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ENHANCING PROVIDER PERFORMANCE & CLINICAL INTEGRATION

Q3 2021 | V 16 NO. 3 | HEALTHTRUST

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THE CONTENTS

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FEATURES

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* 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.)

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CEO perspective

Challenge accepted

Healthcare's response to the needs forced upon us by the pandemic can be summarized as nothing short of extraordinary. I cannot think of a better theme for our conference than "Challenge Accepted" to appropriately acknowledge members across the country who answered the call, working tireless hours in both front-line and behind-the-scenes positions over the course of the last 18 months. A special thank you also to the supplier community, who responded by helping us meet the needs of our membership—many having to pivot and exhibit new ways of collaborating to keep the supply chain resilient and moving forward.

We are excited to host and celebrate members and suppliers during the annual HealthTrust University Conference, July 26, 27 and 28, at the Music City Center in downtown Nashville, Tennessee.

For members who can't be with us in person for HTU, we extend an invitation to join virtually for the general sessions from 8–10 a.m. (Central) on both Tuesday and Wednesday (July 27 and 28). **John Young**, M.D., MBA, and his Clinical Services team have assembled a quality slate of multidisciplinary programs that I hope you will take advantage of as well. (John highlights a few of those sessions in his CMO column on page 6.) Choose from six time blocks over the course of the three-day conference that offer continuing education credit-based sessions.

A LITTLE INSPIRATION

Despite the weariness we may be feeling from the challenges endured over the last 18 months, we will receive some much-needed inspiration from author and keynote speaker **John O'Leary** (**johnolearyinspires.com**) during Wednesday morning's general session. I am honored to get to meet this overcomer in person and look forward to hearing the poignant message he'll use to inspire us to keep forging ahead. Doctors gave John a 1% chance of surviving burns on 100% of his body after a fire—yet he did. And, after enduring months in a hospital bed and years of physical therapy, he will share how he "woke up to what really matters." John offers a perspective to wake us up from what he calls "accidental living" and invites us to embrace three simple truths: 1) Our life is a sacred, awesome gift; 2) We get to choose our mindset in every situation, no matter how bleak it seems, and 3) Together, we can change the world—starting with our own.

ANNUAL MEMBER RECOGNITION

While the work of all member organizations and suppliers during COVID-19 will be celebrated in many ways throughout the HTU event, a smaller number of member organizations submitted applications for official recognition as part of our annual Member Recognition Awards process. These awards will be presented during Wednesday's general session (July 28), followed by an official press release and full story coverage in the Q4 edition of *The Source*.

We look forward to your participation in and feedback on the 2021 HealthTrust University Conference. **HT**

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

FOR MORE INFORMATION on the HTU virtual event, contact conferences@healthtrustpg.com. For more information on Member Education during HTU, contact education@htu.healthtrustpg.com

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CMO perspective

Back to our regular programming

In decades past, at the end of a news soundbite that interrupted a regularly scheduled television show, an announcer would say: "And now, back to our regular programming." That announcement feels somewhat reminiscent of our current transition to life after the pandemic.

After more than a year of the world functioning on amended personal and professional schedules, we are excited to be planning live events again, including the annual HealthTrust University Conference. My team is working with more than 70 presenters to deliver a quality slate of education programs for our live attendees, as well as those of you who will join us virtually on July 26, 27 and 28.

Of particular timeliness is the "COVID-19 Impact & How to Move Forward" panel on July 27, featuring three Physician Advisors: **Howard L. Burley Jr.**, M.D.; **Frank Drummond**, M.D., MBA; and **S. Shaefer Spires**, M.D. Moderated by Clinical Services Vice President **Crystal Dugger**, RN, MBA, the panel will address how health systems can move forward despite the fact that significant changes implemented during the public health emergency will no longer be in effect (see the cover story with Dr. Spires on page 52). These subject matter experts will also address the impact to front-line healthcare workers, vaccine efficacy and the new reality: caring for COVID long-haulers, which has become a specialty.

OUTPATIENT MOVEMENT

Joining me on July 26 for "Procedures Move Toward Ambulatory Surgery Centers (ASCs)" will be **Katie Ford**, MBA (Surgery Partners), along with Physician Advisors **Richard R. Heuser**, M.D., FACC, FACP, FESC, FSCAI, and **Christopher Kauffman**, M.D. We will communicate the general changes to the Center for Medicare & Medicaid Services' final rule for 2021 with regard to outpatient procedures and focus on how health system leaders, physicians and service line leaders can best prepare for this extensive shift in site of care. The outpatient movement will continue to grow as more procedures are removed from the Medicare Inpatient Only list and are performed in hospital outpatient departments (HOPD). ASCs will benefit, as many procedures performed in HOPD will most likely make the ASC-approved list for Medicare reimbursement.

PHYSICIAN COLLABORATION

Rounding out our Physician Advisor participation in the 2021 event are two sessions with a focus on contracting and the importance of using clinical evidence and process improvement to collaborate with physicians in medical device sourcing. Offered on July 27, those sessions include:

- "Physician Collaboration Is Key to Successful Medical Device Sourcing," featuring Physician Advisors **Steve Gremillion**, M.D., FACC, and **Mark Pinto**, M.D., MBA
- "The Osteobiologics Contracting Process," featuring Physician Advisors **Kade Huntsman**, M.D., and **William Payne**, M.D.

In-person invites to HTU are based on IDN allocations. The good news, however, is that all members are invited to attend the virtual event. We look forward to your participation and feedback. **HT**

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

FOR MORE INFORMATION on attending the virtual HTU event, contact the HealthTrust Marketing & Events team at conferences@healthtrustpg.com

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Navigating shifting payor dynamics

Pharmaceutical decision-making is increasingly dictated by expanding payment policies

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In the drug market, payors historically have dictated which medications they will cover. But these demands have expanded dramatically in recent years, mandating where and how healthcare facilities can administer drugs and triggering undesirable ripple effects, such as safety concerns, treatment delays and higher costs for both facilities and patients.

Rules surrounding aspects such as prior authorization, white- and brown-bagging (see definitions on page 10), and site of care are increasingly infringing on pharmaceutical decision-making in perplexing and exasperating ways. HealthTrust is pushing back against such policies while helping member facilities navigate this minefield.

"It's becoming extremely frustrating for healthcare providers. They've always had to deal with the formulary of a payor, but now it is also being mandated as to where they can actually administer the medication," says **Jason Braithwaite**, PharmD, MS, BCPS, AVP of Clinical Pharmacy Services at HealthTrust. "It creates more narrow networks and continually more hoops to jump through."

"Economic pressures—along with an explosion in costs in the outpatient arena in specialty drugs, infusions and novel biopharmaceutical products—are the primary drivers of these shifting payor dynamics," says **Brian Moran**, PharmD, MBA, VP of Pharmacy Services at HealthTrust. "On the acute care side of the business, providers previously experienced formulary decisions being based on outright costs," Moran adds. "But on the outpatient side, payors are becoming increasingly more aggressive with their policies, particularly over the last four years."

LAYERS OF COMPLEXITY

What aspects do these onerous payor policies include? Experts consistently point to drug administration methods such as white- and brown-bagging and

Continued on page 10

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Continued from page 8

"Economic pressures—along with an explosion in costs in the outpatient arena in specialty drugs, infusions and novel biopharmaceutical products—are the primary drivers of these shifting payor dynamics."

– Brian Moran, PharmD, MBA

site-of-care requirements, as well as pre-authorization rules that pervade all of these.

White-bagging is when a prescription drug is dispensed by a third-party specialty pharmacy and shipped to the provider to administer. This method, which applies more often to injectable versus oral drugs, is generally paid under pharmacy benefits instead of medical benefits and almost always places providers and facilities at a disadvantage.

"White-bagging takes away any opportunity for a provider to make their own determination of what the best drug is for a patient to receive," Braithwaite says. "You also take on the risk of administering that drug, as well as the prep time. You're making only the administration fee—not any other revenue from the drug-purchasing side."

Moran called mandatory white-bagging the most difficult payor policy being thrust on pharmaceutical providers. "You either have to adhere to the way they want it done, or you can bill, and they'll deny you," he explains.

Brown-bagging is closely linked. It's when a prescription medicine is ordered by a provider but shipped to the patient who must bring it to their next appointment to be administered in a clinical setting. Subsequently, when a patient has custody of the drug, safety can be jeopardized.

Site-of-care requirements are just that: regulations dictating where treatments may be administered. Often, payors won't cover drug infusions unless they're done at smaller outpatient clinics, which

Continued on page 12

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Continued from page 10

typically cost less. "Site of care is just another layer of complexity, and a lot of providers don't even know they're excluded," Braithwaite says. "Some policies allow them to administer the first dose, and after that, they're not covered. These are not $50 medications; they're often thousands of dollars, and providers end up fighting with the payor or potentially eating the cost."

ADDING STAFF & PUSHING BACK

At Mercy Hospital in Chesterfield, Missouri, Chief Pharmacy Officer **Jon Lakamp**, PharmD, BCPS, feels site-of-care rules have posed many safety challenges. Smaller off-site facilities often don't have the full breadth of equipment or staff necessary in the event of an extreme patient medication reaction. However, even prior authorization rules on specific medications—which are often not a bad thing—are becoming more aggressive as novel drugs with huge price tags are developed.

To cope with the increasing number of policy changes, Mercy has added about three dozen positions in recent years to handle benefit verifications. "This team helps manage the process so our providers can focus on caring for the patient while others concentrate on jumping through hoops," Lakamp says. "We're setting up complex teams to do this, and, at times, it puts time constraints on how quickly we can initiate therapies."

Scott Milner, PharmD, MBA, Senior Director of Pharmacy, Business Development Purchasing/340b and Infusion Services at St. Luke's Health System in Boise, Idaho, says his system had to write off about $3 million in medications in 2017 due to white-bagging requirements.

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"Medications were not shipped on time, so a patient showed up for a scheduled infusion, and their medication was not there," he recalls. "We would then dispense something off our shelf, and when the patient's medication arrived, we couldn't use it."

As a result, St. Luke's fought back, telling payors white- and brown-bagging were not in its business model. Because the nonprofit health system is large—with eight non-oncology and nine oncology infusion centers, as well as 170-plus clinics—its push-back efforts were largely successful, Milner says.

"A couple of years ago, we were writing off about 20% of our infusions; now we're writing off about 3%," he adds.

HEALTHTRUST PROVIDES CLARITY

St. Luke's Health System also boosted HealthTrust's efforts to help members navigate these ever-shifting payor dynamics by presenting its infusion model at last year's HealthTrust University virtual conference. Most members, Braithwaite notes, "still haven't figured out how to manage this complex market."

To provide clarity, HealthTrust has created payor resources that include links to websites and a tool that analyzes the percentage of payors that would pay for certain drugs. "We're also standing up a Payor Collaborative Group focused on our pharmacists and providers to get together and talk about best practices for managing and navigating the market," Braithwaite adds. "From that, we expect to get additional best practices to share with the broader membership."

HealthTrust's guidance has greatly benefited Mercy, Lakamp notes. "As we decide which pharmaceuticals we're using, making clinical decisions along with contracting and financial decisions, HealthTrust has done a great job focusing on tools to help members manage those decisions." **HT**

FOR MORE INFORMATION about how HealthTrust can help your organization navigate payor policies, email Jason Braithwaite at jason.braithwaite@healthtrustpg.com

Blessings in the "burden"

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Consistencies in EHR documentation help inform patient care

A 2018 study[1] revealed that nurses spend 25% of their time on documentation—inclusive of entering patient data into an electronic health record (EHR) or paper chart and then reviewing the information.

Within an acute care environment, these essential functions typically take place at the nurses' station, in the hallway or in patient rooms. While many view documentation as a burden, the rich data that is collected and entered into an EHR is also seen as a potential source of scalable knowledge to inform care delivery and aid in the evaluation of patient outcomes. When standardized across an integrated delivery network (IDN), this data becomes invaluable.

This reality was the motivation of visionaries who set out to develop a national collaborative process to create a minimum set of standard, usable and reusable data from patients' admission history as captured by nurses in an EHR. Their work found that reducing documentation to only that which is essential to care, entered in a standardized format, reduces the "burden" of documentation.

HISTORY OF COLLABORATION

2013

A national collaborative effort began in 2013 at the University of Minnesota (U of M) School of Nursing. Workgroups formed with deliverables, and the collaboration evolved into an annual event—the Nursing Knowledge Big Data Science (NKBDS) Conference. Over the following five years, the workgroups met virtually on a regular basis, and annually in June at U of M to address care coordination, clinical data analytics, context of care, education, encoding and modeling, e-repository, mobile health, nursing value, policy, social determinants of health and transforming documentation.

> "The development of meaningful clinical content requires that, together, we must advance standards and discipline in order to maximize RN efficiency, optimize data design and facilitate value-added reuse."
>
> – Jane Englebright, Ph.D., RN, CENP, FAAN

2018

At the 2018 NKBDS meeting, a joint task force was formed with the focus of usable and reusable data as its charge. The resulting group was the Admission History Task Force, composed of practicing clinicians and experts from academia and the healthcare industry who were members of five NKBDS workgroups: Transforming Documentation, Care Coordination, Social Determinants of Health, Clinical Data Analytics and Encoding/Modeling. The task force was approved to move forward with the goal of creating a repeatable process that could be used for other elements of documentation, for other patient populations in any care setting. An adult patient in the acute care environment was selected as the component of nursing documentation to optimize.

2019

While the topic and related ideas had been in discussion since 2013, the Admission History Task Force members agreed to an aggressive timeline for content development—July 2019—just nine months from its inception. For purposes of the project, participants agreed to assume the patients' acute care admission history as being from the point of the initial patient/family interview (providing background for the current episode of care) and transition to the next phase of care. The task force then defined the categories that were

Continued on page 16

The goal of the Admission History Task Force was to create a repeatable process that could be used for other elements of documentation for other patient populations in any care setting.

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Continued from page 15

the responsibility of nursing and transitioned the document to a separate task force to map related content to the appropriate terminology.

Nursing process and documentation expectations, as well as the experience of organizations that had redesigned admission histories within the last five years, were instrumental in outlining guiding principles for the work of this project. According to article co-author and Admission History Task Force member, **Jane Englebright**, Ph.D., RN, CENP, FAAN, SVP and Chief Nurse Executive at HCA Healthcare, "It was critical that we worked toward generating important data in the context of documentation burden mitigation, but ultimately toward the international desire to share and compare nursing data in patient outcome evaluation."

2021

The work of the task force was highlighted in an article, "A Framework for National Collaboration to Reduce Documentation Burden and Design for Usable and Reusable Data," published recently in *The Journal of Nursing Administration* (JONA).[2] The article details the collaborative journey of the visionary nurse leaders and experts who generated national consensus recommendations on documentation elements related to admission history.

REMEMBER MEANINGFUL USE?

The JONA article also refers to the history of meaningful use guidelines that were ushered in as part of 2009 legislation, when the government provided billions of reimbursement dollars for healthcare providers to expand the use of EHRs. While the expansion was rapid and created a blueprint

Continued on page 18

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Continued from page 16

focused on elements of clinical care delivery, article authors suggest it lacked basic guidelines for design, usability and data reuse, enabling the fragmented environment. Users soon realized that maintaining and expanding EHRs was a huge burden to bear.

Also contributing to issues of meaningful use were data entered in the wrong place, wording inconsistencies and disparate EHRs across a health system's facilities, often due to merger and acquisition activity. Other inconsistencies are often found as well, running contrary to the suggested guiding principles for content and formatting as outlined in the guiding principles sidebar (to the right).

Because the functionality of each EHR varies, article authors advise that "other groups working on similar problems focus on the essence of the content for maximum generalizability." They add, "However, it should be noted that the workflow within the content may come across differently, based on EHR functionality. Additional

Continued on page 21

GUIDING PRINCIPLES OPTIMIZE DATA

The foundation for redesigning clinical documentation is created by guiding principles. Following are the guiding principles used by the Admission History Task Force. Whether you are designing documentation for an initial installation or optimizing current documentation processes and tools, the principles are essential in evaluating each data element. Elements of data that don't meet the guiding principles that your organization establishes should be eliminated.

Additionally, understanding the role of consistency in content and formatting are key to capturing data accurately and the ability to reuse data once it is entered into an EHR. Clinicians should be trained on

best practices for entering patient data, taking into account your specific EHR's functionality.

Guiding principles for content

Content is:

- Essential for patient care decisions with a clear case for use of data in care
- Addressing a regulatory requirement
- Evidence-based, whenever possible
- Not documented elsewhere
- Best documented by a nurse
- Best documented during the admission process, as defined by the organization

Guiding principles for format

- Each item should address a single, structured concept to facilitate mapping and reuse of the data
- Options within the answer sets should be grammatically consistent
- Options within the answer sets should be the minimum necessary with a maximum goal of 12 items
- Avoid yes/no responses whenever possible to facilitate reuse of the data
- Use patient-friendly or plain language, avoiding technical terms
- Avoid abbreviations, acronyms and brand names to reduce misunderstanding

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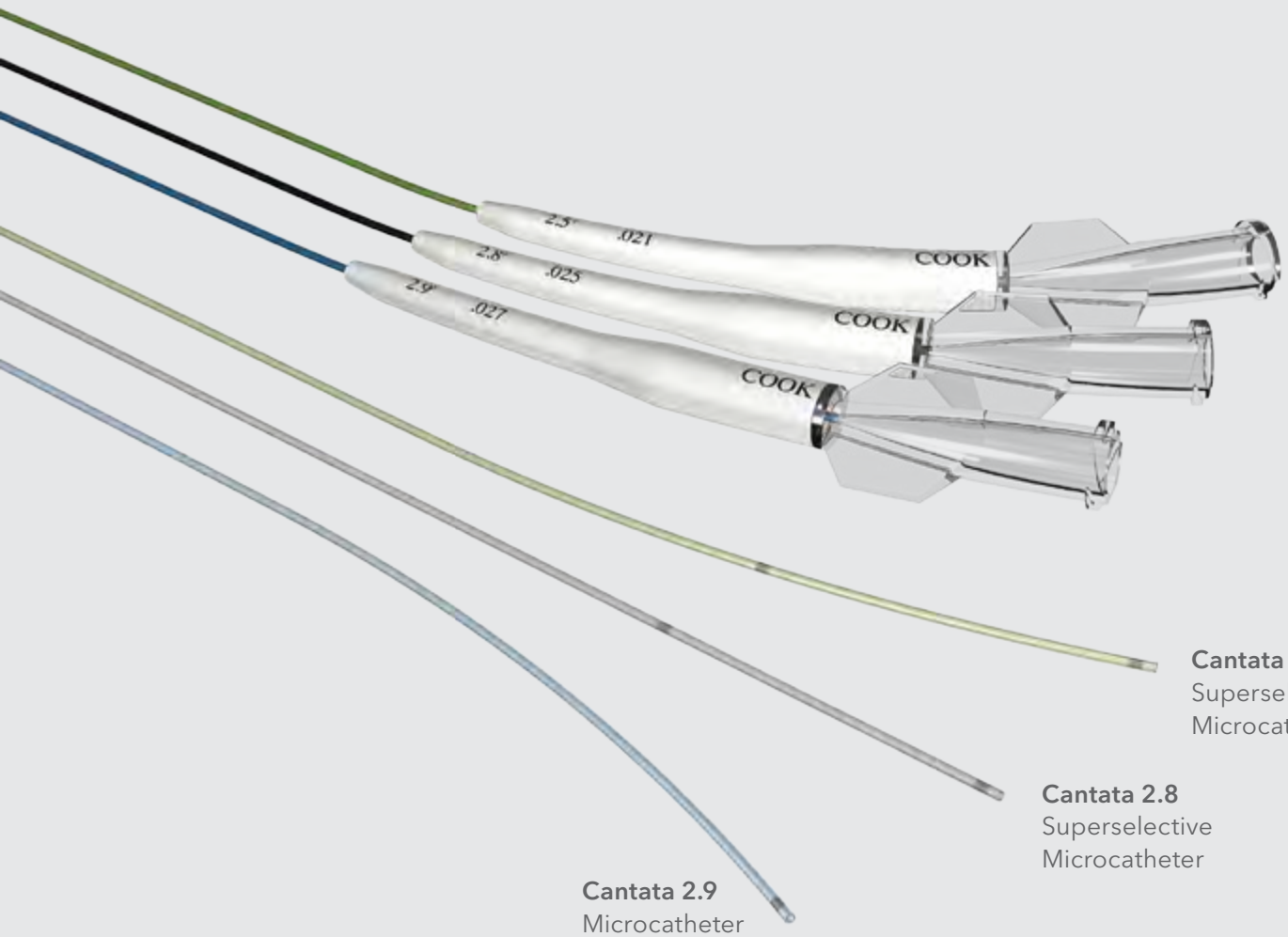

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Continued from page 18

edits may be needed to match workflow in individual organizations."

Article co-author and Admission History Task Force member **Sarah Michel**, MBA, BSN, RN, NE-BC, Director, Research & Clinical Engagement, HealthTrust Clinical Services, adds, "This work proves that collaboration at a national level to reduce documentation burden and improve data usability is possible and highly productive. It has resulted in the creation of a framework, so the process can be replicated across other areas of a patient's record within an EHR."

TO READ an abstract or purchase the full JONA article, visit journals.lww.com/jonajournal/Abstract/2021/03000/A_Framework_for_National_Collaboration_to_Reduce.10.aspx

IN PRACTICE

Tackling documentation burden starts with getting organized and determining participants for the work effort. Five critical teams with expertise from these stakeholders is key:

1. CNO leadership as an executive champion
2. A caregiver who performs admission history interviews
3. Nurse informaticists and information technologists who understand the EHR system
4. Risk management, regulatory compliance, case management, nutrition services &/or rehabilitation services
5. Project management

The Q4 edition of *The Source* will provide more information and tools for providers interested in starting their journey in tackling documentation burden. **HT**

Sources:
1. ncbi.nlm.nih.gov/pmc/articles/PMC6371290/#:~:text=In%20our%20study%2C%20we%20found,and%20paper%20charting%20and%20review
2. pubmed.ncbi.nlm.nih.gov/33570374

Rising to the CHALLENGE

HCA Healthcare pioneers a new tool to help project supply expense

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WITH ELECTIVE PROCEDURES SUSPENDED, outpatient volumes dropping and uncertainty around supply availability, supply chain and financial leaders quickly discovered when COVID hit that traditional methods for projecting supply expense were not accurate during a pandemic.

"We knew we needed a better way to project supply expense, and we couldn't rely on historical information to do it because the new environment was just so different," says **Steve Vecchione**, CFO of HCA Healthcare's Richmond Supply Chain Consolidated Services.

After labor, supply expense is generally a healthcare system's highest cost. Hospitals could not afford to have such a significant expense unknown and uncontrolled. "With COVID, there was such a significant impact to our patient mix that we were seeing double-digit supply expense growth, adjusted by volume," says **Dan Cleeton Jr.**, VP of Financial Operations for HealthTrust Supply Chain. "We needed to get ahead of that growth and address it in real time."

A NEW TOOL OF THE TRADE

So when **Todd LaCaze**, CFO of HCA Healthcare's South Atlantic Division, challenged his Supply Chain CEO **Noel Hodges** to find a better way to project supply expense, Hodges' team rose to the challenge. Vecchione, in collaboration with hospital financial leaders, supply chain operators and data analytic teams across HCA Healthcare, worked to create a tool suitable for the new reality.

Generally, hospitals forecast supply expense based on historical data using supply expense and volume metrics

Continued on page 24

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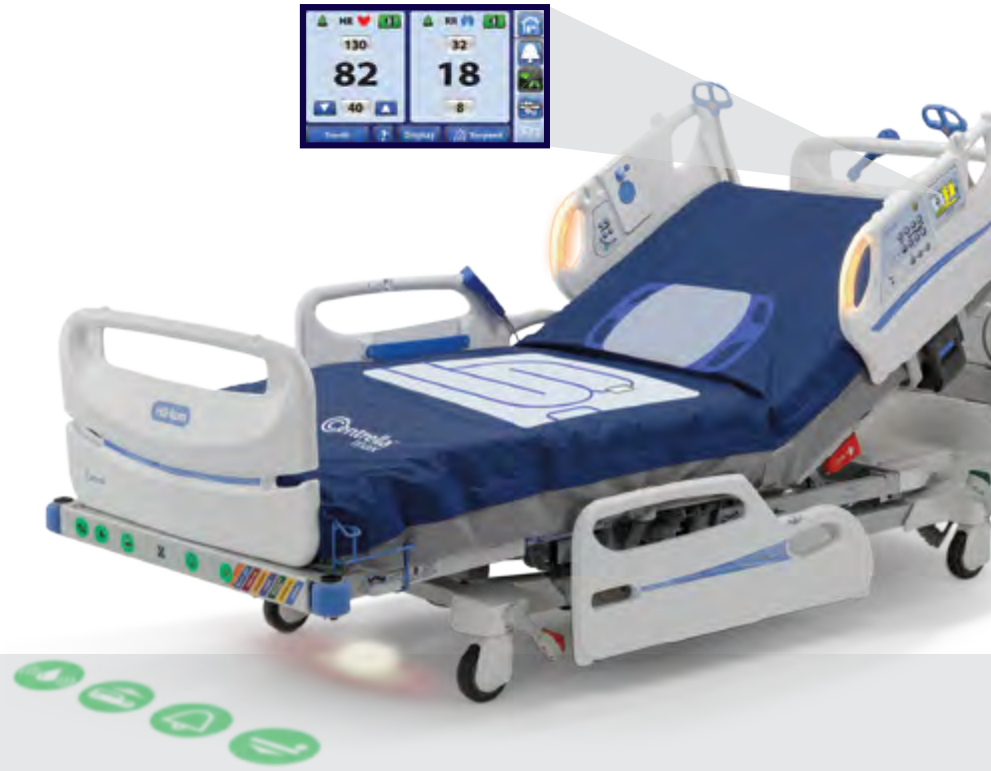

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*Orders must be placed during the group buy period of 6/1/2021 through 8/30/21 and delivery taken by 9/24/2021. Contact Hillrom for more details.

[1] Cuttler, et al. Beyond the Falling Star: Sustained Decrease in Falls and Injuries with Targeted Bed Exit Alarm, Staff Education Icons, and Patient Education Video. Collaborative Alliance for Nursing Outcomes. 2015.

[2] Kennedy, R, Slaughter C, Raygoza, H, Brooks, P. Evaluation of an incontinence management system in the critical care environment: A case series. Presented at NPUAP Annual Conference 2019.

[3] Brown HV, et al. The American Journal of Medicine. 2014; 127:226-232.

 APR241001 rev 2 16-JUN-2021 ENG – US

Continued from page 22

like adjusted admissions or adjusted patient days. "But that approach didn't take surgical volume into account. If you have sharp increases or decreases in surgical volume, it's going to drive supply expense a lot more than the overall admissions number," says Vecchione.

That's why instead of using historical data, this new supply expense projection tool takes a completely different approach. It analyzes month-to-date purchase order activity—which typically accounts for about 90% of supply expense—as a leading indicator, and then forecasts current month supply expense using a rolling 12-month average of purchase order activity as a percentage of supply expense.

"This tool puts a greater emphasis on understanding what our specific product purchases were in order to project total supply spend for that month," says Cleeton.

Not only does the projection tool allow supply chain operators to forecast supply expense, but the extensive detail it provides enables them to take action. For example, it can help answer questions like, "Does my department really need the 10 cardiovascular implants it ordered, when we only used two in the last month, or was the purchase order created incorrectly and the wrong number ordered?"

"It allows supply chain operators to review purchase orders daily to identify where they have new or inappropriate spend. They can request purchase order changes or cancellations in an effort to mitigate avoidable supply expense spend throughout the month," explains Cleeton.

A TEAM EFFORT

A number of teams collaborated over many months to develop the tool. Vecchione indicates that the first step was understanding the best way to pull the data that was needed on a daily basis. He did that by working closely with approximately 15 supply chain operators.

"They would look at the data I was collecting and provide feedback. We took that feedback to figure out how to improve the tool," Vecchione shares. This collaborative approach continued throughout the tool's development, expanding to include hospital finance and IT development

> "Our operators see the value in reviewing yesterday's purchase orders to better understand their projected supply expense and being able to address inappropriate spend before it's received at the hospital dock."
>
> – Dan Cleeton Jr.

teams. One advantage of this approach was the opportunity to test and improve the tool. "It gave us some real-time quality assurance. It enabled us to understand when it didn't work and what caused it, so we could fix it," says Vecchione.

After about six months of iteration, Vecchione was still manually pulling the data and consolidating it into an Excel spreadsheet for supply chain operators. That's when the South Atlantic Division pulled in IT resources led by **Kendrick Miller**, Decision Support Manager for HCA Healthcare's North Florida/South Atlantic Division, to automate as much of the process as possible. "They stepped up and built it into a tool where it was nearly automated. I mostly just had to go in and manipulate a couple of things and send it out," says Vecchione. This was the foundation that the data analytics team, led by **Stephen Ronan Sr.**,

Continued on page 26

Continued from page 25

Financial Analyst at HCA Healthcare/HealthTrust, used to develop its final iteration as a Microsoft Power BI (business intelligence) dashboard.

"The data analytics team created something bigger than I ever thought it could be, including the addition of features that enabled our operators to see other metrics, such as the percentage of contract purchases versus non-contract purchases," says Vecchione.

The projection tool went live in December 2020. Although it's available for anyone within HCA Healthcare to use, Vecchione and the collaborative team are continuing the iterative approach of improving the tool over time.

BEYOND THE PANDEMIC

Because of its advantages over their previous approach, Vecchione and Cleeton expect that this will be HCA Healthcare's new way of projecting supply expense for the foreseeable future, beyond the pandemic.

"Our operators see the value in reviewing yesterday's purchase orders to better understand their projected supply expense and being able to address inappropriate spend before it's received at the hospital dock," explains Cleeton.

Vecchione is also interested in applying what they've learned from its development and use to monitor other spend. "Is there a leading metric or an indicator that we can use to project purchased service spend more accurately, for example, or to develop algorithms that automate the identification of inappropriate spend?" he asks. "I don't have the answers to that, but this is the foundation to advance our analytics capabilities and see how we can continue to leverage data to drive our daily behavior."

For Vecchione, seeing HCA Healthcare's divisions and facilities use the tool is gratifying. "The last thing you want to do is build something that doesn't yield value. A number of colleagues have said this has both reduced the time required and simultaneously improved their ability to manage supply ordering. That is especially nice to hear," he adds. **HT**

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MAKING SENSE of the science

How to review a clinical study

THE COVID-19 PANDEMIC HAS LED TO NEW FORMS OF PERSONAL PROTECTIVE EQUIPMENT, new ways of testing and diagnosing illness, and new treatments and vaccines. And they've all come to fruition thanks to clinical studies. Clinical studies are the foundation on which modern medicine is built. Little by little, step by step, researchers and clinicians make medical advances to benefit the common good. But these studies are only as good as the people who effectively read and interpret them.

How can you ensure that you're correctly digesting a clinical study? HealthTrust's **Angie Mitchell**, RN, AVP of Clinical Services, and **Holly Moore**, MSN, CCRN-K, Director, Clinical Services, walk through the basics of a clinical study, including key components, common jargon and pitfalls to avoid.

CLINICAL STUDY BASICS

A clinical study is a medical observation or experiment done on people to learn more about the effects of a behavior, product or procedure.

What are the types of clinical studies?

- **Observational study:** Researchers observe people in their normal settings and collect information. They may segment people into groups or "cohorts," to look at the differences. For example, researchers discovered several comorbidities increased the risk of severe illness and hospitalization in COVID-19 patients. The researchers do not assign interventions. Rather, they simply observe in

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order to discern the strength of the relationship between the risk factor and the disease.

- **Investigational study:** Also known as clinical trials, these studies test an assigned intervention on people. It could be a new medicine, procedure or behavior. The primary reason for an investigational study is to determine whether a new treatment is safe and effective. Often, the study includes a control group, which does not receive the intervention, and the researchers will measure the predetermined outcomes to see if there are any improvements.

Who conducts clinical studies?

- **Principal investigator:** The study leader, who is often a medical doctor or advanced clinical practitioner
- **Research team:** Medical doctors, nurses, scientists, dietitians, social workers and other healthcare professionals

Who pays for clinical studies?

- **Government agencies**
- **Drug makers**
- **Technology companies**
- **Other product suppliers and manufacturers**
- **Nonprofit organizations**

"A clinical study may be funded by a number of entities, with the most common sources being governmental and private industry," says Moore.

Suppliers often support research, which is a positive, because it helps advance medicine and provide better treatments and patient care. But it's important to watch out for potential bias or conflicts of interest, which can happen if a supplier is compensating the researchers. "In these situations, you'll want to look at the study through a more discretionary lens," advises Mitchell.

Continued on page 30

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Continued from page 29

KEY TERMS

- **Randomized:** Each participant is indiscriminately put into either the test group or control group, so that every individual has an equal chance at receiving the intervention.
- **Controlled:** The study has two groups for the purpose of comparing their results. For example, one group is given a treatment and the other is not.
- **Variable:** This is the person, thing or behavior that the researchers are trying to measure.
- **Placebo**: A substance that has no therapeutic effect.
- **Investigational:** A drug, device or procedure is undergoing active study; it hasn't yet been formally approved for use.
- **Cohort:** Another word for group.
- **Intervention:** Participants are exposed to a treatment to establish whether it is effective.
- **Single-blind:** The participants don't know if they are receiving the intervention (test group) or not (control group).
- **Double-blind:** Neither the participants nor the researchers know who is in which group.
- **IRB:** The Institutional Review Board is responsible for protecting participants by ensuring the study is adhering to standards and guidelines.
- **Sample size:** The number of study participants.
- **Phase:** With clinical trials, there are often three or four phases. The later phases of the study tend to get larger as the researchers establish safety and efficacy.
- **Retrospective:** A study that looks in the past to examine two similar groups where one group has a disease or condition, or exposure to a particular substance, and the other does not have the disease, condition or exposure. It's also known as a case-control study.
- **Prospective:** A study that looks at the present and future, where individuals in a study are followed over time, and data about them is collected as their lives and conditions evolve.
- **Meta-analysis:** This refers to reviewing data from several independent studies on a similar subject to look at trends.

KEY COMPONENTS OF A CLINICAL STUDY

When starting your research review, you first might quickly read abstracts when deciding which studies are relevant to the topic at hand. "Don't stop there," says Mitchell. "Read the entire article because there are always nuances." If you're new to reading clinical studies, here are some sections you might review:

- **Abstract:** The high-level summary of the study
- **Methods:** The outline of the design of the experiment, participants, intervention provided, timeline, primary outcome of interest, data collected and type of statistical analysis
- **Results:** The detailed contrast and comparison between the control and study groups
- **Conclusions and limitations:** A discussion surrounding implications of findings, possible future research needs and study weaknesses that may affect its applicability

BIAS ALERT!

Ask these questions of the study to help you determine how much opportunity exists for potentially biased results:

- Was the study blinded?
- Was the sample size small, making it less applicable to the larger population?
- Who funded the study?
- Do the researchers have any disclosures or conflicts of interest?
- Was the study peer-reviewed and published in a reputable scientific journal?

FINAL THOUGHTS

- **Be patient:** If you aren't familiar with the topic, it might take you longer to process the information.
- **Practice makes perfect:** The more studies you read, the more you'll start to notice that there is a rhythm to them and the more proficient you will become at interpreting what they're saying and not saying.
- **Ask around:** Look to your physicians and advanced practice nurses to help you understand the studies and/or the purported results. **HT**

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HealthTrust assists member health systems in identifying potentially harmful plastics in the NICU

THREE DECADES AFTER RESEARCH BEGAN on the potential health effects linked to the use of polyvinyl chloride (PVC) and di(2-ethylhexyl) phthalate (DEHP), these plastics are still found in products used in neonatal intensive care units (NICUs) across the United States. HealthTrust is helping member facilities identify clinically acceptable alternatives for these products and working with suppliers to offer options without PVC and DEHP.

Continued on page 36

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Continued from page 34

PVC and DEHP are found in a wide array of products in the NICU that come in contact with premature and fragile newborns, including oxygen masks, nasal cannulas, and infusion and nutrition tubes. While these products help address the acute health problems in tiny patients, many studies show that the PVC and DEHP they contain can cause various health issues over the long term, including endocrine disruption. Products with the highest impact are respiratory, infusion and enteral. PVC and DEHP have been banned from items like baby toys, but not from medical products.

Kyle Tafuri, Director of Sustainability for Hackensack Meridian Health in New Jersey, points to many potential items containing PVC and DEHP in a typical NICU. But his health system, which has two Level 3 NICUs, has been steadily phasing out the use of such plastics over recent years. "These babies are the most vulnerable population, and some are in NICUs for extended periods with exposure from many products. It adds up," Tafuri says. "We have a commitment to provide the healthiest environment for our patients. It's the right thing to do."

CONVERSION CHALLENGES

Transitioning to a PVC- and DEHP-free NICU environment isn't easy. The task involves a rigorous audit of what's being used and a change in suppliers for some items, among other efforts, shares **Zoë Beck**, Sustainability Manager at HealthTrust.

"In respiratory and enteral feeding tubes, there are more PVC- and DEHP-free options. Many hospitals have done pretty well in those categories because suppliers have proactively switched," Beck says. "IV bags and tubing are a different story. These are complicated contract categories, in that hospitals are usually using one supplier's products, and converting to another supplier is a huge undertaking."

The ask of suppliers is that they find new, safer materials that maintain the performance of these products—products that are integral in the care of NICU patients and help keep them alive. Changing out these materials is not a simple task.

The European Union has regulated PVC, DEHP and other phthalates, but the U.S. Food and Drug Administration has not yet followed suit, Beck adds. Because the chemicals aren't regulated, tracking how many U.S. hospitals have transitioned away from these chemicals is challenging.

"The existence of and potential issues with these chemicals are not necessarily common knowledge," she says. "While some individual hospitals may be working to remove PVC and DEHP from their NICUs, there are likely not as many organizations working on this at a system level."

ONE SYSTEM'S CONSISTENT EFFORTS

Hackensack Meridian Health's efforts to move away from PVC and DEHP in its NICUs began years ago, with a focus on two categories. "The bulk of the exposure is typically in IV bags and tubing," Tafuri says. "So being able to transition those out was the biggest win we had in our NICUs." But of the 71 products inventoried at Hackensack Meridian Health after that effort, Tafuri says, about a dozen contained the plastics.

The work has continued piecemeal ever since, with a couple of additional products switched out as alternatives were identified. "When you're looking at safer chemicals as a whole, you strike where it's hot—where there are known alternatives. We reached out to manufacturers and stated that we hoped to see a PVC-/DEHP-free product. Where there wasn't an alternative, we put it on the back burner," Tafuri recounts.

Not all alternatives have cost more than the items they replaced. In some cases Hackensack Meridian Health has saved money. "Typical to any product switch, there were instances where something cost a bit more, where it was a wash or where it saved money," Tafuri adds. "It's a mix. Our biggest challenge in doing this is when there isn't an alternative; you're kind of stuck. You hope those companies move forward to switch materials, but for some products there may be only one or two options, or it's a product that's unique and there aren't any alternatives."

BOLD SUPPORT

Over the past year, in particular, HealthTrust has amped up efforts to educate member facilities about the presence of PVC and DEHP in products used in NICUs and ways to streamline moving toward options that do not contain these chemicals. HealthTrust has also been gathering and analyzing data from members that have undertaken such efforts, Beck says. "We can show members where they stand today and where they can do better. It gives them something to measure so they can make changes where they choose," she explains. "Additionally, when we collect information from suppliers, we can go back to those suppliers and say, 'Comparatively, here's where you stand in the marketplace in terms of these chemicals; here is where you have opportunity.' The data serves an educational purpose for both the product end users and the manufacturers."

Tafuri says Hackensack Meridian Health is well supported by HealthTrust in its NICU product transition efforts,

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simplifying the process and saving the health system time. "HealthTrust has been helpful in obtaining information from suppliers and providing us a forum to bring questions forward," he says. "Instead of one member asking a supplier about PVC- and DEHP-free options, HealthTrust can make the ask on behalf of its entire membership. It's a lot of purchasing power."

Beck shares that HealthTrust has initiated conversations with member facilities about PVC and DEHP in the NICU. "HealthTrust is working on education to make sure health systems understand why we're looking at these chemicals," she says. "NICU technology has advanced tremendously, and now that we know more about the harmful effects of these chemicals, we need to help our member facilities evolve." **HT**

FOR MORE INFORMATION on the NICU project and analyzing products for the existence of PVC and DEHP, email Zoë Beck at zoe.beck@healthtrustpg.com

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- 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: 4/2021. 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
See full prescribing information for complete boxed warning

- 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.

----------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.
- Aseptic Meningitis Syndrome may occur in patients receiving OCTAGAM 10%, especially with high doses or rapid infusion.
- 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**

Medical Affairs:
usmedicalaffairs@octapharma.com
Tel: 888-429-4535

Reimbursement:
usreimbursement@octapharma.com
Tel: 800-554-4440 | Fax: 800-554-6744

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

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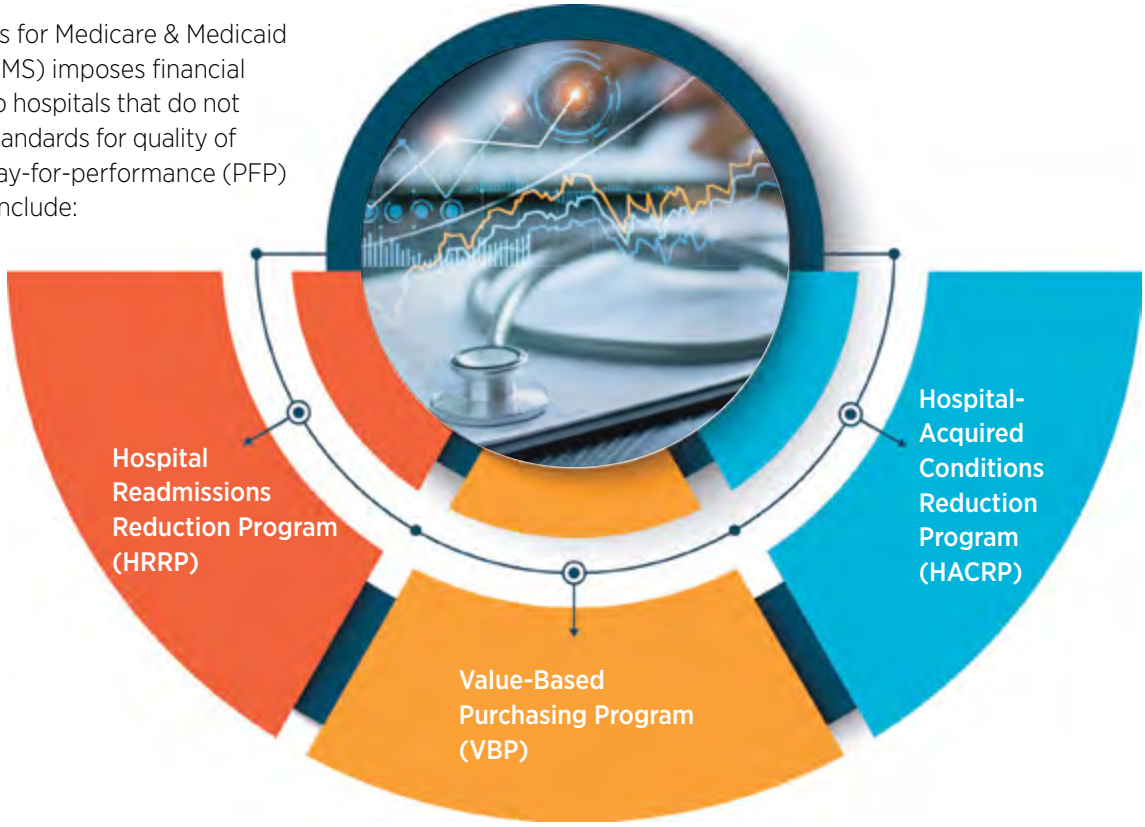
HIGH IMPACT

CMS pay-for-performance targets for hospitals

The Centers for Medicare & Medicaid Services (CMS) imposes financial penalties to hospitals that do not meet the standards for quality of care. The pay-for-performance (PFP) programs include:



THE THREE-PART AIM OF THE CMS PFP PROGRAMS[1]

1. Better care for individuals
2. Better health for populations
3. Lower costs

COST TO THE SYSTEM

In 2020, hospitals that fell short of meeting these standards received penalties from CMS, with these national results:

- Total pay-for-performance impact: **$942** million
- HRRP impact: **$550** million
- VBP impact: **$823K**
- HACRP impact: **$391** million

COMMON TRAITS[2]

Research shows those who are successful in these models have some things in common:

- Data-driven decision-making
- Care variability reduction
- Patient optimization
- Care transitions
- Physician engagement
- Cost reduction

Sources:
1. cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs
2. innovation.cms.gov/files/x/bpci-toolkit.pdf

SUCCESS IN THE NEW REALITY

For the foreseeable future, PFP programs are here to stay. To be successful in this new reality, providers must ensure quality, cost-efficient care. To learn more, access CMS resources, including the toolkit referenced in footnote 2. For guidance on implementing or optimizing a service line structure within your organization, contact **Kimberly Wright**, RN, AVP, Clinical Services, at **kimberly.wright@healthtrustpg.com**

Answering the (DIGITAL) front door

How embracing technology can transform the healthcare experience

THIS ERA OF DIGITAL TRANSFORMATION HAS LED TO CONSUMERS EXPECTING INFORMATION, control and convenience at their fingertips in all aspects of their lives. "There are constants within consumers, regardless of demographics or industry, when selecting a service or product. Consumers desire access to choice, at the highest quality and the lowest cost, and that is growing ever-true in healthcare," says **Peter Kung**, MBA, MS, FACHE, SVP of Hospital Sisters Health System (HSHS).

THE SCOPE OF SOLUTIONS

Enter the "digital front door"—a way for hospitals and healthcare networks to engage or interact with their patients and consumers via a digital access point. From a patient or consumer's perspective, it's an easy and convenient way for them to learn about and manage their healthcare through the same digital tools they already use in their everyday life. It can empower patients to make better healthcare decisions and receive better care.

For many hospitals, the digital front door centers on their websites and patient portals, and may also include:

- mobile apps
- chatbots
- physician ratings and reviews
- social media
- provider search
- online booking
- text communication

Websites at HCA Healthcare act as a key part of its digital front door for patients and consumers to research care and services and then to hopefully take the next step, such as making an appointment or signing up for email newsletters. HCA Healthcare also includes its social media channels among the digital offerings. "A lot of conversations happen on social media, and a number of decisions are driven through social media, so we have to keep those front doors healthy and open," says **Kelly Nye**, VP Digital Strategy & Development at HCA Healthcare.

Making a patient's experience with the hospital seamless and more convenient is a common goal. At LifePoint Health, they're finding ways to make processes easier for patients, such as filling out registration forms online at home to reduce paper use and save time when in the facility or hospital.

The digital front door is about much more than just technology. Technology enables the service, but it is not the service. For example, online retailers all have certain baseline features, like shopping carts or online reviews, but the way they are combined to create unique experiences is based on the organization's mission, says Kung. The same holds true in healthcare. "A digital front door should be easy and frictionless, and more importantly, it should also deliver the differentiating value proposition and experiences that engage and create a lasting relationship," he says.

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THE RETURN ON INVESTMENT

Patients and consumers now expect to be able to interact with their providers in this way. "It's something we have to do to compete for new patients and to retain our current patients. It's an expectation," says **Al Smith**, SVP and CIO, LifePoint Health.

Digital solutions are a selling point for customers: Improving customer access and creating a better experience can strengthen patient loyalty. They also save time and money, allowing hospitals to serve more patients and deliver services at a much greater scale.

"It's economics. We want to keep the patients we have, so we have to make sure that both their experience and the quality of their care is second to none," explains **Ray Gensinger**, M.D., CIO of HSHS.

The digital front door can also help hospitals find new patients and grow their market share. "When people need something, they Google it or go to social media. So a good digital experience can create exposure for providers," explains Nye, who notes the importance of your digital brand being consistent with your traditional marketing channels. "Our websites are often the first interaction someone will have with our brand. It's critical for us to deliver an excellent experience on the web so we can maximize our brand awareness."

DIGITAL CHALLENGES

With such a large network and thousands of digital assets, achieving digital consistency across access points can be a challenge, but it's a challenge worth accepting. It requires diligence and attention to detail. "A large part of our mission as an organization now is a laser-like focus on creating as much consistency and convenience as we can in these

important interactions," says **Chad Wasserman**, VP of ITG Digital Patient Experience at HCA Healthcare.

LifePoint Health has experienced a similar challenge in creating a cohesive and consistent patient experience, resulting from using technology solutions and electronic medical records (EMRs) from multiple vendors. "Because of the way we've acquired hospitals over time, we don't have the consistency of a single EMR platform," says Smith. "We're looking at a couple of different ways to help us have a common look and feel to patients, even if the technology isn't the same behind the scenes."

Hospitals need to consider how to balance the desire for efficiency with the importance of handling patient interactions with care. Nye advises making sure your digital copy and content are clear and accessible. "We're talking to people when they're at their most vulnerable. Making our content easy to digest and understandable helps them move through those decision-making points," she says. It also means designing your digital spaces with accessibility in mind, considering the needs of non-native English speakers and people with disabilities.

Using text, email and push notifications can help personalize interactions and guide people through their hospital experience. With COVID-19, hospitals used this approach to keep people safe while waiting for appointments.

But not all patients want to be guided digitally or have access to digital resources, such as those in rural communities or from older demographics. That's why building experiences with flexibility in mind—like including options for landlines and paper—is important.

The HSHS team is aware that before the pandemic, just 20% of patients were using their patient portal.

"If people aren't using the portal, it's because there's no value to them in it. We don't want to make it difficult for patients, or we're going to end up losing them. We needed to make sure that we created other avenues of access," notes

TIPS FOR IMPLEMENTING MORE DIGITAL SOLUTIONS

Experts provide advice for how to get started with developing your digital front door:

Develop a common lexicon and strategy: Because there's no standard definition of a digital front door, be clear upfront on what it means within your organization and what components are included. **Al Smith**, SVP and CIO, LifePoint Health, says they brought in a third-party company to help them define a common lexicon as well as a strategy.

Listen to your patients: To create an experience that helps your patients and responds to their challenges, you need to know what is most important to them and what frustrates them. "Spend time with your patients and consumers. Sometimes we think we know what's best, but we're so close to the situation, and we experience healthcare differently than the average person," says **Kelly Nye**, VP Digital Strategy & Development at HCA Healthcare.

Know your value proposition: Peter Kung, MBA, MS, FACHE, SVP of Hospital Sisters Health System (HSHS), suggests being clear on the value proposition and the unique experience that you want to drive. By knowing these, your next steps will also become clearer.

Make it part of a greater experience: Your digital solutions should be welcoming, easy to use and part of an overall orchestrated experience for patients, notes **Chad Wasserman**, VP ITG Digital Patient Experience at HCA Healthcare. "As a patient moves across care settings, how do you create an orchestrated experience, not just when it comes to their care, but also in the messaging and the financial experience we provide them, so they can become solely focused on their care?"

Consider your care providers: Technology needs to be easy to use and helpful to your physicians and other healthcare staff, not just your patients, suggests **Ray Gensinger**, M.D., CIO of HSHS. "We have to make sure that the technology our caregivers are using makes them as effective as they can possibly be, so they see it as augmenting the provision of care, as opposed to being a barrier."

Dr. Gensinger, adding that they're also working on how to make their patient portal more useful and valuable.

THE COVID CATALYST

Although the pandemic didn't introduce the concept of a digital front door, it has spurred development for many healthcare systems. "COVID was definitely a catalyst. We couldn't do business the way we had traditionally, so in order to compete and survive, we had to think digitally and improve in this space," says Smith.

A digital environment is an ideal way to communicate with patients while social distancing. Wasserman shares that HCA Healthcare aggressively rolled out digital services to quickly respond to patients' needs while creating efficiency for staff. "Patients did not want to sit in waiting rooms for a long time, so we enabled patients to check in digitally and then receive text messages to essentially notify them of when we were ready to see them. That alleviated a tremendous amount of pressure on our operators and gave patients some reassurance and added convenience," explains Wasserman.

> "We have to make sure that the technology our caregivers are using makes them as effective as they can possibly be, so they see it as augmenting the provision of care, as opposed to being a barrier."
>
> – Ray Gensinger, M.D.

COVID-19 has accelerated consumers' comfort with digital experiences and reinforced the expectation that managing healthcare should be as convenient as ordering from Amazon. "We've got to do a better job of creating a frictionless and intuitive patient experience," says Smith. "I think most people would agree that healthcare has not done a great job of that in the past, but this is where we're going to compete for patients in the future. We've got to get this right." **HT**

The THREAT is real

Cybersecurity remains a critical concern for hospital systems

THE EVER-EXPANDING CYBER WORLD IN HEALTHCARE is a double-edged sword. Advancements in technology to electronically manage health records, track patient outcomes and communicate with, and even treat, patients virtually, contribute to a more robust and efficient healthcare system. But with every advancement comes a new potential threat. These are the risks at the top of healthcare cybersecurity experts' lists and their advice on how to mitigate them.

INCREASE IN COMPROMISED BUSINESS EMAIL ATTACKS

Cybersecurity professionals have been combating a significant increase in the use of phishing to compromise individuals and businesses alike, including hospitals. Phishing is the fraudulent practice of sending emails that appear to be from reputable companies in an effort to get a person to hand over sensitive information, such as passwords, bank accounts and credit card numbers. "In

Continued on page 48

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Continued from page 46

healthcare, we're seeing individuals claiming to be a supplier or purchaser and using language to get people to take action," says **Matthew Webb**, AVP of Product Security at HealthTrust.

How it happens

The emails typically target people in financial roles such as the chief financial officer. They are sophisticated, look legitimate and can often get past all security controls and firewalls. A phishing attack can come from anywhere—from other countries or from someone down the street who uses it as an opportunity to make some quick cash.

"Maybe it's someone masquerading as a purchaser who appears to be in a hurry, saying they've changed bank routing numbers and need to make the update quickly," says Webb. "They're getting the person to provide the routing number and are effectively stealing a lot of money." Every transaction may not be a big sum, but it adds up to a lucrative scheme over time.

Phishing can also happen via text message and phone. Since COVID-19 began, cybercriminals are particularly interested in manipulating online purchasing, where there isn't a way to verify where the information is coming from. "With links in emails or texts, it may say that you must click this link in order to validate," says **Marc Sammons**, Director of Security Sourcing at HealthTrust. That manipulates the user to click on that link.

What you can do

"If you're at work and someone is asking you to provide information, think about steps you can take before complying," says Sammons. "The first step is to use a separate communication where you talk to the person directly and validate that he or she is in fact the person who sent you something." For example, if you get an email from your human resources director asking you to provide password information, call them on their known phone number to verify the email.

"Review the content of the message of what's being asked and whether it seems suspicious," says Webb. "If it's the CFO or CNO, and they're saying it's urgent, ask yourself, would this message normally come through this way?"

If you suspect an email may be phishing, delete it and immediately report it to your IT help desk. Some organizations have an icon within the email or platform that employees can click on to notify the help desk of a possible phishing attempt or attack so that IT can investigate. It is also best practice for IT to then send out a companywide alert to be wary of the attack.

PREVENTABLE RANSOMWARE ATTACKS

Like most of the world today, hospitals, suppliers and other healthcare organizations rely on computer systems for just about every facet of operations, but ransomware can render those systems inaccessible.

How it happens

Ransomware is a cyberattack that essentially locks up a set of systems or servers so that users can't log in. Hackers then send a message telling the organization that, in order to unlock its computer system or service, it will need to pay a large sum of money. Otherwise, the information will be lost.

"Ransomware takes advantage of weaknesses in operating systems where patches haven't been applied properly," says Sammons. A patch is a security update to a computer system to fix vulnerabilities or bugs.

These attacks are paralyzing because of the loss of data, as well as the disruption to communications. "There have been situations where a number of supplier servers were locked up so an entire online solution was down because they couldn't communicate," Sammons explains. If the healthcare facility doesn't have a manual workaround in order to provide care, these attacks can ultimately affect patients.

Cybersecurity experts note that attackers are targeting larger health systems with ransomware. It hasn't yet affected medical devices as much since they are often proprietary or running on a different operating system. But as a physician communicates medical information to a server, those servers are being targeted.

What you can do

Applying patches effectively is key. Just as with phishing, the vulnerability in ransomware attacks lies with the users. "One of the easiest ways to infiltrate a system is through people because, as healthcare professionals, we generally want to help others, and attackers prey on that nature," says Sammons.

In addition, criminals take advantage of the growing number of computers we depend on, making it harder to keep up with system patches. It's important that organizations continue to work with suppliers and IT partners to ensure there is a well-defined patching schedule. Sammons notes that there have been situations where attacks have been deployed on systems that haven't been patched in two years. "Some degree of patching, whether it's monthly, quarterly or even annually, is better than nothing," he adds.

VULNERABILITIES IN CONNECTIVITY & THE INTERNET OF THINGS

Alexa, Siri, Fitbit, the Ring Doorbell. In our personal lives, we've become accustomed to having endless surveillance data available at our fingertips. But we don't often stop to think about what the potential impact would be if that data were to get into the wrong hands—or if that data involved our health information. Medical devices can expose those vulnerabilities.

"These devices are immature in their development because the software components don't yet have the security to protect them," says Webb. "We are trying to balance the value that these devices bring to support a patient, while balancing the maturity to ensure the protection that they don't yet have in themselves."

For example, a pacemaker may be Bluetooth-enabled. When a patient goes to his cardiologist's office, and a nearby device starts reading the telemetry off his implant, how soon could cyberattackers read the data or, worse yet, harm the patient by interacting with the device itself? "It is a question of when, not if, the attackers will have that capability," explains Webb.

> "We expect to see growth in privacy regulations, and suppliers and negotiators can expect a greater focus on incorporating privacy policies and agreements into their language."
>
> – Matthew Webb

The good news is suppliers are aware of these risks and, along with the Food and Drug Administration, are working to mitigate threats. For example, some suppliers have safeguarded their systems to allow devices to operate only within a certain proximity so their connectivity is limited.

Continued on page 50

Continued from page 49

THE ADDED COMPLEXITIES OF TELECOMMUTING & TELEHEALTH

During the past year, the increase in telecommuting rates has led some companies to expand their talent pool when hiring for certain positions. Hospitals have been able to become more flexible and bring on exceptional cybersecurity professionals who may live in another part of the country.

However, this may also increase exposures. "Remote work expands the areas that need to be covered by cybersecurity," explains Webb. "With more folks working from home, it puts devices further away and outside the bounds of company security controls. People are more at risk to click on links and messages that can redirect them off their home network."

Telehealth has been an important way to deliver care throughout the pandemic, and experts expect it to be heavily utilized even when we're past the threat of COVID-19. The good news is that healthcare IT and business leaders have met the challenge and have taken steps to ensure that these systems remain safe and available for the long haul. "I'm excited about the immense progress that's been made to ensure systems are safe and available," says Sammons.

REGULATING PRIVACY

Security and privacy are converging to the point where it won't be possible to have one without the other. The European Union recently passed a larger privacy law that regulates how companies must protect citizens' personal data. States like California are at the forefront of passing stricter privacy laws that require businesses to provide consumers with information about their privacy practices and about how consumer information is being used and shared, as well as the right to have data deleted or opt out of certain practices. For example, Zoom uses cookies to track and analyze user activities in order to gather information and use it to promote their other products. With the California Consumer Privacy Act (CCPA), this practice may be considered a "sale" of personal information, and users can choose to opt out. Other states are not far behind passing similar laws.

"We expect to see growth in privacy regulations, and suppliers and negotiators can expect a greater focus on incorporating privacy policies and agreements into their language," says Webb. Just as there may be a comprehensive security agreement, healthcare organizations can expect to see the same type of approach when it comes to privacy. Webb adds, "Privacy will be a key factor in suppliers being able to deliver what they say they can, and it will be something that their customers will want to know more about and ensure it's part of the solution." **HT**

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HEALTHTRUST LAUNCHES NEW SUPPLIER PRODUCT SECURITY PROGRAM

HealthTrust is proud to introduce a new program that aims to enhance communication and establish a partnership among healthcare organizations and suppliers in order to better understand their approach to security.

Some HealthTrust members may be aware of prior efforts to include security agreements with contracts. The focus of this initiative has been expanded to include supplier security, with leadership from **Matthew Webb**, AVP of Product Security, and **Marc Sammons**, Director of Security Sourcing at HealthTrust.

"Through this program, we hope to serve as the bridge in helping healthcare teams understand how suppliers are addressing security within their organizations and products. Likewise, HealthTrust will help its suppliers to better understand the needs of their healthcare customers, so they can take the information back and apply it to the products," says Webb.

The program offers specific purchase agreements and contractual security agreements that suppliers are required to sign. Members of the HealthTrust Supplier Product Security Program represent the concerns and feedback of a large portion of suppliers and users, and effectively disseminate information and updates about particular products, such as new features suppliers are implementing to address cybersecurity.

"We have a committee that makes sure agreements offer both adequate protection and contain risk mitigation measures should a breach occur. Committee members are really representing the eyes and ears of the current industry," says Sammons. "Suppliers have an opportunity to present and receive feedback, which has been an effective communication mechanism for looking at important things that need to be addressed. It's made for great collaboration."

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AWAITING APPROVAL

How healthcare organizations need to plan for the expiration of EUAs

ON JAN. 31, 2020, THEN SECRETARY OF HEALTH AND HUMAN SERVICES (HHS) **ALEX AZAR** DECLARED THE CORONAVIRUS A PUBLIC HEALTH EMERGENCY, and on March 27, there was a second declaration that authorized the emergency use of drugs and biological products during the pandemic. By law, these declarations enabled the Food and Drug Administration (FDA) to issue emergency use authorizations (EUAs) of an unapproved product or use of an approved product, provided that certain criteria were met. This lifesaving strategy allowed the U.S. to quickly develop solutions for product shortages and new methods for lab testing, treatments and vaccines.

Since the start of the pandemic, the FDA issued EUAs or granted full marketing authorization to almost 1,300 medical devices for COVID-19. These EUAs offered a way forward that has been much faster than the typical, historically yearslong process for standard FDA approvals. But something else sets them apart: EUAs are only temporary.

While health experts can't be sure when we'll be on the other side of the COVID-19 pandemic, they say the time to think about life after the pandemic is now.

Since the start of the pandemic, the FDA issued EUAs or granted full marketing authorization to almost 1,300 medical devices for COVID-19.

FAST-TRACKED SOLUTIONS

In March 2020, the Centers for Disease Control and Prevention (CDC) was first to apply for an EUA for in vitro COVID-19 testing. "Initially, we only had one test that was given to the Department of Health from the CDC, which took three or four days to get results. We would sit there paralyzed with fear while the patient was in isolation," says HealthTrust Physician Advisor **S. Shaefer Spires**, M.D., Assistant Professor of Medicine and Infectious Disease Specialist at Duke University School of Medicine. "Once companies were able to get EUAs for testing, the supply was no longer limited. The EUA process really shows that the FDA did its best to become versatile in this pandemic when we needed to think fast."

With new vaccines, the FDA typically requires at least six months of safety data produced from clinical trials. With the EUA for the COVID-19 vaccines, only two months of safety data was required. "History shows that regarding vaccine trials, the overwhelming majority of adverse effects occur within the first two months of administration. Therefore, the FDA felt that only two months was needed for this particular scenario," explains Dr. Spires.

EUAs also cost a lot less to pursue. "Following patients for six months after they get their trial vaccines costs significantly more money and takes a lot more resources and time," Dr. Spires adds.

Physician Advisor S. Shaefer Spires, M.D., is an Assistant Professor of Medicine and Infectious Disease Specialist at Duke University School of Medicine.

Photography: Mitchell Kearney

Dr. Spires & Connor Deri, PharmD, Infectious Diseases Clinical Pharmacist at Duke University Medical Center, discuss the expiration of EUAs.

Photography: Mitchell Kearney

STEPS TO PREPARE FOR EXPIRING EUAs

1. Assemble your team. Karen Bush, MSN, FNP, BC, NCRP, Director of Clinical Research & Education at HealthTrust, recommends creating a multidisciplinary team that includes supply chain, environmental services, nursing, respiratory therapy, physician, pharmacy and executive membership.

2. Take inventory. Create a process for how you will inventory and keep track of all EUA-approved products in use at your facility, and how often they are used.

3. Monitor the FDA for updates. The FDA regularly sends out and posts updates to EUAs on its website and via e-newsletters to a listserv. Assign an individual or team to check and track changes to EUA products and communicate these changes to the appropriate people in your health system.

4. Look at each product's use and what might need to change. Ask questions such as:

- If a product is previously FDA-approved, can it be used in the capacity that you are currently using it?
- Does it need to be reconfigured to function as previously approved?
- What resources are needed for this conversion?
- If a product is EUA-approved, is the capacity in which you were using it still necessary?
- If the product will be retired from service, will it be disposed of or stored for future use?
- Are there any environmental or expiration concerns?

5. Spread the word. If you're part of a larger organization with lots of resources to track updates, reach out to your community partners who may not have the same bandwidth. Add them to your communications so they can be in the know about product updates, for the greater good.

6. Call on your manufacturers and suppliers. Ask if they plan to pursue full FDA approval for their products or devices. Also, know that sometimes manufacturers may not fully understand what EUAs mean and the nuances of the regulations.

7. Take advantage of subject matter experts. Call on your infectious disease specialists and other experts to review and investigate how you are using a product to ensure it is safe, acceptable and within regulation.

A FLUID SITUATION

However, while EUAs were a quick and efficient way to battle a raging pandemic, they also required that healthcare organizations remain nimble. "As with everything surrounding the pandemic, expertise is developed as experts research and learn," says **Karen Bush**, MSN, FNP, BC, NCRP, Director of Clinical Research & Education at HealthTrust. As the pandemic has continued, clinicians learned more about the virus, its variants and patient reactions to care. This requires the constant evaluation and reevaluation of products that have EUA approval.

For example, not all EUA-approved facemasks are approved by the National Institute for Occupational Safety and Health (NIOSH), the regulatory body that typically authorizes them, so they will ultimately need to be reassessed. In addition, some masks were taken off the EUA-approved list due to potential safety risks.

"We've also seen a lot of changes with decontamination products," adds Bush. The FDA created a broad EUA for some disinfection and air purifiers, and as long as products met specific criteria, they were considered approved under this umbrella. But the details are important. "With N95 masks, for example, there are specific decontamination instructions. Some masks need to go back to the same user, while others can be used by anyone after decontaminating them. It's not the same for every mask and decontamination system."

In addition, some lab diagnostics, specifically antibody tests, were approved for EUA use early in the pandemic and had to be revoked—underscoring the need for clinicians to be diligent when using these products. "It's important to understand the efficacy data behind these tests when it comes to a true positive and a false positive, and how to interpret the technology that you're using," says Dr. Spires. "When it comes to EUA products, healthcare facilities should ensure that they're evaluating their options with intention and diligence and talking to their experts before spending any money on tests."

Continued on page 56

Continued from page 55

POST-PANDEMIC PREP STARTS NOW

EUAs will end once the pandemic ends. However, the government is not required to give health systems a heads up that the state of emergency is over. In 2010, when HHS declared H1N1 over, the CDC sent notice that, effective immediately, the drug Peramivir, which was being used to treat H1N1 patients under an EUA, was to be destroyed, and no new doses would be created. There was no grace period.

COVID-19 is much more wide-ranging than H1N1 was, so the hope is there will be some forewarning. "So much of our healthcare infrastructure is based on EUAs at this point for COVID patients," explains Dr. Spires. Either way, there's reason to plan ahead. "Now is the time to start thinking about what products we can plan to substitute," he adds.

Bush agrees. "Health systems should be asking themselves if they have a process for monitoring EUA products, and if not, they need to start planning," she says.

In fact, the FDA is starting to show signs that it is scaling back on EUAs. In March 2021, the FDA sent notice that it would no longer be reviewing requests and adding new respirator models, which are the non-NIOSH-approved N95 masks. "This is a signal that we probably have enough and don't need to add any more to the list," says Bush. "It makes you wonder if this is a sign of a pivot—that perhaps moving forward, we aren't seeing as much need for N95 masks and have adequate supply."

MAKING THE SWITCH

Products with expiring EUAs are wide-ranging and could have a huge impact, starting with the most basic personal protective equipment (PPE). "Hospitals will likely have a challenge dealing with EUAs for PPE," Dr. Spires notes. "Early in the pandemic, there was an urgent need for decontamination devices for masks, so people were cranking these things out using hydrogen peroxide vapor, UV light and homegrown innovations. Hospitals will have to figure out how to decontaminate products moving forward or ramp up their supply of PPE."

Continued on page 58

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*Highest mean time between failure (MTBF)
1 Siemens, Abbott, Ortho, Beckman assay menus as of February 5, 2020.
2 Internal market research of immunoassay vendors (Siemens, Abbott, Ortho, Beckman).
3 https://captodayonline.com/productguides/instruments/chemistry-immunoassay-mid-high-volume-2019.html (accessed April 6, 2021)

Continued from page 56

Dr. Spires notes that some organizations that purchased EUA equipment will also have to consider what to do with expensive items that will no longer be approved for use. "Some companies will choose to pursue full FDA licensure for their products, but many won't because of the intensive costs and resources needed," he explains.

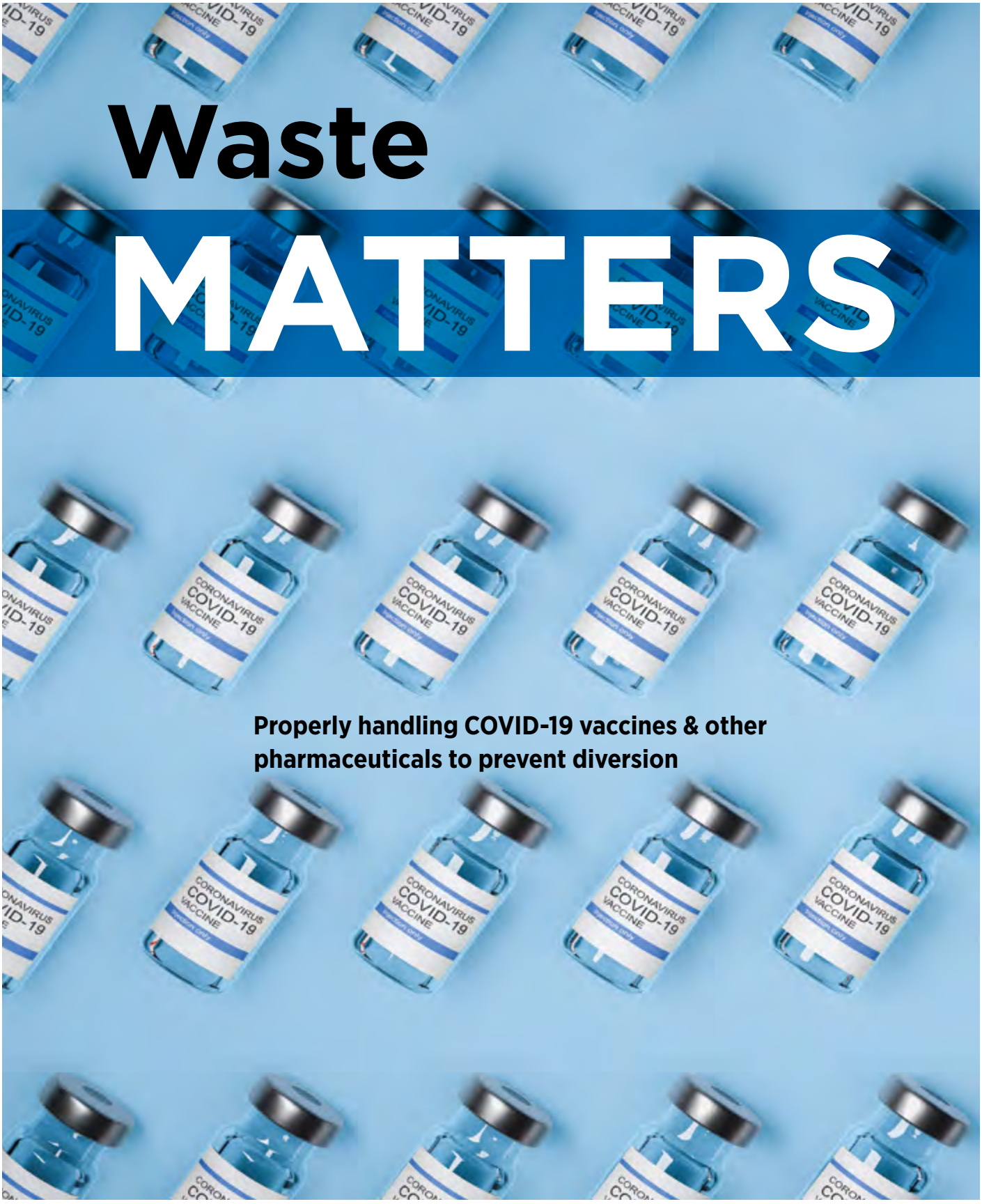
For example, "Early on, hospitals asked car companies to make ventilators," Dr. Spires adds. "It's good that the FDA had this EUA process to get products authorized quickly, but Toyota is not going to apply for the full approval of licensure. A ventilator is a class 3 risk because it supports human life, so I don't expect the FDA to soften the approval process for that. The hope is that hospitals won't have to waste the ventilators they've purchased."

Where should healthcare organizations start? First, consider converting to FDA-approved products. "If you're using a UV light device to decontaminate patient rooms and it was previously FDA approved, then continue using it," explains Bush. "If not, think about what you'll do with that device once the EUA goes away and what you'll use to replace it."

Then, proactively reach out to the manufacturers. "Contact them to see if they're going to go for full approval," says Dr. Spires. "If we have a lab-developed test and have to purchase the reagents, for example, we need to determine if the manufacturer will continue to make those reagents. At some point, manufacturers will stop creating them because the demand will die down. We need to be aware of this."

Still, there is one EUA that is top of mind for all healthcare workers. "The biggest concern for clinicians is the vaccine receiving full licensure. We all know that's the answer to getting this over with," says Dr. Spires, who is optimistic that it's not far off. "I think we're going to see the vaccine manufacturers for the three approved vaccines all go for full approval in 2021. I imagine that HHS will give them a heads up that they are thinking of declaring the pandemic over, and then we will see these companies start flooding resources toward getting full FDA approval." **HT**

Waste MATTERS



Properly handling COVID-19 vaccines & other pharmaceuticals to prevent diversion

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BEFORE COVID-19 VACCINES WERE WIDELY AVAILABLE IN THE U.S., reports surfaced of drug diversion from the intended recipients to other individuals for illicit use.

"While here in the United States we now have what we need, other countries like Colombia and India don't, so that's where we are seeing some of the black market activity," says **Rob Dickey**, Director of Contracts and Direct Sourcing at HealthTrust. "Vaccines are going for $1,200 to $1,500 per dose to people who can't get them."

USE IT OR LOSE IT

The ideal way to avoid vaccine drug diversion, of course, is to use everything you have. Reading Hospital in Pennsylvania, part of Tower Health, made that a priority after rapidly assembling COVID-19 vaccine clinics in hospital conference centers, infusion clinics and a post-acute care unit that wasn't in use. The hospital administered up to 600 doses per day and diligently avoided waste.

"We had to get creative in a short timeframe in order to be successful," says **Mike Kleinschmidt**, PharmD, MBA, BCPS, DPLA, Director of Pharmacy, Sleep and EEG at Reading. "We would walk around the hospital, call law enforcement, EMS—ask anyone we could if they needed a vaccine so that we didn't waste product."

He advises that healthcare facilities determine where the vaccine is needed in the community and reach out to underserved populations. "Our initial strategy was to have people come to us. Now we are doing mobile pop-up clinics out in the community, and extra product has been used there as well," Kleinschmidt explains.

Improperly disposing of pharmaceutical waste creates vulnerabilities to unintended consequences.

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MANAGING UNUSED & EXPIRED PRODUCTS

Hospitals and clinics with expired or unused product should notify the local health department so it doesn't continue sending product if the demand is not there. Then, make sure formal pharmacy waste management policies and procedures are in place to dictate proper disposal of unused and expired vaccine product.

An effective vaccine inventory system is essential in this effort—an effort that includes daily product inventory and reconciliation. "We knew exactly how many vials were pulled, used and given out each day," explains Kleinschmidt.

Improperly disposing of pharmaceutical waste creates vulnerabilities to unintended consequences. "If you have expired product and dispose of it inappropriately, someone could come along and use it for the black market," says Kleinschmidt. "Or, someone could find it and think it was thrown away in error and try to use it, and then we couldn't guarantee the potency or safety of that product."

Controlled substance waste management systems are integral to responsible pharmacy operations.

OPTIONS FOR PHARMACEUTICAL WASTE MANAGEMENT

The U.S. Department of Defense recommends that all biowaste be captured in pharmaceutical waste containers to prevent drug diversion. Stericycle offers comprehensive waste management services, including containers for reusable sharps as well as red bag waste containers. Stericycle's pharmaceutical waste product has a charcoal solution that deactivates the substance.

"Most pharmaceutical waste products must be incinerated. Stericycle owns many of these facilities and has access to incineration capabilities," explains Dickey.

"For narcotic waste, we use Cactus Sink by Stryker," says Kleinschmidt. Cactus

Continued on page 62

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Cactus Smart Sink by Stryker

The U.S. Department of Defense recommends that all biowaste be captured in pharmaceutical waste containers to prevent drug diversion.

Continued from page 60

Smart Sink is a securely locked machine that is installed in medication rooms or where healthcare providers can dispose of medicines on the spot, so that they don't go into the wastewater stream or sink. "The Cactus solution is battery operated, tells you when the container is full (there is a scale inside it), and lets you know when the battery needs recharging. It's also harder to get product out of it," adds Dickey.

Reading Hospital's pharmacy also uses Rx Destroyer, a pharmaceutical disposal system that is distributed by Global Focus Marketing & Distribution. "Rx Destroyer is a user-friendly product, and they have a proprietary solution," says Dickey. Like Stericycle's product, Rx Destroyer uses a reservoir with an activated carbon slurry formula that dissolves medications on contact and deactivates them, so they no longer have any medical properties. Once the substance is disposed into the system, it can be thrown into the trash or picked up by an authorized waste management company.

For vaccine waste, the best practice is to use a reverse distributor. Reading Hospital uses Inmar, which comes to the facility once per quarter for waste collection. Until then, expired vaccine product is stored within the pharmacy in a secure location, segregated from regular medication supply, and clearly labeled "Expired Medications—Not for Use." "Inmar has been a great partner. We're able to leverage some of our expired medication credit for additional product and medication tracking, which has been a big win for us," says Kleinschmidt. **HT**

WASTE SERVICES ON CONTRACT

HealthTrust has three controlled substance waste services suppliers on contract:

Supplier	Product	Contract Number
Stryker	Cactus Smart Sink Controlled Substance Waste Management System	31138
Global Focus Marketing & Distribution	Rx Destroyer Pharmaceutical Disposal System	31335
Stericycle	Stericycle Pharmaceutical Waste Containers	31336

All products are approved by the Food and Drug Administration and the U.S. Environmental Protection Agency, and they meet all pharmaceutical waste requirements from the Bureau of Alcohol, Tobacco, Firearms and Explosives.

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1. Kapp S, Gerdtz M, Gefen A, Prematunga R, Santamaria N. An observational study of the maintenance of the 30o side-lying lateral tilt position among aged care residents at risk of developing pressure injuries when using the standard care pillow and a purpose-designed positioning device. Int Wound J. 2019;1–7. **2.** Brennan, M. and Laconti, D. Using Conformational Positioning to Reduce Hospital-Acquired Pressure Ulcers. Journal of Nursing Quality, 2013,11. **3.** Barakat-Johnson M et al. Evaluation of a fluidised positioner to reduce occipital pressure injuries in intensive care patients: A pilot study. Int Wound J. 2018;1–9. **4.** Kimsey, Diane. A Change in Focus: Shifting From Treatment to Prevention of Perioperative Pressure Injuries. AORN Journal. 2019: 379-393. doi.org/10.1002/aorn.12806.

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Best of BOTH WORLDS

THE TERM "HYBRID" OPERATING ROOM ENTERED CLINICAL VERNACULAR ABOUT 10–15 YEARS AGO, according to **Luann Culbreth**, MEd, MBA, RT, FACHE, Director of Radiology & Cardiovascular Services on the Clinical Operations team at HealthTrust.

Hybrid operating rooms blend a clean environment with an interventional radiology suite, enabling a surgical team to perform highly advanced open procedures that also require imaging.

"Some of the first iterations of these rooms were really just an interventional room in a surgery suite on a different floor," shares Culbreth. There has been tremendous progress over the last decade in both technology and room design.

EARLY ADOPTERS

Heart Hospital of Austin was a pioneer in this space, being the first in Austin, Texas, to open a hybrid OR in 2007. Heart Hospital became part of HCA Healthcare in November 2010 after being acquired by St. David's HealthCare.

"We had two hybrid ORs prior to the merger and acquisition [M&A]. We now have a third hybrid OR, all with state-of-the-art imaging and interventional tools," says **Missi Johnson**, Director of Surgical Services at Heart Hospital of Austin, a campus of St. David's Medical Center.

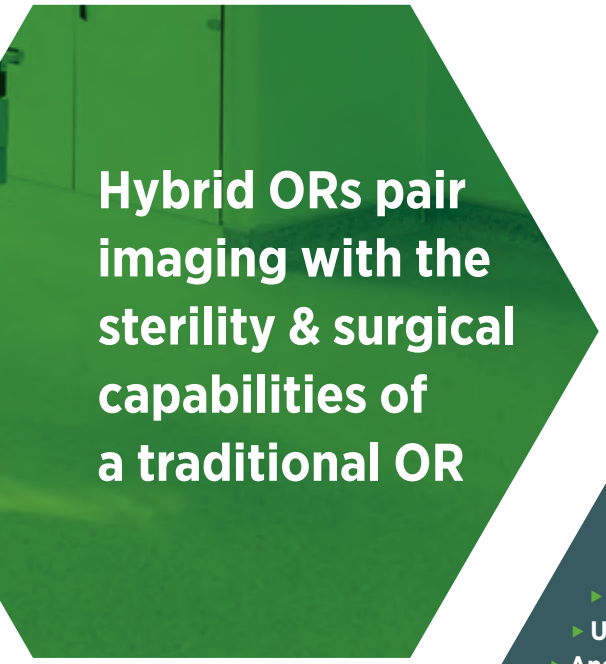
RISING DEMAND

The early pioneers and driving forces behind hybrid ORs can be attributed to cardiovascular surgeries, particularly vascular procedures, and rapid growth in technological advancements. Additionally, hybrid ORs are now being used for providing treatment in thoracic, neurological and orthopedic diseases.

A report published by Allied Market Research in 2020 indicates that the global hybrid OR industry is projected to reach $1.8 billion by 2026—a compound annual growth rate of 11.7% from 2019 to 2026.

STAKEHOLDER FEEDBACK

Experts agree that when designing a hybrid OR suite, the most important component is meeting with your key stakeholders (e.g., surgeons, nurses, OR managers) to understand what your organization needs before setting out to design it. Find out what goals they hope to achieve with the addition of an advanced surgical room, as well as the type of hardware, software and workflows they currently use and what is needed to support interdisciplinary use of the new rooms. You'll want to interview the appropriate specialists, such as vascular and neuro specialists, cardiac surgeons and



Hybrid ORs pair imaging with the sterility & surgical capabilities of a traditional OR

PRODUCT MIX

Products that may be included in a hybrid OR include:

Intraoperative Diagnostic Systems

- Magnetic Resonance Imaging (MRI)
- Computed Tomography (CT)
- Ultrasound
- Angiography systems
- Other imaging systems

Operating Room Fixtures

- Operating tables that meet the expectations of both surgeons and interventionalists
- Operating room lights
- Surgical booms
- Systems for monitoring, communications & the control room

interventionalists (e.g., cardiologists, interventional radiologists, electrophysiologists, neuroradiologists).

SPACE & DESIGN CONSIDERATIONS

Room location and size are important. While a traditional OR is about 700 square feet, industry resources suggest 1,200 square feet as preferable when designing a hybrid OR to accommodate imaging equipment as well as a control room where the procedures are monitored. Hybrid ORs must also allow for the possibility of converting to an open procedure, so they need to be large enough to accommodate both the staff and equipment for two separate clinical teams.

"Enough physical space is key," shares Johnson. "There are large monitors, surgical lights and the c-arm that all compete for ceiling space because they are all mounted on ceiling tracks. You have to move all these pieces to different locations and positions depending on the procedure. If you don't have enough physical space in the room, the booms can collide, which can cause equipment damage. It can also be a challenge to get everything in the right position."

Versatility is also important in design, Johnson explains. "One of our three hybrid ORs also has integrated electrophysiology equipment, so if EP needs an overflow room, we have that capability. Two of the three hybrid OR rooms can also be used for cath lab cases."

ASSISTANCE ABOUNDS

"The good news is," Culbreth shares, "if you're looking to build a hybrid OR, you're not on your own. While not every IDN [integrated delivery network] has the resources for an in-house team to advise on the particulars, the majority of suppliers in this space are more than willing to consult with your stakeholder team on the design and configuration." Culbreth recommends talking to all contracted suppliers in this space. "If there are four suppliers with this expertise, I'd talk to all four and find the best fit for your organization," she adds.

The majority of the big players in imaging have progressed to marry their equipment with the setup of OR equipment from the larger companies. After consulting with supplier partners, most facilities will standardize to a supplier of choice for their hybrid rooms, Culbreth explains. **HT**

HealthTrust is currently reviewing contracts in this space. Watch the *Response* newsletter for updates on the Interventional & Angiography, Equipment & Accessories category, or contact Luann Culbreth for information at luann.culbreth@healthtrustpg.com

BEYOND EFFICIENCY & SAFETY

In addition to the efficiency and patient safety benefits easily found when researching hybrid ORs, there may be others not so apparent. Missi Johnson, Director of Surgical Services, shares some additional reasons why hybrid ORs have proved invaluable to Heart Hospital of Austin.

- **Hybrid ORs have helped create a space where radiologists, cardiologists, surgeons and other physicians can work together with shared diagnostic and interventional tools. Over the last two decades, physician specialty roles have overlapped. The hybrid OR supports this multidisciplinary, collaborative approach in an efficient way.**
- **The integration of complex imaging has been a big improvement for both efficiency and safety. In two of our hybrid ORs we can perform CT-like imaging as needed to support the procedure. This can be helpful in assessing soft tissues. Historically, you would take a patient off the hybrid table and transport them to the CT. Now, the physician can get the clinical information they need without moving the patient.**
- **A patient's previous CT scan can be loaded into the software and overlaid with the imaging happening in real time in the hybrid OR, creating a detailed roadmap of the patient's anatomy.**
- **The staff has growth opportunities. Radiology technologists have been trained to work in the surgical environment and assist in cases, which are much more complex than traditional interventional radiology procedures. Surgical techs are trained to use nontraditional surgical tools such as catheters, guidewires, stents and balloons, which have historically been limited to cath lab environments.**
- **Surgeons love it; the challenge is we don't have enough space and more rooms.**

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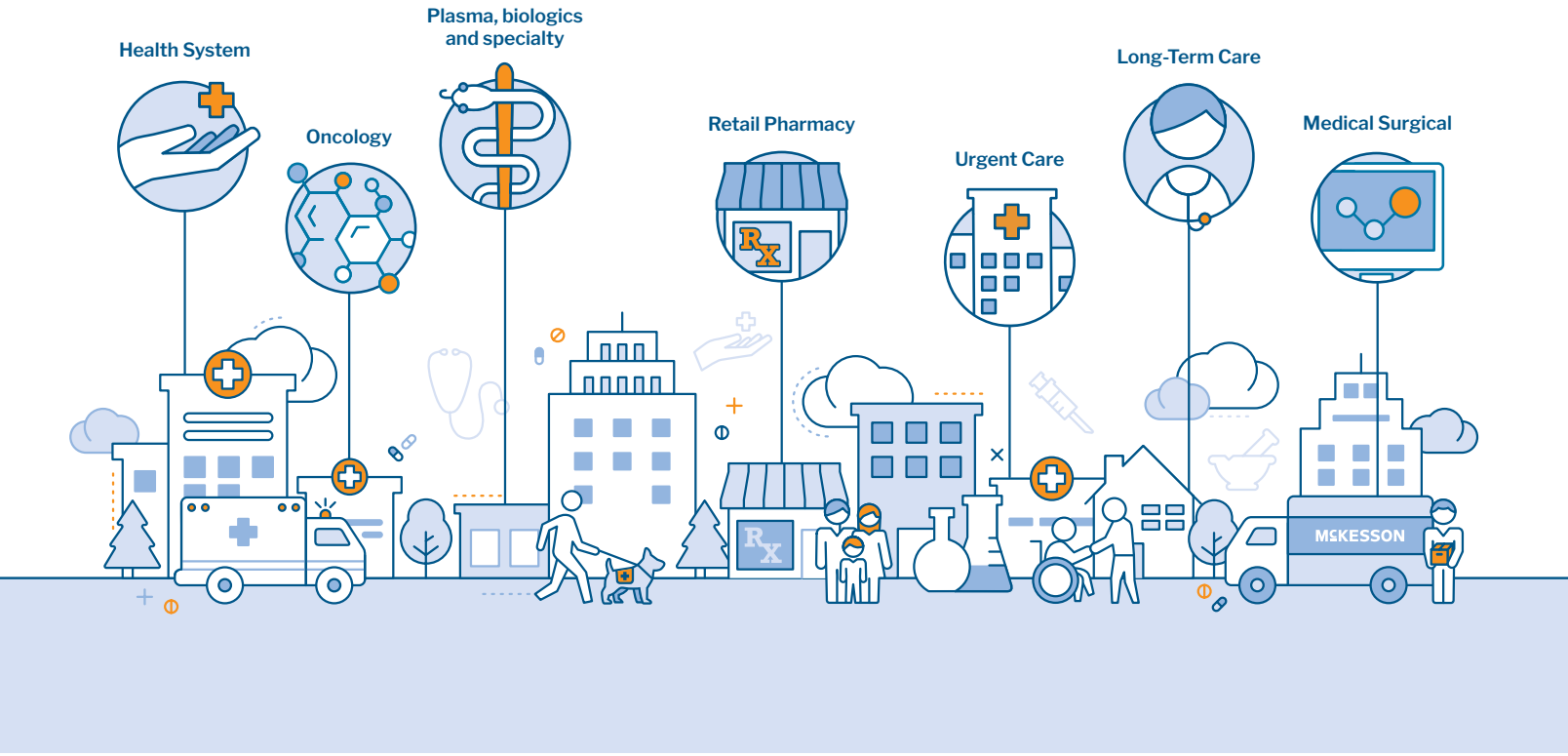

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Karen Bush, RN, MSN, FNP, BC, NCRP, Director of Clinical Research & Education at HealthTrust, explains, "The goal is to provide members with easily consumable information to help everyone get on the same page, stat! The pre-recorded videos are designed to promote increased understanding of a particular procedure, the products used in the procedure, current practice guidelines and any future considerations."

10 Spots will be added to the Clinical Resources section of the public Education site (**education.healthtrustpg.com/videos**) as they are produced. The current library includes seven video presentations narrated by HealthTrust Physician Advisors. **HT**

TO PROVIDE FEEDBACK or share your educational requests, email us at clinical.research@healthtrustpg.com

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Tips on PBM TRANSPARENCY

THE CONCEPT OF TRANSPARENCY IS CENTRAL TO ANY DISCUSSION on contracting for a pharmacy benefit management (PBM) program. But what exactly does that mean? **Joseph M. Dizenhouse**, FSA, MAAA, SVP, Pharmacy Services Group at HealthTrust, offers advice on PBM transparency in a blog recently published on the SHRM* Executive Network.

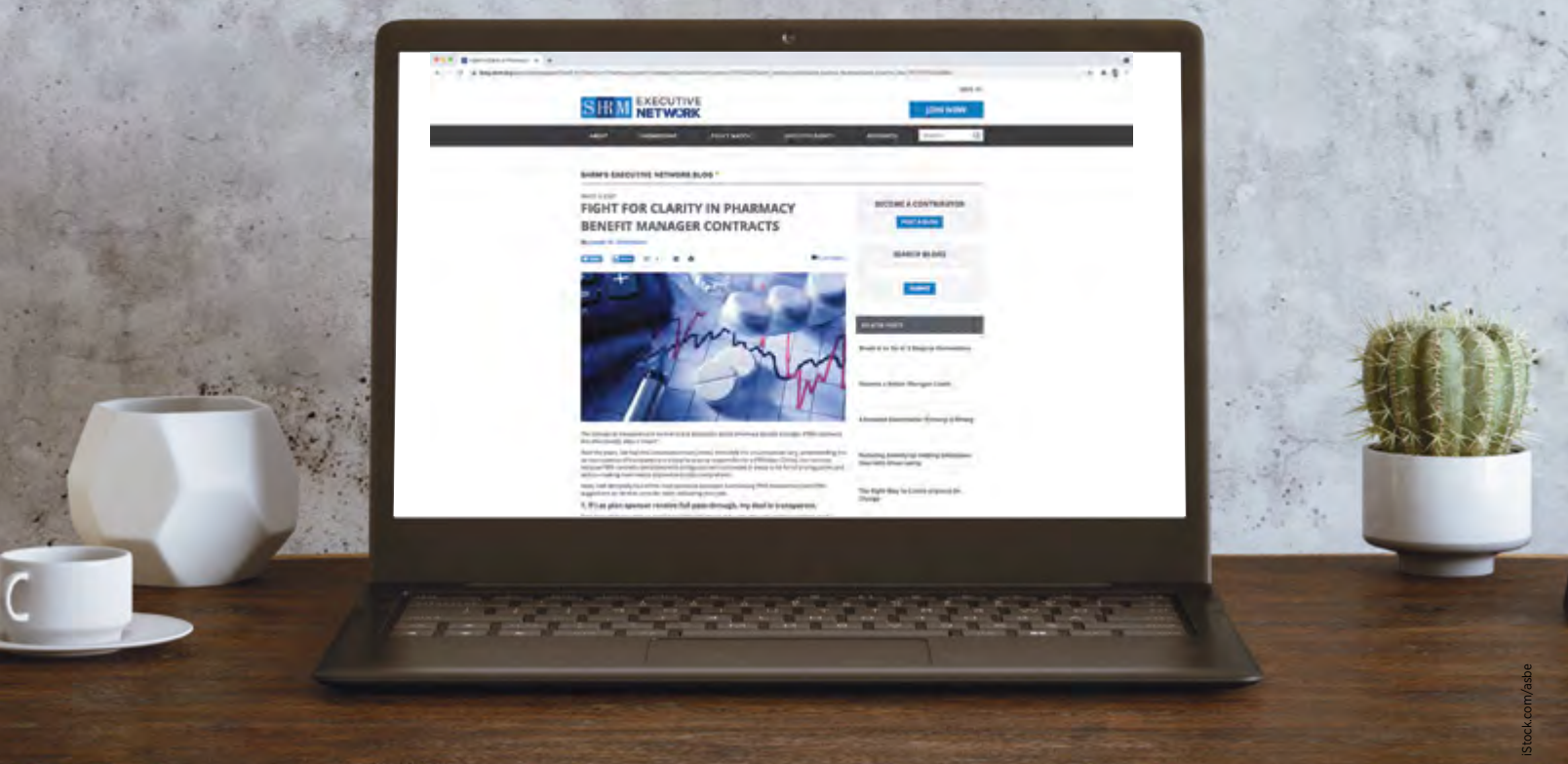
In the article, Dizenhouse demystifies four of the most pervasive misconceptions surrounding PBM deals:

1. If I, as plan sponsor, receive full pass-through, my deal is transparent.
2. I have a transparent deal, therefore my PBM will be incentivized to do the right thing.
3. Transparent deals deliver more efficient plan utilization.
4. Transparent deals lead to effective clinical management.

Dizenhouse also offers suggestions on what to consider when evaluating a PBM program. "Make sure to push aggressively for information, challenge the status quo and never simply rely on the front-facing elements of a PBM proposal," he advises. **HT**

READ the full article at: bit.ly/PBMPrograms

*SHRM is the Society for Human Resource Management



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