

THE SOURCE

ENHANCING PROVIDER
PERFORMANCE &
CLINICAL INTEGRATION

Q1 2020 | V 15 NO. 1 | HEALTHTRUST

TIME (& DATA) HEALS ALL WOUNDS

Caroline Fife, M.D., believes
the use of data can transform
the world of wound care

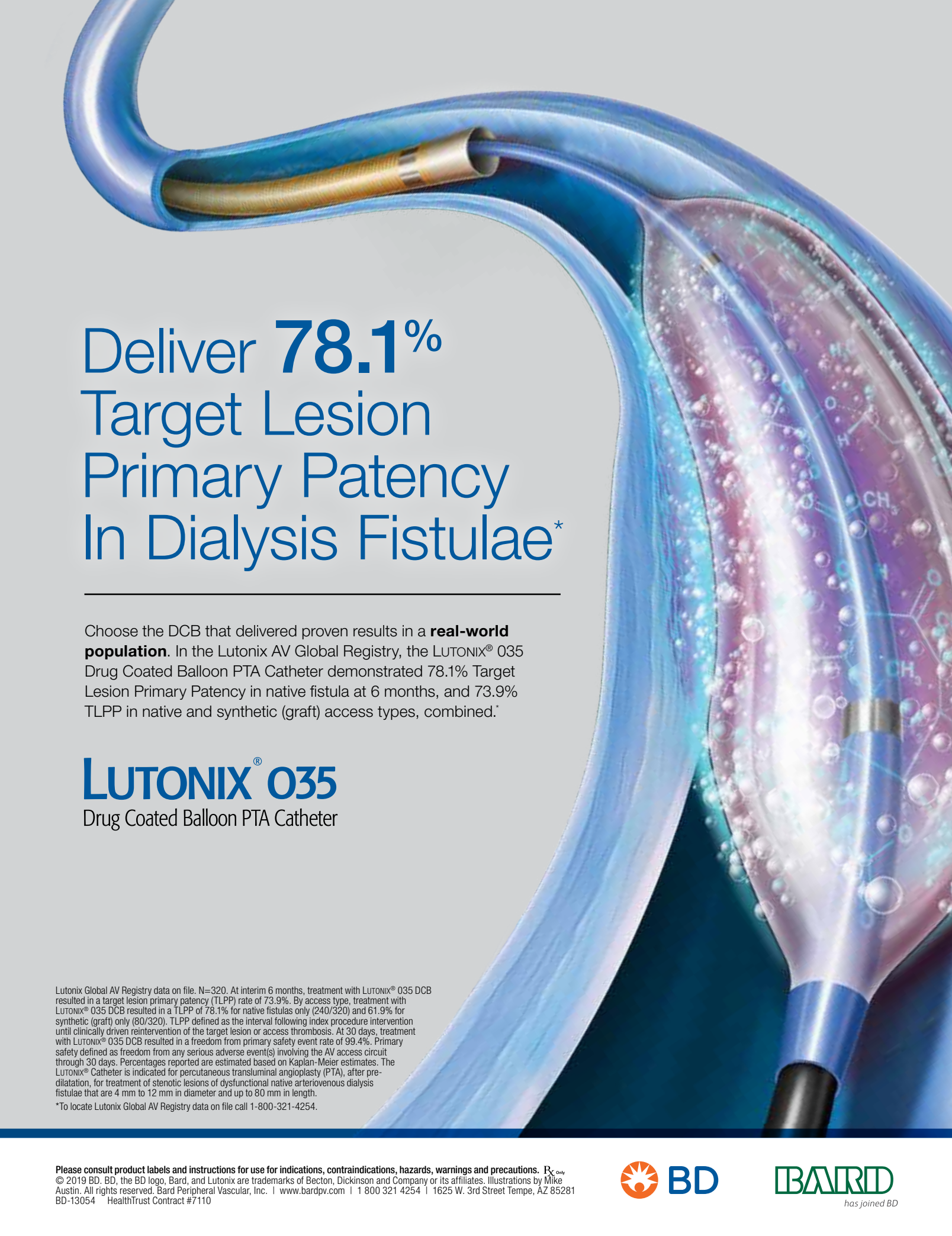
DRESSED TO DEFEND

Attire guidelines focus on
infection prevention

GUIDING THE JOURNEY

The important role of
patient navigators

★ ★ ★ ★ ★
HealthTrust Member
Recognition Award
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See page 8 for details.



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*To locate Lutonix Global AV Registry data on file call 1-800-321-4254.

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DRESSED TO DEFEND

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EDITORIAL CONTRIBUTIONS:

Clinicians and staff within HealthTrust member facilities are invited to share their expertise as part of upcoming stories. Readers are also invited to suggest other experts for interviews or article ideas for publication consideration. Preference is given to topics that represent:

- * Clinical or supply chain initiatives that exemplify industry best practices
- * Physician Advisor expertise
- * Innovation, new technology, insights from data and analytics
- * Positive impacts to cost, quality, outcomes and/or the patient experience

Contact Faye Porter at faye.porter@healthtrustpg.com with suggestions. (Note: HealthTrust reserves the right to edit all articles and information accepted for publication.)

Member address changes: Contact hpgsvc@healthtrustpg.com

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GUIDING THE HEALING JOURNEY

Patient navigators offer unparalleled support that can improve patient experience and outcomes.

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PUBLISHER

Ed Jones
President/CEO

EXECUTIVE PUBLISHER & EDITOR-AT-LARGE

John Young, M.D., MBA, CPE, FACHE
Chief Medical Officer

EXECUTIVE PUBLISHERS

Crystal Dugger, MBA, RN
VP, Clinical Services
Angie Mitchell, RN
AVP, Clinical Services

EXECUTIVE EDITOR

Faye Porter
Director, Member Education & Communications, Clinical Services

CONTRIBUTING EDITOR

Shellie Meeks
Manager, Member Education & Communications, Clinical Services

EDITORIAL & CREATIVE SERVICES

Cara Finnegan
Editor, GLC

Paula Rosenberg Frey, BSN, MS
Contributing Editor, GLC

Enrique "Rick" Cruz
Art Director, GLC

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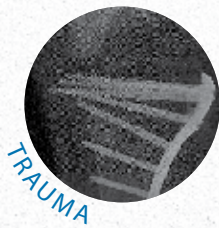
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CEO perspective

Supporting member access to essential medicines

The market for generic injectables continues to be plagued by prolonged drug shortages on mission-critical medications. This serves to threaten patient safety and the ability of medical professionals to consistently provide quality care. In addition, healthcare providers are forced to manage unpredictable medication prices, creating unnecessary hurdles in delivering cost-effective therapy.

In order to help mitigate these concerns, last year the Pharmacy Services team at HealthTrust launched Supply Interruption Mitigation Strategies (SIMS)—a healthcare improvement program targeting more than 75 medications identified by providers and clinical advisory boards as critical to patient care. SIMS enables HealthTrust to protect its member facilities against supply interruptions and sudden, often severe, price increases.

HealthTrust recently added two more mission-critical drugs—propofol and heparin—to its proprietary pharmacy-contracting model. Propofol is a key component of anesthesia delivery. Heparin is one of the most widely used injectable anticoagulants with multiple therapeutic indications.

Suppliers of SIMS products undergo a rigorous vetting centered on supply chain viability and sustainability. In return for scale, predictable purchasing volumes and sustainable pricing, drug makers commit to manufacturing redundancies and firm prices—important factors that can help insulate members from drug shortages. The Pharmacy Services team is working with manufacturers that demonstrate the capabilities necessary to meet the strict criteria for SIMS inclusion. HealthTrust expects to contract for approximately 20 SIMS products in the weeks ahead. Keep apprised of additional contracted products through the Pharmacy Response newsletter and by visiting the Member Portal.



Jason Mallory

MEMBER SATISFACTION

HealthTrust benchmarks member satisfaction annually and identifies opportunities for improvement. Along with industry research, a competitive market assessment and feedback from member business reviews, we refine our five-year strategic plan that identifies market demand, informs our offerings and justifies new investments to support member needs.

The annual survey includes more than 100 questions covering all member-facing areas, including account management, the contract portfolio and technology. The most recent member satisfaction survey was conducted during the HealthTrust University Conference.

One of our key metrics is the Net Promoter Score (NPS), and I'm honored to report it continues to be considered "world class" among all companies of various industries. Members cited the top reasons for the high NPS score as industry-leading price and contract value, account support, leadership strength and integrity, clear direction and mission, culture, and a patient-centered focus and clinical drive.

Continued on page 8



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CMO perspective

Impacting the waste conundrum



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Annual U.S. healthcare expenditures exceed \$3.5 trillion. Healthcare sites and news feeds have been filled with commentary surrounding a study in the October 2019 edition of the *Journal of the American Medical Association* (JAMA). The study reports that waste accounts for roughly one-quarter of all U.S. healthcare spending across six domains developed by the Institute of Medicine: failure of care delivery, failure of care coordination, overtreatment or low-value care, pricing failure, fraud and abuse, and administrative complexity.

The estimated cost of overspending ranges from \$760 billion to \$935 billion annually. These numbers could actually be on the conservative side, as the study's co-authors did not include extrapolations from Medicare data to the population at large. And, what is termed "waste" in the system is actually revenue to some entity, so there are huge political overtones to all of this.

In an October JAMA editorial, former Administrator for the Centers for Medicare & Medicaid Services (CMS) Donald Berwick, M.D., offered comparatives to help provide some perspective: "These are massive numbers. With U.S. healthcare expenditures exceeding \$3.5 trillion annually, 25% of the total would amount to more than \$800 billion per year of waste (more than the entire 2019 federal defense budget, and as much as all of Medicare and Medicaid combined). Even 5% of the total cost is more than \$150 billion per year (almost three times the budget of the U.S. Department of Education). That is worth repeating: by many pedigreed estimates, annual waste in U.S. healthcare equals or exceeds the entire annual cost of Medicare plus Medicaid."

After exploring 54 peer-reviewed studies, government reports and other information, the latest study suggests one-quarter of that spending could be reduced by implementing interventions found to reduce waste. The projected potential savings is estimated at \$191 billion to \$282 billion, excluding savings from administrative complexity. The latter is the only domain with no interventions proven to make an impact.

SIGNIFICANT OPPORTUNITIES FOR SAVINGS

Whether the study's estimates are exactly on point or more on the conservative side, the costs represent

significant savings opportunities for hospitals

and healthcare organizations. HealthTrust is uniquely positioned to assist its members with cost reduction in three of the six domains where there is evidence of known tangible interventions: failure of care delivery, failure of care coordination, and overtreatment or low-value care.

Consulting services at HealthTrust are through our inSight Advisory Services. In collaboration with HealthTrust members, these teams employ performance enhancement strategies for cost reduction and clinical outcomes improvement. Two areas that represent opportunities for substantive savings are part of the teams I oversee within HealthTrust's Clinical Services. Those include care redesign and medical device management. Key strategies are implemented to drive standardization and redesign care delivery models to reduce unnecessary care variation.

inSight Advisory Services offers consulting on these and other areas. To learn how HealthTrust can help you reduce waste and improve outcomes, contact me (physicians@healthtrustpg.com) to start the conversation.

ADDITION OF CLINICAL SERVICES VPs

In October, two executives joined **Crystal Dugger** as Vice Presidents on the Clinical Services team. **Paul Helmering** will lead our Clinical Informatics efforts and **Guy Hallberg** will lead our Medical Device Management team. Crystal maintains responsibility for the Care Redesign consulting team, the Physician Advisors program, and the ongoing development of our research and education programs. **HT**

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CEO perspective

Continued from page 4

We had more than 1,000 responses and many more write-in comments/recommendations—a significant increase over 2018. All survey findings and recommendations are reviewed in detail by each department, with action items developed to address opportunities for improvement.

WELCOME NEW MEMBER

I'm excited to welcome the newest member of our collective, Northern Light Health, an integrated health delivery system in Maine. We look forward to delivering value throughout the supply chain in support of Northern Light Health's mission to be a leader in healthcare excellence throughout the 16 counties it serves in Maine. Northern Light Health employs more than 12,000 team members throughout its hospitals, primary and specialty care practices, long-term and home healthcare, and ground and air medical transport and emergency care.

Northern Light Health will have access to a broad portfolio of contracts encompassing med/surg and pharmaceuticals supplies and services, custom sourcing

guidance for physician preference items and purchased services, and advisory services addressing clinical integration and operational efficiencies.

The HealthTrust team and I look forward to serving all of the membership throughout 2020 and thank you for your commitment and trust in us. **HT**



Ed Jones

President/CEO, HealthTrust

Publisher, *The Source* magazine

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2020 HealthTrust Member Recognition Awards Nomination Process Now Open

Nominations are being accepted for the 12th annual HealthTrust Member Recognition Awards honoring outstanding performance and exceptional contributions. Awards will be presented during the 2020 HTU Conference, Aug. 3-5 in Chicago, Illinois.

HealthTrust members and on-contract suppliers are invited to 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:

**Outstanding Member • Operational Excellence • Clinical Excellence
Pharmacy Excellence • Social Stewardship**

The nomination process is now online at healthtrustpg.com/2020-nominations.
Deadline for submissions is March 31, 2020.
For more information, contact HTUawards@healthtrustpg.com.





It's complicated

The market of complex generics remains untapped, while their power for savings is significant

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Complex generics, a drug category that often flies under the radar, have the potential to save a health system hundreds of thousands of dollars a year.

“Typical generic drugs are fairly simple to make: You get the chemical compound right, and you can produce the product,” says HealthTrust’s **Mark Walsh**, PharmD, Corporate Head of Pharmacy Sourcing. But unlike a regular generic, which can obtain approval from the Food and Drug Administration (FDA) simply by going through the Abbreviated New Drug Application (ANDA) process and proving it’s identical to the branded counterpart, complex generics live up to their name with significant manufacturing and regulatory challenges—making them less prevalent.



WHAT ARE COMPLEX GENERICS?

Complex generics are defined by the FDA as “a generic that could have a complex active ingredient, complex formulation, complex route of delivery or complex drug-device combinations.” These include enoxaparin, low

molecular weight heparin (LMWH), abuse-deterrent generics, parenteral microspheres, topical ointments and those with complex drug-device combinations, such as nasal sprays and transdermal delivery systems.

WHY THE PUSH FOR MORE?

Once several simple generics enter the market, the price can plummet up to 97%, says Walsh. But because there are fewer—often only one—complex generics in a class, the price differential from the branded drug is typically only between 15% and 20%. That’s why the FDA is promulgating policies designed to increase the number of complex generics on the market, including more guidance to address regulatory and scientific challenges.

HOW HAVE THEY WORKED?

Rachael Lu, PharmD, BCPS, Formulary Manager at Trinity Health in Livonia, Michigan, has seen firsthand how the savings can add up. She points to enoxaparin (Lovenox)—an anticoagulant—which used to cost up to **\$30 a day** when



Expect to see more complex generics entering the market. There is an estimated \$4.2 billion a year opportunity for manufacturers.

the branded version was the only one on the market. The complex generic now available, which provides equivalent safety and efficacy, costs about **\$7 a day**, she says. Given the volume of enoxaparin the health system uses, the result is significant. “Decreasing our spend by two-thirds is profound,” she says. “The use of complex generics is another tool we can use to arrive at value-based care for our patients.”

Formulary decisions around complex generics depend on the drug itself, Lu explains. “I don’t think with this type of drug we can have a one-size-fits-all.” Instead, the hospital takes a diverse approach rather than automatically requiring a therapeutic substitution as it does with regular generics.

The agent and how it’s used determine the pathway to formulary placement. Sometimes, she says, approval of a complex generic will drive the Pharmacy and Therapeutics (P&T) Committee to reevaluate the entire class of drugs to see if there is an opportunity to transition more patients to the complex generic version.

WHAT’S IN STORE?

To help its members integrate complex generics into their pharmacies, HealthTrust monitors the market, says Walsh, including patent expirations and litigation, to estimate when the product might be available; takes products through its pharmacy, clinical and operational boards to ensure they will work in various healthcare settings; produces monographs for P&T committees to ease adoption; and serves as subject matter experts to present at conferences and meetings.

Expect to see more complex generics entering the market, adds Walsh, particularly with the FDA push. He recently crunched the numbers and estimated there is a \$4.2 billion a year opportunity for manufacturers. “That’s a huge untapped market,” he says. **HT**

Shifting sands

A growing number of procedures qualify as outpatient, improving patient experience & reducing costs

Historically, improved technologies and increased physician proficiency at less-invasive techniques drove the migration of procedures to either outpatient departments or ambulatory surgical centers (ASCs). Today, payers and consumers are the main influencers for a mounting number of procedures moving to these settings. The result? Lower costs associated with patient care and less patient time in facilities.

In recent years, the Centers for Medicare & Medicaid Services (CMS) added a variety of procedures in the areas of orthopedics and cardiology to its payment schedule for hospital outpatient services and ASCs. For 2020, CMS has finalized the removal of total hip arthroplasty from the inpatient-only list, as well as allowed six cardiac interventional procedures to be performed at an ASC.

“Medicare is one of the main drivers, as it creates rules that allow this shift to happen,” explains **Holly Moore**, MSN, CCRN-K, a Clinical Director within the HealthTrust Clinical Services team. “CMS reviews quality, utilization and cost files annually and updates the inpatient, outpatient and ASC payment systems based on their findings, along with stakeholder expert opinions. What Medicare does, private insurers will typically follow.”



JOINT REPLACEMENTS PEGGED

Total knee arthroplasty was removed from the inpatient-only list in 2018, and total hip arthroplasty has been finalized to soon follow. This shift in orthopedics seems logical, given that the length of hospital stay after joint replacement has shrunk to a point where some patients meet discharge criteria on the day of surgery, according to a 2018 paper in *Acta Orthopaedica*. This transition is largely due to a combination of organizational and medical improvements in pain and anesthetic use, quicker patient mobilization and tighter surgical protocols, says **Kym Smith**, RN, also a Clinical Director within the HealthTrust Clinical Services team.



In 2014, CMS reimbursed about \$50,000 per hospitalization for total joint arthroplasty, totaling about \$7 billion in payments in the category that year, Smith says.

For 2020, CMS has proposed reimbursement rates of \$11,960 per total joint replacement surgery taking place in ASCs—more than \$500 higher than the \$11,419 for inpatient reimbursement.

“Of course, this shift will require some care coordination as well, and patient selection is important because these patients have to be fairly healthy, high-functioning and have low comorbidities for a same-day discharge,” says Smith. Patient selection processes must be in place for total joint arthroplasty in an ASC.

CARDIOLOGY PROCEDURES ON THE BRINK OF CHANGE

In cardiology, six percutaneous coronary interventions (PCIs) have been cleared for ASCs in 2020. This ruling follows 17 diagnostic cardiac cath procedures added to the ASC list in 2019, a shift that CMS initiated in 2016 when pacemaker implants made the list, according to *Cath Lab Digest*.

“This allows individual consumers the flexibility to choose where they want to undergo their procedures, assuming it is safe to do so,” Moore says. “A patient’s comorbidities or chronic conditions and the specific procedure needed will be key determinants to patient selection for PCI in an ASC. Certain emergent situations—where the patient has suffered a heart attack, for instance—will continue to require hospitalization.”

Still, overall, the move to the ASC space is based on evidence that it’s a safe option. “CMS reported acceptable safety profiles for a specific subset of lower-risk cardiac patients and procedures,” Moore adds.

A SMOOTH TRANSITION

More healthcare systems and individual physicians may partner to co-own ASCs, capitalizing on this trend, Moore



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explains. Doing so offers physicians the flexibility to perform procedures in various locations and prevents stakeholders from losing revenue. But providers must ensure continuity of care, Smith adds.

“Providers must ensure systems are in place to provide patients assistance in the immediate post-operative period to address questions and concerns, and minimize the potential for adverse events and hospital admissions,” Smith says.

Smith notes that it’s an educational shift for the patients, staff and providers. “It can be done safely, but patient selection is key.” **HT**

HOW IS THIS SHIFT IMPACTING YOUR ORGANIZATION?

Share your story by contacting Executive Editor Faye Porter at faye.porter@healthtrustpg.com

Rapid recalls

How alert systems & hospital processes are helping to better manage device & drug recalls

In recent years, the number of recalls on medical devices and pharmaceuticals has been on the rise, with more than 40 device recalls and more than 80 prescription and over-the-counter drug recalls in 2019 alone. This has increased the pressure on healthcare systems to pull the affected devices and drugs from the supply chain to ensure patient safety. Here's how some are managing.

INSTANT ALERTS

Angie Mitchell, RN, HealthTrust AVP, Clinical Services, remembers how her hospital handled recalls when she first started as a nurse many years ago: "Everything was manual," she says. This was problematic, because the hospital team didn't learn about the recall until they heard from the supplier or its sales rep, which could take weeks. During that time, patients continued receiving the recalled item, while those who had already had a device implanted had no idea there could be a problem.



Today, the Food and Drug Administration (FDA) posts recalls on its website as soon as they are approved and sends out daily alerts. HealthTrust also contracts with two suppliers that provide an automated service to help hospitals track and implement recalls, Recall Management (contract #20257) and National Recall Alert Center (contract #20246).

These services monitor FDA notifications 24 hours a day, seven days a week, explains **Eric Clapp**, HealthTrust Contract Manager for Strategic Sourcing/Purchased Services. The system then sends the recall notification to the healthcare organization. If the email is not opened within 24 to 48 hours, another message is sent, and the process continues until the supplier receives confirmation that the recall notification has been opened. The service also allows hospitals to create an electronic audit log from the time it receives the alert through the removal and customer notification process.



STANDARDIZED IMPLEMENTATION PROCEDURES

While suppliers can help distribute recall information, it is up to the hospital to implement the recall. Speed is crucial when it comes to patient safety.



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That's what impelled St. Luke's Hospital in Boise, Idaho, to completely revamp its recall program in 2015. "We had a close call with an infant formula recall," says **Crystal Geibel**, Business Intelligence Analyst, who manages the hospital's recall program. The near-miss prompted an internal audit, which revealed an opportunity for centralization and standardization across the system.



Today, the eight-hospital system has a centralized recall program where its facilities receive daily communication about any recalls affecting their areas of treatment. They then have between 24 hours and five days to resolve the issue, depending upon the seriousness of the recall.

Geibel recommends the following to hospitals implementing their own recall programs:

- ▶ **Set standards for resolution times.** The standards should also be integrated into department and system scorecards.
- ▶ **Ensure senior-level engagement.** The effort should be top-down.
- ▶ **Engage employees.** Most are more than willing to participate once they understand that the overall goal of the program is to ensure patient safety.
- ▶ **Choose the right supplier.** Be sure to choose a supplier that serves your facility's specific needs.
- ▶ **Report metrics at all levels.** That includes system, facility, department and individual metrics. Small facilities shouldn't be overshadowed by larger units.
- ▶ **Develop an iterative program.** That means setting realistic goals, addressing the barriers at each level and following a systematic approach.

At St. Luke's, the success of the program is due to both employee buy-in ("This is critical," Geibel says), and supplier collaboration. "We worked closely with our software

There were **more than 40** device recalls and **more than 80** prescription and over-the-counter drug recalls in 2019.

provider to make sure they could serve our needs,” Geibel explains. This process increased transparency on the effects of recalls, ease of resolution by end users and better metrics for leadership.

SUCCESSFUL RESULTS

St. Luke’s has seen noteworthy results, thanks to its new processes. In the past year, the health system has resolved:

- ▶ **100% of Class I recalls** (in which the product could cause serious adverse health consequences or death) within 24 hours
- ▶ **98% of Class II recalls** (in which the product could cause temporary or medically reversible adverse health consequences, or there is little likelihood of serious adverse health consequences) within three days
- ▶ **99% of Class III recalls** (in which the product is not likely to cause harm) within five days

In 2017, the hospital was a finalist for the ECRI Institute’s Health Device Achievement Award based on its revamped recall system.

Geibel emphasizes that effectively developing a program takes a measured strategy. “Don’t try to tackle everything at once,” she adds. **HT**

TOP REASONS FOR RECALLS

Devices

- Software issues
- Mislabeling issues
- Quality issues
- Performing outside of FDA specifications

Pharmaceuticals

- Failed specifications
- Sterility
- Mislabeling
- Foreign materials
- Subpotency



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Falls are the No. 1 cause of injury-related death in people age 65 and older, according to the Centers for Disease Control and Prevention (CDC). And they're becoming increasingly problematic:

The number of deaths from falls increased by 31% from 2007 to 2016.

The nationwide increase in falls—which happen both inside and outside of hospital walls and in every age group—has resulted in more visits to both emergency departments and trauma centers.

A fall with an injury adds an average of 6.3 days to a hospital stay, and the average cost for a fall with injury is around \$14,000, according to The Joint Commission.

Healthcare facilities are responding to this rise in falls by ensuring their fall prevention programs are in line with industry standards.

“Most facilities have some type of fall prevention program in place, and they really drive training and compliance for all of their clinicians in that area,” says **Tara Coleman**, MBA, BSN, RN, Director of Nursing Services, Clinical Operations at HealthTrust.

Coleman says all healthcare facilities are held to a high standard for decreasing falls within the hospital. “No one wants their loved one to



go into a facility and come out with an injury they didn't have when they went in,” she adds. Clinicians are looking at different ways they can keep their patients safe, and there are a number of solutions on the market.

CONTRACTED PRODUCTS FOR FALL PREVENTION

HealthTrust-contracted products in the fall prevention space include everything from pagers to protective garments. Of particular importance are the following products, ranging from basic to high-tech:

Slippers

Bottom grip slippers are an integral part of a fall prevention strategy, and HealthTrust recently renewed its slipper category. The HealthTrust Nursing Advisory Board completed a full review of different slipper suppliers, looking at how they fit, their clinical efficacy, the ability to accommodate every patient population, the grips, the quality of the cloth and the color, among other variables.

Slipper color is especially important, Coleman says, because it can be used as an indicator. Yellow socks indicate that a patient is a fall risk, and they alert everyone on staff to take the appropriate precautions to prevent a fall from occurring.

Wristbands

Some hospitals use colored wristbands (such as yellow) to alert staff that the patient in question is a fall risk. “If those patients are seen in the halls or common areas, staff know

that attendants should be assisting them,” Coleman notes.

Bed alarms

Bed alarms are another important part of any fall prevention strategy. They are set off if a patient starts moving in bed, immediately alerting hospital staff.

Lindy Barry-Brown, BSN, RN, Nursing Portfolio Director for HealthTrust, says some bed and chair alarms can be portable. They’re not integrated into the beds, but rather they’re a stand-alone alarm system, Barry-Brown says, which adds another layer of precaution. These portable alarms can be placed on the bed, on a toilet in the bathroom, on a wheelchair or on a stand-alone chair beside the bed.

Virtual sitters

Virtual sitters are a relatively new form of technology that allow healthcare professionals to remotely monitor patients who are a fall risk. The technology uses infrared sensors to detect a patient’s movement.

THE JOINT COMMISSION LAUNCHES EDUCATIONAL FALL PREVENTION CAMPAIGN

In July 2019, The Joint Commission launched the “Speak Up to Prevent Falls Campaign,” with resources to help prevent falls, including tips for how patients can take extra precautions, make small changes in their homes and ask for help when needed.

The Joint Commission offers campaign materials for use in healthcare facilities and recommends posting them in waiting rooms, patient rooms and bathrooms, cafeterias and in patient admission packets.

Visit www.jointcommission.org/topics/speak_up_to_prevent_falls.aspx to access the materials, including infographics and videos.

One study published in *The New England Journal of Medicine* found that incorporating virtual sitters into a hospital’s clinical workflow led to a 40% reduction in fall-related injuries.

Through the use of these products and fall prevention programs, facilities can be poised to stand firm on slowing this trend. **HT**

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Changes in the lab analytics space offer advantages & challenges

DRAMATIC INNOVATIONS IN THE LAB ANALYTICS SPACE OVER RECENT YEARS ARE CHANGING THE FACE OF CLINICAL CARE, presenting both benefits and obstacles to providers and patients.

Emerging technologies are improving the speed, sensitivity and accuracy of rapid test results. This helps in diagnosing and treating a bevy of infections beyond strep and flu, such as *Clostridium difficile*, sepsis and encephalitis. But these costly tests need to be understood and used appropriately to achieve the desired results.

“The flu and strep tests are good examples of that,” Blankenship explains. “The advent of molecular testing at the point of care allows providers to have a definitive answer while the patient is present, and that’s a

Choosing the best patients for rapid tests, and understanding the limitations of certain tests, should shape how providers utilize them.

“There’s been so much progress in the last five years that we’re doing things at the point of care we wouldn’t have dreamed of 10 years ago.”

– Diane Blankenship, BS, MLT, CLS, ASCP

“In the molecular field particularly, there’s been so much progress in the last five years that we’re doing things at the point of care we wouldn’t have dreamed of 10 years ago,” says **Diane Blankenship**, BS, MLT, CLS, ASCP, Senior Director of Laboratory Services at Community Health Systems in Franklin, Tennessee, and a member of HealthTrust’s Laboratory Advisory Board.



huge advantage. Infectious disease is really making a comeback, which may be the result of overuse of antibiotics—the pathogens we see now are much more resistant to them across the board. It’s important we keep our diagnostic abilities ahead of that, and the molecular piece is key.”

RECOGNIZING STRENGTHS & WEAKNESSES

Sometimes dubbed “Lab 2.0,” the development of rapid diagnostics has influenced how microbiology laboratories operate, essentially making the lab a member of the clinical team, says **Christa Pardue**, MBA, MT(AMT), Director of Laboratory Services, Clinical Operations for HealthTrust. But choosing the best patients for rapid tests, and understanding the limitations of certain tests, should shape how providers utilize them.



Molecular testing at the point of care allows providers to give patients answers, and treatment, right away. But its high price tag can potentially lead to wasted resources.



For example, Pardue explains, “If its high expense is not considered, rapid flu testing can become one of the highest wastes of resources in the health system.” She notes that children and the elderly are high-risk groups for whom rapid testing is best used to prevent complications and improve outcomes. “Basic flu screening is the most effective for the majority of the population,” she adds.

Advances in microbiology have optimized testing capabilities. Results can be determined days faster than with traditional testing, improving patient outcomes.



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At times, the sensitivity of rapid molecular testing becomes a weakness as much as a strength, Pardue says. This is true for C-diff, where a molecular test can be positive—because of the presence of the bacteria—without an actual infection, spurring overdiagnosis. To counteract this, in 2017 the Centers for Disease Control and Prevention (CDC) recommended an algorithm for C-diff testing that not only detects the bacteria, but also the actual inhibitory activity of the pathogen producing C-diff toxins that indicates an active infection causing serious illness—therefore reducing the risk of overdiagnosis, Pardue explains.

“This is just one example where understanding the technology is essential,” she adds.

In the case of sepsis, microbiology advances have optimized detection days faster than traditional testing could, improving not only survival rates but quality of life, Pardue says. Similarly, encephalitis can be treated much faster. “Rapid testing can precisely identify the offending viral pathogen faster than the spinal fluid cell count, and the differential can be completed,” she says.

PROVIDERS ARE ENTHUSIASTIC

Providers are generally pleased with the advantages offered by rapid diagnostics and excited for the opportunity to use them, Pardue and Blankenship say. But their enthusiasm may be tempered by budgetary restrictions that limit their choices.

“There are so many different products on the market right now that no one has everything,” Blankenship says. “So it forces labs to make decisions on how to spend their money. Part of the responsibility of the Lab Advisory Board is to be first in line to make sure the products our customers have available to them are what they need and to service all our customers—from large facilities to small critical access hospitals—so they can improve patient care.” **HT**

TO FIND OUT WHICH RAPID TESTS ARE ON CONTRACT, refer to the Member Portal for a link to CatScan, or contact your HealthTrust account manager.

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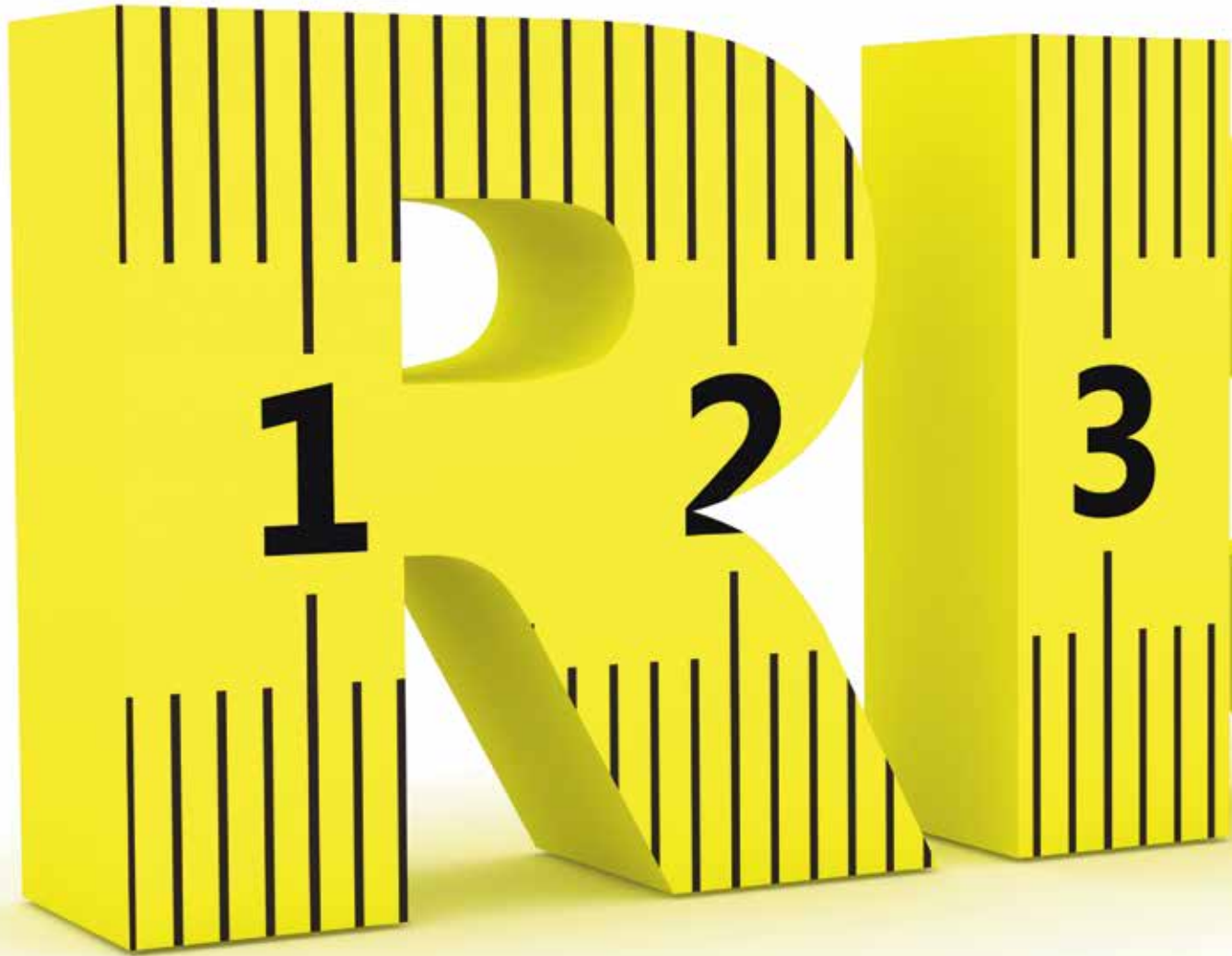
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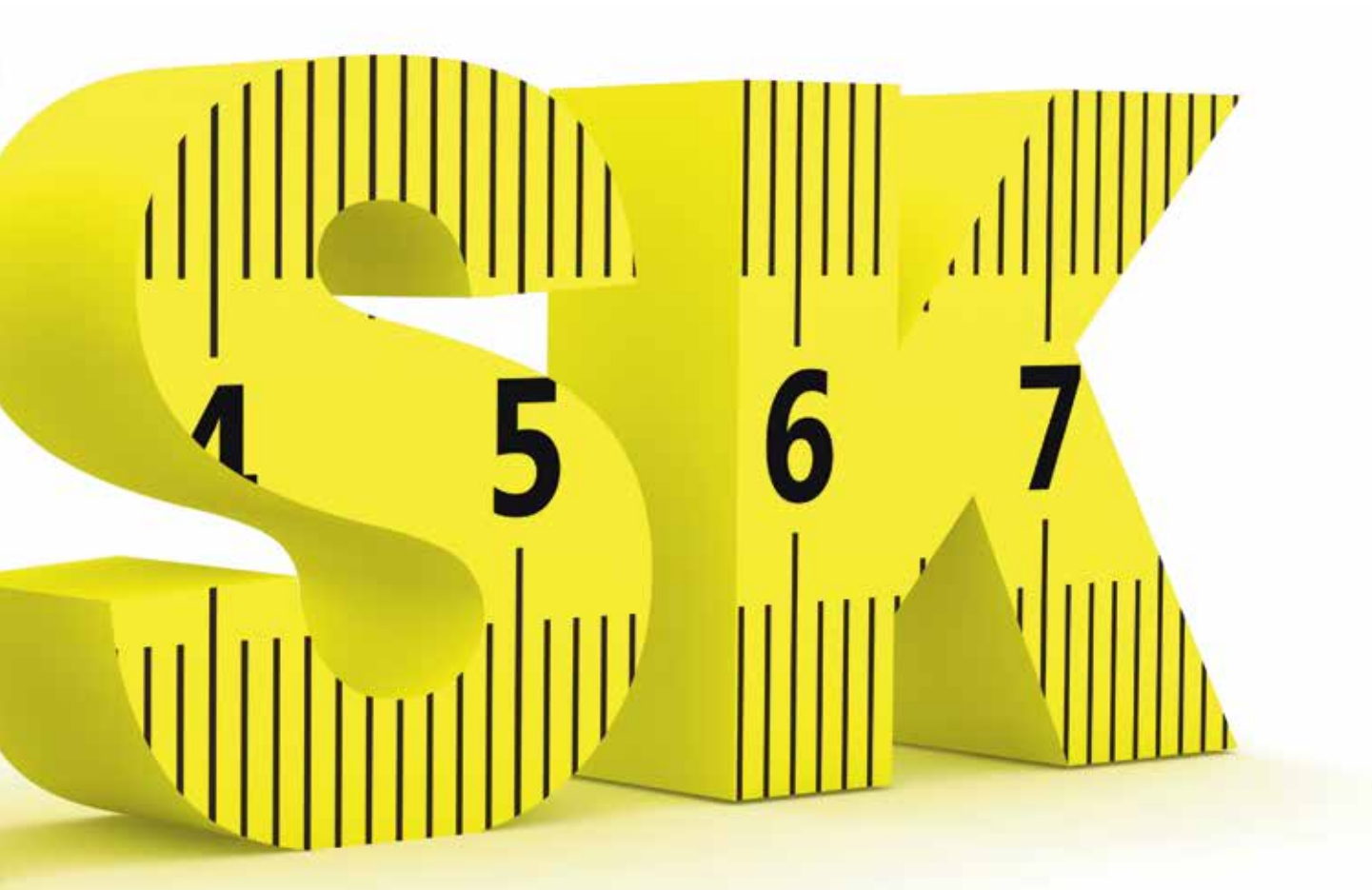
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Measuring



Risk assessment tools across the continuum of care can help improve patient outcomes

IMAGINE A WORLD WHERE YOU COULD PREDICT THE FUTURE AND KNOW ABOUT ALL OF YOUR HEALTH ISSUES BEFORE THEY HAPPEN. While we're not there yet, healthcare professionals can now use predictive analytics, an area of statistics that provides the power to assess risk across various care settings. If used correctly, this analysis can help predict whether a patient will experience an adverse event before it occurs.



Michelle Smith, PharmD, FACHE, is Hospital Sisters Health System's (HSHS) Chief Performance Improvement Officer for Information Technology. The health system uses tools to inform protocols. "We use risk assessments to look at how local system policies and procedures can be evaluated for common cause variation, share best practices and develop system standards that can be measured for actionable improvement," she says.



Here are some of the options in today's risk assessment toolkit, and what to keep in mind for the best results.

PRE-SURGERY OR PRE-PROCEDURE RISK ASSESSMENTS

Procedure-related assessments, such as the **Society of Thoracic Surgeons (STS) Online Risk Calculator**, are used

to identify a patient's risk of developing complications. A score is calculated for many of the potential risks, including renal failure, stroke, prolonged ventilation, length of stay, infection, re-operation and mortality. This enables more-informed conversations among providers, patients and their families in shared decision-making, as well as improved preparation of the surgeon and staff.

Karen Bush, MSN, FNP, BC, NCRP, Director of Clinical Research & Education at HealthTrust, says to keep in mind that obtaining the score is only part of the puzzle. Using the score to appropriately treat the patient requires a directed team approach and a physician who is engaged in the process. "The drawback of this type of system is that typically the information used for these risk assessments must be manually entered into a proprietary system to



obtain a score. Often, these are not integrated into the hospital or physician office's electronic medical record," she adds.

In July 2019, the American College of Surgeons launched a new geriatric assessment tool called the **Geriatric Surgery Verification (GSV) Program**. Recognizing that the population is rapidly aging and has specific needs, the group created a program that addresses 30 standards of surgical care for older adults. The benefits include better patient-physician communication about the patient's goals, as well as higher-quality, lower-cost surgical care.

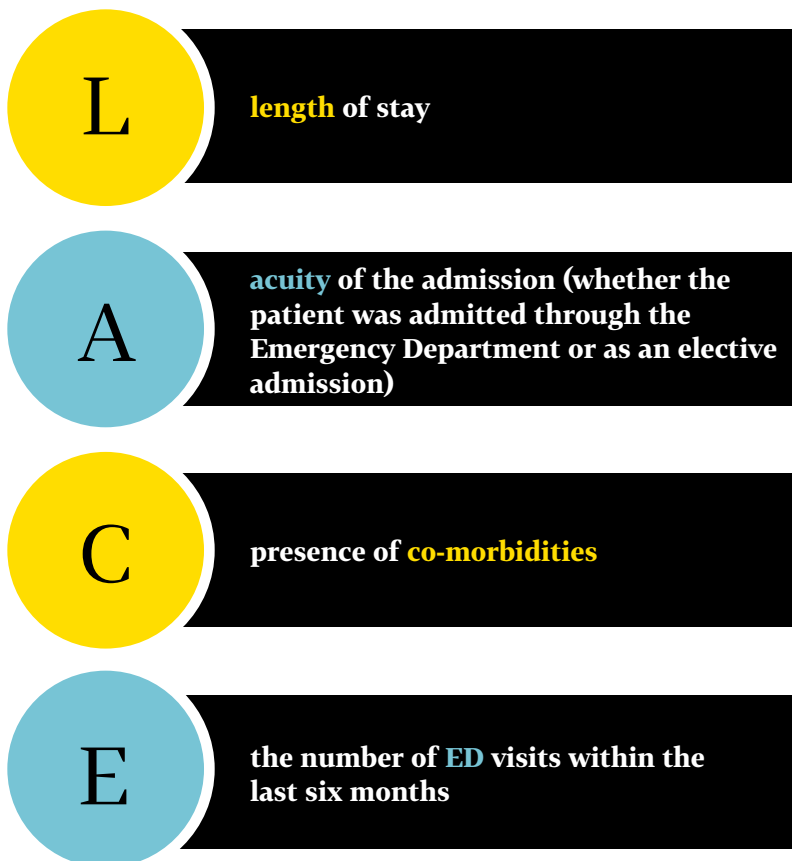
WARNING SCORE SYSTEMS

Early Warning Scoring (EWS) systems are used to detect the risk of potential adverse events while a patient is in the hospital. Assessments such as the **Modified Early Warning Scoring (MEWS)** use physiologic data points in the medical record to create an early warning system to notify hospital staff that a patient's condition is worsening, as well as the severity of the situation.

Smith shares that one of her organization's ongoing priorities is fall prevention. "At HSHS, we use the **Hendricks Fall Risk Assessment**, which we have built into our screenings," says Smith. The HSHS process is to escalate a patient's fall risk potential based on algorithms. If clinicians see an uptick of falls in a certain area, they can use the assessments to create a plan of action for improvement.

"We are looking at the number and types of falls to categorize them," says Smith. This information allows the team to better determine where to focus their efforts. "Falls can really be a setback for our patients as they try to heal. They can lead to a longer hospital stay and higher bills. We want to make sure we aren't adding to the cost of care, and that is why we are looking at how to prevent falls in a sustainable way based on the patient population." (See more about falls prevention on page 14.)

Evaluating patients' vulnerabilities as they transition from hospital to home offers healthcare staff the ability to identify risk and provide additional resources to avoid adverse events. **The LACE Risk Assessment** is used to evaluate a patient's risk of death or readmission after discharge from the hospital and to drive interventions for patients, based on the patient's score. The score is calculated using the four categories shown in the following graphic.



For example, heart failure patients who are identified as high risk for readmission on a LACE score may have a transition coach assigned to their case with additional education or tools employed while in the hospital. They may also receive more frequent touchpoints via phone or in person after hospital discharge, follow-up appointments made with the patient's regular physicians within a week of discharge, and additional resources such as home healthcare or cardiac rehabilitation.

No matter which tools facilities employ for the prevention of adverse outcomes, they should be easy to use and effective at identifying risk, Bush points out. Most important, risk assessment tools must be used to influence patient care to reduce that risk. "A tool that is used to calculate risk without specific protocol as to who should do what with the results is like having a car with no gas. It doesn't go anywhere," she says. **HT**

FOR MORE INFORMATION on risk assessment tools, contact Kimberly Wright, RN, AVP of Clinical Data Solutions, at kimberly.wright@healthtrustpg.com



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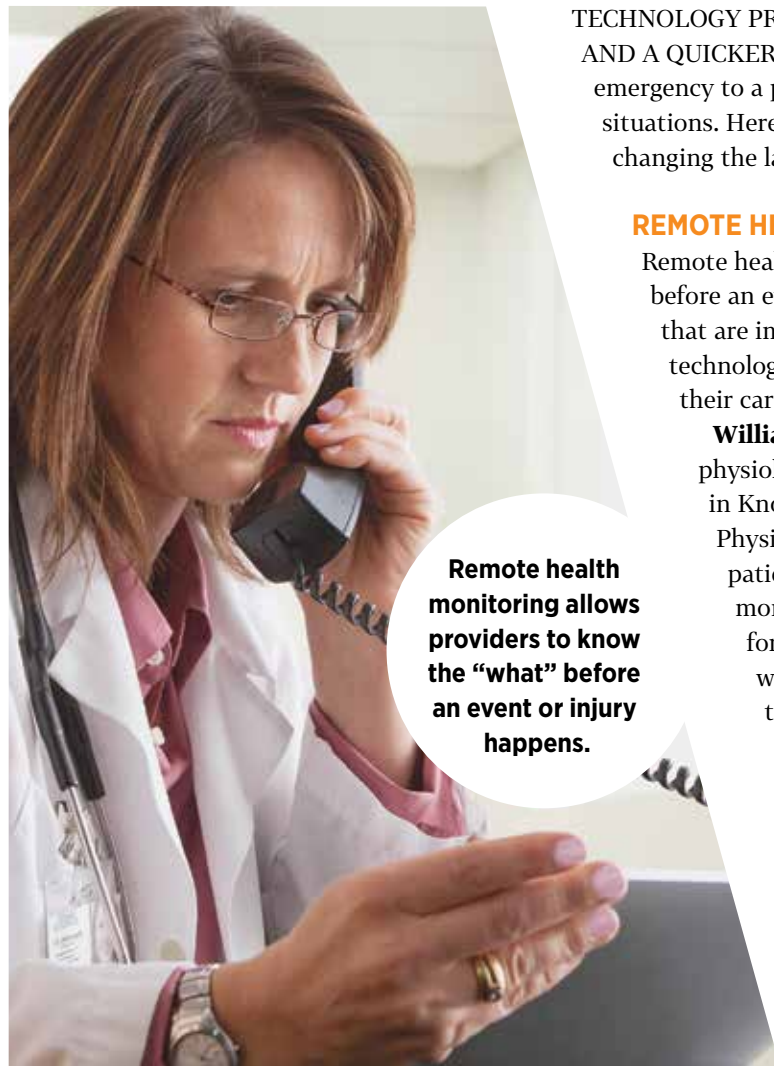
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Remote health monitoring allows providers to know the “what” before an event or injury happens.

TECHNOLOGY PROVIDES US WITH EASIER ACCESS TO INFORMATION AND A QUICKER WAY TO RESPOND TO EVERYTHING from a work emergency to a personal one—but it can also alert us to life-and-death situations. Here are two notable technological advancements that are changing the landscape of patient care and safety.

REMOTE HEALTH MONITORING

Remote health monitoring allows providers to know the “what” before an event or injury happens. Advance alerts are devices that are implanted in patients while they are in the hospital. The technology can then be used after a patient is discharged to guide their care.

William C. Lindsay, M.D., an electro-physiologist with Tennova Medical Group in Knoxville, Tennessee, and a HealthTrust Physician Advisor, says that when a patient goes into heart failure, remote monitoring technology makes it possible for physicians to catch issues earlier



while they’re in an outpatient situation. “If you can find them before they start getting into trouble, then you can fix them and the patient can remain an outpatient,” he says.

Dr. Lindsay finds that remote monitoring devices provide useful information to the entire team. “Electrophysiologists have a unique opportunity to help their hemodynamic colleagues, their mutual patients and their hospitals by taking advantage of readily available information, such as the heart failure monitoring metrics in some implantable cardiac defibrillators (ICDs),” he says.

SERVING patients where they are

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The vast majority of patients who have ICDs implanted have documented heart failure to some degree. Since most newer defibrillators now have heart failure monitoring capabilities, Dr. Lindsay's process is to notify cardiology counterparts when their patients might be in trouble. "The heart failure monitoring is primarily based on the thoracic impedance measurements, which are plotted over time and are available when the device is checked, either in the clinic or remotely," says Dr. Lindsay. Other devices can also measure respiratory rate, activity levels and heart rate, among other indicators, which add to the data supporting a heart failure diagnosis.

Dr. Lindsay notes that remote monitoring is also beneficial to hospitals and health systems, since one of Medicare's areas of focus for penalties is readmission of heart failure patients within 30 days of a hospitalization.

Another example of an advance alert is the cardioMEMS, a remote monitoring system used in some heart failure patients. After patients are discharged, they use a sensor to send biometric readings to a physician's office for review. "Studies have linked cardioMEMS to a reduction in hospitalizations," says **Karen Bush**, MSN, FNP, BC, NCRP, Director of Clinical Research & Education at HealthTrust. "But it's important to know that it's only approved for NYHA class III heart failure patients who were hospitalized for heart failure in the past year, and both the patient and the provider must be engaged."



PORTABLE CT SCANNERS

In many healthcare settings, such as an ICU, ambulance or trauma center, seconds matter and safety is paramount. Patients in critical care environments often have immediate needs and require many lifesaving interventions. Addressing both time and safety concerns, portable CT scanners can be a critical solution—eliminating the need to move patients and providing diagnostic images immediately for viewing right in the ICU.

"The portable CT scanner offers multiple benefits in the hospital setting," says **Luann Culbreth**, MEd, MBA, RT, CRA, FACHE, Director of Radiology and



Cardiovascular Services, Clinical Operations at HealthTrust. "Taking the CT scanner directly to the patient in the ICU, surgery, trauma or other procedural area saves medical professionals from having to move the patient and transfer care."

Portable scanners are battery-powered and wirelessly connected, with a drive system that enables easy movement through the facility. They use the same technology as traditional CT scanners, although some applications may be limited depending on the type of scanner being used.

These scanners can be used beyond the ICU. "There are other mobile applications for these scanners, such as an ambulance for dedicated stroke programs," says Culbreth. And, they can be part of a mobile clinic in rural areas.

As for what's in store, scanners could one day be used in medical helicopter transport—indicating that for these technologies, the sky's the limit.

Portable CT scanners from Samsung Neurologica are available for contracting as of Feb. 1, 2020.

HealthTrust continues to explore new technologies that enhance care delivery and patient safety. Suppliers with new technology are encouraged to submit products for review year-round at: www.healthtrustpg.com/healthtrust-innovation-center. Subject matter experts and service line clinical experts from within the HealthTrust membership will determine whether those products are clinically acceptable, and whether the financial and operational impacts are of such value to add them to the HealthTrust contract portfolio. **HT**





THE STATE OF HAIs

Prevention & control of healthcare-associated infections

Healthcare-associated infections (HAIs) are one of the most common adverse events in care delivery and a major public health problem with an impact on morbidity, mortality and quality of life. These infections also present a significant economic burden at the societal level. However, a large percentage of HAIs are preventable through effective infection prevention and control (IPC) measures. ¹

10% of patients get an infection while receiving care. ²

\$35 to \$45 billion
Annual overall direct cost of HAIs to U.S. hospitals ²

How length of stay is affected by HAIs ³

Type of HAI	# of extra days in the hospital	Excess costs per patient	Extra length of stay if patient also has MRSA (in days)	Extra cost to hospital if patient also has MRSA
Clostridium difficile Infection (CDI)	3.3	\$11K		
Central Line-Associated Bloodstream Infection (CLABSI)	10.4	\$45.8K	15.7	\$58.5K
Surgical Site Infection (SSI)	11.2	\$20.8K	23	\$42K
Ventilator-Associated Pneumonia (VAP)	13.1	\$40K		
Catheter-Associated Urinary Tract Infection (CAUTI)		\$1K		

1 in 31 hospital patients has at least 1 HAI on any given day. ³

5x-10x

Likelihood of ICU vs. non-ICU patients acquiring an HAI ³

Impact of IPC programs

Effective IPC programs show a **30%** reduction in HAIs. Many infection prevention and control measures, including hand hygiene, are simple, low-cost and effective; however, they require staff accountability and behavioral change. ⁴

¹ Source: World Health Organization's "Guidelines on Core Components of Infection Prevention and Control Programmes at the National and Acute Health Care Facility Level," ©2016

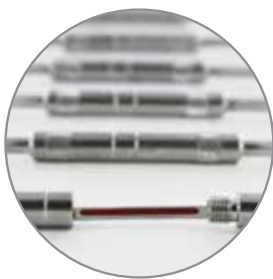
² Source: Centers for Disease Control and Prevention (CDC)

³ Source: 2015 Webinar: *The True Cost of HAIs: Reduce Cross Contamination & HAIs*. Lynn White, M.D., Staff Anesthesiologist, Partner, Physician Anesthesia Services, PC & Chief Medical Officer with Patient Shield Concepts, LLC.

⁴ Source: World Health Organization

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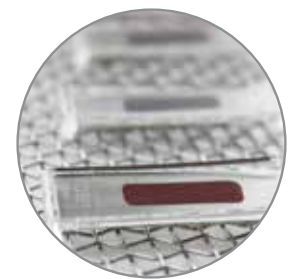
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HealthTrust's recent wound care summit brings fresh ideas to the forefront to improve treatment & cost management

A RECENT SUMMIT SPONSORED BY HEALTHTRUST ON THE STATE OF WOUND CARE BROUGHT TOGETHER 40 REPRESENTATIVES FROM SEVERAL HEALTH SYSTEMS to review current practices in managing wound care patients, share knowledge and experiences, and establish the action plans for each of their health systems and/or facilities. The result was an impressive array of takeaways and next steps that have the potential to change the landscape of wound care.

Participants expressed several areas of opportunity for improving wound care, including communication; standardization of wound documentation, diagnosis, treatment, outcomes tracking, product utilization and cost effectiveness; and the impact of patient comorbid conditions.

A key revelation: Data is essential. “The biggest take-home from the meeting is that people need to make data-driven decisions about the products they buy and use,” says **Caroline Fife**, M.D., HealthTrust Physician Advisor and wound care expert.

Dr. Fife highlights several data-related issues in the wound care field:

- 1 **The lack of consistent, high-quality/evidence-based wound care**
- 2 **Misrepresented outcomes or not reporting wound outcomes related to patient acuity: For example, if healing rates of 90% or higher are reported, but the outcomes of the sickest patients are not, it's impossible to explain to payers why expensive treatments were needed or justify their use**
- 3 **The presence of monetary incentives to provide certain treatments regardless of whether they work, which can result in payers just saying “no”**
- 4 **Insufficient knowledge as to what treatments or products are effective in practice because of a lack of risk stratification or real-world data**
- 5 **A lack of understanding about the value of certain treatments (including cost savings from avoided complications)**

Felvy Sanchez

TIME (&

Dr. Fife emphasizes that data-based knowledge is essential for identifying effective treatments.

DATA) heals all wounds



Caroline E. Fife, MD
Medical Director of Women's Health

Through brainstorming and discussions, the participants worked together to address some of these challenges.

STREAMLINING DATA

Several summit participants reported using a combination of contracted and internally managed wound centers, typically staffed with registered nurses, licensed practice nurses and hyperbaric oxygen (HBO) technicians with physician oversight. In addition, there is a wide variety of data and analytic efforts among participants. At WellSpan, for instance, quality metrics and data required for registry reporting come directly from the electronic health record (EHR). Community Health Systems (CHS) in Franklin, Tennessee, uses a vendor to capture patient satisfaction, healing rates, median days to heal and outlier rates from the EHR.

Facilities under management contracts report the percentage of patients who are healed per month, as well as the days-to-heal per diagnosis. This data is benchmarked against the management company's own internal data. The data is not stratified by wound or patient severity, however, so it can't be compared to facilities outside of the contract, Dr. Fife notes.

The facilities also measure patient satisfaction and pain intervention as internal quality performance indicators. This enables physicians to compare risk-stratified wound healing rates as part of their quality reporting under the Merit Based Incentive Payment System (MIPS). Although Medicare has set national benchmarks for venous leg ulcer (VLU) and diabetic foot ulcer (DFU) healing rates based on a severity scoring system called the Wound Healing Index, few wound management practitioners report their data, Dr. Fife says.

TriStar Health, which has 10 outpatient wound clinics, reports four- and 16-week wound volume reduction, debridement rates, wound types, HBO complications and ancillary services used.

"There was huge variability in wound care programs from institution to institution on the level of service they offered," Dr. Fife says. "And that has a big impact on what they perceive they need in terms of supplies."

Denise Dunco, RN, MSN, a Director of Clinical Research on HealthTrust's Clinical Services team, adds that in some cases, a lack of data complicates matters. "People don't know which product to use and which is best because of such limited data."



CHOOSING PRODUCTS

HealthTrust Physician Advisor **Dean Vayser**, DPM, addressed product choice



from the physician perspective at the summit. The key factor when choosing the right product should first be based on the evidence, he says. Next, consider the type of research conducted to demonstrate efficacy, followed by cost considerations. "We're driven in the medical environment by cost, and I think that evidence and pricing are very important in selecting the product that will be the most beneficial."

However, physician awareness of wound care products, evidence and pricing is very limited, Dr. Vayser adds. Doctors still obtain most of their information from pharmaceutical and medical supply companies. "Frequently, physicians are driven by what a supplier representative tells them but are not actually doing the due diligence of learning about the product and whether the outcomes are there to justify use of the products," he says. "The physician needs to understand the etiology, the root problem of why the wound has occurred and what the product is supposed to do in order to choose the best product for that wound."

Dr. Fife also noted the lack of any type of "game-changing" technology since Negative Pressure Wound Therapy became the standard in the 1990s. An even older treatment, the total contact cast (TCC), heals about 80% of DFUs in an average of 40 days. "No new technology has beaten that," she explains, noting that she helped bring two biologics to market and neither was as effective as TCC.

CORRALLING COSTS

The cost of wound care in the U.S. is unsustainable, Dr. Fife says. Estimates are that Medicare spends between \$28.1 billion and \$94 billion a year on wound care, with nearly 15% of Medicare beneficiaries suffering from a chronic wound.

One major challenge in the wound care world, Dr. Fife adds, is reimbursement. For instance, Medicare covers cellular- and/or tissue-based products (CTPs) primarily for DFUs and VLUs. However, highly restrictive criteria limits coverage to the least serious wounds in relatively healthy patients based on the criteria used in clinical trials. While the number of cellular products is growing all the time, Dr. Fife says, "payers are limiting coverage for them, citing a lack of evidence for their effectiveness."

Reemphasizing the necessity for data, Dr. Fife told participants of the summit that healthcare systems also require a method to collect and analyze CTP data, because the products are expensive for hospitals to purchase. They vary in price from \$30 to \$700 per square centimeter, yet no data is available to justify this price differential among patients.

"CTPs also have the most challenging documentation, reimbursement and coding requirements of anything I can

think of,” she says. “They can help patients yet negatively impact hospital finances at the same time. We have to have a way to understand the most appropriate utilization and make sure that we use them in a way that allows us to get paid for our services.”

SOLVING THE PROBLEMS

Dr. Fife points to several potential solutions to the issues facing wound care today. Her recommendations include:

- ▶ **Report wound care quality measures using risk stratification.**
- ▶ **Move to different reimbursement models, including bundled payments (something Medicare is likely to do within the next year or two).**
- ▶ **Collect real-world data from wound registries to report clinical effectiveness.**
- ▶ **Find partners that care about wound care costs, such as group purchasing organizations and state agencies, to help implement these approaches.**

“The cost of wound care in the U.S. is unsustainable. Estimates are that Medicare spends between \$28.1 billion and \$94 billion a year on wound care, with nearly 15% of Medicare beneficiaries suffering from a chronic wound.”

- Caroline Fife, M.D.



One of the highlights of the meeting came from the solutions-driven small group discussions. Members developed action plans to take back to their organizations, outlining goals, strategies and next steps around coverage and reimbursement, clinical evidence and practice, data and analytics registries, and organizational change/program implementation.

They also strategized on ideal education and awareness initiatives for wound care, a management approach for standardizing care for patients with chronic wounds, strategies for measuring and evaluating success for enhancing wound care, and proposals to engage physicians in implementation.

The action planning process was a “very

valuable” part of the summit, says **Cindy Christofanelli**, MS, RN, CVAHP, Divisional Director Clinical Resource Management at Hospital Sisters Health System. “It allowed us to think about what we’ll do when we go back to our organizations and engage our stakeholder groups, put together goals, identify



the purpose of our team, and develop a timeline and deliverables to address our challenges.”

HealthTrust conducted a follow-up conference call in December with participants to check on the progress of action plan implementation. Stay tuned for additional updates in future editions of *The Source*. **HT**

A SUCCESSFUL SUMMIT

September’s Wound Management Collaborative Summit brought together 40 representatives from Beaumont Health, CHRISTUS Health, Community Health Systems, HCA Healthcare, Hospital Sisters Health System, Kindred Healthcare, LifePoint Health, Scripps and WellSpan Health. Attendees were impressed with the value of the two-day workshop.

“Just working with your colleagues who are in a different environment, with similar yet somewhat different problems, is the best way to get a fresh perspective on what you’re trying to do,” says panelist and HealthTrust Physician Advisor **Aron Wahrman**, M.D., Associate Professor of Plastic Surgery at the University of Pennsylvania.



“The event granted an opportunity to examine what you’re doing right and maybe what you’re doing wrong and how you can improve.”

Participant **Nate Verrelli**, System Program Director of Wound Care & Hyperbaric Oxygen at WellSpan, says: “[The summit] gives you the confidence to go back and do what you were afraid you couldn’t do. The value is just off the charts.”

In addition to Drs. Fife, Vayser and Wahrman, other HealthTrust Physician Advisors included plastic surgeon **Salvatore Pacella**, M.D., and podiatrist **Bert Altmanshofer**, DPM. Industry specialist **Kathleen Schaum**, MS, shared her expertise in the area of wound care reimbursement.

TOP CHALLENGES IN WOUND CARE

Summit participants highlighted the top challenges they faced in their wound care programs:

- ▶ Patient issues, including multiple comorbidities, nonadherence to care plans, missed appointments, transportation issues and educational gaps in their understanding of wound causes and treatment
- ▶ Insurance coverage and reimbursement
- ▶ System support, including appropriate staff and provider coverage and specialist partnerships
- ▶ Variability in the supply chain between facilities
- ▶ Lack of inpatient/outpatient coordination and continuity of care using clinical pathways
- ▶ Decentralization within the hospital system
- ▶ Lack of standard protocols and processes
- ▶ Patient out-of-pocket costs
- ▶ The need for a robust and cost-effective product portfolio
- ▶ Managing complex and expensive regenerative tissue therapies
- ▶ Physicians who don’t provide timely documentation or follow clinical practice guidelines
- ▶ Coding and documentation issues
- ▶ Lack of wound care training for home health aides
- ▶ Lack of efficacious CTP options for patients with larger wounds
- ▶ Inadequate off-loading in the home and in long-term care facilities
- ▶ Lack of consistent prevention practices

YOU'RE EITHER PROTECTED OR YOU'RE NOT

TRADITIONAL 3-DOSE HEPATITIS B VACCINES MAY CREATE A FALSE SENSE OF SECURITY THAT PUTS PATIENTS, HEALTHCARE PROVIDERS, AND INSTITUTIONS AT RISK.^{1,2}

IT'S TIME TO DO SOMETHING DIFFERENT.

HEPLISAV-B provided faster and higher rates of protection than Engerix-B.^{3*}

HEPLISAV-B is the only 2-dose vaccine that can be administered in 1 month and is unanimously recommended by the ACIP.³⁻⁵

HEPLISAV-B protected >90% of adults in head-to-head trials with Engerix-B, including hyporesponsive patients.^{3†}

**NOW AVAILABLE FOR PURCHASE FROM ALL HEALTHTRUST AUTHORIZED DISTRIBUTORS.
(HEALTHTRUST CONTRACT #50985)**

INDICATION

HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.

IMPORTANT SAFETY INFORMATION

Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B.

Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

The most common patient-reported adverse reactions reported within 7 days of vaccination were injection site pain (23%-39%), fatigue (11%-17%), and headache (8%-17%).

Please see Brief Summary of Prescribing Information on the following pages.

*In study 2, the immunogenicity population comprised 1121 subjects who received HEPLISAV-B and 353 subjects who received Engerix-B. The mean age was 54 years for both groups. The primary analysis compared the seroprotection rate at week 12 for HEPLISAV-B with that at week 32 for Engerix-B. Noninferiority of the seroprotection rate induced by HEPLISAV-B compared to Engerix-B was demonstrated.³

†Trial 3 study design: A clinical trial in adults aged 18 to 70 years who received HEPLISAV-B (N=4537) or Engerix-B (N=2289). The primary analysis evaluated the noninferiority of the rate of protective immunity at week 28 induced by HEPLISAV-B (n=640) to Engerix-B (n=321) in patients with type 2 diabetes mellitus. A secondary immunogenicity objective was to demonstrate the noninferiority of the rate of protective immunity with HEPLISAV-B at week 24 compared with Engerix-B at week 28 in all subjects and in subgroups defined by age, sex, body mass index, and smoking status among adults aged 18 to 70 years.⁴

Abbreviation: ACIP, Advisory Committee on Immunization Practices.

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Visit HeplisavB.com to learn more.

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted] Solution for Intramuscular Injection

1 INDICATIONS AND USAGE

HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus. HEPLISAV-B is approved for use in adults 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular administration.

2.1 Dose and Regimen

Administer two doses (0.5 mL each) of HEPLISAV-B one month apart.

2.2 Administration

HEPLISAV-B is a clear to slightly opalescent, colorless to slightly yellow solution.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

Administer HEPLISAV-B by intramuscular injection in the deltoid region using a sterile needle and syringe.

3 DOSAGE FORMS AND STRENGTHS

HEPLISAV-B is a sterile solution for injection available in 0.5 mL single-dose vials and prefilled syringes. [see *How Supplied/Storage and Handling* (16.1)].

4 CONTRAINDICATIONS

Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (e.g. anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast [see *Description* (11)].

5 WARNINGS AND PRECAUTIONS

5.1 Managing Allergic Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B.

5.2 Immunocompromised Individuals

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B.

5.3 Limitations of Vaccine Effectiveness

Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

A total of 9597 individuals 18 through 70 years of age received at least 1 dose of HEPLISAV-B in 5 clinical trials conducted in the United States, Canada, and Germany. Data from 3 of these trials are provided below.

Study 1 in Subjects 18 through 55 Years of Age

Study 1 was a randomized, observer-blind, active-controlled, multicenter study in Canada and Germany in which 1810 subjects received at least 1 dose of HEPLISAV-B and 605 subjects received at least 1 dose of Engerix-B® [Hepatitis B Vaccine (Recombinant)]. Enrolled subjects had no history of hepatitis B vaccination or infection. HEPLISAV-B was given as a 2-dose regimen at 0 and 1 month followed by saline placebo at 6 months. Engerix-B was given at 0, 1, and 6 months. In the total study population, the mean age was 40 years; 46% of the subjects were men; 93% were white, 2% black, 3% Asian and 3% Hispanic; 26% were obese, 10% had hypertension, 8% had dyslipidemia, and 2% had diabetes mellitus. These demographic and baseline characteristics were similar in both vaccine groups.

Solicited Local and Systemic Adverse Reactions

Subjects were monitored for local and systemic adverse reactions using diary cards for a 7-day period starting on the day of vaccination. The percentages of subjects who reported local and systemic reactions are shown in Table 1.

Reaction	Table 1 Study 1: Percent of Subjects Who Reported Local or Systemic Reactions Within 7 Days of Vaccination				
	HEPLISAV-B %		Engerix-B %		
	Post-Dose*		Post-Dose*		
	1	2	1	2	3
Local	N=1810	N=1798	N=605	N=603	N=598
Injection Site Pain	38.5	34.8	33.6	24.7	20.2
Injection Site Redness†	4.1	2.9	0.5	1.0	0.7
Injection Site Swelling†	2.3	1.5	0.7	0.5	0.5
Systemic					
Fatigue	17.4	13.8	16.7	11.9	10.0

Reaction	Table 1 Study 1: Percent of Subjects Who Reported Local or Systemic Reactions Within 7 Days of Vaccination				
	HEPLISAV-B %		Engerix-B %		
	Post-Dose*		Post-Dose*		
	1	2	1	2	3
Headache	16.9	12.8	19.2	12.3	9.5
Malaise	9.2	7.6	8.9	6.5	6.4
	N=1784	N=1764	N=596	N=590	N=561
Fever‡	1.1	1.5	1.8	1.7	1.8

Note: only subjects having data are included. Clinical trial number: NCT00435812

*HEPLISAV-B was given as a 2-dose regimen at 0 and 1 month followed by saline placebo at 6 months. Engerix-B was given at 0, 1, and 6 months

† Redness and swelling ≥ 2.5 cm.

‡ Oral temperature ≥ 100.4°F (38.0°C).

Unsolicited Adverse Events:

Unsolicited adverse events within 28 days following any injection, including placebo, were reported by 42.0% of HEPLISAV-B recipients and 41.3% of Engerix-B recipients.

Serious Adverse Events (SAEs)

Subjects were monitored for serious adverse events for 7 months after the first dose of vaccine. The percentage of subjects reporting serious adverse events was 1.5% in the HEPLISAV-B group and 2.1% in the Engerix-B group. No acute myocardial infarctions were reported. No deaths were reported.

Potentially Immune-mediated Adverse Events

Potentially immune-mediated adverse events that occurred within 7 months of the first dose of vaccine were reported in 0.2% (n = 4) of HEPLISAV-B recipients and 0.7% (n = 4) of Engerix-B recipients. The following events were reported in the HEPLISAV-B group in one subject each: granulomatosis with polyangiitis, lichen planus, Guillain-Barré syndrome, and Grave's disease. The following events were reported in the Engerix-B group in one subject each: Bell's palsy, Raynaud's phenomenon, and Grave's disease. One additional Engerix-B recipient with a history of mixed connective tissue disease had p-ANCA-positive vasculitis.

Study 2 in Subjects 40 through 70 Years of Age

Study 2 was a randomized, observer-blind, active-controlled, multicenter study in Canada and the United States in which 1968 subjects received at least 1 dose of HEPLISAV-B and 481 subjects received at least 1 dose of Engerix-B. HEPLISAV-B was given as a 2-dose regimen at 0 and 1 month followed by saline placebo at 6 months. Enrolled subjects had no history of hepatitis B vaccination or infection. Engerix-B was given at 0, 1, and 6 months. In the total population, the mean age was 54 years; 48% of subjects were men; 82% were white, 15% black, 1% Asian and 6% Hispanic; 44% were obese, 30% had hypertension, 30% had dyslipidemia, and 8% had diabetes mellitus. These demographic and baseline characteristics were similar in both vaccine groups.

Solicited Local and Systemic Adverse Reactions

Subjects were monitored for local and systemic adverse reactions using diary cards for a 7-day period starting on the day of vaccination. The percentages of subjects who experienced local and systemic reactions are shown in Table 2.

Reaction	Table 2 Study 2: Percent of Subjects Who Reported Local or Systemic Reactions Within 7 Days of Vaccination				
	HEPLISAV-B %		Engerix-B %		
	Post-Dose*		Post-Dose*		
	1	2	1	2	3
Local	N=1952	N=1905	N=477	N=464	N=448
Injection Site Pain	23.7	22.8	18.4	15.9	13.8
Injection Site Redness†	0.9	0.7	0.6	0.2	0.2
Injection Site Swelling†	0.9	0.6	0.6	0.6	0.2
Systemic					
Fatigue	12.6	10.8	12.8	12.1	9.4
Headache	11.8	8.1	11.9	9.5	8.5
Malaise	7.7	7.0	8.6	7.1	5.1
Myalgia	8.5	6.4	9.6	8.0	4.5
	N=1923	N=1887	N=472	N=459	N=438
Fever‡	0.6	0.6	0.6	0.9	0.7

Note: only subjects having data are included. Clinical Trial Number: NCT01005407

*HEPLISAV-B was given as a 2-dose regimen at 0 and 1 month followed by saline placebo at 6 months. Engerix-B was given at 0, 1, and 6 months

† Redness and swelling ≥ 2.5 cm.

‡ Oral temperature ≥ 100.4°F (38.0°C).

Unsolicted Adverse Events

Unsolicted adverse events within 28 days following any injection, including placebo, were reported by 35.4% of HEPLISAV-B recipients and 36.2% of Engerix-B recipients.

Serious Adverse Events

Subjects were monitored for serious adverse events for 12 months after the first dose of vaccine. The percentage of subjects reporting serious adverse events was 3.9% in the HEPLISAV-B group and 4.8% in the Engerix-B group. Acute myocardial infarction occurred in 0.1% (n=2) of HEPLISAV-B recipients and 0.2% (n=1) of Engerix-B recipients.

Autoimmune Adverse Events

Subjects were monitored for the occurrence of new-onset potentially immune-mediated adverse events for 12 months after the first dose of vaccine. Events were adjudicated as to whether they were autoimmune by an external group of experts blinded to treatment assignment. As determined by the adjudicators, new-onset autoimmune adverse events were reported in 0.2% (n=3) of HEPLISAV-B recipients: two subjects with hypothyroidism and one subject with vitiligo. None of these events was considered related to vaccination by the expert group. No new-onset autoimmune adverse events were reported in the Engerix-B group. Although not referred to the external group of experts, one HEPLISAV-B recipient was determined to have Tolosa-Hunt syndrome which is presumed to have an immune-mediated etiology. This event was not considered related to vaccination.

Deaths

One subject (0.05%) died of a pulmonary embolism in the HEPLISAV-B group and 1 subject (0.2%) died of heart failure in the Engerix-B group. Neither death was considered related to vaccination.

Study 3 in Subjects 18 through 70 Years of Age

Study 3 was a randomized, observer-blind, active-controlled, multicenter study in the United States in which 5587 subjects received at least 1 dose of HEPLISAV-B and 2781 subjects received at least 1 dose of Engerix-B. Enrolled subjects had no history of hepatitis B vaccination or infection. HEPLISAV-B was given as a 2-dose regimen at 0 and 1 month followed by saline placebo at 6 months. Engerix-B was given at 0, 1, and 6 months. In the total study population, the mean age was 50 years; 51% were men; 71% were white, 26% black, 1% Asian, and 9% Hispanic; 48% were obese, 36% had hypertension, 32% had dyslipidemia, and 14% had type 2 diabetes mellitus. These demographic and baseline characteristics were similar in both vaccine groups.

Unsolicted Medically-Attended Adverse Events

Subjects were monitored for unsolicted medically-attended adverse events, those for which a subject sought medical care, for 13 months after the first dose of vaccine. Overall, medically-attended adverse events were reported in 46.0% of HEPLISAV-B recipients and 46.2% of Engerix-B recipients. Herpes zoster was reported in 0.7% of HEPLISAV-B recipients and 0.3% of Engerix-B recipients. Unsolicted medically-attended adverse events within 28 days following any injection, including placebo, were reported by 20.1% of both HEPLISAV-B and Engerix-B recipients.

Serious Adverse Events

Subjects were monitored for serious adverse events for 13 months after the first dose of vaccine. The percentage of subjects who reported serious adverse events was 6.2% in the HEPLISAV-B group and 5.3% in the Engerix-B group. Acute myocardial infarction (AMI) was reported in 0.25% (n=14) of HEPLISAV B recipients and 0.04% (n=1) of Engerix-B recipients. An analysis of serious adverse events likely representing myocardial infarction (MI) was conducted using the standard Medical Dictionary for Regulatory Activities (MedDRA) query (SMQ) for MI. This analysis identified a total of 19 HEPLISAV-B subjects (0.3%) and 3 Engerix-B subjects (0.1%) with events included in the SMQ for MI (these events include the 15 reports of AMI). Additional evidence, including information on temporal relationship and baseline risk factors, does not support a causal relationship between HEPLISAV-B administration and AMI. Among the 19 events identified as MI in HEPLISAV-B recipients, three occurred within 14 days, nine occurred within 53-180 days, and seven occurred more than 180 days following any dose of HEPLISAV-B. Among the three events identified as MI in Engerix-B recipients, one each occurred 13, 115, and 203 days following any dose. All 19 HEPLISAV-B recipients and 3 Engerix-B recipients reported one or more baseline risk factors for cardiovascular disease.

Autoimmune Adverse Events

Subjects were monitored for the occurrence of new-onset potentially immune-mediated adverse events for 13 months after the first dose of vaccine. Events were adjudicated as to whether they were autoimmune by an external group of experts who were blinded to treatment assignment. As determined by the adjudicators, new-onset autoimmune adverse events were reported in 0.1% (n=4) of HEPLISAV-B recipients [one each of: alopecia areata, polymyalgia rheumatica, ulcerative colitis, and autoimmune thyroiditis (with concurrent diagnosis of papillary thyroid carcinoma)]. None of these events was considered to be related to vaccination by the external experts. No new-onset autoimmune adverse events were reported in the Engerix-B group.

Deaths

During the study death was reported in 25 subjects (0.4%) in the HEPLISAV-B group and 7 subjects (0.3%) in the Engerix-B group. No death was considered related to vaccination.

7 DRUG INTERACTIONS

7.1 Use with Immune Globulin

There are no data to assess the concomitant use of HEPLISAV-B with immune globulin. When concomitant administration of HEPLISAV-B and immune globulin is required, they should be given with different syringes at different injection sites.

7.2 Interference with Laboratory Tests

Hepatitis B surface antigen (HBsAg) derived from hepatitis B vaccines has been transiently detected in blood samples following vaccination. Serum HBsAg detection may not have diagnostic value within 28 days after receipt of HEPLISAV-B.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to HEPLISAV-B during pregnancy. Women who receive HEPLISAV-B during pregnancy are encouraged to contact 1-844-443-7734.

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In clinically recognized pregnancies in the US general population, the estimated background risk of major birth defects is 2% to 4% and of miscarriage is 15% to 20%.

There are no clinical studies of HEPLISAV-B in pregnant women. Available human data on HEPLISAV-B administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.3 mL of a vaccine formulation containing 2.5 mcg HBsAg and 3000 mcg cytosine phosphoguanine (CpG) 1018 adjuvant was administered to female rats prior to mating and during gestation. These animal studies revealed no evidence of harm to the fetus due to this vaccine formulation [see Data].

Data

Animal data

Developmental toxicity studies were conducted in female rats. Animals were administered 0.3 mL of a vaccine formulation containing 2.5 mcg HBsAg and 3000 mcg CpG 1018 adjuvant twice prior to mating, and on gestation days 6 and 18 (a single human dose of HEPLISAV-B contains 20 mcg HBsAg and 3000 mcg CpG 1018 adjuvant). No adverse effects on pre-natal and post-natal development up to the time of weaning were observed. There were no vaccine-related fetal malformations or variations observed.

8.2 Lactation

Risk Summary

It is not known whether HEPLISAV-B is excreted in human milk. Data are not available to assess the effects of HEPLISAV-B on the breastfed infant or on milk production/excretion.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for HEPLISAV-B and any potential adverse effects on the breastfed child from HEPLISAV-B or from the underlying maternal condition. For preventive vaccines, the underlying condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

Safety and effectiveness of HEPLISAV-B have not been established in individuals less than 18 years of age.

8.5 Geriatric Use

Clinical trials included 909 adults 65 through 70 years of age who received HEPLISAV-B.

Among subjects who received HEPLISAV-B, a seroprotective level of antibody to HBsAg was achieved in 90% of those 65 through 70 years of age compared to 96% of those aged 18 through 64 years of age.

Safety and effectiveness of HEPLISAV-B in adults older than 70 years of age were extrapolated from findings in subjects younger than 70 years of age.

8.6 Adults on Hemodialysis

Safety and effectiveness of HEPLISAV-B have not been established in adults on hemodialysis.

17. PATIENT COUNSELING INFORMATION

- Inform vaccine recipient of the potential benefits and risks associated with vaccination, as well as the importance of completing the immunization series.
- Emphasize that HEPLISAV-B contains non-infectious purified HBsAg and cannot cause hepatitis B infection.
- Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and www.vaers.hhs.gov.
- Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

DYNAVAX

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New guidelines around clinicians' clothing aim to maximize infection prevention

IN THE 1990s, **CHERYL HERBERT**, MSN, RN, CIC, SERVICE LINE DIRECTOR FOR MEDICAL, SKIN AND WOUND CARE AT CHRISTUS HEALTH, banned long and artificial fingernails for her patient-care staff. The nurses and nail technicians in her town pushed back—hard. But Herbert knew it was a necessary step to help prevent the spread of infection in the hospital.



“There is some evidence that the more unencumbered you are—no rings, no watches—the better your hand hygiene will be,” says Herbert, who works in supply chain now, but has over 40 years of experience in infection prevention. “And anything but your natural fingernail that is a reasonable length can cause problems.”

Research has shown chipped or old nail polish, as well as gel and acrylic nails, can lead to trapped bacteria and fungus that hand-washing doesn't remove. Research has also shown rings to pose a problem, as they not only increase the chances of a glove tear, but the skin under the rings can trap bacteria.

Dressed to

UPDATED SURGICAL ATTIRE STANDARDS

Antibiotic-resistant bacteria can be transmitted on clothing. In July 2019, the Association of periOperative Registered Nurses (AORN) updated its guidelines for infection prevention related to surgical attire.

Key takeaways:

- ▶ Surgical attire should be laundered by the hospital (or an accredited facility) and not at home.
- ▶ Scrubs should be removed before leaving the hospital.
- ▶ Scalp and hair should be covered (as well as beards in certain instances), with head covers being removed either due to contamination or when a shift ends.
- ▶ Employee ID badges must be properly cleaned if they come into contact with blood, bodily fluids or pathogens.
- ▶ Facilities should create standards for personal clothing worn under scrubs, taking a look at things like the fabric and fit, such as sleeve length and turtlenecks.
- ▶ A space should be designated for outside items, like backpacks, to prevent contamination of the central service/sterile processing (CS/SP) area.



HEALTH

“Anything that could obstruct you from doing excellent hand hygiene is an issue,” Herbert says. “When I ran infection prevention in hospitals, I would always say, ‘Why do you want to wear that large ring that will trap bacteria, and possibly get damaged?’ From the tips of your fingers up, you need to establish policies and procedures for infection prevention.”

And it doesn’t stop at your hands. Healthcare facilities across the country, like CHRISTUS Health, which is headquartered in Irving, Texas, are continually adapting their policies to ensure their infection prevention plan is up-to-date with the most current standards for clothing and other attire, from head to toe. Official recommendations surrounding infection prevention in hospital attire change often, meaning facilities must continually adapt as new standards are released.

“Working with HealthTrust in the role of a clinical advisor in supply chain, we use our expertise to keep abreast of evidence-based best practices, so we can support our facilities and ensure they have everything they need to meet changing standards,” Herbert says.



KEEPING UP WITH INDUSTRY STANDARDS

Best practices for infection prevention in attire are typically centered on the following areas:

- ▶ **Bare below the elbows (BBE).** Many facilities have a BBE policy, which prohibits watches, jewelry, ties and long-sleeved shirts.
- ▶ **Laundering attire.** Most facilities launder surgical attire and hospital-issued scrubs on site. All nonsurgical healthcare professionals are typically advised to launder their scrubs daily.
- ▶ **White coats.** Employees who interact with patients should have at least two white coats. White coats are typically recommended to be cleaned once per week if the physician is involved in patient care.
- ▶ **Ties.** The science isn’t definitive in this area, so facilities typically have their own policies for neckties. Some, for example, will recommend that neckties be secured during patient interactions.
- ▶ **Shoes.** Herbert says there is no evidence that shoes pose an infection risk to patients. Most policies involve shoes being professional and clean, with no open toes in clinical areas. In addition, some perioperative areas still dedicate shoes to the operating room, and some employees choose to have separate clinical shoes.

Research has shown that the presence of jewelry and chipped nail polish can trap bacteria that hand-washing cannot remove.

HealthTrust regularly consults official infection prevention recommendations to ensure member facilities have what they need on contract, says **Tara Coleman**, MBA, BSN, RN, Director of Nursing Services, Clinical Operations at HealthTrust.



Coleman says they keep track of new recommendations that are released from organizations like The Joint Commission, the Food and Drug Administration (FDA), the Association for the Advancement of Medical Instrumentation (AAMI), the Association for Professionals in Infection Control and Epidemiology (APIC), the USP 800 and the Occupational Health and Safety Administration (OSHA).

“Standards drive compliance within facilities, which directly impacts our membership and what we have on contract,” Coleman says. “If we don’t have the right products or supplies on contract to meet those standards, it’s difficult to support our members.”

“Standards drive compliance within facilities, which directly impacts our membership and what we have on contract.”

– Tara Coleman, MBA, BSN, RN

GOOD PRACTICE, GOOD BUSINESS

In addition to having the right products and services, an official infection prevention program is a vital component of keeping people safe—both inside and outside a hospital’s walls. Not only are healthcare workers protecting themselves, but also their patients and their families at home.

Infection prevention is also a priority for healthcare facilities, because infection rates are often how patients assess a hospital’s quality of care. Many infection rates are publicly reported, Coleman says.

Continued on page 40

UPGRADED EXPERIENCE, DOWNGRADED COSTS

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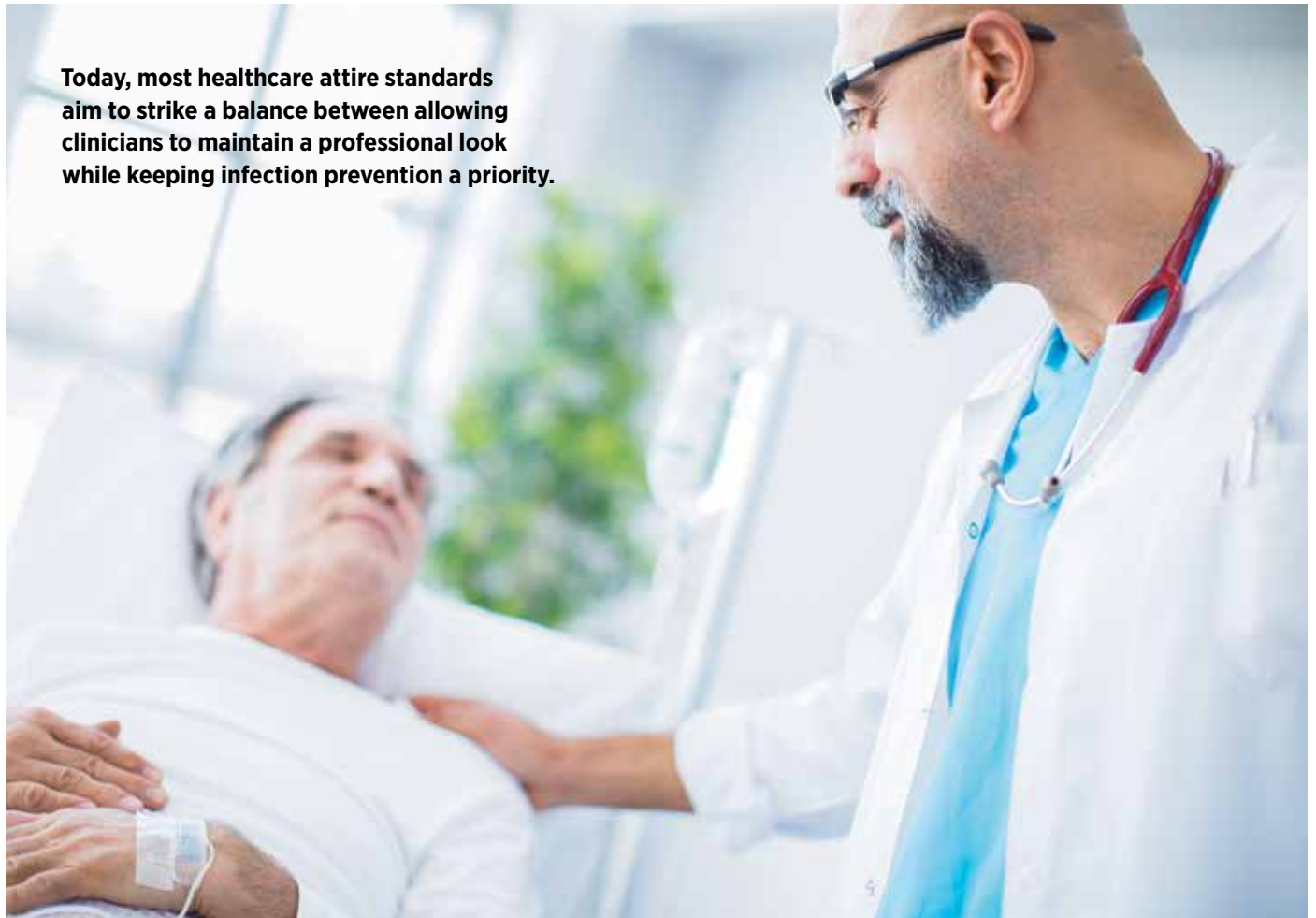
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¹American Council for an Energy-Efficient Economy, *Smart Buildings: Using Smart Technology to Save Energy in Existing Buildings*, Feb 2017, Report A1701, pages 11, 23.


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Today, most healthcare attire standards aim to strike a balance between allowing clinicians to maintain a professional look while keeping infection prevention a priority.

HAND-HELD HAZARD

In the world of infection prevention, the risk posed by infections spread by cellphones and other hand-held devices is continually being researched and discussed. Although the science is not yet definitive in this area, some studies suggest small hand-held devices, like tablets and cellphones, can become contaminated with pathogens.

There are no official standards or recommendations in place for decontaminating devices, meaning healthcare facilities must take precautions as they see fit. Coleman says this is a particularly popular topic in healthcare right now, with many hospitals interested in infection rates related to the use of small electronics.

“Some of our members have expressed interest in what is out there to clean these devices, such as the use of ultraviolet rays,” Coleman says, adding that HealthTrust’s Nursing and Surgical Advisory Boards are reviewing various options for the proper cleaning of small electronics.

Continued from page 39

“Just like we shop for the best deal or search for the five-star rating, people look at the same thing in healthcare because they want the best care,” Coleman says. “They want the surgeon who has the lowest infection rates, and they want to know that when they go into a facility, they’re not at risk for coming out with an infection.”

CAUTIOUSLY PROFESSIONAL

When Herbert first began working as a nurse four decades ago, she says professionalism mattered more than infection control. Back then, blood and bodily fluids were the primary concerns. Attire standards have since shifted slowly toward infection prevention (e.g., scrubs) due to the rise of antibiotic-resistant

“Rather than prescribing to the nth degree—which never works—you need a commonsense approach to preventing infection that goes across the whole continuum of care.”

– Cheryl Herbert, MSN, RN, CIC

bacteria, which can be transmitted on clothing. During this transition, however, healthcare workers adopted an appearance many believed was too casual.

Now, Herbert says, most standards include a balance in which both professionalism and infection prevention are taken into account.

“I think there’s a happy medium between having a professional appearance so a patient can identify you, and following the evidence-based best practices that have come out about cross-contamination and infection prevention based on what you’re wearing,” Herbert says.

At the end of the day, Herbert says common sense is still superior when it comes to balancing professionalism with infection prevention in hospital attire. “Rather than prescribing to the nth degree—which never works—you need a commonsense approach to preventing infection that goes across the whole continuum of care,” she adds. **HT**



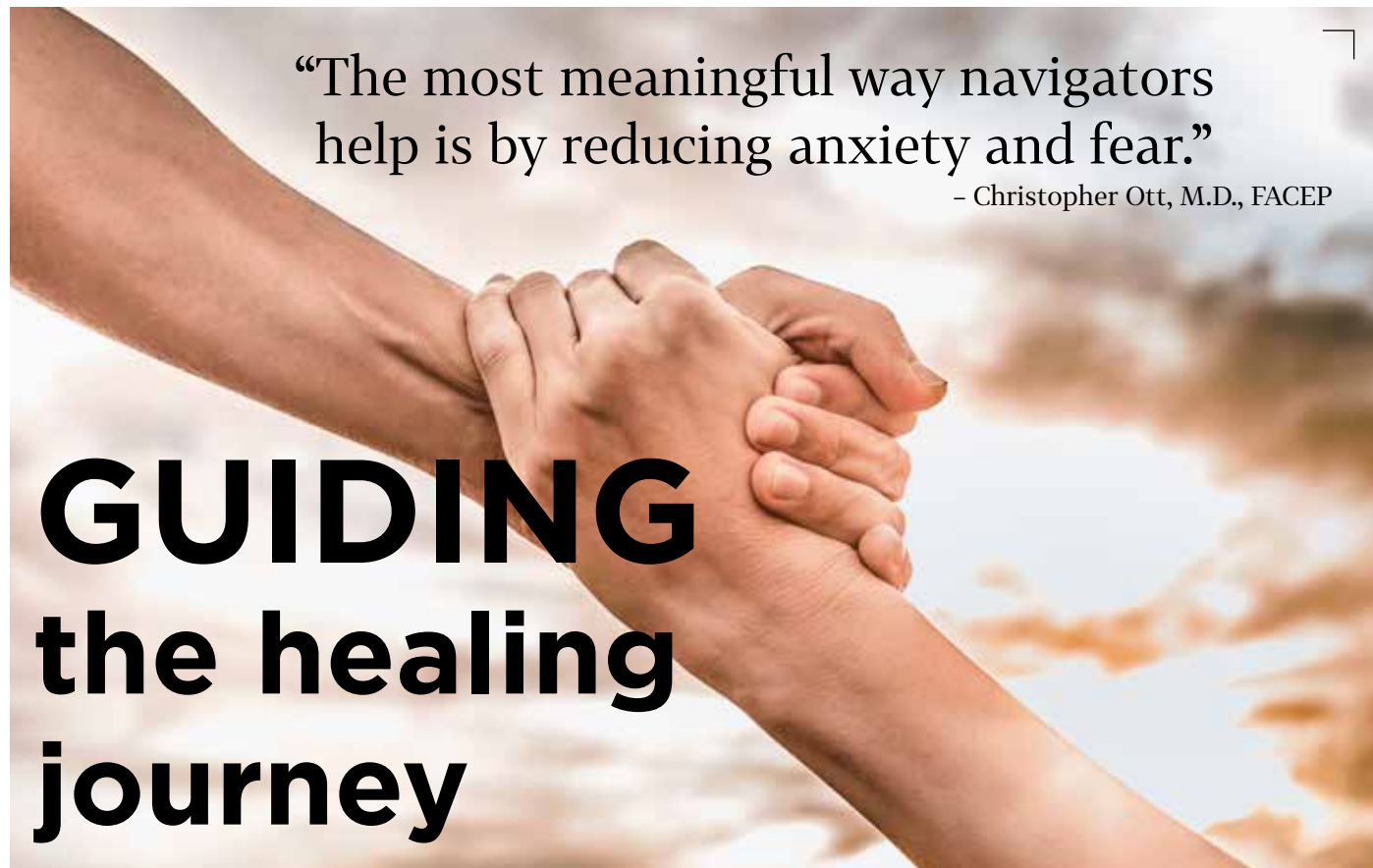
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“The most meaningful way navigators help is by reducing anxiety and fear.”

– Christopher Ott, M.D., FACEP

GUIDING the healing journey

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Patient navigators offer unparalleled support that can improve patient experience & outcomes

IT’S A STORY MANY PEOPLE KNOW ALL TOO WELL: A patient is diagnosed with a complex disease. He has myriad scans, treatments and follow-up appointments to schedule, he’s not sure how his health insurance coverage factors in, and he doesn’t fully understand the details of the diagnosis or the implications of the prognosis. It can feel like the doctors are speaking a foreign language—and it can be scary.

To help patients untangle the intricate web of a complicated health issue, healthcare facilities are employing patient navigators—nurses and healthcare professionals who accompany patients through their care journey to offer support and guidance. This resource can completely change the experience of the patient, says **Christopher Ott**, M.D., FACEP, Chief Medical Officer with HCA Healthcare’s Physician Services Group in Nashville, Tennessee.

“The basic tenet of patient navigation is: Healthcare with a known diagnosis that



needs follow-up or treatment is hard to navigate yourself,” Dr. Ott says. “What navigation does is take out all of the unknowns, giving the patient assurance that they’ve been going through things in a timely manner and have taken all the appropriate steps to have the optimal outcome for their given diagnosis.”

Navigators work in multiple complex services lines and commonly assist patients in oncology, cardiovascular, spine, geriatric and perinatal care. In addition to easing the burden for patients and family caregivers, navigators can also help influence patient outcomes, especially in at-risk communities, says **Crystal Dugger**, MBA, RN, Vice President of Clinical Services at HealthTrust.

“As value-based care models continue to grow, having patient navigators is one of the most effective ways to truly ensure patients are getting the right care at the right time and at the right place,” Dugger explains.



COORDINATING CARE

Patient navigators—also commonly referred to as nurse navigators—are often registered nurses. Their role has become so valuable, due in part to the complexities of our medical systems. Patients need help figuring out their course of action. “I would challenge even those who are medically literate to navigate the system on their own and not have something fall through the cracks,” Dr. Ott says.

For many patients, care is no longer limited to just one building or one provider. For example, Dugger describes a typical experience for cancer patients: They might be diagnosed in a hospital’s imaging center, have their surgery at the hospital’s ambulatory center, go back to the surgeon’s office for follow-up, see a medical oncologist for chemotherapy and then go to yet another facility for radiation.

Patient navigators help people maneuver this complex process. In addition to the logistics of managing various locations, navigators ensure all physicians and caregivers are aligned in a united care path.

“A nurse navigator can come in at the brink of a complicated diagnosis and pull the physicians together to lay out a coordinated path,” Dugger explains. “The navigator is the glue that holds all of the program components together while building trust with the patient.”

BREAKING DOWN BARRIERS

Patients with difficult diagnoses often feel like they need a Ph.D. in a healthcare-related field to make sense of everything. “They suddenly need to be very educated about a condition they know nothing about,” Dugger says. “The patient has to be informed to make key decisions about their treatment, yet they are not physicians, so they are in a very vulnerable state.”

Patient navigators often break things down into understandable terms so a patient can make the best decisions about their care. In addition, their credentials mean they’re qualified to give valuable medical advice—a service that can save patients from wasting time in the ER,

Continued on page 44

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Continued from page 43

or more important, losing time when they should be seen by a doctor.

“Patients often state they worry about calling their doctors to bother them, but they feel very comfortable reaching out to their nurse navigator to say, ‘Hey, is this serious or is this just something where I need to take it easy today?’” Dugger adds.

Navigators can also help patients gain access to important resources. For example, they can help remove financial barriers by connecting patients with financial assistance or remove language barriers by providing access to translation services.

“The navigator’s job is to help that patient walk empowered through the care continuum,” says Dugger.

CARING FOR THE WHOLE PATIENT

“Not only do patients have to figure out our entire healthcare system, but they also have to deal with the fact that they are often scared and completely vulnerable to that system,” says Dugger.

Dr. Ott points out that the most meaningful way navigators help is by reducing that anxiety and fear.

“Navigators are there to help patients through a lot of the unknowns during these difficult times in their lives,” he adds. “They make the unknown known.”

Supporting patients and their families emotionally is rewarding for both the patient and the caregiver. Dugger, who was one of the first nurse navigators in Tennessee in

1999, says she has loved all of her roles helping patients, but working as a navigator has been one of the most fulfilling. “I know navigators who are still close to family members of patients who have passed away,” Dugger says. “To see someone care for your family member that way is just unbelievably impactful.”

DETERMINING THE NEED FOR NAVIGATORS

For administrators who are asking, “Do we need to hire a navigator?” Dr. Ott suggests they look at their own business—the complexity of it as well as the complexity of their patients’ conditions. While a small community hospital may not have the need for a navigator on staff, a larger facility could use several.

Dr. Ott and Dugger have no doubt about the potential value navigators add—not only to patients and their families but also to healthcare settings themselves.

“At first, it can be really difficult for hospitals to understand the value patient navigators are bringing,” Dugger notes. “But it’s easy to demonstrate value when standardized processes with accountability metrics are implemented. When a navigator is in place, pathway adherence and loyalty increase substantially, and that’s proven by metrics.” **HT**

TO LEARN MORE about setting up a patient navigation program, contact HealthTrust’s Clinical Data Solutions AVP Kimberly Wright, RN, at kimberly.wright@healthtrustpg.com

PATIENT NAVIGATOR FAQ

Q: Are patient navigators new to healthcare?

A: Navigators are still a fairly new job in the U.S., but they’re becoming more common each year. “While nursing is a career that predates the 19th century, patient navigation is one of the newer roles in the nursing world,” Dugger says.

Q: Is there a specific certification for patient navigators?

A: Training for patient navigators isn’t standardized, meaning most hospitals create their own training programs. However, there are some certification programs available. For example, the Academy of Oncology Nurse and Patient Navigators (AONN+)

offers certification programs for cancer navigators. These certifications are making significant headway in standardizing the role and value metrics for a patient navigator.

Q: How many patients does a navigator typically work with?

A: It depends on the complexity of the patient’s diagnosis. For a condition that requires a lot of education (like certain perinatal and cancer diagnoses), a navigator may have 200 to 250 patients per year, Dugger notes. For something less complex, virtual programs are valuable, and these navigators could have anywhere from 500 to 1,000 patients a year.



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INCREASINGLY, HEALTH SYSTEMS ARE DISCOVERING that when they engage clinicians around product decisions, improvements to care and cost efficiency take hold. That was the basis of an informative physician panel discussion at the HealthTrust University Conference in August 2019 on best practices in physician-led value analysis.

The talk was facilitated by **John Young**, M.D., MBA, Chief Medical Officer of HealthTrust. Here are some of the key ideas presented in the session, as recapped by **Christopher Ott**, M.D., FACEP, Chief Medical Officer at HCA Healthcare Physician Services Group; and **Lynn Simon**, M.D., MBA, CHE, Chief Medical Officer and President at Community Health Systems.



What strategies can you offer for engaging physicians in value analysis work?

DR. OTT: In my world of ambulatory physician employment and alignment, much of the value analysis we do pertains to payer models, value contracts and resource utilization/cost of care. The greatest success we have seen is in practices and clinical areas where our patient attribution models, data integrity and assignation of responsibilities are all clear, concise and accurate. Get your data right and make your goals transparent—then physicians will engage.

Being transparent with physicians when it comes to data and goals is critical. Dr. Simon, can you share a success story?

DR. SIMON: In looking at the various devices within our cardiac service line, it seemed to us that drug-eluting stents were potentially a commodity. To validate this, we remotely convened a group of interventional cardiologists from across the organization. They represented hospitals with larger cardiac programs and physicians who were using products

Continued on page 48

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References: 1. CALCIUM GLUCONATE IN SODIUM CHLORIDE Injection [package insert]; Approved Drug Products with Therapeutic Equivalence Evaluations 39th Edition (Orange Book); <https://www.fda.gov/media/71474/download> 2. On file WG Critical Care, LLC. To request data on file, please contact Customer Service at 1-888-493-0861 or CustomerService@wgccrx.com

Continued from page 46

from a variety of vendors. By having the physicians review and compare the clinical attributes of the different offerings, they were able to confirm that these products were very similar with regard to their safety, quality and efficacy. They supported the move to a single vendor based on their review. Now, organization-wide, we use a single vendor for bare metal and drug-eluting stents with over 95% compliance; the remaining percentage is for individual patient needs that clinically require a different device.

How can we overcome challenges to getting physicians past their initial resistance to contract compliance?

DR. OTT: Change takes time. Give some grace to those physicians who need a little longer runway to acclimatize to change. And create clinical quality outcome measures that, at a minimum, hold quality outcomes at the current standard, but aim for continuous performance improvement.

Finally, develop financial alignment models that are in accordance with Stark Law and the Anti-Kickback Statute.

What are some tips for how to effectively communicate with providers to get their buy-in?

DR. OTT: Physicians see that efficient healthcare systems grow. Growing organizations invest in clinical services and infrastructure improvements, and they extend their geographic reach far better than inefficient, wasteful systems. Having real successes to point to is really helpful in the engagement conversations with physicians. Things like new operating rooms, modern equipment, growth in bed numbers, advanced clinical platform development, and additional budget for marketing and promoting the platforms—all show physicians that we are aligned with them. It goes a long way when we ask physicians to help make us more efficient and provide more cost-effective care.

“Change takes time. Give some grace to those physicians who need a little longer runway to acclimatize to change.”

– Christopher Ott, M.D., FACEP



It is important for physicians to hear the message that savings can ultimately lead to increased services. How have you seen this come to fruition?

DR. SIMON: While working on our cardiology initiatives, the goal of our supply chain team was to collaborate with physicians to determine which products they needed in order to provide the best care for their patients. We needed physician support to either limit vendors and products to drive share and lower price, or enable broader participation at a lower price point. We heard that what really mattered to most of these physicians was access to newer technologies such as MitraClip, Watchman and TAVR. They preferred that the organization invest in these higher-acuity service lines and devices, so that they and their hospitals could expand their services and clinical offerings.

How do you present data to physicians in a meaningful way that inspires action?

DR. OTT: Make sure you are asking of your data the right question before looking for the answer. This will prevent claims of data manipulation or inaccuracy. And there has to be agreement that the source of the data is the right originating source. The reporting and attribution of outcomes then must lead to the appropriate assignment of a responsibility to act. Then the ask for action has to be made to the party most responsible for affecting the outcome. That is often not the physician, but when it is, following the above parameters will get the conversation off to the right start.

How do you motivate physicians to be a part of the decision-making process—and also reward them for it?

DR. SIMON: Thus far in our experience, the participating physicians seem to have more of an intrinsic motivation. They

want to know that they have input into decisions that potentially impact patient care and that their opinions are not only valued but actually utilized. After one engagement, we received this feedback from a physician: “It is really refreshing to work with a committee that takes the physicians’ input so seriously. This is been a pleasure for me, and I thank you again!” **HT**

HOW IS PHYSICIAN-LED VALUE ANALYSIS IMPACTING YOUR ORGANIZATION?
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Something in the WATER

A focus on water safety is key to infection prevention

YOU HAVE HAND SANITIZERS IN EVERY ROOM. Isolation rooms for infectious patients. Head-to-toe gowns for staff. But did you know that one of the greatest potential threats of infection in your hospital could be flowing throughout your facility?

Micheal Dodson knows. As the Director of Garratt Callahan's Water Safety Group (HealthTrust contract #3968), he and his team are directly responsible for ensuring the water safety of hospitals throughout the country, many of which are HealthTrust members.



Dodson is fascinated by microbes and pathogens. But what really gets him excited about his job is the ability to directly affect patient care.

“Our field has transformed with an ability to keep waterborne pathogens from harming patients or staff,” he says. “This is critical, particularly for patients at high risk of infection, such as those with cancer, burns or recent transplants.”

STANDARDS FOR SAFETY

Dodson has seen the field shift in the past few years with the introduction of the ASHRAE (American Society of Heating, Refrigerating and Air-conditioning Engineers) standards in 2015. Before that, he says, “We just did what we knew was best at the time.” Now, the standards “put framework behind the requirements,” he explains. “Our vision and efforts across the country now come from this framework of understanding and what it takes to manage healthcare water systems from the inside out.”

The Centers for Medicare & Medicaid Services (CMS) also has requirements, updated in 2018. They require that healthcare facilities have water management plans in place.



INFECTIONS TO BE AWARE OF

Of particular concern lately is Legionnaire's disease, caused by the *Legionella* bacterium.

There were **4.5 times** the number of Legionnaire's disease cases in 2014 vs. 2000, **23%** of which were hospital-acquired. **80%** of cases were the result of water exposure.

Having an effective water management program, the Centers for Disease Control and Prevention (CDC) notes, can prevent the majority of infections.

In 2017, ASHRAE released minimum Legionella risk-management requirements for water systems in all types of buildings. That same year, the CDC published a toolkit for facilities to reduce exposure to Legionella, and CMS released its own advisory, requiring that facilities “develop and adhere to policies and procedures that inhibit microbial growth in building water systems that reduce the risk of growth and spread of Legionella and other opportunistic pathogens in water.”

Legionella infection is just one of many that can come from a contaminated water system. Others include *Mycobacterium avium*, *Pseudomonas aeruginosa*, *Stenotrophomonas*, *Acinetobacter*, *Sphingomonas*, *Burkholderia* and *Achromobacter*.

WATER TREATMENT SUPPLIERS

To help our members ensure a safe water supply, HealthTrust contracts with four water safety suppliers:

- ▶ Garratt Callahan (contract #3968)
- ▶ Chem-Aqua, Inc. (contract #7104)
- ▶ Chem-Treat (contract #7271)
- ▶ Nalco (contract #3923)

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HOW SUPPLIERS HELP

The HealthTrust water safety suppliers provide a variety of services, including water quality and system performance assessment, laboratory analysis and Legionella risk minimization. They also offer several water treatment solutions, including reverse osmosis, chemical cleaning, bioaugmentation and cooling water treatment; secondary disinfection systems and sterile water quality systems; and water management programs. **HT**

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SPINAL CORD STIMULATION (SCS), A TREATMENT AVAILABLE FOR CHRONIC PAIN OF THE TRUNK AND EXTREMITIES, IS RELATIVELY SAFE AND USED IN APPROXIMATELY 34,000 PATIENTS WORLDWIDE EACH YEAR. This system consists of leads that attach to the spinal column, a pulse generator and a wireless remote control.

Studies show that 50% to 70% of patients suitable for SCS report a 50% reduction in pain at follow-up.

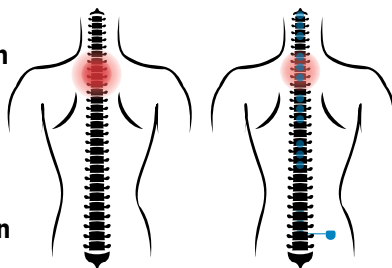
Although SCS has been approved by the Food and Drug Administration (FDA) since 1987, the mechanism of action is not fully understood. Broader theories on SCS effectiveness have resulted in innovative technology with improved outcomes for patients. HealthTrust offers products on contract in this category.

A NEW UNDERSTANDING

Originally, SCS was understood using gate control theory, where electrical pulses sent into the spine block the sensation of pain to the brain by inducing paresthesia (the tingling, “pins and needles” sensation). This approach had some success, but the paresthesia reduced positive outcomes. “Some patients would stop using this therapy because they found the paresthesia to be more adverse than treating the pain with alternative methods,” says **Karen Bush**, MSN, FNP, BC, NCRP, Director of Clinical Research & Education at HealthTrust.



Permanent implantation is recommended if the patient experiences a 50% reduction in pain along with improvement in function and activity level.



But recent research reveals that SCS can release natural pain-relief substances, restoring normal pain inhibition pathways without paresthesia. Two technologies have come to market that reflect this development: burst stimulation, which is proprietary to Abbott Laboratories, and high-frequency stimulation, which is proprietary to Nevro.

“These new technologies do not cause paresthesia, which makes it more comfortable and desirable for the patient,” says Bush. “Clinical trials have shown these technologies to be noninferior, and in some industry-sponsored studies, preferred or superior to low-frequency tonic stimulation.”

COMMUNICATION IS KEY

One significant challenge with SCS therapy, notes Bush, is ensuring adequate communication between the providers involved in a patient’s care.

For a patient to be considered for a permanent SCS system, a trial device is placed in the spine (the generator is maintained externally) for five to seven days, often by a community provider. Permanent implantation, by which the generator is placed in the body, is recommended if the patient experiences a 50% reduction in pain along with improvement in function and activity level. The permanent implantation can be done in the hospital.

Communication between the community provider and implanting physician is crucial for continuity of care, as well as reimbursement for the permanent device. “The hospital’s challenge is that it needs documentation from the community provider for the procedure to be appropriately reimbursed through many of the payer sources. So there has to be a communication system established between the two entities,” explains Bush.

Considering the positive outcomes associated with SCS therapy, overcoming this challenge can be well worth it. **HT**

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