addition to the FD&C Act, some of 503B's original regulations lacked clarity and specificity. Because of this, the FDA continues to refine the guidelines. In early 2018 the organization released its work plan for 503B facilities and continues to produce additional guidance documents for both drug manufacturers and purchasers.

3 Due diligence is essential. Section 503B creates accountability for compounders and assurance for purchasers. The FDA provides oversight through registration and inspections, and outsourcing facilities agree to comply with 503B requirements. Still, guidelines for best practices continue to evolve. Purchasers should do their part to ensure they're obtaining drugs from a reputable facility.

"The process is heavily dependent on the providers or hospitals—whoever is ordering—to do their due diligence on the suppliers from which they are purchasing to ensure they are acting in accordance with both the words and the intent of the regulations governing 503B," Walsh says. "I've seen different suppliers interpret the same language in completely different ways."

For hospitals and other healthcare providers purchasing drugs from outsourcing facilities, Walsh recommends researching different outsourcing facilities and reading the guidance documents on the FDA's website. After all, some vendors may follow the basic requirements set forth by 503B but not the overall intent. "The essence of 503B is that it's trying to protect patients," Walsh adds.

It may sound complicated at first, but with new regulations and added accountability, outsourcing facilities can solve problems for healthcare providers and meet the needs of individual hospitals and patients. ●

To learn more about 503B suppliers or product offerings contracted through HealthTrust, email Mark Walsh at **mark.walsh@healthtrustpg.com**. FDA guidance documents can be found at: **www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding**.

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References: 1. Data on file. Simulated water drainage. N=9 for Aspira Drainage Bag, N=8 for competitor. Bench data may not be represented of clinical outcomes. Different test methods may yield different results. 2. Data on file. Internal diameters measured at the narrowest point. N=10 per device. 3. Data on file. Competitor packaging measurements represent five boxes of competitor kits containing four 1,000 mL drainage bottles and dressings per box. Aspira packaging measurements represent one box of Aspira Essential Kit containing twenty 1,000 mL drainage bags and dressings per box.

HealthTrust Contract #17439

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A PUMPED-UP PROCESS

HealthTrust Releases New Cardiovascular Phase I Contracts

Nearly one in four deaths is caused by cardiovascular disease, now ranked as the leading cause of death in the United States. To combat these statistics, healthcare providers are constantly seeking ways to offer cutting-edge cardiovascular (CV) health services. With its recent release of new CV phase I contracts, HealthTrust now offers opportunities for members to get preferred pricing and services on many of the latest CV products and equipment. The HealthTrust clinical evidence team recently completed the evaluation and reevaluation of CV phase I products, which include the newest, proven technologies for cardiac balloons, defibrillators and drug-eluting stents.

Mark Dumond, BSBA, RTR

While HealthTrust's portfolio of cardiovascular contracts continues to include many of the same products members have relied on for years, the new contracts do feature a number of products, supplies and equipment that represent the latest technologies, says **Mark Dumond**, BSBA, RTR, assistant vice president of technology services at HealthTrust.

New Trends in Cardiology

Negotiating the best price is a vital part of any contracting process, but HealthTrust's contract reviews aren't just about costs. They also include full clinical, evidence-based reviews of various products and services, based on member needs and promising new trials and studies. Members can use this information to make decisions about selecting the right products for their facilities and providers.

Robin Cunningham, MSN, RN

HealthTrust has recently been monitoring controversial, new meta-analysis related to drug-coated balloons and drug-eluting stents for the treatment of peripheral vasculature blockages, according to **Robin Cunningham**, MSN, RN, a clinical director in physician services at HealthTrust.

"Many clinical trials have been conducted around the efficacy of these products in the treatment of leg blockages as compared to the standard of care," she says. "Because these devices can typically be more expensive, our team wants to research which procedures and devices give the best, longest-lasting results for these patients. The clinical evidence team will work with our endovascular specialists across the country to get feedback on the best evidence, outcomes and clinical practice around these devices and procedures.

"The goal is for our members and physicians to have relevant clinical information to make the best decisions for their patients," she adds.

Some of the new cardiovascular products that may attract the most attention will be those included in cardiovascular phase II, which kicks off in early 2019. "We predict HealthTrust clinical board members will be interested in the latest clinical evidence surrounding the devices in CV phase II," Cunningham says. "A few new devices have entered the market in carotid stenting, drug-coated balloons and vascular closure. Our reviews will provide information on these devices, along with sound physician expertise on related outcomes."

HealthTrust board with oversight and final approval to add products to contract: Supply Chain

HealthTrust clinical advisory boards:
Cardiovascular, Laboratory, Nursing, Pharmacy, Radiology, Surgery

HealthTrust non-clinical advisory boards:
Capital Equipment, Facility Infrastructure, Food & Nutrition, Technology

Specialty groups/committees called upon as needed:
Advanced Wound Care, Ambulatory Surgery, Cardiovascular Surgery, Environmental Sustainability Network, Infection Prevention, Perinatal, Purchased Services, Respiratory

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Understanding the Review Process

Since the healthcare field evolves so rapidly, HealthTrust maintains a rigid schedule of evaluating and reevaluating various groups of products and services every few years. Through that process, the clinical evidence team reviews relevant literature and outcomes research on the latest technology in each particular contract area, including pharmaceuticals, to determine if particular products, devices, drugs or services should be considered for contracts.

"Clinical evidence reviews are typically conducted for physician preference and clinically sensitive product categories that have a significant impact on patient care," explains **Denise Dunco**, MSN, RN, a manager in physician services at HealthTrust. The team is aided by input from HealthTrust Physician Advisors, a large and growing group of 160 practicing physicians from 31 member hospitals, as well as members of HealthTrust's clinical and non-clinical advisory boards *(see box on page 18)*. These boards are made up of facility-level representatives, with expertise in their respective specialties, who provide input on or facilitate reviews of products, suppliers and emerging technologies.

Denise Dunco, MSN, RN

Recommendations from the clinical advisory boards are reviewed, along with relevant clinical evidence, and must be approved by the supply chain board prior to awarding a contract.

Contracts Under Consideration

Because cardiovascular health is a broad area with a wide array of related products and services, HealthTrust reviews cardiovascular contracts in three phases. Phase I is now complete, and the contracts, as well as accompanying evidence reviews, can be accessed on the HealthTrust member portal. Contracts and clinical evidence reviews for phases II and III will be available in the coming months.

Here's the breakdown of the types of products and services included in CV Phase I:

- Bare metal stents
- Cardiac balloons
- Cardiac resynchronization therapy
- Implantable cardioverter defibrillators
- Leads and accessories
- Pacemakers
- Device stabilization
- Drug-eluting stents
- Heart failure monitors

ENSURING MEDICAL DEVICE SECURITY

The FDA's Recently Updated Premarket Guidance Demonstrates a Shift in Cybersecurity Best Practices

Cybersecurity has been a top priority for the healthcare community in recent years, because of the significant upsurge in utilizing wireless, internet- or network-connected medical devices and because of the increased number of cybersecurity attacks aimed at healthcare systems and hospitals across the country.

Those attacks are a primary reason the U.S. Food and Drug Administration (FDA) released an updated draft this past October of its premarket guidance concerning medical device cybersecurity, says **Terry Moon**, senior director of strategic sourcing for HealthTrust.

Terry Moon

"I believe this was a reaction from the FDA," Moon explains. "If some of those high-profile cybersecurity vulnerabilities on certain medical devices had not been breached, the FDA would have most likely kept the previous 2014 guidelines in place."

In addition to specifying what information medical device manufacturers should gather prior to submitting new products for FDA review (*see related story on page 46*), the FDA's updated guidance also includes recommendations for manufacturers on how to assess cybersecurity in the development and review of their premarket products. The latter could prove especially useful if an issue with the device were to arise, as this could speed how quickly the problem could be identified and resolved.

Marc Sammons

Marc Sammons, director of strategic sourcing for HealthTrust, says the FDA's shift in tone was what first struck him when reviewing the updated guidelines. "When it comes to medical device security, the reflex is to refer to the FDA's guidance," Sammons explains. "So the fact that the FDA is weighing in on cybersecurity recommendations is positive. This will be helpful when it comes to changing the industry by recognizing that many of these medical devices have to go through a number of different steps to even be approved."

According to Moon, the guidance suggests the FDA is listening to the hospital systems that have been crying for help.

"They haven't had the kind of power or influence to demand change from medical device OEMs [original equipment manufacturers]. So, there seems to be a good alignment between what our members want and what the FDA is suggesting is the right thing to do," he says.

Continued on page 22

THE COST OF CYBER CRIME TO HEALTHCARE

BETWEEN APRIL AND JUNE 2018 ALONE, MORE THAN **3.14 MILLION** HEALTHCARE RECORDS WERE EXPOSED BY DATA BREACHES AT JUST 142 HOSPITALS.[1]

88% OF RANSOMWARE ATTACKS ARE DIRECTED AT HOSPITALS—MORE THAN ANY OTHER TYPE OF BUSINESS.[2]

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THE COST OF A DATA BREACH FOR HEALTHCARE FACILITIES IS ABOUT $408 PER PATIENT RECORD.[3]

FROM 2015 TO 2017 THE TOTAL COST PER STOLEN HEALTH RECORD ROSE FROM **$363 TO $380,** THE HIGHEST COST OF THE 16 INDUSTRIES EXAMINED.[4]

[1]Protenus' Q2 2018 Breach Barometer Report
[2]Solutionary's Security Engineering Research Team (SERT) Q2 2016 Threat Report
[3]Ponemon Institute's 2018 Cost of a Data Breach study
[4]Ponemon Institute's 2018 Cost of a Data Breach study
[5]Identity Theft Resource Center's 2017 Data Breach report

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Continued from page 20

Another striking distinction between the updated guidance and the 2014 version is that the newer version requires manufacturers of internet-connected medical devices to provide customers with a Cybersecurity Bill of Materials (CBOM). Essentially, a CBOM would require manufacturers of internet-connected medical devices to list the commercial or off-the-shelf software and hardware components that could be susceptible to vulnerabilities.

The inclusion of the CBOM rule is seen as a proactive move for those in medical device security.

"Having a list of all the different components involved in making a product work is, at the very least, something that can be entered into an inventory and used to help mitigate risk across the entire organization," Sammons says.

Though the updated premarket guidance may signal the FDA's resolve to strengthen its cybersecurity measures, the vast majority of the guidance is made up of non-binding recommendations—meaning those FDA-recommended responsibilities are not legally enforceable. Similarly, the updated guidance also describes the negotiation of contracts between medical device manufacturers and healthcare providers as a shared responsibility. Sammons explains that while the phrase "shared responsibility" could be open for debate, the FDA does clearly outline what it believes manufacturers need to consider when submitting a premarket product for review.

"Many of the product lines in the medical device space are deficient from a cybersecurity perspective, especially when you compare healthcare to the financial or banking industries," Sammons says. "In finance, there are very specific rules and must-dos. I think this signifies the beginning of a shift where the medical device community is going to start seeing more and more must-dos, instead of should-dos, so the FDA is responding in kind."

Though Moon believes the patient safety recommendations for manufacturers was a positive improvement on the 2014 guidelines, he was disappointed in the lack of legally binding rules. "There still needs to be some sort of penalty for not meeting these guidelines," he adds. "Until that happens, it's never something we can lean on 100 percent. With or without the FDA's support, we have to evaluate all opportunities to protect patients because our job is to continue to push for stronger cybersecurity measures on behalf of all HealthTrust members." ●

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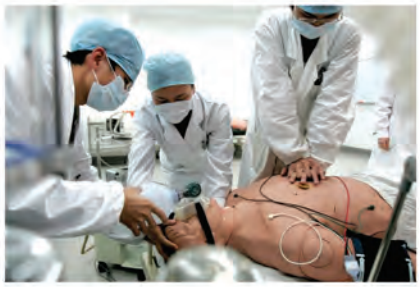

HealthTrust Contract #23280

* "Trends and Disparities in Delivery Hospitalizations Involving Severe Maternal Morbidity," 2006-2015 Agency for Healthcare Research and Quality HCUP Statistical Brief number 243, September 2018

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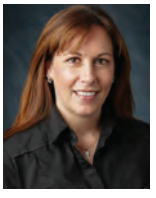
MAKING SURGERIES SAFER

A Look Inside AORN's 2019 Guidelines for Perioperative Practice

When the members of HealthTrust Advisory Boards meet to talk through various products and contracting strategies, they frequently turn to published guidelines from professional healthcare associations to inform their decisions.



Kim Kelly, MSN, RN

"In discussions with clinical advisory board members, we often look to recommendations from the Association of periOperative Registered Nurses (AORN) as our guide to practice, as well as to understand how different members may implement the recommendations," says **Kim Kelly**, MSN, RN, HealthTrust's assistant vice president of clinical operations. "HealthTrust references guidelines for many categories as needed, and we use this information during advisory board calls and meetings and to guide us with contracting recommendations."

Professional guidelines aren't just important for HealthTrust's product vetting and approval process. Kelly adds that these evidence-based positions provide an agreed-upon standard of practice, and they're usually accompanied by clinical evidence, toolkits, training webinars and recommendations for implementation that take into account variations in practice.

Lisa Spruce, DNP, RN, CNS-CP, CNOR, ACNS, ACNP, FAAN

AORN has recently updated its Guidelines for Perioperative Practice, and its 2019 version includes five updated guidelines and one new guideline, according to **Lisa Spruce**, DNP, RN, CNS-CP, CNOR, ACNS, ACNP, FAAN, and director of evidence-based perioperative practice at AORN. The updated ground rules will not only inform HealthTrust contracts, but they will also likely permeate through healthcare practices across the country.

Spotlight on Specific Changes

The 2019 guidelines include a number of changes that can help ensure safer surgeries for patients and providers. Here are some of the highlights.

1. Sterile Technique

The update to this guideline includes a recommendation to not only cover the sterile field during delays, but also to cover portions of the sterile field that are not in immediate use, Spruce says.

"The importance of covering sterile tables during unanticipated delays and during periods of increased activity is emphasized to minimize potential air contamination of the sterile field, which helps to decrease a patient's risk of surgical site infection," she explains.

The guideline also makes the following recommendations:

- Determining the need for physically monitoring the covered sterile field based on individual facility decision.
- Positioning the operating table within

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the unidirectional ultraclean air delivery system (laminar air flow).
- Wearing a surgical helmet system when exposure to blood or body fluids is anticipated.
- Limiting openings of the operating room (OR) door.

2. Design and Maintenance

This guideline has been restructured. Now, rather than addressing only evidence-based design, construction and maintenance recommendations for all areas within the perioperative setting, it "applies to a wide range of phases involved in creating safe OR spaces," Spruce says. That includes:

- Rethinking traffic pattern area designations for unrestricted, semi-restricted and restricted areas.
- Following the patient through perioperative care to plan intuitive design that supports better throughput efficiency and patient safety.
- Standardizing maintenance planning for daily operations.

3. Safe Environment of Care

This standard has also been restructured. Rather than addressing only care activities in the OR environment, it "addresses the evidence for mitigating environmental care risks such as distractions, fire safety and staff exposure to hazards," Spruce says.

WHY REVAMPED GUIDELINES SO SOON?

Because the practice of healthcare is continuously evolving, regular updates of practice standards are essential. In 2018, AORN published six new guidelines and for 2019, the organization's guidelines have been significantly updated. The changes are always in response to clinical evidence, says **Lisa Spruce**, DNP, RN, CNS-CP, CNOR, ACNS, ACNP, FAAN, and director of evidence-based perioperative practice at AORN.

AORN's practice guidelines are regularly updated based on a systematic review of the evidence. A lead author is assigned to each guideline, and he or she works with AORN's medical librarian to develop key search terms for that guideline. The medical librarian then conducts a systematic search of several medical databases using those terms.

With the research in hand, the lead author identifies relevant articles for inclusion in the guideline and then sends the articles to the project team for evaluation, Spruce explains. The team consists of the lead author and two evidence appraisers. The lead author divides the search results into topics and assigns members of the team to review and critically appraise each article. These team members make guideline recommendations based on the evidence identified in their search.

After the team writes the guideline, AORN's Guideline Advisory Board reviews and approves it. Spruce adds that each guideline is placed on AORN's website for public comment for 30 days, and the lead author and the editor-in-chief review any comments and make necessary revisions.

The patient and staff risks addressed in this guidance include the following:

- Conducting a preoperative fire risk assessment as a team.
- Taking precautions to reduce the risk for exposure to thermal injuries from patient warming techniques.
- Mitigating staff exposure to waste anesthesia gases and chemicals.
- Minimizing noise and distractions created by personnel as well as equipment and devices.

4. Sterilization

The standard for sterilization has been updated to provide more detailed and evidence-based practices within each step of the sterilization process, including for immediate-use steam sterilization (IUSS), Spruce explains. Important recommendations for the complete sterilization process include the following:

- Following a complete sterilization process to ensure saturated steam under pressure is used to sterilize heat- and moisture-stable items unless otherwise indicated by the device manufacturer.
- Performing sterilization in an area intended, designed and equipped for sterilization processes.
- Monitoring sterilization processes in all areas of the facility where sterilization processes are performed.

5. Transmission-based Precautions

This guideline has a new title for 2019 and covers how to prevent transmission of pathogens. It offers a number of new recommendations that address the following:

- When and how to put on and remove personal protective equipment (PPE), as well as recommended strategies to address barriers and educational opportunities for correct PPE practices. (*See related PPE story on page 34.*)
- Selecting gown and mask types according to task and degree of anticipated exposure.
- Wearing PPE during patient transport activities.
- Requiring visitors to wear PPE when visiting patients who require transmission-based precautions.

6. Safe Patient Handling and Movement

The evidence for safe handling and movement of patients is addressed by this new guideline, covering topics such as culture of safety, ergonomic design and practices, patient assessment, competence, and product selection tailored to perioperative patients and team members.

The guideline includes eight recommendations for safe patient handling and movement, as well as seven ergonomic tools to help with decision-making in specific perioperative scenarios. “These ergonomic tools should be applied in daily practice to keep staff safe as well,” Spruce adds.

The recommendations include:

Continued on page 28

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1. Hussaini BE, Lu HG, Wolf JA, Thatte HS. Evaluation of endoscopic vein extraction on structural and functional viability of saphenous vein endothelium. J Thorac Cardiovasc Surg 2011;10(6):82
2. Terumo Product Code for VirtuoSaph Plus is VSP550EX

Continued from page 26

- Lateral transfer of a patient from a stretcher to an OR bed.
- Lifting and holding the patient's legs, arms and head while prepping.
- Solutions for prolonged standing.
- Tissue retraction.
- Lifting and carrying supplies and equipment.
- Pushing, pulling and moving equipment on wheels.

As new evidence is published about the most effective approaches, standards and best practices will continue to evolve. That's why practitioners and facility professionals should regularly review updated guidelines to ensure that their techniques and equipment are still appropriate.

"All of the guidelines are important to help perioperative professionals provide safe and high quality care to patients," Spruce says. "AORN supports perioperative practice by critically appraising and synthesizing evidence and making recommendations that enhance team decision-making rather than a one-size-fits-all approach. This ensures that our guidelines are relevant to individual patient encounters." **S**

HEALTHTRUST RENEWS SMOKE EVACUATION CONTRACTS

An operating room (OR) is a place for saving lives—but without proper safety equipment and processes, it can also present dangers. For instance, one UK-based research study found that the smoke produced daily in an OR was comparable to smoking 27 to 30 cigarettes, reports **Jennifer Westendorf**, MSN, RN, director of surgical services at HealthTrust.

Jennifer Westendorf, MSN, RN

The Association of periOperative Registered Nurses recommends hospitals use an evacuation system to provide its employees with a smoke-free, surgical work environment. "We should all be advocating for the use of smoke evacuation systems within the OR to protect both staff and patients," Westendorf says.

HealthTrust recently renewed contracts for a number of smoke evacuation systems to ensure that members are able to purchase the systems that best meet their needs. Clinical evidence reviews for that equipment are available on the HealthTrust member portal. The contracts available in HealthTrust's portfolio include equipment for both electrosurgical and laparoscopic smoke evacuation.

Electrosurgical smoke evacuation:
Buffalo Filter (Contract No. 7119)
Covidien (Contract No. 7175)

Laparoscopic smoke evacuation:
Buffalo Filter (Contract No. 18039)
Conmed (Contract No. 28244)
DeRoyal Industries (Contract No. 18012)
Stryker Endoscopy (Contract No. 17908)

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TECHNOCUT® Brand Premium Surgical Blades

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Eff Date: 3/1/16

RELI® Brand Epidural, Spinal, Quincke, and Chiba Needles

HealthTrust Contract # 18866
Eff Date: 2/1/17

SteriHeel® Brand Safety Heel Stick Lancets

HealthTrust Contract # 6021
Eff Date: 10/1/17

RELI® Brand Blunt Fill Needles

HealthTrust Contract # 6905
Eff Date: 10/1/18

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BEATING INFECTIONS TO THE PUNCH

A Renewed Focus on the Basics, Stewardship, Collaboration & Tech Experimentation Among Top Strategies for Preventing & Knocking Out Infections

In the mid-1800s, a strange phenomenon gripped the maternity clinic at the Vienna General Hospital in Austria. The labor ward staffed by medical students suffered from a maternal mortality rate five times higher than that of the ward staffed by midwives.

Clinic Director Ignaz Semmelweis studied the two wards' practices and realized that the medical students were going directly from dissecting corpses in the cadaver lab to delivering babies in operating rooms, spreading infection with every trip. After requiring the students to dip their hands in a chlorinated lime solution upon leaving the cadaver lab, he watched the mortality rates drop from nearly 20 percent to less than 2 percent. This early antiseptic practice earned Semmelweis the moniker of "savior of the mothers."

Steven Spires, M.D.

It would be decades before Semmelweis' hand-washing discovery gained widespread acceptance and adoption. Today his story offers two important lessons about infection prevention (IP). First, the most basic preventive measures are the most effective. And second, changing behavior can be among the most important—and challenging—aspects of successful IP. As infectious disease specialist **Steven Spires**, M.D., says, "It's not the science of infection prevention that's difficult, but rather rallying your fellow colleagues to believe the same things you believe."

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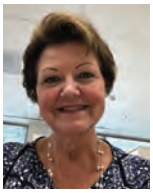
BACK TO THE BASICS

IP experts say simple, common-sense measures continue to see the most success. According to the World Health Organization and Centers for Disease Control and Prevention (CDC), hand-washing is the simplest, most inexpensive approach to reducing the risk of healthcare-associated infections (HAIs) and preventing the spread of antimicrobial resistance. Multiple studies have linked hand-washing to reduced Methicillin-resistant *Staphylococcus aureus* (MRSA) rates and ultimately to reduced rates of HAIs.

"I've learned that if you do the basic things well, such as proper hand hygiene and following clinical practice guidelines, infections will go down," explains Spires, who is assistant professor of infectious diseases at Nashville, Tennessee-based Vanderbilt University School of Medicine, and hospital epidemiologist and physician chair of antimicrobial stewardship at Williamson Medical Center in Franklin, Tennessee.



Cheryl Herbert, RN

Cheryl Herbert, RN, clinical service line director, supply chain at CHRISTUS Health, agrees. "We work hard on the fundamentals like washing hands and wearing protective barriers like gowns and gloves and changing them frequently," she says.

Herbert is part of HealthTrust's IP committee, a branch of the nursing clinical advisory board, which discusses evidence-based practices, new IP initiatives and common obstacles faced by clinicians throughout the membership. These experts also weigh-in on the efficacy of products in categories from hand hygiene to surface disinfectants to nasal sanitizers and share that feedback with HealthTrust.

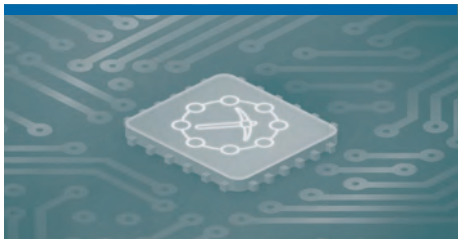
"We depend on HealthTrust to help us identify cost-effective solutions, but they also provide a helpful forum for members to share our personal experiences with devices and products that work well and those that do not," Herbert adds. "The clinical, evidence-based focus is essential."

EXPLORING NEW TECHNOLOGY & DESIGN

Some healthcare facilities are also investing in innovative strategies to bolster their IP programs. They're exploring current trends such as:

• **Ultraviolet (UV) light robots.** These robots kill germs at a level above routine cleaning and disinfection, some of them emitting light in the deep UV range—the most useful for killing germs. These robots are used in facility rooms after patients with multidrug-resistant organisms are discharged in order to prevent transmission to new patients.

• **Real-time location systems (RTLS).** These systems integrate sensors with soap and sanitizer dispensers to detect how much they're being used. When a clinician enters or exits a patient room, a smart hand hygiene dispenser with RTLS technology, or a regular dispenser retrofitted with this technology, can identify if that individual used the dispenser. RTLS can also be used as a tech detective to retrace the steps of infected people to see who they might have come into contact with and where.



• **Harnessing data.** To limit the spread of infections and identify trends within a facility, data mining programs harness the power of such information to identify and potentially isolate certain patients.

• **Rapid diagnostics.** Genetic markers are used to identify a specific bacterium within 24 hours and recognize antibiotic-resistance patterns. These tests allow facilities to treat patients for these infections much faster and limit the transmission to other patients.

• **Design reconfiguration.** According to a 2016 article in *Healthcare Design* magazine, some facilities are exploring ways environmental improvements can boost infection prevention. Partnering with healthcare engineering experts, facility leaders are looking at the way the soap and sanitizer dispensers are positioned (easily accessible and readily available) and how reprocessing departments are set up (adequate sink and counter space, appropriate airflow, and a clear separation of clean and dirty items). They're also reducing the amount of porous and other hard-to-clean surfaces, redesigning bathrooms with splash zones to reduce water-related infections, and using functional space planning in areas such as the emergency department to limit the exposure of pathogens to other waiting patients.

• **Reprocessing redux.** While the widespread infections caused by improper cleaning of endoscopes led some facilities to be wary, many have rebuilt their confidence in reprocessing programs because of advanced sterilization equipment, automated cleaning processes, new guidelines and better training. The reprocessing departments in some larger hospitals have adopted new protocols that quarantine endoscopes after cleaning, then retest them for bacteria before they can be reused. Others are following up manual cleaning processes with a gas sterilization process.

Jacqueline Daley, HBSc, MLT, CIC, CSPDS, FAPIC

"Visual inspection in sterile processing is important, but the industry is starting to use technology aids like borescopes to inspect other equipment like endoscopes, bronchoscopes and ureteroscopes to ensure these items are clean," says infection prevention consultant **Jacqueline Daley**, HBSc, MLT, CIC, CSPDS, FAPIC.

Germ-killing technologies like these can make a difference, but Spires cautions that such measures should only be pursued after implementing IP fundamentals. "A lot of the new IP initiatives and gadgets are reserved for second-tier problems. Once you've done everything backed by evidence and data and are still having a problem, then you pay for technologies," he adds.

SURVEILLANCE & STEWARDSHIP

Even new technologies, robust sterile processing procedures and a hospitalwide dedication to evidence-based practice aren't enough to prevent all HAIs. A holistic IP strategy also depends on the priority given

to antibiotic and antimicrobial stewardship programs.

America's overprescription of antibiotics has led to multidrug-resistant organisms and the rise of *Clostridium difficile*, or C. diff, infections in both hospitals and communities as a whole. "Because the germs are more difficult to kill, maintaining the environment and the equipment becomes more challenging as well," Herbert explains.

Prescribing antibiotics judiciously both lessens pharmacy costs and improves patients' overall resistance to infections. The goal of antibiotic stewardship, Spires explains, shouldn't be to eliminate antibiotic use completely, but rather to "make sure antibiotics are used optimally, so that patients aren't getting over-treated but are getting the right drug, at the right dose, for the right duration."

For IP experts, a key part of their work involves monitoring for resistant organisms. "Infection preventionists do a lot of active surveillance," Daley explains. "We work with pharmacists to mine the data and look at antibiotic use patterns and incidences of outbreaks. Infection prevention has a very critical and active role to play in the impact of overuse of antibiotics."

Antibiotic stewardship can counterbalance the sluggish cycle of drug development. While it doesn't take long for bacteria to develop drug resistance, new antibiotics can take years to hit the market between research, development and approval. "With the limited number of available drugs, it's to our benefit to be smart about how we use them and not over-prescribe or overuse them," Daley says.

COLLABORATION WINS

As Semmelweis discovered, it's not enough to know the science behind infection prevention; there must be buy-in from other healthcare practitioners. "You have to change some level of behavior," Spires adds. "Just because it's the right thing to do doesn't mean everyone is going to do it."

For instance, though most healthcare providers are aware of hand hygiene's importance, high levels of compliance can be difficult to achieve. According to a study published in the Joint Commission's January 2015 issue of *Journal on Quality and Patient Safety*, reasons for noncompliance include forgetfulness, busyness, inconvenience, hand irritation and ineffective education around the topic.

"With hand hygiene, we need to be hardwired so that we do it without even thinking about it," Michael Edmond, M.D., MPH, professor of internal medicine in the division of infectious diseases at Virginia Commonwealth University, told *Infectious Disease News*. Edmond compared the process of washing hands to wearing seat belts, something that most people do now on a subconscious level. "When a behavior like that is hardwired, you can always sense when you didn't do it because you start to feel uncomfortable. It's a long process to get to that point."

IP PROBLEM-SOLVING NOT ONLY TAKES INDIVIDUAL BEHAVIORAL CHANGE, BUT IT ALSO REQUIRES LEADERS TO TAP INTO THE WISDOM OF THEIR TEAMS.

Direct monitoring, accountability policies and a culture of reinforcement will help train clinicians to get in the habit of washing their hands every time they walk in and out of patient rooms. IP habits also have to be augmented across hospital departments—something that requires commitment and collaboration.

Beyond encouraging individual behavioral changes, leaders must tap into their team's collective wisdom when it comes to IP problem-solving. When his hospital encounters a problem like a surgical site infection outbreak, Spires forms a team of surgeons, nurses and stakeholders from the lab, pharmacy and materials department. "We all get to look at each other in the face, understand the problem and then come up with a solution together."

Spires also underscores the importance of involving community healthcare workers in IP initiatives. "Even with an exceptional antimicrobial stewardship program, there are only so many things we can control in the hospital," he says. "When you have people from the community harboring infections and bringing them into the hospital, then we're only touching a fraction of the problem. We have to stop infections at the source."

One way to do this, Spires says, is to develop a task force that includes community stakeholders—from local physicians to nursing home caregivers.

Lindy Barry-Brown, RN

Collaboration is also essential on the purchasing side. "From an IP sourcing standpoint, HealthTrust really listens to the input from our clinical boards, especially our IP committee," says **Lindy Barry-Brown**, RN, nursing portfolio director at HealthTrust. At one clinical board meeting, for example, UV phone disinfectants were under discussion. A member suggested a supplier, and another member shared that they had tried the product without results.

"We listen and learn as our members share their experiences with protocols and technologies, see what the clinical experts and research say, then formulate a strategy to get the membership what they need," she says.

Through commitment and collaboration, hospitals can prevent infection and provide better care for patients. Daley adds, "That's a lot of what everything in infection prevention boils down to: teamwork, collaboration and mutual respect." **S**

For a host of hand hygiene educational resources for healthcare professionals, visit **www.cdc.gov/handhygiene/providers**. The Association for Professionals in Infection Control and Epidemiology has helpful tools for IP programs on its website at **apic.org**. For information on HealthTrust's portfolio of sterile processing tools and equipment, visit the member portal.

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WHAT'S YOUR **RISK?**

6 PPE Considerations for Seasonal & Pandemic Flu & Other Pandemics

One of the biggest challenges related to the three different types of infection outbreaks—seasonal flu, pandemic flu and pandemics caused by special pathogens such as Ebola or cholera—is estimating what types of personal protective equipment (PPE) are needed, as well as the proper amount.

"Some hospitals don't have enough and others are overstocked and preparing for worst-case scenarios," says **Peggy Luebbert**, MS, CLS, CIC, CHSP, CSPDT, an infection preventionist and safety specialist who works with healthcare facilities and Halyard Health to assess infection control and safety.

Peggy Luebbert, MS, CLS, CIC, CHSP, CSPDT

Angie Mitchell, RN

Supply chain leaders also need to evaluate if new and improved PPE products are worth the upgrade.

"The variety of PPE that HealthTrust offers has expanded in the last few years, especially after the Ebola crisis of 2014," says **Angie Mitchell**, RN, assistant vice president of physician services at HealthTrust. "The HealthTrust Sourcing team in partnership with the Infection Prevention Specialty Committee is always working to keep current with the latest technologies."

Luebbert and Mitchell offer the following tips to help hospitals evaluate their risk for outbreaks and plan their PPE purchases accordingly.

1. PREPARE A RISK ASSESSMENT.

Form a multidisciplinary team and utilize a tiered approach to assess your hospital's role in the community in responding to any outbreak, Luebbert advises. "Will you be a frontline hospital during an Ebola-type event, or are you going to be an assessment or treatment hospital? If you have a pact among regional hospitals, the larger hospitals may take the pandemic and influenza patients, while your hospital takes the overflow."

A hospital will also need to determine which of its employees would potentially be exposed in a pandemic. Will there be a core team to care for patients, or do you expect all employees to be able to wear PPE and be put at risk?

2. ENSURE THAT THE PROPER EQUIPMENT IS ON HAND.

The amount of PPE needed for each day of patient care during an outbreak will depend on multiple factors such as expected number of patients, acuity of patients, projected number of staff expected and the number of employees.

For a seasonal event, surgical masks should be worn when entering a flu patient's room, and gloves, gowns and eye protection are necessary for tasks that might involve fluids. To calculate amounts, start by basing it on the past four or five years of patient load, Luebbert suggests. Ask questions such as: What PPE products will most likely have increased demand during an intense flu season? Who will wear the PPE when encountering flu patients?

Though the types of PPE needed for the seasonal and pandemic flu are similar, in a pandemic, the quantity of PPE required is larger and the duration may be longer, typically occurring in at least two waves of 12 weeks each. With high-risk, aerosol-generating procedures, have enough N95 respirators and facial protection on hand to manage the event.

In relation to special pathogens, some lessons learned during the Ebola crisis can be applied to other outbreaks, Luebbert says. "Though large hospitals will bear the majority of such outbreaks, small and rural facilities should have enough PPE available for their emergency department staff to manage the initial intake of patients until they can transfer them to an assessment or treatment hospital."

3. MANAGE THE STOCKPILE EFFICIENTLY.

Whether it's the infection prevention, emergency management or supply chain department, make sure the task of stockpile management is included in the list of formal responsibilities and that other departments know who's in charge.

Good stockpile management requires an awareness of each product's shelf life. Most equipment necessary for outbreaks expires somewhere between two to five years. "It's a good idea for annual infection control and prevention reports to show a clear inventory of what PPE is on hand and what's expiring in the next year," Luebbert suggests.

It's also important for the stockpile manager to institute protocols to prevent damage, contamination, spoilage and even supplies disappearing. Most facilities don't have a lot of space to spare, so it can be a challenge to find the proper PPE storage area that avoids dampness or improper temperatures—but not doing so can be costly.

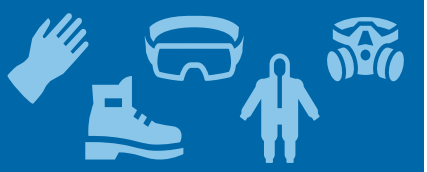
"When we pulled gloves out of one stockpile, they shredded in our hands because they were so old and the temperature extremes were so bad," Luebbert recalls. "In another, the respirators in the stockpile were an older design and different than the recommended N95 respirators the hospital was now using."

Continued on page 36

WHAT QUALIFIES AS PPE?

Personal protective equipment (PPE) is defined as any clothing or other equipment that protects an individual from exposure to chemicals, heat, biohazards, hazardous pathogens and airborne particles associated with patient care. It includes disposable, fluid-resistant barriers such as gloves; goggles; N95 respirator masks and face shields; shoe covers; and impermeable gowns, single-use coveralls and other impervious clothing. Lab coats, scrubs and surgical attire are not considered PPE because they are pervious.

Due to the wide variety of PPE options available, contact your HealthTrust Account Director for assistance in locating the products you need.



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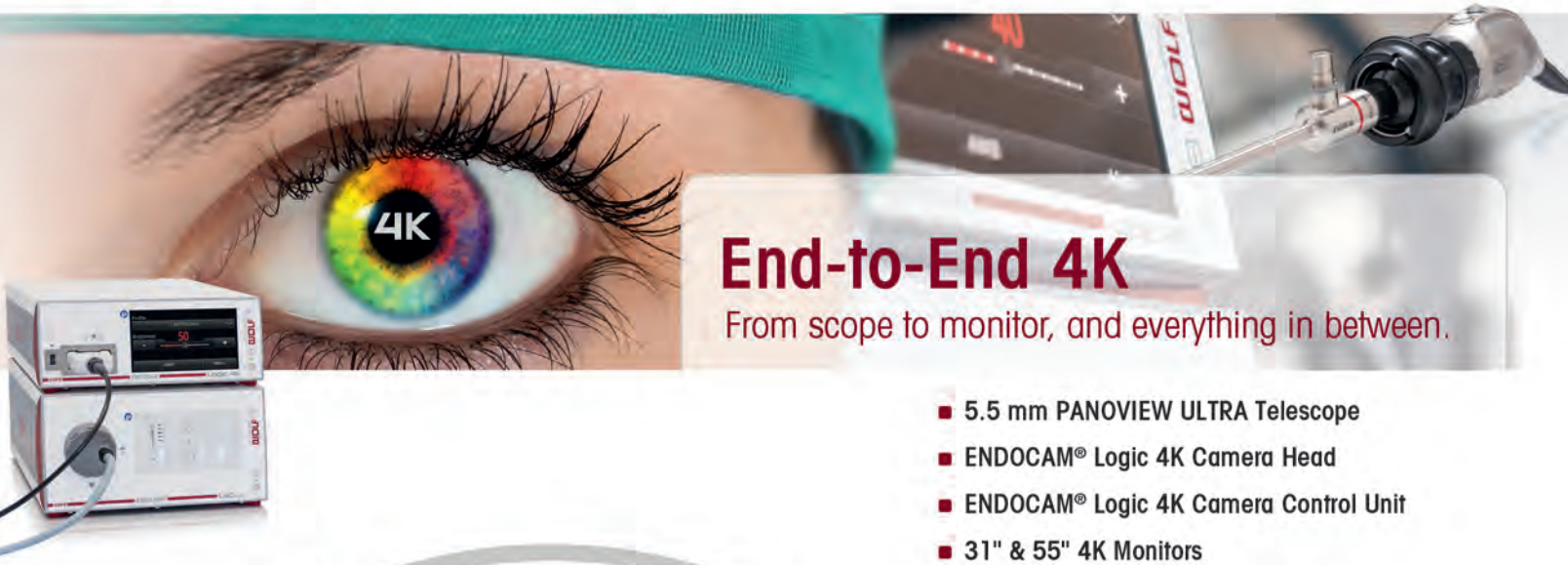

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Continued from page 34

Mitchell also advises that the management of PPE encompasses more than flu season and pandemic readiness; "it includes the right protective products for cleaning patient rooms, disinfecting contaminated instruments and protecting against airborne particles," she says. "There's a lot to consider when you think about all of the products used in the daily operations of the hospital."

4. TRY CREATIVE SOLUTIONS FOR STORAGE.

"Some facilities are exploring the idea of a community or regional stockpile that facilities can pull from when they need them," Luebbert says. Other hospitals may be able to work with some suppliers to store critical items in their warehouses that can be shipped or delivered immediately in case of emergency. Collaborate with your supplier, distributor or facility warehouse to understand what the response time would be in the case of increased demand, keeping in mind that your facility or healthcare system may not be the only one experiencing an urgent need. For those items ordered directly from the supplier, the distance from the facility to the manufacturing plant may extend the delivery time for a large emergency order.

5. PRIORITIZE TRAINING.

It's helpful for facilities to include emergency planning in new employee orientation as well as in annual competencies for clinicians. "Training needs to be scheduled on a quarterly or biannual basis to keep up the level of competency and help healthcare providers practice for the unexpected," Luebbert says. "Some hospitals do quarterly tabletop trainings or full-scale disaster drills to prepare for unique pathogens like Ebola."

Training should include practice drills with actual PPE. "You can go through all the PowerPoint educational presentations you want, but until you actually don and doff the gowns, gloves and N95 respirators, you won't be comfortable doing it when an actual pandemic occurs," Luebbert continues.

6. CONSIDER COSTS.

The risk assessment process should include input from the facility's financial administrators and suppliers. "You have to weigh the risk of cost versus the risk of an outbreak actually occurring," Luebbert says. "You want to balance good financial stewardship with preparedness."

"Some HealthTrust members help control their costs in this area by developing a formulary that identifies products in certain categories that they're going to stick to," Mitchell says. "This keeps them from having six different types of gloves or gowns that offer the same level of protection." **S**

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YOUR **Q1 GUIDE** TO VENDOR CREDENTIALING, ADVANCING WOUND CARE & THE EVOLVING ROLE OF CLINICAL MANAGERS

SAFETY FIRST

HealthTrust and many of its members champion a vendor credentialing standard that addresses safety and regulatory issues

Tracy Cleveland, director of operational integration at Trinity Health, was part of HealthTrust's vendor credentialing standards committee.

Patient safety considerations encompass more than preventing medical errors, reducing surgical complications or lowering the instance of healthcare-acquired infections. Another important, but often overlooked, factor in implementing a culture of patient safety is strengthening vendor credentialing, the process that verifies supplier representatives who visit various areas of a hospital. Before allowing access to specific areas of the hospital, the process ensures that suppliers are vetted with background checks, the proper immunizations, drug tests, certifications and training. Though most hospital systems acknowledge the value in a standard process, vendor credentialing requirements aren't consistent and are rarely standardized.

That's where a vendor credentialing standard comes in. A comprehensive standard can dismantle roadblocks to heighten patient safety and solve regulatory and liability challenges for healthcare facilities. It can also help a health system streamline its contract compliance and supplier visitation policies, saving clinicians' time to devote to patient care. However, a solid vendor credentialing standard isn't solely beneficial for hospital leaders: It may also reduce variance and iron out costly duplications for the supplier community, which can ultimately reduce waste and expense for the entire industry.

HEALTHTRUST ORGANIZES INDUSTRY COLLABORATION

A few hospital systems have standardized vendor credentialing requirements (*see Trinity Health's example on page 39)*, but there's wide variation in what other IDNs and hospitals mandate, and costs and red tape can add up quickly for suppliers. "Vendor representatives have to pay to obtain certifications and remain compliant with third-party vendor credentialing service providers, and the fees can be very expensive—especially if individual hospitals have their own unique credentialing requirements," says **Allen Wright**, senior vice president, strategic sourcing at HealthTrust.

Allen Wright

"Based on the number of facilities that reps call on and the number of unique hospital credentialing requirements, combined with multiple third-party credentialing firms with which they have to deal, it can be extremely expensive, inefficient and difficult for suppliers to juggle the multiplying, overlapping and sometimes repetitive credentialing requirements," he continues. "There are various estimates that the lack of standards across the industry is costing the system $1-2 billion annually. Ultimately, these costs are indirectly embedded in the cost of products and services sold across the healthcare system."

The expense and variation of such standards were among the frustrations HealthTrust heard from its supplier community at the 2016 HealthTrust University Conference, and leadership decided to take action. In late 2016, HealthTrust asked member representatives to designate clinical, HR and supply team personnel to participate in a multidisciplinary committee to establish the HealthTrust vendor credentialing standards. **Tracy Cleveland**, director of operational integration for Trinity Health, and **Scott Gasiorek**, Trinity Health's director of supply chain informatics, joined other member representatives in a quest to develop a set of recommended guidelines to gain consistency in credentialing requirements.

"BASED ON THE NUMBER OF FACILITIES THAT REPS CALL ON AND THE NUMBER OF UNIQUE HOSPITAL CREDENTIALING REQUIREMENTS ... IT CAN BE EXTREMELY EXPENSIVE, INEFFICIENT AND DIFFICULT FOR SUPPLIERS TO JUGGLE THE MULTIPLYING, OVERLAPPING AND SOMETIMES REPETITIVE CREDENTIALING REQUIREMENTS."

Allen Wright | Senior Vice President, Strategic Sourcing | HealthTrust

HealthTrust started by surveying the member participants about their standards and reported the results at a two-day credentialing summit held in March of 2017. "Members shared best practices as well as policies and procedures that would benefit the entire industry," Wright says. In the two years since, HealthTrust's

JEFF KOWALSKY

committee has refined those standards. Members who participated in developing the standards have started to implement them across their health systems. HealthTrust is now ready to release the standards to the broader membership.

Other organizations have tried to standardize the supplier credentialing requirements and convince hospitals to move together in one direction. However, those efforts have not been successful because of the inability to align standards among different hospitals and IDNs, Wright explains.

"HealthTrust is distinctively capable of establishing these standards because of the collaborative culture of our aligned membership," he continues. "We are making these standards publically available to both members and non-members to promote efficiencies across the industry." *Find a copy of the standards at https://healthtrustpg.com/supplier-standards.*

TRINITY HEALTH'S EXPERIENCE

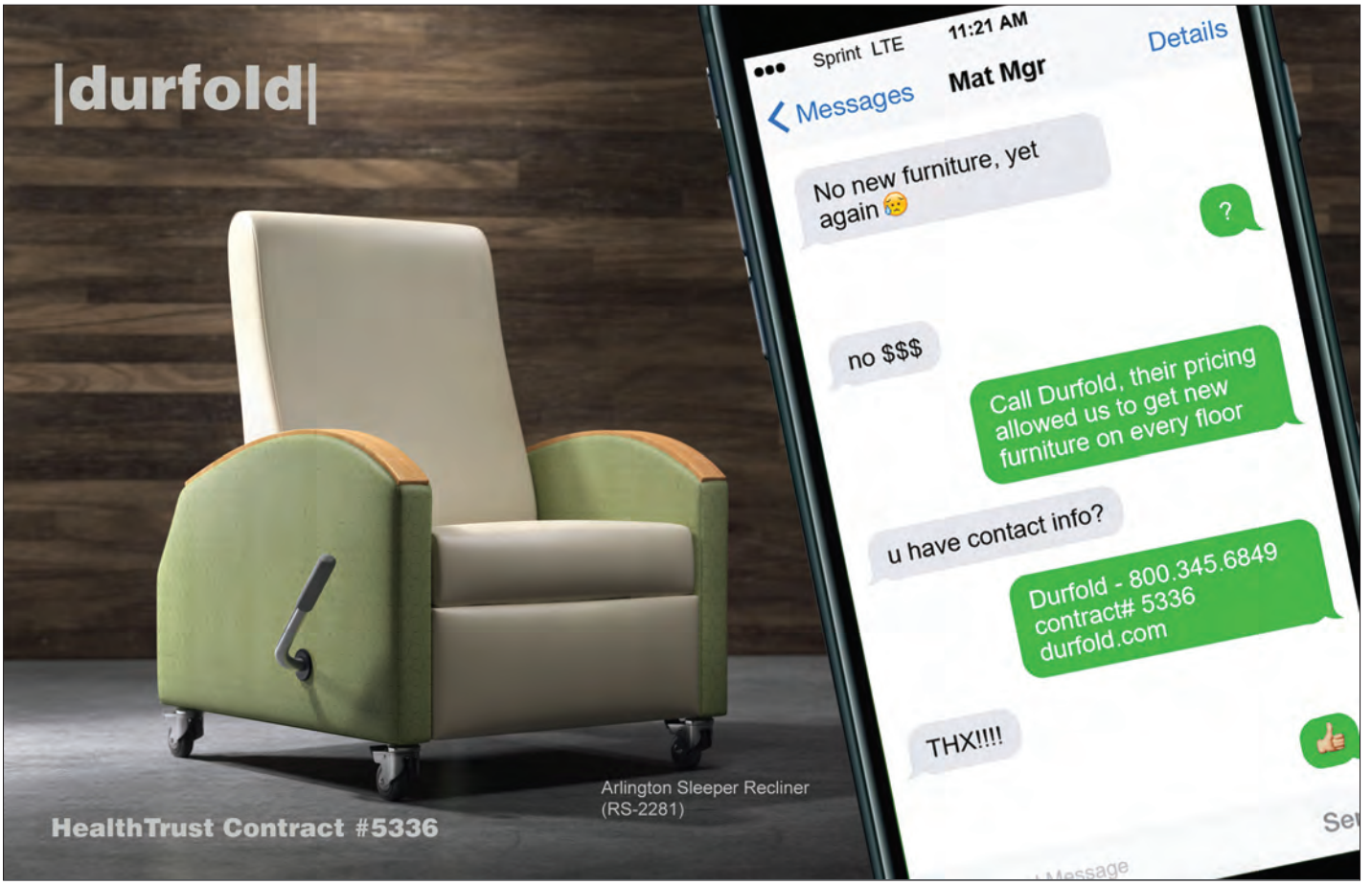
Cleveland has been with Trinity Health since 2013. He has worked in the healthcare supply chain industry since 1992. "In my 25 years of experience, I've seen everything from a spiral-bound notebook to maintain vendor credentials to the current state of credentialing portals and everything in between," he recalls.

To register vendor representative visits, Trinity Health's solution has evolved to institute credentialing portals across its acute-care hospital space. If reps are not compliant with the standards, a badge will not be issued, and the supplier will not be allowed into the facility. "The portals are by far the best method we have had," Cleveland says.

The credentialing system at Trinity Health strengthens the health system's culture of patient safety while limiting the entry of supplier representatives into the facility. "First and foremost, vendor credentialing is a safety issue," Cleveland says. "We have an obligation to make sure all of our visiting vendors and contractors are legitimate, authentic and aligned with our approved processes. Limiting access helps ensure a safe and less disruptive environment for patients and their families, and for our clinicians and colleagues."

Cleveland says the system has also helped with regulatory compliance. "Having a credentialing program enables us to collect required information on vaccination status, criminal background history, technical competency and professional accreditation for access at any of Trinity Health's facilities nationwide," he says.

The system has had other concrete benefits, too. It has helped drive contract compliance and standardization, which impacts



supply costs. It also ensures suppliers are meeting their agreements with the hospital and only selling products they are authorized to sell.

Now that Trinity Health has implemented vendor credentialing standards across their health system, next steps include refining the process, including taking close looks at elements like managing vendor appointments and the frequency of supplier visits. Cleveland believes the system will increase efficiency by reducing uninvited vendor visits to facilities.

"We added up the number of registered visits captured through the credentialing portal system and the time associated with those visits was staggering," Cleveland says. "So, now we're moving toward a more centralized approach in which supplier reps work with our strategic sourcing team instead of taking up the valuable time of clinicians in our hospitals. It's an optimization initiative that can give those responsible for patient care more time with the people they serve."

Cleveland acknowledges that there are plenty of good reasons for suppliers to visit a facility—to provide education and training on medical devices and to repair and maintain equipment, to name a few—but it's also important to separate vital conversations about patient care from selling products and services. "When administrative rules such as the vendor credentialing system and centralized sales calls are put into place, it takes the sales pressure off the vendor-clinician relationship that has been building over time," he explains.

"Establishing a standard set of criteria for the supplier community to gain access to our facilities has brought welcome change to the process," Cleveland says. "The shift makes these vendor credentialing standards easy to implement while offering significant benefits—both to health systems and the people they serve." ●

VERIFY PROFESSIONALS THROUGH HEALTHTRUST WORKFORCE SOLUTIONS

HealthTrust Workforce Solutions serves as a third-party vendor credentialing provider for hospitals across the U.S. Born from decades of real-world experience, it reliably credentials the widest range of healthcare professionals—from vendor representatives and technicians to nurses and other non-employee clinicians. Industry-leading, proprietary technology ensures the highest levels of transparency for vendor compliance and operational audits. Developed in a collaborative environment, the technology and registration processes are intuitive and streamlined to achieve more efficient and reliable registration and credentialing. To learn more about HealthTrust Workforce Solutions as a vendor credentialing service provider, contact **Tony Pentangelo**, executive vice president of managed services, at **Anthony.Pentangelo@HealthTrustWS.com**.

Q&A *With Caroline Fife, M.D.*

WOUND CARE WARRIOR

Caroline Fife, M.D., medical director of the CHI St. Luke's–Wound Care Clinic at The Woodlands, Texas, is passionate about advancing care for chronic wounds, improving the reporting of wound care data and developing wound care-related quality measures.

How did you decide to make wound care your specialty?

I didn't set out to do this at all! I'm board-certified in hyperbaric medicine, and I did a hyperbaric and environmental medicine fellowship at Duke. I came to Houston because of the offshore diving industry and neutral buoyancy laboratory at NASA. I had an exciting career taking care of divers in the Gulf of Mexico and helping those involved in getting a space shuttle built.

Because I was running the hyperbaric chamber at the Texas Medical Center, doctors began to send me patients with wounds. I went to my chairman to complain that somebody should start a wound center, and he told me that I had to do it. So, in 1990 I started a venous leg ulcer clinic using only a handout that Dr. Claude Burton at Duke had given me when I visited his clinic. Within just a few months, it was so busy, I couldn't see all the patients. There was no one else in the Texas Medical Center providing wound care.

How do chronic wounds affect people?

Chronic wounds impact people both emotionally and psychologically, in a way that other chronic problems do not. These patients are in pain. They're up all night. Many patients have dealt with these problems and suffered for years. Wounds can prevent people from leaving their house, going to church or spending time with grandchildren. The average patient comes to a wound center for almost eight months, and they never have just one wound. Some of these people have many illnesses they are dealing with, but we do our best to treat their wounds and hopefully make that part of their lives better.

How do you define and diagnose an infection within a wound? Walk us through the operational perspective when assessing a patient with a chronic wound and determining their plan of care.

Diagnosing infection is a moving target. To get a precise diagnosis, we do a biopsy of tissue and look at the number of bacteria per unit of tissue. We sometimes also do assays that analyze the DNA of these heavily colonized wounds to analyze all of the bacteria that make up the biofilm. It is not uncommon to have 10 or 15 bacteria identified by DNA assay.

There are no hard and fast guidelines. It's a complicated decision tree that's based on how vulnerable the patient is, the type and quantity of bacteria present, the needs of the wound and whether it is getting better or worse, the presence or absence of systemic symptoms, whether healing is our goal or comfort, and even the financial realities. When making decisions about treatment protocol, I ask for a lot of input from the nurses. The nurses have more insight into these patients' daily lives and practical issues that might affect their treatment.

For example, a wound could be colonized with bacteria, yet not rise to the level of an infection, which we usually define as the patient's body deciding to go to war with the bacteria (and vice versa). However, when a wound is heavily colonized, the current thinking is that the bacteria inhibit healing because the bacteria utilize the resources that the body needs to grow tissue.

Because these bacteria are making a mess, we would prefer to kick them out so that the cells can get back to work. But we're always trying to decide how aggressive to be with colonizing bacteria. If someone has a fever and red streaks coming from the wound, we would all agree it's infected and is going to need either IV or oral antibiotics. But there's a gradation; we first have to decide how sick the patient is. We might have to put them in the hospital for IV antibiotics because we just can't get ahead of it. If the patient isn't necessarily sick, but their wound is colonized heavily with bacteria, we might use oral or topical antibiotics. If we think we can beat it with topical agents, we have to decide if we're going to use antimicrobial dressings, which wound cleansers can best help without hurting and how often they need to be applied.

How do these practical variables inform your decision-making on certain dressings?

We consider practical questions such as: What other medications are these patients on? How frequently do their dressings need to be changed? Who is going to help them with their treatment at home? Are there any limitations in terms of insurance, or do we need to provide a recipe for a very inexpensive cleanser they can make at home?

We try to match treatment with what is practical for the individual patient. It wouldn't be possible to create an algorithm that could do what we do as we plan and negotiate at the bedside what makes the most sense for a particular patient. We sometimes learn in these examinations that the patient has the dressing on backward, or that the dressing has slipped out of place. I listen to patients when they say the dressing isn't working for them. I want to make sure everybody is on board with the treatment.

What are some best practices that focuses on antimicrobials?

The antimicrobial products used to help either kill or suppress bacterial growth in chronic wounds usually contain silver or iodine preparations, though some products with honey may also be considered to be part of that category. There are no large prospective trials evaluating the antimicrobial effect of honey dressings, but they perform well in clinical practice and patients like them.

Silver is the most popular antimicrobial, but it's also the more expensive option. The Food & Drug Administration (FDA) is afraid that patients may be developing a resistance to silver, even though there is no practical and reimbursable test for it.

The topic of antimicrobial dressings is a controversial one. These dressings are expensive, but CMS doesn't put antimicrobials in a separate category for reimbursement purposes. It may be hard to justify their high cost if we are not sure we can demonstrate a specific benefit. Can we show that they decrease pain, decrease odor, prevent maceration, reduce drainage volume, decrease nonviable tissue in the wound bed or reduce the risk of clinical infection? Those seem to me to be better endpoints than healing since most dressings are only used for a few days at a time.

I'm watching a new category that may be the next big thing for antimicrobials: antibiofilm agents. These agents are not drugs or dressings, so as a result, they are not covered by CMS. They don't actually kill bacteria, but they reduce the bacteria's ability to adhere to the wound bed. In some cases, the patient's response to these products has been spectacular. At between $70 and $250 dollars per tube, however, they are cost prohibitive, and the patients must purchase them out of pocket. Even if the manufacturers produce them in single-use packets, the reimbursement rate for an outpatient clinic visit is probably too low to cover it. That may not be true in settings where patients are under a capitated rate, and if the antibiofilm agent allows them to be discharged sooner.

How do you handle supply costs and the negotiation of physician preference items?

At our clinic at The Woodlands, we all strive to be cost-conscious. However, the reality is we're never putting just one product on a wound—there could be a seaweed-based dressing impregnated with silver, an absorbing foam to control draining and a compression wrap to control swelling and hold it all in place. We have to think about the total cost we can pay for dressing supplies and still keep the clinic afloat.

Recently our supply prices got out of control. Our clinical manager, **Sherrill White-Wolfe**, and I gathered everyone together and said we have to contain or lower costs while maintaining quality. We asked everyone to come up with the products they couldn't live without and which ones they could bend on. We set the standard in the very beginning that we will only do what is in the best interest of the patients.

We put a price list in front of our clinicians, which was enlightening to all of us. It made a huge difference to our doctors and nurses who thought they had to have certain products. Once they saw that the price was so much higher than an equivalent, they couldn't justify paying that much more for what was essentially the same product. Even though I might have a preference toward a certain supplier's product, there might not be enough of a difference in the elements between the two to justify paying four times as much for essentially the same thing.

It didn't feel like finger pointing; it was really a conversation where we tried to find a way to move forward together. We went around the table and said, "Every clinician can have one product they don't think they can manage good patient care without." The most surprising thing was that once everyone got their "favorite thing," they were then willing to compromise and negotiate on the others.

How has the industry changed since you first started treating wound care patients?

One of the biggest negative changes has to do with what I call "fantasy healing rates." In part because of the way we were doing clinical trials, people got used to the idea that "all wounds heal." So, many companies that run wound centers have their contracts tied to healing rates. In fact, our clinical manager is under a lot of pressure to report healing rates as a metric of how well our program performs.

But what people forget is that if a wound isn't healing, there's usually a good reason why. Our body's system of healing wounds normally works perfectly, but when it doesn't, it's because there's something horribly wrong. Our job is to figure out what's wrong and fix it. A chronic wound is a symptom of another disease or condition, such as diabetes or malnutrition, etc. It's not really that a patient just has a diabetic foot or vein ulcer, it's that they have congestive heart failure that's poorly controlled and have fluid shifts where their legs suddenly swell. Or they're malnourished because they have chronic diarrhea and can't hang on to their proteins.

It's not just about what dressing we're going to use, but how we are going to do something about all of their medical problems. Even if we were to fix that one wound, it would come back if there are underlying issues.

We report honest healing rates to CMS using risk stratification, which levels the playing field by reporting healing rates in relation to the predicted likelihood of healing, so that doctors taking care of the sickest patients don't look like they have worse outcomes. CMS approved our risk stratified pressure ulcer healing measure for physician reporting as part of MIPS in 2019.

Why are chronic wounds so expensive to treat? What kind of healthcare payment model would be needed to cover costs?

Since so many patients have wounds as a symptom of underlying medical conditions, most of the expense is not during brief hospitalizations. The expense is going to be the months and maybe years of nursing home services, home nursing services or outpatient therapy. DRGs (diagnostic-related groups) have controlled the cost of inpatient hospitalization, but outpatient costs continue to soar. Since wounds can take months to heal and require very expensive therapies, Medicare's cost of caring for them is a staggering $96 billion per year.

If you look across the board at most wound centers, at least 50 percent of patients with chronic wounds are Medicare beneficiaries. Many of these patients have limited incomes and may not have a secondary insurance. I am worried, for example, that the high-cost "skin substitutes" commonly used in wound care are almost off limits to Medicare patients without a secondary insurance. And there are other barriers to access. I spent 23 years in a medical center and the average patient there struggled to pay the daily $12 parking fee. Many seniors can't afford the nutritional supplements that I recommend and yet the simplest and most important thing that I correct every day are nutritional deficiencies.

If we are going to spend $96 billion a year caring for patients with wounds, someone is going to have to be focused on reducing those costs. Medicare is leaning toward episode-based payments for some treatments like "skin substitutes." Private insurance companies thought they could be more efficient with care and save money, but they didn't realize how much wound care for these patients was actually going to cost. I believe the situation could improve drastically if we came up with a different approach to allocating what is actually covered. While the concept of linking payment with outcome is supposedly the focus of Medicare's Quality Payment Program (QPP), it doesn't have any wound care measures. That's why the U.S. Wound Registry (USWR) had to create some. Unfortunately, for a host of reasons, only a handful of wound care practitioners report wound care quality measures, even though I can prove that doing so improves patient outcomes.

What is one of the wound care field's biggest challenges?

The coordination of care is one of our biggest challenges. One way to solve that is through wound care coordinators, similar to transplant coordinators. Transplant coordinators deal with patients that have a lot of complicated diseases that require multiple medicines. They're committed to making sure those patients are taken care of at every stage. I think it's a great model for wound care because our patients, on average, have up to 10 major comorbid conditions and take 12 medications. We can't manage them nearly as well without the help of a coordinator.

We also need a better reporting system so we have the analytics to determine which products or techniques work best on patients. The USWR is perhaps the largest repository of detailed, structured data on patients with wounds, but many electronic health record (EHR) vendors have blocked the transmission of data to the USWR. We hope to have a "SMART App" available for the Epic EHR in 2019 that will facilitate the reporting of wound care quality measures from hospitals with that system. ●

Dr. Fife shares additional thoughts on wound care on her blog at https://carolinefifemd.com.

Caroline Fife, M.D.

Caroline Fife, M.D., is medical director of the CHI St. Luke's–Wound Care Clinic at The Woodlands, Texas, and a professor of geriatrics at the Baylor College of Medicine in Houston, Texas. She is the chief medical officer of Intellicure, a Texas-based health information technology company that provides a specialty specific electronic health record to wound and hyperbaric centers across the U.S. Fife is the executive director of the U.S. Wound Registry, a nonprofit organization recognized by CMS as a Qualified Clinical Data Registry (QCDR) for MIPS reporting and the development of quality measures for wound care physicians.

Fife received her bachelor's and master's degrees from Texas A&M University College of Medicine. After a residency in family medicine at the University of Texas, Southwestern, she completed a fellowship in undersea and hyperbaric medicine at Duke University, then joined the University of Texas Health Science Center, Houston, where she served on the faculty for 23 years. She is board-certified in undersea and hyperbaric medicine through the American Board of Preventive Medicine and has been a certified wound specialist since 1998. She has served on the boards of the American Academy of Wound Management, the Association for the Advancement of Wound Care and the American Professional Wound Care Association. She initiated the Memorial Hermann Center for Wound Healing, which is affiliated with the University of Texas, Houston, in 1990, and the Memorial Hermann Center for Lymphedema Therapy in 1998. She is currently the co-chair of the Alliance of Wound Care Stakeholders.

DRIVERS OF CARE

The Evolving Role of Clinician Managers

The healthcare industry has seen dramatic change over the past 40 years. The shift from a retrospective payment system to DRGs (diagnostic-related groups) in the 1980s changed the way hospitals and healthcare providers were reimbursed for care. Nearly nine years ago marked the passage of the Affordable Care Act, beginning the ongoing transition to value-based care. In 2013, the Association for Health Care Resource & Materials Management launched its CQO (cost, quality, outcomes) movement to help guide healthcare supply chain through the changing environment. The Institute for Healthcare Improvement (IHI) refers to this transition as the "triple aim" of healthcare—improving the care experience, improving population health and reducing per capita costs. Left to decipher the details of care delivery amid these significant changes are clinical managers—the overseers and supervisors of hospital departments, such as surgery, nursing, pharmacy, critical care units and physical therapy.

"Years ago, clinical managers were only expected to know the clinical aspects of their jobs," explains **Judith Pins**, RN, MBA, MHRD, president of Pfiedler Education, a continuing medical and nursing education company. "Today, however, you cannot be in any type of clinical management position without also having a thorough knowledge of the financial and business aspects of a hospital. Clinical managers have to stay informed about the healthcare industry and ongoing changes to reimbursement because of the impact on care delivery."

Judith Pins, RN, MBA, MHRD

UNDER PRESSURE

A Moody's Investors Services report from December 2018 suggests that not-for-profit hospitals will continue along their same course in 2019, with expenses continuing to outpace revenues, meaning hospitals will see even more margin compression than they have in the past.

As clinical managers move into 2019 and beyond, it means they must shoulder more of the burden of reducing costs and increasing revenue. "Everyone in the healthcare industry is under tremendous pressure to cut costs," Pins adds. "We need clinical managers who can streamline processes, drive out costs and become even more efficient."

That's easier said than done considering many of the other struggles these managers are dealing with:

> Staffing issues continue to plague the industry, with almost 31 percent of hospital leaders reporting they can't find enough candidates to fill open positions.

> 56 percent of healthcare organizations still don't have a comprehensive data governance plan in place, despite the investment and interest in big data. A data governance plan—an organizationwide framework for managing a patient's health information from the moment it's entered into the system until well after the patient is discharged—is essential for helping healthcare facilities achieve the goals of the IHI's triple aim.

> C-suite, supply chain and clinical leaders don't always agree on the same goals. For example, consider a scenario involving a switch in surgical tools. The chief financial officer and director of supply chain may want to use a new tool or eliminate products to save money. A clinical manager is the go-between and responsible for communicating this change to the physicians and nurses who use those products daily. There's likely going to be resistance from the clinicians, and the clinical manager is at the center of that shift.

HONING THE TOOLS

Challenges like these can certainly seem insurmountable. But Pins suggests clinical managers can overcome the hurdles by targeting their already-strong skillset toward the following three priorities:

1. **Supporting colleagues through the stress of change.**

Healthcare organizations are required to constantly adapt to modifications in medical

care, technology, evolving reimbursement models, patient expectations and more. This pressure can lead to "change fatigue," or a tendency to distrust change from organizational leadership. It's easy to get frustrated with what seems like constant shifts, whether it's switching to a new brand of surgical gloves in the operating room or modifying the way performance reviews are handled.

However, adaptation is necessary for a hospital's survival, and clinical managers can be the agent of change to ease their colleagues into new processes and procedures. They have to learn to be proficient at encouraging and helping their teams navigate ongoing modifications in their departments. They can start by focusing their efforts on communication, stress management and recognition of employee achievements.

However, C-suite support is essential for clinical managers to lead more proactively. It's in the hospital's best interest to encourage this new structure for clinical managers since they are a "lynchpin in the success of a change initiative," according to Prosci, a change management consulting organization. In Prosci's 2018 study, "Best Practices in Change Management," research participants identified support and engagement from middle management as the top contributor to change management success. Hospital leadership should ensure that clinical managers have the skills and tools they need to successfully lead their teams through such efforts.

> "EVERYONE IN THE HEALTHCARE INDUSTRY IS UNDER TREMENDOUS PRESSURE TO CUT COSTS. WE NEED CLINICAL MANAGERS WHO CAN STREAMLINE PROCESSES, DRIVE OUT COSTS AND BECOME EVEN MORE EFFICIENT." **Judith Pins**, RN, MBA, MHRD | President | Pfiedler Education

2. Learning to interpret and analyze data.

According to a 2016 article in *Becker's Hospital Review*, the pressure to control the increasing costs of medical devices has led many healthcare providers to demand more information before making purchase decisions, such as proof of product superiority from manufacturers.

In the example of a hospital considering a new, $1,000 stent, a manufacturer may present clinical studies that prove the product is safe for coronary artery procedures, but clinicians will also want to see that this product produces better outcomes than the stent they're currently using. So now, clinical managers must be able to gather and analyze clinical data to make evidence-based product decisions. They're involved in the supply chain decision-making process, and that was never the case before. But now, the clinical point-of-view on such decisions has become more vital and valued.

3. Embracing innovation.

In a competitive and consumer-oriented healthcare environment, hospitals are challenged to find novel solutions to deliver care. Innovation is often associated with new tools and technologies, but it also applies to the implementation of new processes, clinical workflows and training methods.

A 2017 article from the *New York Times* suggests that innovation can be as simple as a trauma team leader wearing an orange vest to be more easily spotted in a hectic emergency room or a new pain scoring system using toy-like objects in a pediatric unit.

Clinical managers need to learn ways to bring innovation to their teams. They can no longer say, "This is the way we've always done it." Hospitals are often the largest employer in their towns, but that doesn't mean competitors aren't looking to replace them. "Look at Walgreens and CVS Pharmacy offering medical services, and retail giants like Amazon and Walmart entering healthcare. Either disrupt the disrupter or you will be disrupted," Pins says.

As naturally good problem-solvers in their daily jobs, clinical managers are often the individuals in a hospital in the best position to identify potential innovations or the reinvention of processes such as reducing the 45 minutes it takes to admit a patient to a room, or decreasing the 20 minutes it currently takes to clean a patient room. Their roles as department leaders and their experience in both clinical and financial settings often positions them as the people with the most realistic, workable ideas.

THE EDUCATION SOLUTION

The value of continuing education for clinical managers—whether through product training or educational conferences and meetings—cannot be overstated, Pins explains.

"As hospitals try to cut costs, education may not always be a top priority," she says. "There's a time and place to save, but also to spend money on educational resources."

When learning about new products, Pins suggests making use of the resources available through HealthTrust such as clinical evidence or new technology reviews. When making non-HealthTrust contracted purchases, clinical managers should ask prospective suppliers to provide both brand-specific resources and accredited, non-brand-specific resources to help them make evidence-based decisions.

Pins also points to the need for multidisciplinary meetings and conferences that invite physicians, pharmacists, nurses and other clinicians to learn about and find solutions for the same topic together. "We believe that this actually improves patient care," she says.

"I'm consistently impressed with the educational summits presented by HealthTrust, such as the 2017 perioperative pain collaboration summits," she adds. "Groups of clinicians from across the membership came together to discuss pain and, specifically, how to decrease opioid addiction. There's great value in this kind of collaboration." ●

Pfiedler Education is the accredited provider of continuing education credits for HealthTrust University Conference and select member summits and webinars throughout the year. Learn more about HealthTrust's educational offerings at **healthtrustpg.com/education**.

THE ROAD TO APPROVAL

Understanding the FDA's Clinical Investigation Process

When a healthcare facility considers adopting a new medical device or adding a new medication to its formulary, one of the first questions asked is, "Has it been approved by the FDA?"

Approval by the U.S. Food and Drug Administration (FDA) is vital for making decisions about which items to purchase, but as **Angie Mitchell**, RN, assistant vice president of physician services at HealthTrust shares, many supply chain professionals and healthcare providers don't fully understand how the FDA's approval process works. A clearer understanding of the FDA's inner workings may help healthcare organizations have appropriate expectations for new product releases and better appreciate what that required approval means.

Angie Mitchell, RN

Denise Dunco, MSN, RN

In November, Mitchell and **Denise Dunco**, MSN, RN, manager of physician services at HealthTrust, attended the FDA's three-day Clinical Investigator Training Course, receiving an insider's look at the FDA approval process. Below, they share some insight that can offer HealthTrust members a deeper understanding.

A CLOSER LOOK AT CLINICAL TRIALS

The responsibilities of a principal investigator conducting a clinical trial was a focus of the course. Attendees learned the basic design concepts of a clinical trial and what to look for in drugs and medical devices that are being investigated in a clinical trial. Mitchell shares that this information will assist HealthTrust members in reviewing clinical data for sources of bias and error. Those skills can provide them with more reliable information regarding drugs and medical devices that are undergoing clinical trials, enabling them to make more informed decisions for their facilities and patients.

In recent years, the FDA has promoted greater transparency into its decision-making process and instituted post-market surveillance. "The FDA was extremely open about what they share with study investigators, and I think they really want those conducting the review process to succeed," Mitchell says. "Some people have the perception that you send clinical trial paperwork into the black hole of the FDA and wait for an answer, but from the information presented, it offers opportunities for pre- and post-meetings with the investigator and team to clarify questions and provide direction. Patient safety is the FDA's No. 1 priority."

MORE CLARITY ON MEDICAL DEVICE APPROVALS

The development of drugs and medical devices follows well-established pathways to make sure they are safe and effective when they reach the public. "Although the medical device pathway is different from drugs, the FDA's standards are the same," Dunco says. "The medical device pathway to approval is divided into three classes depending on the type of information needed to ensure safety and efficacy." (*See sidebar below for details on the three classes.*)

The FDA is currently re-evaluating the way devices are approved under the 510(k) process. "Currently, a device is considered substantially equivalent if it has the same intended use and the same technological

DIFFERENCES BETWEEN FDA MEDICAL DEVICE CLASSES

Class I devices include items like cotton swabs, antimicrobial medical gloves, elastic bandages and tongue depressors. These devices are generally exempt from premarket submissions to the FDA.

Class II includes devices such as X-ray machines, powered wheelchairs, surgical drapes and some diagnostic tests. Most of these devices require a 90-day review before being cleared by the FDA. That review requires that the new devices be substantially equivalent to predicated devices, or existing similar products that have already been cleared. If a predicate device does not exist, the new device requires a 150-day review. If special controls can be designated that provide a reasonable assurance of the device's safety and effectiveness it will be regulated by the FDA, explains **Angie Mitchell**, RN, assistant vice president of physician services at HealthTrust.

Class III includes advanced devices such as defibrillators and implantable middle ear devices, digital mammography, minimally invasive and non-invasive glucose testing devices. These products require premarket approvals. These devices must have a 180-day review and additional regulatory oversight. Any risks for Class III devices cannot be mitigated by special controls.

Trials for new medical devices are different from drug trials in many ways. For instance:

- Device trials tend to enroll fewer participants.
- Many device trials assess iterative improvements to existing devices.
- Device design and procedures may be modified during the trial.
- Adaptive device designs are increasingly common.
- Existing data can substitute for prospective trial data.

characteristics as a device that is already legally marketed," Dunco explains. "To help keep pace with the increasing complexity of rapidly evolving technology, the FDA is modernizing the 510(k) clearance pathway, which accounts for the majority of devices the FDA reviews."

The Center for Devices and Radiological Health (CDRH) is the branch of the FDA responsible for the premarket approval of all medical devices. CDRH also oversees the manufacturing, performance and safety of these devices.

CDRH is working to achieve its vision of providing access to high-quality, safe and effective medical devices through several strategic priorities, Mitchell says. It plans to establish a national evaluation system for medical devices so that users can access and use real-world data for making decisions. The organization also partners with healthcare providers and patients to solicit their thoughts and opinions on regulatory decisions. Often before the FDA finalizes their approval for a category or product, they may open it up for public comment for a designated period.

As medical device approvals evolve, a deeper understanding of the process will help Mitchell, Dunco and their colleagues make more informed decisions about product approvals at HealthTrust. Before adding a new medical device to HealthTrust's contract portfolio, clinical professionals who are often subject matter experts in that area review all the clinical device information. "We determine the type of FDA approval a device received, and we have a dedicated team member who continually monitors the FDA website for recalls or changes," Mitchell says.

THE GLOBAL ANGLE

The number of international sites and trial participants contributing data to support U.S. marketing applications for drug and device approval is increasing.

To expedite the approval process of both drugs and devices, the FDA does accept data from studies conducted internationally if the data meets criteria specified under FDA regulations. For instance, the study must be well-designed, performed by qualified investigators and conducted in accordance with good clinical practices. If necessary, the FDA must also be able to validate the data through on-site inspection.

Research and technology will continue to expand around the world as scientific minds uncover new treatments and medical devices to improve patient outcomes. And, the FDA will remain committed to ensuring that those new developments are safe and effective. Meanwhile, HealthTrust clinical experts will monitor such developments and keep its members informed about the latest in FDA approvals and recalls. ●

Mark Dumond, HealthTrust's assistant vice president of technology services, monitors FDA activity and provides a monthly update to HealthTrust members. Find the information in the "Clinical Evidence" tab, "FDA Updates" section of the member portal.

HEALTHTRUST LOOKING TO HONOR CLINICAL & SUPPLY CHAIN ACCOMPLISHMENTS

Nominations Open for the 2019 HealthTrust Member Recognition Awards

Deadline for Submissions: **March 31, 2019**

Nominations are being accepted for the 11th annual HealthTrust Member Recognition Awards, honoring outstanding performance and exceptional contributions. Awards will be presented during the 2019 HTU Conference, Aug. 12-14 in Nashville, Tennessee.

HealthTrust members and on-contract suppliers may submit nominations or members can self-nominate. The awards recognize individuals or teams who have gone above and beyond to deliver measurable results in the following five categories:

- Operational Excellence
- Clinical Excellence
- Outstanding Member
- Social Stewardship (Sustainability, Diversity or Community Outreach)
- Pharmacy Excellence

The nomination process is now online at **http://survey.healthtrustpg.com/s3/2019MemberNomination**

Contact **HTUawards@healthtrustpg.com** with any questions.

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