

Vizient

TechWatch

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Virtual visits propel
digital health strategy
at children's hospitals

Sedation for procedure
comfort and needed
regulatory requirements

COVID-19 vaccines
and children



When it comes to pediatric patients, health care providers must consider the unique physical and emotional developmental issues that kids face. The Vizient® *Tech Watch: Pediatrics* supports clinicians by offering insights and information on innovative technologies shaping the future of pediatrics.

This issue highlights the latest pediatric products and pharmaceuticals, new and emerging technologies, pricing projections for supplies and products and information on

trends in pediatric care. This information is intended to give health leaders the insights they need to keep pace with rapidly evolving technologies to ensure the best possible care of their patients and maintain a competitive edge in the market. The insights within this publication can be used as a springboard to make more informed decisions and enhance discussions with clinicians and supply chain professionals.





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Market watch

Virtual visits propel robust digital health strategy at children's hospitals



The COVID-19 pandemic enabled rapid adoption of virtual health, shifting organizational-level digital strategy from a “nice to have” to a “must have”. Synchronous video visits became a vital solution to recapture volumes lost due to social distancing guidelines, with many children’s hospitals growing their virtual visit volumes by orders of magnitude in a matter of weeks. In fact, pediatric patients ages 10 and older emerged as one of the highest users of virtual visits.¹ Such uptake reinforces the utility and importance of virtual health, driving children’s hospitals to invest not only in an integrated, scalable telemedicine platform, but a multifaceted digital health portfolio aligned with broader enterprise goals.

Virtual visits

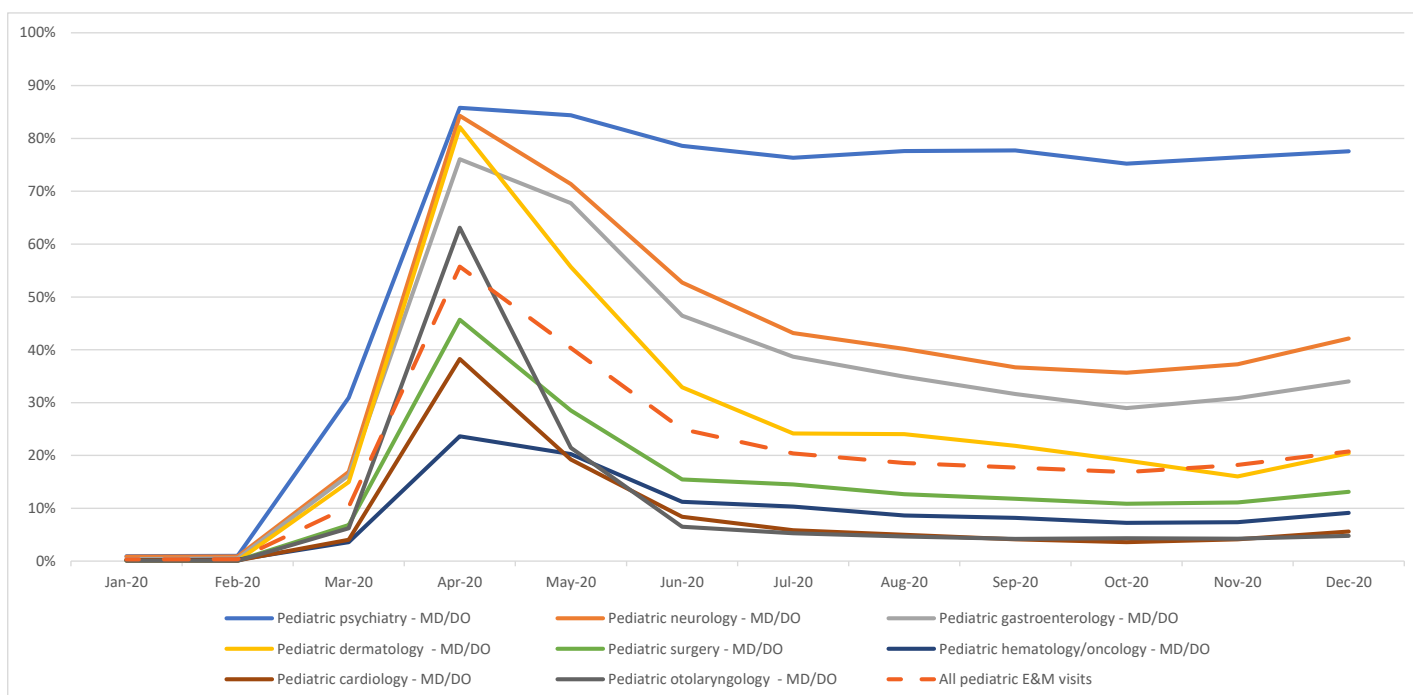
While tremendous utilization declines and care delays occurred in the spring of 2020, a significant portion of pediatric visits that did occur were conducted virtually (e.g., phone or video). Throughout 2020, approximately 18% of all pediatric evaluation and management (E&M) visits were conducted virtually. While select pediatric subspecialists (e.g., pediatric psychiatrists) optimized telemedicine solutions and continued their use, others returned to in-person care quickly (e.g., pediatric otolaryngologists) (Figure 1). In April 2020, approximately 55% of pediatric E&M visits were conducted virtually; the proportion dipped down to around 17% in the subsequent fall months, and

back up to approximately 20% in December 2020. This left many children’s hospitals speculating the extent of sustained adoption of virtual visits beyond the COVID-19 pandemic.

Sg2®, a Vizient company specializing in health care intelligence and market analytics, expects the broad infrastructural investments made into virtual health platforms during 2020 — along with consumer’s widespread exposure to utilizing virtual visits — will facilitate ongoing and optimized use of virtual health. Pediatric-specific lessons learned and efficiencies gained via virtual visits will sustain and drive steady growth in virtual E&M visits over the decade. Overall, Sg2 projects approximately 24% of all pediatric E&M visits to be conducted virtually by 2029 (Figure 2). Behavioral health clinicians will utilize virtual visits more than any other service area at 44% of all E&M visits, while pediatric hematology oncology providers will utilize virtual visits the least, at 10%.

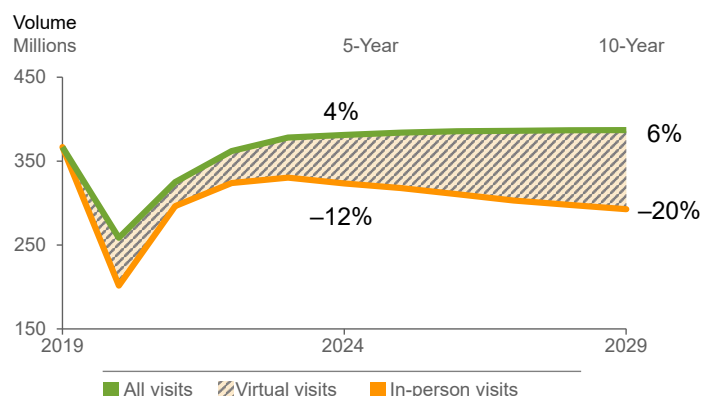
During the pandemic, pediatric patients ages 10 and older emerged as one of the highest users of virtual visits.¹

Figure 1: Proportion of virtual evaluation and management visits by pediatric subspecialty type, US market



Note: Overall, evaluation and management (E&M) utilization in peak pandemic months (March-May 2020) was lower than average, historically.
Source: Clinical Practice Solutions Center, data sample.

Figure 2: Pediatric evaluation and management visit forecast by site of care, US market, 2019 - 2029



Note: Analysis includes 0–17 age group only.
Source: Impact of Change®, 2021; HCUP National Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP) 2018. Agency for Healthcare Research and Quality, Rockville, MD; Claritas Pop-Facts®, 2021; Sg2 Analysis, 2021.

Other key digital health delivery models

In addition to virtual E&M visits, children’s hospitals continue to deploy various digital health offerings that support their organizations’ strategic initiatives. In some instances, virtual tools will drive growth in traditional health system volumes (e.g., access expanders); and in others, virtual tools may drive declines in traditional health system volumes (e.g., direct-to-consumer tools). The following are several examples.

Virtual physical therapy, outpatient therapy, speech psychotherapy: During the pandemic, virtual therapy services were successfully delivered and have even driven quality and access improvements that support ongoing sustainability. For example, providers leverage household items during virtual appointments to deliver physical and occupational therapy — in a more comfortable and familiar home environment for children. Further, the virtual environment has enabled safe, maskless speech therapy. Virtual psychotherapy, on the other hand, is an established offering in the behavioral health System of CARE that is critical to access, and the pandemic drove greater adoption due to relaxed regulations, increased reimbursement, and growing demand among the pediatric population. In this case, virtual visits offer additional access opportunities and therefore drive growth. However, direct-to-consumer or self-guided applications could reduce provider-led therapy services.

Hybrid visits: Hybrid care is composed of encounters or care episodes that include both virtual and in-person elements. Examples include virtual check-in for an in-person visit, or mixed visits in which physical exam is

conducted in person, while consultation is done virtually. Though originally intended to minimize the risk of infection exposure during the pandemic, many providers now realize efficiency gains and more satisfied consumers as a result — and support ongoing utilization of hybrid care models. Hybrid care models are likely to drive growth in patient encounters overall but could also reduce brick-and-mortar facility demands.

Remote patient monitoring: Remote patient monitoring (RPM) uses digital technologies to collect medical and other health data from patients in one location and electronically transmits that information securely to health care providers in a different location for assessment. Children’s hospitals are leveraging RPM technologies to manage two patient populations in particular: children with chronic diseases (e.g., diabetes, asthma); and children with medical complexities (e.g., congenital anomalies, cancer). In both populations, RPM can be associated with reduced exacerbations and inpatient stays. While RPM can drive declines in inpatient utilization, new types of outpatient support are required (e.g., a provider that reviews transmitted data) and drive growth in low-acuity services.

Digital therapeutics: To prevent and treat various conditions, providers leverage evidence-based therapeutic interventions, in use alone or with other medication, devices or therapies. Some clinical applications include therapies for patients with behavioral health disorders and chronic conditions. In fact, a recent study highlighted the efficacy of EndeavorRx, a videogame-like therapeutic approved for children ages 8 to 12 with attention deficit hyperactivity disorder, with or without accompanying stimulant medication. Though digital therapeutics are typically a supplement to therapy, some consumers using digital therapeutics may reduce use of traditional health care services, driving declines.

Virtual infrastructure: Though costly, digitizing the hospital has enabled significant efficiency and quality improvements. Strategies deployed at children’s hospitals across the country include command centers, technology-equipped rooms that enable virtual rounding, and virtual team-based care models that enable provider consults from anywhere on campus. Though not necessarily patient facing, infrastructural virtual tools should align with the overall digital strategy.

Virtual engagement: Children’s hospitals are leveraging their advanced virtual capabilities to reconnect with their communities, such as families and pediatricians, via virtual engagement. Some examples include virtual scheduling and check in, one-stop-shop applications connected to the electronic medical record, and even town-hall style meetings hosted on a social media platform. Successful organizations integrate consumer-based tools with virtual tools used for direct patient care.

Expanding your organization's digital health strategy

The adoption of digital health offerings can have significant implications across other strategic priorities, but investment must be deliberate and well-integrated to transform care delivery and accrue benefit for both growth and value. Key steps include:

Balance reimbursement uncertainties with programmatic goals. Reframe digital offerings in terms of cost reduction, such as improving operational efficiencies, increasing panel sizes, and improving customer experience over fee-for-service goals.

Prioritize service areas and patient populations that would benefit most from digital offerings. Key populations may include patients in need of behavioral health services in a market with limited providers, or patients with medical complexities who are at a higher risk of complications from the spread of infectious disease.

Assess all possible impacts of expanded digital health offerings. Understand the impact of digital offerings on traditional patient encounters. For example, will an offering replace, reduce or add patient encounters? How will these offerings impact your organization's facility needs? Tools such as virtual therapy and digital therapeutics have the propensity to drive a direct-to-consumer utilization shift, so prepare for the positive and negative impacts of that shift.

Include providers. Identify which clinical areas have interest in a broader-scale effort, as well as clinical areas that are uniquely suited for digital health offerings. Align with physicians to ensure a shared vision and loop them in on feasibility assessments.

Approximately 24% of all pediatric evaluation and management visits will be conducted virtually by 2029.²

In conclusion

Virtual tools are now an integral component of pediatric health care delivery. Children's hospital leaders must invest in a robust digital health strategy, of which virtual visits are only one element. A deep understanding of the full portfolio of digital options, along with their alignment to the organizational mission, is crucial to success. Doing so will enable informed decisions on capital investment and workforce deployment. Type and degree of impact may vary by individual tools; holistic value, though, comes from successful integration of a comprehensive set of solutions.

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About the author

Rhae Gamber contributes to the delivery of content and thought leadership for women's health and pediatrics. At Sg2, a Vizient subsidiary company, she works closely with members to provide comprehensive research and analytics-driven strategic insights, leveraging her clinical experience in maternal-fetal medicine and pediatrics to inform decision making. In her current role, Rhae leads the development of the annual women's health and pediatric Impact of Change forecast and numerous service line publications. She contributes to consulting engagements as a subject matter expert and regularly presents national trends and market-specific data to members. Rhae also works closely with Sg2's children's hospital members, sharing her special interest and expertise in the unique strategies deployed by this cohort.

Catie Hjerpe contributes to the delivery of content for pediatrics and topics that span the System of CARE, including ambulatory strategy. At Sg2 she works closely with members to provide comprehensive research and analytics-driven strategic insights, leveraging her clinical experience in pediatric behavioral health care. In her current role, Catie conducts primary and secondary research and analyses, develops custom intelligence, and frequently connects with members to share her expertise in pediatrics, ambulatory care and behavioral health.

Pediatric sedation for comfort during procedures and correlating regulatory requirements



Establish medical staff rules and regulations plus hospital policies to govern sedation practices

Hospitalized pediatric patients encounter many painful procedures, so the role of health care providers includes ensuring their patients' comfort to prevent undue psychological and physical trauma. Initial measures to address patient comfort should focus on nonpharmacological means, such as positions of comfort

and distraction techniques. However, to ensure comfort, practitioners often use pharmacological means, such as sedation, when a pediatric patient undergoes a more invasive and painful procedure requiring the patient's stillness to complete the procedure efficiently and without harm. Further, assessing nonpharmacologic versus pharmacologic by a multidisciplinary team is most appropriate for each of the different developmental stages of the pediatric patient, prior to even some nonpainful procedures that require either short or long timeframes and are often traumatic to pediatric patients.

Hospital sedation policy is the primer for caregivers when assessing their sedation approach. As the cadre of board-certified pediatric specialists grows and training programs change, hospitals and medical staff must adjust policies and medical staff rules and regulations to reflect the most current professional practice guidelines. The Centers for Medicare & Medicaid Services (CMS) requires that the medical staff and governing board define the criteria for determining the privileges to be granted, and these criteria should reflect current standards and state scope of practice.¹ Keep in mind, sedation medication administration can be dictated by state law and medication instructions for use.

Pediatric hospitals provide services for the most vulnerable and highest acuity populations, so ensuring safe sedation practices during procedures is paramount.

When constructing hospital policy, the governing body and medical staff should address the type of sedation privileges (moderate or deep) and the required practitioner specialty or training. Next, depending on the level of sedation being administered, the hospital policy should define how many practitioners — and the required credential; for example registered nurse, nurse practitioner and/or medical doctor — should be present for performing the procedure, administering the sedation medications and monitoring the patient. Some pediatric hospital policies describe sedation medications allowable for administration by anesthesia personnel and/or other practitioners, thereby incorporating state law requirements. Further, hospital policy should outline that anesthesia personnel are the lead to provide services in cases where general anesthesia is necessary due to the age or developmental stage of the patient.

Practitioner sedation privileges is another part of hospital policy. A governing board may grant privileges for no more than two years to requesting practitioners. Granting privileges must incorporate consideration of the medical staff rules and regulations, and a practitioner's competency or training and additional certification requirements (specialty board certification and maintenance thereof, infant and pediatric resuscitation, and advanced cardiovascular life support). Since sedation is a continuum where the patient can drift into general anesthesia from other stages of sedation, CMS requires the director of anesthesia to serve as the sedation coordinator with

accountability for oversight of all sedation services at the pediatric hospital.² The criteria used to grant privileges is based on the consensus of the medical director and the director of anesthesia. The evidence of how the practitioner met the criteria is then evaluated prior to sending a recommendation to the governing body.

Compliance with policies, rules and regulations is critical. When surveyors review closed medical records for sedation and anesthesia practices and processes, they will gather names of the providers and nurses involved in the patient care, and then review the practitioners' files to validate that the hospital's policies and medical staff rules and regulations are being followed.

Monitor quality outcomes and integration into your QAPI program

Quality outcomes can be monitored in several ways. Historically, hospitals collected data on the use of reversal agents. When framing sedation quality and regulatory requirements, often providers can link measures and be able to assure safe patient care while simultaneously gaining comprehensive knowledge about patient and family satisfaction, along with provider competency. Tracking and trending cancellation of procedures that use sedation can distill information about scheduling accuracy, patient preparation and sedation quality. Throughput data can highlight patient and family satisfaction, staff resources, procedure completion times and patient recovery times. With such data, leaders are better informed to guide decisions that support safety and quality, thus fulfilling CMS requirements for Quality Assurance and Performance Improvement (QAPI) program monitoring.³

Professional practice evaluation

Focused Professional Practice Evaluation (FPPE) and Ongoing Professional Practice Evaluation (OPPE) indicators are vital to the privileging process and must be specific to the provider's scope of practice and privileges granted, as required by CMS and The Joint Commission (TJC).^{1,4}

These agency surveyors review files of the providers with sedation privileges and weigh in on qualitative measures used by the credentialing committee to recommend sedation privileges reappointment to the governing body.

The qualitative data used for practitioners can be aggregated and incorporated into hospital quality outcome goals as well, thus bringing together historically separate goals for professional practice evaluations and organizational performance improvement goals. Sorting the data by department, location or specialty can also support regulatory survey queries. Frequently surveyors cite lack of sedation data, and this is often due to a hospital tracking the practitioner's performance in other

categories but not for sedation privileges. For example, a pediatric intensivist has bronchoscopy privileges and data is tracked for bronchoscopy procedures. In addition, that pediatric intensivist has sedation privileges but there is no data tracking of when he/she provides sedation during procedures. Thus the need for multipronged tracking to derive both procedural and sedation data.

Using data can provide leaders information to guide decisions that support safety and quality, thus fulfilling CMS requirements for Quality Assurance and Performance Improvement.

Leaders maintain a focus on patient needs

As pediatric hospital census grows due to referrals for specialized care that most often includes sedation, hospital leaders need to strategically evaluate the resources available to accommodate the new and/or larger patient volumes. Frequently, more patients or new services translate into more sedation requests. When leaders round, they should be cognizant of the patient, staff

and provider needs by observing and having informal discussions. More formal opportunities for evaluating needs, such as focus groups, are also strategies to assure resources and processes meet patient and staff needs. Leadership standards of TJC and CMS require hospital-wide planning to establish structures and systems that provide quality patient care. Feedback during rounding and formal processes should contribute to the analysis of current resources, and identification of appropriate distribution or additional resources needed to provide safe, high quality patient care as the volume of sedation cases grows.

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About the author

Susie Cymbor, MD, is a physician accreditation advisor for Vizient Accreditation Services. Dr. Cymbor is a board-certified pediatric anesthesiologist who provides accreditation and regulatory services to member organizations. She conducts off- and on-site mock survey assessments, provides coaching during surveys and delivers education presentations on accreditation and CMS compliance topics.



Protecting high-risk
patients from unsafe
chemicals in the
supply chain

A child born today will grow up exposed to more chemicals than a child from any other generation in our nation's history.¹

Currently there are more than 85,000 synthetic chemicals in use across the U.S., yet only 1% have been tested for safety to human health.^{1,2} Many hazardous chemicals are commonly found in most personal care products and cosmetics, packaging and containers, as well as medical supplies and health care equipment. Of the small number of chemicals tested, many are linked to negative impacts on human health and development, such as cancer, endocrine disruption, genetic disruption, immune system disruption, and damage to the brain, lungs, kidneys, liver and reproductive system.^{3,4,5}

According to the U.S. Environmental Protection Agency (EPA), contamination from unsafe chemicals is pervasive in society (Table 1). At particularly high risk for the negative impacts of unsafe chemical exposure are pregnant women, unborn fetuses, infants and young children. The agency reported that babies born in the U.S. today have, on average, more than 280 industrial chemicals and pollutants in their bloodstreams the day they are born.¹ Prenatal and early life exposure to phthalates, for example, is linked to asthma, allergies, and cognitive and neurodevelopmental problems such as hyperactivity, anxiety, depression and aggression.^{3,4,5} Phthalates have also proven to disrupt reproductive development in boys.^{3,4,5} During pregnancy, chemicals such as lead, mercury, arsenic and cadmium are shown to cross the placenta and fetal blood-brain barrier and disrupt critical periods of brain development. Triclosan, a common antimicrobial used in toothpaste and hand soap, has been found in the bloodstreams of more than 75% of American adults and in nearly all samples of breast milk tested.⁶

Studies show that endocrine-disrupting chemicals such as polyfluoroalkyl substances (PFAS) are polluting the bloodstreams of more than 95% of American children and 99% of American adults on any given day.^{5,6} Polyfluoroalkyl substances are linked to kidney and testicular cancer, elevated cholesterol, decreased fertility, thyroid problems and decreased immune response in children.^{5,8} Elevated amounts of PFAS in the bloodstream also increase the risk of suffering severe COVID-19 complications.^{8,9}

In addition to concerns of unsafe chemical exposure in high-risk patient populations, health care employees are becoming increasingly concerned about risk of exposure to unsafe chemicals during their daily work. A national survey of nurses by the Environmental Working Group suggests links between chemical exposure at work and serious health problems, such as cancer, asthma, miscarriages and birth defects.¹⁰ A report by Physicians for Social

Responsibility also found correlations between toxic chemical exposure at work and adverse outcomes, such as reproductive dysfunction, learning and developmental dysfunctions, metabolic syndrome and cancer.¹¹

Legislation to limit exposure to unsafe chemicals is nothing new. For example, efforts to limit low levels of exposure to lead began in the U.S. in the early 1970s.¹² Since then, many states have begun to recognize the need to improve protection of public health from additional unsafe chemicals. In the last 50 years, 35 states adopted new legislation aimed at protecting public health from unsafe chemical exposure.¹³

While the number of legislative policies under discussion at state and national levels is growing, many health care organizations (HCOs) are proactively creating their own policies to protect patients and staff from unsafe chemical exposure based on the “do no harm” bioethical principle of medicine. HCOs have found success through adoption of policies to screen unsafe chemicals in the supply chain as both patient and staff safety initiatives, as well as moral and ethical responsibilities.

Given the multitude of lifelong negative impacts from unsafe chemical exposure to pregnant women, unborn fetuses, infants and young children, screening unsafe chemicals in the health care supply chain should be prioritized, at a minimum, for high-risk patient care areas. Although many hospitals have safer chemical policies in place, a recent study shows that hazardous chemicals are found in at least 250 different products used in the average hospital pediatric care room.¹⁴

Case Study

In collaboration with a 620-bed nonprofit community hospital on the West Coast, Vizient conducted a case study on six product categories of medical supplies actively used in high-risk patient care areas, using chemical attribute classifications linked to categories of health impacts (Table 1).

Output from this case study provides a sustainable, scalable, data-driven approach for HCOs to monitor unsafe chemicals in their supply chain, while also evaluating the chemical transparency of products and potential health risks. The full study provides waste reduction attributes of products used in patient care settings so that HCOs can begin to efficiently collect and match environmentally preferable attribute information to product purchases.

Table 1: Chemical classification and health impact glossary*

Chemical classification	Health impact	Definition
Natural rubber latex	Allergens	Chemicals linked to inducing allergies or immune system sensitivity
<ul style="list-style-type: none"> • European Union Restriction of Hazardous Substances (EU RoHS) Directive • Polyvinyl chloride (PVC) • Phthalates • California Proposition 65 chemicals • Flame retardants • Metals 	Carcinogens	Chemicals linked to different types of cancer
<ul style="list-style-type: none"> • EU RoHS Directive • Bisphenols • PVC • Phthalates • California Proposition 65 chemicals • Flame retardants • Metals • Perfluorinated chemicals (PFCs) 	Developmental toxins	Chemicals linked to interference with normal growth, differentiation, development, behavior or homeostasis during prenatal development through puberty
<ul style="list-style-type: none"> • Bisphenols • Phthalates • California Proposition 65 chemicals • Flame retardants • PFCs 	Endocrine disruptors	Chemicals linked to interference with the synthesis, secretion, transport, binding, action or elimination of hormones responsible for normal development, behavior and maintenance of cell metabolism
<ul style="list-style-type: none"> • EU RoHS Directive • PVC • California Proposition 65 chemicals 	Genetic disruptors	Chemicals linked to interference with DNA development or damage to DNA structure
<ul style="list-style-type: none"> • Phthalates • California Proposition 65 chemicals • Antimicrobial/antibacterial agents • Flame retardants 	Immune system disruptors	Chemicals linked to failures, insufficiencies or delays at any level of the immune system response
<ul style="list-style-type: none"> • EU RoHS Directive • Bisphenols • PVC • Phthalates • California Proposition 65 chemicals • Flame retardants • PFCs 	Reproductive toxins	Chemicals linked to damaged or inactivated ovaries or testes, damaged chromosomes, and/or adversely affected reproductive hormones

*As indicated by the U.S. Department of Human Health and Services, the U.S. Environmental Protection Agency, the National Cancer Institute, the U.S. Agency for Toxic Substances and Disease Registry, California Prop 65, the Oregon Toxic-Free Kids Act, the Green Science Policy Institute, and the International Agency for Research on Cancer.

Our results strongly suggest that the health of all children is threatened by trace amounts of hundreds of synthetic chemicals coursing through their bodies from the earliest stages of life.⁷

By focusing on active product purchases for high-risk patient care areas, HCOs can prioritize cleansing their supply chain of unsafe chemicals to prevent unnecessary exposure. The study also shows how environmentally preferable attribute information can be efficiently collected, analyzed and prepared for 360-degree value analysis to

support HCO decision-making with more than financial, clinical and operational impacts — ideally, purchasing can include consideration of the environmental and social impacts of purchasing decisions and capture more comprehensive product quality evaluation.

Ultimately, as data-driven methods are innovated and adopted, the screening and removal of unsafe chemicals from health care settings worldwide will evolve from aspiration to expectation.

To learn more, access the full case study, **“Protecting High-risk Patients From Unsafe Chemicals in the Supply Chain.”**

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Technology watch

KidsX: the Accelerator class of 2021 |

Here's 13 startup companies focused on innovation for pediatric care

Children's Hospital Los Angeles brought together 40 pediatric health systems to launch KidsX, a virtual 13-week pediatric digital health accelerator program. Applications for the program were accepted in 2020, and the program officially launched in early 2021. The goal of KidsX is to help digital health innovators pilot and deploy digital health solutions that improve the care delivery for pediatric patients, and then grow and scale these products.

KidsX providers selected the following 13 startup companies as part of its inaugural accelerator cohort. These companies will be mentored by the participating hospitals, preparing them to enter the pediatric market and giving them a place to test their innovations. During the program, entrepreneurs will work closely with decision-makers and digital health leaders at the most innovative children's hospitals — collaboration that is sure to bring exciting products to the pediatric market.

The KidsX Accelerator program supports early-stage digital health companies achieve product and business model validation in the pediatric market.

Augment Therapy

Augment therapy is an interactive software-based pediatric physical therapy program. It was developed by a pediatric physical therapist and can be used in clinic, via telehealth or at home. It uses augmented reality (AR) to create a fun, entertaining environment for the children. Depth-sensing cameras allow exercise data to automatically generate during the physical therapy sessions and no wearable devices are needed.

Curbside Health

Curbside Health developed an artificial intelligence (AI) enabled predictive analytics solution that provides real-time, point-of-care intelligence. The technology supports point-of-care decision optimization as well as clinical effectiveness management. This tool decreases variability by standardizing patient care, optimizes throughput, mitigates risk and maximizes reimbursement.

Dock Health

Dock Health provides a HIPAA-compliant task management platform for health care. It is available via the web and through a mobile app, and allows the care team to collaborate on clinical and operational tasks to improve the level of patient care.

Kiddo

Kiddo is a wearable health monitor developed for children ages 3 through 10. It combines both remote patient monitoring and care management solutions. The device is targeted to children with conditions such as autism, asthma and cyclic vomiting syndrome. The unit monitors vital signs like heart rate and body temperature, as well as health conditions such as fever, respiratory distress and stress. Kiddo helps parents and children utilize the care system more efficiently and effectively with a virtual telehealth component that allows for at-home treatment.

Kinsugi

Kinsugi is an app that scores clinical depression and anxiety on the patient health questionnaire-9 and general anxiety disorder-7 scales, in less than a minute of speaking. The AI-enabled app uses voice biomarker technology to measure, and then suggest strategies to improve mental well-being. The app is available 24/7 and it provides wellness exercises, tracks progress through journal entries, and offers a support community.

Limbix

Limbix creates prescription digital therapeutics with accessible technologies to improve the mental health of adolescent patients. The first product is Limbix Spark, which is a mobile, self-guided cognitive behavior therapy for adolescents with depression. Limbix was recently awarded a grant of \$3.6 million from the National Institutes of Mental Health. The grant will fund a large scale clinical trial of Limbix Spark in conjunction with the Duke Clinical Research Institute.

Moxie

Moxie is a robot designed by a team of engineers, roboticists, neuroscientists, child development specialists and story tellers. Moxie uses advanced technologies such as AI, machine learning and abductive-logic programming along with evidence-based therapy approaches to assist children ages 5 through 10 with social, emotional and cognitive skills. The play-based therapy includes weekly themes such as kindness or respect, reading activities, creative projects and mindfulness.

Pieces Tech

Pieces combines AI, clinical knowledge and community networks to quantify social barriers to care and provide actionable solutions. The suite of products includes Pieces Predict, Pieces Connect and Pieces Guide. The Predict module uses AI, machine learning and analytics to predict outcomes — better enabling health care providers to deliver proper care. The Connect module is a cloud-based case management and referral platform to coordinate care for those who need community resources. The Guide module provides a repository of community services with program eligibility requirements, as well as hours of operation. Community services may include food pantries, transportation services or housing assistance.

Rose

Rose is a tool that helps monitor mental health through a mobile application used by patients and a provider, web-based clinical dashboard. Patients have the ability to track their mental health on the application and the clinician can remotely track patient status through the portal. Sessions can be scheduled live or remotely. In a Johns Hopkins Medicine Institutional Review Board study, Rose was proven to clinically improve patient outcomes.¹

Spellbound

Spellbound is a therapeutic tool that uses an AR platform to provide 3D experiences through mobile devices for hospitalized children. The ARISE product is set up as an AR scavenger hunt and use by pediatric patients encourages play and mobility, while distracting from pain and anxiety. The use of kid-friendly games such as ARISE and other AR products has been shown to reduce pain perception in children, as well as enhance their comfort in the clinical environment.²

Vitals

Vitals allows for remote patient monitoring of vital signs such as temperature, heart rate, respiration rate and blood oxygen saturation level. It consists of a wearable monitor, Tego, that is wireless, waterproof and suitable for use in children older than age 2. Vitals is compatible with iOS, Android and all web browsers. This technology allows for continuous remote monitoring that provides actionable data to the care team.

Well

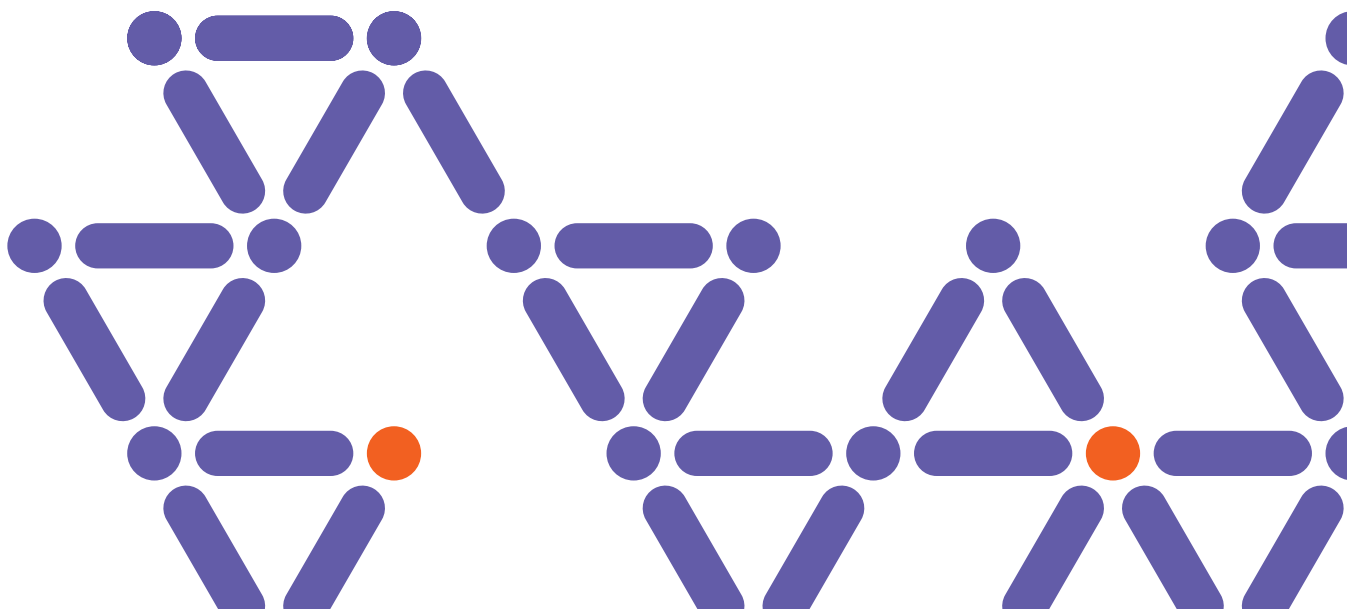
Well is a product that provides a two-way digital platform for patient messaging. The patient has the option to select text, email, telephone or live chat. Well integrates with existing clinical and administrative systems and provides analytics on patient communication. Well connects with the patient's electronic health record and can send appointment reminders, instructions and follow-up messages.

Xploro

Xploro is a clinically validated health care platform that delivers health care information to children. The platform uses AR, gameplay and AI to deliver the information. Kid-friendly features include an avatar chatbot, interactive models of hospital environments, equipment and processes, customizable avatars, treatment-themed games and a diary. Additionally, there is a parent app and a clinician management system.

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Innovative
pediatric care
technologies

To help your organization stay abreast of technology advancements in pediatric health care, this article features technologic products presently available and additional innovative products in development.

Currently available products

bili-hut from Little Sparrows Technologies

The bili-hut offers innovative care for neonatal jaundice by delivering neonatal intensive care unit (NICU) level treatment at the mother's side in the hospital or at home. The bili-hut is a best-in-class phototherapy device available to treat neonatal jaundice, which is one of the most common neonatal conditions affecting newborns in their first week of life. The device's unique design improves baby's thermoregulation and meets American Academy of Pediatrics requirements for high-intensity phototherapy.

MiniMed 770G System from Medtronic

The Medtronic MiniMed 770G System is the first Food and Drug Administration (FDA) approved hybrid, closed-loop system that monitors glucose and automatically adjusts the delivery of long-acting or basal-insulin based on the user's glucose reading in users 2 years old and up. The system is comprised of a continuous glucose monitor (CGM) that measures the user's glucose levels for up to seven days, an insulin pump that delivers insulin to the user, and a glucose meter that calibrates the CGM. A previous version of this device (MiniMed 670G System, without the Bluetooth capability) was approved only for users 7 years old and up.¹

A study of 46 participants ages 2 to 4 years, provided data supporting the use of this 770G device in young children. The clinical trial included an initial two-week period where the system's hybrid closed loop was not in use, followed by a three-month period when trial participants used the system's hybrid closed-loop feature as frequently as possible. The clinical trial proved that the device is safe for use in persons as young as 2 years who have Type 1 diabetes.

The glucose readings are wirelessly sent via Bluetooth low energy to the insulin pump. The readings are visible on the pump screen, along with glucose trend information, alerts and alarms. The insulin pump delivers a prescribed dosage of insulin through an infusion set and has capability to automatically adjust the delivery of insulin using a mathematical equation, or algorithm, that incorporates information from the CGM.

NTrainer System from Innara Health

The NTrainer System is the only FDA-cleared device designed to improve oral coordination in newborns and infants born prematurely. NTrainer provides both assessment and therapy for diagnosing and enhancing

a pre-feeding skill known as non-nutritive suck (NNS). It provides a somatosensory intervention to bridge and organize NNS skills through patterned and frequent modulated oral stimulation. NTrainer NNS therapy has been shown to increase NNS skills and enhance NNS and nutritive feeding ability. The pulse therapy is delivered through a pacifier-enabled handset on a mobile medical cart system.

Pediatric congenital heart disease stent from Renata Medical

Renata Medical created an adjustable stent for pediatric patients that is uniquely designed to last a lifetime. The stent is placed in the child at birth at an initial size of less than 2 millimeters in diameter and can grow to greater than 20 millimeters in diameter as the patient grows. Currently, a majority of devices implanted in children are off-label or not specific to pediatrics resulting in the possibility of multiple invasive and costly surgeries. This stent solution can be beneficial to the more than 40,000 children born with congenital heart disease each year in the United States.²

The Medtronic MiniMed 770G System is the first FDA-approved hybrid closed-loop system that monitors glucose and automatically adjusts the delivery of long-acting or basal insulin, based on the user's glucose reading in users age two years and older.

Sonallev MR-HIFU from Profound Medical

Profound Medical's device, Sonallev MR-HIFU, uses MRI to deliver focused, high intensity ultrasound (sound) energy to treat osteoid osteomas, a benign painful bone tumor that is typically found in the arms or legs of children and young adults. In a clinical study, nine patients ages 7 through 24 were treated with Sonallev MR-HIFU. After four weeks, eight of the patients experienced long-term pain relief and did not require pain medication.³

Sports Science Q-Collar

The Q-Collar is a noninvasive device worn around the neck of athletes 13 years and older during sports activities to protect the user’s brain from the effects of repetitive subconcussive head impacts. It is a C-shaped collar that applies compressive force to the neck that in turn increases blood volume in the cranial space. The increased volume helps reduce movement of the brain that may occur during head impacts and can help reduce the occurrence of specific changes in the brain associated with brain injury. The Q-Collar should be worn with other protective sports equipment such as helmets and shoulder pads. The Q-Collar can be worn for up to four hours at a time. It should be replaced after two years of active use or the expiration date of the product, whichever comes first. Q30 Sports Science LLC is granted FDA marketing rights for the Q-Collar.⁴

Products in development

Biosense

Biosense is developing what is set to be the first noncontact electrocardiography (ECG) that is reusable, has a 10-second, and pain-free acquisition time, and eliminates lead wires. Without skin contact, the unit’s small and flexible sensors effectively detect the ECG signal through multiple fabric and clothing layers and do not emit signals that interfere with other devices in a medical setting. The device integrates with patient monitoring applications in the NICU, labor and delivery, and burn units, and also works for adult monitoring.

Eclipse Regeneration

Eclipse Regeneration is currently developing the Eclipse XL1 to provide a revolutionary approach for treating short bowel syndrome. The device has an entirely mechanical and repeatable method devised to grow healthy intestinal tissues two to three times longer within two to three weeks. This will provide the world’s first tissue regeneration therapy.

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COVID-19 vaccines and children



At the time of this publication, there are three vaccines approved in the United States for adults and older teens. MRNA-1273 (Moderna) and JNJ-78436735 (Johnson & Johnson) were authorized for 18 years of age and older.^{1,2} The BNT162b2 (Pfizer-BioNTech) vaccine was authorized for individuals older than 12 years of age.³

The emphasis of vaccine efficacy and safety on individuals younger than 16 years has not been a priority due to the reduced severity and mortality of COVID-19 in children and adolescents. As of June 1, 600 COVID-19 related deaths occurred in patients less than 18 years of age compared to 579,030 COVID-19 related deaths in patients greater than 18 years of age.⁴

Now that the U.S. has updated vaccine administration providing availability to adults, it is time to shift the focus to the efficacy and safety of these vaccines in the population under 16 years of age. According to the 2019 census, the United States has more than 328 million people, 22% of which are under 18 years of age, and it is believed that vaccination in children will be required to effectively reach herd immunity of 70% to 80% of the population.⁵

All three vaccine manufacturers have critical ongoing efforts to support broadening global vaccination and expanding their knowledge for safety and efficacy of their vaccines in the younger population (Table 1). Pfizer-BioNTech designed a randomized, placebo-controlled trial of 2,260 adolescents, 12 to 15 years of age. The

vaccination dose was the same as the adult dose being provided. Results from the adolescent trial show strong immunogenicity one month after the second dose regardless of whether the adolescent had been exposed to SARS-CoV-2 in the past. BNT162b2 was well tolerated, with side effects consistent with adult studies. In a phase 3 clinical trial (NCT04368728), BNT162b2 was shown to be highly effective at protecting this age group against systemic disease.^{5,6} Based on these results, Pfizer-BioNTech was granted approval from the Food and Drug Administration (FDA) for its emergency use authorization (EUA) with patients ages 12 to 15 for BNT162b2.⁶

Moderna has not formally published results of their TeenCove study (NCT04649151) of their vaccine (mRNA-1273) for ages 12 to 17. However, preliminary information shows similar efficacy and tolerability to that of the adult population. Moderna finished enrolling 3,000 patients aged 12 to 17 years in February, and results will be published 30 days following the second dose of the last participant.⁸

Johnson & Johnson announced on April 2, that it would begin to enroll individuals 12 to 17 years of age in its ongoing adult trial (VAC3158COV2001). Initially, the vaccine will be evaluated in a smaller number of adolescents 16 to 18 years of age. After reviewing the initial data from the Phase IIa trial, the study will be extended to a bigger group of younger adolescents.⁹

For individuals younger than 12 years of age, both Moderna and Pfizer-BioNTech have announced they plan to initially conduct smaller dose-finding studies for ages 6 months to 12 years. Pfizer plans to conduct its study using three age groups: 6 months to 2 years, >2 years to 5 years, and

>5 years to 11 years. Three different doses will be tested in 144 participants. The results from this initial dose-finding study will be evaluated, then followed by a larger trial of 4,700 children between U.S. and Europe to study the optimal dose determined in the initial study.^{6,7}

Moderna announced in March the enrollment of their first participant in a Phase 2/3 study (NCT04796896) of kids 6 months to 11 years old. The company plans to enroll 6,750 participants following a study of lower doses. In part 1, a small subgroup of patients 2 to 12 years of age will receive 50 or 100 mcg doses. Participants ages 6 months to 2 years will receive three dose options: 25, 50 or 100 mcg. Once Moderna compiles results, the dose that shows to be the most safe and effective will be studied in the larger group (Part 2).^{8,10}

The investments in vaccine efficacy and safety are pivotal in expanding the potential use of vaccines to younger people, allowing manufacturers to collaborate with the FDA, the National Institutes of Health and each other to speed the process of studying and reporting results. It is unclear if the FDA will allow the vaccines for use in patients as young as 5 years of age under EUA by the time schools open in the fall. However, there is mounting evidence that vaccination of the younger population will be needed to achieve herd immunity and enable a return to more normal environments.

Table 1. Vaccine manufacturer younger population safety and efficacy studies

Manufacturer	Vaccine name	Start date	Trial name	Status*	Age range
Moderna	MRNA-1273	7/2020	NCT04470427	Approved for use	18 yo and older
		12/2020	NCT04649151 TeenCove cohort	Completed – awaiting results	12 - 17 yo
		3/2021	NCT04796896	Started 5-11yo	6 months - 12 yo
Johnson & Johnson	Ad26.COV2.S JNJ-78436735	8/2020	NCT04436276	Approved for use	18 yo and older
		Anticipated 4/2021	NCT04535453	Not started	16 - 17 yo
Pfizer-BioNTech	BNT162b2	04/2020	NCT04368728	Approved for use	16 yo and older
		08/2020	NCT04368728	Approved for use	12 - 15 yo
		3/2021	NCT04816643	Started 5-11yo	6 months - 12 yo

Abbreviations: EUA = emergency utilization authorization; yo = years old

*Status at the time of the publication of the *Vizient Tech Watch: Pediatrics*, Vol. 7, 2021

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About the author

Emily Diehl, Pharm D, BCPPS, is a pharmacy executive director of Vizient pharmacy services and is a clinical specialist with more than 18 years of experience as an individual contributor and manager of clinical and operational pharmacy program development. Dr. Diehl obtained her doctorate of pharmacy from University of Missouri-Kansas City School of Pharmacy. She completed a pharmacotherapy pediatric specialty residency from University of Tennessee Health Science Center and LeBonheur Children's Hospital in Memphis, Tennessee.



New medications and indications



Unlike most areas of patient care, the pediatric segment has been less affected by the COVID-19 pandemic. Overall, the greatest impact of COVID-19 for this population has been slowing of the approval of high-cost drugs for rare diseases.¹ This article features new medications and new indications that will provide additional pharmaceutical options to pediatric patients.

New medications

Ansuvimab-zykl (Ebanga) for injection for intravenous use – Ridgeback Biotherapeutics

Ansuvimab is the second biologic approved for treatment of Ebola in adult and pediatric patients. Regeneron's triple antibody cocktail, Inmazeb, was approved last October. The efficacy of both ansuvimab and Inmazeb were evaluated in the PALM trial, which was conducted during an Ebola

outbreak in the Democratic Republic of Congo. Compared with an investigational control, treatment with ansuvimab was associated with a reduction in 28-day mortality (49.4% vs. 35.1%, respectively).

Carglumic acid (Carbaglu) tablet for oral suspension for oral use – Recordati Rare Diseases Inc

With this new indication, carglumic acid is the first and only drug approved for the treatment of acute hyperammonemia due to propionic acidemia or methylmalonic acidemia in pediatric and adult patients as adjunctive therapy. Food and Drug Administration (FDA) approval of the new indication was supported by results from a double-blind, multicenter trial (NCT01599286) that evaluated carglumic acid vs. placebo in 90 hyperammonemic episodes occurring in 24 patients. The median time to reach the primary endpoint – time from first dose of drug to the earlier of plasma ammonia level ≤ 50 micromol/L or hospital discharge – was 1.5 days

vs. 2.0 days in the carglumic acid and placebo groups, respectively (difference: 0.5 days; 95% CI, -1.2-1). During the first three days of treatment, more carglumictreated episodes reached the primary endpoint than placebo-treated episodes.

Dasiglucagon (Zegalogue) injection for subcutaneous use – Zealand Pharma

Dasiglucagon is a glucagon receptor agonist indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 6 years and older. Approval was based on the results of three multicenter, randomized, double-blind, placebo-controlled, phase 3 trials (NCT03378635, NCT03688711, NCT03667053), in which Type 1 diabetic patients with hypoglycemia were randomized to receive dasiglucagon, glucagon or placebo. Trials A and B were conducted in adults, while trial C was conducted in children (6 to < 18 years of age). The primary endpoint for all three studies was time to plasma glucose recovery, defined as an increase in blood glucose of ≥ 20 mg/dL from time of administration and without additional intervention for 45 minutes. In all three trials, the median time to recovery with dasiglucagon was 10 minutes vs. 35, and 40 minutes with placebo vs. 10 and 12 minutes with other glucagon products on the market.

Evinacumab-dgnb (Evkeeza) injection for intravenous use – Regeneron

Evinacumab is a first-in-class agent that binds to and blocks the function of ANGPTL3. It joins multiple agents that are currently FDA-approved for the treatment of homozygous familial hypercholesterolemia (HoFH) in pediatric patients older than 12 years of age. HoFH, an ultrarare inherited condition, affects approximately 1,300 individuals in the U.S. Approval was based on data from the phase 3 ELIPSE HoFH trial (NCT03399786), which randomized patients to evinacumab (n = 43) or placebo (n = 22), both in combination with other lipid-lowering therapies. The mean baseline LDL-C level in both groups was 255 mg/dL. At week 24, evinacumab-treated patients demonstrated a 47% reduction in LDL-C (vs. a 2% increase with placebo; $P < .0001$). Almost all patients were on a statin at baseline and approximately 80% were also on a PCSK9 agent.

Fosdenopterin (Nulibry) injection for intravenous use – Origin Biosciences Inc

Fosdenopterin is a novel agent and the first FDA-approved drug for molybdenum cofactor deficiency (MoCD) Type A. It provides an exogenous source of cPMP, a substrate required in the cascade for activation of molybdenum-dependent enzymes. It has an orphan drug designation with less than 150 individuals globally. Approval was based on a combined analysis of data from clinical trials (NCT02047461, NCT02629393) compared to data from a genotype-matched historical control. Patients receiving

fosdenopterin or the active moiety (n = 13) vs. patients untreated (n = 18), were compared for overall survival. In the fosdenopterin or active moiety-treated group, two deaths were reported vs. 12 in the untreated-group (hazard ratio: 0.18; 95% CI, 0.04-0.72). The estimated annual cost for a 9.1 kg patient is \$493,152, representing a significant financial barrier. The cost of therapy will continue to compound as the dosage is weight-based.

Rilonacept (Arcalyst) injection for subcutaneous use – Regeneron

Rilonacept joins anakinra (Kineret) as the only drugs that are FDA-approved for the treatment of the ultrarare, auto-inflammatory disease, deficiency of interleukin-1 receptor antagonist (DIRA). Rilonacept is also approved for the treatment of Cryopyrin-Associated Periodic Syndromes, including Familial Cold Auto-inflammatory Syndrome and Muckle-Wells Syndrome. The approval of this new indication was based on results from a two-year, open-label study of six patients who were previously treated with anakinra. In the study, all patients met the criteria for remission at six months and sustained remission for the remainder of the two-year study. In April, rilonacept added a new indication for treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older.

Rituximab-arxx (Riabni) injection for intravenous use – Amgen

Rituximab-arxx joins rituximab-abbs (Truxima) and rituximab-pvvr (Ruxience) as the third FDA-approved biosimilar to rituximab (Rituxan) and as the fifth Amgen biosimilar approved in the U.S. Rituximab-arxx became commercially available in January. Rituximab-arxx is indicated for all the same indications as reference rituximab except for the treatment of Pemphigus Vulgaris in adults and treatment of GPA/MPA in pediatric patients 2 years of age and older. Approval was based on totality of evidence, including comparative analytical, nonclinical, and clinical data. Clinical equivalence was established in the phase 3 JASMINE study that evaluated rituximab-arxx and reference rituximab in patients with grade 1, 2, or 3a follicular B-cell NHL and low tumor burden. At launch, rituximab-arxx is expected to be priced 16.7% below the average selling price of rituximab.

Viloxazine hydrochloride (Qelbree) extended-release capsule for oral use – Supernus Pharmaceuticals Inc

Viloxazine joins atomoxetine (Strattera) as the second selective norepinephrine reuptake inhibitor to be FDA-approved for attention deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age. Approval was based on results from three multicenter, randomized, double-blind, three-arm placebo-controlled, phase 3 trials (NCT03247530, NCT03247543, NCT03247517), in which adolescents 6 to 17 years of age were randomized to receive viloxazine or placebo. The primary endpoint in all

three was the change from baseline on the total score on the ADHD rating scale. In study 1 (n = 399), the placebo-subtracted difference in the 100-mg arm was -5.8 (95% CI, -8.9 to -2.6) and -6.9 (95% CI, -10.0 to -3.8) in the 200-mg arm. In study 2 (n = 252), the placebo-subtracted difference in the 200-mg arm was -6.0 (95% CI, -10.0 to -1.9) and -5.8 (95% CI, -9.9 to -1.7) in the 400-mg arm. In study 3 (n = 266), the placebo-subtracted difference in the 200-mg arm was -4.5 (95% CI, -8.4 to -0.6) and -5.1 (95% CI, -8.9 to -1.3) in the 400-mg arm. Viloxazine does not have the liver toxicity concerns associated with atomoxetine.

New indications

Adalimumab (Humira) injection for subcutaneous use – AbbVie Inc

This new approval expands the use of adalimumab to pediatric patients ≥ 5 years of age with ulcerative colitis (UC). Approval was based on the data from the phase 3 ENVISION I study (NCT02065557), a randomized, double-blind, multicenter trial that evaluated different dosage regimens in pediatric patients 4 to 17 years of age. At week 8, 60% achieved clinical remission per Partial Mayo Score in the higher dosage group vs. 43% in the lower dosage group. At week 52, 45% achieved remission per Full Mayo Score in the higher dosage group vs. 29% in the lower dosage group vs. 33% of patients randomized to placebo. No safety signals were observed for the patient population. This indication distinguishes adalimumab from the six biosimilars entering the market in 2023 and the other TNFs indicated for UC in patients ≥ 6 years of age.

IncobotulinumtoxinA (Xeomin) for injection for intramuscular or intraglandular use – Merz Pharmaceuticals LLC

IncobotulinumtoxinA is FDA-approved to treat pediatric patients with chronic sialorrhea. Although not approved, onabotulinumtoxinA (Botox) and abobotulinumtoxinA (Dysport) are frequently used off-label for this indication. Approval was based on results from a phase 3 (NCT02270736) randomized, double-blind, placebo-controlled study conducted in 216 pediatrics aged 6 to 17 years with chronic sialorrhea. An additional 35 patients ages 2 to 5 years received open-label treatment. In the 6- to 17-year-old cohort, incobotulinumtoxinA was associated with significant decreases in unstimulated Salivary Flow Rate and Carer's Global Impression of Change Scale compared with placebo, beginning at week four post-injection.

Liposomal bupivacaine (Exparel) injection for surgical site use – Pacira Pharmaceuticals Inc

This new approval expands the use of liposomal bupivacaine to pediatric patients ≥ 6 years of age as a single-dose infiltrate for postsurgical local analgesia. FDA approval was based on data from the phase 3 PLAY trial (NCT03682302), a multicenter, open-label trial, in which adolescents (12 to < 17 years of age; group 1) were administered a single 4 mg/kg dose of liposomal bupivacaine (n = 30) or a single 2 mg/kg dose of bupivacaine (n = 28) via local infiltration at the end of spine surgery, and children (6 to < 12 years of age; group 2) were administered a single 4 mg/kg dose of liposomal bupivacaine via local infiltration at the end of spine surgery (n = 5) or cardiac surgery (n = 28). The primary endpoint was area under the plasma concentration-versus-time curve. The pharmacokinetic findings were similar to those found in adults. One patient experienced vomiting and one patient had a fungal infection at the wound site, although no other serious adverse events were noted.

Mirabegron (Myrbetriq) extended-release tablet and granule for oral use – Astellas Pharma US Inc

Mirabegron is the first-in-class Beta-3 agonist indicated to treat neurogenic detrusor overactivity (NDO) in pediatric patients 3 years and older weighing 35 kg or more. With this new indication, mirabegron is approved for two indications, including treatment of overactive bladder in adults. FDA approval was based on data from the phase 3 CROCODILE trial (NCT02751931), a multicenter, open-label, baseline-controlled trial, in which children (3 to < 12 years of age, n = 43) and adolescents (12 to < 18 years of age, n = 25) with NDO using clean intermittent catheterization received an initial dose of 25 mg once daily and up-titrated to 50 mg once daily. The primary endpoint was change from baseline in maximum cystometric capacity (MCC) at week 24. In the children cohort, the change in MCC from baseline was 72.09 mL (95% CI, 45.28- 98.89; P $< .001$) and 113.21 mL (95% CI, 78.95-147.47; P $< .001$) in the adolescent cohort. A new formulation, extended-release granule, was approved for use at the same and is not interchangeable with the tablet.

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Product information regarding new medications, indications, and formulations is based on information retrieved from respective product prescribing information and the Food and Drug Administration website available at Drugs@FDA, accessed April 2021.

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Price projections affecting the pediatric market



Projected price changes

Vizient expects overall market prices for supplies to increase 2.3% in 2021 and the first half of 2022. Table 1 shows projected supply chain price inflation over the next 18 to 24 months.

The consumer price index “medical care services” (Figure 1) primarily tracks the cost consumers pay for hospital and related services, professional services, and health insurance. Table 2 shows past and projected change for this price index.

Vizient market researchers expect overall market prices for supplies to increase 2.3% in 2021.

Table 1. National price inflation projections^a

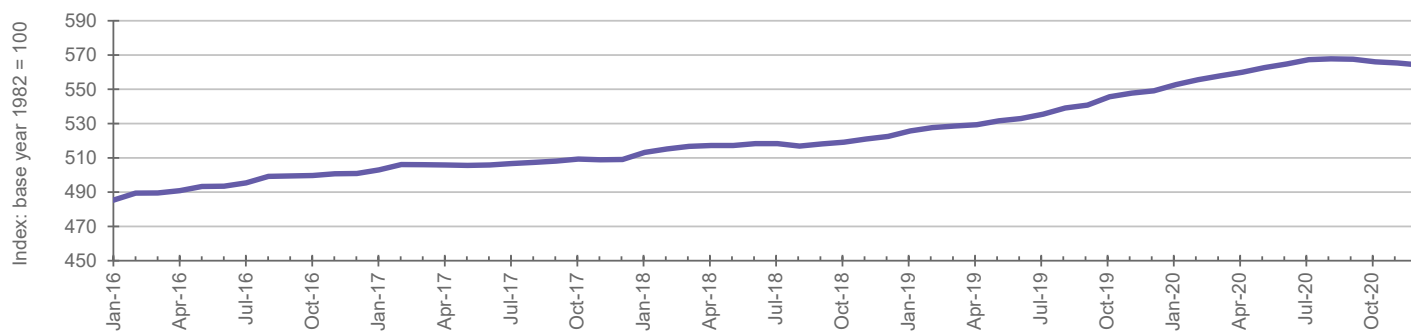
Product category	National price inflation projection, %	Product category	National price inflation projection, %
Cardiology overall	1.5	Medical gases	4.1
Cardiac rhythm management	0.0	Purchased services	2.1
Orthopedic overall	-0.6	IT hardware	-2.0
Orthopedic supplies	0.1	IT software	-0.5
Joint implant	-1.0	IT services	3.5
Spinal	-0.4	Commercial printing	1.4
Trauma	0.5	Office supplies	3.0
Neurosurgical	1.5	Furniture	2.9
Electrophysiology	2.2	Construction	2.0
I.V. solutions	2.5	Water	4.5
Medical supplies	2.8	Electricity	3.1
Surgical supplies	1.5	Natural gas	3.6
Medical equipment	1.4	Telephone, wireless	-0.5
Imaging equipment	0.0	Internet	0.5
Laboratory equipment	0.8	Food overall	3.8
Laboratory consumables	1.0	Overall projected price change	2.3

^aThe projections are for the next 18 to 24 months and are calculated using historical pricing trends, raw material trends, internal resources, the producer price index, the consumer price index and The Financial Forecast Center.

Source: Vizient Budget Impact Projections Report, January 2021.

Abbreviations: IT = information technology; I.V. = intravenous.

Figure 1. Consumer price index: medical care services



Source: Vizient Budget Impact Projections Report, January 2021

Table 2. Consumer price index change

Consumer price index	December 2020	One-month change, %	Three-month change, %	12-month change, %	Three-year change, %	Forecast
Consumer price index: medical care services	564.2	-0.2	-0.6	2.8	10.8	→

Source: Vizient Budget Impact Projections Report, January 2021

As a reminder: COVID-19 presents the most unique market variables and possibly the greatest effect ever on the health care industry. Estimates and forecasts should be used with a greater level of caution than in the past. The volatility in the markets and the large number of unknowns currently make forecasting exceedingly difficult. Markets can change abruptly with a drastic rise or fall, daily or weekly. We suggest a conservative approach when using this data and err on the side of caution.



Supplier watch - Dräger

The synergy of an integrated workplace

As a two-time Vizient Pediatric Supplier of the Year award recipient, Dräger understands that pediatric providers' main goal is to get kids back home with their families by creating a "return to wellness" at the earliest opportunity. Dräger designs its solutions with compatible technology and consistent design strategies to improve critical care for neonatal and pediatric patients.

Synergistic benefits of compatible technology

The following hypothetical example illustrates how Dräger solutions can work together in your children's hospital.

A baby born prematurely at 35 weeks is showing signs of respiratory distress and a possible congenital cardiac anomaly. She is transferred from the labor and delivery unit to the neonatal intensive care unit (NICU) via the Dräger Isolette TI500, an internal transport incubator that provides stable thermoregulation and protection during the transfer.

The baby is admitted to the NICU and is placed in a Babyleo TN500 IncuWarmer for thermoregulation and neuroprotective protocols. Since the microenvironments of both incubators are similar, the transition from one to the other puts minimal stress on the baby.

The NICU nurse screens the baby for jaundice using the JM 105 jaundice meter, a noninvasive device that's fast and easy to use. Compared with taking an invasive total serum bilirubin measurement, there's less stress on the newborn and her parents. The jaundice meter connects to the hospital information system, providing a seamless transfer of data to the infant's electronic medical record.

More conservative noninvasive respiratory intervention is not successful as the baby continues to show signs of distress, so she is next placed on a Babylog VN500 for mechanical ventilatory support. The respiratory care team uses lung-protective ventilation modes to minimize any potential damage to the baby's fragile lungs.

Further diagnostics confirm the baby has a cardiac defect that must be surgically repaired. The baby is transported to the operating room via the Babyleo TN500, while remaining connected to the Babylog VN500 ventilator which delivers NICU-quality care during transport.

The baby receives anesthesia using the Perseus A500 anesthesia workstation, which supports infant, pediatric and adult patients. Due to Dräger's consistent design philosophy, the lung-protective ventilation modalities of the Perseus are virtually identical to those of the Babylog VN500 ventilator.

After surgery, the baby returns to the Babyleo TN500 for recovery and further treatment. Mechanical ventilatory support continues with the Babylog VN500 until she can be weaned from the ventilator — a process supported by Dräger's proprietary volume-guarantee mode.

Dräger's comprehensive neonatal and pediatric solutions work together by design — providing even higher value to hospitals, staff, patients and families.

The NICU, which was designed at the Dräger Design Center, includes dedicated family space so the parents can actively participate in their baby's care. The Babyleo's kangaroo care mode makes it easy for the parents to bond with their daughter. Concurrently, the staff has dedicated space that provides full access to the baby and facilitates a more efficient workflow through a well-organized, easy-to-navigate, easy-to-clean workplace.

Once the baby is weaned from the ventilator and can maintain a normal body temperature, the Babyleo makes a seamless transition from closed care to open care — without disturbing the baby's environment. The baby is discharged and goes home with her family.

"The NICU staff use the family view screen to engage parents and give them access to their baby's information and enable a better communication and understanding of their baby's condition. The families generally feel more confident being around the bed and participating in the care process."

*Lisa R. Morelli, MSN, RN, CPN
Clinical Program Director
Advent Health for Children*



Real-world results

BiliLux helps Phoenix Children’s Hospital reduce NICU costs

Within the first six months of using BiliLux phototherapy, the hospital identified four patients who were potential candidates for exchange transfusion but instead received the noninvasive BiliLux phototherapy treatment, thus:

- Avoiding an average of \$500 per patient in treatment costs*
- Reducing labor costs by four hours per patient*
- Decreasing stress on patients, families and clinical staff

* actual savings may vary

“Dräger’s BiliLux phototherapy light has helped us effectively minimize the risk of severe jaundice across our entire patient population — and by doing so, supports our performance goals.”

*Mary Callaway
Clinical Education Manager
Phoenix Children’s Hospital*

Dräger’s patient-centered workplaces are built from the ground up to help clinical teams perform at their best. By leveraging extensive design experience and today’s leading practices, Dräger can help you streamline clinical workflows, optimize infection control and adapt to future needs.

Achieving significant benefits

As your specialist in critical care, Dräger uses a consistent, integrated approach to technology that considers ultimate outcomes as well as short-term tasks — enabling the hospital to achieve significant results. These include reduced length of stay and readmissions, infection protection, as well as connected data that supports more complete documentation. In addition, the Perseus anesthesia machine reclaims anesthetic sampling gases rather than releasing them into the environment — which saves money and supports green initiatives.

Vizient awarded agreements - Dräger pediatric:	
Dräger anesthesia	CE7151
Dräger ventilation	CE7292
Dräger infant care, phototherapy	CE3332
Dräger lights, columns, booms	CE7206



Supplier watch - Kimberly-Clark

Advancing bedwetting solutions

Kimberly-Clark is driving innovation and sharing updates on two new products to care for pediatric patients with moderate bedwetting.

The **Goodnites Absorbent Insert** design provides discreet and reliable protection for moderate bedwetting. Now, male pediatric patients who may need moderate protection at night while in the hospital can simply use the Goodnites Absorbent Insert versus wearing a full nighttime protection pant. This gives a sense of security while allowing the child to use their own undergarments. The absorbent inserts feature Kimberly-Clark's Comfort-Flex leak barriers to provide comfortable overnight protection while helping lock in wetness and prevent leaks. The insert holds up to 325 milliliters, and it is made with soft, clothlike material that helps pull moisture away from skin, which helps promote skin health and provides a more comfortable experience to support sleep.

Features of the Goodnites Absorbent Insert:¹

- Reliable protection: Goodnites Absorbent Inserts for boys provide discreet and reliable protection for moderate bedwetting
- Fits inside regular underwear: an insert that lets him wear his own underwear at night. Goodnites Absorbent Inserts are best worn with close-fitting briefs or boxer briefs
- Leak protection: Comfort-Flex leak barriers provide comfortable overnight protection while helping lock in wetness and prevent leaks
- Soft and comfortable: made with soft, clothlike material that helps pull moisture away from the skin so he can sleep comfortably through the night
- Durable adhesive: helps keep the insert in place all night

Pull-Ups New Leaf² are super soft training underwear made with plant-based* ingredients and breathable materials to support healthy skin. Ingredients like sugarcane and fluff pulp are carefully selected and crafted to provide the same level of protection that parents and health care facilities know and trust from the Pull-Ups



brand. They contain soft, adjustable side fasteners to provide great fit and easy changes. The snowflake design on the front of the pant fades to indicate that the training pant is wet. Pull-Ups New Leaf provide up to 12 hours of leakage protection for pediatric patients, keeping them comfortable and confident throughout their hospital care and at home. Pull-Ups New Leaf is also the only training pant that features Frozen II designs, Disney's most popular character franchise.

Features of the Pull-Ups New Leaf:³

- Hypoallergenic, plant-based and breathable materials made without harsh ingredients for healthy skin
- Soft, adjustable side fasteners for great fit and quick, easy changes
- Cottony soft and gentle leak protection design makes pediatric patients feel comfy and confident with Pull-Ups' trusted protection
- A special snowflake design that fades when wet to help indicate time to change

* 28% by weight

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Vizient awarded agreement - Kimberly-Clark:

Kimberly-Clark infant diapers

MS3702



Supplier watch - P&G

Reinventing preemie diapers to support the tiniest fighters

When babies are born preterm, their physical and neurological development is interrupted. These preterm infants need sleep to allow their bodies to grow and their brains to continue to mature and develop — especially between clustered care times.^{1,2} To help protect their sleep and healthy development, the Pampers team from P&G and neonatal intensive care unit (NICU) nurses reinvented the diaper for preterm infants weighing less than 1,800 grams. The new P2 size Pampers preemie diaper promotes uninterrupted sleep by providing up to six hours of absorbency and a customizable fit.

The importance of sleep

Sleep is essential to support brain development, which continues after birth.² Sleep is likewise associated with improved weight gain and immune function, stabilization of heart rate, and establishment of the circadian rhythm and diurnal melatonin cycle.^{3,4} It is also a part of other complex systems such as those that regulate stress hormones, increase growth hormones and enhance immune function.³

Necessary interventions in an infant's care, such as diaper changes, can cause stress, disrupt sleep, impact vital signs and compromise the energy needed to thrive. The more premature the baby, the less time the nervous system has to develop and the more likely these stressors will affect the brain, with potential long-lasting consequences.² In the NICU, there can be as many as 200 stressful events, disruptions or handling events during a 24-hour period.⁵ These include necessary procedures like medical assessments, repositioning and diaper changes, which can be stressful and can total as many as six to eight per day.^{6,7} Other unnecessary interruptions include those due to noise (> 45 decibels)⁸ and poor-performing diapers that result in more frequent diaper and linen changes.

The reinvented preemie diapers were designed and tested with NICU nurses to support up to six hours of absorbency for uninterrupted sleep. Through interviews, collaboration on diaper design, usage and feedback, the new diaper emerged to help minimize disruptions by improving skin and leak protection, comfort and ease of use while enabling healthy positioning to support and protect preemie sleep and development.

Our combined responsibility

Hospital NICUs continually seek to provide better outcomes for premature infants through practices that help protect and promote sleep. As these infants transition from the womb to the NICU and home, a well-performing diaper can help minimize disruptions and support uninterrupted sleep, leading to better outcomes. This is especially true as medical technology continues to improve the survival rates of earlier and earlier pre-term births.

Nurse preference study

P&G conducted an in-use-based survey of NICU nurses at two hospitals to test the performance of the Pampers Swaddlers preemie P2 size diaper. This survey assessed nurse reaction to the new preemie diaper and its ability to improve the sleep of preemies. Compared to the current standard of care, 95% of NICU nurses surveyed said they would recommend the new preemie P2 size diaper to other NICU nurses. More than 70% of the NICU nurses surveyed preferred this diaper (77%) and agreed its design supports uninterrupted sleep (71%).⁹

More than 50 years serving hospitals

What started with the first disposable diaper has become more than 50 years of partnership in service to hospitals, with a mission to support babies' happy, healthy development through the health care professionals who make it possible. Pampers has a proven track record for innovating diapers and wipes to improve patient outcomes.

In 2002, Pampers introduced the first micropreemie diaper and in 2016 introduced the size P3 diaper, the smallest ever. And to meet changing needs, Pampers introduced a reinvention of the preemie Swaddlers size P3 and P2 diapers allowing for customizable fit and six hours of absorbency for uninterrupted sleep.



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Vizient awarded agreement - P&G:

Procter & Gamble infant diapers

MS3701

Pediatric Pulse low-air-loss pulsation therapy mattress

Pediatric patients suffer from pressure injuries and skin breakdown just like older patients. But support surfaces that traditionally help adult pressure-injury patients are not suitable for children and babies. The Pediatric Pulse mattress from Sizewise is specifically sized to meet the pressure redistribution needs for your smallest patients.

Pediatric Pulse, made in the U.S., is a low-air-loss pulsation therapy support surface designed specifically for pressure injury treatment and prevention in patients 1.6 to 200 pounds. Pediatric Pulse provides continuous, powered low air loss and supports microclimate management through laser-cut micro holes in the air cells, thereby keeping the patient cool and dry. Pulsation therapy adds gentle stimulation to increase capillary blood flow to the skin, supplying greater oxygen and nutrients for improved skin integrity.¹

Vizient awarded agreements - Sizewise:

Sizewise bariatric and therapeutic beds - purchase	CE3355
Sizewise bariatric and therapeutic beds - rental	CE3365


**Innovative
Technology
Designated
Product**

vizient
Awarded Supplier

Improved sleep pattern, and a decrease in neonatal abstinence syndrome (NAS) from 11-14 days to 5-8 days, are both associated with the integration of a powered, low-air-loss mattress for patients diagnosed with NAS.¹



The industry-leading First Point of Contact top cover is free from latex and harmful chemicals, and is produced with nonhazardous, fire-retardant materials making it the safe choice for this most vulnerable patient population.

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Supplier watch - TransLite

Revolutionizing pediatric care with two new vascular imaging products

Vascular access procedures are commonly used in the provision of pediatric care. However, placing vascular devices in kids is fraught with difficulties, in part because of their tiny and fragile anatomy, along with the need to minimize physical and emotional distress. That's why it's paramount for vascular access procedures to be as smooth as possible.

Veinlite NEO

The Veinlite NEO is the only device on the market designed to locate both veins and arteries in neonates – perfect for use in the neonatal intensive care unit (NICU) and newborn nursery. Veinlite NEO uses “through the body” transillumination, allowing gentle care of even the tiniest newborns.¹ Using the Veinlite NEO, finding and accessing veins and arteries on neonates is made easier than ever before.² The Veinlite NEO was released in 2019 and NICU nurses have raved about it ever since. Featuring three different colored lights — green for arteries, orange for vein imaging and a white exam light — the Veinlite NEO is ideal for use in the NICU.³

Veinlite PEDI2

The all-new PEDI2 is a great solution for eliminating multiple sticks in children during venipuncture procedures. It's the leader in vein access devices for use in pediatric medicine. It is compact and versatile, and suitable for children of all ages, from infants to adolescents.⁴

The PEDI2 helps caregivers achieve 100% vein access success in children, eliminating multiple failed I.V. attempts. In clinical trials, the first-attempt success rate was significantly higher when using Veinlite compared with the standard of care (93% vs. 72%).⁵

The portable, hand-held vein finder features one-handed operation for ease of use, as well as switchable light colors for vein imaging, with three levels of adjustable brightness control.⁴

Plus, the PEDI2 meets Infusion Nurse Society and Centers for Disease Control guidelines for infection control, using affordable disposable plastic covers to prevent patient-to-provider and patient-to-patient contamination.⁴

The Veinlite PEDI2 can be used on children of all ages — neonate to 17 years — and saves time and stress when accessing veins in children.⁴

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Vizient awarded agreement - TransLite:

TransLite vascular imaging

CE7122





Supplier watch - WishBone Medical

The value proposition of single-use sterile procedure kits

As surgeons take on a surge of cases post-COVID-19 pandemic, the need for single-use, sterile packed procedure kits becomes increasingly apparent. WishBone Medical offers single-use, sterile packed procedure kits that enable hospitals to address supply chain obstacles and sterility issues inherent to reusable case and tray systems. The single-use model is crucial to making product accessible to Vizient member hospitals and surgery centers, while simplifying tracking and billing. The WishBone portfolio provides anatomically appropriate pediatric orthopedic solutions: orthopedic plates and fixators, orthopedic screws and pins, and single-use, sterile packed procedure kits.

29%

volume of health care expenditures attributed to surgical procedures⁴

17.7%

volume of health spending that accounts for nation's gross domestic product¹

Despite years of reform, the health care system in the United States remains strikingly inefficient and is becoming increasingly expensive. Increases in health care expenditure continue to outpace inflation, growing 4.6% in 2019, and reaching \$3.8 trillion or \$11,582 per person. Health spending accounts for 17.7% of the nation's gross domestic product.¹ It is clear that value-based health care delivery can bring sustainable change to the health care market. Value in health care delivery is defined as health outcomes achieved per dollar spent.² Optimization of value delivery demands a thorough understanding of cost drivers and patient outcome measures.³ Value optimization is crucial as reimbursement models shift toward alternative payment contracts in which provider organizations or physicians assume responsibility for maximizing efficiency.

Value-based health care delivery in surgical procedures

The importance of value-based health care delivery is particularly important in surgery since 29% of health care expenditures are attributed to surgical procedures.⁴ Surgery is increasingly performed on an outpatient basis with cardiology, spine and orthopedic procedures fueling the shift toward ambulatory surgery.⁴ The trend toward ambulatory surgery has been especially rapid in pediatric surgery.⁵ Based on a provider survey, Bain and Company estimates that the volume of procedures performed at ambulatory surgery centers (ASCs) is growing at a rate of 6.4%.⁶ This shift will increase price pressure on medical devices and products because ASCs have lower reimbursement rates and ASC-based physicians are more

price sensitive than hospital-based peers. Importantly, surgeons at ASCs have greater direct influence over purchasing decisions for medical equipment and implants compared with physicians working in hospitals, where procurement departments play a larger role. At ASCs, 70% of physicians have direct influence on purchasing decisions compared with approximately 45% of physicians at hospitals.⁶

Increased scrutiny of costs for processing reusable surgical instruments

As focus on cost drivers for surgical procedures grows, there is increased scrutiny of costs related to the cleaning and processing of reusable surgical instruments. This was carefully investigated using activity-based costing by Stockert and Langerman at the University of Chicago.⁷ In this observational study, the labor cost of cleaning and repackaging a single instrument was 10 cents, even if the instrument was unused. Adding instrument depreciation per use and central sterile processing operating expenses including detergent, biologic or quality checks, and equipment maintenance and repair, the total processing cost per instrument increases to 51 cents or more. In this study, based on the typical number of instruments opened, the average cost to process reusable instruments for a single case was approximately \$285. Interestingly, the investigators noted that only 13% to 22% of all instruments opened actually passed through a surgeon's hands during the entirety of the procedure, suggesting a tremendous market opportunity for the development and use of streamlined, single-use sterile kits for common surgical procedures.

Eliminating the cost of instrument cleaning and reprocessing

In a single-use sterile kit, all surgical instruments and implants are new and have never been previously used. The manufacturer typically includes a sufficient variety and number of extra implants to safely complete the targeted case. For example, in a single-use sterile kit designed for fracture fixation, the manufacturer would include a sufficient number of spare screws to account for variability in bone morphology, and to give the surgeon flexibility and peace of mind. Since single-use kits eliminate the cost of instrument reprocessing they offer tremendous potential to decrease procedure costs.

As surgeons take on a surge of cases post-COVID-19 pandemic, the need for single-use, sterile packed procedure kits becomes increasingly apparent.

A recent cost modeling study that compared total knee arthroplasty performed with single-use instruments versus reusable instruments suggested a mean cost savings of \$994 per case, primarily related to decreased instrument processing costs.⁸ Single-use sterile kits are carefully designed to contain a small number of high-yield instruments, in order to efficiently and safely execute the targeted procedure while minimizing waste and environmental impact.

In a recent study⁹ comparing reusable instruments to single-use sterile kits for one-level lumbar fusion, there was a 45% reduction in overall environmental impact with single-use kits, including a reduction in energy demand and global warming potential, primarily due to a reduction in instrument cleaning and reprocessing.

Increasing surgical efficiency in the O.R.

The use of reusable instrument trays also impacts surgical efficiency. Stockert and Langerman observed that more than 10% of trays are delivered to the operating room with missing instruments and 5.9% of trays with broken instruments. Instrumentation issues were found to dramatically increase by tray size, with an error rate of approximately 50% for trays with more than 40 instruments. These errors resulted in the surgeon requesting an additional tray in more than 30% of cases, resulting in an average delay of more than seven minutes.⁷ Given estimates that operating room costs are \$36 to \$37 per minute, delays related to missing or faulty instrumentation may increase costs by approximately \$260 per case.¹⁰ Single-use sterile kits have tremendous potential to improve surgical efficiency. Routine use could allow facilities to complete more cases per day in a single operating room, increasing the total number of billable cases and profitability.

Reducing the risk of health care associated infections

For all these reasons, single-use sterile kits may offer substantial financial advantages to provider organizations. But surgeons may be more drawn to single-use sterile kits due to potential safety advantages, as surgical site infections represent 21.8% of all health care associated infections.¹¹ Improperly reprocessed reusable instruments are a significant contributor to hospital-associated infections and have been investigated by The Joint Commission on behalf of the Centers for Medicare & Medicaid Services.¹² Challenges that hinder reprocessing are related to the efficacy of cleaning protocols, the complexity of reusable medical device design, and the impact of human factors throughout the reprocessing cycle. Potential infection from reprocessed devices is a major concern because of unique microbial populations known as

biofilms — dynamic microbial populations retained within a secreted extracellular polysaccharide matrix. A dramatic reduction in susceptibility to antibiotics and antimicrobials makes biofilms significantly more resistant to reprocessing protocols than non-biofilm bacteria. In a recent study evaluating orthopedic surgery loaner trays, residual biofilm, soil and bone were identified on a substantial number of reusable instruments and implants.¹³

The incidence of surgical site infection is estimated at 1% to 5% in patients undergoing inpatient surgery, with an estimated annual incidence in the United States ranging from 51,000 to 280,100.^{11,14} Surgical site infections have a tremendous impact on patient morbidity and mortality, especially in children where the margin for error is often small. In addition, the direct costs of managing a surgical site infection are substantial. In a recent study examining common ambulatory procedures, the cost of managing a serious infection averaged \$16,000 to \$21,000 following anterior cruciate ligament reconstruction, cholecystectomy and hernia repair.¹⁵

In conclusion

Given the potential safety concerns and the high level of direct and indirect costs associated with processing reusable instruments, as well as the potential improvement in operating room efficiency with single-use kits, there is a growing interest among surgeons regarding single-use sterile kits. Given the known advantages, the viability of single-use sterile kits will ultimately be dependent on safety, quality and the ability of a procedure-specific kit to contain sufficient tools and implants to cover the majority of patients for whom they are designed. There are a number of promising comparative studies that have started to appear in the literature. In a recent prospective, randomized study of total knee arthroplasty procedures performed using single-use instruments were found to have comparable patient outcomes to procedures performed with reusable instruments at six weeks and one year following surgery.¹⁶

Single-use sterile kits may offer substantial financial advantages to provider organizations.

But, surgeons may be more drawn to single-use sterile kits due to potential safety advantages, as surgical site infections represent 21.8% of all health care associated infections.

Pricing will be an important factor in determining whether the use of single-use sterile kits proliferates. A recent study comparing reusable trays and conventional implants with a single-use kit for distal radius fractures

suggested that overall cost was comparable, despite the cost savings associated with reduced instrument processing.¹⁷ In contrast, a recent investigation of single-level lumbar fusions at the Rothman Orthopaedic Institute demonstrated decreased costs with single-use kits compared to reusable instrumentation.¹⁸ Neither of these studies consider the improvement in operating room efficiency with single-use sterile kits, which may allow surgeons to complete more cases in a single operating room and unlock unrecognized opportunities to improve hospital and ASC profitability.¹⁹

While further investigation is needed, the potential for single-use sterile kits is promising. There is no question regarding the potential benefits with respect to patient safety, infection control and reduced instrument processing expenses. As provider organizations continue to implement use of single-use kits, the keys to value-based transition will be based on establishing a clear record of improving patient outcomes while minimizing production costs to take advantage of the reduction of human labor expenses related to instrument processing.

Vizient awarded agreement - WishBone:

WishBone Medical, pediatric
orthopedic products

MS9390

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About the author

Apurva Shah, MD, MBA, is the assistant professor of orthopaedic surgery and director of orthopaedic research at the Children’s Hospital of Philadelphia and the University of Pennsylvania Perelman School of Medicine. Dr. Shah is a nationally recognized expert in pediatric hand and upper

extremity surgery. He is one of a small group of surgeons in the country who perform complex reconstructive surgery for infants and children with brachial plexus birth palsy, including nerve grafting, nerve transfers, shoulder tendon transfers and humeral osteotomy.

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Contributors

Vincent Aguilera, Senior Program Services Manager, Pediatrics, Vizient

Brigitte Chorey, Senior Director, Pediatrics Sourcing and Program Management, Vizient

Susie Cymbor, MD, Physician Accreditation Advisor, Vizient

Emily Diehl, Consulting Director, Pharmacy, Vizient

Rhae Ana Gamber, MPH, Consulting Director, Sg2 Intelligence

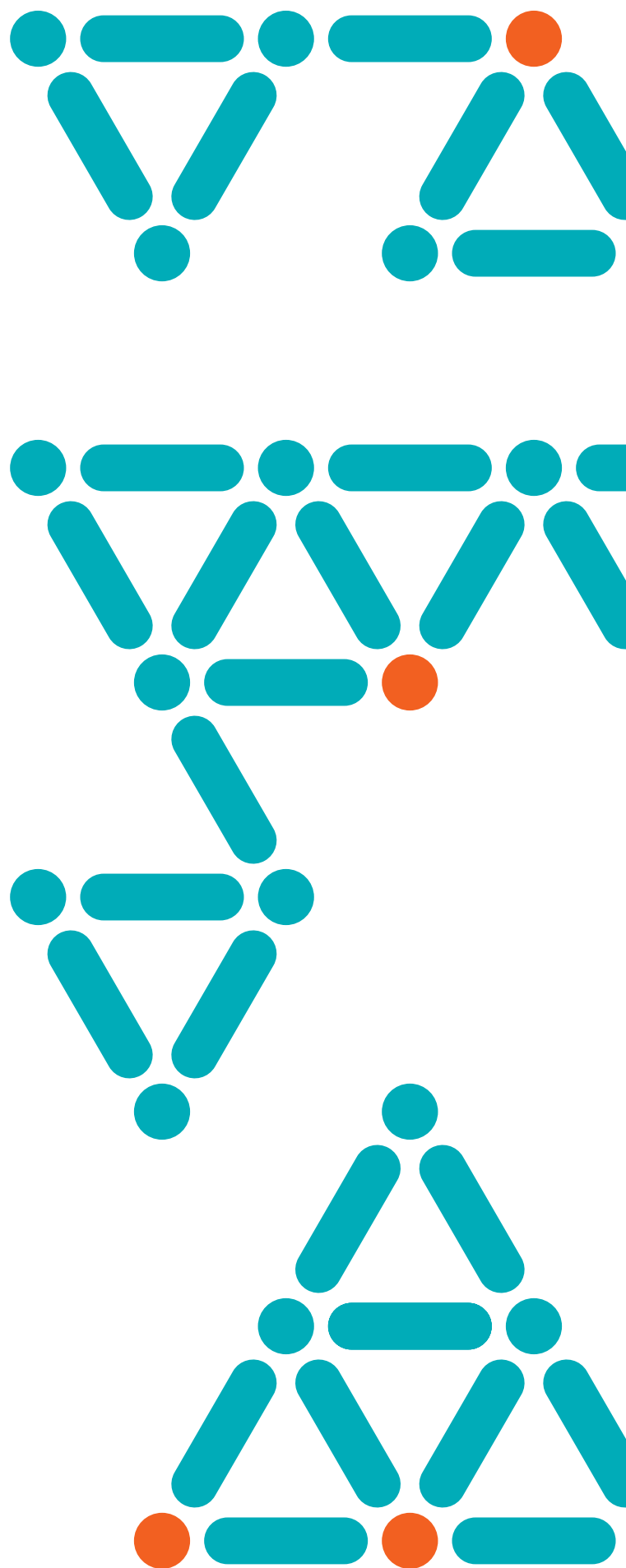
Catie Hjerpe, Consultant, Sg2 Intelligence

Kevin Lewis, Consulting Director, Vizient

Michael McGiboney, Director, Pharmacy

Melissa Nguyen, Senior Program Services Manager, Vizient

Apurva Shah, MD, MBA, Assistant Professor of Orthopaedic Surgery and Director of Orthopaedic Research, Children's Hospital of Philadelphia and the University of Pennsylvania Perelman School of Medicine





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290 E. John Carpenter Freeway
Irving, TX 75062
vizientinc.com

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