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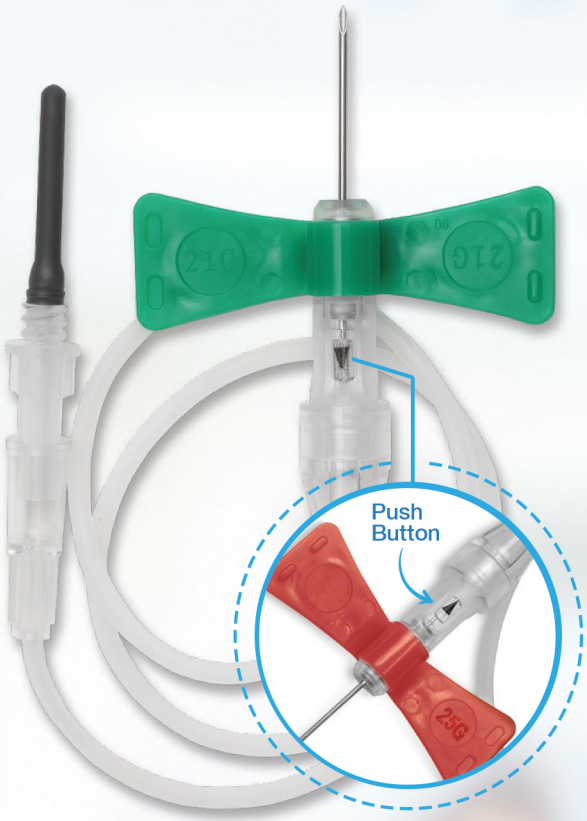

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Clinicians and staff within HealthTrust member facilities are invited to share their expertise as part of upcoming stories. Readers are also invited to suggest other experts for interviews or article ideas for publication consideration. Preference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

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

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

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HealthTrust Performance Group (HealthTrust) is a healthcare performance improvement organization owned and operated by health systems and dedicated to strengthening provider performance and clinical excellence through an aligned membership model and advisory solutions that leverage expertise, scale and innovation. Headquartered in Nashville, Tennessee, HealthTrust serves approximately 1,900 hospitals and health systems in the U.S. and the United Kingdom, and more than 90,000 non-acute sites of care, including ambulatory surgery centers, physician practices, long-term care and alternate care sites. HealthTrust has been recognized as a Top Workplace in Middle Tennessee for four consecutive years.

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Partnerships Generate Powerful Platforms

Members of HealthTrust are given an opportunity to provide feedback through the annual Member Satisfaction Survey. Results are compiled and reviewed with the broader team as leaders prioritize initiatives for the coming year and evolve our services to meet member needs. (See article on page 42.) One area on which we are proud to focus in the coming months is our partnerships with two respected industry suppliers to deliver powerful platforms for the benefit of our membership.

Crimson AI powered by HealthTrust

In partnership with Optum, we are proud to launch Crimson AI Powered by HealthTrust—an analytics platform that was created by hospital operators and informed by real-world healthcare environments (see page 28).

With a focus on reducing uncertainty around supply, pricing and operational variability, Crimson AI translates HealthTrust data into focused insights that help leaders anticipate risk, identify trends and act earlier—before issues become disruptions.

This analytics capability is now part of the HealthTrust model—integrated into the relationship and built to strengthen the value members already receive. It will also integrate with Signal—HealthTrust's AI-enabled intelligence platform—providing clear insights across a provider's clinical, financial and operational data. We will feature more on Signal in the Q2 edition.

Enabling data-driven decisions

GHX, a long-time supplier with HealthTrust, recently partnered with us to co-develop a unified data asset. It serves as the foundation for three new solution packages available exclusively to our membership on the GHX platform: Foundations, Foundations Plus and Operations Excellence.

Designed to address persistent industry challenges such as labor shortages, cost pressures and fragmented decision-making, these offerings help providers streamline procurement, reduce manual work and enable smart data-driven decisions. This includes:

- Foundations automates ordering validated against current GPO and local contracts, minimizing price discrepancies and exception handling.
- Foundations Plus adds a guided e-commerce portal to steer buyers toward on-contract items and introduces a mobile app for near real-time reconciliation of products used at the point of care, accelerating requisition and payment.
- Operations Excellence integrates advanced value analysis tools that help clinical, financial and supply chain teams evaluate product performance, manage category spend and align purchasing decisions with care outcomes.

Crimson AI, powered by HealthTrust
helps members:

- Gain earlier visibility into supply & pricing trends
- Reduce variability that creates downstream operational strain
- Support planning & standardization efforts with evidence
- Align sourcing decisions with real operational needs

Beyond these unique market offerings, HealthTrust and GHX are jointly advancing industry data transparency—supporting suppliers and providers to drive early visibility into supply disruptions, eliminate pricing discrepancies and align on clean item data to secure unprecedented transaction automation. We look forward to empowering your decision-making with these insightful tools. As always, we thank you for your trust in us. ●

Ed Jones
President/CEO
HealthTrust Performance Group
Publisher, *The Source* magazine

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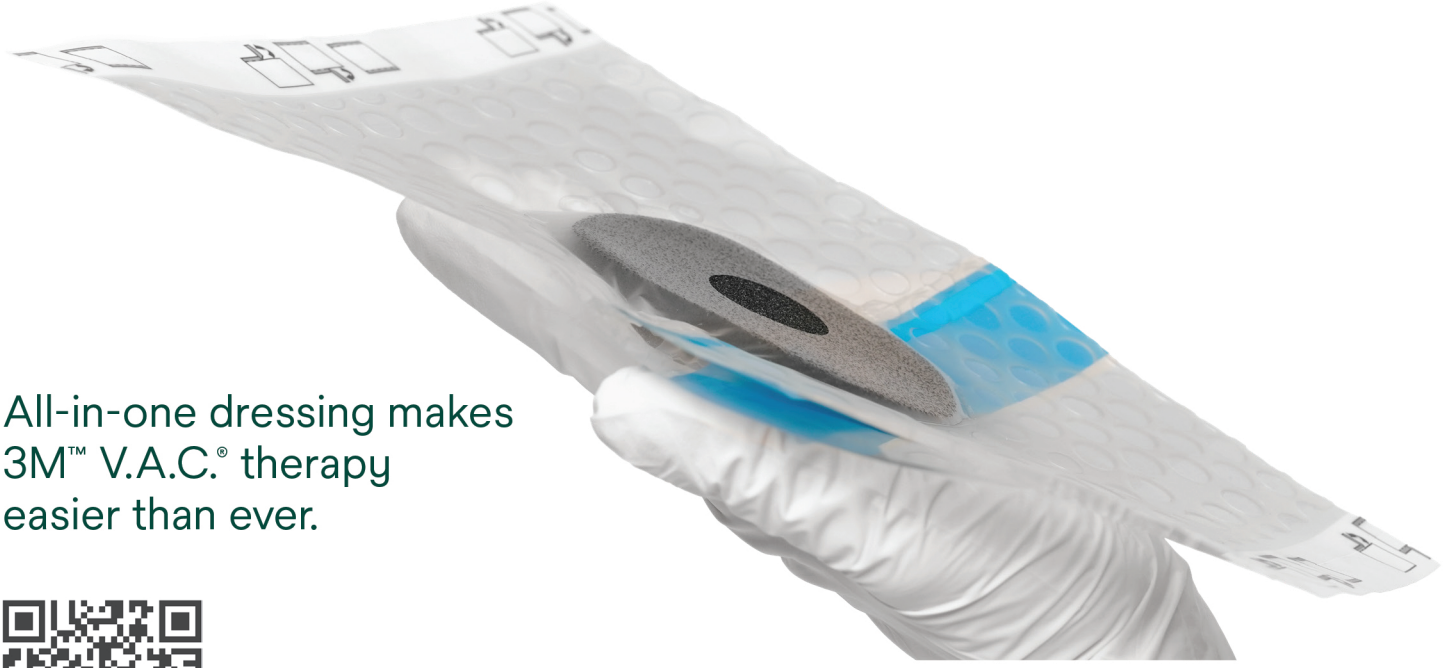

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1 SAT-BSER-05-869347 VAC Peel and Place (Ganymede) BSER.

2 In a simulated use test with 12 nurse and surgeon users. Average time of 01:48. SAT-MTF-05-995965 Marketing study for 3M V.A.C. Peel and Place dressing.

* Compared to 3M traditional NPWT foam dressing.

3 Source: Allen D, Robinson T, Schmidt M, Kieswetter K. Preclinical assessment of novel longer-duration wear negative pressure wound therapy dressing in a porcine model. Wound Rep Reg. 2023;31:349-359. Information contained within conducted animal studies has not been evaluated by the U.S. Food & Drug Administration.

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Facing Unavoidable Challenges Head On

Aashish Shah, M.D., J.D.
Senior Vice President &
Chief Medical Officer
HealthTrust Performance Group

While the phrase "The only easy day was yesterday" is a motto attributed to U.S. Navy SEAL teams, it certainly has applicability to healthcare and other industries. In essence it means: Challenges are constant and ongoing; as you overcome one set of difficulties you can expect that the next day may bring new (and often tougher) obstacles. This philosophy is meant to instill a mindset that one must never stop pushing his/her limits and striving to grow.

In much the same way, hospital decision-makers are faced with a dual-faceted imperative—achieving cost efficiencies while ensuring patient safety and quality outcomes. Even though the path may not be easy, I encourage providers to face these and other performance improvement challenges head on.

Physicians want to be part of the solution

Many physicians recognize the importance of understanding the cost of care, with a significant majority agreeing they have a responsibility to control costs and reduce unnecessary utilization. In a recent survey, 63% of physicians reported that they consider the cost of care "all" or "most of the time" when making treatment choices. However, 72% express uncertainty about the costs associated with the treatments they provide.

Standardizing on PPI

Engaging physicians is fundamental to managing supply costs. Their firsthand knowledge of clinical needs enables effective standardization of physician preference items (PPIs) that balances quality and cost.

However, PPI standardization efforts often encounter barriers from both administrators and physicians. Hospitals may consider the standardization process controversial, citing provider skepticism, competing demands for physicians' time or fear of alienating a referral source. For their part, physicians sometimes resist with concerns related to individual autonomy, choice and patient care.

Optimizing clinical supply spend is essential

Despite the challenges, health systems can no longer afford to avoid addressing physician preference head on. The impact of PPIs alone on a hospital's expenses, revenue and margins can be considerable:

- 5% to 15% potential savings from a health system's external spend baseline after identifying and implementing spend optimization opportunities. This is in addition to the savings gained from simply negotiating prices.
- PPI typically represents just 3% of purchase orders; however, it accounts for 20% of a health system's total supply chain spend.

80%+
U.S. physicians believe they can reduce supply cost without affecting quality.

Despite a willingness to participate in optimizing PPI spend, nearly the same percentage of physicians said they currently engage with supply chain fewer than one or two times per quarter.

~McKinsey survey

Overcoming irrational fears

It's long been understood that physicians have disproportionate influence over the cost of care through their ordering decisions. But their professional culture also aspires to protect quality of care despite downward pressures on cost. I believe we are afraid to use evidence-based strategies and strong clinical financial decision-making to address PPI based upon an irrational fear of losing a physician's loyalty.

In my experience working with physicians and hospitals routinely on this issue, the pushback isn't really from the physicians; most often it is reticence on the part of hospital leadership. Securing buy-in from hospital leadership is essential to prioritize and successfully achieve PPI standardization.

Continued on page 43

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Award Type	Sole	Sole
Description	Single-Dose Vial	Multiple-Dose Vial
Strength	10 mg per mL	5 mg per mL
Concentration	10 mg / 1 mL	10 mg / 2 mL
Fill Volume	1 mL	2 mL
Vial Closure	13 mm	13 mm
Unit of Sale	10 Vials	10 Vials
Barcode	3 65145 15110 0	3 65145 11910 0

The container closure is not made with natural rubber latex

Please see full prescribing information, including boxed warning, for PROCHLORPERAZINE EDISYLATE Injection, USP.

Wholesale Item Numbers	Phytonadione Injectable Emulsion, USP	Prochlorperazine Edisylate Injection, USP
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Building the Modern Pharmacy Workforce

Hospitals are expanding pharmacists' roles, improving infusion center viability & strengthening shortage preparedness

Aigner George

Derek Szesny

Jennifer Higdon

Pharmacy managers face growing pressures to expand services while trying to balance patient care with financial sustainability. During a presentation at HTU, **Aigner George**, PharmD, HealthTrust's Assistant Vice President, Performance Solutions, moderated a discussion with pharmacy executives about those pressures as well as potential solutions.

Preparing for the future

Spurred by the American Society of Health-System Pharmacists' (ASHP) Practice Advancement Initiative, pharmacy leaders are working toward setting the profession up to meet current and future practice and payment model demands. ASHP's recommendations are not groundbreaking. For example, creating continuing professional development plans and leveraging or expanding scope of practice. However, as panelists agreed, some of it is hard to do.

To meet the goal of advancing pharmacy roles in all practice settings, ScionHealth, which has specialty and community hospitals and senior living communities across 28 states, created collaborative practice agreements and instituted inpatient patient protocols at its long-term acute care and community hospitals, says **Derek Szesny**, PharmD, MPH, BCGP, Vice President of Pharmacy & Clinical Supply Utilization at ScionHealth.

For example, they've instituted a drug regimen review quality measure, which is applied to patients moving to

a post-acute care facility. That review doesn't necessarily need to be done by a pharmacist, Szesny says, however, "We took that as an opportunity to position our pharmacists where they are needed most and to ensure they have the right training. We provided a pharmacist with specialties in geriatric medicine and microbial stewardship to execute in that space."

ScionHealth has also encouraged pharmacist participation and appropriate certification to support their oncology clinics across a spectrum, from managing oncology therapies to catheter management and patency. "Our team has been focusing on how to resource those hospitals with the right tools and knowledge to execute on those problems as opposed to driving a lot down from the system level," Szesny says.

At Beacon Health System, which serves parts of Indiana and Michigan, they've advanced the role of pharmacy through an integrated care model, says **Jeanne Anderson**, PharmD, MBA, BCPS, Executive Director of Pharmacy Services at Beacon. At ambulatory and anticoagulation clinics, they've embedded pharmacists and support personnel to help guide oncology and rheumatology patients. "From the point that the provider decides they're going to prescribe a medication, the pharmacist is available to do the teaching," she says. "There is a liaison who helps with financial counseling and the prior authorization process. In most cases, we're able to make sure those patients receive their medications more quickly than if they were to try and navigate the system on their own."

Additionally, as a system, Beacon employs two disease management pharmacists to work with its own employees, who are part of its self-insured health plan. Employees can work with them on chronic disease management at no cost to the employees, Anderson says. "We're seeing decreased utilization of the acute care services and better patient outcomes as a result."

Optimizing site of care strategy for infusion centers

With increasingly more health systems expanding into infusion centers, the pharmacy profession "wants to make sure that they're doing things right in this space," says **Jennifer Higdon**, PharmD, MBA, MS, then HealthTrust Assistant Vice President, Pharmacy Operations; now Vice President, Pharmacy Services, Ardent Health.

Part of "doing things right" for Beacon Health System, a 340B participant, is understanding that their strategy must be site-specific, says Anderson. "Anybody who works in this space knows critical access and rural referrals are subject to orphan drug exclusion, and that's going to include a lot of your infusions," she says. Given that, when they're looking at site-specific strategies, they evaluate the product needed by the patient, determine if it's only a reference product and if there's an opportunity to shift to one of their disproportionate-share hospitals without logistically or financially disadvantaging the patient. They then investigate whether the product has a biosimilar, which might have pricing closer to what's available through the 340B program.

> **"From the point that the provider decides they're going to prescribe a medication, the pharmacist is there to do the teaching."**
>
> **Jeanne Anderson**, PharmD, MBA, BCPS

Beacon has also pulled their patient zip codes and mapped them to their centers, contacting patients to see if they'd be open to going elsewhere. "Really, it goes back to staying viable and taking it to the next level," Anderson says.

Meeting the drug shortage challenge

Facility pharmacy managers face pressure to make sure they have what they need when it's needed, given rising demand for certain drugs, the difficulty of obtaining critical ingredients or supply chain disruptions like those caused by the COVID pandemic or extreme weather events. The most useful strategy Anderson, Higdon and Szesny have in their toolkits, they agree, is communication.

Other recommended strategies include leveraging technology to create real-time dashboards accessible at all sites, looping in business office managers in order to streamline product movement, staying in contact with partners in the field and putting in place and sharing resources that help and encourage forward thinking in order to anticipate potential supply disruption.

"It takes partnership across the entire organization, with supply chain and clinical leaders coming together, to develop the tools to ensure they are supporting one another," says Higdon.

Key questions pharmacy leaders should ask

- Are pharmacists working at the top of their license?
- Are we leveraging collaborative practice agreements?
- Do infusion sites align financially with patient access?

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Beyond the Laundry Room

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Targeted strategies, from reject bags to AI-powered tracking, are reducing loss & improving infection control

Often viewed as simply an operational need, laundry and linen is a major driver of costs and can impact a healthcare facility's quality scores and reimbursement. With the help of the HealthTrust team, facilities can implement strategies and tap into resources that significantly improve quality and reduce costs systemwide.

Not just clean sheets

To prevent infection and keep patients and staff safe, healthcare facilities must meet specific state and federal laundry and linen regulations. "There's a lot that goes into ensuring everyone's kept safe and that patient needs are met, from both an infection prevention and a patient satisfaction standpoint," says **Tara Roth**, MSN, RN CENP, HealthTrust's Director of Nursing Services, Clinical Operations.

From an infection prevention perspective, those regulations cover everything from rewash rates and water temperature to microbial colony counts and chemical concentrations. Working with laundry partners certified by the Healthcare Laundry Accreditation Council or the Textile Rental Services Association helps ensure providers understand regulatory standards and have the facilities, equipment and processes to meet them.

The HealthTrust team can help members identify and vet potential laundry service providers or provide guidance on what to look for, such as accreditation, facility standards and contamination prevention processes, says **Trevor Rotondo**, Director, Purchased Services Strategic Sourcing at HealthTrust.

The team also ensures stakeholders, environmental services, nursing and infection control, are involved in the contracting process

"There's a lot that goes into ensuring everyone's kept safe & that patient needs are met..."

Tara Roth, MSN, RN CENP

Continued on page 12

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TRINITY STERILE

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Linen right-sizing formula

Clean linen per patient day = historical usage + safety buffer.

Checklist:

- Linen Committee
- Reject Bags
- Soiled Bag Protocol
- Software Tracking
- Standardized Closet Par Levels

"You're saving on labor hours & somebody's actually tracking it for you, so that's something you don't have to worry about."

Trevor Rotondo

so everything from sheet specifications to infection protection protocols are addressed early. "That's a beneficial service with a premium price tag," Rotondo says, "but you're saving labor hours by not sending an EVS person to do the job, and someone is tracking it for you."

Using custom strategies to right-size linens

Bobby Self

Besides advising about contracted suppliers, the HealthTrust team supports members' cost and infection control goals by working with them to create custom strategies, says **Bobby Self**, HealthTrust's Director of EVS, Support Services.

Linen processing is often a system's second largest spend category after labor, Self explains. With infection protection top of mind, the HealthTrust team analyzes members' usage and processes and looks for places where efficiencies can benefit both costs and safety.

"For example, the team began working with a large hospital system earlier this year with a savings goal of $800,000. The system is trending to save more than $1.7 million," Self says.

To achieve these results, Self and the HealthTrust team came up with a number of tactics that the hospital system implemented. They started by examining the system's historical data to determine exactly how much clean linen should be in patient rooms.

"Units, historically, have too much linen," he notes. When excess clean linen is placed in a patient room, unused items are often discarded as soiled when the patient is discharged. Once the team determined a precise amount of linen per patient day, they created a new metric that would allow for easy tracking of the changes they were making. To help the hospital system meet the recommended amount of clean linen per patient day, the team proposed these specific tactics:

1. **Establish a linen committee.** The committee should consist of someone from hospital administration, a clinical member, such as the chief nursing officer, someone from the infection prevention team and the EVS director. Including administration, clinical leadership, infection prevention and EVS helps align expectations with actual patient needs and shift long-standing assumptions, Self says.
2. **Use linen management software.** Besides keeping track of stock, linen management software can be tailored to the health system's management goals, so that staff using the software won't have to do any calculations. It can also record and track historical volume to more easily understand fluctuations, eliminating the need to have staff manually count stock. This in turn reduces physical handling and limits contamination risks.
3. **Adopt reject and soiled linen bags.** Laundry service providers don't want to deal with torn and worn textiles, which can cause issues with equipment and are hard to effectively clean because they can harbor microorganisms, and facilities don't want bedding with holes in it because shoddy bedding can negatively affect patient satisfaction scores. With these things in mind, train hospital staff to examine bedding when making up beds, and put torn and worn bedding into "reject" bags. Likewise, train housekeeping staff to carry a "soiled" bag on their carts in addition to trash, with the goal of all soiled linens going into the soiled bag instead of accidentally

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Optimal Outcomes

Continued from page 12

going into the trash, which cuts down on loss, Self adds, and the hazards of soiled linens going into the waste stream.

Looking ahead, Self says the HealthTrust team is exploring additional strategies to enhance efficiency and strengthen infection prevention efforts. One approach involves establishing par levels for each linen type that align with patient-volume demands in the centrally located clean linen storage rooms. Historically, these rooms contained an excessive number of storage racks, which led to chronic overstocking and made effective management difficult.

Another tactic is to work with developers of linen management software to take advantage of artificial intelligence. "Leveraging AI in the future is going to be huge," Self says, with the expectation that it will make some real improvements in the laundry and linen space. As these technologies mature, AI could transform linen operations from a reactive necessity into a strategic advantage.

Rawpixel via Getty Images

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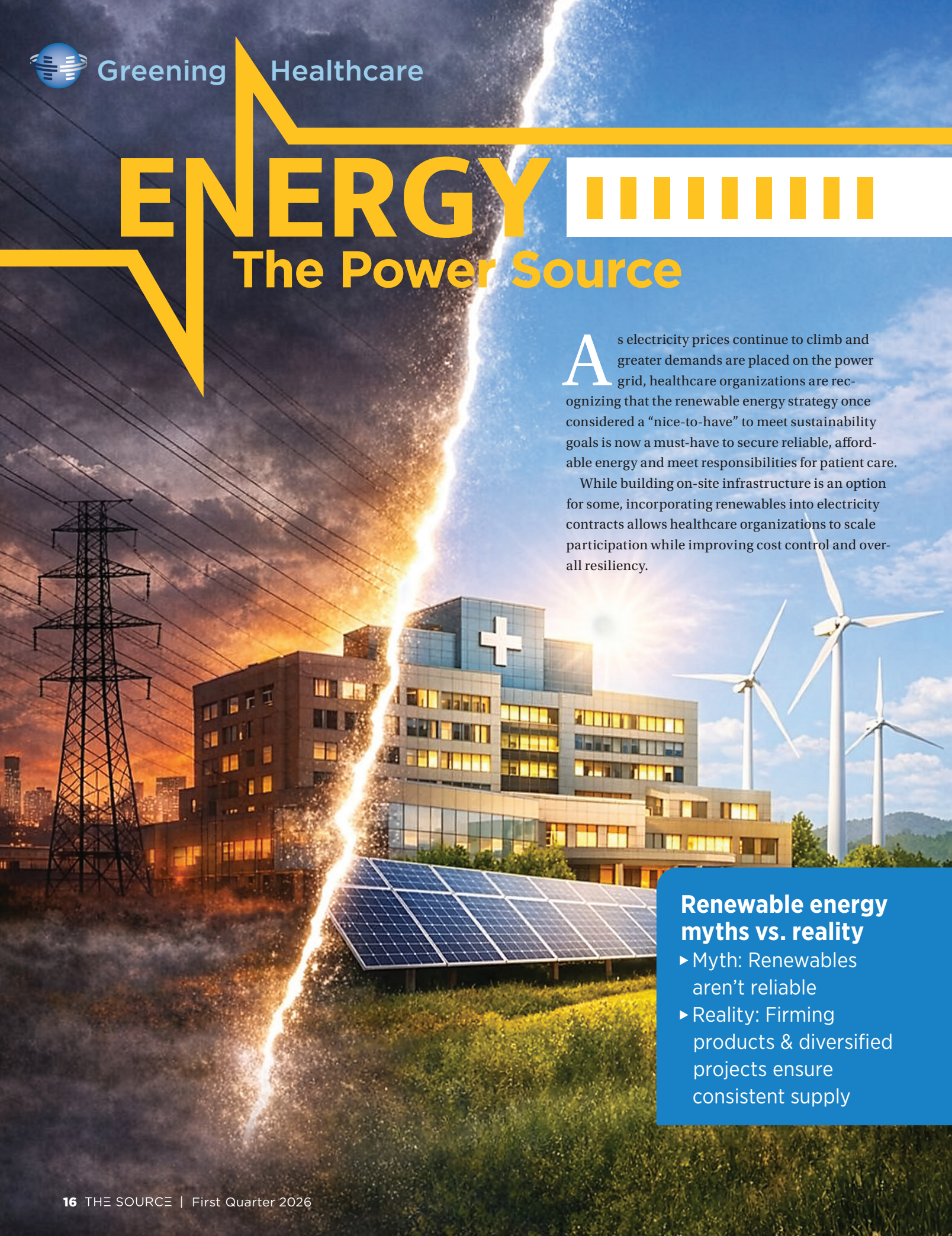
ENERGY

The Power Source

As electricity prices continue to climb and greater demands are placed on the power grid, healthcare organizations are recognizing that the renewable energy strategy once considered a "nice-to-have" to meet sustainability goals is now a must-have to secure reliable, affordable energy and meet responsibilities for patient care.

While building on-site infrastructure is an option for some, incorporating renewables into electricity contracts allows healthcare organizations to scale participation while improving cost control and overall resiliency.



Renewable energy myths vs. reality

- Myth: Renewables aren't reliable
- Reality: Firming products & diversified projects ensure consistent supply

Why renewables are no longer optional

The electrical grid's aging infrastructure, extreme weather events and climate impacts are just some of the reasons why healthcare organizations need to integrate renewable energy into their electricity contracts now, explains **Nikko Giovino**, Assistant Vice President, Strategic Sourcing, Commercial Products at HealthTrust. Other reasons include the rising demand for electricity that comes from data centers, electric vehicles, heat pumps and even artificial intelligence.

"We're seeing increases of 200% across the board right now for delivery costs associated with supply," Giovino shares. "If hospitals can get off the grid, it creates resiliency and is a strong price avoidance tactic."

It's not just about saving money. "Having renewables in your energy portfolio also means protecting patients," Giovino says. "Think of it as a resiliency play, as lives could be lost if a hospital's power grid goes down."

Debunking the reliability myth

Despite the promise of renewables, there is still some reluctance to rely on them, says **Bill Miller**, HealthTrust's Director, Strategic Account Integration, Energy. "The reluctance centers around if the sun doesn't shine, they're not getting any electricity from solar. If the wind doesn't blow, there's no generation from the wind projects," Miller explains. "And while that's true, there are firming products that can be added to the energy portfolio that ensure electricity accessibility even if the sun isn't shining in their location."

In practice, this may involve participating in large utility-scale projects, such as a facility generating hundreds of megawatts of electricity, and contracting for only a portion of that output. And that can be done over a number of projects in a variety of locations. Think of it as being like a diversified 401(k) portfolio, Miller says: If one system is out, there are others to rely on.

Optimizing renewable options

The power purchase agreement (PPA) is one of the most powerful tools for integrating renewables into an energy strategy, Giovino and Miller suggest.

PPAs allow healthcare organizations to purchase renewable energy from off-site projects or support the development of on-site infrastructure at a fixed rate, typically over 10- to 20-year terms and often with no upfront capital investment.

"With a PPA, you're going to get resiliency, you're going to have more budget certainty, and you'll be able to hit sustainability goals quicker than with most projects," Giovino says.

The value proposition, Miller adds, is hard to ignore: "If you can lock your price in for 15 to 20 years with no escalation, why wouldn't you do it?"

Long-term commitments can feel daunting, but organizations don't need to transition fully to renewables to see meaningful benefits. Even covering 30% of energy needs through fixed-price renewable contracts can generate substantial savings as market rates for the remaining supply continue to rise.

Taking the first step

Miller and Giovino encourage leaders not to be intimidated by long-term contracts or lingering concerns about reliability.

"We've got to be more serious about this now," Giovino says, noting that competition for renewable projects is intensifying. "A lot of big firms like Amazon, Facebook, Google—if there's a power project out there, they're going to snap it up before you blink."

A strong starting point is connecting with HealthTrust's Energy team. Whether an organization is evaluating a single project or exploring a broader renewable strategy, the team can assess opportunities, weigh risks and identify the most effective path forward.

Healthcare organizations shouldn't assume renewables are out of reach. "Let us do an analysis," Miller says. High-level discussions can lead to tailored solutions that strengthen energy reliability while delivering long-term cost management.

"High-level discussions can lead to tailored solutions that strengthen energy reliability while delivering long-term cost management."
Bill Miller

Why healthcare can't wait

- Rising electricity prices
- Grid reliability risks
- Growing competition for renewable projects
- Patient safety requirements

"If hospitals can get off the grid, it creates resiliency & is a strong price avoidance tactic."
Nikko Giovino

Balfaxar®
Prothrombin Complex Concentrate, Human-lans

Urgently Reverse VKA Therapy

Confidence at Every Moment

BALFAXAR. Total Support.

BALFAXAR was **proven non-inferior** to the market-leading product in hemostatic efficacy in a **head-to-head warfarin reversal study**[1,2]

8HR

BALFAXAR is **stable at room temperature for 8 hours** after reconstitution[a]

Based on the results of a usability study, **the nextaro® transfer device is preferred** over the Mix2Vial by HCPs[3,b]

HealthTrust Contract #4861

Indications

BALFAXAR (prothrombin complex concentrate, human-lans) is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with need for an urgent surgery/invasive procedure.

Important Safety Information

WARNING: ARTERIAL AND VENOUS THROMBOEMBOLIC COMPLICATIONS

Patients being treated with Vitamin K antagonists (VKA) therapy have underlying disease states that predispose them to thromboembolic events. Potential benefits of reversing VKA should be weighed against the potential risks of thromboembolic events, especially in patients with the history of a thromboembolic event. Resumption of anticoagulation should be carefully considered as soon as the risk of thromboembolic events outweighs the risk of acute bleeding. Both fatal and non-fatal arterial and venous thromboembolic complications have been reported with BALFAXAR in clinical trials and post marketing surveillance. Monitor patients receiving BALFAXAR for signs and symptoms of thromboembolic events. BALFAXAR may not be suitable in patients with thromboembolic events in the prior 3 months.

BALFAXAR is contraindicated in patients with known anaphylactic or severe systemic reactions to BALFAXAR or any of its components. BALFAXAR is also contraindicated in patients with a known allergy to heparin, a history of heparin-induced thrombocytopenia (HIT), and IgA deficient patients with known antibodies against IgA.

In clinical trials, the most frequent (≥3%) adverse reactions observed in subjects receiving BALFAXAR were procedural pain, wound complications, asthenia, anemia, dysuria, procedural vomiting, and catheter-site-related reaction.

BALFAXAR is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

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

[a]BALFAXAR can be stored for up to 36 months at 2°C to 25°C (36°F to 77°F) from the date of manufacture.
[b]User preference was determined from the responses of 16 healthcare providers using an 11-item questionnaire about the usability of the nextaro® and Mix2Vial transfer devices.[3]

References: 1. BALFAXAR, Prothrombin Complex Concentrate (Human) Full Prescribing Information. Paramus, NJ: Octapharma USA Inc. **2.** Sarode R, Goldstein JN, Simonian G, et al. Vitamin K antagonist reversal for urgent surgery using 4-factor prothrombin complex concentrates: a randomized clinical trial. JAMA Netw Open. 2024;7(8):e2424758. doi:10.1001/jamanetworkopen.2024.24758 **3.** Data on File, Octapharma 2023.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BALFAXAR safely and effectively. See full prescribing information for BALFAXAR.

BALFAXAR (prothrombin complex concentrate, human-lans) lyophilized powder for solution, for intravenous use
Initial U.S. Approval: 2023

WARNING: ARTERIAL and VENOUS THROMBOEMBOLIC COMPLICATIONS
See full prescribing information for complete boxed warning.
Patients being treated with Vitamin K antagonists (VKA) therapy have underlying disease states that predispose them to thromboembolic events. Potential benefits of reversing VKA should be weighed against the potential risks of thromboembolic events, especially in patients with the history of a thromboembolic event. Resumption of anticoagulation should be carefully considered as soon as the risk of thromboembolic events outweighs the risk of acute bleeding.
- Both fatal and non-fatal arterial and venous thromboembolic complications have been reported with BALFAXAR in clinical trials and post marketing surveillance. Monitor patients receiving BALFAXAR for signs and symptoms of thromboembolic events.
- BALFAXAR may not be suitable in patients with thromboembolic events in the prior 3 months.

INDICATIONS AND USAGE

BALFAXAR (prothrombin complex concentrate, human-lans) is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with need for an urgent surgery/invasive procedure.

DOSAGE AND ADMINISTRATION

For intravenous use after reconstitution only.
- BALFAXAR dosing should be individualized based on the patient's baseline International Normalized Ratio (INR) value, and body weight.
- Administer Vitamin K concurrently to patients receiving BALFAXAR to maintain factor levels once the effects of BALFAXAR have diminished.
- The safety and effectiveness of repeat dosing have not been established and it is not recommended.
- Administer reconstituted BALFAXAR at a rate of 0.12 mL/kg/min (~3 units/kg/min) up to a maximum rate of 8.4 mL/min (~210 units/min).

Pre-Treatment INR	2-< 4	4-6	> 6
Dose[a] of BALFAXAR (units[b] of Factor IX) / kg body weight	25	35	50
Maximum dose[c] (units of Factor IX)	Not to exceed 2500	Not to exceed 3500	Not to exceed 5000

[a]Dosing is based on body weight. Dose based on actual potency is stated on the vial, which will vary from 20-32 Factor IX units/mL after reconstitution. The actual potency for a 500-unit vial ranges from 400-640 units/vial. The actual potency for a 1000-unit vial ranges from 800-1280 units/vial.
[b]Units refer to International Units.
[c]Dose is based on body weight up to but not exceeding 100 kg. For patients weighing more than 100 kg, maximum dose should not be exceeded.

DOSAGE FORMS AND STRENGTHS

BALFAXAR is available as a white to ice-blue lyophilized powder for reconstitution for intravenous use in a single-dose vial, provided in a nominal strength of 500 Factor IX units in 20 mL reconstitution volume and 1000 Factor IX units in 40 mL reconstitution volume per vial. BALFAXAR contains the coagulation factors II, VII, IX, and X and antithrombotic Proteins C and S.

CONTRAINDICATIONS

- Known anaphylactic or severe systemic reactions to BALFAXAR or any of the components of the product.
- Known allergy to heparin or history of heparin-induced thrombocytopenia (HIT).
- IgA deficient patients with known antibodies against IgA.

WARNINGS AND PRECAUTIONS

- Discontinue infusion if allergic or anaphylactic-type reactions occur. Initiate appropriate treatment.
- Arterial and venous thromboembolic complications have been reported in patients receiving BALFAXAR. Monitor patients receiving BALFAXAR for signs and symptoms of thromboembolic events.
- BALFAXAR is made from human plasma; therefore, may carry the risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

ADVERSE REACTIONS

The most common adverse reactions observed in ≥ 3% of subjects were procedural pain, wound complications, asthenia, anemia, dysuria, procedural vomiting and catheter site related reaction.

To report SUSPECTED ADVERSE REACTIONS, contact Octapharma USA Inc. at 1-866-766-4860 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Revised: **07/2023**

Medical Affairs:
usmedicalaffairs@octapharma.com

Reimbursement Support:
Tel: 800-554-4440

Drug Safety:
For all inquiries relating to drug safety, or to report adverse events, please contact our local Drug Safety Officer:
Tel: 201-604-1137 | Cell: 201-772-4546 | Fax: 201-604-1141 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

octapharma

Sustainable Anesthesia

How health systems are eliminating desflurane

Clinical evidence along with strong clinician engagement and careful planning are helping hospitals retire one of healthcare's common anesthesia-related greenhouse gases—without risking patient safety.

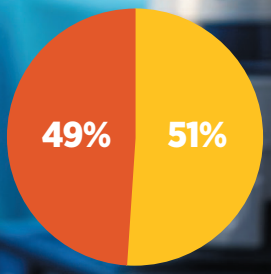
A data-driven case for change

When **Avery Palardy**, MBA, MS, joined Beth Israel Deaconess Medical Center (BIDMC) in 2019 as a sustainability program manager, she knew removing desflurane from the formulary would have significant impact. "The anesthesia gas has 2,400 times the global warming potential of carbon dioxide," she explains.

But environmental impact alone wasn't enough. Ensuring patient safety—and clinician confidence—would determine whether the transition succeeded. Anesthesiologist **Satya Krishna Ramachandran**, M.D., Vice Chairman for Quality & Safety at Beth Israel Lahey Health, partnered with Palardy to explore and validate the clinical implications.

Satya Krishn Ramachandran

Operating room emissions breakdown



> "The anesthesia gas has 2,400 times the global warming potential of carbon dioxide."
>
> **Avery Palardy**, MBA, MS

ELIMINATION PROCESS MAP

PILOT | SAFETY DATA | CONTRACT TRANSITION | SYSTEM ROLLOUT | CONTRACT TRANSITION | VAPORIZER REMOVAL | MONITORING DASHBOARD

A departmental poll at Beth Israel Lahey Health revealed anesthesiologists preferred to retain desflurane. "People in leadership strongly supported continuing its use, while national and international consensus was to move away from it," relays Dr. Ramachandran.

The solution: Treat the project as both a clinical safety investigation and a change-management initiative.

Dr. Ramachandran approached it from a patient safety perspective first. "What if it is a more polluting drug but it's a safer drug for patients?" he asked. To ensure patient safety wouldn't be affected, he gathered and reviewed the data. He conducted a retrospective analysis of tens of thousands of anesthesia cases, comparing safety outcomes between desflurane and sevoflurane. The results showed no significant difference. "That gave me great confidence bringing the recommendation to the executive decision group," he says.

Pilot to proof

BIDMC launched a pilot in early 2020. Desflurane remained available, but clinicians had to retrieve it from the pharmacy and assemble the vaporizer themselves. "No one did that," Dr. Ramachandran says. Meanwhile, he monitored for issues, such as delayed recovery or airway complications after sevoflurane use, and again found no differences.

The combination of clinical reassurance and real-world success paved the way for rollout across 11 additional hospitals within the system. "Clinician understanding of environmental issues—and our organizational commitments—made the transition easier," says Palardy, now Executive Director of Climate & Sustainability.

The problem with desflurane

According to the Commonwealth Fund, healthcare accounts for 8.5% of U.S. greenhouse gas (GHG) emissions. The operating room contributes disproportionately, representing 5% of a hospital's total emissions, with anesthetic gases making up 51% of OR emissions.

Sevoflurane has much lower environmental impact than desflurane and is less expensive. Desflurane has about 26 times the global warming potential as sevoflurane. It's not easy to find projects that provide both cost savings and greenhouse gas reductions. As a Scope 1 emission—meaning the health system directly controls its release—this is a change that offers a practical opportunity for sustainability initiatives.

"The project must have a strong anesthesiologist involved; outsiders telling the department that they're taking away desflurane will be met with a lot of resistance."

Ethan Sims, M.D.

Change management

Eliminating desflurane isn't simply a formulary update—it requires cultural change. "Awareness at the top level determines how these projects work," Dr. Ramachandran says. Buy-in from executives, anesthesia leadership and clinicians across an organization is key.

"The project must have a strong anesthesiologist involved; outsiders telling the department that they're taking away desflurane will be met with a lot of resistance," says **Ethan Sims**, M.D., an emergency department physician at St. Luke's Health System in Idaho, and Executive Director of Idaho Clinicians for Climate and Health.

Dr. Sims partnered with an anesthesiologist who was already working with

RESULTS THAT MATTER

St. Luke's Health System

1,050
million metric tons of greenhouse gas emissions reduced from 2021 to 2024

$214K
saved in 2024

Beth Israel Lahey Health

$400K
saved annually

Systemwide elimination by end of 2025

$2M+
saved over five years' utilization

Jennifer Westendorf

The details on desflurane

- Has the highest global warming potential among inhaled anesthetics
- Persists in the atmosphere for 14 years
- Represents the top contributor to anesthesia-related emissions globally

the pharmacy to reduce desflurane usage, based on cost alone. "We decided to expedite the process and include the environmental impact of it," Dr. Sims says. Several anesthesia leaders then spoke at the departmental meeting about it, improving knowledge and support. Still, about 20% of anesthesiologists were resistant to the change. Dr. Sims brought in a physician from Providence (Portland, Oregon) as outside expertise. Brian Chesbro, M.D., joined Dr. Sims in speaking to the group from an anesthesia and workflow perspective, answering questions and erasing their doubts. After a successful pilot, rolling out the initiative system-wide became easier.

Measuring outcomes

St. Luke's monitors desflurane usage on an active dashboard, using Epic and supply chain information to assist the team with focused communications. In addition to measuring cost and emissions reductions, St. Luke's measures provider satisfaction. "The biggest concern people had was OR turnover time," Dr. Sims says. They were concerned it would take longer for patients to wake after sevoflurane use; however, anesthesiologists provided no negative comments about sevoflurane's workflow impact.

The next frontier: nitrous oxide reduction

Success with desflurane reduction is now inspiring organizations to address nitrous oxide, a potent greenhouse gas.

BIDMC's study found 40%–50% leakage from its nitrous oxide systems. "It's associated with a lot of nonclinical waste and has very toxic environmental impacts," says Dr. Ramachandran. "It lasts more than 100 years in the environment. After desflurane, it is the No. 1 pollutant."

Decommissioning the nitrous lines from systemic piping to e-cylinder machines in OR and labor rooms is more complicated. It involves logistical and project management issues: policy updates, education, workflows, procurement processes and tank movements.

"There's no impact on patient care and safety, and it's ultimately cost neutral," says Palardy. "It's an initiative that is purely environmental." Since decommissioning their systemic piping, BIDMC has experienced at least a 90% reduction in nitrous oxide emissions.

It costs $10,000–$15,000 to decommission a facility's nitrous system, says Dr. Sims, but the switch paid for itself in less than two years. St. Luke's also saved several hundred thousand dollars by not installing a central nitrous oxide system in a new construction project.

More health systems are making the move

"A growing number of health systems have converted from desflurane or are starting the process to convert," says **Jennifer Westendorf**, DNP, RN, CNOR, AVP, Environmental Performance & Surgical Services at HealthTrust. There's a big opportunity for ambulatory surgery centers to follow suit. ●

READY TO START?

HealthTrust offers support documents in the Knowledge Library and a toolkit and evidence review is available from the pharmacy team in the Member Portal. Members can also ask questions and learn from other health system experts about their sustainability initiatives by joining the HealthTrust Huddle. Additional questions? Email sustainability@healthtrustpg.com

HEALTHTRUST Performance Group | Optum

13:1 AVERAGE ROI

Drive Transformation

Crimson AI

*powered by HealthTrust**

This integrated analytics platform combines HealthTrust's robust clinical and financial data assets with Optum's outcomes-based insights, all layered with your facility's case-level data to provide a comprehensive view of your service line operations. Powered by AI, the platform helps identify opportunities for cost savings and quality improvement, enabling evidence-based decisions that drive measurable impact across your organization.

Ready to *Propel Change* Across Your Service Lines?

**HealthTrust and Optum have collaborated to develop Crimson AI powered by HealthTrust*

Hidden Value$

In purchased services, fragmented supplier management is costing hospitals millions—new tools make fragmented spend visible & actionable

CHECK OUT THESE COXHEALTH RESULTS

$750K avoided capital purchase + **$350K** annual savings

20% variance spotted in one area of spend

$20K saved on paint alone

Many health systems lack tools and resources to address Purchased Services contracting, which accounts for 50% of non-labor spend on average. CoxHealth was no different. To address this, it launched a three-year engagement with Valify Advisory in 2024. While the chief supply chain officer (CSCO) and contracting manager were focused on supply chain strategy and medical supplies, neither had the time to examine purchased services in depth. Valify Advisory brought the technology and subject matter expertise to focus on Purchased Services and encouraged CoxHealth to hire its own resource. **Chris Bryant**, experienced in healthcare leadership but new to supply chain, stepped into the role of Director of Strategic Sourcing.

Working with Bryant, Valify Advisor brought structure, tools and expertise. "Most hospital purchasing teams just don't have the bandwidth to really capitalize on these opportunities. Valify provides that help and support," says **Andy Motz**, Vice President of Valify Advisory Services.

One of the first and biggest wins in 2025 was helping CoxHealth avoid a $750K capital purchase to replace its printing devices and infrastructure. The six-hospital, 80-clinic system in southwest Missouri had been managing all printing in-house, using laser printers and multifunctional devices operated by a non-HealthTrust supplier. The expenditure seemed unavoidable—until a Valify Advisory review completely changed the picture.

Instead of spending $750K, CoxHealth found that a contracted HealthTrust provider could eliminate the capital investment altogether and reduce ongoing costs by another $350,000 per fiscal year.

Purchased services—everything that keeps hospitals functioning but isn't a drug, device or surgical supply—represent an enormous slice of operating expenses. This category spans food and nutrition, environmental services, translation, laundry, office supplies, elevator maintenance, print management and more. Yet, in many health systems, oversight of these services is fractured across departments, making it easy for inefficiencies and duplicated spend to compound unnoticed.

"After the official engagement with Valify ends, we'll continue to reap the benefits from the structure we've put in place."
Chris Bryant

And the numbers add up quickly. In large organizations, the lack of centralized coordination can mean tens to hundreds of millions of dollars spent on redundant suppliers, inconsistent contract terms or unmanaged service agreements.

A structured approach

The turning point for CoxHealth came when its CSCO realized that purchased services were a significant blind spot during discussions with Valify. Departments were negotiating contracts independently, and the same supplier might be providing different services across multiple areas without anyone realizing it.

"No one knew that Engineering was using them for one thing, and Environmental Services was using them for something else," Bryant recalls.

Building a framework for control

Through weekly meetings with Motz, Abbi Elzinga (HealthTrust Performance Solutions) and a dedicated project manager, Bryant began

A 20% year-over-year spend variance revealed an unmanaged service agreement

$1M+ saved in year 1

$20K saved annually by switching a single supplier to a HealthTrust contract

"The benchmarking tools consider the financial opportunities & contract compliance…to help the healthcare system determine its savings goals."
Andy Motz

learning how to manage this sprawling category: setting priorities, reviewing contract compliance, building a savings pipeline, structuring negotiations and using Valify's analytics.

"The tools take all of our purchased services spend and break it down into categories," he explains. These insights help identify which categories offer the greatest financial opportunity and where duplicative or non-compliant contracts may sit.

Valify's engagement model is intentionally designed to shift responsibility over time. Year by year, organizations build stronger internal processes—eventually creating a mature purchased services program that includes sourcing strategies, contract templates and a predictable renewal cadence.

"You're not just fixing today's problems," Motz says. "You're building a system that prevents them from coming back."

Lessons that change behavior

Part of the engagement process is education, which can pay dividends over the long run. When Motz initially used Valify Insights to compare CoxHealth's current 12-month spend to its previous 12-month spend, he saw a 20% variance in one category. Bryant dug deeper and uncovered the reason: A newly purchased surgical robot carried a service agreement negotiated without supply chain involvement.

"Any time you buy large pieces of equipment, you should work with your supply chain or contracting team on the front end to get a better deal," Motz says. If not, once warranties expire, the leverage disappears.

This was a practice-changing lesson for CoxHealth. "It helped the entire system understand when it is appropriate to contact the supply chain office and who should be involved," Bryant says.

Making costs visible

Valify Insights is a suite of tools that highlights year-over-year spending variances, helping healthcare organizations take better control of their purchased services. Some projects are simple switches, and some involve more effort to reach the optimum results.

Bryant says one easy project was the organization's paint contract. CoxHealth already worked with the paint supplier, but reached out to the company through its HealthTrust contract. The health system continues to work with its local store, but by switching from no contract to a HealthTrust contract, the health system saved $20,000 annually. "That happened with a couple of suppliers," Bryant says, including those used for anesthetic gas, kids' stickers, and building and office supplies.

More complex categories involve multiple stakeholders and often touch patient experience. With Valify's help, another HealthTrust member consolidated from three suppliers to one—generating more than $10 million in annual savings.

But consolidation isn't always the answer. Take interpretation services, for example. "Because of rare languages, you need backups," Motz says. One system saved $2 million a year by reducing suppliers—but not expecting a single interpretation supplier could meet all their language needs.

Valify's new Insights module

The recently enhanced Valify Insights module gives executives a snapshot of where costs are rising and where duplicate suppliers exist. Valify created a proprietary scoring system for purchased services categories. The Valify Score indicates what categories should be in scope, which categories should have a higher priority, and how they compare across the system or hospital.

"Valify Insights points leaders toward the categories that need attention, where multiple suppliers are providing the same services," Motz explains.

mustafaU via Getty Images

TOP 5 TAKEAWAYS

- Centralize oversight to eliminate duplicated spend
- Use analytics to reveal hidden supplier overlap
- Engage supply chain early in equipment purchases
- Consolidate where appropriate—but maintain necessary backups
- Build a repeatable contracting & renewal process

The tool encourages broad access across the health system: CFOs, facilities managers, lab directors and others can use Valify Insights to understand spending patterns relevant to their operations.

A systemwide shift in mindset

Bryant urges other health systems to explore engaging with Valify to at least review their purchased services spend. The discovery process alone proved revealing. "There have been instances where we have the same supplier being used across the system by three different hospitals, and no one knew that."

The stakes are significant. CoxHealth exceeded its first-year goal, saving more than $1 million. In year two, Bryant estimates another $2 million in potential savings.

According to Bryant, the effort quickly paid for itself. "It is worth it, given the millions we're potentially going to save. After the official engagement with Valify ends, we'll continue to reap the benefits of the structure we've put in place."

For organizations not seeking a full engagement, Valify can still conduct an assessment to help focus on high-impact purchased services. The advisory service requires no upfront cost. "We're truly a business partnership. We don't make money unless we save you money," Motz shares. "We're at risk and we work to get you as much in savings as possible."

From Bryant's perspective, the message is clear: Health systems seeking savings must evaluate purchased services. "It's that simple; there are significant savings out there." ●

Drive value in purchased services for your organization by contacting the Valify Client Success team today at info@getvalify.com

Turning Insight Into Impact

New platform connects cost, quality & outcomes

Shrinking margins, workforce constraints and rising patient expectations continue to test hospitals nationwide. Success today requires more than cost control—it demands a coordinated approach that connects cost, quality and outcomes across every decision.

At HealthTrust Performance Group, that approach is coming to life through Crimson AI Powered by HealthTrust, an analytics platform co-developed by HealthTrust and Optum to transform complex clinical and operational data into actionable intelligence. The result: real-time learnings, smarter decisions and improved care delivery across a healthcare organization.

Crimson AI in action

- **For executives:** Access real-time dashboards linking financial performance directly to patient results
- **For clinical leaders:** Identify high-risk encounters, reduce readmissions & address root causes of variation with actionable insights
- **For supply chain teams:** Leverage integrated cost & utilization data to negotiate smarter & optimize product selection

"The HealthTrust and Crimson AI alignment brings together clinical, financial and supply chain data in a way the industry has never achieved before, creating a single actionable view that enables real improvement across the care continuum," says **John Kontor**, M.D., Senior Vice President & General Manager of Clinical Decision Support at Optum.

"We're moving from retrospective measurement to real-time insight, enabling providers to act, not just analyze," shares **Aashish Shah**, M.D., J.D., MBA, HealthTrust SVP & Chief Medical Officer.

Integrating cost & quality with data-driven precision

At its core, the Crimson AI platform aligns three strategic imperatives:

- Cost: Eliminating waste, variation and inefficiency across the care continuum
- Quality: Ensuring consistent, safe, evidence-based care delivery
- Outcomes: Sustaining measurable performance improvement over time

Data is transformed into targeted interventions. Through guided workflows, flexible reporting and AI-enabled recommendations, members can proactively identify performance trends and manage high-risk encounters.

These capabilities help leaders strengthen safety, streamline reporting and improve regulatory performance, supporting better clinical results and stronger sustainability for organizations.

"Layering advanced AI on top of robust clinical, financial and supply chain data allows us to identify opportunities for improvement faster and guide users to solutions that truly move the needle," says Dr. Kontor.

"Crimson AI is about precision: linking the right clinical decisions with operational data in real time. This helps our members see the full picture, so every choice supports both patient outcomes & financial sustainability."

Aashish Shah, M.D., J.D.

Reducing operative variation & waste

The Surgical Cost Module gives hospitals a comprehensive view of supply utilization, benchmarking and procedural cost variance, which then allows for data-informed decisions in one of the most cost-intensive care settings.

Key features:

- AI-powered preference cards that recommend optimal supply selections based on cost and outcomes
- Cost-per-case analytics that help identify high-variance procedures and engage surgeons in improvement
- Spend analytics and benchmarking tools to strengthen supplier negotiations and procurement strategy

By visualizing supply data in new ways, surgical leaders can reduce variation, increase standardization and optimize performance without compromising patient care.

Delivering outcomes-driven intelligence across an enterprise

Crimson AI Powered by HealthTrust serves as a unified performance platform

that connects data, teams and strategy. With embedded EHR integration and more than 400 risk adjustment and effectiveness measures across inpatient and ambulatory settings, it enables leaders to visualize and act on performance metrics faster than ever before.

Clients can work with value advisors who help translate data into actionable initiatives—accelerating speed to value.

AI-Assist, Crimson AI's open chat feature, provides instant data interpretation that empowers confident decision-making.

This combination of AI enablement and advanced benchmarking ensures that members are analyzing data and using it to deliver measurable impact.

"We finally have a tool that allows us to focus on transparency and transformation," explains Dr. Shah.

Looking ahead: the next phase

As the healthcare landscape continues to evolve, the ability to connect data across departments will define the next generation of performance excellence. Members can move from reactive reporting to predictive insight—turning Crimson AI into a strategic advantage.

HealthTrust's approach enables members to make smarter, faster and more unified decisions that enhance both patient outcomes and organizational resilience.

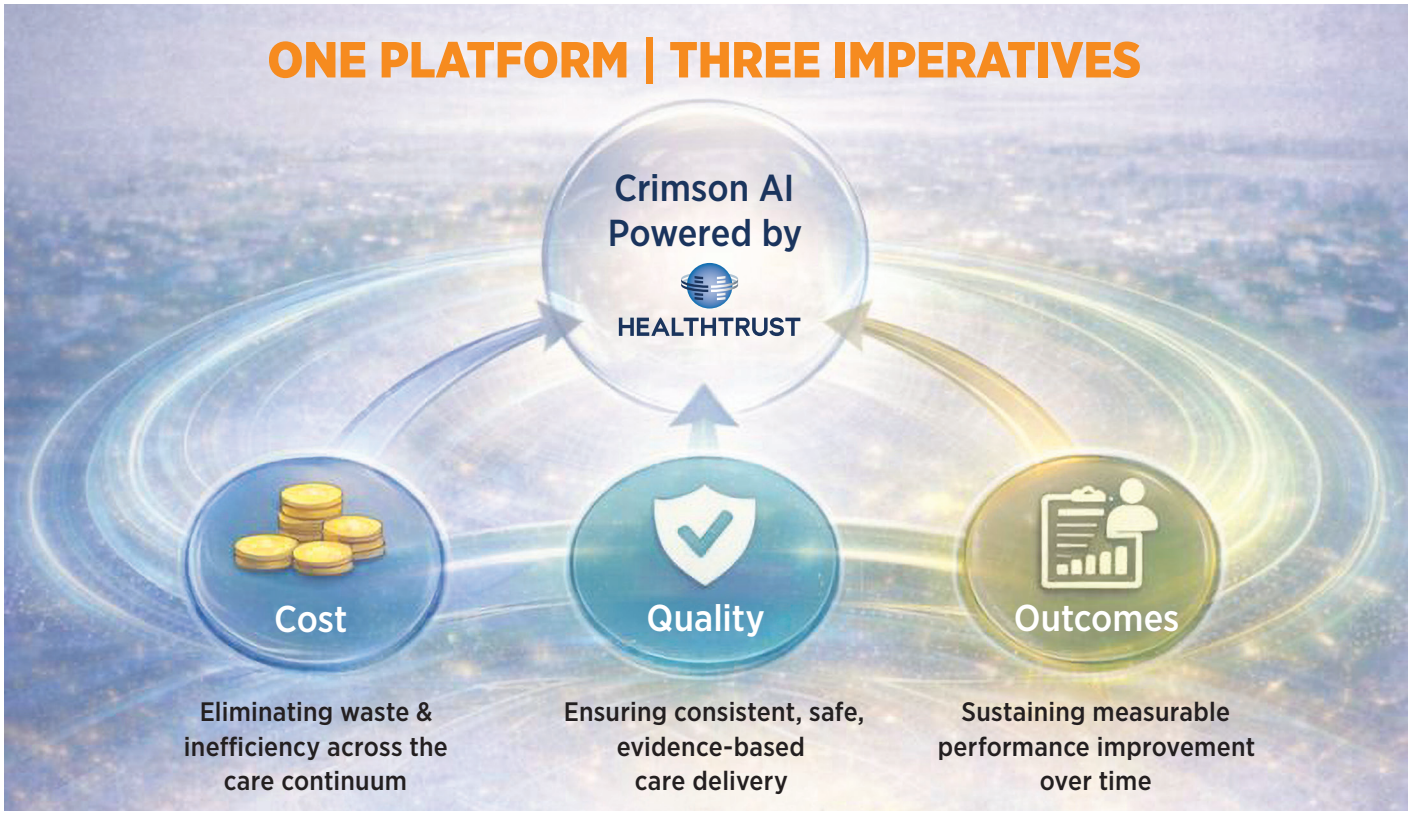
"By aligning end-to-end clinical and cost data across more than 1.5 million lives, this initiative sets a new benchmark for how healthcare organizations can measure performance and drive meaningful change," adds Dr. Kontor. ●

"This initiative isn't just about data integration. It's about improving outcomes for patients & HealthTrust members by ensuring smarter decisions across care delivery, cost management & resource utilization."

John Kontor, M.D.

READY TO START?

Put Crimson AI Powered by HealthTrust to work for your organization. Contact your HealthTrust Account Manager to start the conversation or email: performancesolutions@healthtrustpg.com



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Our commitment is resolute to deliver exceptional quality, dependable supply, and thoughtful planning that sustainably and resiliently supports long-term stability.

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HealthTrust Contracts:

NEW! #135825	Lab Coats & Jackets – Disposable	NEW! #137755	Bandages – Elastic Self Adherent
#1992	Examination Gloves	#785	Personal Protective Gowns & Apparel (PPE) – Disposable
#7222	Headwear and Footwear	#5210	Non-Sterile Elastic Bandages
#7561	Face Masks – Surgical & Procedure	#4468	N95 Respirator Face Mask Products

Why EXPAREL? Why now?

Clinical and economic updates are improving patient access to non-opioids like EXPAREL

Recent HEOR data

Separate Medicare reimbursement at ASP+6% using J0666[1-3]

Now On Contract (HealthTrust #136810)

EXPAREL uses pMVL technology to control postsurgical pain for up to 96 hours[4-10]

- **Proven to decrease opioid use**[5,6,11]*
- **Established reductions in the need for rescue pain medications**, supporting a faster and more comfortable recovery[5,6,11]
- **Demonstrated superiority vs bupivacaine HCl** in 2 LENB pivotal trials and a phase 4 local infiltration study in TKA[5,6,8†]

ASP, average sales price; HCl, hydrochloride; HEOR, Health Economics and Outcome Research; LENB, lower-extremity nerve block; pMVL, proprietary multivesicular liposome; TKA, total knee arthroplasty; TSA, total shoulder arthroplasty.

INDICATION

EXPAREL® (bupivacaine liposome injectable suspension) is indicated to produce postsurgical local analgesia via infiltration in patients aged 6 years and older and regional analgesia in adults via an interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and an adductor canal block. Safety and efficacy have not been established in other nerve blocks.

IMPORTANT SAFETY INFORMATION

- EXPAREL is contraindicated in obstetrical paracervical block anesthesia
- Adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via nerve block were nausea, pyrexia, headache, and constipation
- Adverse reactions with an incidence greater than or equal to 10% following EXPAREL administration via infiltration in pediatric patients six to less than 17 years of age were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, vision blurred, pruritus, and tachycardia
- Do not admix lidocaine or other non-bupivacaine local anesthetics with EXPAREL. EXPAREL may be administered at least 20 minutes or more following local administration of lidocaine
- EXPAREL is not recommended to be used in the following patient populations: patients <6 years old for infiltration, patients younger than 18 years old for nerve blocks, and/or pregnant patients
- Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease

WARNINGS AND PRECAUTIONS SPECIFIC TO EXPAREL

- Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL
- EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks **other than interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and adductor canal block**, or intravascular or intra-articular use
- The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dosage administered and may last for up to 5 days, as seen in clinical trials

EXPAREL®
BUPIVACAINE LIPOSOME INJECTABLE SUSPENSION

Please see accompanying Brief Summary.
For more information, visit www.EXPARELPro.com or call 1-855-793-9727.

EXPAREL was associated with lower outpatient costs and shorter inpatient stays[12,13]

In outpatient TSA vs patients not treated with EXPAREL[12‡]

16%
lower
costs at 30 days
(*P*<0.05)

15%
lower
costs at 90 days
(*P*<0.01)

In inpatient lumbar spinal fusion vs bupivacaine[13§]

33%
reduction
in length of stay
(1.8 days vs 2.7 days, *P*<0.05)

16%
lower
direct costs for overall hospital stay
(*P*<0.001)

Better is possible with EXPAREL—contact Pacira to see how non-opioid options can improve postsurgical recovery for your patients

*The clinical benefit of the decrease in opioid consumption was not demonstrated in the pivotal trials.

†EXPAREL showed superiority to bupivacaine in the adductor canal nerve block pivotal trial, the sciatic nerve block in the popliteal fossa pivotal trial, and the phase 4 local infiltration study in TKA.[5,6,8]

‡**Study Design:** The retrospective cohort study assessed adults who underwent TSA in a hospital outpatient department between January 1, 2019, and December 31, 2021, using deidentified patient data from 20% of the Medicare beneficiaries in the Centers for Medicare & Medicaid Services (CMS) database. Patients were required to have continuous enrollment at least 6 months prior to surgery and 12 months following the surgery date to be included in the study. Propensity score matching (1:1 ratio) was conducted between the EXPAREL and non-EXPAREL cohorts based on age, sex, race, comorbidities, procedure year, and region. The final cohort was composed of 2,050 EXPAREL patients and 2,050 non-EXPAREL patients, with the majority being females (56%) with osteoarthritis (94%) and an average age of 74.[12]

§**Study Design:** The retrospective cohort study assessed adults who underwent posterior lumbar spinal fusion surgery between April 2015 and September 2016. Propensity score matching (1:1 ratio) was conducted between the EXPAREL cohort and the bupivacaine HCl cohort based on age, sex, race, and Charlson Comorbidity Index. The final cohort was composed of 105 EXPAREL patients and 105 non-EXPAREL patients with an average age of 60 years, mostly white (98%) and equally split between the sexes.[13]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS FOR BUPIVACAINE-CONTAINING PRODUCTS

- **Central Nervous System (CNS) Reactions:** There have been reports of adverse neurologic reactions with the use of local anesthetics. These include persistent anesthesia and paresthesia. CNS reactions are characterized by excitation and/or depression
- **Cardiovascular System Reactions:** Toxic blood concentrations depress cardiac conductivity and excitability, which may lead to dysrhythmias, sometimes leading to death
- **Allergic Reactions:** Allergic-type reactions (eg, anaphylaxis and angioedema) are rare and may occur as a result of hypersensitivity to the local anesthetic or to other formulation ingredients
- **Chondrolysis:** There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use
- **Methemoglobinemia:** Cases of methemoglobinemia have been reported with local anesthetic use

References: 1. CMS.gov. Published October 10, 2024. Accessed January 30, 2025. https://www.cms.gov/files/document/2024-hcpcs-applicationsummary-quarter-3-2024-drugs-and-biologicals-posted-10-02-2024.pdf; **2.** CMS.gov. 2024. Accessed June 4, 2024. https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price; **3.** Consolidated Appropriations Act 2023. Accessed October 31, 2024. https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf; **4.** Dagenais S, et al. *Expert Opin Drug Saf*. 2018;17(6):545-552. doi:10.1080/14740338.2018.1474200; **5.** Schwartz G, et al. *J Clin Anesth*. 2024;94:111402. doi:10.1016/j.jclinane.2024.111402; **6.** Gadsden J, et al. Poster presented at: 48th Annual Regional Anesthesiology and Acute Pain Medicine Meeting; April 20, 2023; Hollywood, FL. Poster 4381. **7.** Patel MA, et al. *Pain Med*. 2020;21(2):387-400. doi:10.1093/pm/pnz103; **8.** Mont MA, et al. *J Arthroplasty*. 2018;33(1):90-96. doi:10.1016/j.arth.2017.07.024; **9.** Golf M, et al. *Adv Ther*. 2011;28(9):776-788. doi:10.1007/s12325-011-0052-y; **10.** Gorfine SR, et al. *Dis Colon Rectum*. 2011; 54(12):1552-1559. doi:10.1097/DCR.0b013e318232d4c1; **11.** Dobson A, et al. *J Med Econ*. 2021;24(1):9931001. doi:10.1080/13696998.2021.1963100; **12.** Abboud Poster presented at the AMCP Nexus 2025; October 27-30, 2025; National Harbor, MD; **13.** Roh, et al. *Clin Spine Surg*. 2020;33(8):E359-E363. doi:10.1097/BSD.0000000000001006

Please see accompanying Brief Summary.
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EXPAREL®
BUPIVACAINE LIPOSOME INJECTABLE SUSPENSION

pacira BIOSCIENCES

EXPAREL®

(bupivacaine liposome injectable suspension)

Brief Summary

(For full prescribing information refer to package insert)

INDICATIONS AND USAGE

EXPAREL is indicated to produce postsurgical:

- Local analgesia via infiltration in patients aged 6 years and older
- Regional analgesia via an interscalene brachial plexus nerve block in adults
- Regional analgesia via a sciatic nerve block in the popliteal fossa in adults
- Regional analgesia via an adductor canal block in adults

Limitations of Use: The safety and effectiveness of EXPAREL have not been established to produce postsurgical regional analgesia via other nerve blocks besides an interscalene brachial plexus nerve block, a sciatic nerve block in the popliteal fossa, or an adductor canal block.

CONTRAINDICATIONS

EXPAREL is contraindicated in obstetrical paracervical block anesthesia. While EXPAREL has not been tested with this technique, the use of bupivacaine HCl with this technique has resulted in fetal bradycardia and death.

WARNINGS AND PRECAUTIONS

Warnings and Precautions Specific for EXPAREL

As there is a potential risk of severe life-threatening adverse reactions associated with the administration of bupivacaine, EXPAREL should be administered in a setting where trained personnel and equipment are available to promptly treat patients who show evidence of neurological or cardiac toxicity.

Caution should be taken to avoid accidental intravascular injection of EXPAREL. Convulsions and cardiac arrest have occurred following accidental intravascular injection of bupivacaine and other amide-containing products.

Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL.

EXPAREL has not been evaluated for the following uses and, therefore, is not recommended for these routes of administration or types of analgesia:

- epidural
- intrathecal
- intravascular or intra-articular use
- regional nerve blocks other than interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and adductor canal block

EXPAREL has not been evaluated for use in the following patient populations and, therefore, is not recommended for administration to these groups.

- patients younger than 6 years old for infiltration
- patients younger than 18 years old for interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and adductor canal block
- pregnant patients

The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dose administered and may last for up to 5 days as seen in clinical trials.

ADVERSE REACTIONS

Clinical Trials Experience

Adverse Reactions Reported in All Local Infiltration Clinical Studies in Adults

The safety of EXPAREL (local administration into the surgical site) was evaluated in 10 randomized, double-blind, clinical studies that included 823 adult patients who had various surgical procedures. Patients were administered an EXPAREL dose ranging from 66 to 532 mg (two times the maximum recommended dose of 266 mg). In these studies, following EXPAREL administration, the:

- *Most common* adverse reactions (incidence greater than or equal to 10%) were nausea, constipation, and vomiting.
- *Common* adverse reactions (incidence greater than or equal to 2% to less than 10%) were pyrexia, dizziness, peripheral edema, anemia, hypotension, pruritus, tachycardia, headache, insomnia, postoperative anemia, muscle spasms, hemorrhagic anemia, back pain, somnolence, and procedural pain.

Adverse Reactions Reported in All Local Infiltration Clinical Studies in Pediatric Patients Aged 6 to Less Than 17 Years

The safety of EXPAREL in 110 pediatric patients between the age of 6 and 17 years old who had spine or cardiac surgical procedures was evaluated in one randomized, open-label, clinical study in which EXPAREL was administered by infiltration into the surgical site and one single-arm, open-label study in which EXPAREL was administered by infiltration into the surgical site. Patients were administered a weight-based dose of EXPAREL at 4 mg/kg (maximum dose of 266 mg) or bupivacaine HCl 2 mg/kg (maximum dose of 175 mg). In these studies, following EXPAREL administration the:

- *Most common* adverse reactions (incidence greater than or equal to 10%) were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, blurred vision, pruritus, and tachycardia.
- *Common* adverse reactions (incidence greater than or equal to 2% to less than 10%) were bradycardia, muscle spasms, tachypnea, oral hypoesthesia, postoperative anemia, dizziness, pyrexia, diarrhea, hypoacusis, hypoesthesia, back pain, hematuria, incontinence, muscular weakness, and visual impairment.

Adverse Reactions Reported in Placebo-Controlled Nerve Block Clinical Studies in Adults

The safety of EXPAREL was evaluated in four randomized, double-blind, placebo-controlled nerve block clinical studies involving 469 EXPAREL-treated adult patients and 357 placebo-treated patients who had various surgical procedures. Patients were administered placebo or an EXPAREL dose of either 133 or 266 mg (two times the maximum recommended dose for these nerve blocks). In these studies, following EXPAREL administration via nerve block (perineural use) the:

- *Most common* adverse reactions (incidence greater than or equal to 10%) were nausea, pyrexia, and constipation.
- *Common* adverse reactions (incidence greater than or equal to 2% to less than 10%) were muscle twitching, dysgeusia, urinary retention, fatigue, headache, confusional state, hypotension, hypertension, oral hypoesthesia, generalized pruritus, hyperhidrosis, tachycardia, sinus tachycardia, anxiety, fall, increased body temperature, peripheral edema, sensory loss, increased hepatic enzyme, hiccups, hypoxia, and post-procedural hematoma.

Adverse Reactions Reported in Active-Controlled Nerve Block Clinical Studies in Approved Populations

The safety of EXPAREL was evaluated in two randomized, double-blind, active-controlled nerve block clinical studies in 189 adult patients who had a bunionectomy or a total knee arthroplasty. Via nerve block, patients received 133 mg of EXPAREL, 266 mg of EXPAREL (two times the maximum recommended EXPAREL dose), or 133 mg of EXPAREL admixed with 50 mg of bupivacaine HCl. In both of these studies the active comparator was 50 mg of bupivacaine HCl.

The *most common* adverse reactions (incidence greater than or equal to 10%) in both of these studies following:

- EXPAREL administration as a nerve block were nausea and constipation.
- Administration of EXPAREL admixed with bupivacaine as a nerve block were nausea, constipation, muscle spasms, and headache.

The *common* adverse reactions (incidence greater than or equal to 2% to less than 10%) in both of these studies following:

- EXPAREL administration as a nerve block were pruritus, vomiting, dyspepsia, headache, peroneal nerve palsy, rash and hypertension.
- Administration of EXPAREL admixed with bupivacaine as a nerve block were vomiting, dyspepsia, increased heart rate, hypokalaemia, hyponatraemia, back pain, disorientation, oropharyngeal pain, hypoaesthesia, pruritus, dizziness, insomnia, hypertension, hypoxia, hypotension, pyrexia, and tachycardia.

Postmarketing Experience

These adverse reactions are consistent with those observed in clinical studies and most commonly involve the following system organ classes: Injury, Poisoning, and Procedural Complications (e.g., drug-drug interaction, procedural pain), Nervous System Disorders (e.g., palsy, seizure), General Disorders And Administration Site Conditions (e.g., lack of efficacy, pain), Skin and Subcutaneous Tissue Disorders (e.g., erythema, rash), and Cardiac Disorders (e.g., bradycardia, cardiac arrest).

DRUG INTERACTIONS

The toxic effects of local anesthetics are additive and concomitant use should be used with caution including monitoring for neurologic and cardiovascular effects related to local anesthetic systemic toxicity. Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL.

Patients who are administered local anesthetics, including EXPAREL, may be at increased risk of developing methemoglobinemia when concurrently exposed to the following drugs, which could include other local anesthetics:

Class	Examples
Nitrates/Nitrites	nitric oxide, nitroglycerin, nitroprusside, nitrous oxide
Local anesthetics	articaine, benzocaine, bupivacaine, lidocaine, mepivacaine, prilocaine, procaine, ropivacaine, tetracaine
Antineoplastic agents	cyclophosphamide, flutamide, hydroxyurea, ifosfamide, rasburicase
Antibiotics	dapsone, nitrofurantoin, para-aminosalicylic acid, sulfonamides
Antimalarials	chloroquine, primaquine
Anticonvulsants	Phenobarbital, phenytoin, sodium valproate
Other drugs	acetaminophen, metoclopramide, quinine, sulfasalazine

Bupivacaine

Bupivacaine HCl administered together with EXPAREL may impact the pharmacokinetic and/or physicochemical properties of EXPAREL, and this effect is concentration dependent. Therefore, bupivacaine HCl and EXPAREL may be administered simultaneously in the same syringe, and bupivacaine HCl may be injected immediately before EXPAREL as long as the ratio of the milligram dose of bupivacaine HCl solution to EXPAREL does not exceed 1:2.

Non-bupivacaine Local Anesthetics

EXPAREL should not be admixed with local anesthetics other than bupivacaine. Nonbupivacaine based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more. There are no data to support administration of other local anesthetics prior to administration of EXPAREL.

Other than bupivacaine as noted above, EXPAREL should not be admixed with other drugs prior to administration.

Water and Hypotonic Agents

Do not dilute EXPAREL with water or other hypotonic agents, as it will result in disruption of the liposomal particles.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no studies conducted with EXPAREL in pregnant women. In animal reproduction studies, embryo-fetal deaths were observed with subcutaneous administration of bupivacaine to rabbits during organogenesis at a dose equivalent to 1.6 times the maximum recommended human dose (MRHD) of 266 mg. Subcutaneous administration of bupivacaine to rats from implantation through weaning produced decreased pup survival at a dose equivalent to 1.5 times the MRHD [see Data]. Based on animal data, advise pregnant women of the potential risks to a fetus.

The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk in the U.S. general population of major birth defects is 2-4% and of miscarriage is 15-20% of clinically recognized pregnancies.

Clinical Considerations

Labor or Delivery

Bupivacaine is contraindicated for obstetrical paracervical block anesthesia. While EXPAREL has not been studied with this technique, the use of bupivacaine for obstetrical paracervical block anesthesia has resulted in fetal bradycardia and death.

Bupivacaine can rapidly cross the placenta, and when used for epidural, caudal, or pudendal block anesthesia, can cause varying degrees of maternal, fetal, and neonatal toxicity. The incidence and degree of toxicity depend upon the procedure performed, the type, and amount of drug used, and the technique of drug administration. Adverse reactions in the parturient, fetus, and neonate involve alterations of the central nervous system, peripheral vascular tone, and cardiac function.

Data

Animal Data

Bupivacaine hydrochloride was administered subcutaneously to rats and rabbits during the period of organogenesis (implantation to closure of the hard plate). Rat doses were 4.4, 13.3, and 40 mg/kg/day (equivalent to 0.2, 0.5 and 1.5 times the MRHD, respectively, based on the BSA comparisons and a 60 kg human weight) and rabbit doses were 1.3, 5.8, and 22.2 mg/kg/day (equivalent to 0.1, 0.4 and 1.6 times the MRHD, respectively, based on the BSA comparisons and a 60 kg human weight). No embryo-fetal effects were observed in rats at the doses tested with the high dose causing increased maternal lethality. An increase in embryo-fetal deaths was observed in rabbits at the high dose in the absence of maternal toxicity.

Decreased pup survival was noted at 1.5 times the MRHD in a rat pre- and post-natal development study when pregnant animals were administered subcutaneous doses of 4.4, 13.3, and 40 mg/kg/day buprenorphine hydrochloride (equivalent to 0.2, 0.5 and 1.5 times the MRHD, respectively, based on the BSA comparisons and a 60 kg human weight) from implantation through weaning (during pregnancy and lactation).

Lactation

Risk Summary

Limited published literature reports that bupivacaine and its metabolite, pipecoloxylidide, are present in human milk at low levels. There is no available information on effects of the drug in the breastfed infant or effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EXPAREL and any potential adverse effects on the breastfed infant from EXPAREL or from the underlying maternal condition.

Pediatric Use

The safety and effectiveness of EXPAREL to produce postsurgical local analgesia via infiltration have been established in pediatric patients aged 6 years and older. Use of EXPAREL for this indication is supported by evidence from adequate and well-controlled studies in adults, and pharmacokinetic and safety data in pediatric patients aged 6 years and older.

The safety and effectiveness of EXPAREL have not been established to produce postsurgical local analgesia via infiltration in pediatric patients aged less than 6 years old, or regional analgesia via an interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, or adductor canal block in pediatric patients.

Geriatric Use

Of the total number of patients in the EXPAREL local infiltration clinical studies (N=823), 171 patients were greater than or equal to 65 years of age and 47 patients were greater than or equal to 75 years of age. Of the total number of patients in the EXPAREL nerve block clinical studies (N= 1046), 312 patients were greater than or equal to 65 years of age and 70 patients were greater than or equal to 75 years of age. No overall differences in safety or effectiveness of EXPAREL have been observed between patients 65 years of age and older and younger adult patients.

In clinical studies, differences in various pharmacokinetic parameters have been observed between patients 65 years of age and older and younger adult patients. Bupivacaine is known to be substantially excreted by the kidney, and the risk of adverse reactions to bupivacaine may be greater in patients with renal impairment than in patients with normal renal function. Because patients 65 years of age and older are more likely to have renal impairment, increase monitoring for EXPAREL-associated adverse reactions.

Hepatic Impairment

Amide-type local anesthetics, such as bupivacaine, are metabolized by the liver. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations, and potentially local anesthetic systemic toxicity. Therefore, consider increased monitoring for local anesthetic systemic toxicity in patients with moderate to severe hepatic disease.

Renal Impairment

Bupivacaine is known to be substantially excreted by the kidney, and the risk of adverse reactions to EXPAREL may be greater in patients with renal impairment than in patients with normal renal function. Therefore, in patients with renal impairment, increase monitoring for EXPAREL-associated adverse reactions.

OVERDOSAGE

Clinical Presentation

Acute emergencies from local anesthetics are generally related to high plasma concentrations encountered during therapeutic use of local anesthetics or to unintended intravascular injection of local anesthetic solution.

Signs and symptoms of overdose include CNS symptoms (perioral paresthesia, dizziness, dysarthria, confusion, mental obtundation, sensory and visual disturbances and eventually convulsions) and cardiovascular effects (that range from hypertension and tachycardia to myocardial depression, hypotension, bradycardia and asystole).

Plasma levels of bupivacaine associated with toxicity can vary. Although concentrations of 2,500 to 4,000 ng/mL have been reported to elicit early subjective CNS symptoms of bupivacaine toxicity, symptoms of toxicity have been reported at levels as low as 800 ng/mL.

Management of Local Anesthetic Overdose

At the first sign of change, oxygen should be administered.

The first step in the management of convulsions, as well as underventilation or apnea, consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as thiopental or thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to the use of anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor dictated by the clinical situation (such as ephedrine to enhance myocardial contractile force).

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted.

Endotracheal intubation, employing drugs and techniques familiar to the clinician, may be indicated, after initial administration of oxygen by mask, if difficulty is encountered in the maintenance of a patent airway or if prolonged ventilatory support (assisted or controlled) is indicated.

DOSAGE AND ADMINISTRATION

Important Dose, Preparation, and Administration Instructions

- EXPAREL is for single administration only.
- EXPAREL is **not** substitutable with other bupivacaine products even if the strength is the same. Therefore, it is not possible to convert a dose from other bupivacaine products to an EXPAREL dose and vice versa.

- Do **not** dilute EXPAREL with water or other hypotonic agents, as it will result in disruption of the liposomal particles.
- Do **not** administer EXPAREL if it is suspected that the vial has been frozen or exposed to high temperature (greater than 40°C or 104°F) for an extended period.
- Inspect EXPAREL visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do **not** administer EXPAREL if the product is discolored.
- Do **not** heat or autoclave before use.
- Do **not** filter during administration.

Recommended Dose for Local Analgesia via Infiltration

Local Analgesia via Infiltration in Adults

The recommended dose of EXPAREL for local infiltration in adults is up to a maximum dose of 266 mg, and is based on the following factors:

- Size of the surgical site
- Volume required to cover the area
- Individual patient factors that may impact the safety of an amide local anesthetic

As general guidance in selecting the proper EXPAREL dose for local infiltration in adults, two examples are provided. In adult patients undergoing:

- Bunionectomy, a total of 106 mg (8 mL) of EXPAREL was administered, with 7 mL infiltrated into the tissues surrounding the osteotomy, and 1 mL infiltrated into the subcutaneous tissue.
- Hemorrhoidectomy, a total of 266 mg (20 mL) of EXPAREL was diluted with 10 mL of saline, for a total of 30 mL, divided into six 5 mL aliquots, injected by visualizing the anal sphincter as a clock face and slowly infiltrating one aliquot to each of the even numbers to produce a field block.

Local Analgesia via Infiltration in Pediatric Patients

The recommended dose of EXPAREL for one-time infiltration in pediatric patients, aged 6 to less than 17 years, is 4 mg/kg (up to a maximum of 266 mg), and is based upon two studies of pediatric patients undergoing either spine surgery or cardiac surgery.

Recommended Dose for Regional Analgesia

The maximum recommended dose of EXPAREL via perineural use for interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and adductor canal block is 133 mg. For all these nerve blocks, administer additional analgesics, which may include other immediate-release local anesthetics, as appropriate (for example, Mayo field block for bunionectomy, infiltration between the popliteal artery and capsule of the knee (IPACK) block for total knee arthroplasty).

Regional Analgesia via Interscalene Brachial Plexus Nerve Block in Adults

The recommended dose of EXPAREL for interscalene brachial plexus nerve block in adults is 133 mg and is based upon one study of patients undergoing either total shoulder arthroplasty or rotator cuff repair.

Regional Analgesia via Sciatic Nerve Block in the Popliteal Fossa in Adults

The recommended dose of EXPAREL for sciatic nerve block in the popliteal fossa in adults is 133 mg and is based upon one study of patients undergoing bunionectomy.

Regional Analgesia via Adductor Canal Block in Adults

The recommended dose of EXPAREL for adductor canal block in adults is 133 mg (10 mL) admixed with 50 mg (10 mL) 0.5% bupivacaine HCl, for a total volume of 20 mL, and is based upon one study of patients undergoing total knee arthroplasty.

Compatibility Considerations

Some physicochemical incompatibilities exist between EXPAREL and certain other drugs. Direct contact of EXPAREL with these drugs results in a rapid increase in free (unencapsulated) bupivacaine, altering EXPAREL characteristics and potentially affecting the safety and efficacy of EXPAREL. Therefore, admixing EXPAREL with other drugs prior to administration is **not** recommended.

- Non-bupivacaine based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more.
- Bupivacaine HCl administered together with EXPAREL may impact the pharmacokinetic and/or physicochemical properties of EXPAREL, and this effect is concentration dependent. Therefore, bupivacaine HCl and EXPAREL may be administered simultaneously in the same syringe, and bupivacaine HCl may be injected immediately before EXPAREL if the ratio of the milligram dose of bupivacaine HCl solution to EXPAREL does not exceed 1:2.

  The toxic effects of these drugs are additive and their administration should be used with caution including monitoring for neurologic and cardiovascular effects related to local anesthetic systemic toxicity.
- When a topical antiseptic such as povidone iodine (e.g., Betadine®) is applied, the site should be allowed to dry before EXPAREL is administered into the surgical site. EXPAREL should not be allowed to come into contact with antiseptics such as povidone iodine in solution.

Studies conducted with EXPAREL demonstrated that the most common implantable materials (polypropylene, PTFE, silicone, stainless steel, and titanium) are not affected by the presence of EXPAREL any more than they are by saline. None of the materials studied had an adverse effect on EXPAREL.

CLINICAL PHARMACOLOGY

Pharmacokinetics

After administration of EXPAREL, the systemic plasma levels of bupivacaine were observed for 96 hours after local infiltration, 120 hours after interscalene brachial plexus nerve block, 168 hours after sciatic nerve block in the popliteal fossa, and 168 hours after adductor canal block. In general, peripheral nerve blocks have shown systemic plasma levels of bupivacaine for extended duration when compared to local infiltration. Systemic plasma levels of bupivacaine following administration of EXPAREL are not correlated with local efficacy.

PATIENT COUNSELING INFORMATION

Inform patients that use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. Advise patients or caregivers to seek immediate medical attention if they or someone in their care experience the following signs or symptoms: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue.

Inform patients in advance that EXPAREL can cause temporary loss of sensation or motor activity that may last for up to 5 days.

Manufactured for Pacira Pharmaceuticals, Inc.,
a wholly owned subsidiary of
Pacira BioSciences, Inc.
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For additional information call 1-855-RX-EXPAREL (1-855-793-9727) or visit www.EXPARELpro.com

Rx only
October 2025

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It's All in the Details

ST108 & its impact on water quality standards for medical device processing

Having high standards of cleanliness and safety is non-negotiable in healthcare. Every reusable medical device must be processed correctly to prevent healthcare-associated infections (HAIs) and protect patients. One critical standard shaping this effort is **AAMI ST108**, introduced by the Association for the Advancement of Medical Instrumentation (AAMI). This guideline establishes water quality requirements for cleaning, disinfection and sterilization processes—an often-overlooked but essential component of sterile processing.

At **HealthTrust Connect 2025**, industry leaders gathered for a panel session focused on the updated standard to unpack what this means for healthcare organizations and how to implement it effectively.

Continued on page 38

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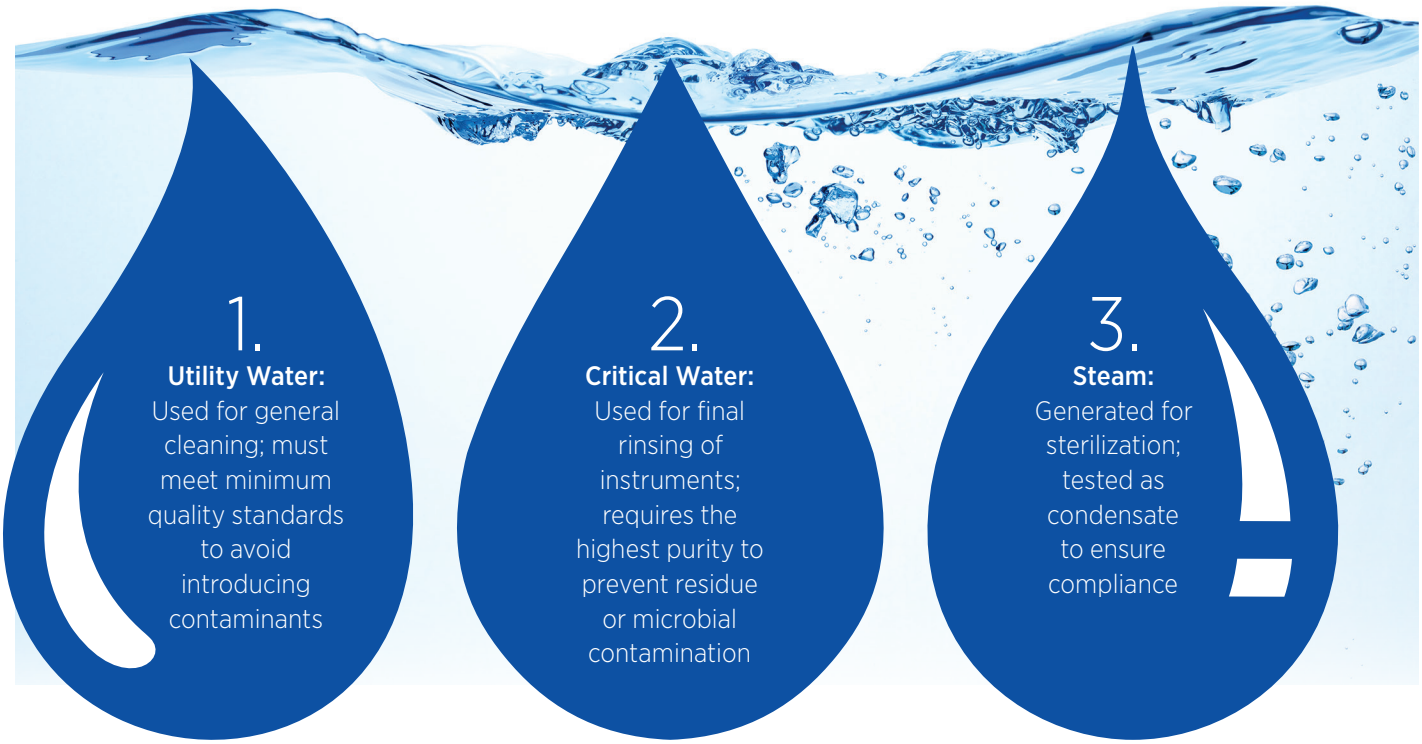
ST108 categorizes water into three main types:



Continued from page 36

What is ST108?

ST108 replaces previous guidelines, known as AAMI TIR34, and serves as a blueprint for water quality management in medical device processing. It provides detailed guidance on:

- Selecting appropriate water quality for different stages of reprocessing
- Treatment and distribution systems
- Monitoring and corrective actions
- Strategies for bacterial control and environmental impact

The goal is simple, yet critical: Ensure that water used in sterile processing does not compromise device cleanliness or patient safety. Poor water quality can lead to mineral deposits, biofilm formation and ineffective sterilization—all of which increase infection risk and threaten compliance with Joint Commission requirements.

Why it matters

Water is the foundation of every cleaning and sterilization cycle. If water quality is inconsistent, even the most advanced sterilizers and washers cannot perform optimally. As one panelist shared, the intent is patient safety. While compliance will

Jeffrey Keane, BSN, RN, CNOR, Director of Perioperative Projects, Perioperative Services, is helping lead the implementation process at Beth Israel Deaconess Medical Center. He offers three practical tips for other leaders looking to implement ST108:

Tip #1: Work closely with sterile processing, consultants & equipment suppliers to ensure your system meets capacity needs during peak sterile processing hours.

Tip #2: Having Infection Control team members at the table is critical. They help risk-stratify what happens if you don't comply versus the long-term benefits of investing in compliance.

Tip #3: Location is key. These systems take up a large footprint, so you need immediate visibility for monitoring, audible alarms & maintenance activities.

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Continued on page 40

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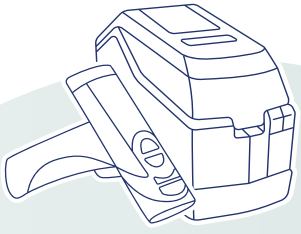

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Continued from page 38

look different for every facility, the end goal is the same. ST108 provides a road map for healthcare facilities to:

- Reduce HAIs
- Maintain accreditation readiness
- Protect expensive surgical instruments from damage caused by impurities

Implementation best practices

Jennifer Westendorf

"Surveyors are already asking about ST108, even if enforcement hasn't started. It's more of a standard now—it uses language like 'shall' and 'must,' not just 'should,'" said one panelist about the imminent requirements for healthcare facilities.

"Implementing ST108 requires a collaborative approach, as it involves teams and departments that include Facilities, Maintenance, Infection Control, Sterile Processing leadership and clinicians," said panel moderator **Jennifer Westendorf**, DNP, RN, CNOR, Assistant Vice President, Environmental Performance & Surgical Services at HealthTrust. Constant communication with these teams is essential—especially when planning around disruptions that are likely to occur during installation.

Senior leadership must understand that these new standards are a significant capital investment, but they have meaningful impact on patient safety and operational efficiency.

Roles & responsibilities

Compliance with ST108 is more than a regulatory checkbox—it's a commitment to patient safety and operational excellence. Facility managers help oversee infrastructure and ensure compliance, while Sterile Processing personnel monitor water quality during device reprocessing. Infection Control specialists can develop systemwide policies and assess risk, while Clinical Engineering teams design and maintain water treatment systems.

This multidisciplinary collaboration ensures every aspect of water use is safe, effective and compliant.

While change won't happen overnight, starting before the standard becomes mandatory will be helpful. As one panelist summed it up: "You don't want to tell a surveyor you're six months away from compliance."

READY TO START?

Listen to the full session that was held on this topic during HealthTrust Connect at share.vidyard.com/watch/2wng8t4nKi92FZridZquK

Asia-Pacific Images Studio via Getty Images

HealthTrust contracted suppliers for water treatment & sterile processing

Within the Commercial Portfolio

The suppliers listed below can provide specific water processing and monitoring services and equipment to support HealthTrust members creating a plan to meet ST108. In coordination with the facilities, they will work to achieve agreed-upon water system designs and water quality best practices based on the health of local water and the engineering data, operational projections and space considerations provided by the facility. Contracted suppliers include:

Chem-Aqua, Inc. (Contract #7104)
Southwest Engineers (Contract #135726)
Nalco Co., LLC (Contract #3923)
Garratt-Callahan Co. (Contract #3968)
Chemtreat, Inc. (Contract #7271)

Within the Med/Surg Portfolio

To minimize issues with sterile processing equipment, leaders should collaborate with their facilities teams and sterile processing equipment suppliers like the ones below to ensure the appropriate water is being utilized for each phase of the decontamination and sterilization process. Contracted suppliers include:

Getinge (Contract #81849)
Steris (Contract #4675)

FOR MORE INFORMATION about HealthTrust contracted suppliers in the water treatment and sterile processing categories, reach out to your HealthTrust Account Manager or contact the Commercial team at commercial@healthtrustpg.com

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The Results Are In!

Members share feedback through annual satisfaction survey

Annually, the membership is given an opportunity to provide feedback through the organization's Member Satisfaction Survey. Results are compiled and reviewed with the HealthTrust executive team. The insights help leaders and their teams prioritize initiatives for the coming year and evolve the organization's services to best meet member needs.

In the 2025 survey, 88% agreed that HealthTrust's contracting philosophy, focused on member commitment and contract portfolio compliance, enhances overall value. HealthTrust members were also asked to rate their level of satisfaction in certain areas. The following showcases the percentage of those who responded "Extremely Satisfied" or "Satisfied." ●

> **"I have worked in healthcare supply chain management for years. Throughout my tenure, our hospital has switched GPOs. Overall, HealthTrust is the very best & none of the competitors can match their pricing. Large or small, hospitals get the best pricing through HealthTrust."**
>
> HealthTrust member

88%
Quality of Products & Services

86%
Depth & Breadth of Contract Portfolio

83%
Price Advantage Relative to Other GPOs

78%
Purchased Services Contract Portfolio

Tell me more ...

Top capabilities members would like to know more about:

- **Purchased Services Portfolio** | Delivering cost savings, enhancing service quality & streamlining procurement in complex categories such as laundry & linen, security staffing, blood & waste services. Learn more by emailing **commercial@healthtrustpg.com**
- **340B Support** | Providing program compliance, optimization support & legal landscape consultation for covered entities. Learn more by emailing **pharmacy360@healthtrustpg.com**
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Continued from page 6

If done correctly, physicians are willing to get on board with supply chain transformation when they are confident that a health system is putting patients first. Physicians view managing these costs as part of their responsibility and indicate they would like to be involved with supply chain initiatives.

Supply chain as a strategic clinical partner

Through physician engagement, data-driven decision-making and a structured approach to value analysis, progressive health systems have demonstrated how the supply chain can evolve from an administrative function into a strategic clinical partner.

Overcoming physician objections requires effective communication, data-driven decision-making, collaboration and the right GPO partner. A recent study analyzing the effectiveness of healthcare GPOs found no evidence that their reduction of supply expenses comes at the cost of the quality of care, nor by means of selective patient admission.

Margin maximization is possible

At HealthTrust Performance Group our prescription for improving provider performance involves aligning physician, clinical, operational and financial leadership to drive cohesive decision-making and implementation. Our Performance Solutions team is made up of operators and business advisors who accelerate the delivery of margin maximization through the alignment of both clinical and financial goals. One of the tools used by our performance experts is Crimson AI powered by HealthTrust. Read more beginning on page 28 of this edition. ●

YOUR TURN

Ready to implement a systemwide approach to solving your organization's challenges? Reach out to me or your HealthTrust Account Manager to start the conversation. Our Performance Solutions experts stand ready to deliver measurable results. In the meantime, stay well.

Read the "5 essential steps to overcoming physician objections" in the online version of this article

More Value at the Table

HealthTrust's second live bidding event delivers additional savings while strengthening member alignment & supplier partnerships

Through HealthTrust's live bidding events, members who participate can benefit from additional savings on equipment and medical supplies while achieving their standardization goals.

"The objective of a HealthTrust-initiated live bidding event is to gain additional value for members who commit to a specific supplier through a competitive and transparent bidding process," explains Strategic Sourcing Assistant Vice President **Junette Grant**, a co-leader of the recent live bidding initiative.

Junette Grant

Jennel Lengle

Jennifer Westendorf

To date, HealthTrust has hosted two live bidding events—the most recent one in September for monopolar supplies. Member participation has increased since the inaugural event that focused on operating room surgical tables. "We certainly built on the momentum of the first live bidding event we held last year, going from seven participating health systems to eight this time around," shares **Jennel Lengle**, MSN, RN, Vice President of Supply Chain Board & Clinical Operations.

With a vision of creating a more dynamic and interactive negotiation experience, the live bidding concept was the brainchild of the late Michael Berryhill. (He served as HealthTrust's President of GPO Operations from 2013 to 2025.)

Selecting a category

HealthTrust relies on its members to assist in identifying contract categories to consider for a live bidding event. The organization targets categories where its clinical boards determine it is necessary for the GPO to contract as a multisource due to several factors (resiliency, install base, etc.). There are, however, health systems with the capability to standardize and commit further through a live event. "The voice of the member plays a critical role," says **Jennifer Westendorf**, DNP, RN, CNOR, Assistant Vice President of Environmental Performance & Surgical Services. "Early on, our Sourcing team surveyed members from both the Surgical Advisory Board and the Supply Chain Board to get their input on what would be most impactful for them."

> **"We were able to leverage the live event to gain even more value for the entire HealthTrust membership."**
>
> **Junette Grant**

Members of the Surgical Advisory Board connected directly with participating suppliers leading up to the event, and viewed their products live during August's HealthTrust University Conference in San Antonio. Board members completed a clinical scorecard, which included criteria that the participating members agreed upon, such as safety features, device ergonomics, ease of use, universal compatibility, breadth and depth of product portfolio and overall performance. This initial clinical review ensured that all suppliers participating in the event had clinically acceptable products and portfolios that could support the members participating.

Choosing the supplier

Members included in the recent live bidding event committed to purchase from the winning supplier over a fixed period of time. Given past supply shortages in the monopolar supplies category,

the bidding process was rigorous. Members used a weighted scorecard to evaluate the bids, and suppliers had the opportunity to demonstrate their inventory readiness and the overall health of their supply chain.

After multiple in-person rounds of clinical and financial vetting, the participating members identified the "winning" supplier based on clinical, financial and supply chain resiliency factors. Post event, members said that they enjoyed connecting and collaborating with one another, and how positive the experience was. Westendorf shares that the organization is excited to host more of these events in the future.

Ready to participate in a future live bidding event or have a category for us to consider? Reach out to your HealthTrust Account Manager today or post it to the HealthTrust Huddle.

Why members participate

HealthTrust's live bidding events give members the opportunity to:

- Achieve additional savings beyond standard contracting
- Advance standardization goals
- Evaluate suppliers through a clinically driven, transparent process
- Strengthen collaboration with peer health systems

How a live bidding event works

1 Members help identify the contract category
2 Clinical boards vet suppliers using a standardized scorecard
3 Suppliers participate in live competitive bidding
4 Members commit to a winning supplier for a fixed term

HealthTrust Connect 2025 Highlights

HealthTrust's largest gathering exclusively for Healthcare Construction, Facilities and Energy professionals—HealthTrust Connect 2025—brought together more than 400 members, staff, suppliers and trade partners for two days of education, networking and solution-focused discussions. The aptly named event served as a hub for connections, addressing some of the most pressing challenges in healthcare today—cost containment and technology adoption.

"The conversations at HealthTrust Connect reflect the urgency and opportunity in healthcare today—how we can align strategies to deliver value in these categories," says **Paige Dodson**, Senior Director, Construction & Facilities.

Paige Dodson

Connect is where collaboration meets innovation—helping members tackle today's challenges & prepare for tomorrow's opportunities.

In between networking opportunities and sessions, exhibitors showcased their contracted healthcare construction and facilities products, services and solutions to HealthTrust members through an exhibit hall, including:

- Mechanical
- Electrical & Lighting
- Plumbing
- Flooring
- Roofing
- Medical Gases
- Prefabrication
- Water Treatment

Impactful education

Networking and education are at the heart of HealthTrust Connect, with the goal of providing members access to solutions and content they can take back to their organizations and turn into actionable insights. Highlights included:

Water Treatment for the Processing of Medical Devices (ST108): A deep dive into AAMI's new water quality standard and its implications for sterile processing and patient safety (see article on pg. 36).

Strategic Risk Mitigation for Healthcare: Disaster Preparedness & Restoration: Practical strategies for minimizing operational disruptions and ensuring continuity of care during emergencies.

Continued on page 48

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HealthTrust's Performance Solutions are the key to *unlocking* operational and financial improvement for leaders.

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Discover the *key* to better performance.

Continued from page 46

GENSHIFT: "Exploring Generations in the Workforce" was the keynote delivered by Generational Strategist **Dr. Katherine Jeffery**. Attendees divided up by generation and learned how those dynamics influence workplace culture, leadership styles and team collaboration—critical insights for any organization managing a diverse workforce.

By combining education, collaboration and innovation, HealthTrustConnect equips leaders with the tools and relationships they need to navigate healthcare's complex landscape and deliver meaningful improvements in patient care and operational performance. ●

Ready to identify new ways you can improve your construction and facilities management? Scan the QR code to download HealthTrust's Construction & Facilities Playbook for more actionable insights.

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