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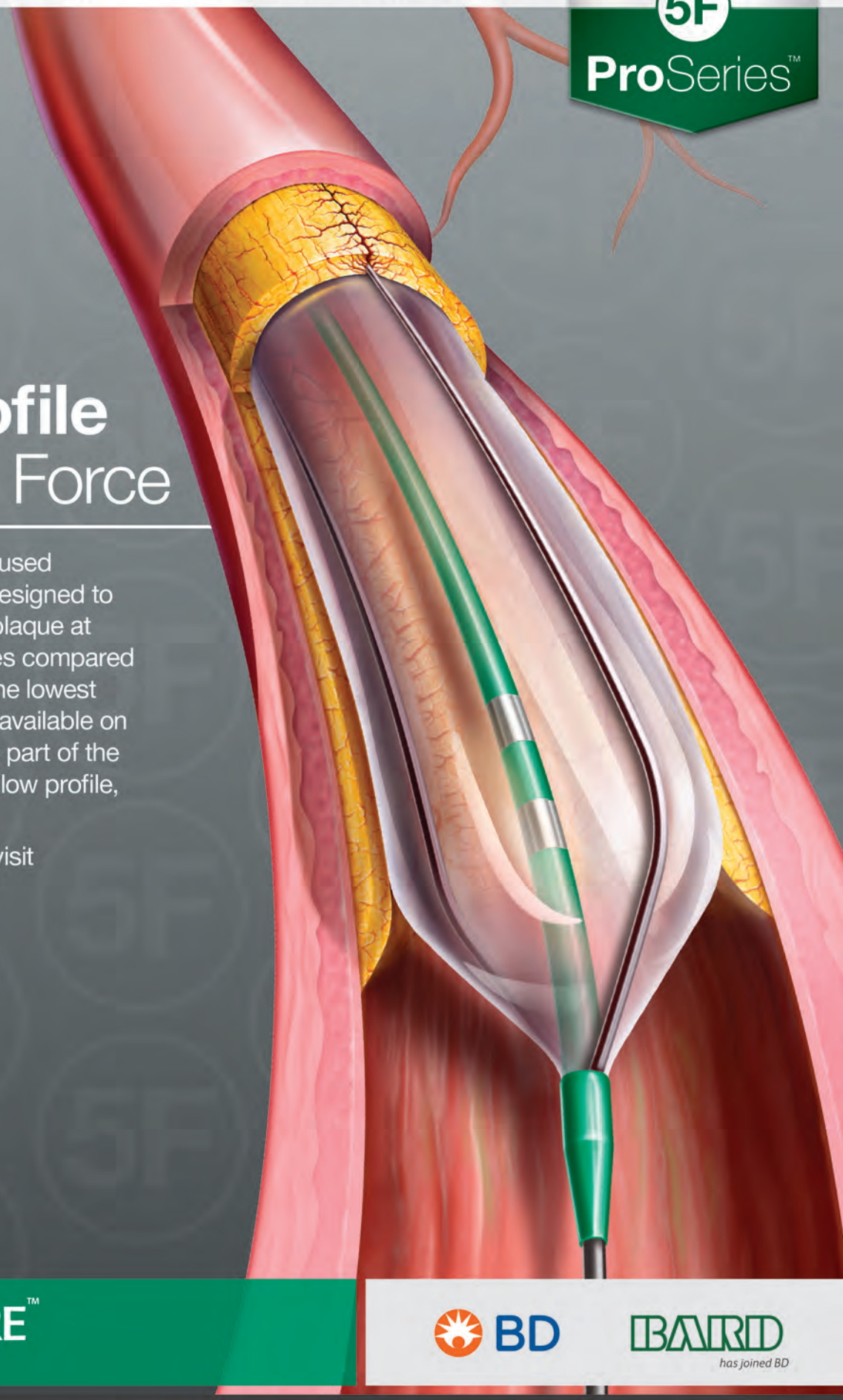

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Photography by Sheri O'Neal

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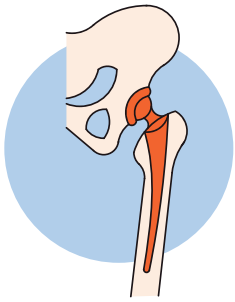

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Disruption as an Agent of Change

Just a year after the devastating presence of Hurricanes Harvey and Irma, it's déjà vu all over again for hospital, government and local emergency response teams and volunteers in countless locations impacted by the Atlantic and Gulf Coast hurricane season.

For those on the outside looking in, a storm changing direction or a re-forecast of predicted landfall aftermath is simply another news story. For those organizing response or planning an evacuation of patients, this kind of disruption can trigger immediate modifications to the "best-laid plan" or signify rapid movement to a "plan B." And, for those in the wake of Florence and Michael, it's the inches of remaining rain that have continued to wreak havoc on life and business as usual for thousands of people.

Words seem inadequate to express the appropriate gratitude and appreciation for the frontline care providers within the HealthTrust membership, as well as our staff and suppliers. Countless individuals remained committed to helping providers serve their patients and communities throughout the affected areas, many having their own hardships to wrestle with at home.

The Genius of Disruption

Other disruptions can lead to positive change. In the world of innovation, new markets have been created based on the genius of disruptors who interrupt business as usual.

Clayton Christensen, author of *The Innovator's Dilemma* and Harvard Business School professor, cites Netflix as a classically disruptive model since it eventually drove Blockbuster into bankruptcy in 2010. Christensen has also applied his theories to other industries, including healthcare, always "attempting to teach people how to think about business rather than what to think. Smart companies fail because they do everything right. They cater to high-profit-margin customers and ignore the low end of the market, where disruptive innovations emerge from," he said in a *Wired* interview.

Time will tell as to the success of the extraordinary aspirations of Facebook founder Mark Zuckerberg and his pediatrician wife, Priscilla Chan, M.D., who plan to invest $13B to help scientists develop and use tools such as artificial intelligence and blood monitors to identify and quickly treat illnesses. The stated goal of the Chan Zuckerberg Initiative (CZI) is to "cure, prevent and manage *all* diseases by the end of this century, including heart disease, cancer, infectious diseases and neurological diseases." The duo realize CZI's goal may sound far-fetched, but Chan indicated the initiative aims to "focus on empowering scientists with tools to unlock their work and the field—that goal could be within our reach."

Think Big

To "think like a disruptor" is the encouragement I offer each of you. How can our facility and health system members, the supplier community and the HealthTrust team maximize our collective brain power and collaborate to combat the rising costs of healthcare and pharmaceuticals, curb the opioid epidemic, prevent the next hospital cyberattack or tackle any of the other points survey respondents cited as part of the top 10 list of challenges healthcare executives will face in 2019. Those challenges, according to a recent survey developed by the HealthCare Executive Group and Change Healthcare, include:

- Data & analytics (especially clinical)
- Total consumer health
- Population health services
- Value-based payments
- The digital healthcare organization
- Rising pharmacy costs
- External market disruption
- Operational effectiveness
- Opioid management
- Cybersecurity

Go forth and think big! Don't be afraid of shaking things up or disrupting the status quo at this stage of your thinking. Your suggestions can assist us in the development of breakout sessions and tracks for the 2019 HealthTrust University Conference. Share your ideas with me through university@healthtrustpg.com.

Ed Jones
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Innovation at Work

Innovation is top of mind for many of us at HealthTrust as my team and I hosted the organization's fourth Innovation Summit in mid-October. The annual event is an avenue for suppliers with FDA-approved products to present their new technology to physician advisors and invited service line clinicians from within the HealthTrust membership. These experts assessed the technology in an exhibition-type setting and then adjourned to specialty meetings where they discussed the benefits of adding some of these products to the HealthTrust contract portfolio.

INNOVATION FURTHERED BY HEALTHTRUST GRANT

This issue's cover story is also centered on a similar theme as LifePoint Health was recently awarded HealthTrust's Innovation Grant for its achievements in promoting the appropriate use of antimicrobials at all 72 of its facilities over the last year. Valued at $50,000, the grant will help offset the cost of further developing an in-house tool to advance tracking and reporting of the organization's systemwide antimicrobial stewardship initiative. (*See page 58.*) The tool, currently in use at 32 LifePoint hospitals, automatically pulls data from EHRs on a weekly basis, providing near real-time reporting on days of therapy, antimicrobial resistance as well as benchmarking and trending of operational, clinical and financial outcomes.

A successful implementation was critical to an initiative that involves eight departments within LifePoint Health. HealthTrust is honored to recognize the team who developed and implemented an antimicrobial stewardship reporting tool that simplifies compliance with national reporting requirements and provides facility leaders the detailed data they need to encourage the appropriate and cost-effective use of antimicrobials. I look forward to following the work of this team and receiving updates over the next year.

UPDATE ON 2017 GRANTEE

Meanwhile, Scripps Health has furthered both its perioperative opioid stewardship and ERAS initiatives as our 2017 Innovation Grant recipient. (*See page 10.*) **Valerie Norton**, M.D., provided an update on the organization's progress during July's HealthTrust University Conference.

Last fall, Scripps Health launched what it refers to as an OSP (opioid stewardship program) with its first wave of implementation focused on preventing surgery patients from becoming chronic users of opioids by setting realistic expectations of postoperative pain. Grant money has been used to develop patient education materials, including an informational video. After gaining leadership buy-in at the start of its initiatives, the implementation team has also focused on a systemwide approach to reforming prescriber habits and changing the way physicians and clinicians think about pain.

Scripps Health plans to continue the work of its opioid stewardship committee as it has been instrumental in developing and disseminating patient and clinical education, developing policies to identify patients at high risk of opioid abuse and tracking outcomes. The committee is composed of physicians, pharmacists, nurses and clinicians, including those in surgery, anesthesiology, ED medicine and hospice who now champion these initiatives across the enterprise.

PRIORITIZING THE 2019 CLINICAL AGENDA

HealthTrust's Physician Advisor program has more than 150 doctors currently engaged. To intensify the value and impact provided throughout more of the organization's contract portfolio, I'm excited to announce some changes to the existing program. We are evolving from what has been an ad hoc engagement style to a specialty-based council structure that supports a service line-oriented approach. We will also be seeking physician input in strategic categories outside of the traditional PPI (physician preference item) space.

Each council will include approximately 20 to 25 physician advisor representatives from across the HealthTrust membership. The initial three councils—*Surgery* (cardiothoracic, general OB/GYN, etc.), *Ortho/Spine* and *Cardiovascular* (interventional cardiology, electrophysiology)—met in person during the HealthTrust Innovation Summit in October. Specialty councils will be formed as contract categories warrant.

Research is also an area where I envision establishing a more robust agenda going forward. Physicians attending the national meeting in October are exploring potential areas of clinical research for 2019.

I continue to work diligently with the experts who lead the areas of clinical data and analytics for which I have responsibility. Based on feedback from our membership, we are collaborating to create progressive, integrated and aligned clinical data and analytics capabilities that will assist providers in making decisions that positively impact cost, quality and outcomes.

As always, feel free to share your thoughts or suggestions with me on how we can help you advance your organization's clinical agenda at thesource@healthtrustpg.com.

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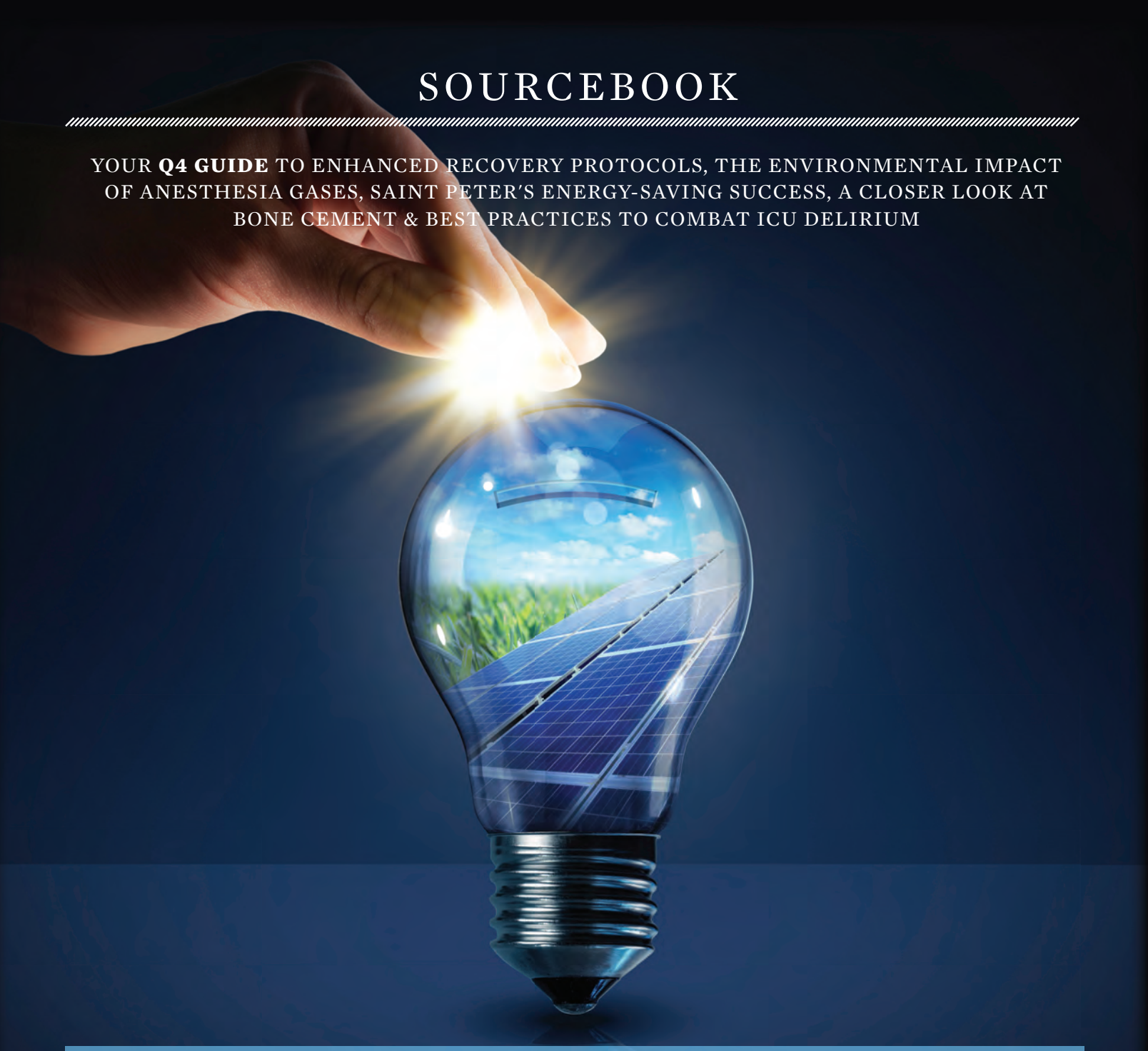

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Patient-centered ERAS Protocols Upend Conventional Wisdom With 'Wildly Successful' Results

In 1995, Danish physician Henrik Kehlet, M.D., published a revolutionary paper documenting the recovery of eight elderly patients who had undergone elective colonic resections for cancer. The procedure typically kept patients in the hospital for 12–15 days; under Kehlet's care, they were discharged in two or three days.

Although Kehlet accomplished something groundbreaking, his methods were simple. He optimized patients for their surgeries by educating them, setting clear expectations about the procedure and recovery, and equipping his team to provide patient-centric care. Together, these steps laid the foundation for what is now called Enhanced Recovery After Surgery, or ERAS.

More than 30 years later, enhanced recovery is slowly yet steadily gaining momentum in the United States. ERAS is the umbrella term for a bundle of nearly 20 perioperative recovery protocols, many of which overturn long-accepted practices.

"It's been dogma for decades that patients were not allowed to eat or drink for at least eight hours before surgery," says **Valerie Norton**, M.D., chief operations executive physician for Scripps Mercy Hospital, San Diego and HealthTrust Physician Advisor. "It turns out that's wrong. The evidence shows just the opposite—if you let patients drink clear fluids until two hours before surgery, they get better faster, go home sooner and have fewer surgical site infections."

Valerie Norton, M.D.

Other ERAS protocols include keeping a patient warm before and during surgery—no

Continued on page 12

ERAS Success at Scripps Health

HealthTrust awarded its 2017 Innovation Grant to Scripps Health for perioperative opioid stewardship and ERAS initiatives—and a year later, the team has been busy putting the award to use. Scripps team member **Valerie Norton**, M.D., reports that the in-kind portion of the grant is being used to create two patient education videos, one

on pain management and the other on ERAS protocols.

"We give patients so many things to read—it seems like reams and reams of paper," she says. "These videos are another way to approach the same material in a way that's really going to stick with patients." The Scripps team also used the cash grant to launch and support a robust opioid stewardship program.

Over the past year, implementing ERAS protocols at Scripps Health has shortened length of stays by up to 50 percent. Adoption continues to increase across units: "We went from zero percent last year to 60 percent of bariatric surgeries that are now ERAS protocols," Norton says. She reports that patients are thrilled to be up and moving faster, and back home sooner.

For their part, nurses love it, too. "My vision is for the nurses to be the drivers for this process," Norton says. "A lot of enhanced recovery is just about very careful attention to the environment the patient is in: keeping them warm, getting them up and walking, letting them drink fluids. To the extent that we can put this on autopilot, the more success we'll have."

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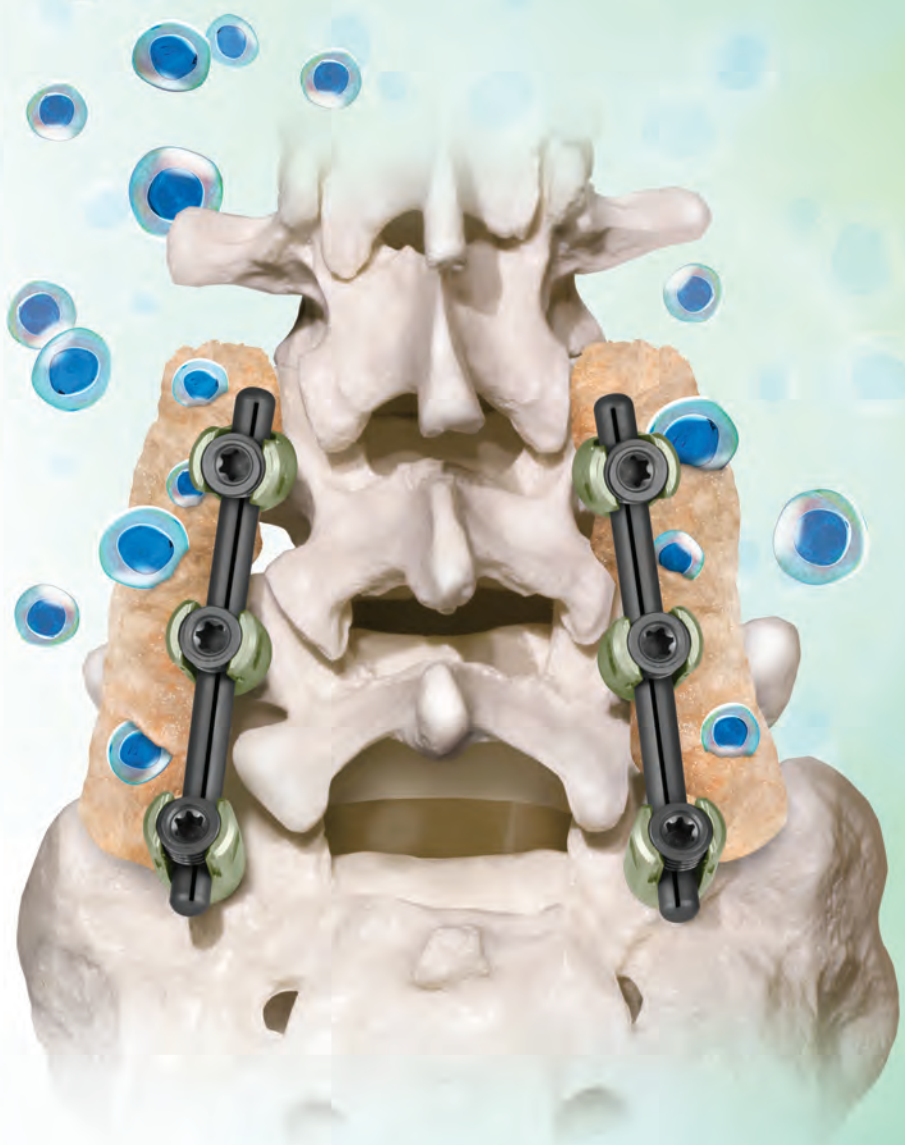

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Continued from page 10

small task considering thin hospital gowns and heavy air conditioning—and getting them walking shortly after an operation. Enhanced recovery also encompasses multimodal pain management techniques to minimize opioid use and prevent addiction.

Though hospitals may have adopted various enhanced recovery practices over the years, ERAS bundles these best practices.

"Enhanced recovery protocols enable a patient-centered approach with physicians and clinicians thinking about what patients will most want to know about an upcoming surgery," says **Mikio Nihira**, M.D., clinical professor of obstetrics and gynecology at the University of California Riverside School of Medicine and a HealthTrust Physician Advisor.

Mikio Nihira, M.D.

Doctors put patients at ease and help them optimize their recovery by communicating what to expect before, during and after a procedure. Enhanced recovery promotes education about everything from the level of pain a patient can expect to how much support they'll need once discharged.

"If patients are armed with a good mental model of how capable or incapable they will be following surgery, they can arrange with family members for the support they need," Nihira explains. Perhaps more important, if they're mentally and emotionally prepared for postoperative setback, they can maintain motivation on the road to recovery. As Nihira tells his patients, "Pain is part of surgery, and not all pain is bad."

Prior to their procedure, most surgery patients spend very little time in hospitals. Their concerns tend to revolve around matters that surgeons and nurses might overlook: where to park, what their copay will be, how much the procedure will hurt.

"As surgeons, we tend to focus on the technical aspects of our performance, and we have a limited understanding of the patient's individual experience," Nihira notes. Yet patients are eager to learn the details of their hospital stay and become more comfortable with the entire experience—before, during and after their time on the operating table. ERAS takes these details into account and equips hospital staff to answer questions and prepare patients in a more holistic way.

While education and accurate expectations help patients feel at ease, a speedy discharge and recovery have the greatest impact on patient satisfaction. This is where enhanced recovery protocols can make a difference. By implementing a bundle of best recovery practices, doctors significantly reduce their patients' hospital stays and recovery time. This makes for happier patients and cuts costs for hospitals by limiting stays and readmittance.

"ERAS IS A WIN-WIN-WIN SCENARIO. PATIENTS LIKE IT BETTER, THERE'S BETTER QUALITY OF CARE AND RECOVERY, AND IT LOWERS COSTS."

Valerie Norton, M.D. | chief operations executive physician | Scripps Mercy Hospital | San Diego

"ERAS is a win-win-win scenario," Norton says. "Patients like it better, there's better quality of care and recovery, and it lowers costs for the hospital."

Enhanced recovery can lead to what Nihira calls "wildly successful" results. To illustrate, at Magee-Womens Hospital in Pittsburgh, the use of ERAS protocols bumped a 40 percent same-day discharge rate to a 93 percent same-day discharge rate—in a single year. Yet despite its transformational potential, hospitalwide adoption can be slow going.

"It's hard to get people to change their processes, especially if their unit doesn't benefit from the change," Nihira adds. For example, multimodal pain management may require a new pain control drug or device. Frequently a hospital unit such as the pharmacy will incur these expenses, but it won't necessarily experience the benefits of releasing a patient earlier. Successfully adopting ERAS protocols requires buy-in from the entire hospital—something that takes time and staff education.

Hospitals willing to build a mature ERAS program can expect to see changes as dramatic as those Kehlet first introduced in 1995. The adoption process has been slow thus far, but committed health systems are realizing the benefits of an ERAS initiative—limited hospital stays, reduced costs and happier, healthier patients being released—faster than they anticipated. ●

To learn more, visit the American Society for Enhanced Recovery at https://aserhq.org.

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SUSTAINABLE PRACTICES WITH **ANESTHESIA GASES**

Inhaled anesthetics are necessary agents in the operating room, yet only about 5 percent of anesthesia gas administered during surgery is actually metabolized by a patient. The other 95 percent is released into a tube as a patient exhales and vented into the atmosphere through a scavenger system. Such waste becomes greenhouse gas, accounting for about one-third of any surgical procedure's carbon footprint and 5 percent of total hospital emissions.

Adding insult to injury, exhaled anesthetic gases remain in the atmosphere for a long time, impacting the environment until they break down completely, according to a study by Jodi Sherman, M.D., assistant professor of anesthesiology at Yale School of Medicine. Consider the atmospheric lifespan of these inhaled gases:

- Sevoflurane.....1.1 years
- Isoflurane.....3.2 years
- Desflurane .....14 years
- Nitrous oxide .....114 years

On a case-by-case basis, the impact may seem minimal. But that's the wrong way of looking at it, says **Bryan Sabbe**, M.D., division chief of anesthesia at TriStar Centennial Women's Hospital and The Children's Hospital at TriStar Centennial in Nashville, Tennessee, and a HealthTrust Physician Advisor.

Bryan Sabbe, M.D.

"There are many things we can do in our lives to help curtail changes in the atmosphere and spending 10+ hours a day delivering sustainable anesthetics would certainly help limit our environmental footprint," he says.

The American Society of Anesthesiologists (ASA) is leading efforts to reduce the carbon footprint of anesthesia gases. Its Environmental Task Force created a sustainability checklist, outlined in "Greening the Operating Room and Perioperative Arena: Environmental Sustainability for Anesthesia Practice." The checklist features several strategies for reducing emissions without compromising patient care, including:

- Utilizing low, fresh gas flows
- Avoiding the use of high-impact inhaled anesthetics, including desflurane and nitrous oxide
- Using intravenous and regional techniques, when appropriate
- Investing in waste trapping and/or waste destroying technology for the anesthesia equipment

Last year, the organization also launched an "inhaled anesthetic challenge," asking hospitals to reduce facilitywide inhaled anesthetic carbon emissions 50 percent by the year 2020.

Sherman, who co-chairs the ASA's environmental task force, has dedicated her research at Yale to quantifying the environmental impact of different anesthesia gases and techniques. In 2012, she co-published a study offering a life cycle analysis for the four inhaled agents named previously.

The study looked at the impact of these agents from cradle to grave—including manufacturing, delivery and disposal—and concluded that desflurane had the biggest impact: 15 times that of isoflurane and 20 times that of sevoflurane when delivered with 1L/minute of fresh gas flow (FGF). FGF is the amount and combination of gas (air, oxygen, nitrous oxide) that gets mixed with the anesthetic gas during the delivery of an inhaled anesthetic.

The study also indicates that greenhouse gas emissions increased significantly when all three drugs were administered with a FGF of 2L/minute, which produces a greater quantity of waste gas entering the scavenging unit and ultimately the atmosphere.

Findings like these help anesthesiologists like Sabbe choose the best gas for each procedure. For short cases and those requiring a laryngeal mask airway, sevoflurane is his agent of choice. "It does require a higher FGF, but typically nitrous oxide is not used in these cases, so that helps offset it," he says. For longer procedures and cases where an endotracheal tube is used, Sabbe prefers isoflurane, explaining that, "The FGF can be kept very low and it has the lowest carbon footprint if FGF is kept below 1 L/min."

To minimize desflurane use, Sabbe recommends removing desflurane vaporizers from anesthetic machines and requiring special requests for their use—or removing the drug from the formulary altogether. Removing nitrous oxide tanks from anesthetic machines, except in locations where pediatric anesthesia will be administered, is a similar tactic.

Patrick Greene, PharmD

HealthTrust is also advocating clinical strategies that will lead to a reduction in overall anesthesia gas unit utilization. "This can help our members lessen their environmental impact and cost burden," adds **Patrick Greene**, PharmD, HealthTrust director, negotiations and special projects. "A facility can shift utilization from desflurane, which has a longer atmospheric lifespan and larger carbon footprint, to an agent like sevoflurane. They will also see cost savings in choosing the more environmentally friendly sevoflurane."

Continued on page 16

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1 CDC Weekly U.S. Influenza Surveillance Report. Available at: https://www.cdc.gov/flu/weekly/. Accessed on March 12, 2018.
2 Rapid diagnostic testing for influenza: Information for health care professionals. Centers for Disease Control and Prevention website. http://www.cdc.gov/flu/professionals/diagnosis/rapidclin.htm#table Accessed March 12, 2018.
3 Roche **cobas**® Liat® Influenza A/B Package Insert

Continued from page 14

There are several strategies to minimize FGF beyond choosing an anesthetic gas that requires a lower FGF, as each patient and anesthetic gas choice has a minimum amount of FGF to safely deliver the anesthetic, Sabbe explains.

"The underlying question is, 'What is the minimum safe level of fresh gas flow?' " he says. "You have to supply enough oxygen to satisfy the patient's oxygen consumption while accounting for removal of gas through the sampling system and unnoticed leaks in the circuit."

In order to match FGF as closely as possible to what the patient is actually consuming and to pinpoint the minimum-safe FGF, continuous monitoring of inspired and expired oxygen concentration is required.

The ASA's Environmental Task Force report delineates that high fresh gas flow is only necessary with a rapid change in the concentration of anesthetic gas—usually during induction or emergence. "Once the desired concentration of anesthetic vapor has been established in the circuit, it is possible to reduce the fresh gas flow," the task force report outlines. "The maintenance phase of a procedure is often the longest part of the procedure and typically does not require rapid changes in gas concentrations. The maintenance phase, therefore, is the best opportunity to minimize fresh gas flows."

As with most sustainability programs, opportunities exist to increase adoption and implementation. Provider education, Sabbe suggests, is probably the most significant.

"As anesthesia providers, our practice is focused on vigilance, patient safety and leadership in the OR," he says. "Sustainability requires both changes to and adoption of new practices by those delivering the anesthetic, which may differ from their current day-to-day routine."

How can supply chain leaders get providers thinking about the environmental impact of anesthesia gases? Sabbe points to several resources that can help spur conversation. These include an anesthesia carbon calculator and participation in the ASA's Inhaled Anesthetic Challenge 2020. As part of the challenge, participating facilities can anonymously pool their annual procured volume of inhaled anesthetics and receive a report detailing their carbon footprint.

"Any single case does not produce that much waste," Sabbe says. "But that small number multiplied by the thousands of anesthetics given daily in various facilities across the country and around the world has a huge environmental impact." ●

For more information and to check out the anesthesia carbon calculator, visit the American Society of Anesthesiologists's Inhaled Anesthetic 2020 Challenge at www.asahq.org/resources/resources-from-asa-committees/environmental-sustainability/inhaled-anesthetic-2020-challenge.

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[1]https://nrra.net/sweep/time-is-running-out-the-u-s-landfill-capacity-crisis/
[2]Data from a 2010 Clover-funded Life Cycle Analysis (LCA) conducted by RIT

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Under Robert Mulcahy's leadership, Saint Peter's University Hospital installed a new computerized building management program to control heating and air (left) and solar panels across its four campuses.

SAYING YES TO A GREENER WORLD

Saint Peter's University Hospital Does Its Part

When Bill Miller, director of strategic initiatives at HealthTrust's inSight Advisory Services–Energy, recently called **Robert Mulcahy**, vice president of facilities, operations and support services at Saint Peter's University Hospital, the conversation did not go as expected. Miller hoped to help Saint Peter's procure energy, increase efficiency and decrease costs. Miller asked Mulcahy what he always asks HealthTrust members during initial consultations: Do you have on-site solar? Have you implemented energy-saving measures at the hospital? Do you have an energy procurement plan for the next 12 months?

Bill Miller

"Robert was the first person who said 'yes' to his facility already doing all three," Miller says. During his tenure at Saint Peter's, Mulcahy has turned the hospital into a sustainable energy leader. When Miller called Mulcahy more than five years ago, the New Brunswick, New Jersey-based hospital had already installed solar panels across four campuses. They had retrofitted boilers with high-efficiency burners and purchased a new computerized building management program to control heating and air. They had also replaced regular bulbs with LED lighting.

Miller quickly realized that Saint Peter's didn't need convincing to pursue energy efficiency; they needed support for projects that were already underway. Together, Miller and Mulcahy designed a plan that would optimize Saint Peter's established initiatives and make the hospital even more sustainable.

HealthTrust's inSight Advisory Services–Energy consultants help members purchase energy. As Miller explains, energy contracts are not one-size-fits-all.

"We come up with the most optimal way to contract so that a member doesn't overbuy or underbuy," he says. Because Saint Peter's used energy-efficient hospital equipment and solar panels, the hospital was at risk for overbuying power. Mulcahy also planned to install on-site generation, which would require more natural gas but less electricity. Miller adds, "To give Robert the flexibility he needed, we advised him on how to enter into contracts so he could buy energy on the open market."

Robert Mulcahy

Identifying a better contract for purchasing gas and electricity cut Saint Peter's already-reduced energy costs. Miller and his team also identified peak usage times and advised Saint Peter's to curb usage at certain hours, reducing the hospital's reliance on the grid. "The relationship with HealthTrust has helped us maximize everything we could," Mulcahy notes. "We've made the most of our return on investment because of Bill's expertise."

Today, Saint Peter's and HealthTrust continue their dynamic partnership. HealthTrust continues to monitor Saint Peter's solar system to ensure energy goals are reached. "We make certain nothing falls through the cracks and that everything is operating as we expect it to," Miller adds. When Saint Peter's

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Robert Mulcahy | vice president of facilities, operations and support services | Saint Peter's University Hospital

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electricity contract expires, HealthTrust will help the hospital reevaluate its needs and purchase wisely.

Since that first phone call, Saint Peter's and HealthTrust have collaborated to implement further conservation measures, negotiate optimal energy contracts and build resilience against catastrophic events. With funds from the state of New Jersey's Energy Resilience Bank, the hospital recently installed a combined heat and power (CHP) system. The system went online in August 2018 and is slated to save over $1 million annually.

"We're the first hospital in New Jersey to have the source up and running," Mulcahy says. In the event of another disaster like Hurricane Sandy that affected the hospital, the CHP system allows Saint Peter's to run completely off the grid.

"Saint Peter's was so far out in front of everybody getting incentives and rebates from utility and equipment companies," Miller adds. "We want every HealthTrust member to be forward-thinking and realize there's so much money sitting out there."

By taking advantage of state and federal incentive programs like the Energy Resilience Bank, along with consultation from inSight Advisory Services–Energy, Saint Peter's has implemented more than $20 million worth of projects with minimal capital outlay.

"Saint Peter's has a new heart—in terms of infrastructure—that is very efficient," Mulcahy says. "We don't have to lay out capital for the future; we can save it instead for clinical needs." In other words, instead of paying for gas and electricity to keep the hospital running, Saint Peter's can direct funds toward life-saving innovations.

The results of such forward-thinking practices speak for themselves. Back in 2011, Saint Peter's utility costs topped $7.5 million a year. Today the hospital's projected annual budget is $3.5 million—a $4 million savings every year.

For Mulcahy, the savings are satisfying, but he's even more excited about the impact these energy efficiency measures have on the local community.

Mulcahy adds, "We deliver 5,500 babies here a year, and those children are going into a cleaner environment that we helped establish for this community. I'm proud to say Saint Peter's is doing its part." ●

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Indication and important safety information you should know about Sevoflurane

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Findings taken from patient and animal studies suggest that there is a potential for renal injury when Sevoflurane is used at low flow rates, which is presumed due to Compound A. The level of Compound A exposure at which clinical nephrotoxicity might be expected to occur has not been established. To minimize exposure to Compound A, Sevoflurane exposure should not exceed 2 MAC-hours at flow rates of 1 to <2L/min. Fresh gas flow rates<1L/min are not recommended. Because clinical experience in administering Sevoflurane to patients with renal insufficiency (creatinine >1.5 mg/dL) is limited, its safety in these patients has not been established. Sevoflurane may be associated with glycosuria and proteinuria when used for long procedures at low flow rates. KOH containing CO_2 absorbents are not recommended for use with Sevoflurane. An exothermic reaction occurs when Sevoflurane is exposed to CO_2 absorbents. This reaction is increased when the absorbent becomes desiccated. Rare cases of extreme heat, smoke, and/or spontaneous fire have been reported during Sevoflurane use in conjunction with the use of desiccated CO_2 absorbent, specifically those containing potassium hydroxide (e. g., Baralyme). Reports of QT prolongation, associated with torsade de points (in exceptional cases, fatal), have been received. Caution should be exercised when administering Sevoflurane to susceptible patients (e. g. patients with congenital Long QT Syndrome or patients taking drugs that can prolong the QT interval). Rare increase in serum potassium resulting in cardiac arrhythmias and death have been noted in pediatric patients during the postoperative period following the use of inhaled anesthetic agents. Contributing risk factors appear to be latent or overt neuromuscular disease, particularly Duchenne muscular dystrophy. Concomitant use of succinylcholine has been associated with most, but not all, of these cases. Early, aggressive intervention to treat both hyperkalemia and resistant arrhythmias, and subsequent evaluation for latent neuromuscular disease, is recommended. During the maintenance of anesthesia, increasing the concentration of Sevoflurane produces dose-dependent decrease in blood pressure. Due to Sevoflurane's insolubility in blood, hemodynamic changes may occur more rapidly than with other volatile anesthetics. Excessive decrease in blood pressure or respiratory depression may be related to depth of anesthesia and may be corrected by decreasing the inspired concentration of Sevoflurane. Seizures have been reported in association with Sevoflurane use, the majority of which have occurred in children and young adults, most of whom had no predisposing risk factors. Clinical judgment should be exercised when using Sevoflurane in patients who may be at risk for seizures. **Drug interactions:** Benzodiazepines and opioids would be expected to decrease the MAC of Sevoflurane. 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Adverse events reported by ≥5% of the surgical patients receiving Sevoflurane during clinical trials during induction included: bradycardia, tachycardia, agitation laryngospasm, airway obstruction, breath-holding, and increased cough; during maintenance and emergence: shivering, hypotension, bradycardia, somnolence, agitation, nausea, vomiting, and increased cough were reported.

- **For full prescribing information, please see Sevoflurane, USP package insert at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3dbab949-6ab7-4040-9c81-314e5bb61d41.**
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Joint replacement surgeries have revolutionized the treatment of arthritis and allowed a generation of older adults to stay active for decades longer than their ancestors. Bone cement, which is used to fix joint replacement implants to bone, makes many of those surgeries possible, allowing surgeons to transfer body weight and service loads from the prosthesis to the bone and increase the joint's weight-bearing capacity.

In an ongoing effort to prevent post-surgical infections, antibiotic-loaded bone cement was designed to allow for the implantation of infection-fighting drugs during surgery. Researchers have found varying results with standard and antibiotic-loaded bone cements, but some controversy exists regarding their use and efficacy. For many physicians, there's no easy answer to the "With or without antibiotics?" question.

PROCEDURE DETERMINES CEMENT CHOICE

For example, at Nashville, Tennessee-based Southern Joint Replacement Institute (SJRI), orthopedic surgeon **Craig Morrison**, M.D., frequently uses bone cement—but he uses both antibiotic-loaded and standard, depending on the patient and the surgery.


Craig Morrison, M.D.

"I cement 100 percent of my knee replacements and about 2 percent of my hip replacement stems," he says. "For primary knee replacements, I rarely use antibiotics in the bone cement."

Morrison avoids using antibiotic-loaded bone cement with most knee replacements because he doesn't believe the research justifies the extra cost. "Most of the recent large studies looking retrospectively at historical data do not show a difference in infection rates when antibiotics are used in the cement," he says.

An August 2014 *Journal of Arthroplasty* article showed no difference in infection rates in more than 3,000 knee replacements at different points in time up to one year after surgery. Additionally, the large Kaiser Permanente National Total Joint Replacement Registry has shown similar findings in over 20,000 knee replacements.

Though the research doesn't warrant using antibiotic cement with all knee replacement surgeries, Morrison may opt to use it under certain circumstances. "Although somewhat controversial, it may be reasonable to choose to use antibiotic cement only in patients with a high risk of infection like inflammatory arthritis, morbid obesity or diabetes—likely the minority of patients in most practices," he says. "Additionally, I use premixed antibiotic bone cement in my revision knee replacements."

While he uses antibiotic-loaded cement sparingly with knee replacements, Morrison generally uses antibiotics in the bone cement for hip replacement surgeries. "The Norwegian Arthroplasty Register has shown a lower revision rate for infection and aseptic stem loosening in total hip arthroplasty patients who received antibiotic bone cement," he says.

WEIGHING THE PROS AND CONS

The advantage of antibiotic-loaded bone cement is its ability to fight infection. At SJRI, the product is used most for infection treatment, especially when a joint replacement patient has developed an infection and a revision surgery must be performed. For instance, when Morrison performs a resection arthroplasty for a hip or knee infection, he puts in a temporary articulating spacer until the second stage revision. He adds 3 grams of the antibiotic Vancomycin and 2.4 grams of the antibiotic Tobramycin to each 40 grams of regular cement. On average, Morrison uses three packs of cement in these cases.

One of the arguments against using antibiotic-loaded bone cement is that the practice could potentially create antibiotic resistance. But based on research published in the *Journal of Arthroplasty*, Morrison says antibiotic resistance as a result of antibiotic cement does not appear to be a problem. Instead, the main issue is cost. Premixed antibiotic bone cement adds about $300 per case, "and it is difficult to justify this cost based on the literature specific to knee replacements," he says.

While there is a place for antibiotic-loaded bone cement, ongoing cost pressures are leading some facilities and physicians to look more closely at each case before choosing to use it. "As surgeons become more engaged in cost-savings measures through bundle programs and aligned incentives with hospitals, I believe the routine use of antibiotic-laden cement will go down," Morrison says.

PROVIDING CHOICES

Traditionally, HealthTrust provided a contract with a single supplier for bone cement. However, member hospitals continued to use a variety of different providers. A clinician member of the HealthTrust's Physician Services team recently developed a clinical evidence review (CER) by combing through and summarizing the available clinical research and soliciting physician feedback.

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The bone cement CER revealed that many orthopedic surgeons do not use antibiotic-loaded cement only or standard cement only; instead, they prefer to choose whatever option is best for each particular surgery or patient.

Other results from HealthTrust's clinical evidence review:

- No randomized clinical trials compare standard or antibiotic-loaded bone cement.
- Use of antibiotic-loaded cement in knee replacement surgery is controversial except in high-risk patients.
- Bone cement is rarely used in total hip replacement surgeries, but the American Academy of Orthopaedic Surgeons recommends it for hip fracture patients.
- Physician preferences are not driven by clinical differentiation between products.
- Tinted or colored cement is preferred because it is easier to identify if the patient requires revision surgery.
- Higher viscosity cement is usually preferred for total knee replacements, and lower viscosity cement is required for total hip replacements.
- Pre-mixed, antibiotic-loaded bone cement should not be used for treating infected joint replacements because the antibiotic dose is intended for infection prophylaxis only.
- High-dose antibiotic bone cement spacers are used to treat active joint replacement infections.

In an effort to create value for facilities and respect physician needs and practice patterns, HealthTrust decided to implement a strategy that offers physicians more choices among bone cement suppliers that offer clinically equivalent products.

Bone cement from different suppliers can differ in color, viscosity, and presence and dosage of antibiotics. But in most cases, those differences can be left to physician preferences since the clinical outcomes are similar. However, prices of bone cement vary among suppliers and by facility. Without antibiotics, bone cement can cost between $40 and $185 per standard dose; with antibiotics, it can range from $117 to $663 per standard dose. Physicians now have more opportunities to select from contracted cements that best meet the individual needs of patients undergoing specific procedures. ●

To access HealthTrust's CER on bone cement, visit the member portal. To learn which suppliers have opted to accept fair market pricing, contact ***Todd Lockhart****, director of inSight Advisory–Medical Devices at (todd.lockhart@healthtrustpg.com).*

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Please see accompanying Highlights of Prescribing Information for additional important information.

References: 1. Berntorp et al. Haemophilia. 2009;15:122-130.

HealthTrust Contract #4861

Date of preparation: 5/2018. WIL-0149-PAD

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use WILATE safely and effectively. See full prescribing information for WILATE.

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Indications and Usage 8/2015

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WILATE is indicated in children and adults with von Willebrand disease for:

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WILATE is not indicated for treatment of hemophilia A

DOSAGE AND ADMINISTRATION

For Intravenous Use Only

- Use the following formula to determine required dosage:

  Required IU = body weight (BW) in kg x desired VWF:RCo rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL)
- Adjust dosage and duration of the substitution therapy depending on the severity of the VWD, on the location and extent of the bleeding, and on the patient's clinical condition
- Dosing recommendations:

Type of Hemorrhages/Surgery	Loading Dosage (IU VWF:RCo/ kg BW)	Maintenance Dosage (IU VWF:RCo/ kg BW)	Therapeutic Goal
Minor Hemorrhages	20-40 IU/kg	20-30 IU/kg every 12-24 hours	VWF:RCo and FVIII activity trough levels of >30%
Major Hemorrhages	40-60 IU/kg	20-40 IU/kg every 12-24 hours	VWF:RCo and FVIII activity trough levels of >50%
Minor Surgeries (including tooth extractions)	30-60 IU/kg	15-30 IU/kg or half the loading dose every 12-24 hours for up to 3 days	VWF:RCo peak level of 50% after loading dose and trough levels of >30% during maintenance doses
Major Surgeries	40-60 IU/kg	20-40 IU/kg or half the loading dose every 12-24 hours for up to 6 days or more	VWF:RCo peak level of 100% after loading dose and trough levels of >50% during maintenance doses

In order to decrease the risk of perioperative thrombosis, FVIII activity levels should not exceed 250%.

DOSAGE FORMS AND STRENGTHS

WILATE is available as a sterile, lyophilized powder for reconstitution for intravenous injection, provided in the following nominal strengths per single-use vial:

- 500 IU VWF:RCo and 500 IU FVIII activities in 5 mL
- 1000 IU VWF:RCo and 1000 IU FVIII activities in 10 mL

CONTRAINDICATIONS

Do not use in patients with known hypersensitivity reactions, including anaphylactic or severe systemic reaction, to human plasma-derived products, any ingredient in the formulation, or components of the container.

WARNINGS AND PRECAUTIONS

- Anaphylaxis and severe hypersensitivity reactions are possible.
- Thromboembolic events may occur. Monitor plasma levels of FVIII activity.
- Development of neutralizing antibodies to FVIII and to VWF, especially in VWD type 3 patients, may occur.
- WILATE is made from human plasma and carries the risk of transmitting infectious agents.

ADVERSE REACTIONS

The most common adverse reactions (≥1%) in clinical studies on VWD were hypersensitivity reactions, urticaria, and dizziness.

USE IN SPECIFIC POPULATIONS

Pregnancy: no human or animal data. Use only if clearly needed.

Lactation: There is no information regarding the presence of WILATE in human milk, the effect on the breastfed infant, and the effects on milk production.

Pediatric Use: No dose adjustment is needed for pediatric patients as administered dosages were similar to those used in the adult population.

Geriatric Use: Although some of the subjects who participated in the WILATE studies were over 65 years of age, the number of subjects was inadequate to allow subgroup analysis to support recommendations in the geriatric population.

PATIENT COUNSELING INFORMATION

- Advise the patients to read the FDA-approved patient labeling (Patient Information and Instructions for Use).
- Inform patients of the early signs of hypersensitivity reactions including hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis. If allergic symptoms occur, advise patients to discontinue the administration immediately and contact their physician to administer appropriate emergency treatment.
- Inform patients that undergoing multiple treatments with WILATE may increase the risk of thrombotic events thereby requiring frequent monitoring of plasma VWF:RCo and FVIII activities.
- Inform patients that there is a potential of developing inhibitors to VWF, leading to an inadequate clinical response. Thus, if the expected VWF activity plasma levels are not attained, or if bleeding is not controlled with an adequate dose or repeated dosing, contact the treating physician.
- Inform patients that despite procedures for screening donors and plasma as well as those for inactivation or removal of infectious agents, the possibility of transmitting infective agents with plasma-derived products cannot be totally excluded.

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LIBERATING PATIENTS FROM ICU DELIRIUM

Ashley Cundiff, MSN, RN, keeps a close eye on patients in her 32-bed intensive care unit (ICU) at Chippenham Hospital in Richmond, Virginia. She's watching for more than changes to their vital signs. She's looking for what they may not be able to communicate. She's trying to keep them from slipping into delirium.

Ashley Cundiff, MSN, RN

"We call it the matrix," says Cundiff, director of the medical/surgical trauma ICU at Chippenham. "They look like they are asleep, but they're just in a whole other realm."

Cundiff knows that no matter how vigilant she and her nursing team are, some of her patients will descend into this delusionary state. Her mission is to pull them out before they plunge too deeply into it.

"These patients are sick enough already, and we never want to bring anything else on them," Cundiff says. "We're constantly asking ourselves what we can do to prevent them from going into the matrix, so when they get better, they're not suffering lifelong consequences."

Marked by sudden and intense periods of confusion, hallucinations and paranoia, ICU delirium has become an alarmingly common experience for patients in critical care units. Patients who succumb to it have longer hospital stays, poorer outcomes and higher mortality rates. Even after leaving the hospital, some are left with night terrors and cognitive repercussions equivalent to a blow to the head or early Alzheimer's disease, according to a 2013 study in the *New England Journal of Medicine*. A growing number of hospitals are becoming aware of the dangers of ICU delirium and searching for ways to free patients from its grip.

The dilemma has even commanded the attention of the Society of Critical Care Medicine (SCCM), which launched an ICU Liberation initiative in 2015 to rescue patients from the harmful effects of pain, agitation and delirium in the ICU. The organization is working with hospitals nationwide to implement new research-based guidelines for the Management of Pain, Agitation and Delirium (PAD). SCCM has also partnered with critical care innovators at the Vanderbilt School of Medicine, the University of Chicago and other institutions to promote what's called the "ABCDEF care bundle," which includes protocols for assessing and managing pain, minimizing the use of sedatives and ventilators, getting patients up and moving and encouraging family engagement. (*See box below.*)

Laura Reed, MSN, RN

"We create some of our own problems," says **Laura Reed**, MSN, RN, associate chief nursing officer at Chippenham Hospital, which has implemented the ABCDEF bundle across its critical care departments. "The first thing we used to do when a patient started showing signs of delirium was medicate them, but that just exacerbated the issue. Then you had to restrain them, which often led to more problems. If we can prevent delirium from the beginning, we can limit their stay in the ICU and improve their outcome."

As Essential as Your ABCs

These are the elements of the ABCDEF care bundle:

- **A** Assess, Prevent & Manage Pain
- **B** Both Spontaneous Awakening Trials & Spontaneous Breathing Trials
- **C** Choice of Analgesia & Sedation
- **D** Delirium: Assess, Prevent & Manage
- **E** Early Mobility & Exercise
- **F** Family Engagement & Empowerment

Source: www.sccm.org/ICULiberation/ABCDEF-Bundles

THE DELIRIUM SPIRAL

When Reed started working in the ICU nearly 30 years ago, nurses were urged to wean patients off ventilators as quickly as possible, but over the years the pendulum swung toward sedating them for days while they recovered.

"We used to think if we kept patients sedated and calm, we could leave the life-saving tubes and devices in them until they got better," agreed **Beverly Shields**, DNP, MSN, RN, CCRN, director of critical care and medical surgical services for Franklin, Tennessee-based Community Health Systems (CHS).

Beverly Shields, DNP, MSN, RN, CCRN

While drugs such as benzodiazepines and other anti-anxiety medications do make patients calmer and less combative in the short term, they ultimately fuel the cycle of delirium, and patients are often confused and delirious when they wake up, says **Seenu Reddy**, M.D., director of cardiac surgery outreach for Nashville, Tennessee-based TriStar Cardiovascular Surgery and chair of HealthTrust's Physician Advisor Surgery Council. Older patients who are already experiencing cognitive decline or taking a lot of medication are even more susceptible.

Seenu Reddy, M.D.

"Combine that scenario with an unfamiliar environment full of alarms, beeps and buzzers going off at all hours, strangers coming in and out of your room, fluorescent lights and a complete inversion of your days and nights, and it's basically set up to cause delirium in the susceptible patient," Reddy adds.

"We're in their rooms all the time," Reed says. "We wake them up at all hours, and there aren't consistent times for allowing patients to sleep."

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The lack of rest, combined with hours of lying in the same position in cramped rooms with little, if any, natural light, can agitate patients even more. Though delirium is typically associated with hyper, belligerent patients who try to climb out of bed or rip out tubes and monitors, many delirious patients act just the opposite.

Reed notes, "They may be looking at you and answering questions, but not really understanding anything you're saying or what's happening around them."

Because delirium can develop within a day or two and fluctuate in its severity, catching it early is vital for elimination without resorting to antipsychotic medication, which can cause adverse effects. While going along with what a delirious patient is saying or doing may seem more convenient in the hustle and bustle of the ICU, overlooking delirium can trigger a cascade of consequences for patients that can prolong their ICU stay and follow them home.

"As nurses, we pat ourselves on the back for saving people and getting them out of the hospital," Reed says. "But when they return home, some of these patients never get back to their previous level of functioning. So it's important to be thinking longer term."

PUSHING PATIENTS OUT OF THE COCOON

For ICU nurses at Chippenham Hospital, protecting patients from the ravages of delirium starts with keeping them as awake and alert as possible and being more mindful in helping them manage pain.

"If we can keep patients less sedated, they're usually able to reason better and understand when we say, 'Don't pull this tube out,' " Cundiff says. "You can explain things to them, and they tend to work with you because they're not on so many mind-altering substances."

Scaling back the amount of sedation patients receive and time spent on ventilators required critical care teams at Chippenham to change their way of thinking. However, seeing how well patients responded brought everyone around.

"The most successful transition for us was recognizing that, while we were trying to help our patients, what we were doing for them was often making them worse," Reed says.

> "IF WE CAN KEEP PATIENTS LESS SEDATED, THEY'RE USUALLY ABLE TO REASON BETTER AND UNDERSTAND ... YOU CAN EXPLAIN THINGS TO THEM, AND THEY TEND TO WORK WITH YOU BECAUSE THEY'RE NOT ON SO MANY MIND-ALTERING SUBSTANCES."
>
> **Ashley Cundiff**, MSN, RN | director, medical/surgical trauma ICU | Chippenham Hospital

Managing patient expectations about pain with surgery can also help, Reddy adds. "For decades, there was an expectation that patients should be treated so aggressively with medications that they wouldn't experience any pain after surgery—but that's changing," he says. "Now we're better at explaining preoperatively that patients will have discomfort with surgery, but we're going to try to minimize it."

Combining fewer opioids with milder pain relievers is another alternative many ICUs are using for postoperative pain management, along with strategies as simple as changing how a patient is positioned in bed.

"You don't always have to bring out the big guns to bring relief from pain," Cundiff notes. "Sometimes Tylenol is enough."

As part of the ABCDEF bundle, many care teams perform spontaneous awakening and breathing trials every morning to rouse patients and evaluate their ability to follow commands and breathe on their own. "If they start getting anxious from breathing on their own, you can try putting their sedation back on by half," Cundiff says.

There is also a growing number of quick, bedside assessments available to measure pain, agitation and delirium in patients, including the Behavioral Pain Scale (BPS), the Richmond Agitation-Sedation Scale (RASS) and the Confusion and Assessment Method for the ICU (CAM-ICU).

Nurses at Chippenham use these assessments daily to monitor patients for delirium. Tools like these keep delirium on nurses' radar and prompt them to think critically about how to handle it, Reed says. "If something is off scale, that's a cue for our teams to intervene."

Getting patients moving helps, too. Nurses at Chippenham work closely with physical therapists to encourage patients to sit up, stand and walk—even while on a ventilator. Not only does mobility reduce their risk of pneumonia, blood clots and bedsores, but it also helps regulate their circadian clock and puts them in the present moment.

"We try to mimic the routine they have at home and help them maintain their muscle strength," Cundiff adds.

FAMILY SUPPORT & HUMAN CONNECTION

Delirium is often hardest on the families of patients who rarely see it coming and struggle to understand why their loved one is acting so out of character. While they may wonder if their loved one will ever be the same, their support is the best lifeline for helping patients break free of delirium.

"We are doing a much better job of involving families and having open visitation, so they can be there to reorient patients," Reed says.

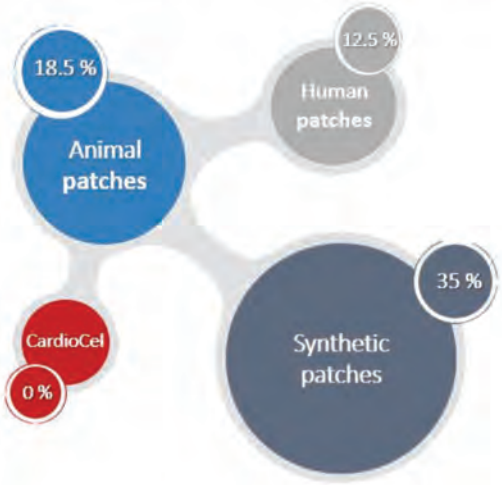
Having family and friends at the bedside gives patients familiar faces among the rotating ICU staff and keeps them grounded. Hospitals can help by educating family caregivers on how they can create more normalcy for patients, from decorating their room with family photos to bringing in their glasses, hearing aids or favorite music. Families can also engage loved ones by talking or reading to them or doing activities with them they enjoy such as crossword puzzles or checkers.

Including families in bedside reports and giving them a chance to ask questions helps caregivers and patients feel like they have a voice in their care. So does explaining what you are doing to patients and asking about their lives.

Continued on page 30

ADAPT

According to results of a meta-analysis[1] of published literature evidence, patch calcifications leading to the reoperation were present in:



"The development of the CardioCel® patch (Admedus) is an important milestone in preventing early calcification in young recipients who are particularly susceptible to complications due to calcification of the graft."[7]

ADAPT® benefits[2,3,4]

- Superior biocompatibility
- Optimized biomechanics
- Proven resistance to calcification

Our value to hospital, surgeon and patient[2,5,6]

- Lowest re-intervention rate
- Improved outcomes
- Improved patient satisfaction and quality of life

ADMEDUS

www.admedus.com

References:

1. Data on file. Admedus Synergus Health Economic Analysis (2016).
2. Data on file. Admedus Pre-clinical studies; Arch Meta Analysis (2018); and Phase II Clinical Follow-up Report (2017).
3. Bell, D., et al., Durability of Tissue-Engineered Bovine Pericardium (CardiolCel) for a Minimum of 24 Months When Used for the Repair of Congenital Heart Defects. Interactive CardioVascular and Thoracic Surgery (2018) 1-7.
4. Prabhu, S., JE Armes, D. Bell, R. Justo, P. Venugopal, T. Karl, and N. Alphonso. Histologic Evaluation of Explanted Tissue-Engineered Bovine Pericardium (CardioCel). Seminars in Thoracic and Cardiovascular Surgery. 2017;29(3):356-363.
5. Bell, D., et al., Multi-Center Clinical Outcomes 830 Implants of Tissue Engineered Bovine Pericardium (CardioCel) Used for the Repair of Congenital Heart Defects, APPCS (2018).
6. Velickovic, V., et al., Congenital Heart Defect Repair with ADAPT Tissue Engineered Pericardium Scaffold: An Early Economic Evaluation. POLS ONE (2018).
7. Pavy, C. et al., Initial 2-year results of CardioCel patch implantation in Children. Interactive CardioVascular and Thoracic Surgery (2017) 1-6.

ADAPT transformative repair CARDIOCEL

ADAPT transformative repair CARDIOCEL NEO

ADAPT transformative repair VASCUCEL

HealthTrust Contract #34080

Continued from page 28

"Even if patients are in a delirious state, you never know what they may be comprehending," Cundiff says.

Helping patients set goals for what they want to accomplish day-to-day also gives them back a sense of control and motivates them to look ahead.

"Critical care nurses are very list-driven," Cundiff adds. "We love to go in and say, 'This is what I'm going to do for you today.' But we need to be asking, 'What's your goal for today? If I could do anything to help you, what would it be?' "

CHANGING THE CULTURE

Delirium used to be viewed as an inevitable consequence of an ICU stay for some patients, Reddy says. But with research and awareness about delirium growing, more clinicians are understanding how they perpetuate it—and, more important, how they can help combat it.

"Nurses and physicians are more attuned to it now," Reddy says. "We're catching it earlier than we ever have before, and we're creating interventions to minimize it."

CHS is working to help its hospitals change the culture around delirium by providing ICU staff with easy-to-use, evidence-based tools to help them recognize symptoms and tackle it early.

"We developed a gap analysis for our hospitals using guidelines condensed from the American Association of Critical-Care Nurses, so clinicians can see what they are doing well and where they need to improve," Shields says.

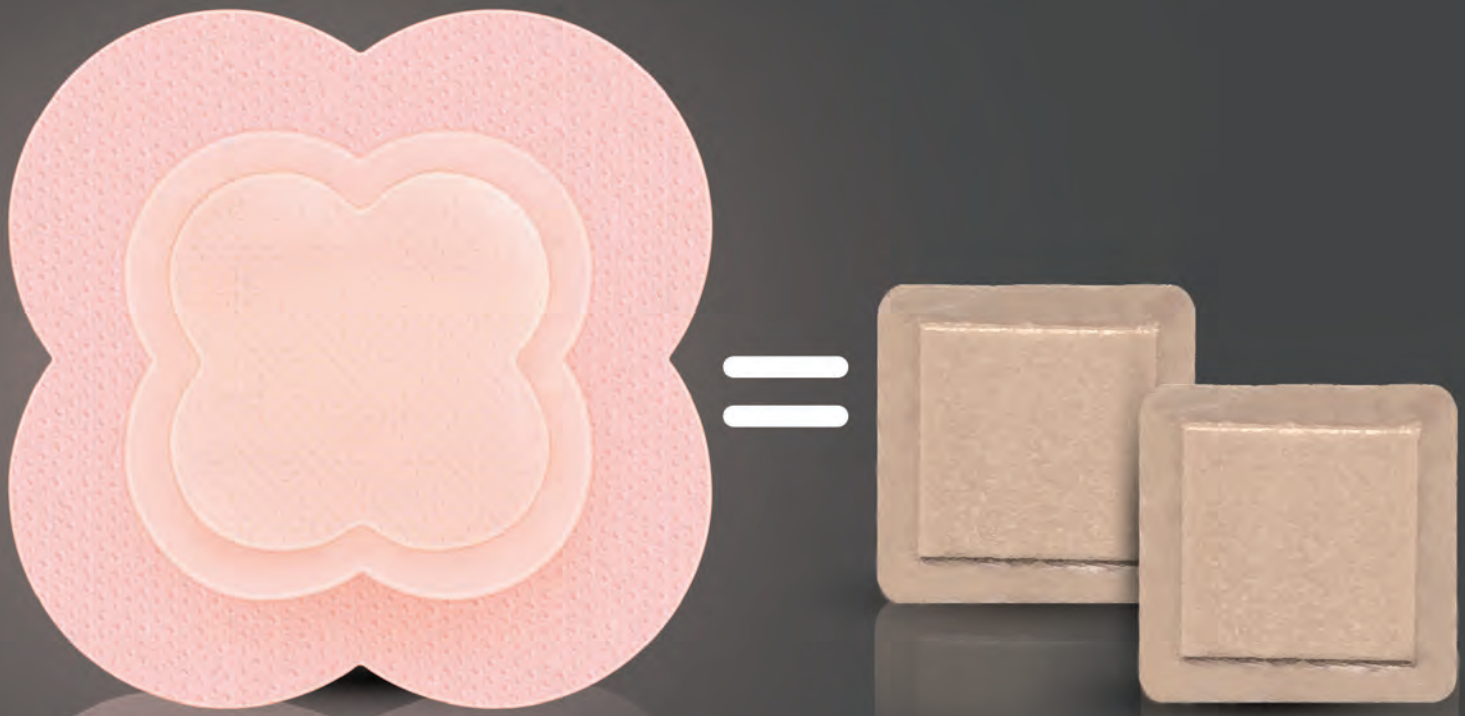
Those efforts are paying off. Now patients who used to sleep all day are "up walking around in the unit and maintaining their strength and energy," Shields notes. "We get patients out of the hospital a lot faster, and they are much better in the long run."

At Chippenham, ventilator days—the measurement they use to track their success with the bundle—are down by at least a day for most patients, and ICU nurses are seeing the positive impact of their interventions.

"We like to think we know what our patients experience and that we're always doing what's best for them," Cundiff says. "But we're starting to see that our patients are capable of more than we necessarily believed. Until you give them that chance, you never know." ●

For more information, visit the Society of Critical Care Medicine's ICU Liberation website at www.sccm.org/ICULiberation, or the American Association of Critical-Care Nurses' website at www.aacn.org/clinical-resources.

HealthTrust contract #24201



Layers that last and lower your cost[1]

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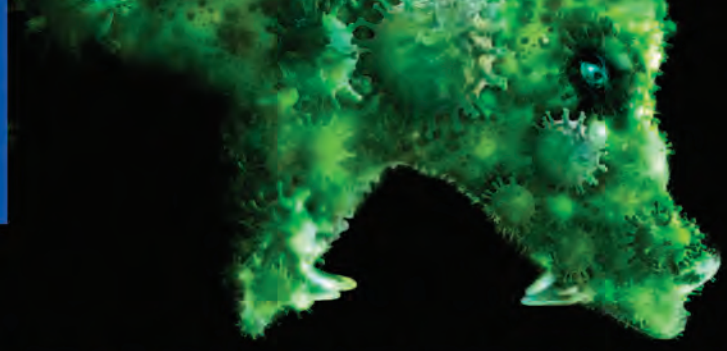
Contact your HealthTrust Smith & Nephew Director, National Accounts
Jeremy Spencer at (704) 562-5862
jeremy.spencer@smith-nephew.com

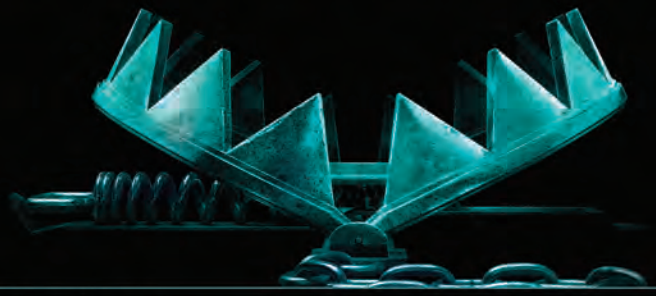
References: 1. Joy H et al. A collaborative project to enhance efficiency through dressing change practice. Journal of Wound Care. Vol 24. No 7. July 2015 P3-4. 2. Data on File Report GMCA-DOF/08 –April 2016, A. Rossington. Product Performance of Next Generation ALLEVYN LIFE.

INFORMATION RELATED TO PATIENTS 50+[1,2,a,b]

HealthTrust Contract #2327



THE THREAT OF INFLUENZA IS FORMIDABLE BUT NOW SO ARE YOUR VACCINE OPTIONS



ONLY 2 INFLUENZA VACCINES are proven in randomized controlled trials to prevent more cases of influenza relative to their standard-dose vaccine comparators in older adults[1-4]

FLUZONE HIGH-DOSE VACCINE EFFICACY IN ADULTS 65+:

PRIMARY ENDPOINT

24.2% **BETTER PROTECTION FROM INFLUENZA** compared with Fluzone vaccine[1,3]

Primary endpoint of the study was the occurrence of laboratory-confirmed, protocol-defined, influenza-like illness caused by viral strains regardless of their antigenic similarity to vaccine components.

SECONDARY ENDPOINT

51.1% **BETTER PROTECTION FROM INFLUENZA** compared with Fluzone vaccine[1,3]

A secondary endpoint of the study was the occurrence of culture-confirmed influenza caused by viral types/subtypes antigenically similar to those contained in the respective annual vaccine formulations in association with a modified Centers for Disease Control and Prevention-defined influenza-like illness.

FLUBLOK QUADRIVALENT VACCINE EFFICACY IN ADULTS 50+:

PRIMARY ENDPOINT

30% **BETTER PROTECTION FROM INFLUENZA** compared with a standard-dose quadrivalent inactivated influenza vaccine[2,4]

The primary endpoint of the study was PCR[c]-confirmed, protocol-defined, influenza-like illness due to any influenza virus type or subtype.

SECONDARY ENDPOINT

43% **BETTER PROTECTION FROM INFLUENZA** compared with a standard-dose quadrivalent inactivated influenza vaccine[2,4]

The secondary endpoint of the study was culture-confirmed, protocol-defined, influenza-like illness due to any influenza virus type or subtype.

Results from both clinical trials published in the ***New England Journal of Medicine.***

Please see Important Safety Information on the next page.

Fluzone® *High-Dose* INFLUENZA VACCINE
APPROVED FOR PATIENTS 65+

Flublok® *QUADRIVALENT Influenza Vaccine*
APPROVED FOR PATIENTS 18+

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SAUS.SFLU.18.08.4934 9/18 Printed in USA

IMPORTANT SAFETY INFORMATION FOR FLUBLOK QUADRIVALENT AND FLUZONE HIGH-DOSE VACCINES

Flublok Quadrivalent and Fluzone High-Dose vaccines should not be administered to anyone who has had a severe allergic reaction (eg, anaphylaxis) to any component (including egg protein for Fluzone High-Dose vaccine) or previous dose of the respective vaccine. In addition, Fluzone High-Dose vaccine should not be administered to anyone who has had a severe allergic reaction to a previous dose of any influenza vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following previous influenza vaccination, the decision to give Flublok Quadrivalent or Fluzone High-Dose vaccine should be based on careful consideration of the potential benefits and risks.

The most common local and systemic adverse reactions to Flublok Quadrivalent and Fluzone High-Dose vaccines include pain at the injection site; headache and myalgia. Other adverse reactions may occur. Vaccination with Flublok Quadrivalent or Fluzone High-Dose vaccine may not protect all individuals.

INDICATION FOR FLUBLOK QUADRIVALENT AND FLUZONE HIGH-DOSE VACCINES

Flublok Quadrivalent and Fluzone High-Dose vaccines are indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B virus(es) contained in each vaccine. Flublok Quadrivalent vaccine is approved for use in persons 18 years of age and older. Fluzone High-Dose vaccine is approved for use in persons 65 years of age and older.

Before administering Flublok Quadrivalent or Fluzone High-Dose vaccine, please see brief summaries of the full Prescribing Information on the following pages.

To order Fluzone High-Dose or Flublok Quadrivalent vaccine, go to **VaccineShoppe.com**® or call **1-800-VACCINE** (1-800-822-2463).

Fluzone and Fluzone vaccines are manufactured and distributed by Sanofi Pasteur Inc.
Fluzone High-Dose vaccine (CPT®[d] code 90662) is a covered benefit under Medicare Part B.
Flublok Quadrivalent vaccine is manufactured by Protein Sciences Corporation, a Sanofi company, and distributed by Sanofi Pasteur Inc.
Flublok Quadrivalent vaccine (CPT® code 90682) is a covered benefit under Medicare Part B.

[a] Fluzone High-Dose vaccine is approved for use in adults 65 years of age and older.[1]
[b] Flublok Quadrivalent vaccine is approved for use in adults 18 years of age and older.[2]
[c] PCR = Polymerase chain reaction.
[d] CPT (Current Procedural Terminology) is a registered trademark of the American Medical Association.

Fluzone® High-Dose
INFLUENZA VACCINE

Flublok®
Influenza Vaccine

References: 1. Fluzone High-Dose vaccine [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc. **2.** Flublok Quadrivalent vaccine [Prescribing Information]. Meriden, CT: Protein Sciences Corporation. **3.** DiazGranados CA, Dunning AJ, Kimmel M, et al. Efficacy of high-dose versus standard-dose influenza vaccine in older adults. *N Engl J Med.* 2014;371:635-645. **4.** Dunkle LM, Izikson R, Patriarca P, et al. Efficacy of recombinant influenza vaccine in adults 50 years of age or older. *N Engl J Med.* 2017;376:2427-2436.

SANOFI PASTEUR

Flublok® Quadrivalent (Influenza Vaccine) Sterile Solution for Intramuscular Injection

2018-2019 Formula

Initial US Approval: 2013

℞ only

BRIEF SUMMARY: Please consult package insert for full prescribing information.

INDICATIONS AND USAGE

Flublok Quadrivalent is a vaccine indicated for active immunization against disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Flublok Quadrivalent is approved for use in persons 18 years of age and older.

CONTRAINDICATIONS

Flublok Quadrivalent is contraindicated in individuals with known severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine.

WARNINGS AND PRECAUTIONS

Managing Allergic Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Guillain-Barré Syndrome

If Guillain-Barré Syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give Flublok Quadrivalent should be based on careful consideration of the potential benefits and risks.

Altered Immunocompetence

If Flublok Quadrivalent is administered to immunocompromised individuals, including persons receiving immunosuppressive therapy, the immune response may be diminished.

Limitations of Vaccine Effectiveness

Vaccination with Flublok Quadrivalent may not protect all vaccine recipients.

ADVERSE REACTIONS

Clinical Trials Experience

Flublok Quadrivalent has been administered to and safety data collected from 998 adults 18-49 years of age (Study 1) and 4328 adults 50 years of age and older (Study 2).

Study 1 included 1330 subjects 18 through 49 years of age for safety analysis, randomized to receive Flublok Quadrivalent (n=998) or a comparator inactivated influenza vaccine (n=332). Table 1 summarizes the incidence of solicited local and systemic adverse reactions reported within seven days of vaccination with Flublok Quadrivalent or the comparator vaccine.

Table 1: Frequency of Solicited Local Injection Site Reactions and Systemic Adverse Reactions (≥5%) within 7 Days of Administration of Flublok Quadrivalent or Comparator[1] in Adults 18-49 Years of Age, Study 1 (Reactogenicity Populations)[2,3]

	Flublok Quadrivalent Percentage (N=996)			Comparator Percentage (N=332)		
Reactogenicity Term	**Any Grade**	**Grade 3**	**Grade 4**	**Any Grade**	**Grade 3**	**Grade 4**
Subjects with ≥1 injection site reaction[3,4]	51	1	0	52	2	0
Local tenderness	48	1	0	47	1	0
Local Pain	37	1	0	36	1	0
Firmness / Swelling	5	0	0	3	0	0
Subjects with ≥1 systemic reaction[3,5]	34	2	<1	36	3	<1
Headache	20	1	0	21	2	<1
Fatigue	17	1	0	17	1	0
Muscle Pain	13	1	0	12	1	0
Joint Pain	10	1	0	10	1	0
Nausea	9	1	<1	9	1	0
Shivering / Chills	7	1	0	6	1	0

NOTE: Data based on the most severe response reported by subjects. [1]Comparator = U.S.-licensed comparator quadrivalent inactivated influenza vaccine (Fluarix Quadrivalent, manufactured by GlaxoSmithKline) [2]National Clinical Trials registry: NCT02290509. [3]Reactogenicity Populations: All randomized subjects who received study vaccine according to the treatment actually received and who had at least one non-missing data point for injection site, systemic or body temperature reactogenicity categories. Grading for local pain, tenderness and systemic reactions: 1=No interference with activities; 2=Prevented some activities, and headache may have required non-narcotic pain reliever; 3=Prevented most or all normal activities or required prescription medications; 4=Required visit to ER or hospitalization. Grading for injection site redness and firmness/swelling: 1=25-50 mm; 2=51-100 mm; 3=>100 mm; 4=necrosis or exfoliative dermatitis. [4]Injection site reactions: Flublok Quadrivalent n=996; Comparator n=332. [5]Systemic reactions: Flublok Quadrivalent n=994; Comparator n=332.

Through 6 months post-vaccination, no deaths were reported. SAEs were reported by 12 subjects, 10 (1%) Flublok Quadrivalent recipients and 2 (0.6%) Comparator recipients. No SAEs were considered related to study vaccine. In the 28 days following vaccination, one or more unsolicited treatment emergent adverse events occurred in 10.3% of Flublok Quadrivalent and 10.5% of Comparator recipients.

Study 2 included 8672 subjects 50 years of age and older for safety analysis, randomized to receive Flublok Quadrivalent (n=4328) or comparator inactivated influenza vaccine (n=4344). Table 2 summarizes the incidence of solicited local and systemic adverse reactions reported within seven days of vaccination with Flublok Quadrivalent or the comparator vaccine.

Table 2: Frequency of Solicited Local Injection Site Reactions and Systemic Adverse Reactions (≥5%) within 7 Days of Administration of Flublok Quadrivalent or Comparator[1] in Adults 50 Years of Age and Older, Study 2 (Reactogenicity Populations)[2,3]

	Flublok Quadrivalent Percentage (N=4312)			Comparator Percentage (N=4327)		
Reactogenicity Term	**Any Grade**	**Grade 3**	**Grade 4**	**Any Grade**	**Grade 3**	**Grade 4**
Subjects with ≥1 injection site reaction[3,4]	38	<1	<1	40	<1	<1
Local tenderness	34	<1	<1	37	<1	<1
Local Pain	19	<1	0	22	<1	<1
Subjects with ≥1 systemic reactogenicity event[3,5]	25	1	<1	26	1	<1
Headache	13	<1	<1	14	1	<1
Fatigue	12	<1	0	12	<1	<1
Muscle Pain	9	<1	<1	9	<1	<1
Joint Pain	8	<1	0	8	<1	<1
Nausea	5	<1	0	5	<1	<1
Shivering / Chills	5	<1	0	4	<1	<1

NOTE: Data based on the most severe response reported by subjects. [1]Comparator = U.S.-licensed comparator quadrivalent inactivated influenza vaccine (Fluarix Quadrivalent, manufactured by GlaxoSmithKline) [2]National Clinical Trials registry: NCT02285998. [3]Reactogenicity Populations: All randomized subjects who received study vaccine according to the treatment actually received and who had at least one non-missing data point for injection site, systemic or body temperature reactogenicity categories. Grading for local pain, tenderness, and systemic reactions: 1=No interference with activity; 2=Some interference with activity; 3=Prevents daily activity; 4=Required ER visit or hospitalization. [4]Injection site reactions: Flublok Quadrivalent n=4307; Comparator n=4319. [5]Systemic reactions: Flublok Quadrivalent n=4306, Comparator n=4318.

20 deaths occurred in the 6 months post-vaccination, including 8 Flublok Quadrivalent and 12 Comparator recipients. No deaths were considered related to study vaccine. SAEs were reported by 145 (3.4%) Flublok Quadrivalent recipients and 132 (3%) Comparator recipients. No SAEs were considered related to study vaccine. In the 28 days following vaccination, one or more unsolicited treatment emergent adverse events occurred in 13.9% of Flublok Quadrivalent and 14.1% of Comparator recipients.

Post-Marketing Experience

There is no post-marketing experience with Flublok Quadrivalent.

DRUG INTERACTIONS

Data evaluating the concomitant administration of Flublok Quadrivalent with other vaccines are not available.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy outcomes in women who have been exposed to Flublok Quadrivalent during pregnancy are being monitored. Sanofi Pasteur Inc. is maintaining a prospective pregnancy exposure registry to collect data on pregnancy outcomes and newborn health status following vaccination with Flublok Quadrivalent during pregnancy. There were no developmental studies of Flublok Quadrivalent formulation performed in animals. A developmental study of Flublok (trivalent formulation) has been performed in rats. This study revealed no evidence of harm to the fetus due to Flublok (trivalent formulation).

Lactation: It is not known whether Flublok Quadrivalent is excreted in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Flublok Quadrivalent and any potential adverse effects on the breastfed child from Flublok Quadrivalent or from the underlying maternal condition.

Pediatric Use: Safety and effectiveness of Flublok Quadrivalent have not been established in children 3 years to less than 18 years of age.

Geriatric Use: Data from an efficacy study (Study 2) are insufficient to determine whether elderly subjects respond differently from younger subjects.

PATIENT COUNSELING INFORMATION

- Inform the vaccine recipient of the potential benefits and risks of vaccination with Flublok Quadrivalent.
- Inform the vaccine recipient that Flublok Quadrivalent contains non-infectious proteins that cannot cause influenza.
- Inform the vaccine recipient that Flublok Quadrivalent stimulates the immune system to produce antibodies that help protect against the influenza viruses carrying the proteins contained in the vaccine, but does not prevent other respiratory infections.
- Instruct the vaccine recipient to report any adverse events to their healthcare provider and/or to the Vaccine Adverse Event Reporting System (VAERS).
- Provide the vaccine recipient with the Vaccine Information Statements which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to vaccination. These materials are available free of charge at the Centers for Disease Control (CDC) website (www.cdc.gov/vaccines).
- Encourage women who receive Flublok or Flublok Quadrivalent while pregnant to notify Sanofi Pasteur Inc., by calling 1-800-822-2463.
- Instruct the vaccine recipient that annual vaccination to prevent influenza is recommended.

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US license 1795.
Distributed by Sanofi Pasteur Inc.

MKT33220

Fluzone® High-Dose (Influenza Vaccine) Suspension for Intramuscular Injection

2018-2019 Formula

℞ only

Initial US Approval: 2009

BRIEF SUMMARY: Please consult package insert for full prescribing information.

INDICATIONS AND USAGE

Fluzone® High-Dose is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B virus contained in the vaccine. Fluzone High-Dose is approved for use in persons 65 years of age and older.

CONTRAINDICATIONS

A severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or to a previous dose of any influenza vaccine is a contraindication to administration of Fluzone High-Dose.

WARNINGS AND PRECAUTIONS

Guillain-Barré Syndrome

If Guillain-Barré syndrome (GBS) has occurred within 6 weeks following previous influenza vaccination, the decision to give Fluzone High-Dose should be based on careful consideration of the potential benefits and risks. The 1976 swine influenza vaccine was associated with an elevated risk of GBS. Evidence for a causal relation of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1 million persons vaccinated.[1,2]

Preventing and Managing Allergic Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Altered Immunocompetence

If Fluzone High-Dose is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the expected immune response may not be obtained.

Limitations of Vaccine Effectiveness

Vaccination with Fluzone High-Dose may not protect all recipients.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trial(s) of a vaccine cannot be directly compared to rates in the clinical trial(s) of another vaccine and may not reflect the rates observed in practice. Two clinical studies have evaluated the safety of Fluzone High-Dose. Study 1 (NCT00391053, see http://clinicaltrials.gov) was a multi-center, double-blind pre-licensure trial conducted in the US. In this study, adults 65 years of age and older were randomized to receive either Fluzone High-Dose or Fluzone (2006-2007 formulation). The study compared the safety and immunogenicity of Fluzone High-Dose to those of Fluzone. The safety analysis set included 2573 Fluzone High-Dose recipients and 1260 Fluzone recipients.

Table 1 summarizes solicited injection-site reactions and systemic adverse events reported within 7 days post-vaccination via diary cards. Onset was usually within the first 3 days after vaccination and a majority of the reactions resolved within 3 days. Solicited injection-site reactions and systemic adverse events were more frequent after vaccination with Fluzone High-Dose compared to Fluzone.

Table 1: Study 1[a]: Frequency of Solicited Injection-Site Reactions and Systemic Adverse Events Within 7 Days After Vaccination with Fluzone High-Dose or Fluzone, Adults 65 Years of Age and Older

	Fluzone High-Dose (N[b]=2569-2572) Percentage			Fluzone (N[b]=1258-1260) Percentage		
	Any	Moderate[c]	Severe[d]	Any	Moderate[c]	Severe[d]
Injection-Site Pain	35.6	3.7	0.3	24.3	1.7	0.2
Injection-Site Erythema	14.9	1.9	1.8	10.8	0.8	0.6
Injection-Site Swelling	8.9	1.6	1.5	5.8	1.3	0.6
Myalgia	21.4	4.2	1.6	18.3	3.2	0.2
Malaise	18.0	4.7	1.6	14.0	3.7	0.6
Headache	16.8	3.1	1.1	14.4	2.5	0.3
Fever[e] (≥99.5°F)	3.6	1.1	0.0	2.3	0.2	0.1

[a] NCT00391053

[b] N is the number of vaccinated participants with available data for the events listed

[c] Moderate - Injection-site pain: sufficiently discomforting to interfere with normal behavior or activities; Injection-site erythema and Injection-site swelling: ≥2.5 cm to <5 cm; Fever: >100.4°F to ≤102.2°F; Myalgia, Malaise, and Headache: interferes with daily activities

[d] Severe - Injection-site pain: incapacitating, unable to perform usual activities; Injection-site erythema and Injection-site swelling: ≥5 cm; Fever: >102.2°F; Myalgia, Malaise, and Headache: prevents daily activities

[e] Fever - The percentage of temperature measurements that were taken by oral route or not recorded were 97.9% and 2.1%, respectively, for Fluzone High-Dose; and 98.6% and 1.4%, respectively, for Fluzone

Within 6 months post-vaccination, 156 (6.1%) Fluzone High-Dose recipients and 93 (7.4%) Fluzone recipients experienced a serious adverse event (SAE). No deaths were reported within 28 days post-vaccination. A total of 23 deaths were reported during Days 29–180 post-vaccination: 16 (0.6%) among Fluzone High-Dose recipients and 7 (0.6%) among Fluzone recipients. The majority of these participants had a medical history of cardiac, hepatic, neoplastic, renal, and/or respiratory diseases. These data do not provide evidence for a causal relationship between deaths and vaccination with Fluzone High-Dose.

Study 2 (NCT01427309, see http://clinicaltrials.gov) was a multi-center, double-blind post-licensure efficacy trial conducted in the US and Canada over two influenza seasons. In this study, adults 65 years of age and older were randomized to receive either Fluzone High-Dose or Fluzone (2011-2012 and 2012-2013 formulations). The study compared the efficacy and safety of Fluzone High-Dose to those of Fluzone. The safety analysis set included 15,992 Fluzone High-Dose recipients and 15,991 Fluzone recipients.

Within the study surveillance period (approximately 6 to 8 months post-vaccination), 1323 (8.3%) Fluzone High-Dose recipients and 1442 (9.0%) Fluzone recipients experienced an SAE. Within 30 days post-vaccination, 204 (1.3%) Fluzone High-Dose recipients and 200 (1.3%) Fluzone recipients experienced an SAE. The majority of these participants had one or more chronic comorbid illnesses. A total of 167 deaths were reported within 6 to 8 months post-vaccination: 83 (0.5%) among Fluzone High-Dose recipients and 84 (0.5%) among Fluzone recipients. A total of 6 deaths were reported within 30 days post-vaccination: 6 (0.04%) among Fluzone High-Dose recipients and 0 (0%) among Fluzone recipients. These data do not provide evidence for a causal relationship between deaths and vaccination with Fluzone High-Dose.

Post-Marketing Experience

The following events have been spontaneously reported during the post-approval use of Fluzone or Fluzone High-Dose. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to Fluzone or Fluzone High-Dose.

Events Reported During Post-Approval Use of Fluzone.

- *Blood and Lymphatic System Disorders*: Thrombocytopenia, lymphadenopathy
- *Immune System Disorders*: Anaphylaxis, other allergic/hypersensitivity reactions (including urticaria, angioedema)
- *Eye Disorders*: Ocular hyperemia
- *Nervous System Disorders*: Guillain-Barré syndrome (GBS), convulsions, febrile convulsions, myelitis (including encephalomyelitis and transverse myelitis), facial palsy (Bell's palsy), optic neuritis/neuropathy, brachial neuritis, syncope (shortly after vaccination), dizziness, paresthesia
- *Vascular Disorders*: Vasculitis, vasodilatation/flushing
- *Respiratory, Thoracic and Mediastinal Disorders*: Dyspnea, pharyngitis, rhinitis, cough, wheezing, throat tightness
- *Skin and Subcutaneous Tissue Disorders*: Stevens-Johnson syndrome
- *General Disorders and Administration Site Conditions*: Pruritus, asthenia/fatigue, pain in extremities, chest pain
- *Gastrointestinal Disorders*: Vomiting

Other Events Reported During Post-Approval Use of Fluzone High-Dose.

- *Gastrointestinal Disorders*: Nausea, diarrhea
- *General Disorders and Administration Site Conditions*: Chills

DRUG INTERACTIONS

Data evaluating the concomitant administration of Fluzone High-Dose with other vaccines are not available.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C: Animal reproduction studies have not been conducted with Fluzone High-Dose. It is also not known whether Fluzone High-Dose can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Fluzone High-Dose should be given to a pregnant woman only if clearly needed.

Pediatric Use: Safety and effectiveness of Fluzone High-Dose in persons <65 years of age have not been established.

Geriatric Use: Safety, immunogenicity, and efficacy of Fluzone High-Dose have been evaluated in adults 65 years of age and older.

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2. Baxter R, et al. Lack of Association of Guillain-Barré Syndrome with Vaccinations. Clin Infect Dis 2013;57(2):197-204.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information).

- Inform the patient or caregiver that Fluzone High-Dose contains killed viruses and cannot cause influenza.
- Among persons aged 65 years and older, Fluzone High-Dose stimulates the immune system to produce antibodies that help protect against influenza.
- Among persons aged 65 years and older, Fluzone High-Dose offers better protection against influenza as compared to Fluzone.
- Annual influenza vaccination is recommended.
- Instruct vaccine recipients and caregivers to report adverse reactions to their healthcare provider and/or to Vaccine Adverse Event Reporting System (VAERS).

Manufactured by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA

Product information
as of June 2018.
Printed in USA

MKT33221

7228

NEXT-GENERATION HEALTHCARE

As the healthcare industry continues to shift from volume to value, providers are under mounting pressure to cut costs and deliver higher-quality care. This becomes even more challenging as the population ages, healthcare needs increase and the healthcare labor market gets tighter. In addition, knowledgeable consumers are driving demand for even more personalized care and a better patient experience.

To meet these demands, savvy healthcare organizations are rethinking their traditional processes, approaches and even design of their facilities. As new methods bring success, the healthcare industry will continue to evolve—with its future likely to look much different from its past. Here are some of the trends expected to change the face of healthcare in the near future.

Continued on page 38

GETTY IMAGES

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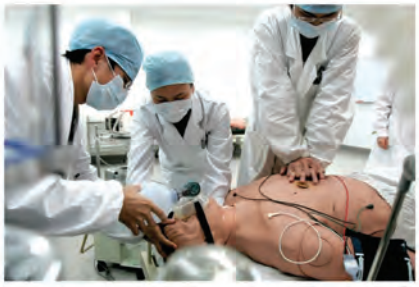

HealthTrust Contract #23280

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FACILITY AMENITIES

When Nashville-based TriStar Centennial Medical Center designed its newly opened Advanced Joint Replacement Institute, leaders were especially focused on making the "hospital within a hospital" a comfortable, calming environment for patients, families and staff. "Creating a space that feels or appears more like a hotel or spa, rather than a hospital, makes for a pleasant experience for all involved," says **Jeffrey Hodrick**, M.D., orthopedic surgeon at TriStar Centennial and HealthTrust Physician Advisor.

Jeffrey Hodrick, M.D.

The focus of providing a relaxing experience while ensuring more traditional creature comforts is becoming increasingly important in attracting and keeping patients. A 2010 study conducted at the University of California showed that hotel-like amenities, such as chef-prepared food and beautifully designed surroundings, can increase patient demand for a hospital's services by more than 38 percent, even more than clinical quality. And while bringing more patients in the door is critical for a hospital's bottom line, that's not the only result. Those modern amenities have also shown a correlation to improving patient outcomes.

For example, when one of two McGill University hospitals in Montreal, Canada, switched from shared rooms in its intensive care unit (ICU) to all private ICU rooms, the hospital's rate of bacterial infection decreased by more than 50 percent, according to the *Journal of the American Medical Association*. In addition, average patient lengths of stay in the ICU decreased by 10 percent.

A groundbreaking 1984 study by Roger Ulrich, a visiting professor at the Center for Healthcare Architecture at Chalmers University of Technology in Sweden, showed that postoperative patients with "tree views" experienced faster recovery times and needed less pain medicine than those with views of the walls. Over the years, as other studies have shown that proximity to nature or natural views can contribute to positive health outcomes, more healthcare facilities are incorporating gardens or windows with views of nature. Indoor atriums, rooftop gardens and even simulated outdoor views, such as replica window "views" of a scene in nature, are becoming increasingly common in hospital environments.

HSHS St. Mary's Hospital Medical Center in Green Bay, Wisconsin, has several gardens on site, including a 4,000-square-foot healing garden near the hospital's main lobby, a 20,000-square-foot rooftop garden, an infusion garden, a prayer garden and a vegetable garden.

"The impact of the gardens is immeasurable," says **Daniel Rocheleau**, campus and sustainability facilitator for HSHS Eastern Wisconsin Division. "Patients, family members, staff and even the general public use the gardens daily as a place of sanctuary to help them relax and reduce stress from illness or job-related functions."

In addition to their healing power, the gardens also enrich the hospital environment, replacing lost habitats for wildlife such as birds, rabbits and squirrels, reducing thermal heating from surrounding concrete areas, and absorbing rainwater to reduce the amount of runoff entering municipal stormwater facilities, Rocheleau adds. "Whether we look at gardens for their environmental effect or for personal health, they have a profound impact on our everyday lives."

> "The impact of the gardens is immeasurable. Patients, family members, staff and even the general public use the gardens daily as a place of sanctuary to help them relax and reduce stress from illness or job-related functions."
>
> **Daniel Rocheleau** | campus and sustainability facilitator | HSHS Eastern Wisconsin Division

VIRTUAL CARE OPTIONS

With a shortage of qualified healthcare professionals and a need to cut healthcare costs, the demand is growing for virtual care options. These options utilize technologies such as video, mobile apps, text messaging, sensors and social platforms to deliver health services, independent of time or location.

For instance, a number of hospitals are installing self-service kiosks, where patients can check themselves in, respond to intake

Continued on page 40

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Conversion Overview

More than **50** ORs

>50% SKU reduction across the health system

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Conversion Overview

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Conversion Overview

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[1]GHX Units, All Channels, Q1, 2018. Of surgical glove suppliers in the U.S. market, Cardinal Health has the greatest percentage of market share at 40% ($193.6M surgical glove units, annualized).

HealthTrust Contract #853

Continued from page 40

questions, and even pay their co-pays or bills. At HCA's Clear Lake Regional Medical Center in Webster, Texas, patients who visit the emergency room can check in with a self-service kiosk by scanning an ID or credit card, or entering their information manually. The kiosks have improved service by eliminating the paper check-in process for emergency room visitors, offering two language options, better managing information and accurately capturing patient arrival times.

Similarly, to reduce patient wait times and optimize electronic health record (EHR) data integration, Memorial Hermann Health System in Houston allows patients to check in online before arriving at any one of its six urgent care clinics. According to a recent article in *Internet Health Management*, when patients check in online, they can see how many people are currently in line ahead of them and select a specific time to be seen.

> "We included surgeons, nurses, anesthesia, environmental services and transport personnel in the discussion and design meetings. There was tremendous value in hearing their ideas and incorporating them into the finished product."
>
> **Jeffrey Hodrick**, M.D. | orthopedic surgeon | TriStar Centennial

HYBRID OPERATING ROOMS

Though minimally invasive surgery isn't new—its techniques have been in use since the 1990s—advancements in technology continue to result in a better patient experience and less hospital time. Patient outcomes have also been improved with technologies that enable smaller cuts, less pain and less trauma to the muscles, tissue and nerves. One of those technological advancements is the development of hybrid operating rooms, which combine surgery and imaging systems. Increasingly, these new facilities will help clinicians replace conventional, more traumatic surgery with minimally invasive surgery.

Though the new Advanced Joint Replacement Institute at TriStar Centennial Medical Center opened in 2018, its design process started about four years prior "with all the major stakeholders conceptualizing what a patient-focused joint replacement hospital could be," Hodrick says. "We included surgeons, nurses, anesthesia, environmental services and transport personnel in the discussion and design meetings. There was tremendous value in hearing their ideas and incorporating them into the finished product."

The new institute allows for the complete care of the patient, from arrival to recovery, to occur in one centralized location. "This improves the experience of not only the patient, but also of the caregivers," Hodrick adds. "The family waiting room serves as a quiet, comfortable environment while offering modern amenities such as a coffee bar and charging stations throughout the space."

In addition, the waiting room includes state-of-the-art patient tracking technology that functions similarly to a flight board at an airport. With this technology, patients' family members and loved ones are updated about where the patient is as he or she moves through the surgical process.

Each of the large operating rooms is fully equipped with the latest in X-ray and robotic equipment. The operating theaters also include windows, "which offer the advantage of natural light as well as spectacular views of the Nashville skyline," Hodrick says.

Professionals in the central sterilization department no longer work in the basement—they now work in a dedicated, windowed space right in the OR suite. And, the patient experience is improved with headphones as well as light dimming and soothing imagery that happen automatically as a patient enters the OR.

As healthcare moves into the future, Hodrick believes the industry will continue to see more technologies incorporated into the patient care space. "This could be in the form of robotics in the OR, or highly personalized patient experience amenities while on the hospital floor," he says.

But even as healthcare delivery models change and evolve, strengthening the relationship between the provider and the patient will always be the first priority, Hodrick says.

"We must find a way to keep that relationship at the center of the discussion while we strive to improve outcomes and efficiency of care," he adds. "Patient experience and satisfaction is a powerful driver of patient referrals. Our hope is that providing the absolute best patient-focused environment, while also offering the most experienced and talented joint surgeons, will lead to sustained success. I believe the administration at any hospital can see the value in that." **S**

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Dream Systems

Maximizing Collective Intelligence With Telepresence

Terriance Moody

"Videoconferencing on steroids." That's how Terriance Moody, CEO of Dream Systems, describes telepresence, a simulation technology that enables the next-generation of face-to-face video meetings. Moody's Nashville, Tennessee-based company uses robotics, multiple high-definition video screens, and precise audio and video technologies to help healthcare professionals quickly communicate their expertise across the country and around the world.

Dream System's telepresence technology simplifies collaboration between long-distance participants by creating the illusion that everyone in the videoconference is in the same room. The technology enables content to be shared across multiple displays and walls-sized canvases, with flexible screen configurations that aid in decision-making at meetings such as tumor review boards. With a screencast application, a participant's screen can be shared wirelessly with the entire group, and graphics and PDFs can be added to a workspace before and during the meeting to allow for presentations and documents to be viewed. To facilitate real-time collaboration, remote presenters can connect their laptop or iPad to a Dream System robot—called a "Double"—and project their faces on the robot's screen and maneuver it remotely.

"When some people hear the word robot, they think of a sci-fi device that's scary and hard to use—and one that takes the job of a real person," Moody remarks. "But artificial intelligence is not about eliminating the need for people. Our robots give physicians and clinicians the opportunity to provide more care. We help as a force multiplier; in other words, we help multiply physicians' capabilities, so that they can turn around and give additional time and better care to more patients."

Dream Systems' robots are particularly helpful for physicians who are traveling and specialists who need to communicate with patients in rural hospitals. Each robot can easily be driven in and out of meeting rooms and along hospital floors, helping physicians

make decisions and collaborate with other clinicians. By enabling health records and images to be viewed remotely and securely, the technology allows oncologists, radiologists and others to treat more patients in less time.

Dream Systems' technology can also be adapted to a hospital's surgical suite. Its surgical presence suites provide real-time, virtual, secure communication to and from specialists and administrators, no matter their location. A specialist in New York City can "scrub in" virtually to a procedure taking place in Denver.

Dream Systems was awarded a HealthTrust contract (**No. 23957)** after presenting its solutions at the 2017 HealthTrust Innovation Summit, an annual gathering of decision-makers who vet healthcare technology.

THE EVOLVING DREAM

Moody, who studied engineering and artificial intelligence in graduate school, began his career as a NASA researcher looking at how the international space station could collaborate with earth-based scientists using virtual technologies. He realized that these communication tools could be used to spread life-saving health information worldwide.

He began making those connections right around the time his wife, a Ph.D. in molecular biology, was researching Chagas disease, an illness caused by a parasite that can lead to severe digestive and cardiac problems and even sudden death.

"It affects 30 million people a year, particularly those in low-income areas with no healthcare access, yet it is 100 percent curable," Moody says. "Education is the key to prevention. The challenge for public health professionals was getting this vital information to the people who needed it."

Learning about Chagas disease lit a spark that inspired him to create Dream Systems in 1999.

The name's origin comes from Moody's dream to connect people—especially those in dire need—to the help, expertise and information they require. "Our solutions facilitate global communication, but more important, they can be used to help save lives."

TAILORING THE TECHNOLOGY

As his company has grown, Moody has traveled the globe studying healthcare systems and how telepresence technology could solve cost and personnel challenges.

"Every country's system has either a challenge with cost or capacity—either there's enough doctors but not enough money or enough money but not enough doctors," he explains. "Our solution could help countries experiencing a physician shortage by leveraging the expertise they do have."

Moody acknowledges that cultural adoption of these technologies is happening faster in consumer companies than in healthcare. "We want to help clinicians and patients by providing an easy user interface with simplified and beautiful design," he says.

Accordingly, Dream Systems trains hospital staff—virtually and in-person—on how to operate its robots and provides a back-office team to handle implementation, support and continuous remote monitoring. Its system can be customized to a client's specific goals, budget, space limitations and IT infrastructure specifications. **S**

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SUPPLIER DIVERSITY

HOW SMALL & DIVERSE COMPANIES IMPACT & IMPROVE COMMUNITIES

To celebrate its 35th year in business, O'Fallon, Missouri-based Phoenix Textile Corporation is pulling out all the stops. But in lieu of champagne toasts or team trips to an exotic location, President **Linda Haberstroh** had something else in mind—ramping up the company's commitment to community support.

Phoenix's employees have helped build and fund a Habitat for Humanity house; delivered meals to seniors through the Meals on Wheels program; and participated in a cycling challenge to raise money for cancer research at Siteman Cancer Center and Siteman Kids, benefitting St. Louis Children's Hospital.

Phoenix is also passionate about serving U.S. troops. Monthly, for 11+ years, the company has sent more than a million cookies and supplies to active-duty service members, and it recently funded an adaptive bike for a local veteran who sustained permanent combat injuries. Employees also pooled together their airline miles and donated them to Honor Flight Network, which provides military veterans a free trip to Washington, D.C. to visit their respective war memorials.

What is the benefit to this type of community involvement? It helps make teams stronger and more loyal: "We all spend so much time at work," Haberstroh says. "When people feel they can be passionate and support the community they care about—while they're doing their job—that only increases their commitment to their career and our shared mission at Phoenix."

Linda Haberstroh

Turnover at the 100-employee company is low: Average length of employment is more than 14 years, with nine of the 11 original employees still employed, or working there until their retirement.

Hospital and health system clients are also taking notice of the

Continued on page 46

GETTY IMAGES

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Continued from page 44

work Phoenix Textile Corporation is doing for the community. "Frequently, meetings we've had with new clients have included a discussion on community involvement," Haberstroh says. "It's been really encouraging and a welcome focus." The company's nationwide footprint allows the Phoenix team to participate in wider regional efforts—and occasionally creates friendly competition.

When customers see the charitable impact of buying from a small business that supports the community, it can create differentiation from a big brand that doesn't have the same local connections. And in the case of Phoenix Textile Corporation, a woman-owned business, such visibility can also help HealthTrust members meet their strategic goals for supplier diversity.

Joey Dickson

SUPPORT FOR DIVERSE SUPPLIERS

HealthTrust has long recognized the value of a diverse supply chain.

"Supplier diversity gives healthcare entities a way to show that they're supportive and representative of the communities in which they're located," says **Joey Dickson**, assistant vice president of supplier diversity. "It aligns with our members' missions, and it can also mean a lot to their bottom lines. Sometimes the best value they find is in relationships with diverse suppliers."

In late 2017, Linda Haberstroh hosted Eric Hargan, deputy secretary of the Department of Health and Human Services, at one of Phoenix's facilities.

> "When people feel they can be passionate and support the community they care about—while they're doing their job—that only increases their commitment to their career."
>
> **Linda Haberstroh** | president | Phoenix Textile Corporation

Due to limited resources, these diverse suppliers can sometimes have difficulty getting exposure to members. Small companies often focus resources on product development and customer service, not marketing.

Continued on page 48

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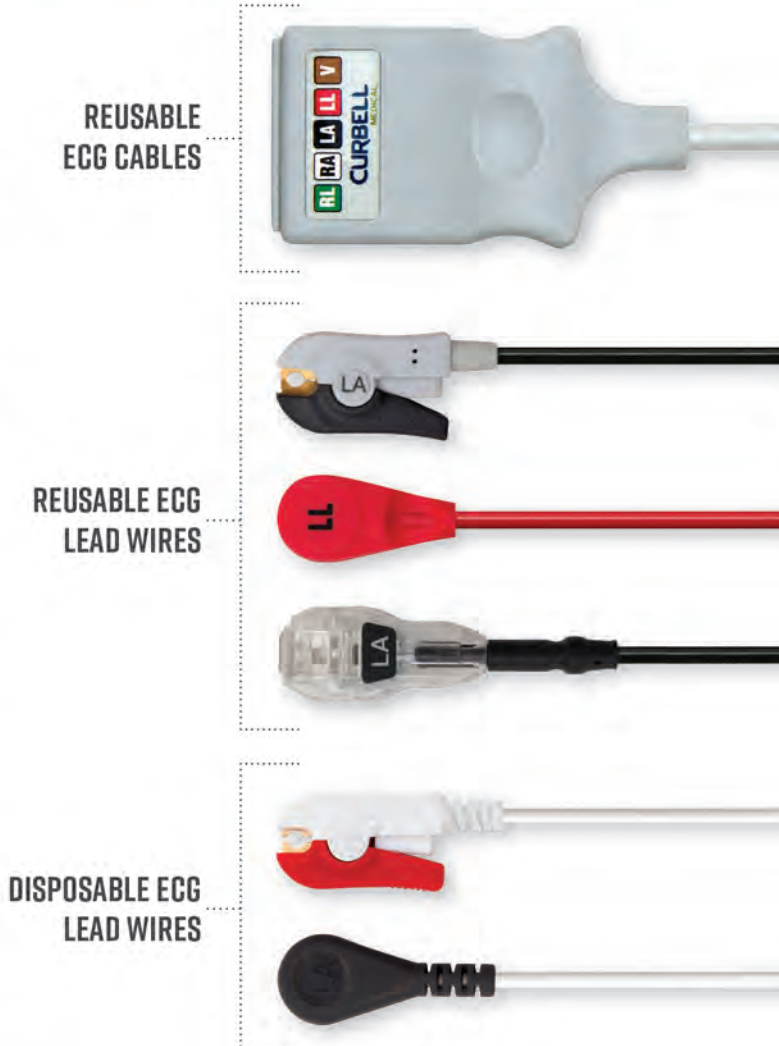

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(HealthTrust contract #23131)

CURBELL MEDICAL

Continued from page 46

In 1999, with the inception of HealthTrust, the Supplier Diversity Program was created to help level this playing field and connect minority-, woman-, service-disabled, veteran-owned small business enterprises (MWSDVEs) to HealthTrust members. Last year, 92 MWSDVEs held 168 contracts with HealthTrust, representing more than $294 million of annual contract spend.

Janet McCain

"All of our diverse suppliers go through the same rigorous vetting process as any other supplier," says **Janet McCain**, director of business diversity for HealthTrust. "There are no special considerations for them. However, we do help them through the system, providing advocacy, guidance and mentoring on the request for proposal (RFP) process, presentations to advisory boards and interactions with members."

> "While we are proud to be a diverse supplier, we are a viable supplier first and foremost."
>
> **Sam Kumar** | CEO | Myco Medical

EXCEEDING EXPECTATIONS

Though Myco Medical has been a HealthTrust contracted supplier in the surgical blades and sharps safety category since 2006, the company only became part of the Supplier Diversity Program after being certified as a minority-owned small business through the National Minority Supplier Development Council (NMSDC) in 2011.

"While we are proud to be a diverse supplier, we are a viable supplier first and foremost," says CEO **Sam Kumar**. "Because we're smaller, we have to perform at a higher level than our competitors. We have to ensure that our product not only meets expectations, but exceeds them."

Sam Kumar

Because of its experience, the Apex, North Carolina-based Myco Medical has served as an example to other diverse suppliers with products and services included in HealthTrust's portfolio. The company even received a Supplier Excellence Award at the 2018 HealthTrust University Conference, recognizing its product quality, on-time delivery, billing accuracy, customer service, and overall price and value.

"Traditionally, the HealthTrust Supplier Diversity Program has focused on developing strong relationships with our suppliers," Dickson says. "We're working on a greater awareness of the program across the membership as well as stronger alignment with our members' diversity objectives. With a better understanding of our members' diversity goals, we can pair them with contracted suppliers to help them achieve those goals."

Among its networking opportunities, HealthTrust hosts an annual supplier diversity symposium. Mostly informal, the event's objective is two-fold—help members forge one-on-one personal relationships with diverse suppliers and educate the suppliers about members' needs and their diversity goals.

Both Haberstroh and Kumar found the 2018 symposium valuable. It gave Haberstroh an opportunity to learn about HealthTrust's growth plans and talk to members about a lesser-known service line offered by her company.

"We are contracted with HealthTrust for more than just linens," she says. "I learned of several hospitals that had design projects in the works. As a result, we were able to actually submit proposals for healthcare design services," she says.

Kumar appreciated the one-on-one facetime with members. "Getting a few minutes with the right contact so I can deliver our elevator speech in a very conversational way is always useful," he says. "As an added bonus, several of our current customers were there, and they were more than happy to recommend us. That was very validating."

For small companies, every additional contract means a bigger impact for its employees and community.

"We're privately held, so we're not planning from quarter to quarter," Kumar says. "We're always looking at the long term. We want to build a sustainable company, but more important, a sustainable community. That means ensuring our employees are well taken care of and ensuring there's engagement and outreach not just to our local community, but also to communities everywhere.

"The perception that only big brands are able to make an impact is wrong," he continues. "Collectively, it's the smaller companies that are able to do so much more." **S**

Meeting Diversity Goals With Tier 2 Spend

You may be contracting with more diverse suppliers than you realize. That's because your suppliers have their own suppliers—and many of them might just be MWSDVEs.

"Oftentimes, members will have a contract with a non-diverse supplier, but that supplier sub-contracts with diverse suppliers," says **Joey Dickson**, assistant vice president of supplier diversity for HealthTrust.

He points to Northfield Medical, on contract for medical device repair and service, as one example. While Northfield Medical is not a diverse supplier, one of its major subcontractors, Altomec Endoscopy, is.

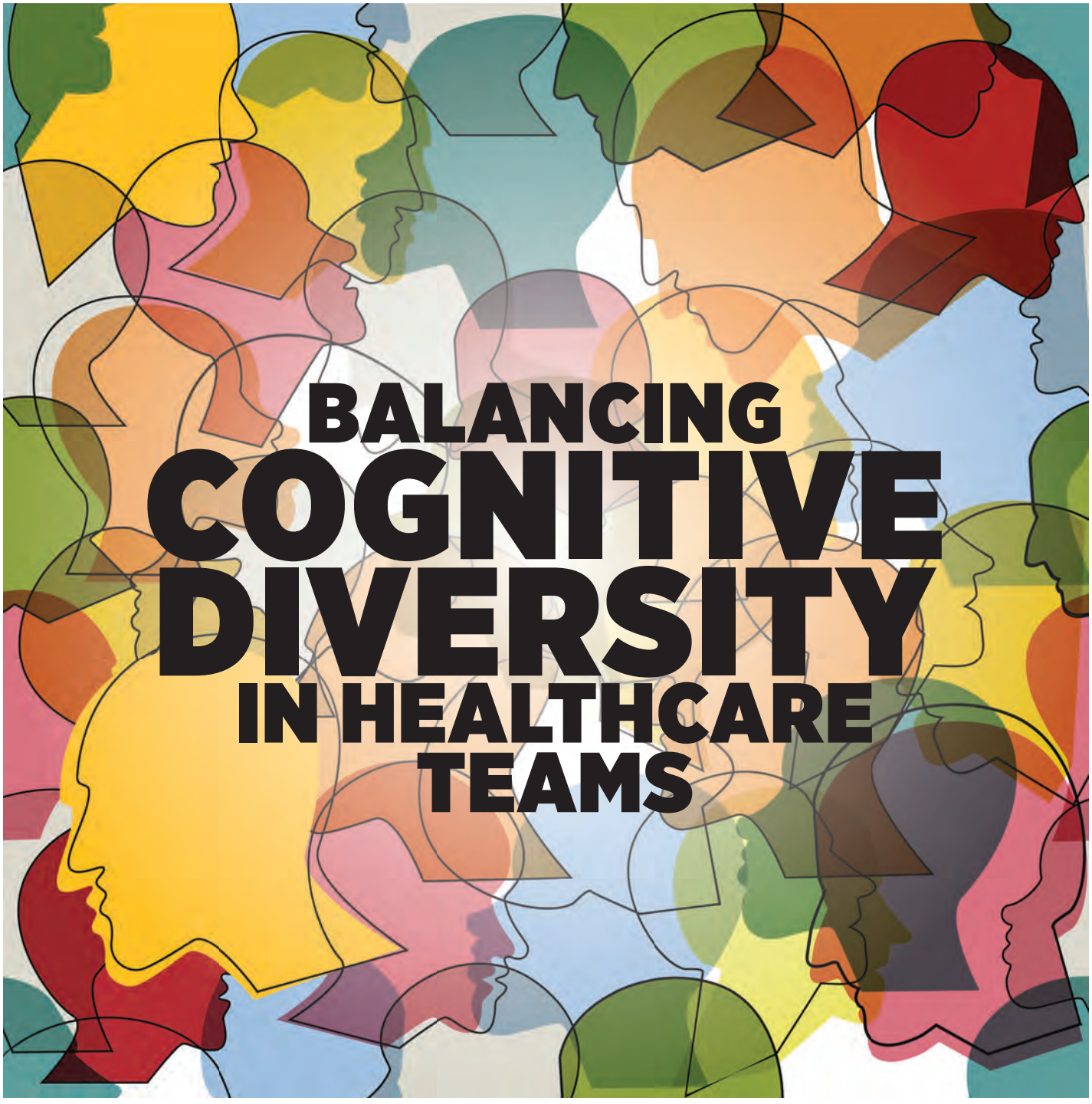
"Tier 2 spend represents a big opportunity in supplier diversity because smaller, diverse suppliers are often found further down the supply chain," Dickson says. "Boosting your diversity spend could be as simple as knowing about these tier 2 suppliers."

One of Dickson's objectives for 2019 is building the capability to recognize tier 2 spend in the supplier diversity program.

"Ultimately, we want to make sure members are aware of it so they can count it toward their supplier diversity goals," he says.

As HealthTrust develops solutions to better capture tier 2 spend, Dickson recommends that members ask suppliers for their diversity spend reports. Just like hospitals and health systems, major suppliers have their own diversity initiatives, so they're likely already tracking this information.

"When a member is able to support a diverse supplier—because it has the right product, at the right time, for a good price—and receive top-level service," he says, "it's a win-win both for the institution and the community."



BALANCING COGNITIVE DIVERSITY IN HEALTHCARE TEAMS

GETTY IMAGES

A nursing career can be full of joy and satisfaction—it's a chance to make a difference and positively impact people's lives—but its many responsibilities can also make the job demanding, fast-paced and stressful. While riding the various tides of change currently making waves across the healthcare industry, nurses also simultaneously face a learning curve when it comes to new devices, medications and technology.

Continued on page 52

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Continued from page 50

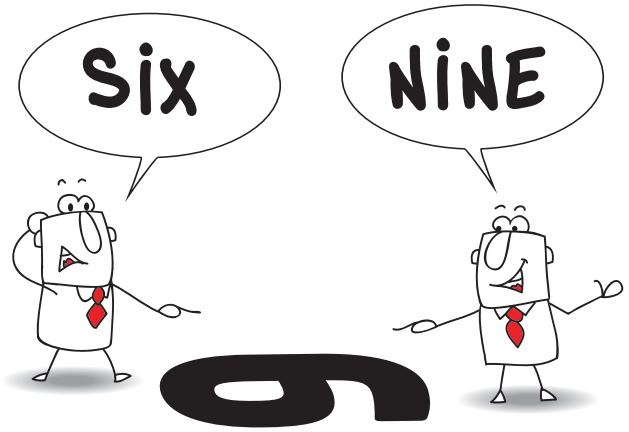
Though on-demand problem-solving and juggling an array of high-priority tasks is standard for nurses, a relatively new strategy is being utilized in healthcare organizations that could help build in more short- and long-term success for nursing teams: cognitive diversity.

A 2017 article from the *Harvard Business Review* defines cognitive, or functional, diversity as the "differences in perspective or information processing styles." Think of cognitive diversity as a step above diversity related to gender, age, ethnicity or religion. Invisible but present everywhere, cognitive diversity is squarely focused on how individuals think about and engage with situations that are uncertain, complex and new.

Angie Mitchell, RN, HealthTrust's assistant vice president of physician services, says that the topic of workplace diversity has historically been studied through physical traits such as age and gender. "While there's no question that those traditional diversity markers go into the makeup of who we are, cognitive diversity views it from a psychological perspective, including how you look at a situation, consider your past experiences and how you process them to reach a resolution," she says.

Angie Mitchell, RN

One example Mitchell uses when explaining cognitive diversity is to show a drawing of the number six lying on its side. (*See illustration.*) One man stands to the left of the number



> "Neither one is wrong.
>
> That's why I constantly remind people that just because somebody sees or does something differently doesn't necessarily mean it's wrong—it's just different."
>
> **Angie Mitchell**, RN | assistant vice president, physician services | HealthTrust

GETTY IMAGES

and another to the right. Because of their difference in perspective, the man on the left sees a six while the man on the right sees a nine.

"Neither one is wrong," Mitchell explains. "That's why I constantly remind people that just because somebody sees or does something differently doesn't necessarily mean it's wrong—it's just different."

As healthcare organizations and leaders focus on long-term strategies to build and sustain a workforce for the future, cognitive diversity could prove instrumental in successfully addressing the nation's nursing shortage and in managing nurses who span generations.

COMBATING THE NURSING SHORTAGE

Before she became chief nursing officer of HealthTrust Workforce Solutions, **Shaun McCamant**, MSN, RN, worked as a nurse at HCA for 18 years. Though managing 24,000+ nurses is different than her days working at the patient bedside, she clearly remembers the strain nurses face.

Shaun McCamant, MSN, RN

"Nurses can burn out fairly quickly because they have so much to do and give 100 percent every day. We're trying to ensure they know their voice is heard," McCamant says. "That's why we're looking at innovative ways not only to recruit nurses into the field, but also get them to stay with us as they continue to learn and grow."

Recruiting new nurses and retaining experienced nurses is a pain point for healthcare systems across the country. The issue will only worsen as baby boomers require more care in the coming years and nurses prematurely retire at rapid rates.

The United States currently has about 3 million registered nurses (RNs); the American Nurses Association estimates that the country will need to produce more than 1 million new RNs by 2022 to fulfill its healthcare needs. Because today's population of nurses over the age of 50 is growing and it is becoming more difficult to bring in new career nurses, the shortage of nurses is worsening. McCamant adds that it also costs about $40,000 every time a nurse leaves her job, not to mention the stress and burden it places on other staff members.

With such a high demand for nurses, hospital leadership that harnesses teamwork-building strategies through the lens of cognitive diversity could find new talent and keep the skilled nurses they already have.

How well a person thinks and reacts and how quickly they make decisions, particularly in stressful situations, is crucial to the field of nursing, McCamant explains. "We want to attract more people into this career, while also finding more ways to bring value to our nurses' shifts. If we can reinforce the positive, then it can remove a lot of their stress."

One way HealthTrust Workforce Solutions hopes to inspire lifelong nursing careers is through a cognitive and skill assessment called Prophecy. "After nurses are hired, this information offers insights into how individuals learn best and how they manage stress. It can also be used to better utilize their strengths and help them succeed," McCamant says.

McCamant and Mitchell agree that this cognitive diversity-inspired strategy can boost efficiency and job satisfaction, whether those nurses are recent graduates or have been working at patient bedsides over the past 40 years.

"We've got to find a way for team members to find meaning in their work," Mitchell says. "That's part of what leads to recruitment and retention successes in the field of nursing."

BETTER TOGETHER

Cognitive diversity can also produce better workplace outcomes. Different personalities manage problems uniquely, but 2018 research by Deloitte argues that it's a good thing since cognitive diversity can enhance innovation by 20 percent, reduce risk by 30 percent and ease implementation once decisions are made. Similarly, the same study contended that cognitive diversity, when balanced alongside identity diversity, could drive superior business outcomes.

GETTY IMAGES

As healthcare organizations and leaders focus on long-term strategies to build and sustain a workforce for the future, cognitive diversity could prove instrumental in successfully addressing the nation's nursing shortage and in managing nurses who span generations.

Mitchell says that establishing a shared language among nurse team members can enhance the performance of the entire team, and also avoid unnecessary role conflicts.

"Understanding how different nurses process or seek new knowledge and skills is a key factor in reaching a resolution that's efficient and effective," she says. "Usually individuals tend to side with other like-minded folks or default to the expertise of a supervisor. With cognitive diversity, nurses find a way, using their shared language, to quickly assess a situation, consider different suggestions or recommendations, and develop a solution or resolution from there."

A prime example of cognitive diversity in action came recently when HCA implemented a new charting system for nursing.

"Many of our nurses had muscle memory for how they would document this and that, so we had to go in and retrain their brains," McCamant explains. "And even though this was ultimately a positive change, it was still a challenge, so we were very purposeful in asking for nurses' input, emphasizing what was going to be different and what the rollout would look like."

After the charting platform upgrade, a team from HealthTrust Workforce Solutions went to nursing councils and teams to ask questions like: How did the process go? What could we have done better? How does this affect you?

"Nursing councils allow us to look at our nurses across the continuum, because each unit is its own individual family, and some units work best when they function differently than others," McCamant says. "Using the information will inform our future work and help us continue to perform better by taking their shared perspectives into account."

Applying cognitive diversity strategies has the potential to help a hospital stabilize both its current and future workforce, as healthcare systems struggle to deal with the nationwide nursing shortage and as nursing teams confront learning differences among nurses who span generations.

"At the end of the day, happy nurses inspire happy physicians and patients," McCamant says. "Teams that work well together create a community where people want to come to work with you, and that's a wonderful thing." **S**

TEAMWORK TOOLS

YOUR **Q4 GUIDE** TO ADVANCING ANTIMICROBIAL STEWARDSHIP, PROVIDING CARE & EDUCATION TO UNDERSERVED AREAS & IMPROVING WOMEN'S HEALTHCARE

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MEMBER SUCCESS STORY: Brentwood, Tennessee-based LifePoint Health is the recipient of the 2018 HealthTrust Innovation Grant. The $50,000 award, which includes cash and consulting services from HealthTrust experts, will help further the health system's efforts to develop and implement a reporting tool to simplify antimicrobial compliance and reporting requirements.

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MANAGEMENT MATTERS: At least half of the world lacks access to essential medical care, according to a 2017 report from the World Health Organization. HealthTrust members have heeded the call, partnering with global humanitarian organizations to donate equipment and supplies and deliver high-quality medical treatment to people in underserved areas.

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LEADERSHIP LINK: As chairman of obstetrics at Scranton, Pennsylvania's Moses Taylor Hospital, **Frank Kolucki**, M.D., has helped lead the facility in obtaining a coveted perinatal certification from The Joint Commission. This HealthTrust Physician Advisor talks to *The Source* about his goals for improving women's health and decreasing maternal morbidity and mortality.

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[1] Amsterdam EA et al. J Am Coll Cardiol 2014; 64:2645-2687 (NSTE-ACS)

[2] Levine GN et al. J Am Coll Cardiol 2011; 58:e44-e122 (PCI)

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METRICS THAT MATTER

LifePoint Health Receives 2018 HealthTrust Innovation Grant for Advances in Antimicrobial Stewardship

Just a year after starting a systemwide antimicrobial stewardship program, Brentwood, Tennessee-based LifePoint Health reported some significant achievements in promoting the appropriate use of antimicrobials at all of its facilities (numbering 72 at the time). In June 2016, when the enterprisewide initiative began, just five hospitals had signed letters of support from hospital administrators for antimicrobial stewardship. By June 2017, that number jumped to 67. In the same time period, antibiotic spend per adjusted patient day dropped from $6.75 to $6.34, which represents a $1.6 million (9.4 percent) savings to the organization.

Physician leaders were energized by the progress and ready to accelerate efforts at the hospital level, but they challenged system administrators to provide better, more meaningful data.

> "This project proved that antimicrobial stewardship belongs to the entire organization, not just to pharmacy."
>
> **Ken Gagnon**, PharmD | vice president, pharmacy services | LifePoint Health

The antimicrobial stewardship team is led by clinical leadership from LifePoint's Health Support Center, including **Ken Gagnon**, PharmD, vice president, pharmacy services; **John Theobald**, PharmD, group director, pharmacy services; and **Chris Frost**, M.D., national medical director. This team had already supplied a number of key metrics to hospitals, such as days of therapy and antibiotic spend per adjusted patient day, but those only provided a high-level picture of antimicrobial use.

"Our data was fairly rudimentary," Gagnon says. "It gave us an idea about antimicrobial consumption overall, but it wasn't detailed enough to give us the ability to impact care going forward."

At the same time, LifePoint Health was also looking for a less labor-intensive way to comply with the National Healthcare Safety Network's (NHSN's) antimicrobial usage and resistance (AUR) reporting program.

"Right now, reporting is voluntary," Theobald notes. "We're fairly certain that it's going to be mandatory in the next year or so. We're doing what we can to prepare for it and other eventual reporting requirements, such as those likely to come from the Centers for Medicare & Medicaid Services (CMS)."

In addition, LifePoint Health reports data for the Leapfrog Hospital Survey of which AUR reporting is included. The reporting tool could help ensure LifePoint meets upcoming requirements from the CMS—the NHSN's AUR reporting is one of the Additional Public Health Registry options for Meaningful Use 3.

Together, these needs led the antimicrobial stewardship team to develop and implement a related reporting tool that simplifies

Left to right: Ken Gagnon & John Theobald

SHERI O'NEAL

compliance with reporting requirements and provides facility leaders with the detailed data they need to encourage appropriate and cost-effective use of antimicrobials.

CURBING INFECTIONS & COSTS

Because of LifePoint's efforts, HealthTrust recognized the implementation team, representing eight distinct departments within the organization, as the recipient of its 2018 HealthTrust Innovation Grant. Valued at $50,000, the grant will help offset the cost of further developing the in-house tool and provide HealthTrust expertise to advance the organization's reporting capabilities.

"Misuse and overuse of antimicrobials is one of the world's most pressing public health problems," says **John J. Young**, M.D., chief medical officer of HealthTrust. "People infected with antimicrobial-resistant organisms are more likely to have longer, more expensive hospital stays, and may be more likely to die as a result of an infection. By tracking, reporting and taking action based on these data, LifePoint will help curb hospital-acquired infections and improve the cost, quality and outcomes associated with treating them."

Initially, the team considered an outsourced solution. But given LifePoint's unique needs, which included consolidating and normalizing data from nine disparate electronic health record (EHR) platforms, the cost was just too high—$700,000 plus an annual maintenance fee of $235,000—for a tool that could not deliver the full range of services that stakeholders sought.

Developing the in-house reporting capability presented a cost-savings opportunity, but success required an all-hands-on-deck approach that went beyond the team's initial expectation.

"That first meeting about the tool included just four or five people," Frost says. "By the next month, we had to move the weekly meetings into a bigger room. Every team member we added allowed us to further modify the tool to meet the demands of all of our stakeholders."

LifePoint service lines that played a role in the development and implementation of the reporting tool included supply chain operations; pharmacy services; health informatics and technology services; quality operations; enterprise data and program management services; physician services; nursing services; and diagnostic imaging services.

"This project proved that antimicrobial stewardship belongs to the entire organization, not just to pharmacy," Gagnon says. "Unlike other drugs, antibiotics have a transmissible loss of efficacy over time. Because of that, it really takes the entire organization to support this."

LIFEPOINT HEALTH'S ANTIMICROBIAL STEWARDSHIP PROJECT TEAM

(Above, left to right)

Ken Gagnon, *PharmD, vice president, pharmacy services*
Chris Frost, M.D., *national medical director, quality resources*
Allen Armstrong, *director, business intelligence*
John Theobald, *PharmD, group director, pharmacy services*
Sandi Hyde, *director, quality resources*
Alex Ladd, *manager, medication management informatics*
Greg Hostetler, *senior vice president of supply chain operations – executive sponsor (not pictured)*

REFINING THE REPORTING

While the team indicates the reporting tool can potentially be used for many metrics, including those outside of antimicrobial stewardship, it started where the need was greatest—days of therapy.

In May 2018, not even a year after the initial team meeting, the first detailed days of therapy report was generated. Using Power BI, a Microsoft platform, the tool automatically pulls data from EHRs on a weekly basis, giving hospitals as close to real-time reporting as possible on days of therapy, antimicrobial resistance, and the benchmarking and trending of operational, clinical and financial outcomes. The dashboard is interactive, allowing viewers to sort by a variety of metrics, including medication class, medication, disease state, prescriber and patient location, such as med/surg or ICU.

The reporting tool is currently available at 32 hospitals, all of which utilize two of the nine LifePoint EHR platforms. By the end of this year, the team expects the tool to be in place at 90 percent of its hospitals. For now, it's being used as needed, but Gagnon expects quarterly reports will be distributed once the tool has been implemented at more facilities.

> "That first meeting included just four or five people. By the next month, we had to move the weekly meetings into a bigger room. Every team member we added allowed us to further modify the tool to meet the demands of all of our stakeholders."
>
> **Chris Frost**, M.D. | national medical director | LifePoint Health

Gagnon adds, "We know each hospital has different needs, so the quarterly reports provide enterprisewide data to identify and drive change for the organization. We also plan to produce an annual report for all LifePoint facilities that provides more focused details around specific opportunities for appropriate antimicrobial use.

"For example," he continues, "one hospital might have a quinolone problem so we want to give an individual facility the

flexibility to drill down into what their pain points might be. In a standardized report, those might not be as visible."

The team also has plans to roll out additional reporting modules, including order set utilization, adherence to sepsis bundles and other clinical pathways targeting various infectious diseases like C. diff. Frost says these should help the organization pinpoint variations in care, which will provide an opportunity to enhance clinical care and identify potential cost savings.

"When you look across a healthcare organization of our size, you will see a fair amount of unintended clinical variation," he says. "There are circumstances where practicing outside traditional guidelines to meet the clinical needs of a specific patient is appropriate.

"However, a significant amount of the variation we see is not this type of intentional decision-making, " Frost says. "Instead, the variation is driven by non-adherence to evidence-based guidelines. Appropriate use of antimicrobials and the decision to de-escalate antimicrobials are two examples where this type of variation exists. In order to identify these opportunities, we need robust, detailed reporting. This type of reporting will help us improve clinical care and improve our overall efficiency."

Continuous improvement is a key part of any product lifecycle, and this reporting tool is no different.

"We know there's still work to be done," Gagnon notes. "As facilities use the tool, we have been able to make it even better. Within days of roll out, we got our first request to add month-to-month trending, since the tool previously only provided quarter-over-quarter and year-over-year trending."

The tool, in its current state, is only the beginning. The team has plans to share the capability—and the knowledge acquired—with other service lines, including ambulatory and emergency prescribing practices.

"We don't want this project to live in its own discrete silo," Gagnon says. "We often talk about a domino effect in a negative way. The work that has been done on this project has the potential to have a positive domino effect. The exciting part is yet to be seen."

As part of its innovation grant, the team plans to utilize the $25K of HealthTrust expertise to develop provider education, improve existing metrics and identify additional tracking possibilities. ●

Watch for details and deadlines on submitting applications for the 2019 Innovation Grant in the Q1 2019 issue of The Source.

Left: A mobile clinic in Belle Anse, Haiti
Above: A child in a Nepali village

IMPROVING THE WORLD'S HEALTH

HealthTrust Members Offer Aid & Education to Places Near & Far

Midwives in a Nepali village

At least half of the world's population lacks access to essential health services, according to a 2017 report from the World Health Organization (WHO) and the World Bank. In addition, many families around the world are pushed into extreme poverty because of tremendous health expenses, the report suggests. For healthcare providers who have dedicated their lives to caring for and improving the health and well-being of others, these realities spark a desire to deliver basic healthcare and humanitarian aid to developing countries. The following stories offer just a few examples of HealthTrust members who are devoted to the mission of helping people in underserved areas of the world.

HEALTH STARTS WITH EDUCATION

In Nepal, a South Asian country with a population of nearly 29 million, infant mortality continues to be a significant health challenge. Compared to neighboring countries such as India, Bangladesh and Sri Lanka, the infant mortality rate is high—46 deaths for every 1,000 live births. In the mountainous Himalayas, the number is even higher—73 deaths for every 1,000 live births, according to a 2017 study published in the journal *BMC Public Health*.

Billy McRae

It's statistics like these that drive **Billy McRae**, director of CHRISTUS Health's community clinics in Central Louisiana, to use his vacation time and serve on a medical missions team in the Himalayas.

McRae first traveled to Nepal in 2015 after an earthquake ravaged the capital city of Kathmandu, killing nearly 9,000 people and injuring almost 22,000. On that trip, his team directed their efforts toward disaster relief, helping to clean up wreckage and rebuild city structures. The following year, he returned to work with a medical team in a Himalayan mountain village.

"In the small village where we served in Nepal, they have a couple of midwives and women who are trained in the very basics of medicine," McRae says. "While we did see some patients and provide treatment, our goal was to offer training and medical education to help the midwives."

McRae and other medical professionals, including physicians from CHRISTUS Health, primarily helped educate midwives on postnatal care. "There are many cultural differences," he notes.

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Billy McRae and colleagues in Nepal in 2016. They're wearing hats called "Dhaka topi," given as a gift by locals.

"If a newborn or infant is sick and throwing up, they believe you should withhold fluids to prevent more sickness. So, babies would get a gastrointestinal virus or something similar, then get dehydrated from lack of fluids and die. We offered training on the importance of hydration and keeping newborns and infants warm and protected."

Billy McRae and team members hiking along the Karnali River

To reach the village, McRae and his team members flew into Kathmandu, then took two more flights to the city of Jumla. From there, they hiked eight hours up in the mountains before reaching their final destination, amounting to nearly three days of traveling. Necessary supplies—gauze, IV fluids, laceration trays, etc.—were carried in on their backs.

For the residents of this tiny village perched in the clouds, the expertise brought in by McRae's team is sorely needed, as are the supplies, which are donated by CHRISTUS Health.

"Every year, we come up with a list of supplies," McRae says. "Every time I have gone to our CEO, he has said, 'Yes, we'll get you everything you need.' "

MOBILIZING TO BRING CARE

For **Shelly Meyers**, RN, BSN, quality facilitator at HSHS St. John's Hospital in Springfield, Illinois, it was her daughter who got her involved with Haitian Christian Outreach, which has an office in Kokomo, Indiana, and does fieldwork and operates a clinic, hospital, schools and churches in cities and towns in southeast Haiti.

Shelly Meyers with Haitian children in Anse à Boeuf

"In 2011, my then-teenage daughter went on a one-week mission trip to Peredo, Haiti," Meyers says. "The following year, she was asked to return and work as a summer intern. I first became involved by supporting her."

In 2014, Meyers traveled to Peredo for the first time with a church group from Virginia. For a week, she helped the on-site clinic workers sort through donated medical supplies and expired medications. Subsequently, she was asked to

Continued on page 66

HOMETOWN MISSIONS

Participating in medical missions doesn't always mean traveling overseas. Sometimes, it means stepping into your own backyard. Earlier this year, volunteers from Surgery Partners' Specialty Surgical Center in Beverly Hills, California, partnered with Mending Kids International to spend a Saturday performing life-changing surgeries for children in the Greater Los Angeles area.

Mending Kids, a global leader in pediatric surgical care, works to attend to the healthcare needs, specifically surgical care, of children around the world—including in the United States. Mending Kids' U.S. Hometown Missions provide free surgeries to children from underserved communities, or those who have been denied coverage from the government and/or private insurance.

In July, 25 Surgery Partners employees, including five physicians, four anesthesiologists and four physician assistants, spent a day performing life-changing surgeries for 16 children. In addition to providing free surgical care, the volunteers performed pre- and postop diagnostic exams and helped Mending Kids recruit and screen patients.

Danny Bundren

"Our surgery center and our company embraced the idea that for one day we can be the safety net for children who need medical services," says **Danny Bundren**, vice president of Surgery Partners. "To see the faces of the children and the gratitude of their parents certainly made all of the planning, preparation and execution worthwhile."

Danny Bundren and volunteers from Surgery Partners and Mending Kids International gather around a patient on July 21, 2018, a day clinicians spent performing free surgeries for children in the Greater Los Angeles area.

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Continued from page 64

serve on a healthcare board for Haitian Christian Outreach, providing feedback and ideas on the construction, staffing and provision of care for Peredo Community Hospital. Those experiences eventually led to Meyers being asked to lead healthcare teams in Haiti.

In July 2018, Meyers led her first medical group to serve with Haitian Christian Outreach. "At first, I was skeptical about putting together a team and whether I was qualified to lead it," she explains. The organization helped by offering feedback on what direction they wanted to go with medical care, asking for emergency-trained physicians and obstetricians.

"In fall 2017, I started sending emails to fellow HSHS employees who fit those service areas, seeking participants," Meyers says. "The team really built itself from that point."

The team—made up of two physicians, several nurses, pre-med students, a couple of high school students and a prison security officer with no medical training—met monthly, before shifting to weekly meetings.

"Not only did we take care of logistical things like organizing passports, raising funds and making sure immunizations were completed, but we also did cultural training," Meyers shares. "We used learning programs and videos based on the book *When Helping Hurts: How to Alleviate Poverty Without Hurting the Poor and Yourself*. For those who had never been out of the country, we discussed what they were going to see, the conditions people lived in and what poverty actually means."

The HSHS St. John's Hospital team carried medical supplies, equipment and medications donated by the hospital and Hospital Sisters Mission Outreach.

Once in Haiti, Meyers' team conducted mobile clinics, traveling to remote areas of Haiti by bus and boat. Their first stop was in Jacmel, where they treated more than 185 people over the course of six hours. The next day, they traveled four hours by boat to Belle Anse, treating another 175 patients. Their last destination was Anse à Boeuf, a remote community accessible only by boat, where people live in huts made of sticks, palm fronds and tarps. There, they treated around 55 people.

According to UNICEF, there are only two doctors for every 10,000 Haitian patients, and 60 percent of Haitians lack access to basic healthcare. At Peredo Community Hospital, 17 medical professionals are working to overturn these statistics, and physicians saw almost 5,000 patients in 2017, Meyers says.

HSHS St. John's Hospital is doing its part to help, too. Though the trip isn't sanctioned by HSHS, volunteers carried medical supplies and equipment donated by Hospital Sisters Mission Outreach and medications donated by HSHS St. John's Hospital.

Catie Sheehan

"Hospital Sisters Mission Outreach cares for people in need through recovery and worldwide distribution of life-saving medical supplies and equipment," says **Catie Sheehan**, advocacy and communications vice president for Hospital Sisters Health System. "Donations from 73 hospital partners and select corporate partners are sorted and packaged for

Continued on page 68

Memorial Health of Savannah Embraces Hill-Rom Bed Donation Program

Much of the developing world lacks essential medical supplies—even something as seemingly simple as hospital beds. Patients often have to resort to lying on dirty floors or old ragged cots, explains **Lorie Way**, national accounts executive at Hill-Rom. In many cases, more than one patient has to fit on each cot, she says.

Matthew Hasbrouck

That's why Hill-Rom is working with HealthTrust members like Memorial Health of Savannah to donate their used hospital beds to medical facilities in third-world countries. Hill-Rom is partnering with MedShare, a nonprofit organization that takes surplus medical supplies and equipment from U.S. hospitals and redistributes them to hospitals in need in developing countries. MedShare determines where the needs are the greatest and helps to coordinate the donation process.

Shayne George

In February 2018, Nashville, Tennessee-based HCA Healthcare acquired Memorial Health, a 612-bed hospital in Savannah, Georgia. With this acquisition, HCA leadership identified capital investments that needed to be made throughout the facility—including the purchase of new beds.

"In the past seven months, we've identified 250 beds that need to be replaced in both the critical care and med/surg units," says **Matthew Hasbrouck**, COO of Memorial Health.

Not all 250 beds will be sent to the program—they must first go through a standard examination procedure with Hill-Rom to make sure they're of acceptable quality. So far, more than 90 beds have been donated by Memorial Health and sent via MedShare to developing countries in Africa. Overall, HealthTrust members have donated more than 500 beds as part of the recent Hill-Rom/Medshare donation drive.

"At HCA Healthcare, our mission statement is 'above all else, we are committed to the care and improvement of human life,' " says **Shayne George**, CEO of Memorial Health. "That doesn't just mean here in Savannah. With this project, we're able to help improve the quality of life for those in Africa. We're excited to do this. It makes us feel good to know these beds are going to find a home at facilities in need."

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5. Clinical Trial Data- Held on File

Continued from page 66

distribution around the globe. Founded by the Hospital Sisters of St. Francis in 2002, Mission Outreach has saved and redistributed 11 million pounds of surplus medical equipment and supplies valued at over $75 million that would have otherwise ended up in landfills."

"We took 550 pounds of medications and supplies to Haiti with us," Meyers adds, explaining that to save money on baggage fees, "every person on the trip packed lightly for themselves, then packed supplies and medications in their bags."

COLLABORATING WITH LOCAL PROVIDERS

Physicians and nurses from Centennial, Colorado-based Centura Health have been doing medical mission work as an organization since 2006. Today, Centura Health defines their global ministry as Global Health Initiatives, or GHI, says **Morre Dean**, FACHE, senior vice president and chief integration officer.

Morre Dean, FACHE

Centura Health collaborates with hospitals and local medical providers in Rwanda, Nepal, Peru and Tanzania to provide care. "We tailor our global trips around the needs of the local community," Dean says. "For example, in Rwanda, more than 400 children are born every year with club foot. We sent an orthopedic-focused surgical team to work with surgeons and doctors there."

Peruvian government officials, Centura Health executives and administrators from Clinica Adventista Ana Stahl hospital

The goal, Dean explains, is to help local providers sustain the work they're doing and improve the region's healthcare. "We want to collaborate with doctors and healthcare providers to make a long-term impact on the community's health," he says.

For instance, in Peru, Centura Health partners with the Clinica Adventista Ana Stahl hospital and the regional Ministry of Health to bring the evidence-based Helping Babies Breathe (HBB) training to the isolated Loreto region in the Amazon. The HBB training was developed by the WHO, American Academy of Pediatrics and other global health leaders to reduce deaths among babies in the first 28 days of life. Since Centura Health began the project in July 2015, the lives of 650 babies have been saved.

"With medical missions, we're not always taking care of a patient every day; we're building an infrastructure to support the community's health," Dean adds. ●

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1. Donelli A, Jansen JRC, Hoeksel B, et al. Performance of a real-time dicrotic notch detection and prediction algorithm in arrhythmic human aortic pressure signals. *J Clin Monit.* 2002;17(3-4):181-185. Study sponsored by Teleflex. Dr. Schreuder was formerly a paid consult of the study sponsor. Coauthors J. Bovelander and R. Hanania are current or former employees of the study sponsor.

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Q&A *With Dr. Frank Kolucki:*

A CHAMPION FOR WOMEN'S HEALTH

Frank Kolucki, M.D

Frank Kolucki, M.D., a board-certified obstetrician-gynecologist, has served health systems in northeastern Pennsylvania for more than two decades. At Scranton's Moses Taylor Hospital, now an affiliate of Community Health Systems (CHS), Kolucki serves as chairman of the department of obstetrics and helped establish the Women's and Children's service line. In 2015, he led a team that enabled the hospital to attain the coveted Joint Commission's Perinatal Certification.

Driven to reduce the staggeringly high rate of maternal morbidity and mortality in the United States, where pregnancy-related deaths have more than doubled since 1987, Kolucki is passionate about creating and communicating better protocols and practices to promote good health, identify and treat early warning signs of adverse pregnancy outcomes, and ensure patient safety.

What have been the results of your health system's focus on patient safety?

In 2006, Moses Taylor Hospital instituted what we called a culture of safety where patient safety supersedes all else. In our quest to make patient safety a priority, we looked at taking a team approach to caring for patients. We broke down departmental silos that were preventing good communication and collaboration. We also promoted continuing education, emphasizing that everyone should use their collective intellect to protect patients from harm.

From an obstetrics and gynecologic standpoint, we have positive patient outcomes. In July 2015, we were very proud to be the first hospital in the nation to be certified by the Joint Commission as a perinatal center. We were recertified in December 2017—one of only five in America at that time.

Describe some of your clinical and educational responsibilities.

I am the national physician advisor for the CHS obstetrics and pediatrics council. I also work as a clinical professor at two local institutions of higher learning, and I conduct webinars and conference presentations on issues such as quality, safety and decreasing maternal morbidity and mortality. Education has been an important part of my career, and now I'm working closely with HealthTrust on expanding member education related to women's health. I have a small sphere of influence in northeast Pennsylvania, but when I work with a national organization like CHS or HealthTrust, it is my great privilege to expand that influence and be able to help physicians and clinicians across the country.

HealthTrust recently decided to concentrate on women's health categories. Why is that significant?

The category represents a variety of products and implants used in gynecological and urogynecological procedures. HealthTrust was forward-thinking in focusing on this category because thousands of women across the United States (and the world for that matter) suffer from conditions such as stress urinary incontinence (SUI) or pelvic organ prolapse (POP).

POP occurs when the tissue and muscles of the pelvic floor no longer support the pelvic organs, resulting in the drop, or prolapse, of the pelvic organs from their normal position. SUI is the leakage of urine during moments of physical activity that increases abdominal pressure, such as coughing, sneezing, laughing or exercise.

A lot of women suffer from these lifestyle-altering conditions in silence, but there are operative and non-operative solutions available. HealthTrust is trying to help physicians make sound, evidence-based decisions about the right way to treat these individuals.

How are these conditions being managed and treated?

Better screening would help identify certain conditions before surgery is necessary. In August 2018, the Women's Preventive Services Initiative, working with the American College of Obstetricians and Gynecologists, issued new guidelines for the annual screening of women for urinary incontinence beginning in adolescence. The screening assesses urinary incontinence and how it affects their quality of life. Clinicians should refer these women to gynecologists for further evaluation and treatment, when appropriate.

If surgery is needed to repair POP or SUI, a graft is used to recreate the natural anatomic support. Graft materials include autologous, allograft, xenograft and synthetic. Synthetic surgical mesh has been used for many years. It was first used in the general surgical community for hernia repairs, and then later for urogynecological procedures, including the repair of POP and SUI. A positive aspect of synthetic mesh is that it lends itself to a more minimally invasive approach to the surgery.

However, mesh is not perfect. It can have an adverse effect on intimacy and it can lead to some adverse consequences, including mesh erosion, chronic pain and injury to adjacent structures like bowel, bladder and urethra. It can also result in a necessity for reoperation.

The big question is whether or not to select an autologous graft using the patient's own tissue versus a synthetic graft using surgical mesh. If you opt for mesh, you need to counsel the patient fervently and appropriately about it, then make the best decision you can regarding the type.

The physician community is not saying that synthetic mesh should never be used, but it needs to be used with an abundance of caution. The FDA has been clear in recent advisories on the safety and effectiveness of using surgical mesh implants for urogynecologic procedures. These statements acknowledge that such products are not without potential problems, and one has to closely examine the evidence and research to make a well-informed decision.

Continued on page 72

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What is HealthTrust's position on these products?

HealthTrust's role is to inform providers of what's available, the advantages and disadvantages of each option, and the clinical evidence to support it.

As with any new technology or device, new products need to be vetted extremely carefully before a provider decides to purchase or use them. Unless there is significant, reproducible clinical evidence that an item is safe and effective, it should be used cautiously.

What are some ways that HealthTrust assists physicians in their decision-making?

HealthTrust conducts timely reviews of all the current clinical evidence available and distills that information into an executive summary that can be used by HealthTrust physician advisors and clinical advisory boards to make sound decisions as to what is best for patients. If someone has a busy clinical practice, it can be an arduous task to go through all of the most recent studies. HealthTrust does a lot of that work for them and publishes it in a user-friendly format to aid them in their patient care. Clinical evidence reviews (CERs) are helpful because they may help physicians think about these products in new ways. For HealthTrust members in supply chain roles, the CERs can be helpful in discussing product choice with physicians at their health system or facility.

All of the information HealthTrust is distributing regarding women's health categories is incredibly important. But it's also important to remember that women's health is much more than gynecologic surgery issues. That's why the physician services team is focusing on women's healthcare as a whole—including products that decrease the risks associated with pregnancy and childbirth.

For example, we are renewing our focus on preventing a national tragedy—the high rate of maternal morbidity and mortality. The United States is currently ranked 60th of all developed nations in the rate of maternal death. It's a distressing problem, and it should not occur at this rate.

Unfortunately, many of these women are dying needlessly—approximately 40 to 50 percent of all those deaths are preventable. We have well-written guidelines to help prevent pregnancy-related deaths. For instance, robust protocols are available through the American College of Obstetricians and Gynecologists, yet some hospitals and providers don't use them regularly, often leading to tragic results.

What are some of the reasons for the high rate of maternal morbidity in the United States?

There are multiple environmental factors, but the first thing I try to reiterate is that we should never blame the patient—it's not her fault. Even if she's of an older maternal age, has high blood pressure or diabetes, or is obese, that's inconsequential as to how we will treat that patient. Yes, those conditions may make treating that patient a little more difficult and complex, but the onus is on the provider and care

team to out-think these obstacles and comorbidities. We should prepare for the complications that may occur and treat that patient appropriately, in an effective, highly reliable, evidence-based fashion. If you do that, most times you're going to have a positive outcome.

That's not to say that bad things aren't going to happen—people are going to get sick. But working together on the issues as a team is where you can make a difference. We want to improve women's health through education. Knowledge is power over disease.

I've been passionate about this issue throughout my career. And, I'm happy that it's getting attention in the lay press. With HealthTrust's outreach to so many different providers and institutions, such involvement can have far-reaching, positive consequences. I'm honored to be part of that effort.

Now that you have been a HealthTrust physician advisor for about two years, what are your next goals?

HealthTrust has engaged me to help educate members on ways to decrease these high maternal mortality rates. When it comes to addressing the tragic problem, we have to help stem the tide, turn the ship around and get the issue focused in a right direction for patients. To that end, I will be working with the physician services team at HealthTrust to develop a webinar series that emphasizes high reliability, quality and safety. Programs will also address the four most important targets for reducing maternal morbidity and mortality: decreasing postpartum hemorrhaging, venous thromboembolism and hypertensive emergencies in pregnant women. ●

Frank Kolucki, M.D., a board-certified obstetrician-gynecologist, is the chairman of the department of obstetrics at the Community Health Systems-affiliated (CHS) Moses Taylor Hospital in Scranton, Pennsylvania. He is a graduate of Boston College and the Georgetown University School of Medicine, where he also completed his OB/GYN residency. Kolucki began his practice at Physicians' Health Alliance, at the time an affiliate of the Moses Taylor Health Care System.

Kolucki serves as the national physician advisor of the CHS's Obstetrics/Pediatrics Council and as a HealthTrust physician advisor. He is an assistant clinical professor at Geisinger Commonwealth Medical College and a clinical professor in the physician's assistant program at Marywood University. Kolucki is a fellow in the American College of Obstetrics and Gynecology. He serves on the boards of directors of Moses Taylor Hospital, Physicians' Health Alliance and Pennsylvanians for Human Life. In 2017, he won the Community Service Award from Maternal and Family Health Services, a nonprofit organization that works to meet the health and nutrition needs of Northeastern Pennsylvania.

HEALTHTRUST ENGAGEMENT Means Cost Savings & Clinical Advances for Ardent Health Services' Pharmacy Group

Based in Nashville, Tennessee, Ardent Health Services operates 31 hospitals in seven states. While the hospital group has long partnered with HealthTrust to assist with managing its supply chain and supply expenses, leaders recognized a few years ago that the pharmacy also offered significant cost-savings opportunities.

Kara Fortune, PharmD, BCOP

In 2014, Ardent Health launched a number of new clinical and supply chain initiatives, including a pharmacy engagement with HealthTrust. The pharmacy partnership has decreased total pharmacy expense and increased total pharmacy revenue, saving the organization's facilities more than $7 million, says **Kara Fortune**, PharmD, BCOP, corporate system director of pharmacy services at Ardent Health Services.

"We started out looking for savings by managing expenses for pharmacy supplies," she says. "But as we examined every piece of the pharmacy role, we came to realize how much could really be done to cut costs and improve outcomes at the same time."

Clinical Initiatives

Many of the cost-savings initiatives Ardent Health's pharmacy group has undertaken have involved clinical changes based on data analytics and enhanced training. For instance, the system has increased its use of IV push antibiotics (the rapid injection of a one-time dose of intravenous medication) rather than administering antibiotics via IV piggyback, when possible.

With IV push antibiotics, there are fewer delayed doses, increased accuracy of doses, easier scheduling of multiple antibiotics and reduced time administering the medication, Fortune adds. This enables nurses to have more quality time with patients to discuss their antibiotics, treatment goals and possible side effects, which positively impacts the patient experience. Patients are no longer confined by the IV pole, yet they benefit from the same results at a lower price.

For example, a one-gram adult dose of Cefazolin, traditionally administered by an IV, costs hospitals about $4.32 for supplies, along with IV pumps and the labor services of a registered nurse, pharmacist and pharmacy tech. The same one-gram dose with IV push administration costs hospitals about $1.78 for supplies, along with a registered nurse.

In addition to boosting the use of IV push administration, Ardent Health's pharmacy group implemented a number of other clinical initiatives, including moving team members out of operational roles "to grow a robust clinical program," adds **Travis Lawler**, PharmD, director of pharmacy at BSA Health System in Amarillo, Texas, an affiliate of Ardent Health Services.

Travis Lawler, PharmD

To illustrate, BSA has hired five new clinical pharmacists in the past four years. It has also created a pain team that has seen a 50 percent reduction in postoperative opioid use among patients in an Enhanced Recovery After Surgery (ERAS) program, and an antimicrobial stewardship program that has achieved a 24 percent reduction in antimicrobial spend. Other accomplishments include an emergency room pharmacist initiative, a penicillin skin allergy testing program and a new PGY-1 pharmacy practice residency.

Additionally, the pharmacy initiatives have contributed to improved patient outcomes and increased patient satisfaction. Ardent's HCAHPS (the Hospital Consumer Assessment of Healthcare Providers and Systems) score in the "communicates about meds" category has risen after implementing an initiative to provide more extensive and specific medication education by pharmacists.

Operational & Distribution Improvements

Along with changes at the clinical level, Ardent Health has made extensive changes to its supply chain processes with HealthTrust's assistance.

"We embedded a pharmacist at the

Continued on page 76

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Continued from page 74

Drew Preslar

corporate level to identify opportunities and develop implementation tools for facilities, such as communication templates, clinical evidence and talking points," says **Drew Preslar**, assistant vice president of HealthTrust's inSight Advisory Services. "This was originally a part-time resource, but it was expanded to full to broaden the scope."

In addition, the HealthTrust team has helped Ardent with operational assessments and distribution conversions. The team is working to align Ardent Health facilities and the corporate pharmacy and therapeutics (P&T) committee to improve communication and execution. And HealthTrust has identified significant cost savings across a variety of these clinical and operational initiatives, Preslar says.

A new operational cornerstone is the installation of a perpetual inventory management system. Before implementing the system, Ardent facilities used a manual process, with staff spending a full weekend once a year to create a list of items in inventory.

"With a perpetual system, we know our inventory levels at any given time," Lawler says. "The system knows what's coming in because it automatically orders the supplies we need. When received items are scanned in, the system can also flag discrepancies between what was ordered and what was received."

The new system has allowed Ardent Health to reduce inventory by almost 50 percent and reduce pharmacy spend by 20 percent, Lawler says.

Though implementing the changes has been a team effort, Ardent Health leaders applaud the role their HealthTrust partners have played in these successes. "Without a doubt, the partnership is successful because of the people," Lawler says. "We consider the HealthTrust staff we work with—**Tom Chickerella** and Kara Fortune—our teammates. They are top-notch individuals, and we are fortunate to have their leadership."

From HealthTrust's perspective, a strong working relationship with Ardent Health leaders has been a powerful starting point for bottomline results. "We have a highly collaborative approach to our work with Ardent," Preslar adds. "We focus on engaging the right stakeholders at the corporate and facility level and also make the effort to spend one-on-one time with leaders and staff at the hospitals." ●

Note: Lawler and his team were recipients of HealthTrust's 2017 Gita Wasan Patel Pharmacy Excellence Award. Read more in the Q3 2017 edition of The Source *at www.healthtrustsource.com.*

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At HealthTrust, we use science supported by data. Others may claim big data. But they can't duplicate our experience and insight in guiding informed decision-making that supports improved care and lowered cost. Let us help you amplify your voice and turn data into action.

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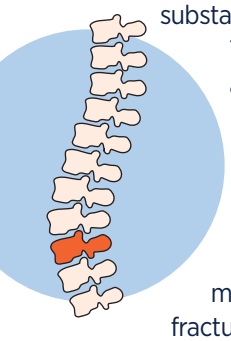
HEALTHTRUST®

Biologics of the ortho- and osteo- types are substances that promote healing in bones and bone-related disorders and help treat fractures, tendons and ligaments. HealthTrust refers to both substances categorically as osteobiologics.

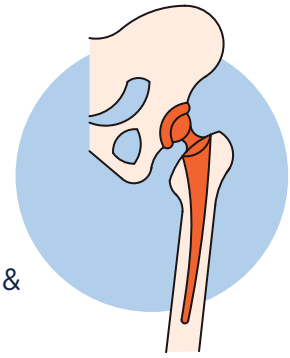


The list of osteobiologics is rapidly expanding as new products incorporating osteoconductive materials are mixed with a variety of osteoinductive proteins, demineralized bone and preparations of osteogenic cells. The growth in osteobiologics has been stimulated by the early success of osteoconductive materials as graft substitutes in the repair of fractures and by the increasing demand for grafts in all areas of orthopaedics.

The market for osetobiologics is also growing rapidly due to the aging baby boomer population and a general increase in the prevalence of orthopedic procedures.

Use of Osteobiologics in Common Procedures

- Spinal fusion surgery
- Hip preservation surgery
- Trauma surgery
- Reconstructive surgery
- Rotator cuff surgery
- Tendon repair
- Treatment of osteoporosis & related fractures



HealthTrust Annual Osteobiologics Member Spend

Allograft	$70,043,111	18.2%
Bone morphogenetic protein (BMP)	$116,971,314	30.4%
Cell-based allograft	$82,635,147	21.5%
Demineralized bone matrix (DBM)	$58,479,814	15.2%
Synthetic	$56,368,589	14.7%
GRAND TOTAL	**$384,497,974**	**100%**

Source: *HealthTrust inSight data, August 2017—July 2018*

GLOBAL CURRENT STATE

2017 Osteobiologics Revenue = **$5 BILLION GLOBALLY** (+3.1% versus 2016)

TOP 10 PLAYERS CONTROL 64% OF THE MARKET

10% OF THE ORTHOPEDIC MARKET'S OVERALL REVENUE IS OSTEOBIOLOGICS

MARKET GROWTH

2022 osteobiologics revenue expected to surpass **$5.9 BILLION GLOBALLY**

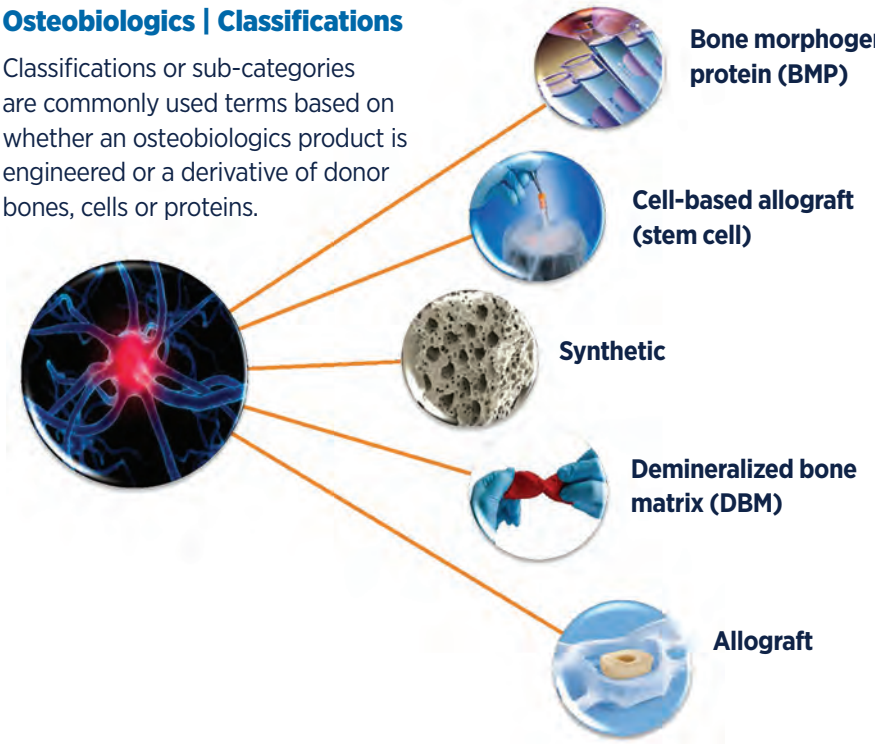
27 NUMBER OF COMPANIES WITH REGULATORY & PRODUCT LAUNCH ACTIVITY IN 2017

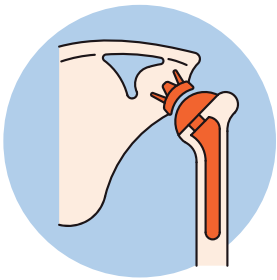
ROBUST CLINICAL DATA WILL CONTINUE TO BE REQUIRED FOR REGULATORY, PAYOR & HOSPITAL APPROVALS

COLLABORATIONS & PRODUCT ACQUISITIONS ARE EXPECTED TO CONTINUE

Osteobiologics | Classifications

Classifications or sub-categories are commonly used terms based on whether an osteobiologics product is engineered or a derivative of donor bones, cells or proteins.





HealthTrust's medical device management is a team composed of subject-matter experts who utilize a data-centric approach to help clients navigate their medical device service lines. Contact a member of the team at 615.344.3387 for more information.

Sources: *OrthoWorld, Inc. ©2018 annual report; National Center for Biotechnology Information; pubmed.gov; ncbi.nlm.nih.gov*

Battling Influenza

With Leading-edge Vaccines

Influenza is one of the world's most devastating vaccine-preventable diseases, which makes staying ahead of the disease with leading-edge immunology science even more crucial.

"Though it's hard to make projections on the upcoming flu season based on a prior season," explains **Dan DiVito**, senior director influenza vaccines for Sanofi Pasteur U.S., "we look closely at activity in the Southern Hemisphere because its winter season—and its flu—hits during our summer. Their activity is usually pretty predictive of ours. In countries such as Australia and South Africa, the influenza strains were less severe as the prior year, but that doesn't always predict exactly what will happen here."

By the end of the 2017 flu season, which usually starts in October and peaks between December and February, the Centers for Disease Control and Prevention (CDC) reported a vaccine effectiveness of about 40 percent.

"We'd like that number to be better, but it's typical," DiVito says. "The entire vaccine enterprise needs to get better at communicating how important intervention is. The flu can be so severe that a 40 percent effective vaccine can have tremendous public health impact."

According to the CDC, flu vaccination prevented an estimated 85,000 flu-related hospitalizations during the 2016–2017 flu season. A 2018 study indicated that from 2012–2015, flu vaccinations reduced the risk of adult flu-related ICU admissions by 82 percent.

Data has shown the adverse impact that influenza has on the management of chronic disease. According to the CDC, flu vaccination has been linked to lower rates of some cardiac events among people with heart disease. It has also has been shown to be associated with reduced hospitalizations among people with diabetes and chronic lung disease.

"To fully manage chronic conditions such as cardiovascular disease and diabetes you also have to keep influenza out of the picture," DiVito says.

An Evolving Science

Sanofi Pasteur manufactures Fluzone High-Dose and Flublok Quadrivalent, injectable vaccines made to protect against the flu viruses that are predicted as the most likely to cause illness for a particular flu season. Fluzone High-Dose vaccine contains four times the amount of antigen contained in regular flu shots, which offers better protection from influenza for adults age 65 and older. The Flublok Quadrivalent vaccine is the first vaccine proven to prevent more flu than the standard quadrivalent influenza vaccine for adults age 50 and older.

The manufacturing processes for vaccines can differ, potentially influencing efficacy of the products, DiVito explains. The most traditional way to make an influenza vaccine involves growing the virus first in some other medium, such as in a chicken egg or a mammal cell. With this process, the virus has to be changed in order for it to grow at the speed and scale needed to manufacture vaccines.

However, the recombinant manufacturing process, which is how Flublok Quadrivalent is made, is quite different. The virus does not have to be grown with the traditional process. Instead, the genetic code for the protein that's chosen for the vaccine is copied and mass-produced, making the vaccine an exact genetic match for the flu virus.

"The technology is exciting, but the positive clinical results are even more interesting," DiVito says. "In a 2017 study published in the *New England Journal of Medicine*, Flublok Quadrivalent provided 30 to 43 percent better protection against the influenza disease in adults 50 and older versus a standard quadrivalent flu vaccine."

Sanofi and other vaccine manufacturers, biotechnology companies and government organizations are working on what's classically called a universal vaccine, but more accurately called a "broadly protective" vaccine.

DiVito explains, "The term 'universal' makes people think it's a one-time shot for all flu viruses, but that may never come. But the idea of creating a vaccine that prevents more strains or lasts more than one season is probably within reach, and we are progressing toward that. It won't be next season or three seasons from now—we're talking in the more distant future. In the near-term, we're also focused on expanding use of the improved vaccines we already have."

Building Trust

Manufacturers are feeling pressure to deliver vaccines much earlier each year, with pharmacies, physicians and hospitals eager for them as soon as shipments can be delivered. "We have healthcare providers who want 100 percent of their flu vaccines on

Continued on page 82

Tracking the Future of EMR

Walmart's Move Toward Blockchain-enabled Medical Records

In August, Walmart was awarded a patent that may signal what the future holds for electronic medical records (EMRs). As Walmart wades into the healthcare business, the nation's largest private employer is exploring blockchain technology's application for medical records.

"Walmart was one of the first companies to manage behavioral data and consumer-related information, and use that data effectively," says **Ed Hickey**, AVP, clinical data and analytics at HealthTrust. "So while we don't know precisely where Walmart is headed in healthcare—there were reports earlier this year that they were looking to purchase Humana—we know that they are very serious about customer information, and how to unleash its power to improve the customer experience."

Ed Hickey

Blockchain technology stores transactional data through a distributed ledger composed of encrypted blocks. Records are visible to credentialed users, who may add to the transactions but not alter or delete them. Transactions are verified collectively and time-stamped, forming an immutable chain.

Walmart's patent for a blockchain-enabled medical records storage system allows first responders to access patient information in the event of an emergency.

With the patented system, patients' records would be stored on a blockchain database and on a wearable item, such as a bracelet, that could be scanned by a radio-frequency identification (RFID) scanner. In an emergency, first responders could scan the device and access an encrypted public key. A second private key would be a biometric identifier, like a retinal scan or fingerprint. After both keys were scanned, a patient's medical record could be securely accessed.

Walmart has already shown interest in blockchain for uses in its core retail business; now it joins other non-healthcare companies such as Apple, Microsoft and Google in developing blockchain-enabled solutions around medical records.

"Blockchain has the potential to solve the EMR problems experienced by patients, providers and payers—the siloed nature of information that makes it difficult to tie all of the details in the medical record together," Hickey says. "That one of the leading consumer-centered businesses sees its application for healthcare is interesting. There are plenty of issues to sort through before this patent tells us more than that, but it's worth paying attention." ●

Read The Source*'s Q3 2018 article on blockchain at https://healthtrustpg.com/healthcare-technology/blockchain.*

Survey Says ...

Annual HealthTrust Member Survey Results

Part of our commitment to members is asking for feedback as part of an annual satisfaction survey. The results, along with industry research, a competitive market assessment and discussions held during member business reviews, are part of our yearly planning process. We refine a five-year strategic plan that identifies market demand, informs our offerings and justifies new investments in support of member needs.

The 2018 survey was offered over the summer. Nearly 600 members responded to the survey with 84 percent indicating they "strongly agree" or "agree" that HealthTrust provides a superior value in the marketplace. We are proud to offer the industry's benchmark contract portfolio, and members once again underscored the value of a committed purchasing model as their primary reason for partnering with HealthTrust.

At 74, HealthTrust's Net Promoter Score (NPS) was the highest it's been to date. The NPS is a customer loyalty measurement, and ours has seen a steady improvement since the member satisfaction survey began in 2008.

Areas rated the highest were customer service, account management and the advisory boards. While we are pleased with the survey results overall, we know there is always room for improvement. HealthTrust will continue to invest in the areas of technology, contract category expansion, advisory board process improvements and implementation support. We will provide details of our progress via our business reviews with members held throughout the year. ●

Continued from page 81

August 5th. But when we look at the timing of the actual immunization, it's not getting much earlier—providers typically don't start immunizing until after Labor Day, peak in October, and probably won't finish immunizing until March. They want to have it in their refrigerator for seven months rather than it be in ours."

DiVito sees the decision to warehouse vaccines as evolving from shortages that occurred years ago. "That fear of having a patient show up for an immunization and it not being in the refrigerator drives providers to store a surplus of the product," he notes.

To build customers' trust, Sanofi Pasteur is inviting them to schedule shipments throughout the influenza season. "Healthcare organizations can order vaccines a week at a time so they don't have to worry about getting stuck with excess inventory," DiVito says. "Even if the product is on our shelves instead of theirs, the customer can trust that it will be there. This will allow providers to order it in a more rational fashion like they order other vaccines and products."

Although the stockpiling is unsettling, DiVito is more concerned about the slowdown of orders in November and December. "We see a dramatic tail off in immunizations around Thanksgiving, even though the typical peak of disease is in January and February," he says. "Nearly 200 million Americans go unvaccinated every year. There are additional months they could be vaccinated." ●

To learn more, visit www.cdc.gov/flu/about/qa/vaccineeffect.htm.

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INDICATIONS

The XIENCE Sierra stent system is indicated for improving coronary artery luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease due to *de novo* native coronary artery lesions (length ≤ 32 mm) with reference vessel diameters of ≥ 2.25 mm to ≤ 4.25 mm. In addition, the XIENCE Sierra stent system is indicated for treating *de novo* chronic total coronary occlusions.

CONTRAINDICATIONS

The XIENCE Sierra stent system is contraindicated for use in:

- Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or the post-procedural antiplatelet regimen.
- Patients with hypersensitivity or contraindication to everolimus or structurally related compounds, or known hypersensitivity to stent components (cobalt, chromium, nickel, tungsten, acrylic, fluoropolymers), or with contrast sensitivity.

WARNINGS

- It is not recommended to treat patients having a lesion that prevent complete inflation of an angioplasty balloon.
- Judicious patient selection is necessary because the use of this device carries the associated risk of stent thrombosis, vascular complications, and/or bleeding events.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

PRECAUTIONS

- Ensure that the inner package sterile barrier has not been opened or damaged prior to use.
- Stent implantation should only be performed by physicians who have received appropriate training.
- Stent placement should be performed at hospitals where emergency coronary artery bypass graft surgery (CABG) is accessible.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. Long-term outcomes following repeat dilatation of the stent are presently unknown.
- Care should be taken to control the guiding catheter tip during stent delivery, deployment and balloon withdrawal. Before withdrawing the stent delivery system, visually confirm complete balloon deflation by fluoroscopy to avoid guiding catheter movement into the vessel and subsequent arterial damage.
- When DES are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the SPIRIT family of trials.
- Compared to use within the specified Indications for Use, the use of DES in patients and lesions outside of the labeled indications may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death.
- Orally administered everolimus combined with cyclosporine is associated with increased serum cholesterol and triglycerides levels.
- A patient's exposure to drug and polymer is proportional to the number and total length of implanted stents. See Instructions for Use for current data on multiple stent implantation.
- Safety and effectiveness of the XIENCE Family of stents have not been established for subject populations with the following clinical settings:
  - Patients with prior brachytherapy of the target lesion or the use of brachytherapy for treated site restenosis, patients in whom mechanical atherectomy devices or laser angioplasty catheters are used in conjunction with XIENCE Family stents, women who are pregnant or lactating, men intending to father children, pediatric patients, unresolved vessel thrombus at the lesion site, coronary artery reference vessel diameters < 2.25 mm or > 4.25 mm or lesion length > 32 mm, lesions located in saphenous vein grafts, unprotected left main coronary artery, ostial lesions, lesions located at a bifurcation or previously stented lesions, diffuse disease or poor flow (TIMI < 1) distal to the identified lesions, excessive tortuosity proximal to or within the lesion, recent Acute Myocardial Infarction (AMI) or evidence of thrombus in target vessel, multivessel disease, and in-stent restenosis.
- Everolimus has been shown to reduce the clearance of some prescription medications when administered orally along with cyclosporine (CsA). Formal drug interaction studies have not been performed with the XIENCE Family of stents because of limited systemic exposure to everolimus eluted from the stent.
- Everolimus is an immunosuppressive agent. Consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.
- Oral everolimus use in renal transplant patients and advanced renal cell carcinoma patients was associated with increased serum cholesterol and triglycerides, which in some cases required treatment.
- Non-clinical testing has demonstrated that the XIENCE Sierra stent, in single and in overlapped configurations up to 71 mm in length, is MR Conditional. It can be scanned safely under the conditions in the Instructions for Use.
- The XIENCE Family of stents should be handled, placed, implanted, and removed according to the Instructions for Use.

POTENTIAL ADVERSE EVENTS

Adverse events (in alphabetical order) which may be associated with percutaneous coronary intervention treatment procedures and the use of a coronary stent in native coronary arteries include, but are not limited to, the following:

- Abrupt closure, hematoma, or hemorrhage, Acute myocardial infarction, Allergic reaction or hypersensitivity to latex, contrast agent, anesthesia, device materials (platinum, polymer, cobalt, chromium, nickel, tungsten, acrylic, fluoropolymers), and drug reactions to everolimus, anticoagulation, or antiplatelet drugs, Arterial rupture, Arteriovenous fistula, Arrhythmias, atrial and ventricular, Bleeding complications, which may require transfusion, Cardiac tamponade, Coronary artery spasm, Coronary or stent embolism, Coronary or stent thrombosis, Death, Dissection of the coronary artery, Fever, Hypotension and/or hypertension, Ischemia (myocardial), Myocardial infarction (MI), Nausea and vomiting, Palpitations, Peripheral ischemia, Pseudoaneurysm, Renal Failure, Restenosis, Shock/pulmonary edema, Stroke/cerebrovascular accident (CVA), Total occlusion of coronary artery, Unstable or stable angina pectoris, Vascular access complications which may require vessel repair, Vessel dissection

The risks described below include, but are not limited to, the anticipated adverse events relevant for the cardiac population referenced in the contraindications, warnings, and precautions sections of the everolimus labels.

- Abdominal pain; Anemia; Angioedema; Constipation; Cough; Diarrhea; Dyslipidemia (including hyperlipidemia and hypercholesterolemia); Dyspnea; Edema (peripheral); Headache; Hyperglycemia; Hypertension; Hypokalemia; Elevations of serum creatinine; Infections: bacterial, viral, fungal, and protozoan infections (may include opportunistic infections); Lymphoma and skin cancer; Male infertility; Oral ulcerations; Nausea; Non-infectious pneumonitis; Pain; Proteinuria; Pyrexia; Rash; Thrombotic microangiopathy (TMA)/Thrombotic thrombocytopenic purpura (TTP)/Hemolytic uremic syndrome (HUS); Urinary tract infection; Upper respiratory tract infection; Vomiting

Live vaccines should be avoided and close contact with those that have had live vaccines should be avoided. Fetal harm can occur when administered to a pregnant woman. There may be other potential adverse events that are unforeseen at this time.

Caution: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available), at *eifu.abbottvascular.com* or at *Manuals.sjm.com* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Photos on file at Abbott.

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1.800.227.9902

www.Vascular.Abbott

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RESOURCES:

Read the entire FDA letter issued in September:

www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/TubingandLuerMisconnections/default.htm

On-demand content from HealthTrust webinars:

http://education.healthtrustpg.com/calendar/reducing-risk-medical-device-tubing-misconnections

http://education.healthtrustpg.com/calendar/reducing-the-risk-of-medical-device-tubing-misconnections-update-on-enfit-enteral-connectors

A new HealthTrust webinar on this topic is in development and will be posted to the education website later in Q4. Visit **www.healthtrustpg.com/education** and search key words "tubing misconnections" for details.

The FDA's Next Step in the Device Misconnections Crusade

The Federal Drug Administration (FDA) continues its collaboration with standards organizations, federal partners, professional societies, patient advocacy groups, individual patients and other stakeholders on an important patient safety issue—reducing the chance of medical device misconnections. Such coaction aims for a result that ensures patient safety and facilitates the availability of products that work for various patient populations, uses and care environments.

Inspired by continued reports of misconnections with enteral devices, in September the FDA issued a letter to enteral feeding tube manufacturers and distributors, healthcare professionals and hospital purchasing departments recommending that hospitals and clinicians use enteral devices with connectors that meet the ISO (International Organization for Standardization) 80369-1 or ISO 80369-3 standard, or that are otherwise designed to reduce the risk of misconnections.

In the two-page letter published on the FDA website, the director of the office of device evaluation indicates that misconnections between enteral devices and other medical devices, such as tracheostomy tubes, have been associated with patient deaths and serious injuries. The FDA is also concerned that many misconnections are either severely underreported, fail to be reported at all or are misreported as medication errors.

For the first time since its 2009 involvement in an international effort to develop and implement standards for noninterchangeable connectors for small bore medical connectors, the FDA's recent document has strong recommendations for manufacturers, two of which include:

- Implement design changes to meet the ISO standards to reduce the likelihood of errors and provide safeguards for safe use of these devices and products.
- Implement an appropriate strategy that will lead to the eventual removal of legacy devices that have an increased risk for misconnection. ●

HealthTrust contracts with a number of suppliers who offer connectors in line with the ISO standards. Visit the contract catalog or contact your HealthTrust account director for additional guidance.

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See Important Safety Information referenced on Page 83.

INDICATIONS
The XIENCE Sierra stent system is indicated for improving coronary artery luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease due to *de novo* native coronary artery lesions (length ≤ 32 mm) with reference vessel diameters of ≥ 2.25 mm to ≤ 4.25 mm. In addition, the XIENCE Sierra stent system is indicated for treating *de novo* chronic total coronary occlusions.

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