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A CULTURE OF SAFETY

David Stepansky, M.D., reflects on initiatives at CHS & a new national action plan that advances patient & workforce safety

LESSONS IN INFECTION PREVENTION

Top takeaways from the COVID-19 front lines

SWIFT, SAFE & SOUND

The planning & logistics involved in delivering a COVID vaccine

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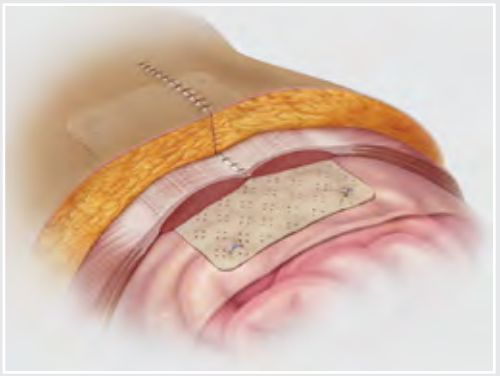

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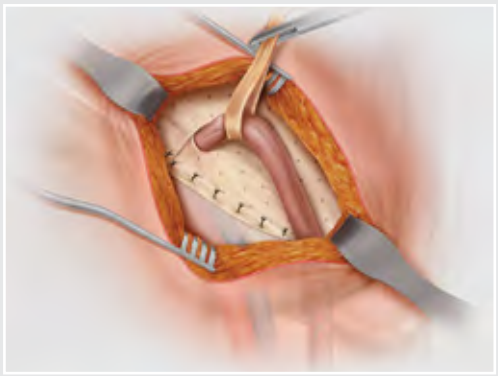

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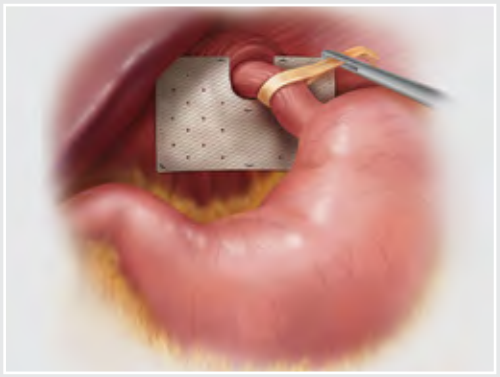

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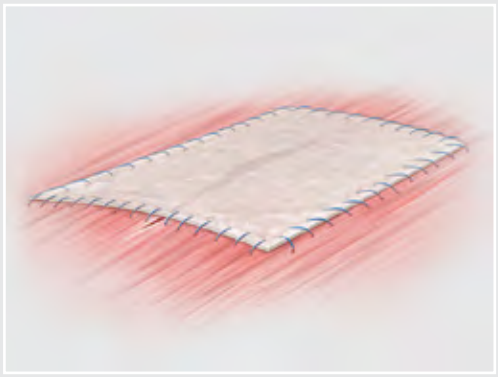

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FEATURES

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

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

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

Member address changes: Contact **hpgsvc@healthtrustpg.com**
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Mail: *The Source*, c/o HealthTrust, 1100 Dr. Martin L. King Jr. Boulevard, Suite 1100, Nashville, TN 37203

HealthTrust (Healthtrust Purchasing Group, L.P.) is committed to strengthening provider performance and clinical excellence through an aligned membership model and the delivery of total spend management advisory solutions that leverage our operator experience, scale and innovation. Headquartered in Nashville, Tennessee, HealthTrust (**healthtrustpg.com**) serves over 1,600 hospitals and health systems, and more than 55,000 other member locations, including ambulatory surgery centers, physician practices, long-term care and alternate care sites. Follow us on Twitter **@healthtrustpg**.

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Ed Jones
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EXECUTIVE PUBLISHER & EDITOR-AT-LARGE
John Young, M.D., MBA, CPE, FACHE
Chief Medical Officer

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

EXECUTIVE EDITOR
Faye Porter
Director, Member Education & Communications, Clinical Services

CONTRIBUTING EDITOR
Shellie Meeks
Manager, Member Education & Communications, Clinical Services

EDITORIAL & CREATIVE SERVICES
Cara Finnegan
Editor, GLC

Paula Rosenberg Frey, BSN, MS
Contributing Editor, GLC

Enrique "Rick" Cruz
Art Director, GLC

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CEO perspective

Strengthening the supply chain

The pandemic revealed to hospitals across the country the impact of relying on foreign manufacturers to supply the vast majority of much-needed personal protective equipment (PPE). For HealthTrust, it presented an opportunity to explore U.S. diversification of some of those supplies.

As we explain in more detail on page 48 of this edition, finding a partner for domestic mask production is one critical step among others toward creating a more secure supply chain for our membership. Up and running just a year from the time that **Rosalind Holloway**, Vice President of Global Sourcing, initiated the idea, HealthTrust is supporting a joint-venture between HCA Healthcare and a company that will manufacture level 1 and level 3 masks in the United States. We will also continue to support the evaluation of other opportunities to diversify the portfolio of products manufactured in the U.S.

2020 SURVEY RESULTS

HealthTrust identifies opportunities for improvement and benchmarks member satisfaction annually. The most recent Member Satisfaction Survey was conducted entirely by email in the third quarter since a live HealthTrust University Conference did not take place in 2020.

Of the members responding to the 100-question survey, 83% believe that HealthTrust provides a superior value in the marketplace relative to other group purchasing organizations (GPOs)—up from 79% in 2019. Other high levels of satisfaction include the depth and breadth of our contract portfolio, the quality of products and services offered, customer service, account management, strategic sourcing, strong values, the leadership team and healthcare education offerings.

Along with a competitive market assessment, industry research and feedback from member business reviews, results from the survey are utilized as part of our planning process for each new year.

All survey findings and recommendations are reviewed in detail by each department, with action items developed to address opportunities for improvement. I am also pleased to share that in response to member feedback from previous years, we recently launched an updated commitment system to process LOCs (letters of commitment), and a new contract catalog system to replace CatScan is expected to launch in 2021.

WELCOME NEW MEMBER

I'd like to welcome to membership the New Orleans-based healthcare system, LCMC Health, and its acute care facilities (Children's Hospital New Orleans, New Orleans East Hospital, Touro Infirmary, University Medical Center New Orleans, West Jefferson Medical Center and East Jefferson General Hospital). In addition to LCMC accessing the GPO portfolio, we look forward to implementing value-added services benefiting ambulatory, ancillary and physician practices affiliated with LCMC Health.

The HealthTrust team and I look forward to serving all of the membership throughout the new year, and thank you for your commitment and trust in us. Here's to a healthy and happy 2021! **HT**

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

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CMO perspective

Vaccines offer a glimmer of hope

Because of timeliness and fluidity of information, I hesitated writing about the COVID-19 vaccine in a quarterly column. However, I'd be remiss to not address the importance of this topic, since news of the pandemic and its spread dominated not only hearts and minds, but also healthcare headlines for the first three quarters of 2020.

With anticipation building, news in quarter four shifted to details surrounding the warp speed-to-market of a preventative vaccine, offering what many hope is a glimpse toward some end in sight to what has been an unforgettable year in world history, to say the least.

HealthTrust offered a vaccine webinar in mid-November, providing nearly 700 attendees with information on the numerous U.S. candidates seeking approval and what healthcare providers need to do to prepare for the vaccine's arrival. HealthTrust colleagues **Jason Braithwaite**, PharmD, MS, BCPS, and **Karen Bush**, MSN, FNP, BC, NCRP, offered their insights on clinical and operational topics that included the logistics related to the highly complex distribution of this vaccine, with both delivery and storage impacted by the ability to maintain a cold chain.

SCALING DISTRIBUTION

Operation Warp Speed (OWS), led by the Department of Health and Human Services and the Department of Defense, will assist in delivering 300 million doses of the COVID-19 vaccine. The distribution of these vaccines has been described as the hardest undertaking since WWII. At the time of this writing, military liaisons and regional coordinators are collaborating on how vaccines will be prioritized, packaged and shipped.

OWS is utilizing the Tiberius platform to integrate data related to manufacturing, clinical trials, supply chain, allocation, state and territory planning, delivery and administration. All 50 states submitted COVID-19 distribution plans which will help the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices determine how to prioritize allocation of the limited doses that will be available initially. Using several logistical factors, Tiberius will compute the quantities to be allocated to each jurisdiction; the jurisdictions will use the data to decide where every allocated dose will be distributed. These decisions will then be sent to distributors to complete delivery across the country.

SETTING EXPECTATIONS

Based on interim data, Physician Advisor **Kelly Moore**, M.D., MPH, President of the Vaccine Advisor and Associate Director of Immunization Education with the Immunization Action Coalition, shares on page 29 that scientists expect the two-dose COVID-19 vaccine to perform similarly to the influenza vaccine and not to provide a level of full protection as, say, the measles vaccine. While it will be a critical tool in fighting this pandemic, wearing masks, practicing good hand hygiene and distancing are behaviors that will remain essential for the foreseeable future. **HT**

John Young, M.D., MBA, CPE, FACHE
Chief Medical Officer, HealthTrust
Executive Publisher & Editor-at-large, *The Source* magazine

ACCESS up-to-date COVID & vaccine-related resources at education.healthtrustpg.com/covid-19-resources/#vaccine-information

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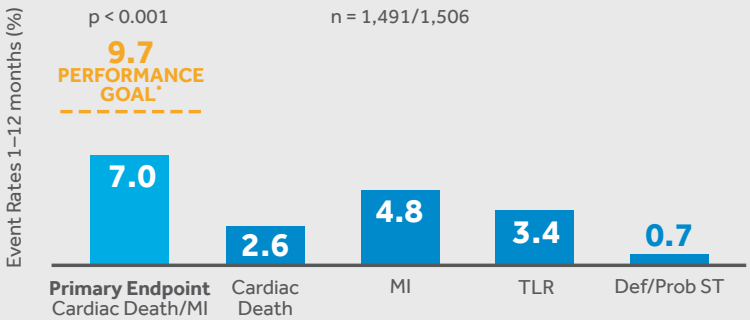

Highly Complex Patient Population[2]

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*Performance goal derived from contemporary 1-month DAPT trials, including ZEUS, LEADERS FREE, and SENIOR trials.
†Matching LEADERS FREE inclusion criteria.
[1]Resolute Onyx DES IFU.
[2]Kirtane A, et al. One Month Dual Antiplatelet Therapy in High Bleeding Risk Patients: Primary Results of Onyx ONE Clear. Presented online at ACC 2020.

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Keeping watch when it matters most

HealthTrust's 'COVID Squad' provides critical information & education to members amid ever-evolving regulatory guidance

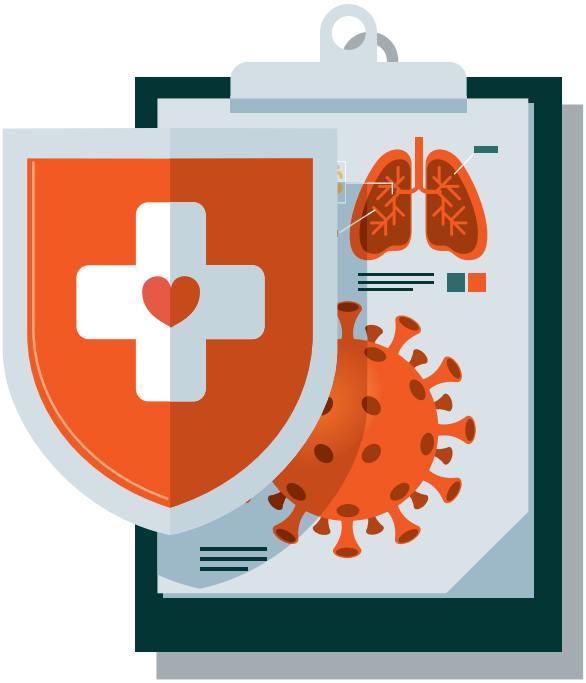
Keeping up with change is seldom as challenging as it's been for HealthTrust's "COVID Squad," which has mounted a monumental effort to educate members about the new disease, treatments and products, amid a constantly shifting landscape—including monitoring regulatory sites for updates on best practices during the global health crisis.

Before they focused on COVID-19, many members of this group, comprised mostly of nurses who are experts in research and education, consulted with hospitals to improve quality outcomes primarily in the cardiac and orthopedic service lines. Others had long-provided clinical documents, comparative product feature summaries and other resources to keep HealthTrust members informed about products and procedures.

"The pandemic shifted our attention to a sole focus of getting accurate and up-to-date information on every aspect of COVID-19 to all of our members," explains **Karen Bush**, MSN, FNP, BC, NCRP, Director of Clinical Research & Education, Clinical Services.

The quickly evolving guidance from the Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), and Centers for Disease Control and Prevention (CDC) on matters such as personal protective equipment (PPE) and its use, as well as decontamination procedures, made vigilance imperative.

"Because COVID and its treatment process is rapidly changing, each nurse [in the squad] was given an area of



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focus and a site they're assigned to monitor," Bush says. "We create and publish educational resources for staff and patients on the disease and treatment. As we receive questions from members at various integrated delivery networks [IDNs], we research and then respond with the best evidence that is currently available on related tools, products or methods."

While the flurry of regulatory guidance modifications has tapered somewhat since the early days of the crisis, HealthTrust's COVID Squad continues its vigilance and has added more than 150 pandemic-related documents to the organization's public education site. HealthTrust Physician Advisors are often tapped for assistance on these documents, reviewing data and lending their particular insights and experiences.

"We not only created the resources, but we continue to update them as information changes," says **Sarah Michel**, MBA, BSN, RN, NE-BC, Director of Research & Clinical Engagement at HealthTrust. "As the focus of providers shifted to the COVID-19 vaccination, we began creating vaccine-related support documents, infographics and a webinar—all promoted through our websites and social media." (See page 29 for more on the COVID-19 vaccine.)

With scientific evidence on the SARS-CoV-2 virus and its ramifications generated daily, Bush and Michel agree that HealthTrust members need to remain vigilant about staying informed. **HT**

TO LEARN MORE, visit education.healthtrustpg.com/covid-19-resources

FDA KEEPS PACE WITH RAPID CHANGE

When the coronavirus pandemic prompted car manufacturers to produce ventilators and clothing companies to make face masks, the Food and Drug Administration (FDA) had to be equally nimble to ensure the safety of medical device products. It stepped up to the challenge by:

- Creating 10 emergency use authorization (EUA) templates and 23 guidance documents to provide regulatory flexibility and accommodate innovation
- Issuing 516 medical-device EUAs—nearly 10 times the number authorized in all prior national emergencies
- Reaching out to more than 1,000 manufacturing sites across 12 countries to assess supply chain vulnerabilities
- Sending 13.7 million emails to stakeholders on COVID-19 topics, among other efforts

"The EUA was a path that helped hospitals get things they desperately needed—such as ventilators, gowns, gloves and tests—and also encouraged the FDA to examine and refine its larger process," explains **Angie Mitchell**, RN, AVP of Clinical Research and Education at HealthTrust. "It also used different ways to reach out and respond to emails and phone queries, and stepped up its monitoring of websites, advertising and product claims."

See page 22 for an infographic about how the FDA responded to the unprecedented clinical demands of the pandemic from January through September 2020.

HEALTHTRUST'S COVID SQUAD

HealthTrust's COVID Squad is a team of researchers, writers and consultants with nursing and other expertise. Squad members include:

Clinicians:
Karen Bush, MSN, FNP, BC, NCRP
Sarah Michel, MBA, BSN, RN, NE-BC
Angie Mitchell, RN
Holly Moore, RN, MSN, CCRN-K
Kym Smith, RN
Kyla Stripling, MMHC, MSN, ACNP
Kim Wright, RN

Editorial & Design:
Faye Porter
Emily Wright

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Revisiting the rules

The COVID crisis redefines requirements for visitors & suppliers

When the COVID-19 crisis made it necessary for hospital visitors—even hospitalized patients' family members—to stay away, it only made sense that suppliers would face similar restrictions to ensure their own safety, along with that of staff and patients. But creating revised policies around this unique circumstance has proven to be daunting for some facilities, prompting HealthTrust to share example protocols and templates to smooth the path forward.

"On a typical pre-pandemic day in a healthcare setting, tons of suppliers were dropping off new products, assisting with procedures and exchanging old products for new," says **Sara Crittenden**, Vice President of Strategic Accounts at HealthTrust. "What COVID created was really a mandate: If you're not vital to this hospital, you're not allowed in."

Crittenden adds that some of those reductions in visits happened naturally: "With no elective procedures taking place, that automatically cut back and restricted the number of reps in our members' facilities," she says. "But they still needed protocols in place in the event a rep was onsite. And they had to figure out how to handle reps coming back for an essential purpose."

Some HealthTrust member facilities were quick to create work requirements governing supplier visits shortly after the pandemic emerged, while others had questions about the best way to implement new processes. Crittenden and her colleagues collected samples of member policies and drafted examples of guidelines other members could adapt to meet their own needs. "To me, one of the benefits of being part of a GPO [group purchasing organization] is learning from your peers," she explains.

New restrictions around supplier visits typically require that they do the following:

- Prove visits are "mission critical," such as those that provide support in specific procedural cases
- Complete internal assessment and approval forms before visits are approved and scheduled
- Check-in only through a defined entrance
- Complete a screening at check-in, such as temperature checks, face-mask usage and COVID-19 questionnaires
- Avoid lingering after an approved visit

"If a rep shows up and is turned away, that's obviously a problem," Crittenden says, adding that time and money are both wasted in such a scenario. "The importance of respecting everyone's time and the rules that govern engagement is a big piece of this."

Many HealthTrust members identified specific protocols based on their facilities' needs and specialties, Crittenden explains. "Most of our members have infectious disease protocols, safety and risk management, and clinical expertise," she says. "Those were the different groups that usually weighed in and had opinions on how this would be handled."

Regardless of which specific protocols a facility adopts, clear and precise communication about the policies to suppliers is a must.

As the conditions of the pandemic fluctuate, so too must healthcare facilities' requirements, Crittenden says.

"Certain regions are having their highest cases of COVID-19 to date. Facilities know they'll put these protocols in place and may have to change them in very short order to protect patients and clinicians," she says. "But in healthcare, and especially in supply chain, there are always new regulations they have to enforce and change. I think our customers probably adapt better than most." **HT**

VISIT the Vendor & Supplier Visits During COVID-19 toolkit on the HealthTrust clinical resources site at education.healthtrustpg.com/SupplierVisits

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A 'new existence'

COVID-19 challenges hospitals to rethink the patient experience

While a lot has changed in hospitals since COVID-19, the fundamentals of a quality patient experience haven't changed at all, according to **Jason Wolf**, Ph.D., CPXP, President of The Beryl Institute, a global community of practice dedicated to improving the patient experience through collaboration and shared knowledge. In fact, these fundamentals have only been elevated by what we've learned throughout the pandemic.

"The power of human connection has been realized to a much greater extent," says Wolf.

THE VALUE OF TOGETHERNESS

COVID-19 has forced us to create space—space between patients, families and healthcare workers. For many, the results are feelings of isolation and burnout.

As hospitalized patients have had severe restrictions when it comes to visitors, staff have found new ways to fill the gaps in human connection. "They are not only holding the hand of a patient as they die, but they're also holding the phone or iPad in front of them for the family member on the other end," says Wolf.

An added challenge is that without the patients' loved ones there to provide important information about the patient, there are barriers to giving care. This environment puts healthcare professionals under an incredible amount of pressure, so it's no surprise that many feel some level of exhaustion.

"All of this has elevated the importance of not just the patient and family experience, but also the experience of all those who show up every day to provide care," says Wolf.

PAUSING DATA COLLECTION

As the pandemic caused hospital surges in many areas of the United States, it instantly changed a number of aspects of patient care, skewing data benchmarks. To account for this, and to help free up clinicians from paperwork so they could place all of their focus on caring for patients, the Centers for

Medicare & Medicaid Services (CMS) waived many reporting requirements for Medicare quality data.

The Hospital Inpatient Quality Reporting Program data, which includes the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey data, a national survey of patients' perspectives of hospital care, was made optional in the fourth quarter of 2019. It also removed data requirements for the first two quarters of 2020.

Attempting to use the data to compare hospitals and reimburse them would be challenging, at best. "It would be like playing baseball in a football stadium. The stats wouldn't make any sense," Wolf says.

CONSIDERING THE QUALITY OF VIRTUAL CARE

Still, hospitals are paying attention to HCAHPS, which remains an important window into understanding what matters to patients. One thing we've learned in 2020 is that healthcare innovation can move a lot faster than previously thought. We are finding new ways to connect with people through telehealth—the use of which has increased exponentially across the country.

"Healthcare organizations have realized that virtual visits provide a better experience for some patients because they don't have to drive, wait in traffic, pay to park in a garage or sit in a waiting room," says Wolf. He predicts that models of care will be challenged in a positive way because they will be consumer-driven.

OUT OF MANY, ONE SHARED EXPERIENCE

The future of optimal healthcare quality is viewing the care team as one that includes patients, families and providers. It's important to consider the well-being of every member of the care team because they are interconnected. "We have to think about them as a whole. Otherwise, we are shortchanging the experience," says Wolf.

As we continue to move through this COVID crisis, healthcare leaders will need to keep rethinking the field as patient expectations have changed, including how we connect with one another and how we create a more equal experience for all.

"It's no longer the new normal," says Wolf. "It's the new existence." **HT**

SUPPLY & DEMAND

Out of a pandemic, PPE best practices emerge

PRIOR TO COVID-19, PERSONAL PROTECTIVE EQUIPMENT (PPE) WAS LIKELY TAKEN FOR GRANTED IN MANY HOSPITALS AND HEALTH SYSTEMS. But when the pandemic hit in March 2020, hospitals went from needing PPE for a small targeted population in specific circumstances, to needing some form of PPE for virtually everyone in most care scenarios. Fears that hospitals across the United States would run out of PPE became a reality for some.

"Before COVID-19, if a patient was on isolation or precautions, you would open the drawer to the isolation cart and it was all there for you—the mask, the hat, the gown, the gloves," says **Angie Mitchell**, RN, AVP, Clinical Services at HealthTrust. "This has been a pretty significant wakeup call."

The concerns around PPE supply and demand during the pandemic have led clinicians and supply chain professionals to reflect on what was being used and for what purpose—for example, in some cases staff with low risk of exposure and no patient contact would wear N95 masks. As shortages loomed, those practices and others were reevaluated.

"At HealthTrust, we have used evidence-based care to show that not everyone needs an N95 mask," says **Sarah Michel**, MBA, BSN, RN, NE-BC, Director of Research & Clinical Engagement at HealthTrust. "Appropriate PPE use at the appropriate time has helped conserve PPE."

SOURCING & CONSERVING

Mitchell, Michel and their colleagues at HealthTrust continue to evaluate alternative potential sources of masks, gowns, shields, gloves and other PPE products, monitoring the Food and Drug Administration (FDA) for updates. For instance, to help hospitals through the initial crisis period, the FDA issued emergency use authorizations (EUAs) for some masks and other PPE products not normally used in healthcare settings.

The Centers for Disease Control and Prevention's (CDC) PPE Burn Rate Calculator has been an important tool in predicting how quickly hospitals will go through PPE compared to baseline use. "The calculator helps providers have a better handle on what they need during a surge, so they know when they are reaching crisis mode," says Michel. The PPE Burn Rate Calculator can be found on HealthTrust's clinical resources site at **education.healthtrustpg.com/PPECalculator**

Before COVID-19, hospital supplies would sit at-the-ready on a shelf. When something got down to par level, it would be reordered. But everything changed during the pandemic. "Once COVID-19 hit, all of a sudden, par levels weren't valid anymore," says Mitchell. "Hospitals started to look at how to get back on top of this and conserve PPE."

> "Once COVID-19 hit, all of a sudden, par levels weren't valid anymore. Hospitals started to look at how to get back on top of this and conserve PPE."
>
> – Angie Mitchell, RN

One conservation strategy has been to decontaminate and safely extend the life of products that are otherwise intended for one-time use. To that end, the FDA has granted EUAs for vaporized hydrogen peroxide and steam sterilization decontamination systems.

CENTRALIZED DISTRIBUTION

"If PPE is all over the facility, it's hard to calculate the actual amount available," says Michel. That's why many hospitals have centralized all of their PPE to one location for distribution and safe keeping on supply versus demand, helping to maintain accurate supply levels.

Many facilities have adjusted how PPE is distributed, with one staff member serving in the role of gatekeeper—handing out PPE to hospital employees and keeping the rest secured for more controlled use. HealthTrust outlined this type of PPE management for members as part of our PPE toolkit available at **education.healthtrustpg.com/PPEToolkit**

LOOKING FORWARD

Now more than ever, hospitals have awakened to the need to remain diligent about having their supply pipelines carefully managed. Mitchell and Michel indicate that product shortages are still a valid concern, as are product validity and integrity, especially in light of possible future surges of COVID-19. Indeed, early in the pandemic, questionable brokers and sellers were frequently delivering underperforming products to hospitals, if they provided anything at all. "We rely on our manufacturers for a continuous supply of safe and effective products, so if something happens to upset supply and demand, there could be challenges," says Mitchell. "That said, we are cautiously optimistic about supply availability." **HT**

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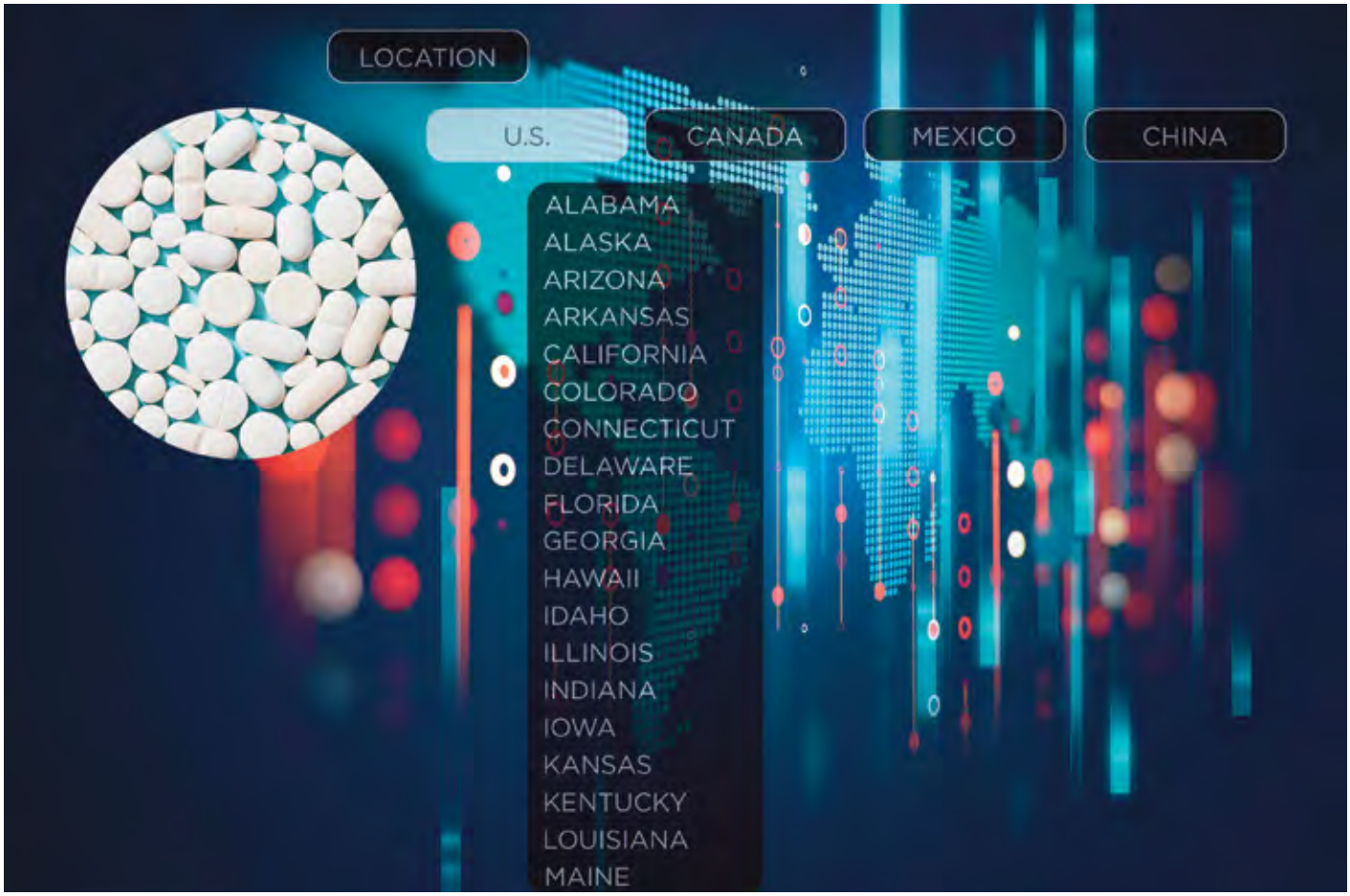

A prescription for a smarter supply chain

Facing pharmaceutical supply challenges with artificial intelligence

PHARMACEUTICAL PROCUREMENT, INVENTORY AND DISTRIBUTION CAN ALL BE AFFECTED BY GLOBAL FACTORS beyond a healthcare system's control—a lesson that has become all too clear during a worldwide pandemic.

This challenge not only presents major financial implications for healthcare organizations, but it could potentially impact patient care. **Aigner George**, PharmD, Senior Director, Pharmacy Solutions at HealthTrust, says the biggest obstacles in pharmaceutical supply chain are around efficiency and inventory, which ultimately affect patient care. "The most essential responsibility of a pharmacist is to get the right drug to the right patient at the right time," says George. "The more we optimize our processes and our inventory, the better the pharmacy team members can do that effectively and safely."

THE ROLE OF BUSINESS INTELLIGENCE

George cites the use of artificial intelligence as being transformative in this effort. "As you start to comb through

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HealthTrust Contract #7062

New & Improved

Calcium Gluconate

in Sodium Chloride Injection

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  *With **60 days stability** outside the overwrap[1]
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AVAILABLE IN
2,000 mg per 100 mL
1,000 mg per 50 mL

Calcium Gluconate Ready To Use Bags
Saves time, increases efficiency with no need to compound

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NDC #	Total Amount	Fill Volume	Container Type	Concentration	Pack Size	WHOLESALER ITEM NUMBERS				
						Amerisource Bergen	Cardinal	McKesson	HD Smith	Morris & Dickson
44567-620-24	1,000 mg	50 mL	100 mL Premix Bag	20 mg/mL	24	10209105	5503305	3672185	5792684	511089
44567-621-24	2,000 mg	100 mL	100 mL Premix Bag	20 mg/mL	24	10225251	5547013	3959640	6162044	718312

NDC# 44567-620-24

NDC# 44567-621-24

Indications and Usage
Calcium Gluconate in Sodium Chloride Injection is a form of calcium indicated for pediatric and adult patients for the treatment of acute symptomatic hypocalcemia. Limitations of Use: The safety of Calcium Gluconate Injection for long term use has not been established.

Important Safety Information
Contraindicated in hypercalcemia and in neonates receiving ceftriaxone. Warnings and Precautions: cardiac arrhythmias may occur with concomitant cardiac glycoside use; use caution when administering with ceftriaxone as a precipitate may form in the IV line; tissue necrosis and calcinosis may occur with or without extravasation; hypotension, bradycardia and cardiac arrhythmias may occur with rapid administration; contains aluminum which may cause toxicity. The most common adverse events are local soft tissue inflammation and necrosis; calcinosis cutis and calcification related to extravasation; vasodilation, decreased blood pressure, bradycardia, cardiac arrhythmia, syncope and cardiac arrest.

Please see full Presribing Information, inluding Warnings, Precautions, and Important Safety Information for this product at the WGCC website.

References: 1. On file WG Critical Care, LLC. To request data on file, please contact Customer Service at 1-888-493-0861 or CustomerService@wgccrx.com

SA140

U.S. Patent Number 10, 130, 646

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the data elements that exist within pharmacy supply chain—the logistics from procurement to administration—and you think about how to tie those elements into something actionable, it's business intelligence," explains George. "We need business intelligence solutions to be able to identify successful tactics in supply chain management."

While other innovations, like automated dispensing cabinets and medication carousels, are also helping to maximize pharmaceutical efficiencies, artificial intelligence is a thread that ties it all together. It creates a system that can identify inventory needs and helps pinpoint the best purchasing decisions.

Member organization RWJBarnabas Health is implementing an artificial intelligence software tool to help manage its supply. **Bob Pellechio**, RPh, MPA, Vice President of Pharmacy at RWJBarnabas Health, says **this move could equate to annual cost savings of 5% to 10%**. "From a decision-making perspective, it will make it a lot easier for us to obtain inventory from where we need to purchase it," he says. "It will let us know how much product we have within the system and, ultimately, allow us to shift product within the system without having to go out and buy more. We're looking forward to the process being more automated."

This type of software can help pharmacy leaders make decisions based on factors they can't control—or even anticipate. "What we hear is that AI [artificial intelligence] is going to be extended to social media," says Pellechio. "It's going to pull in data about certain trends throughout the world to help us improve planning for the future. It can warn us: 'There's a hurricane coming, and it's heading this way. Maybe you should purchase more of a certain drug or take alternate steps.' The information will be laid out to us, and then it will be up to us to make the decision on what actions to take."

HOW COVID-19 HAS NECESSITATED AUTOMATION

Pellechio says the pandemic has been instructive when it comes to supply chain vulnerabilities. "A lot of products that we typically purchase, or their active ingredients, are made in China, India or Italy. These countries actually closed down the export of these products, and it really hurt us," he says. "One of the things we've learned is to make sure we know where all the ingredient supplies are coming from and diversify a little bit more, so we have more options in the future. "

To that end, HealthTrust is helping Pellechio's health system, and others, find options. "We're expanding our purchasing and broadening our scope of companies that we source from for some of these products," says Pellechio. "HealthTrust has set up alternate suppliers. So we'll have a different source to buy from should we need to do so."

A close eye on inventory will also be essential. "A lot of facilities found that they were lacking a real view into what inventory looks like for critical medications related to COVID-19," George says. "A big lesson learned

is that members have to have a more accurate picture at a moment's notice, in real time, on what their inventories are."

George's hope is that as we move forward through the pandemic, organizations will look to streamline and optimize their inventory through business intelligence. "When we think of inventory management, we often think it's just operational," she says. "COVID-19 has proven that it's also driving patient care—because if you don't have visibility into the inventory status of medications, then you don't have a real handle on your ability to treat patients. It's a disservice to you from both a patient care and a fiscal perspective."

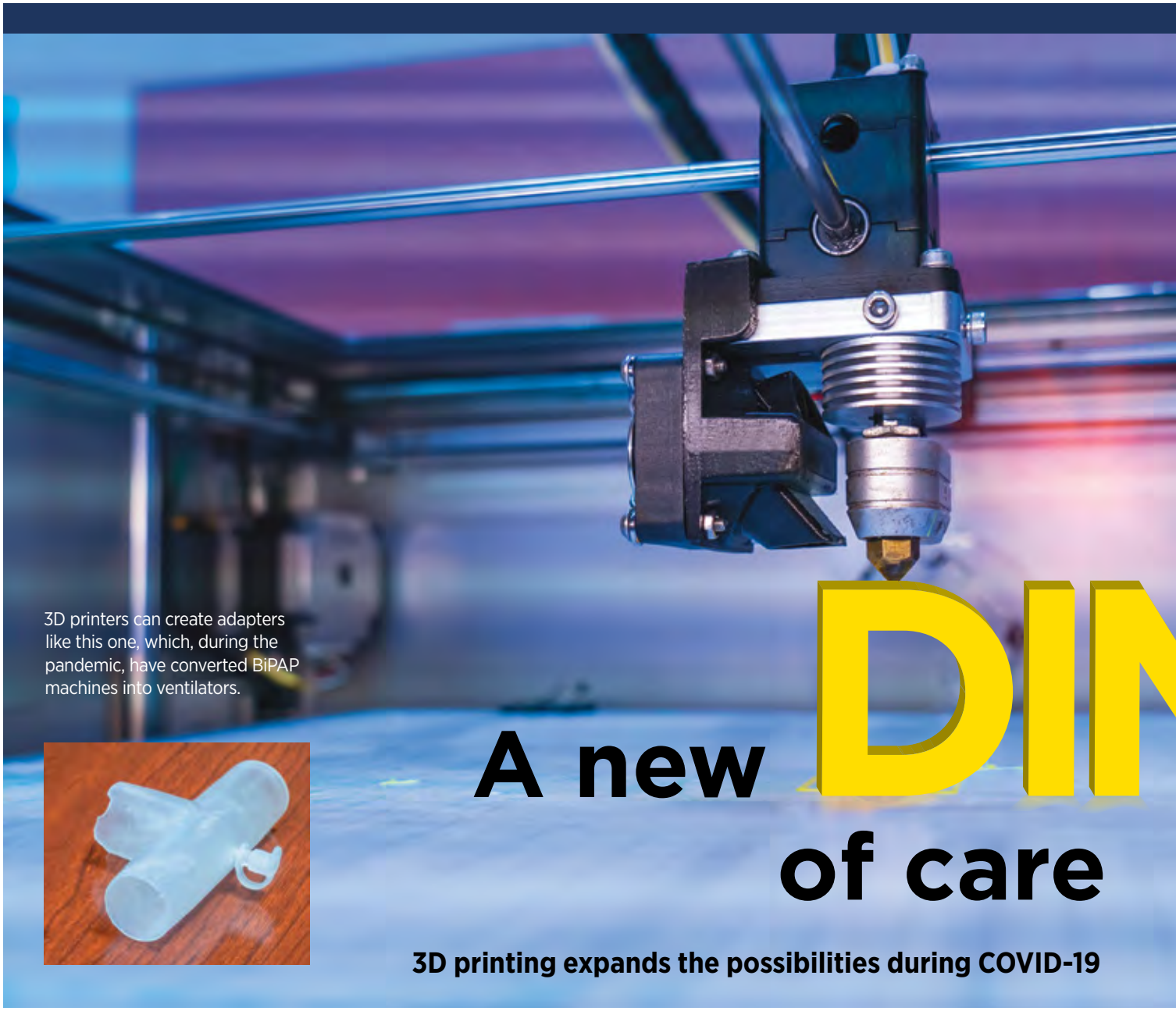
HOW HEALTHTRUST CAN HELP

Pellechio has seen the value of HealthTrust as a group purchasing organization. "When HealthTrust negotiates contracts on our behalf, they're negotiating within the verbiage of the contract for 110% to 120% of supply. So the companies they're negotiating with will hold 10% or 20% of supply with this alternative wholesaler for shortage reasons," he explains.

HealthTrust Pharmacy Solutions can help guide facilities on using this technology and managing their overall pharmacy supply chain operations to maximize efficiencies. "We become your team member to help you manage through all of the major focus points within pharmacy optimization," says George.

That's only one piece of the puzzle, George explains. "We focus on every aspect of pharmacy optimization; for example, supply expense management, clinical programs, quality initiatives and leadership development," she adds. "It's important for members to know that we are a strategic partner to help you move to your next level of success. We want to be there to support you." **HT**

FOR MORE INFORMATION about Pharmacy Solutions from HealthTrust, contact Aigner George at aigner.george@healthtrustpg.com



3D printers can create adapters like this one, which, during the pandemic, have converted BiPAP machines into ventilators.

A new DI of care

3D printing expands the possibilities during COVID-19

DURING THE FIRST SURGE OF THE COVID-19 PANDEMIC, when personal protective equipment (PPE) supplies were low and anxiety was high, manufacturers like Ford Motor Company saw the urgent need to help and got creative. Ford used 3D printing technology to print face shields and other gear, helping keep front-line workers safe. It turns out, that was only beginning—not only of the pandemic, but also of the role 3D printing would play in meeting the unique challenges created by the pandemic. While this technology has been around for decades, its promise and potential have become newly evident.

HOW 3D PRINTING IS HELPING

3D printing is the process of creating three-dimensional objects from a digital file by adding multiple layers of a material to a single structure. In the healthcare world, it's used to create custom guides, templates, implants and prostheses. For example, surgeons can use 3D-printed models produced from patient imaging to clarify treatment decisions and practice interventions before surgery. These anatomical models are also used in patient education—to help patients understand their condition and treatment—and in training medical students and residents.

MENSION

Now, 3D printing is being used to furnish supplies for COVID-19 care. "3D printing has provided a rapid response to the changing environment," says **Sarah Michel**, MBA, BSN, RN, NE-BC, Director of Research & Clinical Engagement at HealthTrust.

When ventilators were in short supply at the height of the pandemic, one 3D-printer manufacturer obtained an emergency use authorization (EUA) from the Food and Drug Administration (FDA) for a 3D printed adapter, which turned BiPAP machines into ventilators. And when faced with a dwindling supply of nasopharyngeal swabs for use in COVID-19 testing, some healthcare facilities were able to use 3D printing to meet that demand.

Historically, most 3D printing has been outsourced, but now technology has advanced enough that in-house printing is a viable option for many hospitals. This allows for a faster turnaround time, immediate customization and—after an initial investment—a decreased individual case cost.

But because point-of-care 3D printing (done in-house at the hospital and not marketed to customers) can be done without FDA approval, there are sterilization and quality issues to mitigate.

According to a HealthTrust Physician Advisor, one limitation to incorporating 3D printing into clinical practice has been the software required to do the surgical manipulation and the design of surgical guides and models. "Previously, this was difficult to do and required the use of an engineer with one of the design companies. Now, software is available that allows the surgeon to perform this, which opens the possibilities of printing your own models and guides."

WHAT'S AHEAD

How 3D printing is used in daily practice continues to evolve. As the technology advances, more applications and use cases are being developed. In considering future applications, one HealthTrust Physician Advisor stated: "I envision machinery that can make not just resin models or forms, but also has the interchangeable tooling to process fragile biologics like nerve and cartilage, as well as custom-make metal plates and osteotomy guides and screws."

The critical role 3D printing has played during the pandemic is another potential source of future innovation. "I think we should look at the on-demand solutions that 3D printing provided for COVID-19 as key takeaways in addressing future hospital needs," says Michel. **HT**

Center for Devices and Radiological Health's Response to COVID-19

FDA U.S. FOOD & DRUG ADMINISTRATION

TIMELINE: JANUARY 1 – SEPTEMBER 18, 2020

REGULATORY FLEXIBILITY

Proactively issued policies to provide regulatory flexibility

to address the pandemic

10 EUA TEMPLATES

&

23 GUIDANCE DOCUMENTS

Including policies intended to help:

Car manufacturers making ventilators

Apparel manufacturers making masks

3D printers making ventilator components

EMERGENCY USE AUTHORIZATIONS

516 MEDICAL DEVICES AUTHORIZED UNDER **EUAs**

(ALMOST **10X** THE NUMBER AUTHORIZED IN ALL PRIOR NATIONAL EMERGENCIES)

INCLUDING:

248 TESTS

OF WHICH ARE

198 MOLECULAR

4 ANTIGEN

46 ANTIBODY

TESTS

RECEIVED

1,734 Pre-EUAs

3,040 EUAs

SHORTAGE MITIGATION ACTIVITIES

Outreach to **1,000+** **manufacturing sites**

ACROSS

12 COUNTRIES

to assess supply chain vulnerabilities

RESULT

Identified potential supply chain issues early and worked to minimize disruptions

PUBLIC HEALTH SERVICE CORPS DEPLOYMENT

58 CDRH Commissioned Corps officers

HAVE BEEN **DEPLOYED**

78 TIMES

in support of the COVID-19 mission

ENGAGEMENT WITH STAKEHOLDERS

Sent

13.7M E-MAILS

to stakeholders on COVID-19 topics

RESPONDED TO:

337,000 E-MAIL & PHONE QUERIES from patients, health care personnel, industry, & others

HOSTED

39 COVID-RELATED WEBINARS

&

TOWNHALLS WITH

36,000+ PARTICIPANTS

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Four critical lessons in INFECTION PREVENTION

LESSON 1

Communication is key.
Education & communication are key to effective infection prevention.

LESSON 4

Antimicrobial stewardship is as essential as ever.
COVID-19 has added complexity to this already complicated challenge.

Top IP takeaways from the COVID-19 front lines

WHILE INFECTION PREVENTION IS ONE OF THE UTMOST GOALS IN A hospital setting, the COVID-19 pandemic has revealed a renewed focus on giving healthcare providers the tools and support they need to stop the spread.

"The staff know now we're coming to help them do better," says **Jennifer Sanguinet**, DrPH, Director of Infection Prevention at HCA Healthcare's Sunrise Hospital in Las Vegas.

Out of struggle come lessons learned. And healthcare systems have learned many when it comes to infection prevention in the pandemic era.

LESSON 1: COMMUNICATION IS KEY

Sanguinet says communication has played an important role in this effort, particularly given some of the misinformation in the public domain. "We recognized early on that we weren't going to know everything and that things were changing very rapidly, so communication became the No. 1 priority," she explains. That often meant daily messages from the hospital's CEO. "This helped people feel more confident that we were sharing what we knew as soon as we knew it," she says.

Angie Mitchell, RN, AVP of Clinical Services at HealthTrust, agrees: "The key to infection prevention has always been education and communication," she says. "But the pandemic brought it to the forefront, where it's more appreciated and seen in a new light."

LESSON 2: CREATIVITY & CRITICAL THINKING ARE REQUIRED

Creativity and flexibility have been critical in managing infection spread during the pandemic, Sanguinet says. Her team recognized that they would need more respirators. As they waited for more to arrive, they worked diligently to keep the almost constantly used machines up and running, and ready to go for the people who needed them.

The team also began using decontamination powered air-purifying respirators (PAPRs), following decontamination guidelines from the Centers for Disease Control and Prevention (CDC). They just had one challenge. They needed a quick way to keep track of the PAPRs' locations throughout the hospital so they could be available at a moment's notice. After brainstorming, the team came up with a solution: attaching Tile Trackers to each machine.

"You never know what the talents are on your staff until you put them to the test," Sanguinet says.

"These infection prevention specialists needed to be fast on their feet," says **Tara Coleman**, MBA, BSN, RN, HealthTrust's Infection Prevention Subcommittee Lead and Director of Nursing Services, Clinical Operations. And they were. "The people who go into this are exceptional critical thinkers, and they were challenged to put those skills into hyperdrive, while at the same time maintaining the confidence and composure to guide the staff."

LESSON 3: MATERIALS MATTER

For Coleman, the importance of "fit testing," which the Occupational Safety and Health Administration (OSHA) requires to ensure that N95 respirators work properly, emerged as a critical lesson.

Clinical staff typically only need to undergo fit testing annually because they

use the same type of mask for every circumstance. But with the pandemic, providers used different mask types, and there was a lot of time and effort spent ensuring the masks fit, Coleman explains.

Technology that can bring this process down from 20 minutes to about seven is under review.

Coleman also saw a greater appreciation for the equipment front-line clinicians needed to do their jobs. "Clinicians often took it for granted they would always have the equipment they needed and never worried about keeping up with their mask or counting how many days until it had to be cleaned. It was an eye-opening experience," she says. "We realized there were a lot of suppliers out there, but many don't meet the efficacy standards required to protect the clinician."

Coleman and her team also spent a lot of time educating members about their gear—for example, steps they could take to prevent the skin breakdown that can occur with extended use of N95 respirators.

LESSON 4: ANTIMICROBIAL STEWARDSHIP IS AS ESSENTIAL AS EVER

Like everything else during the pandemic, antimicrobial stewardship has become more challenging—in part because of the increased susceptibility of patients with COVID-19 to antibiotic-resistant infection from prolonged hospitalization and the use of immunosuppressing agents such as dexamethasone. But that doesn't mean antimicrobial stewardship should become secondary.

"There's a temptation, justifiably so, to focus on emerging COVID treatments at the expense of day-to-day antimicrobial stewardship interventions," says **Charles Jensen**, PharmD, Antimicrobial Stewardship Coordinator at St. Luke's Health System–Treasure Valley in Boise, Idaho. "Competing priorities make this a constant struggle. But the last thing our patients need is to wrap up their hospital stay with a bout of C-diff [*Clostridioides difficile*] or a multidrug-resistant infection due to lax stewardship."

It's vital to identify the responsible pathogen as quickly as possible so the right antibiotic—or none at all—is used, says **Jason Braithwaite**, PharmD, HealthTrust's Senior Director of Clinical Pharmacy Services. "That's antimicrobial stewardship 101," he says. "But it sometimes gets lost when a patient is really sick and you're trying to figure out what to do next."

One challenge is that the immunosuppressants widely used with critically ill COVID patients alter white blood counts. "This confounds our ability to track patient improvement," Braithwaite says. That's why it's so important to work closely with the infectious-disease experts. "Using their experience and knowledge is key."

Rachael Craft, PharmD, Clinical Pharmacist of Infectious Diseases at Mercy Medical Center in Canton, Ohio, works closely with infectious disease physicians to review antimicrobial usage on COVID patients. "I think it is more crucial than ever to have an antimicrobial stewardship team in place at the hospital," she says. "The physicians do a thorough job evaluating these patients to see if they have any risk factors for a predisposing bacterial infection." They then rely on lab values to help guide decisions. "I think we have a good handle on this situation because we have the team and proper policies and protocols in place to help us be successful," she adds.

"During the early stages of the pandemic, clinical uncertainty was high," says **John Hwang**, PharmD, Pharmacist at St. Vincent Charity Medical Center in Cleveland, Ohio. "When it came to treating patients with multiple comorbidities, the risk of secondary bacterial infections was a major concern."

In addition, Hwang notes that early studies suggested that the unnecessary use of antibiotics was high among patients with COVID-19, despite little to no evidence of bacterial infections. "Although there has been an increasing amount of research involving the use of antimicrobials on COVID-19 patients, the results have been inconclusive," he explains. "As a stewardship pharmacist, it's my duty to keep up with the new literature and recommendations from the CDC and NIH [National Institutes of Health] to ensure antibiotics are used judiciously."

Looking ahead, these lessons learned are integral in facing the pandemic as it continues in real-time and pivoting when required. "Everyone is stretched thin deciphering the latest pre-prints, addressing shortages and navigating emergency usage authorization nuances affecting COVID treatments," says Jensen. "We'll all need to find innovative solutions to make sure basic stewardship interventions like de-escalations are still happening consistently."

"Many of the efforts initiated as a response to COVID will remain a part of infection control protocols and processes to avoid disruptions," predicts Mitchell. "We used to talk about 'what ifs' like a pandemic in the future, but the future is now." **HT**

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- Thrombosis may occur with immune globulin intravenous (IGIV) products, including Octagam® 10%. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.
- Renal dysfunction, acute renal failure, osmotic nephropathy, and death may occur with the administration of Immune Globulin Intravenous (Human) (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Octagam 10% does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction or renal failure, administer Octagam 10% at the minimum infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Important Safety Information

Octagam® 10% is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin. Octagam 10% contains trace amounts of IgA (average 106 µg/mL in a 10% solution). It is contraindicated in IgA-deficient patients with antibodies against IgA and history of hypersensitivity. The most serious drug-related adverse event reported with Octagam 10% treatment was a headache (0.9% of subjects). The most common drug-related adverse reactions reported in >5% of the subjects during a clinical trial were headache, fever, and increased heart rate.

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

HealthTrust Contract #4861

Date of preparation: 5/2020. GAM10-0201- PAD

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OCTAGAM 10% safely and effectively. See full prescribing information for OCTAGAM 10%.

OCTAGAM 10% [Immune Globulin Intravenous (Human)]
liquid solution for intravenous administration
Initial U.S. Approval: 2014

WARNING
THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE
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----------INDICATIONS AND USAGE ----------

- OCTAGAM 10% is an immune globulin intravenous (human) liquid preparation indicated for the treatment of chronic immune thrombocytopenic purpura (ITP) in adults.

---------- DOSAGE AND ADMINISTRATION ----------

For intravenous use only.

Indication	Dose	Initial Infusion rate	Maintenance Infusion Rate (if tolerated)
Chronic ITP	1 g/kg daily for 2 consecutive days	1.0 mg/kg/min (0.01 mL/kg/min)	Up to 12.0 mg/kg/min (Up to 0.12 mL/kg/min)

- Ensure that patients with pre-existing renal insufficiency are not volume depleted; discontinue OCTAGAM 10% if renal function deteriorates.
- For patients at risk of renal dysfunction or thrombotic events, administer OCTAGAM 10% at the minimum infusion rate practicable.

----------DOSAGE FORMS AND STRENGTHS----------

Solution containing 10% IgG (100 mg/mL)

---------- CONTRAINDICATIONS----------

- History of anaphylactic or severe systemic reactions to human immunoglobulin
- IgA deficient patients with antibodies against IgA and a history of hypersensitivity

----------WARNINGS AND PRECAUTIONS ----------

- IgA-deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions to OCTAGAM 10%. Epinephrine should be available immediately to treat any severe acute hypersensitivity reactions.
- Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure.
- Falsely elevated blood glucose readings may occur during and after the infusion of OCTAGAM 10% with testing by some glucometers and test strip systems.
- Hyperproteinemia, increased serum osmolarity and hyponatremia may occur in patients receiving OCTAGAM 10%.
- Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to OCTAGAM 10% treatments. Risk factors for hemolysis include high doses and non-O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.
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- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury (TRALI)).
- OCTAGAM 10% is made from human plasma and may contain infectious agents, e.g. viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

---------- ADVERSE REACTIONS----------

The most common adverse reactions reported in greater than 5% of subjects during a clinical trial were headache, fever and increased heart rate.
To report SUSPECTED ADVERSE REACTIONS, contact Octapharma at 1-866-766-4860 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------

The passive transfer of antibodies may:
Confound the results of serological testing.
Interfere with the immune response to live viral vaccines, such as measles, mumps, and rubella.

---------- USE IN SPECIFIC POPULATIONS----------

- Pregnancy: no human or animal data. Use only if clearly needed.
- Geriatric Use: In patients over age 65 or in any person at risk of developing renal insufficiency, do not exceed the recommended dose, and infuse OCTAGAM 10% at the minimum infusion rate practicable.

Revised: **August 2018**

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Swift, SAFE & SOUND

The planning & logistics involved in delivering a COVID-19 vaccine

THE COVID-19 PANDEMIC HAS THRUST THE HEALTHCARE WORLD INTO SCENARIOS WE'VE NEVER BEFORE EXPERIENCED—including the speed at which vaccines are being developed. The first two vaccines for COVID-19 were made available by the end of 2020, just one year after the first cases of the virus were reported. As soon as the data was available that met the requirements for emergency use authorization (EUA) by the Food and Drug Administration (FDA), authorization was granted and states began distribution.

The distribution of these highly anticipated vaccines is the latest "first" that we will witness as this pandemic plays out—one that is rife with complexities. "I can't emphasize enough how complicated the logistics of this will be," says Physician Advisor **Kelly Moore**, M.D., MPH, President of the Vaccine Advisor and Deputy Director of the Immunization Action Coalition.

As of press time, here's what the experts are saying we might expect.

PRIORITIZING HEALTHCARE PROFESSIONALS

Two vaccines produced by Pfizer and Moderna were approved at the end of 2020 by the FDA under an EUA.

The approved vaccines were first available in small supplies. About 20 million doses were shipped by the end of 2020.

Pfizer projects that it can supply 100 million doses to the U.S. market by the end of March 2021. Public health advisory groups, including the National Academy of Medicine and the federal Advisory Committee on Immunization Practices, recommend that healthcare professionals be prioritized as the first in line to receive the earliest doses of the vaccine due to their risk for exposure to COVID-19. Dr. Moore says those who work at long-term care facilities will be a particular focus. "There is careful planning taking place with long-term care facilities to ensure that these healthcare workers are highly prioritized," she says.

State health departments are developing vaccine program plans that involve partnering with hospitals and health systems to set up clinics and administer the vaccine to all healthcare staff who work in patient care areas. The vaccines will become more widely available once these needs have been met.

ADMINISTRATIVE CHALLENGES

Many aspects of this vaccine program won't be typical. First, these are two-dose vaccines. People must have a second dose three to four weeks after their first dose to be fully protected. Dr. Moore says hospitals should prioritize the patient experience to ensure people come back for the second dose. "If people have a good experience, they're well informed and their questions are answered, then they're much more likely to come back for dose two."

Another challenge is storage. The Moderna vaccine, distributed in 100-dose minimum shipments, can be stored in a regular freezer for up to six months or at refrigerated temperatures for 30 days. The Pfizer vaccine, distributed in 975-dose minimum shipments, requires storage on dry ice or in an ultra-low temperature freezer (which most hospitals don't have) for up to six months, or just five days at refrigerated temperatures. The Pfizer product will be more easily used in urban, highly populated settings, while the Moderna vaccine will be easier to use when vaccinating in sparsely populated rural regions.

To solve the freezing issue, Pfizer designed its shipping boxes to double as storage containers. The box comes with enough dry ice to allow for 10 days of shipping time. Once opened, the dry ice can be replenished upon receipt and every five days after for a maximum storage time of 15 days in the Pfizer thermal shipper.

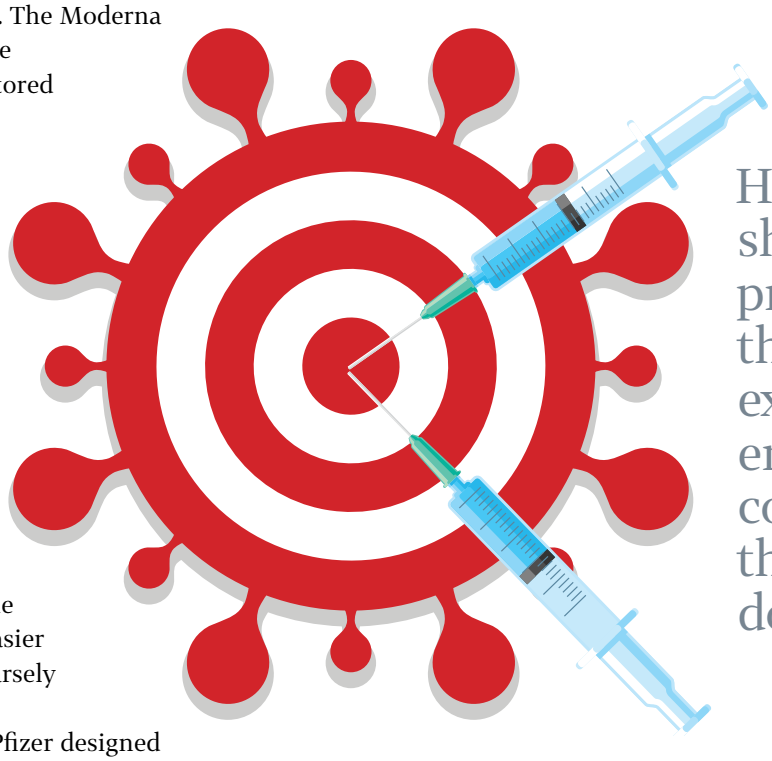
The frozen liquid concentrate comes in a five-dose vial, which can be kept in a refrigerator for up to five days. Once it's diluted, each vial has to be used within six hours or be discarded—the vaccine doesn't include preservatives.

Every dose has to be reported back to the state immunization registry within 24 hours of administration. "The data entry and reporting are more stringent than any routine vaccination program because we have to be sure people come back for dose two and because these vaccines are not interchangeable—if a patient starts the series with one brand they must complete the series with the same brand," explains Dr. Moore.

COST & ACCESS

Experts expect that health insurance companies will be billed for vaccine administration, and patients will not have out-of-pocket expenses. Those without health insurance will still be able to receive the vaccination; a federal program will be available to help people who can't afford it.

"The most important thing is to get people vaccinated," says Dr. Moore. "We don't want any barriers to access."



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> Hospitals should prioritize the patient experience to ensure people come back for the second dose.

In addition, immunization providers should not have any upfront costs associated with the program. Hospitals will receive the vaccine and all ancillary supplies necessary to administer it at no cost. Hospital providers will place vaccine orders with their states, and the products and supplies will be shipped to them through the federal system.

One of the unknowns is when the vaccines will be made available to all people, but it will likely take several months. The first-available vaccines will come from the federal government by way of the state governments, pharmacy

Continued on page 32

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"As long as we need the vaccine to help us fight this pandemic, the priority is, everyone who needs it gets it."

– Kelly Moore, M.D., MPH

Although the research and development process has been greatly accelerated, public health officials say corners have not been cut when it comes to safety. The vaccine clinical trials involved 30,000 to 44,000 volunteer participants.

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Continued from page 30

chains and the VA health system. As more vaccine becomes available, as indicated by public health officials, it will be more widely distributed.

"As long as we need the vaccine to help us fight this pandemic, the priority is, everyone who needs it gets it," says Dr. Moore. The groups prioritized after healthcare workers are likely to include essential workers in critical non-healthcare occupations who need to be vaccinated because their jobs require them to have some exposure to others with COVID-19. Also in this tier are people who are considered high risk, including the elderly and the medically fragile.

States are working closely with hospitals and health systems in rural areas, including tribal lands, to make sure there will be equitable access to the vaccine. "Mobile clinics and special clinics will be set up in remote areas," says Dr. Moore.

EFFICACY & SAFETY

The FDA requires the vaccine to perform at least as well as a typical influenza vaccine in order to be approved, but vaccines may not come as close to eliminating the risk of infection with the virus as some others

do, such as the measles vaccine. Pfizer and Moderna interim analyses showed 95% and 94.5% effectiveness, respectively.

"We hope the vaccine will significantly reduce the risk of severe illness from COVID-19, especially the kind that requires hospitalization in older adults," Dr. Moore says. But even when we begin using these vaccines, uncertainty remains about how well the vaccines will prevent asymptomatic infection and how long their protection will last. In addition, it will take months to vaccinate enough people to protect communities. So while it will be a critical tool in fighting this pandemic, wearing masks, practicing good hand hygiene and avoiding indoor crowds are behaviors that will continue to be essential in 2021.

Although the research and development process has been greatly accelerated, public health officials say corners have not been cut when it comes to safety. The vaccine clinical trials involved 30,000 to 44,000 volunteer participants. Even though the vaccines have initially been approved to be administered under the EUA, their manufacturers will go on to apply for full FDA licensure.

While the current clinical trials tell scientists a lot about the common side effects of the vaccines, the possibility of rare side effects won't be fully determined until more of the population receives them. "Our knowledge at this point has limits, and we need to be honest about that," says Dr. Moore.

The Centers for Disease Control and Prevention (CDC) has plans to enhance its existing vaccine safety monitoring system with an additional smartphone-based volunteer safety monitoring program for the earliest recipients, so officials can check in on how they're doing and scientists can continue to learn. **HT**

FOR UP-TO-DATE INFORMATION on the status of the vaccine and its distribution, visit HealthTrust's vaccine resources at education.healthtrustpg.com/covid-19-resources/#vaccine-information

A CULTURE

New guidelines give specific tools to providers to help prioritize patient safety

TO FURTHER SUPPORT PROVIDERS IN THEIR CONTINUOUS EFFORTS TO IMPROVE PATIENT SAFETY, the Institute of Healthcare Improvement (IHI) released a new national patient safety action plan in September 2020.

The IHI's "Safer Together: A National Action Plan to Advance Patient Safety," distills into four focal points and 17 recommendations the evidence-based best practices that healthcare providers have followed since the landmark patient safety report, "To Err Is Human: Building a Safer Health System," was released two decades ago. The report's creators—the IHI's National Steering Committee for Patient Safety—say these recommendations are essential for creating "total systems safety." HealthTrust member facilities are seeing the importance of these recommendations in action.

THE VALUE OF SPECIFICS & GOVERNANCE

While there aren't surprises among these recommendations, the value is in the specifics, says HealthTrust Physician Advisor **David Stepansky**, M.D., Vice President for Quality at Community Health Systems (CHS). The action plan and its accompanying self-assessment tool and implementation guide provide concrete ways for health systems to improve.

"Everybody knows these are important things to do," he says. "But the IHI recommendations get more specific within each of those areas as to how to do it better."

RWJBarnabas Health's Senior Vice President of Quality and Patient Safety, **Deborah Larkin-Carney**, MBA, BSN, RN, CPPS, agrees. "I think this hits the heart," she says. "IHI did a really good job. The hospitals can take this and do something with it."

The self-assessment tool will help healthcare providers decide when and how to prioritize safety measures. "The self-assessment tool has delineated scoring, so you know where you are and where you need to be," Larkin-Carney explains. The IHI also provides an associated resource guide that offers specific tactics for implementing the plan's recommendations.

A FAMILY MATTER

One IHI recommendation is to actively engage patients and their families and care partners in patient care and safety planning. But it's one that may face some resistance, notes Dr. Stepansky.

For example, many physicians are not used to or comfortable with getting input from patients or their families, he says, and hospital leadership may have concerns about operational and legal issues with doing so. But this input can provide a valuable perspective on what's going on directly with the patient's health and their experiences during care.

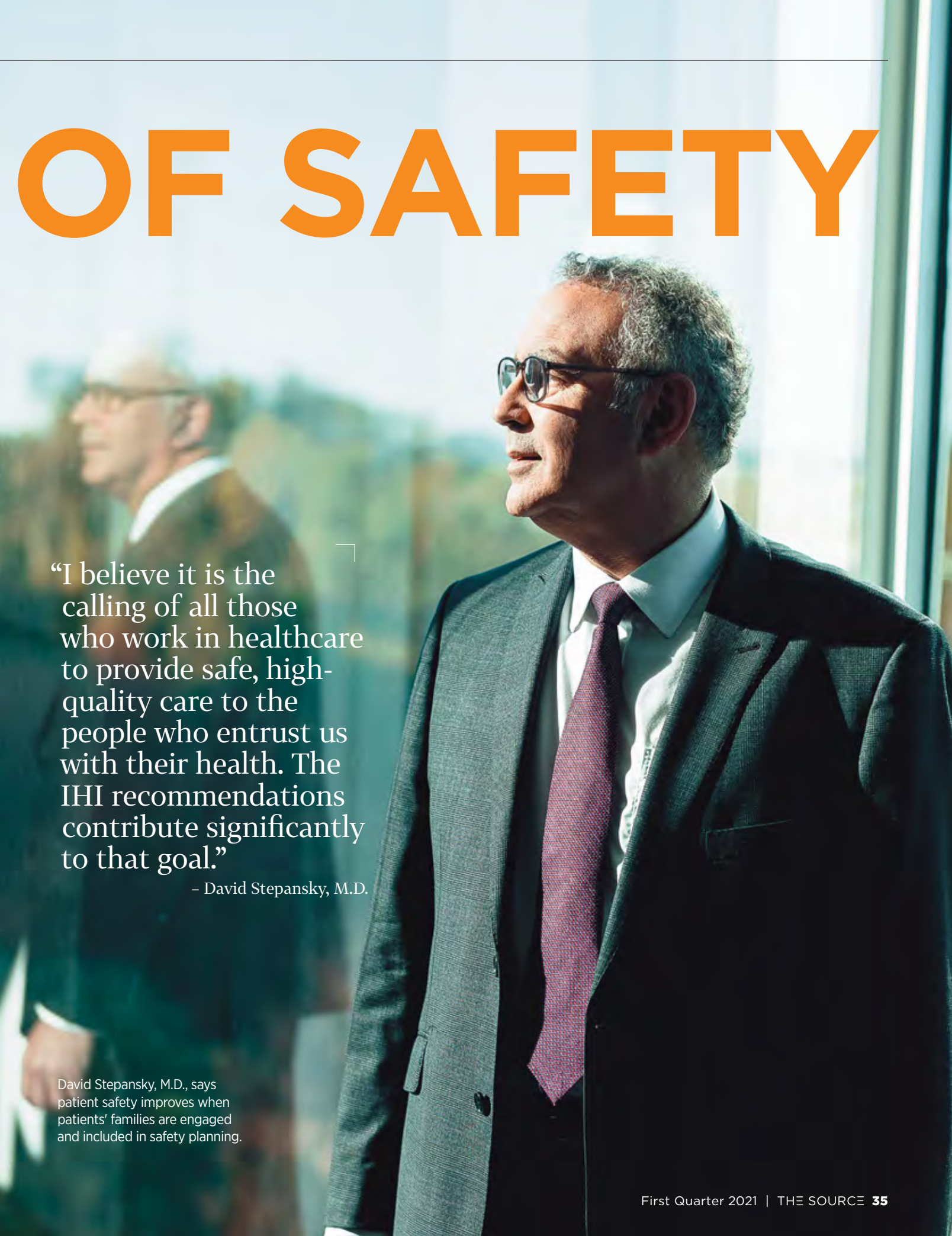
"It doesn't mean that patients and their families have to be medical experts, but they have major things they can contribute in terms of promoting safety and good communication," Dr. Stepansky says.

The IHI action plan also advocates for including patients and their families in the healthcare facility's patient safety infrastructure. CHS began doing so over a year ago, explains Dr. Stepansky, when each of its 89 hospitals in 16 states established a patient family advisory council (PFAC). "Everyone agreed that involving patients and families is critically important," he says.

One successful patient and family engagement protocol the health system has implemented is the bedside shift report with a patient safety assessment. During this time, patients, their families and caregivers are encouraged to participate, says **Terrie Van Buren**, BSN, Vice President and Patient Safety Officer at CHS. At these bedside-shift hand-offs, the outgoing and incoming nurses go over with the patient and family or caregiver what happened during the last shift and what the expected plan of care is for the rest of the day or evening. They also discuss any

Abigail Bobo

OF SAFETY



"I believe it is the calling of all those who work in healthcare to provide safe, high-quality care to the people who entrust us with their health. The IHI recommendations contribute significantly to that goal."

– David Stepansky, M.D.

David Stepansky, M.D., says patient safety improves when patients' families are engaged and included in safety planning.

special precautions that need to be taken to keep the patient safe from healthcare-acquired conditions, such as pressure injuries, falls, blood clots and infections.

It's a practice that has helped to reduce healthcare-acquired conditions, Van Buren points out. She notes that these patient safety assessments at shift change have been instrumental in the health system's ability to maintain an 85% Serious Safety Event Reduction (SSER) rate. "Engaging patients and family in safety has been key," she says.

SAFE SURROUNDINGS

The IHI's emphasized focus on workforce safety is also notable, Dr. Stepansky adds. "The same principles that are useful in keeping patients safe are often the same principles that keep your workforce safe," he shares. "Plus, having a safe, healthy and happy workforce enjoying their work is very important in terms of them being able to provide good care."

Some of the workforce safety initiatives CHS-affiliated hospitals have instituted are:

- Hospitals hold a daily huddle to discuss patient and workforce safety-related issues/occurrences and lessons learned. "These safety huddles are 'hard-wired' within our hospitals," Dr. Stepansky says. As an example, some hospitals practice "Worker Safety Wednesday," where issues impacting workforce safety are discussed among all leaders in the Daily Safety Huddle on Wednesdays.
- Designated employees are trained to lift patients properly and supplied with lifting devices to prevent injury.
- Designated employees are trained in de-escalating difficult circumstances that could otherwise lead to violence.

"We believe these activities have resulted in fewer employee injuries," adds Dr. Stepansky.

Larkin-Carney is pleased to see that psychological safety is included in the IHI's action plan because she considers it an important part of workforce safety.

RWJBarnabas Health locations use tactics similar to the IHI's Root Cause Analyses and Actions (sometimes referred to as RCA squared) to understand how and why medical errors occur. Leadership has taken that process to the next level by creating a culture of psychological safety to encourage people to talk about what happens when things do not go as planned. They offer the opportunity for caregivers to gather in safe spaces to talk about tough things that come up and to provide emotional support. "We started this two years ago, and it's been extremely popular," Larkin-Carney says.

CONTINUOUS LEARNING

IHI's action plan also focuses on learning systems, in which Larkin-Carney is also a big believer. RWJBarnabas Health has instituted a number of learning systems, including biweekly meetings to analyze events, daily huddles that serve as more immediate check-ins, and annual forums where various locations within the health system can share their best practices.

Dr. Stepansky is particularly interested in the possibilities of interorganizational sharing and is curious to see how that develops as healthcare systems digest and implement the action plan in the coming months. "Currently, one healthcare organization might informally share information with other healthcare systems at a conference. But the IHI suggests more formal lines of communication, recommending that organizations engage with established local, regional, state and national learning systems," explains Dr. Stepansky. "For example, a local or state medical society or national hospital association might sponsor summits for the purpose of organizations collaborating on how to improve patient safety and quality of care."

Dr. Stepansky and Terrie credit workplace safety initiatives with lowering employee injury rates.

Abigail Bobo

Larkin-Carney, Van Buren and Dr. Stepansky all agree there's a lot to digest. Implementing the national action plan "is not something that you do in six months," Larkin-Carney stresses. That's where the self-assessment tool that accompanies the action plan comes in.

The intensity of IHI's national action plan may be overwhelming for some healthcare providers, but it is doable for everyone, explains Larkin-Carney. What is required for success, though, is leadership commitment. "Leadership has to want it and believe in it," she says. "You could put certain parts in place and start making inroads—but to do this plan effectively, you really need that buy-in."

Dr. Stepansky notes it's vital to keep the end goal in mind. "At the end of the day, this is about taking good care of patients," he says. "I believe it is the calling of all those who work in healthcare to provide safe, high-quality care to the people who entrust us with their health. The IHI recommendations contribute significantly to that goal." **HT**

NEW GUIDELINES

The four focal points and recommendations of IHI's "Safer Together: A National Action Plan to Advance Patient Safety" are:

1. Culture, Leadership & Governance
2. Patient & Family Engagement
3. Workforce Safety
4. Learning Systems

READ MORE about the IHI's four focal points and 13 recommendations at: healthleadersmedia.com/clinical-care/focus-4-areas-promote-patient-safety-your-organization

The CHANGING FACE of elective surgeries

How hospitals are handling these important procedures during the pandemic

AT THE HEIGHT OF THE PANDEMIC'S FIRST WAVE, governors issued executive orders, and hospitals responded to the looming crisis by suspending elective services. The cancellation of such procedures has had a significant impact, with the potential to affect patient health and quality of life, and the hospitals themselves.

According to the National Institutes of Health (NIH), canceling all elective procedures could not only result in an increase in disease progression and death rates, but it could also cause estimated revenue losses of $16.3 to $17.7 billion per month to U.S. hospitals.

In the months that followed the first wave, hospitals began bringing back much-needed elective surgeries to patients. Member facilities had to carefully approach the reintroduction of these procedures, which is essential to informing how to handle future waves.

THE IMPORTANCE OF ELECTIVE PROCEDURES

"There can be a tendency to conflate elective procedures with optional procedures, but we know that's not the case," says **Kelsey Duggan**, Ph.D., MBA, Assistant Vice President, Medical Device Management at HealthTrust.

Delaying elective procedures can result in more disease, higher rates of increased pain, heightened depression and anxiety, and an overall decline in quality of life for patients. So it became a priority for hospitals to bring them back—carefully. "There is clinical rationale for these procedures, but everything can't launch at once, so there's

typically a phased approach to bringing them back," Duggan says.

In August 2020, Duggan joined **Rick Phillips**, BS, R.T.(R)(MR)(CT)(ARRT), CRA, Vice President, Advisory Services at HealthTrust, and Physician Advisor **Jeffrey Hodrick**, M.D., Orthopedic Surgeon at TriStar Centennial, on a webinar to discuss options for approaching elective procedures in the era of COVID-19. Phillips explained in the webinar that it takes flexibility. "As rigid as we can be with our policies and procedures within healthcare, I've seen policies and procedures change more quickly over the last few weeks and months than I've seen happen in my career," he says.

CHANGING WITH THE TIMES

Many essential infection prevention practices—such as universal masking, visitation policies and patient cohorting—had already been implemented within hospitals, says Duggan, so it wasn't a big pivot when it came time to resume these procedures. "Hospitals have used a lot of the best practices they already had in place to make this transition more seamless," she explains.

However, some changes were required to meet this unique circumstance, including finding ways to reduce the amount of time patients spend at the hospital. At Centennial, Dr. Hodrick notes they now offer some of their pre-procedure patient education online. This new approach has the added benefit of allowing patients to access the learning whenever they need it. They are also using telemedicine for post-op appointments and to triage patients.

To Dr. Hodrick, the need to change the mindset within the operating room stands out as one of the biggest modifications that needed to take place. "It's part of the OR culture that you're used to being tired and run down, but the risk of coming to work if you're not feeling well, and explaining that to our staff, has been one of the big things. It's been a little bit of a cultural shift," he says.

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PLANNING FOR THE NEW NORMAL

The pandemic has reset baselines. When planning for the future, it's necessary to focus on current market drivers and not prior year trends, says Phillips. To anticipate upcoming trends, the Advisory Board recommends tracking indicators around a future surge, such as the levels of social distancing in your community. Other suggestions include:

- Conducting scenario planning and creating short-term contingency plans for each scenario
- Communicating with your community to reassure them you have a safe environment for care
- Concentrating on outpatient capacity

Ongoing communication and collaboration between teams is critical in resuming elective procedures. The recommendation is to bring together key stakeholders from medical leadership, administration, infection control, environmental services, supply chain and bed management on a core governance committee to manage the process. Daily huddles can be used to address emergent or acute needs, with weekly all-hands meetings being better suited for strategic planning and looking at issues such as:

- Staffing levels
- Supply chain sustainability
- Patient safety and cohorting
- Screening of patients, visitors and staff

"Most importantly, communicate the risk of patients avoiding care. We talk about social distancing, but that doesn't mean medical distancing," says Phillips. It's important that patients understand the difference.

He adds, "The more you can do to communicate what steps you have taken and what you're doing to create a safe environment, the more likely your patients are to come back and want to receive care." **HT**

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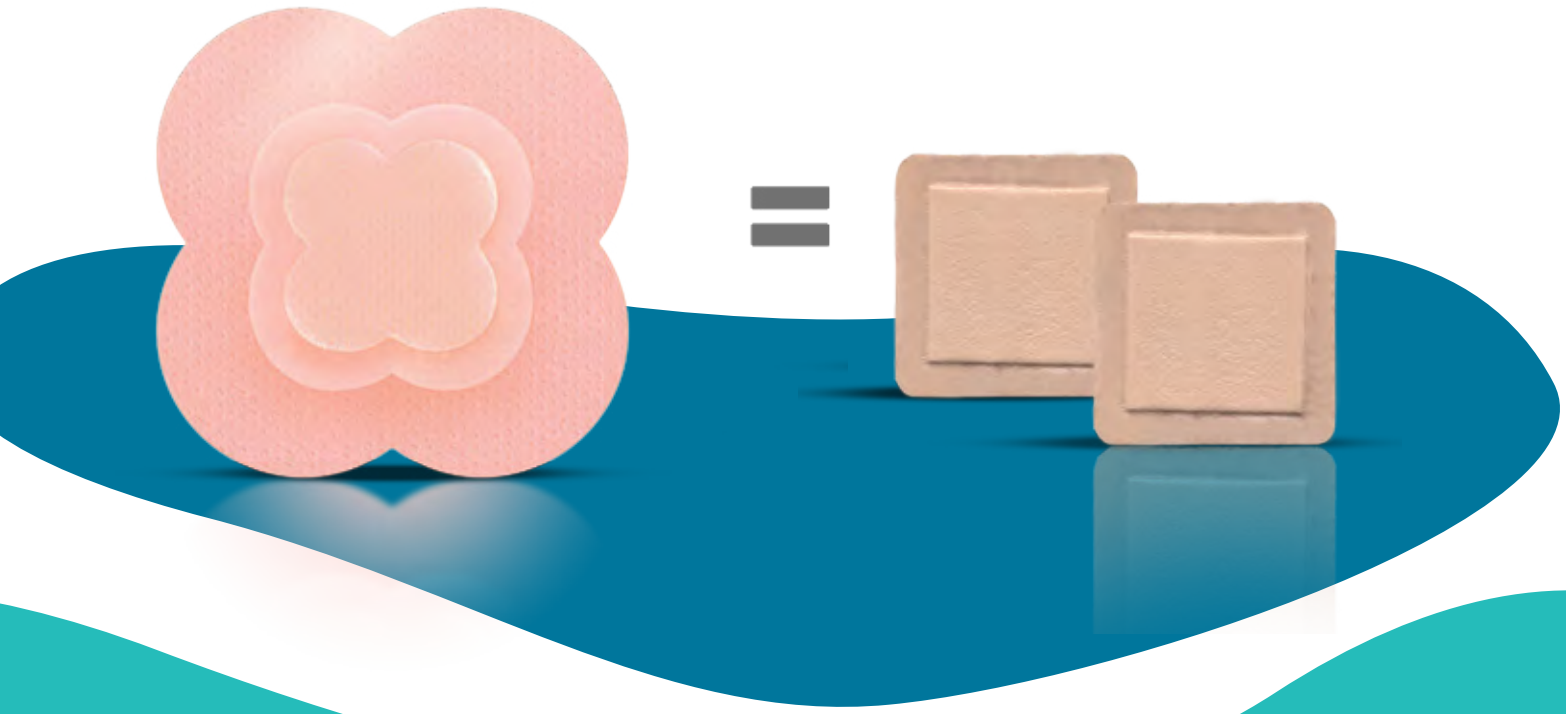

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References: 1. Joy H et al. A collaborative project to enhance efficiency through dressing change practice. Journal of Wound Care. Vol 24. No 7. July 2015 P3-4. 2. Data on File Report GMCA-DOF/08 –April 2016, A. Rossington. Product Performance of Next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

RIGHT PRODUCTS, RIGHT TIME

LifePoint Health's supply chain team is critical to its pandemic response

AS PART OF FULFILLING ITS MISSION OF MAKING COMMUNITIES HEALTHIER, the team at LifePoint Health is committed to anticipating and planning for the unexpected.

When news of the coronavirus broke early last year, the organization began monitoring the situation and taking the steps necessary to ensure its facilities were prepared to provide quality care while also protecting the health and safety of the patients, employees, providers, volunteers and visitors in each of the communities its 88 hospitals serve. A critical part of LifePoint's pandemic response has been the efforts of its supply chain team, led by **Jay Kirkpatrick**, Vice President of Supply Chain Operations.

AT THE OUTSET

"Initially, we had no backup inventory or any kind of pandemic stockpile outside of what individual facilities might have had as part of their own emergency response inventory," Kirkpatrick shares. "From the beginning, a centralized approach was decided on, so we didn't have 88 hospitals going in just as many different directions. Supply chain coordination at the company level ensured that facilities had the products they needed and kept them from situations where they had to purchase products at extreme markups or source them from suppliers with no previous track record in the market, whose quality and safety claims needed to be vetted."

WHO CAN YOU TRUST?

LifePoint relied heavily on the account management and strategic sourcing assistance offered by HealthTrust—especially the supplier and product vetting processes. "As the pandemic spread rampantly in New York and supply disruptions became extremely apparent, predatory pricing kicked in. At the same time," Kirkpatrick says, "I was probably receiving in the neighborhood of 150 emails a day from suppliers, brokers or vendors who came out of the woodwork claiming to have N95 masks, gowns and other types of scarce PPE.

"From a safety perspective, there was no way to know the origin of the products or if they had gone through all of the regulatory agency approvals to ensure they'd protect our staff. Some of these suppliers even wanted cash up front.

"HealthTrust did a fantastic job helping us vet whether or not a supplier was reputable and if its products met required safety standards," he shares. "Account Management at HealthTrust worked with us to get product orders placed efficiently. It was a much more effective process than anything we could have done on our own."

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After the height of the initial surges, LifePoint not only began building a strategic stockpile in the Nashville area, but it also worked with its 88 facilities to ensure that all have a specified level of inventory available across a core set of items.

"The pandemic response has really shown me the strength of our supply chain team. From the workload taken on to standing up a warehouse to house our strategic inventory, the team went above and beyond anything I could have imagined," Kirkpatrick says. "Their efforts resonated throughout the organization, and I'm proud to say that leadership and other staff appreciate the supply chain team that stepped up and did an amazing job." **HT**

As part of its normal course of business, HealthTrust vets products that may be added to the contract portfolio. Clinical Advisory Boards support sourcing by applying evidence and knowledge to the process. Read more about this vetting process that has proved invaluable during the pandemic in protecting members against subpar products and bait-and-switch tactics from unscrupulous suppliers at healthtrustpg.com/VettingSupplies

TO LISTEN to a related podcast with Kirkpatrick, visit healthtrustpg.com/thesource/candid-conversations/supply-chain-protocols-adoption

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Adapting to a VIRTUAL WORLD

Clinical & pharmacy residents embark on career paths with new surroundings

JUST AS THOUSANDS OF MEDICAL AND PHARMACY SCHOOL STUDENTS WERE CELEBRATING MATCH DAY IN MARCH 2020 (many of them virtually), their future hospitals of residence were preparing for a flood of patients due to a looming global pandemic. Their beginnings as newly graduated physicians and pharmacists would be like none before them.

Graduate medical education (GME) leaders were well aware that the pandemic would affect their residency programs. They began thinking through how to provide high-quality training while prioritizing a safe clinical environment.

A ONCE-IN-A-LIFETIME OPPORTUNITY

One could categorize starting your medical career in the midst of a global pandemic as trial by fire. But **Bruce Deighton**, Ph.D., Vice President of Healthcare Graduate Medical Education at HCA Healthcare, views it as a once-in-a-lifetime experience for residents. He oversees 275 residency and fellowship programs at 58 teaching hospitals across the country. These training opportunities span 26 specialties and subspecialties, with more than 4,500 residents and fellows.

"In many ways, our clinical training is enhanced because our residents and fellows have had to pivot and adapt to changing needs," says Deighton. "That kind of agility is an important skill for physicians to learn early on in their careers."

Deighton shares that while residents and fellows have continued to provide clinical care in hospitals throughout 2020, many have also become experts at delivering care via telehealth—largely due to COVID-19 restrictions. "Because of the conservation efforts around PPE [personal protective equipment], fewer residents could enter patient rooms, especially if a patient was thought to be COVID-positive," he explains.

NEWS WAYS OF LEARNING

Jennifer Sternbach, PharmD, BCPS, BCACP, is Corporate Director of Clinical Pharmacy Services at RWJBarnabas Health, which has eight PGY-1 and five PGY-2 pharmacy residency programs throughout the New Jersey health system. In addition, RWJBarnabas Health has physician residency programs in collaboration with Rutgers University.

Sternbach says clinical training has not been affected in her programs; their residents have been part of caring for their patients with COVID-19 and have learned to adapt, along with everyone else. Some adjustments had to be made in some elective rotations, but they've largely given residents a traditional training experience.

"The residents received increased practice in the management of critical care patients," she says. "Many expressed a strong degree of comfort in this care area at the end of their residency."

Heidi Pillen, PharmD, FASHP, Senior Director of System Pharmacy at Beaumont Health, the largest health system in Michigan, explains how COVID-19 caused them to pivot. "Southeast Michigan was a hot spot starting in early March, so we were hit hard and early," she says.

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Pharmacy residents were needed to help take care of patients.

While the clinical training structure remained unchanged, Beaumont, which has three sites offering pharmacy residency training, successfully shifted to provide live, continuous education programming and recordings for home study. In addition, the Leadership Development program was conducted through a virtual platform. These changes were still in effect as Michigan entered a second surge.

Sternbach and her team also adapted their presentations to be delivered virtually. "System meetings that would normally have been in-person are held in smaller groups or remotely. Unique residency experiences such as the Residency Leadership Forum have been held either in smaller groups or in large rooms to allow for social distancing," she says.

A VIRTUAL HIRING PROCESS

Nearly all of HCA Healthcare's GME events have transitioned to an online format, including graduations, resident recruitment interviews and onboarding activities for new residents. Deighton expects this will continue even when the pandemic ends.

"In the past, medical students paid out of their own pockets to travel the country for in-person residency interviews," says Deighton. "Shifting to virtual interviewing makes the process more convenient and less expensive for applicants."

While COVID-19 has certainly thrown a major curveball at physician and pharmacy residency programs for the 2020–2021 academic year, some things haven't changed. Focusing on the basics of training and staying connected to residents and fellows remains as important as ever.

"Program directors across the system are extremely committed to residency development, and we have been able to navigate a new road together," says Sternbach.

Deighton agrees: "Our ultimate goal is helping every resident and fellow become a highly competent, independent physician committed to caring for patients with compassion, purpose and integrity," he adds. **HT**

The essential work of EVS teams

WHILE CLEANING AND SANITATION HAVE ALWAYS BEEN A CRUCIAL FOCAL POINT IN HOSPITALS, the novel coronavirus has brought the importance of these tasks into the spotlight. Hospital staff within environmental service (EVS) departments are working as hard as ever to maintain their high standards.

"There are many other contagions within the environment," says **Matt Oglesby**, Director, Environmental Services, HealthTrust Supply Chain. "We have MRSA, C. diff [*Clostridioides difficile*] and other bacteria that our EVS teams are working hard to get rid of every day."

Still, COVD-19 has forced EVS departments to examine their procedures and adjust where needed.

PRECAUTIONS ALREADY IN PLACE

COVID-19 hasn't meant a lot of change to how hospital EVS departments operate at their core, says Oglesby. The precautions they followed before the pandemic already included guidance that covered safety guidelines for EVS workers and patients to protect from the coronavirus.

"If a patient comes into our hospital and they're on contact isolation, or if they're on airborne isolation, we

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have a policy and a procedure for that. The chemicals and processes that we have in place for those types of isolation are effective against COVID as well."

DOUBLING DOWN ON GOOD PRACTICES

When the pandemic hit the U.S., EVS departments worked to ensure their policies and procedures would keep people safe in light of the new challenges. First up: ensuring the disinfectants in use were products recommended by the Centers for Disease Control and Prevention (CDC) against COVID-19 and securing their supply. Next came making sure staff were up to date on product use. "One thing we did was re-educate teams on the appropriate dwell time for each chemical, which means how long surfaces need to stay wet to be effective against emerging pathogens," says Oglesby.

In addition, the frequency of cleaning in public areas has increased, especially high-touch surfaces such as doorknobs and light switches. Cleaning efforts are also more visible to the public via increased signage, so visitors and patients understand the measures in place to ensure their safety.

However, this increase in cleaning volume hasn't necessarily meant a significant need for more cleaning staff, according to some sources. Some facilities use new technology, such as electrostatic sprayers, to increase cleaning efficiency. Other facilities have managed the workload by moving staff from clinics or elective procedures (that were on reduced hours or closed down because of COVID).

"Office and clinic visits went way down, and at times, we were only allowing one visitor per patient in the building. So we would just move current employees to other spaces to help with COVID needs," says **David Maffeo**, Senior Director of Support Services at Boston Medical Center (BMC). "We also partnered with another cleaning company to utilize about 10 additional employees to help with COVID room response and turnaround at the peak of the pandemic in Boston," he adds.

HCA Healthcare dedicated a specific EVS staff member to each COVID unit. This staff person does not work elsewhere in the hospital and is cohorted with those patients.

COLLABORATION & COMMUNICATION

Keeping facilities clean and safe is a team effort, with EVS working hand in hand with infection control and other teams.

For example, at HCA Healthcare, the Clinical Operations and Infection Prevention teams created a matrix for facilities that outlined which precautions patients require to keep hospital workers safe. This clear information and education has helped to put staff at ease, so they can do their job safely and without fear.

At BMC, historically, housekeeping huddled three times a day to keep staff informed on necessary information. "We talk about cleaning protocols, social distancing and PPE [personal protective equipment]," says Maffeo. "Since we do these huddles anyway, COVID just became the new topic."

Oglesby believes the increase in the cleaning of high-touch areas and the heightened awareness of cleanliness that COVID-19 has brought is the new baseline. "While our teams were doing an excellent job of keeping our facilities safe prior to the pandemic, increased cleaning is never a bad thing," he says. "More than ever, there's a focus on housekeepers truly being heroes and keeping people safe by making sure our facilities are clean." **HT**

VISIT THE HEALTHTRUST MEMBER PORTAL for more information about EVS products and services on contract.

Securing the supply chain CLOSER TO

HealthTrust's search for a U.S.-based, joint-venture partner

WHEN COVID-19 BEGAN TO MAKE ITS APPEARANCE IN THE U.S. LAST SPRING, the acquisition of personal protective equipment (PPE) was a global challenge. Worldwide demand for both the products and the raw materials needed to create them soon surpassed supply by a significant margin.

Supply chain professionals across the country came face-to-face with the impact of relying on foreign manufacturers to supply the vast majority of much-needed PPE to protect providers and patients throughout the healthcare community. What had predominantly been a healthcare safety category soon became a household topic. The need for protection went beyond traditional environments and into the general public, further straining the supply chain.

"The pandemic reinforced the need for redundancy and risk mitigation on critical products," says **Ed Jones**, President and CEO of HealthTrust. "As an organization, HealthTrust supports increasing manufacturing in the U.S. Establishing domestic mask manufacturing is one critical step, among others, toward creating a more secure PPE supply chain for our membership and community as a whole," he adds.

In January of 2020, **Rosalind Holloway**, Vice President of Global Sourcing at HealthTrust, suggested that HealthTrust explore manufacturing in the U.S. to offset its reliance on sourcing imported masks. This became a major focus for colleagues who were part of the organization's Manufacturing/New Sources workstream. (See the Q3 article on the 12 pandemic response workstreams initiated by HealthTrust at **healthtrustpg.com/COVIDWorkstreams**) Holloway led this workstream, which is composed of colleagues with engineering, manufacturing and product backgrounds. Jones explains, "A thorough understanding of product specifications was part of the critical thinking and methodical evaluation processes used to narrow the field to a short list of quality suppliers. Insight from the Clinical Operations and Global Sourcing teams was paramount to shortening the learning curve, enabling us to move quickly."

The workstream vetted 50 to 60 companies as potential supply partners and assessed over 40 sites as possible manufacturing locations.

One source that stood out was a global manufacturer with over 30 years of healthcare experience and know-how in producing high-quality products, looking to grow its presence on U.S. soil. Excited by the opportunity to increase long-term mask production in the U.S. for all healthcare providers, HCA Healthcare and the company agreed to launch a manufacturing joint venture to produce level 1 and 3 masks in the U.S.

"The partnership provides an additional supply option to the market without disrupting current supply sources. As needs arise, we will continue to support the evaluation of other products that might become part of this manufacturing partnership," Jones says.

"HealthTrust values diversification of PPE manufacturing. This joint venture is one way to mitigate risk and create a more stable supply chain while still maintaining valued supplier relationships already in place," he adds. **HT**

FINDING A PARTNER

Searching for the right joint-venture partner involves a number of important considerations. Some of those include:

- Balance between security of supply and economic viability of supply chain costs
- Vertical integration of raw materials to finish goods; many companies are still sourcing raw materials outside of the U.S.
- Relevant healthcare experience and an understanding of the high-quality product standards required by healthcare providers
- Appropriate balance between redundancy and risk
- Compliance with all applicable FDA standards and other legal and regulatory requirements

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[1]Refer to device manufacturer's instructions for use. PDI Study conducted February 2020; https://pdihc.com/wp-content/uploads/2020/07/Sani-HyPerCide-Competitive-Comparison_UPDATE-0720_03202062.pdf

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