Pediatric drug shortage trends and best practices for mitigation strategies

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About the partnership

A long-standing partnership between Children's Hospital Association (CHA) — the voice of children's hospitals nationally — and Vizient®, a health care performance improvement company, enabled them to work together to find innovative ways to use the purchasing power of children's hospitals to reduce supply costs for enrolled hospitals and provide a contracting portfolio that addresses their unique needs. Combining the clinical, sourcing and analytical expertise of both organizations has resulted in awareness and outcomes designed to drive uninterrupted, high-quality care for our pediatric population. Sponsors of this research would like to thank the contributors from CHA and Vizient that participated in this important project to identify the impact of drug shortages on these hospitals.

Executive summary

The Pediatric Drug Shortages Project (PDSP), a yearlong collaborative between the Children's Hospital Association (CHA) and Vizient leadership, was designed to identify if and how self-governed pediatric (CHA) hospitals are uniquely and disproportionately impacted by drug shortages. The project overview can be found in Appendix A.

In reporting our project findings in this report, we will reference two cohorts:

- Pediatric hospitals: refers broadly to the 32 CHA Vizient Pharmacy Program participants or to the CHA hospitals that provided survey responses

- Other hospitals: refers to any other hospital — whether it serves pediatric or adult patients — that is not a CHA Vizient Pharmacy Program participant

This investigation relied upon the following resources:

- Vizient data was used to identify drugs in greater demand in pediatric hospitals and to monitor key metrics (i.e., supply and demand, manufacturers, fill rates and price performance).

- Through monthly and ad hoc meetings with pediatric hospitals as well as on-site visits to key hospitals, the team received guidance and feedback on project deliverables. Members provided firsthand knowledge about the impact of drug shortages on labor, budgets and patient safety, as well as the unique strategies they use to mitigate this impact.

- The Vizient Drug Shortages and Labor Cost Survey included questions designed to investigate the impact of drug shortages as well as mitigation strategies, enabling a comparator analysis to be performed between pediatric and other hospitals.

A number of deliverables resulted from this project, including:

- **A full analysis and discussion of survey findings (comparator analysis) that detail the drug shortage impact on pediatric and other hospitals.** Overall, we have demonstrated that pediatric hospitals are disproportionately and uniquely impacted by drug shortages. The survey analysis resulted in several high-level findings:

  - A statistically significant difference was seen in the number of shortages experienced by pediatric hospitals overall compared to other hospitals, with a higher number of shortages experienced by pediatric hospitals.

  - A statistically significant difference was also seen in the types of drug shortages (drug categories) that most impacted pediatric and other hospitals during the survey period.

  - A higher budgetary impact on pediatric hospitals was seen (statistical significance was not achieved).

  - Pediatric hospital respondents spent more time managing shortages by staff type compared to other hospitals. (A statistically significant difference was demonstrated for buyers/purchasing agents and informatics pharmacists prior to controlling the false discovery rate with the Benjamini-Hochberg procedure.)

  - Pediatric hospitals were more likely to hire additional staff and offer overtime to additional staff to manage shortages, whereas other hospitals were more apt to redistribute the workload among existing staff. Specifically, there was a statistically significant higher response rate for pediatric hospitals hiring additional pharmacists, compared to other hospitals (14.3% vs. 3.5%, P = .031).

- **A list of 30 "drugs of interest"; a shortage of any of these drugs would create a significant disruption and disproportionately impact pediatric patient care.**

  - This list is specified down to the product level (i.e., preferred pediatric concentration).

  - PDSP leadership recognizes that the drug market is not static and that the demand for drug products and risk for shortages can and will change over time; thus, this list will be reviewed and updated, with pediatric hospital project leadership approval, on an ongoing basis.

- **A dashboard that is accessible to project leadership, and features on-demand monitoring of these drugs' key market parameters to assess changes in demand and potential shortage risk.** We will continue to monitor the market and update our list of drugs, as needed.

- **Strategies that have been identified and implemented to protect the supply of these drugs for pediatric hospitals, including:**

  - Taking advantage of protection through the Novaplus® Enhanced Supply Program

  - Seeking additional manufacturers for alternative sourcing for drugs at risk of being in short supply

  - Obtaining 503B support

  - Working with manufacturers to prioritize availability of pediatric preferred formulations

- **An assessment of purchasing patterns in times of a perceived shortage.** In general, when members perceive that a drug may be short, the quantity of drug ordered spikes — typically far beyond baseline values. This practice results in:

  – Skewed communication of demand to manufacturers and distributors, which can impact stocking and allocation.

  – Some members receiving a disproportionately higher share of the drug in question, resulting in other hospitals being unable to obtain the drug and worsening perceptions about the shortage.

  – An apparently lower fill rate, which can also worsen perceptions of the shortage; however, in our investigation into the drugs of interest, we determined that the average quantity of drug supplied in times of a perceived shortage often remains steady and in some cases is even higher than that supplied prior to the perceived shortage, as manufacturers struggle to meet the new demand.

- The identification and discussion of pain points for participating hospitals and **successful management and safety strategies**, including:

  – Being conscientious of the impacts of purchasing behaviors, particularly anticipatory purchasing

  – Implementing strategies to more accurately track supply and drug quantity on hand

  – Standardizing the evaluation of drug shortages and the way in which supply issues are communicated to staff

  – Implementing drug shortage task forces and committees

  – Implementing safety measures around compounding of products

  – Leveraging relationships with distribution representatives

  – Taking advantage of the protections offered by Vizient contracts and Novaplus

Identifying drugs of interest

In an effort to identify pediatric drugs of importance, the Vizient team analyzed over 9,000 drug products and investigated:

- The average spend per pediatric hospital compared to other hospitals (used as a marker for relative demand)

- The average fill rate over a two-year period (used to indicate potential product shortage risk)

Of these 9,000 drugs, a group of 11 drugs were initially selected by project leadership for further analysis. A total of 19 additional drugs were added based not only on critical drug lists provided by our pediatric hospitals, but also at the request of the Member Advisory Group (MAG).

The following metrics were analyzed for each drug to determine appropriateness for inclusion on the list:

- Proportional pediatric hospital demand for a drug compared to other hospitals' spend

- Apparent higher demand not only for each drug, but also for specific product presentations

- Historical fill rate performance (2016-2019)

- History of a documented shortage based on the American Society of Health-System Pharmacists' (ASHP) website

- Analysis of each drug's manufacturer

- Price performance (i.e., change in price over time)

The drug presentations included on this list were deemed to be of high importance to the pediatric population (as demonstrated by a proportionally higher spend) and at risk in one or more categories (e.g., limited suppliers, active shortage or price erosion). The proposed list of drugs was provided to clinical pediatric pharmacists both within Vizient and at pediatric MAG hospitals for review, and final approval was granted by the MAG. The finalized list remains confidential and is only available to Vizient and pediatric hospital project leadership.

Although the project's statement of work specified that 20 to 30 drugs would be identified by project end, PDSP leadership recognizes that the drug market is not static; demand for drug products and the risk of shortages can and will change over time. Thus, this list will be reviewed and updated on an ongoing basis. All parameters investigated for our drugs of interest are available to Vizient and pediatric hospital leadership within our PDSP Dashboard, which, in addition to ASHP shortage information, offers on-demand monitoring of the metrics investigated for each drug.

Mitigation strategies for drugs of interest

The 30 drugs currently identified as drugs of interest for this project would disproportionately impact the pediatric population if they were to go on shortage. Vizient and pediatric hospital leadership have identified five unique strategies that will be used to protect the supply of these drugs for our members:

1. Access products through Novaplus

Novaplus, the nation's largest private drug label program, provides members with added insulation from the impact of drug shortages by giving them access to 190 drugs representing 760-plus national drug codes (NDCs). The average fill rate for drugs accessible through the Novaplus program is over 90%, which is significantly higher than the average fill rate of the same drugs accessed through other group purchasing organizations (GPOs).

Figure 1 shows that of the 30 drugs of interest, 22 are currently on Vizient contract and seven have a Novaplus offering. Of those products not on Vizient contract, two are high-cost branded products, one is not currently being manufactured and five are generic noninjectables for which pricing is generally leveraged through distributors.

Significant enhancements have been made to the Novaplus private label, such as the launch of the Novaplus Enhanced Supply Program, which promotes increased supply chain transparency (including more insight into raw material procurement), accountability (broadened failure-to-supply terms) and commitment to supply (increased inventory requirements for Novaplus products). This program is designed to provide protection for essential medications for which there are no alternatives and high-impact drugs that could disrupt quality of patient care if not available. It adds tens of millions of units back into the pharmaceutical supply chain, and one drug of interest to date — enoxaparin — is included in this program. More information on enhancements made to Novaplus can be found on the Vizient website.

Vizient continues to add to its Novaplus portfolio, and the pediatric hospitals' drugs of interest will help inform our contracting strategy in the months to come.

Figure 1. Drugs of interest currently on Vizient contract
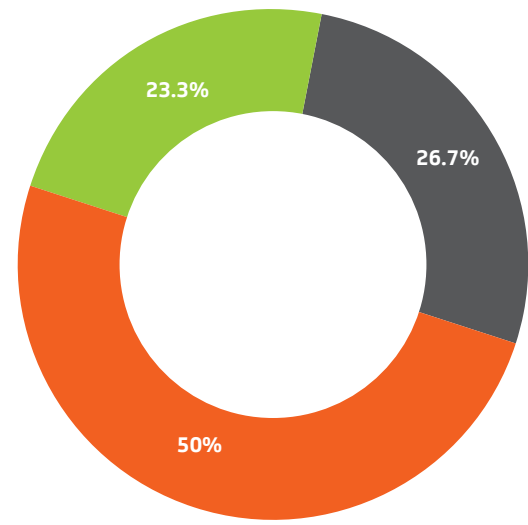
- **Drugs on Vizient contract without Novaplus offering**
- **Drugs on Vizient contract with a Novaplus label**
- **Not on Vizient contract**

Source: Vizient pharmacy data, 2019.

2. Seek additional manufacturers

While reviewing our drugs of interest, it was determined that more than half of them had only one to two manufacturers currently supplying the dosage form most used by pediatric hospitals. For these drugs, PDSP leadership will work with manufacturers to seek additional market entrants, thereby providing supply and pricing stability.

3. Obtain 503B support

To provide enhanced protection when there are a low number of traditional manufacturers or a history of shortages due to a lack of active pharmaceutical ingredients (APIs), PDSP leadership will collaborate with trusted 503B partners to pretest products and decrease the time to market during a shortage.

4. Work with manufacturers to prioritize pediatric preferred formulations

Pediatric pharmacy requires dosage forms that are easily modifiable to accommodate a broad range of patient sizes and responses. Enoxaparin is one example of a drug that is particularly effective in the pediatric population.

Adults are often administered enoxaparin in the inpatient setting for the prevention and treatment of venous thromboembolism. For preventive purposes, doses of 30 and 40 mg are generally administered and are available in prefilled syringes. In cases where weight-based dosing is required, doses are generally rounded to an easily measurable quantity (depending on prefilled syringe titration) and are still administered from prefilled 60-, 80-, 100-, 120- or 150-mg syringes.

In our investigation into the drugs of interest, it was noted that pediatric hospitals had a higher proportional spend on the 300-mg/3-mL vial. Our pediatric hospitals confirmed that this product is used to dose enoxaparin in patients under 30 to 40 kg — a criteria that applies to many pediatric hospital patients.

5. Monitor the market

A handful of drugs on our list appear to have a relatively low risk of shortage based on factors such as number of suppliers and price performance. We will continue to monitor the market to ensure that these factors don't change and that no further action needs to be taken.

Successful management and safety strategies

During work on the collaborative, the PDSP leadership team realized that our pediatric hospital members can benefit by sharing their strategies with other participating hospitals to help mitigate the impact of drug shortages.

Sharing these strategies will hopefully enable members to evaluate and improve their strategies currently in place. However, solutions will need to be tailored to fit the needs of each hospital individually.

Serving as conscientious custodians of drug supply

When we analyzed supply and demand for our drugs of interest — particularly for those with a historical or current shortage — it became apparent that the quantity ordered when a shortage is perceived exceeds the average quantity ordered both prior to and after the perceived shortage period. This, in turn, results in a perceived lower fill rate (ratio of supply to demand). However, we also observed that the average quantity sold to Vizient members during a perceived shortage period generally remains steady and in fact often exceeds the average quantity sold prior to the shortage.

How do we address anticipatory purchasing?

Increased ordering due to a perceived shortage can contribute to peer hospitals experiencing difficulty obtaining drugs, the entry of drugs onto the grey market, price gouging and drug waste (if the quantity obtained exceeds true demand and stock is not accurately tracked).

In an effort to be a responsible steward of the drug chain, one of the pediatric hospitals participating in our on-site visits revealed that it caps all product orders at a 28-day supply. To order additional supply, it must obtain approval by pharmacy financial services.

Implementing ordering restrictions ultimately helps to reduce waste and returns, both of which worsen drug shortages.

Increased ordering due to a perceived shortage can contribute to peer hospitals experiencing difficulty obtaining drugs, the entry of drugs onto the grey market, price gouging and drug waste.

Assessing drug shortages

Tracking supply and quantity on hand

During a drug shortage, hospitals usually attempt to purchase drugs on back order and order product wherever and whenever it's available; ultimately, this leads to intermittent and unpredictable drug delivery, in quantities that may be larger than would generally be delivered when orders are placed regularly. Hospitals often struggle to find storage space for these drugs, with stock overflowing into areas where it would not normally be found and difficulties with accurately tracking quantity on hand.

Moreover, because fractionated weight-based doses are used in the pediatric population, and the same vial or container may be used to dose multiple patients, it can be difficult to accurately determine how much product has been used.

Participating hospitals use a number of different strategies to store and monitor drug products, such as:

Carving out a dedicated space for surplus of short drugs

During our on-site visits, one hospital revealed that it plans to establish a dedicated area for the storage of drugs on back order. While the hospital's purchase strategy has historically been to walk the shelves and visually determine low-quantity drugs, it now plans to label periodic automatic replenishment (PAR) levels for each drug and regularly order product from its primary distributor to help better meet demand.

Using the Kanban system for drug storage and procurement

Several members use the Kanban system — a visual system to help manage work as it moves through a process — to track inventory. The Kanban system helps to:

- Track true demand for a product, with products ordered on an as-needed basis (aligning inventory with demand)

- Reduce overstock and subsequent waste (i.e., expired product) and free up needed storage space

Using this method, drugs are stocked in individual bins, each with a card detailing the acceptable maximum and minimum quantities. A drug is pulled only when it is needed to batch more doses. When the minimum quantity in a bin is reached, staff are alerted to compound or purchase more of that item.

Each drug's progress during the restocking process is tracked using a bar code-enabled card that is placed in different slots on the bin's shelving unit and that corresponds to progress made in the drug's procurement (e.g., "needs to be ordered" or "ordered/awaiting delivery").

Using automated pharmacy storage systems

Another strategy employed by participating hospitals is the use of an automated pharmacy storage system. Not only does a closed system enable more efficient storage of medications and a more accurate, running count of inventory, but a quick glance at inventory after the automated system has been restocked can indicate which products did not get shipped as well as those that may be having supply issues requiring further investigation and monitoring.

Using readily available tools on your desktop (e.g., Microsoft Excel) to track drug supply

A common strategy among the hospitals we visited was the use of software such as Microsoft Excel to monitor drug supply. The complexity of the tracking methodology used varied by institution based on bandwidth and the reasons for tracking these drugs.

For instance, one pediatric hospital's pharmacy management team maintains a list of 20 to 30 drugs for which weekly counts are obtained. This list doesn't necessarily correlate with a true shortage but rather serves as a watch list. This hospital monitors the weekly usage of drugs on this list and can easily perform side-by-side comparisons to see if counts are steady, have decreased or have increased compared with the previous week. This list can be quickly referred to prior to weekly meetings with the shortage team to identify any potential supply issues as well as whether alternatives need to be identified for certain drugs.

Another hospital has created a more complex tracking grid in Excel, which includes parameters such as operational and clinical leads assigned to manage a back order or shortage, an action plan, back order dates, whether the item in question is stocked in an automated dispensing cabinet (ADC), current quantity available and weekly usage translated to the number of days' supply on hand.

This same hospital monitors and tracks drugs that it is unable to obtain from its primary distributor on an ongoing basis. In addition, it breaks them out by those with and without alternatives. In March 2019, it experienced over 100 unique shortages — 25% of which did not have an alternative. It also tracks all items on allocation and when that allocation is not correlating with demand; these metrics have been used to communicate and negotiate allocation with its primary distributor.

A third hospital maintains a drug shortage manager tracking form in a Microsoft Access database. Information contained within this form includes:

- Drug-specific information, including manufacturer, formulation (e.g., concentration), expiration dates, storage location(s) and quantity on hand

- A detailed reason for the shortage, timeline (e.g., when the shortage started and resolved) and status updates (e.g., actions taken and an expected time frame for an update or resolution)

Drugs are placed on this tracking form if the hospital experiences a delay in distribution and there appears to be a true issue with supply. This is determined by analyzing supply trends (e.g., identifying whether back orders are intermittent or ongoing and determining the status of shipment dates) and by leveraging relationships with local sales representatives (e.g., asking if there are regional delays in shipping based on issues such as weather and how quickly they anticipate members will receive supply).

If it is determined that a drug is short, pharmacy staff perform weekly manual counts. In general, this hospital monitors any drugs for which it has less than a 60-day supply. At the time of our visit, it was monitoring approximately 60 drugs.

Standardizing the evaluation of drug shortages

The pediatric hospital discussed above has also implemented a drug product shortage assessment checklist, which standardizes the parameters that are evaluated for each shortage and facilitates the creation of a task list, in which discrete tasks are assigned to individual team members.

Parameters assessed within the checklist include:

- Product information for current drug and potential alternatives (e.g., product presentation[s] and distribution locations)

- Safety concerns (e.g., does product contain preservatives or come in multiple concentrations [risk for dosing error])
  - Look alike, sound alike drugs

- Clinical planning
  - New monitoring considerations or administration requirements
  - Need for review by therapeutic standards committee

- Technological impacts (e.g., electronic health record [EHR], ADC)

- Communication planning (e.g., provider group vs. hospitalwide communication)
  - Communication provided in ISBARQ (introduction, situation, background, assessment, recommendation and question and answer format)

ISBARQ communication

One member hospital highlighted its use of the ISBARQ methodology to communicate information regarding drug shortages. ISBARQ is similar to the SBAR style of communication, but adds sections for introduction and questions:

Introduction: People involved in the handoff identify themselves, their roles and their jobs

Situation: Clearly and briefly defining the situation/problem on hand

Background: The circumstances that led to current situation

Assessment: What the problem is and how it will impact you

Recommendation: What can be done to mitigate the impact of the problem or resolve the issue

Question and answer: Opportunity for questions and answers

In a review of over 900 sentinel events, the Joint Commission concluded that communication gaps are the root cause of over 70% of serious medical errors. Differences in communication styles, varying levels of training and understanding, and hierarchical intimidation are among the factors that contribute to communication errors. Using standardized methodologies such as ISBARQ to communicate within the health care setting ensures that information is organized, precise and presented in a logical sequence. The ISBARQ methodology has been recognized by The Joint Commission and the World Health Organization, among others, as an effective communication tool.[1]

Implementing drug shortage task forces and committees

In the Vizient Drug Shortages and Labor Cost Survey, we asked members to disclose the strategies they have used to mitigate the impact of drug shortages. Surprisingly, only 18 (62%) of the 29 pediatric hospital respondents answered that they had implemented a task force or committee to address drug shortages and allocations at their institution. Below, we discuss how three pediatric hospitals have structured their committees and inventory management teams.

Hospital A

Located in the Midwest, hospital A has 527 licensed beds. This hospital's pharmacy team meets for a half-hour every week. Team members include an information systems representative, an inventory representative, two to three clinical pharmacists, and representatives from operations and medication safety teams. A narcotics technician, lead tech and a coordinator from ambulatory care also attend these meetings.

The team typically identifies four to five drugs to discuss at each meeting. This way, if a drug shortage is recurring or ongoing and has already been reviewed, redundant discussions are avoided.

Because shortages can occur without notice or warning and require additional time to manage, the team may also discuss solutions via email throughout the week.

Hospital B

Hospital B has 700 registered beds and is also located in the Midwest. The drug shortage planning committee at this hospital comprises pharmacy leadership, purchasing and Pyxis leads, clinical specialist(s) and an information technology (EHR) representative. This group's goals include early identification of drug shortages, proactive planning, designing action steps, and providing staff with ongoing communications and updates on drug shortages.

This hospital has defined responsibilities for each member of the committee:

- Leadership – approves new drug alternatives, process changes, revisions or additions to current guidelines and policies; communicates status of drug shortages; engages safety and risk management to identify near misses

- Buyer – identifies drugs on short supply; determines reasons for and duration of shortage, the next shipment date and what's available to order; identifies resolved shortages

- Pyxis lead – proactively monitors inventory; provides weekly usage summary for each unit; centralizes stock for optimal usage; restocks Pyxis when shortage is resolved

- Clinical specialist – categorizes the drugs affected by shortages as high-, medium- and low-priority items; collaborates with providers from affected services to discuss shortages and therapeutic alternatives; provides recommendations for intravenous (IV) to oral conversion, IV push, drug restrictions, etc.

- EHR representative – provides drug shortage notifications and alternatives; updates changes in drug concentrations, order comments, administration and dispensing information; changes order sets

Roughly six to seven internal pharmacy staff members also participate on the committee. The team meets weekly for approximately 1 1/2 hours to review its internal shortages list, which is based on current supply and weekly usage. During these meetings, the team determines which drugs are "critical" in terms of supply. The team also meets at the end of each week to determine which drugs need manual counts. Manual counts are divided among nine staff members, and are performed every Monday.

Hospital C

Hospital C serves the Southwest, and has 656 acute care beds. The hospital's core inventory team oversees the supply of medications for all four of its campuses. The team consists of an inventory pharmacist, a specialist and a supervisor; an operational lead; and a clinical lead. Specifically, the team is responsible for overseeing stock in central pharmacy, 15 pharmacy satellites and two distribution areas; 24 ambulatory clinics; over 200 ADCs at the main campus; close to 800 kits, trays and boxes; and floor stock and formulary additions, deletions and modifications. The core inventory team provides inventory updates for each facility's pharmacy operations team, and meets daily to discuss drug shortages.

Like hospital B, team members have clearly defined roles:

- Inventory pharmacist – coordinates all activities and communicates process changes to the pharmacy department

- Inventory specialist and inventory supervisor – maintain back order supply and provide necessary reports to the inventory pharmacist

- Operational lead – ensures operational issues are addressed and communicates with other department leaders

- Clinical lead – determines clinical restrictions and guidelines, and communicates with the appropriate services

Implementing a drug shortage team is essential in order to effectively respond to product shortages. However, only 18 of the 29 pediatric hospitals surveyed answered that they had implemented a task force or committee to address drug shortages and allocations at their institution.

The hospital receives a daily report from its primary distributor that details what products are in and out of stock. A pharmacist from the inventory team reviews this report every morning; the pharmacy operations team is updated at 10 a.m. regarding identified shortages, so the pharmacist has a window of less than two hours to identify potential alternatives and to develop a plan of action. If a plan of action is in place, the shortage is considered "closed." If there is no plan in place, the team can leave the shortage "open" for up to 24 hours until it determines a solution. Plans of action outline steps that can be taken if quantities reach a certain threshold (e.g., borrow or remove stock from satellites). Findings are sent via email, using a template that includes current quantities on hand (translated to days supply) and a proposal of how to manage the shortage.

Compounding safety measures

Have a plan to insource before you outsource

Although hospitals are prohibited under federal mandate from compounding commercially available products, these restrictions do not apply in the face of a drug shortage. Thus, members may find themselves either compounding new products in-house when a shortage occurs, or outsourcing compounding to a 503B facility.

One member hospital has a policy that states that it will not outsource compounding of a drug unless it first demonstrates the ability to compound it as an insourced medication. This strategy makes sense in light of the fact that, while outsourcing may be appropriate for some drug products based on labor requirements, receiving a timely drug supply is never guaranteed.

Ensure product sterility and stability

This same hospital also performs its own sterility, endotoxin and stability testing in-house. Its cautionary attitude toward drug sterility stems from prior experience: It was one of the hospitals impacted by the contamination of liquid docusate with *Burkholderia cepacia*. This product was manufactured by PharmaTech LLC and was distributed by Rugby Laboratories (among others). Between February and July 2016, 21 cases of *B. cepacia* infection in infants and young children at this hospital were confirmed to match the genetic profile of the contaminant found in the liquid docusate.

The API was produced by Laxachem Organics Pvt. Ltd in India, and because Laxachem refused to allow Food and Drug Administration (FDA) investigators on-site, the FDA banned importation of Laxachem products into the U.S. in August 2016. This hospital recalled that while the FDA was quick to respond to the outbreak (e.g., through on-site visits), the manufacturer was much slower in its response to issue a national recall. When this hospital discovered that the same strain of *B. cepacia* had infected patients at another children's hospital and that no national recall had been initiated, they warned colleagues against using this product through a children's hospital listserv.[2]

Consider stability when compounding

Another member hospital performs independent quality testing for all drugs that are compounded in-house, and thus far has tested almost 200 drugs. One of these drugs is captopril oral suspension.

When a new NDC of captopril — which no longer contained ascorbic acid, as had previous formulations — was used for compounding, it was discovered that the stability of the new solution was 50% lower than that of previous batches. Because of the reduced stability of this product, this hospital began using enalapril.

This example highlights the need for consistent use of the same drug products — down to the NDC level and concentration — for compounding. If a drug goes on shortage and a change is made to the product used for compounding, quality testing should be performed again.

Although hospitals are prohibited under federal mandate from compounding commercially available products, these restrictions do not apply when a drug shortage occurs.

Collect stability data for drugs compounded in a concentration differing from the commercially available product

During a breakout session for sildenafil — one of our drugs of interest — some members mentioned that they compound the 2.5-mg/mL suspension in the face of a shortage. (For reference, the concentration of commercially available sildenafil suspension is 10 mg/mL.) We distributed a survey to pediatric hospital members to find out how many were compounding the 2.5-mg/mL concentration. Of the 17 respondents, 12 (70%) stated that they compound the 2.5-mg/mL suspension.

We visited a pediatric member hospital to gain further insights into this practice. This member has independently tested the 2.5-mg/mL suspension, and is also currently testing the 10-mg/mL suspension, which may encourage other members to conduct stability testing on the 10-mg/mL compounded product. (The only published stability data for compounded sildenafil suspension is for the 2.5-mg/mL concentration, and members may be skeptical about using this concentration until stability data is formally published.)

If there is a shortage of sildenafil, the concentration of the compounded product may change, posing a safety concern. This places the outpatient population using this product at risk for error, as parents of pediatric patients may be unfamiliar with the difference in concentration and the appropriate volume to administer.

Leveraging relationships with distribution representatives

Every hospital that participated in our on-site visits indicated that they communicate with their primary distributor(s) to gain insight into ongoing supply chain issues and drug availability. While this is in and of itself an effective strategy that should be considered to mitigate the impact of drug shortages, our members use a number of other strategies:

Strive to have a close working relationship with your local distribution representative(s) and communicate your needs — specifically, the what, how and when of communication.

One member hospital we visited indicated that it has spent years building a close working relationship with its distribution representative. Together, they have developed a system of communication to ensure that the hospital is informed about products currently short or on back order, can easily communicate back orders that it wishes to place, and receives confirmation and status updates regarding orders already placed.

It receives two main reports from its primary distributor. One is a back order report, which details the products on back order, the back order quantity shipped, and the hospital's place in line to receive additional product. At this member's prompting, its primary distributor also supplies a "daily shorts" list, indicating which products are on back order or short on any given day.

The primary mode of communication between the hospital and its distribution representative is email. Pharmacy team members can email the distribution representative to request that it place back orders for them and to ask any questions that they have, such as when it anticipates availability of a drug.

This hospital has partnered with its primary distributor as well as a drug manufacturer to identify areas for improvement within the distribution chain and to push for increased visibility into product delivery, such as a product's anticipated ship date and when a product is in transit.

Work with your distribution representative to ensure your demand is being communicated and that allocations make sense.

Allocations are necessary in the face of drug shortages. They help ensure that supply is distributed among our members (with everyone ideally receiving a piece of the pie) and can be set by suppliers, distributors or both. Although practices vary among suppliers and distributors, these allocations are generally a percentage of historical demand for product.

One of the primary concerns conveyed by a member hospital during our on-site visit was that it did not feel the allocations set by its primary distributor were reflective of the size and demand of its different campuses. Rather, its experience was that each account was receiving the same allocation of drugs, regardless of size and product utilization.

The Vizient internal distribution team discovered that this hospital did not generally order product on back order through its primary distributor; rather, it ordered from a different distributor that had available product. It is important to continue to place orders reflective of true demand through the back order process, which helps communicate ongoing demand to distributors and ensure more accurate stocking of medications and member allocation.

When Vizient reached out to the primary distributor about this issue, it was motivated to address the hospital's concerns. A compromise was reached in which the hospital agreed to use the back order process to more effectively communicate demand and the distributor agreed to review its current allocation process and make an effort to match usage and facility size moving forward.

When possible, take advantage of the protections offered through Vizient contracts and Novaplus.

Vizient has the most leverage in resolving issues with the purchase of products through distributors when products are on Vizient contract. We have quality and supply requirements with suppliers for any product that we have on Vizient contract, and our distributors have mandatory stocking and fill rate requirements for contracted items. When our members are unable to obtain product, our first priority is getting that product as soon as possible, using whatever means we have available. However, attempting to order contracted products enables Vizient to address the lack of supply with suppliers and distributors as a contractual violation and gives us more leverage.

Effectively communicating drug shortage information

During our on-site visits, all four pediatric hospitals related their struggle to determine when and how to best communicate information regarding drug shortages. There was a shared concern among the members about avoiding undue alarm in the face of potential supply issues. Members must decide when communications should be sent out, to whom they should be sent (e.g., one provider group vs. hospitalwide) and how they should be sent (e.g., email vs. alert within EHR). Participating hospitals are handling communication in a variety of ways, described below.

Hospital D

Hospital D has 564 beds and serves the Northeast. As mentioned before, this hospital uses a drug shortage tracking form when delays in distribution occur and there appears to be a supply issue. This form is used to monitor approximately 60 drugs, and if there appears to be a short, the staff performs weekly manual counts.

Actions taken as a result of these counts vary based on the available quantity:

- If there is at least a 30-day supply on hand, continue to monitor quantity
- If the available quantity drops below a 30-day supply, consult clinicians or specialists, and determine alternatives and what to do with current inventory (e.g., move stock or change PAR levels)
- If quantity drops to a 14-day supply or less, notify physicians

Hospital B

Hospital B, the Midwestern academic medical center (AMC) described on page 10, views EHR alerts as one of the best ways of communicating with prescribers; unfortunately, it is also extremely time-consuming. Because of a rigid change control process in place, it can take days for changes to be approved and implemented by the EHR team.

A general EHR alert (which indicates that a clinical pharmacist should be involved) has been preapproved and can be put into place quickly to inform prescribers about an issue. The hospital also uses email to notify both internal pharmacy staff and practitioners of issues surrounding drug shortages.

Pediatric hospitals struggle with determining both when and how to best communicate information regarding drug shortages. There is a shared concern about avoiding undue alarm in the face of potential supply issues.

Communicate with caution

Pharmacy management highlighted the fact that they feel responsible for minimizing alarm caused by drug shortages. Practitioners are generally only notified of a shortage once it becomes apparent that it will impact clinical care or prescribers' ordering practices. Even communication within the pharmacy department is on a need-to-know basis; many times, buyers are able to resolve issues on their own without them needing to be escalated to management or the drug shortages team. Front-line staff are informed of issues and changes made since they will be the ones fielding calls about these medications. By the time shortages are communicated, the goal is to already have a plan in place, which helps alleviate concerns.

Use SharePoint to communicate information regarding drug shortages

Staff stay up to date on drug shortages by accessing their internal SharePoint site. SharePoint contains links to various websites (e.g., ASHP, University of Utah and FDA) to help track drug shortages; offer information about drug supply issues that the hospital has deemed critical, as well as how the shortage is being managed (e.g., which product to substitute with); and provide access to the drug shortages list. Each drug on the shortages list has an assigned status (e.g., "currently monitoring," "critical –

prescribing practice changes" or "resolved but still monitoring") as well as the date that the information was last updated. If staff members click on a specific drug, additional detail is provided, including a current action plan and any communication that has been sent out regarding the shortage. The goal is to know exactly who has been contacted (and thus who needs to be included in any updates regarding the shortage), what information has been communicated and when.

Hospital A

Hospital A, the other Midwestern AMC discussed on page 10, also stressed the need to use caution when sending out communications about drug shortages. It typically involves its clinical pharmacists in determining product alternatives and plans of action when only six weeks' supply of a drug remains, and communicating to providers once they have less than a 30-day supply.

If the shortage will cause a broader impact (i.e., if it will extend beyond a certain department), it uses its EHR to communicate shortages. Its team tries to use an "alternative screen" in its alerts, which lists current drug alternatives available to practitioners. Practitioners can click on the medication shown and order it directly instead of having to back out of the original order.

Demonstrating the impact of drug shortages on pediatric hospitals

Vizient Drug Shortages and Labor Cost Survey

In March 2019, Vizient performed its first survey of GPO members regarding the impact of drug shortages. This survey was undertaken to investigate the effect of drug shortages on pediatric hospitals and other hospitals from labor, financial, operational and medication safety standpoints and to identify ways in which pediatric hospitals are uniquely and disproportionately impacted.

The survey consisted of 38 questions and was sent via email to 1,642 hospitals participating in the Vizient Pharmacy Program on March 6, 2019. The survey closed on April 4, 2019, with a total of 365 respondents; 330 of these respondents completed the survey in its entirety — 29 of which were pediatric hospitals.

For the purposes of the pediatric hospital sub- and comparator analyses, respondents were identified as hospitals participating in the Vizient Pharmacy Program that completed the survey. Other respondents were identified as Pharmacy Program participants that completed the survey and did not self-identify as being part of a system.

## Results of the comparator analysis

The following are the results of the comparator analysis of pediatric hospitals and other hospitals. All statistical analyses were performed using Microsoft Excel and Minitab 19. For additional survey findings, see Appendix B.

Thinking about July to December 2018, how many shortages of individual drugs (regardless of product presentation) did you have to manage based on the ASHP definition?* For example, if you experienced a shortage of furosemide 20 mg/2 mL, 40 mg/4 mL and 100 mg/10 mL at various times during this six-month period, this should be counted as a total of one shortage.

*ASHP defines a drug product shortage as a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent.

The number of shortages experienced by pediatric hospital and other hospital members was compared using the Mann-Whitney U test. No pediatric hospital respondent experienced less than 11 drug shortages in the specified time frame and there was a statistically significant difference in the number of shortages experienced by other hospitals overall compared to pediatric hospitals (P = .016) (Figure 2).

Figure 2. Number of shortages experienced by responding hospitals

- Pediatric hospitals
- Other hospitals
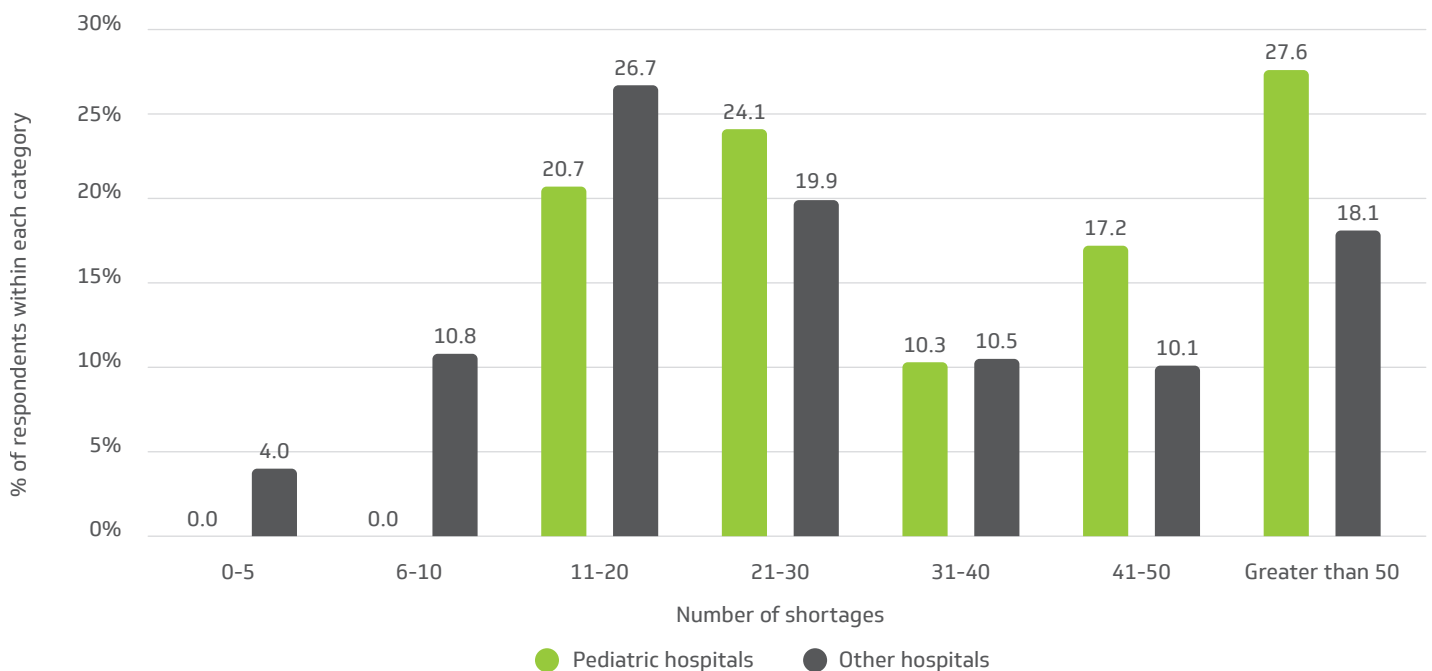
As a result of shortages, which of these drug categories have had the most impact on your facility both in terms of cost and reallocation of resources including informatics changes and labor during July to December 2018? Select all that apply.

Chi-square or Fisher's exact tests were used, as appropriate based on expected value, to compare response rates between pediatric hospitals and other hospital members for categories of shortages experienced; the alpha level was set at 0.05. As multiple tests were performed on data resulting from this question, the Benjamini-Hochberg procedure was applied in the statistical analysis.

Pediatric hospitals experienced a statistically significantly greater shortage impact in the drug categories of antineoplastics, antivirals, controlled substances for pain management, electrolytes, neuromuscular blockers, nonopioid analgesics and plasma products (Table 1).

If the Benjamini-Hochberg procedure is applied, only antineoplastics, neuromuscular blockers, nonopioid analgesics and plasma products have a statistically significantly higher impact.

Which of the following strategies have you used at your institution to mitigate the impact of drug shortages? Select all that apply.

If we look at the responses qualitatively, there is no difference in the top five strategies used by pediatric hospitals and other hospitals:

- Adjusted PAR levels
- Generated email communications to clinicians
- Increased stock of (anticipated) short meds
- Purchased alternative presentations
- Removed drugs from floor stock

Similar to question 2, Chi-square or Fisher's exact tests were used, as appropriate based on expected value, to compare response rates between pediatric hospitals and other hospital members for mitigation strategies used; the alpha level was set at 0.05. As multiple tests were performed on data resulting from this question, the Benjamini-Hochberg procedure was applied in the statistical analysis.

Table 1. Drug categories that had the greatest impact on responding hospitals

Drug category (examples)	Percentage of respondents reporting shortage		P value
	Pediatric hospitals (n = 29)	Other hospitals (n = 268)	
Controlled substances for pain management (buprenorphine, fentanyl, morphine)	93.1	76.9	**.043**
Antibiotics (ampicillin/sulbactam, cefazolin, vancomycin)	79.3	74.6	.580
Electrolytes (calcium chloride, potassium chloride, magnesium sulfate)	79.3	59.0	**.033**
Emergency syringes (epinephrine, atropine)	72.4	76.9	.592
Local anesthetics (bupivacaine, bupivacaine with epinephrine, lidocaine)	69.0	77.2	.319
Benzodiazepines (diazepam, lorazepam, midazolam)	62.1	48.5	.165
Fluids and diluents (normal saline, dextrose 5%, sterile water)	62.1	53.0	.351
Supportive care (diphenhydramine, metoclopramide, ondansetron)	62.1	50.7	.246
Plasma products (immune globulin, albumin)	58.6	26.5	**< .001[a]**
Antineoplastics (busulfan, doxorubicin)	51.7	10.8	**< .001[a]**
Cardiac (intravenous) (amiodarone, dopamine, norepinephrine, diltiazem)	51.7	53.0	.897
Antidotes (acetylcysteine, sodium polystyrene sulfonate, methylene blue)	44.8	37.3	.429
Neuromuscular blockers (rocuronium, vecuronium bromide)	44.8	17.2	**< .001[a]**
Nonopioid analgesics (ketorolac)	41.4	19.8	**.008[a]**
Ophthalmic products (antibiotic eye drops, lubricants, etc.)	41.4	36.6	.610
Endocrine (dexamethasone, levothyroxine)	27.6	29.5	.832
Antifungals (fluconazole)	24.1	19.4	.544
Sedatives (dexmedetomidine, etomidate)	24.1	15.3	.284
Diuretics (bumetanide)	20.7	18.3	.751
Anticoagulants (argatroban, enoxaparin, heparin)	17.2	16.4	1.00
Vaccines (recombinant zoster vaccines)	17.2	23.1	.471
Antivirals (cidofovir, valganciclovir)	13.8	3.4	**.028**
Psychiatric medications (antipsychotics, antidepressants)	3.4	10.8	.332
Other	0.0	1.9	1.00

[a] P value remains statistically significant when Benjamini-Hochberg procedure is applied.

Pediatric hospital members had a statistically significantly higher response rate for adjusting electrolyte replacement guidelines, adjusting PAR levels, implementing drug shortage task force(s) or committee(s), increasing "hang" time for continuous fluids, using the smallest appropriate volume IV product and using unit dosing to prevent waste (Table 2 and Figure 3).

Other hospital members had a statistically significant higher response rate for modifying or amending pharmacy and therapeutics policies and transitioning medications from intermittent or continuous infusion to IV push, where applicable. If the Benjamini-Hochberg procedure is applied, only these last two strategies have a statistically significantly higher use.

Table 2. Clinical strategies used to mitigate the impact of drug shortages

Strategy	Percentage of respondents using strategy		P value
	Pediatric hospitals (n = 29)	Other hospitals (n = 266)	
Adjusted electrolyte replacement guidelines	48.3	29.7	**.041**
Adjusted PAR levels	96.6	79.3	**.025**
Altered/loosened patient's own medication policy to compensate for shortage	20.7	12.4	.244
Compounded in-house	51.7	60.9	.338
Coordinated with other regional facilities (e.g., borrowing/lending)	44.8	49.2	.651
Extended beyond-use dating for products	44.8	42.9	.839
Generated email communications to clinicians	82.8	78.9	.630
Implemented a more aggressive IV-to-oral conversion	58.6	70.3	.196
Implemented drug shortage task force(s)/committee(s)	62.1	38.0	**.012**
Implemented process to expedite updating electronic resources (e.g., adding therapeutic alternatives)	44.8	53.0	.402
Implemented processes to restrict duration of therapy (e.g., for antibiotics)	48.3	39.5	.359
Implemented shortage management software external to EHR	0.0	1.5	1.00
Imported international product as approved by the FDA	41.4	39.5	.842
Increased "hang" time for continuous IV fluids	27.6	7.9	**.003[a]**
Increased stock of medications that were short or expected to become short	93.1	87.2	.551
Modified/amended P&T policies (e.g., added therapeutic interchanges)	34.5	62.8	**.003[a]**
Outsourced compounding to a 503B-compliant manufacturer	65.5	60.9	.628
Purchased alternative drug presentations	93.1	93.2	1.00
Removed drugs from floor stock	96.6	84.2	.095
Removed electrolyte/vitamin from TPN	58.6	39.8	.052
Restricted use of short drugs	69.0	69.9	.915
Switched from automatic to manual order verification for short drugs	20.7	22.2	.854
Transitioned medications from intermittent/continuous infusion to IV push, where applicable	10.3	54.5	**< .001[a]**
Used EHR to communicate drug shortage info	69.0	50.4	.057
Used smallest appropriate volume IV product	62.1	42.1	**.040**
Utilized unit dosing to prevent waste	72.4	46.6	**.008**

[a] P value remains statistically significant when Benjamini-Hochberg procedure is applied.
Abbreviations: EHR = electronic health record; FDA = Food and Drug Administration; IV = intravenous; P&T = pharmacy and therapeutics; TPN = total parenteral nutrition.

Figure 3. Strategies used more frequently by pediatric hospitals than other hospital members
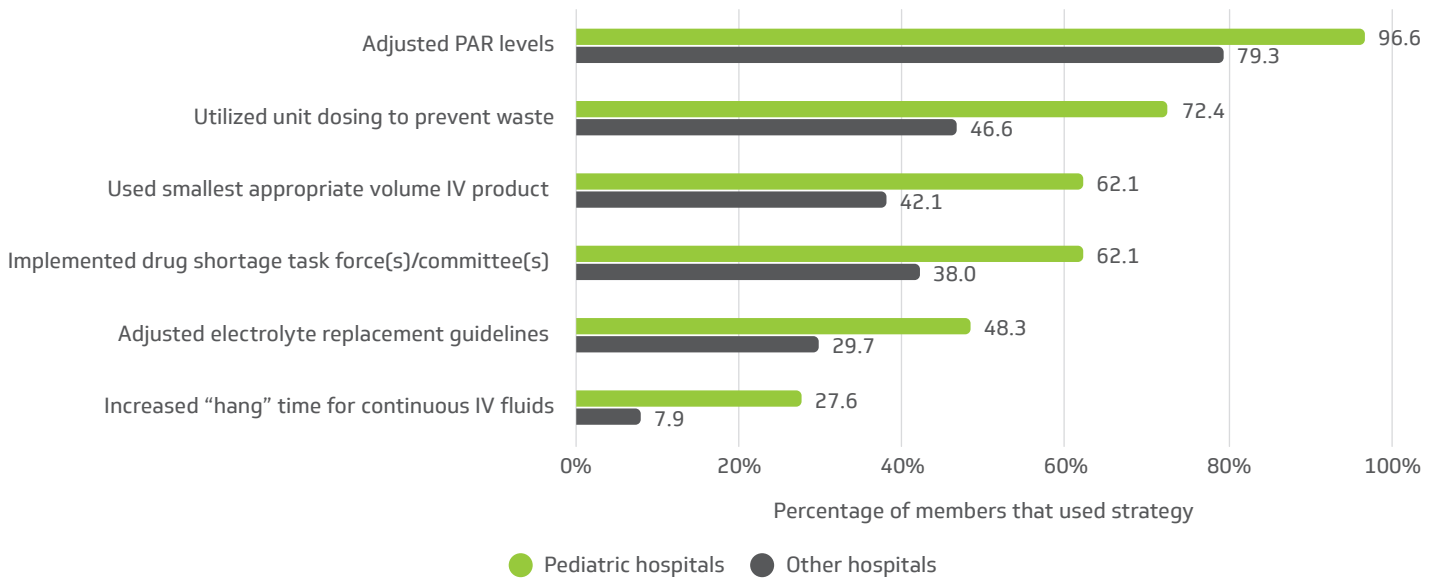

Abbreviations: IV = intravenous; PAR = periodic automatic replenishment.

Thinking about your most recent budgeting period, what percentage over budget was your facility as a result of drug shortages (from all causes)?

Using a Chi-square test, the percentages of members over budget were compared; although a higher percentage of pediatric hospital respondents were over budget compared to other hospital members (83% and 74%, respectively), the difference was not statistically significant (P = .309) (Figures 4 and 5).

To determine if there was a statistically significant difference in the specified percentages over budget between groups, a Mann-Whitney U test was performed. There was not a statistically significant difference between groups in this data subset (P = .163). However, this statistical analysis was performed on an incomplete data set, as one of the answer choices for this question was "we were over budget, but the percentage is unknown"; overall, 27% of pediatric hospital respondents and 36.8% of other hospital respondents selected this option.

Figure 4. Budget impact of drug shortages
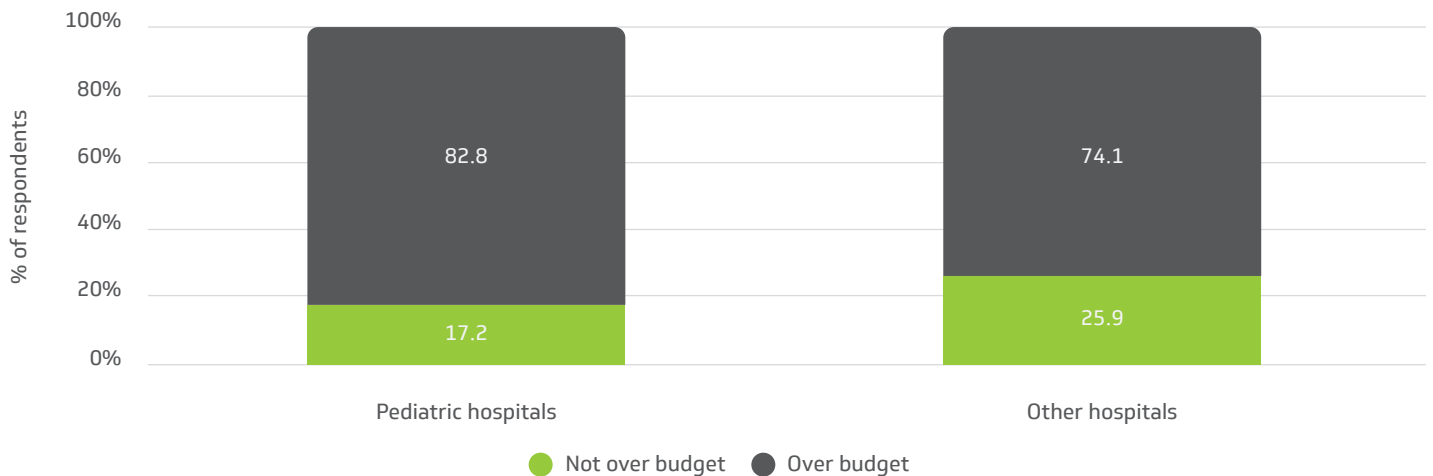
Figure 5. Budgetary impact of drug shortages where specific percentage over budget was known
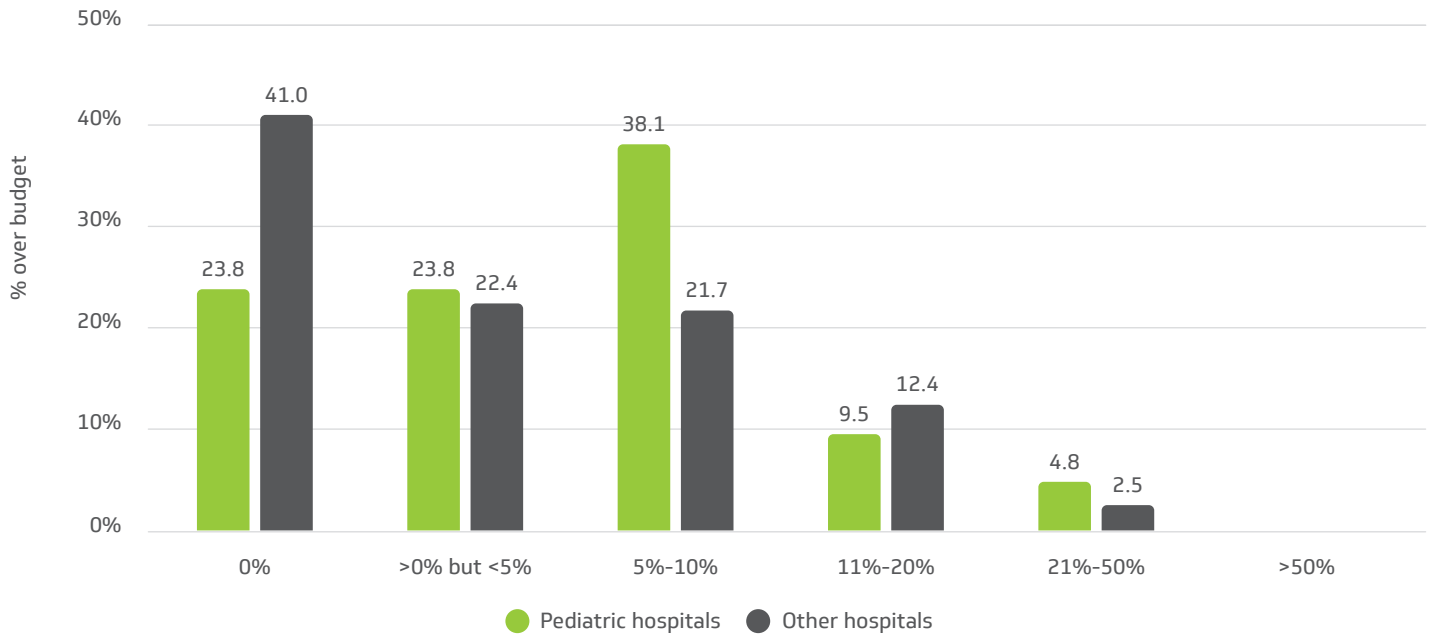
Please enter the cumulative number of hours that each hospital staff type spends on a weekly basis to manage drug shortages.

For example, if two pharmacists go to a drug shortage committee meeting that lasts for one hour, the cumulative amount of time spent is two hours. Time includes evaluating therapeutic substitutions, purchasing alternatives, redistributing stock, modifying electronic tools (e.g., EHR or IV pumps), participating in meetings, and discussing shortages with clinicians and staff.

The mean hours per week spent managing drug shortages were calculated for each profession for both pediatric hospitals and other hospital members and compared using a two-sample t-test. Although mean hours were greater for pediatric hospitals for each profession — and statistically significantly greater for buyers/purchasing agents and informatics pharmacists — once the Benjamini-Hochberg procedure is applied, there is no statistically significant difference between groups (Table 3).

Table 3. Time spent to manage shortages on a weekly basis, by profession

Profession	Total h/wk		Average h/wk per staff member		P value, difference in average h/wk (95% confidence interval)[a]
	Pediatric hospitals (n = 29)	Other hospitals (n = 252)	Pediatric hospitals (n = 29)	Other hospitals (n = 252)	
Buyer/purchasing agent	473	2,930	16.3	11.6	**.031** (0.460, 8.91)
Pharmacist	363	2,282	12.5	9.1	.124 (−1.00, 7.92)
Pharmacy technician	223	1,894	7.7	7.5	.922 (−3.42, 3.77)
Informatics pharmacist	197	882	6.8	3.5	**.033** (0.280, 6.30)
Financial/business office staff	97	288	3.3	1.1	.111 (−0.530, 4.94)
Nurse	61	423	2.1	1.7	.681 (−1.65, 2.50)
Physician	54	325	1.9	1.3	.486 (−1.08, 2.23)
Total hours	1,468	9,024	50.6	35.8	.074 (−1.55, 31.2)

[a] No P value remained statistically significant when Benjamini-Hochberg procedure was applied.

Which of the following statements applies to your institution or system as it pertains to drug shortage mitigation? Select all that apply.
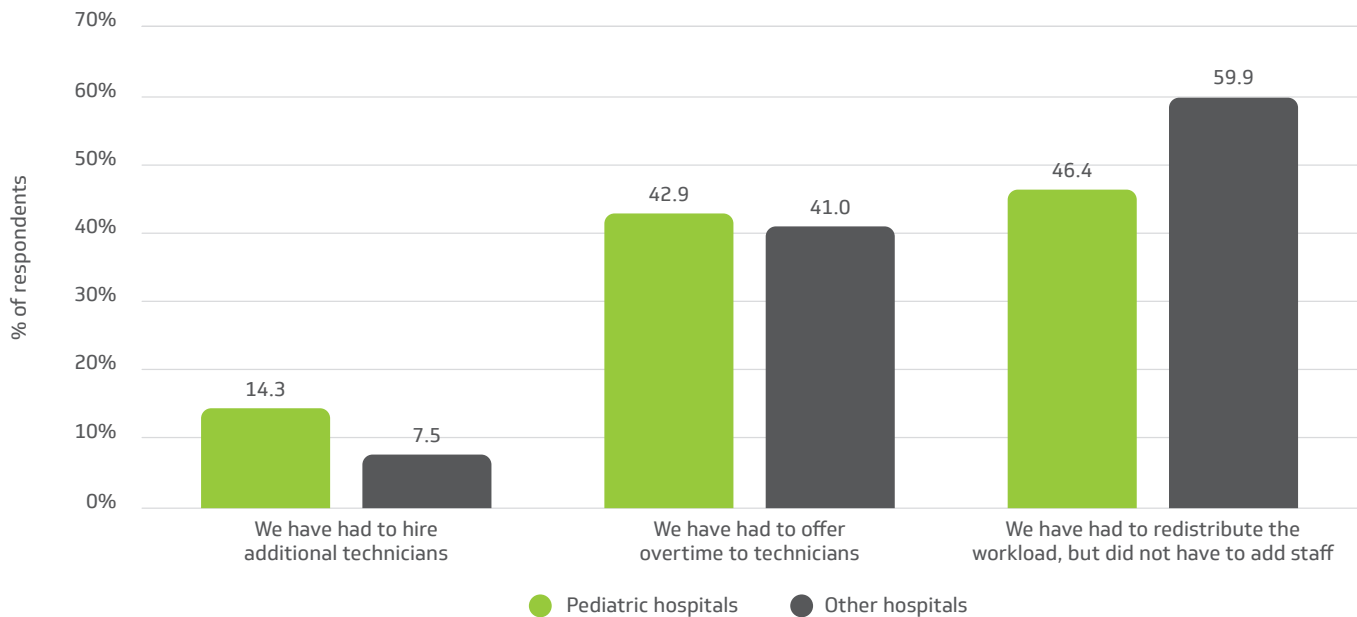
Chi-square or Fisher's exact tests were used, as appropriate based on expected value, to compare response rates between pediatric hospitals and other hospital members for strategies employed to mitigate the labor impact of drug shortages; the alpha level was set at 0.05.

Overall, pediatric hospital members had a higher response rate for hiring additional staff and offering overtime to additional staff to manage shortages, whereas other hospital members were more likely to redistribute the workload among existing staff. Specifically, there was a statistically significantly higher response rate for pediatric hospitals hiring additional pharmacists, compared to other hospital members (14.3% vs. 3.5%, P = .031) (Table 4 and Figures 6-8).

Table 4. Labor-related strategies used to manage drug shortages

Strategy	Percentage of respondents		
	Pediatric hospitals (n = 28)	Other hospitals (n = 227)	*P* value
Hire additional technicians	14.3	7.50	.264
Offer overtime to technicians	42.9	41.0	.848
Redistribute technician workload without adding staff	46.4	59.9	.172
Hire additional pharmacists	14.3	3.50	**.031**
Offer overtime to pharmacists	7.10	17.2	.273
Redistribute pharmacist workload without adding staff	32.1	36.6	.646
Hire additional buyers/purchasing agents	14.3	7.00	.215
Offer overtime to buyers/purchasing agents	50.0	36.6	.167

Figure 6. Labor-related strategies for managing drug shortages: pharmacy technicians

Figure 7. Labor-related strategies for managing drug shortages: pharmacists

Chart — % of respondents by strategy:

- We have had to hire additional pharmacists: Pediatric hospitals 14.3, Other hospitals 3.5
- We have had to offer overtime to pharmacists: Pediatric hospitals 7.1, Other hospitals 17.2
- We have had to redistribute the workload of pharmacists, but did not have to add staff: Pediatric hospitals 32.1, Other hospitals 36.6

Legend: ● Pediatric hospitals ● Other hospitals

Figure 8. Labor-related strategies for managing drug shortages: buyers/purchasing agents

Chart — % of respondents by strategy:

- We have had to hire additional buyers/purchasing agents: Pediatric hospitals 14.3, Other hospitals 7.0
- We have had to offer overtime to buyers/purchasing agents: Pediatric hospitals 50.0, Other hospitals 36.6

Legend: ● Pediatric hospitals ● Other hospitals
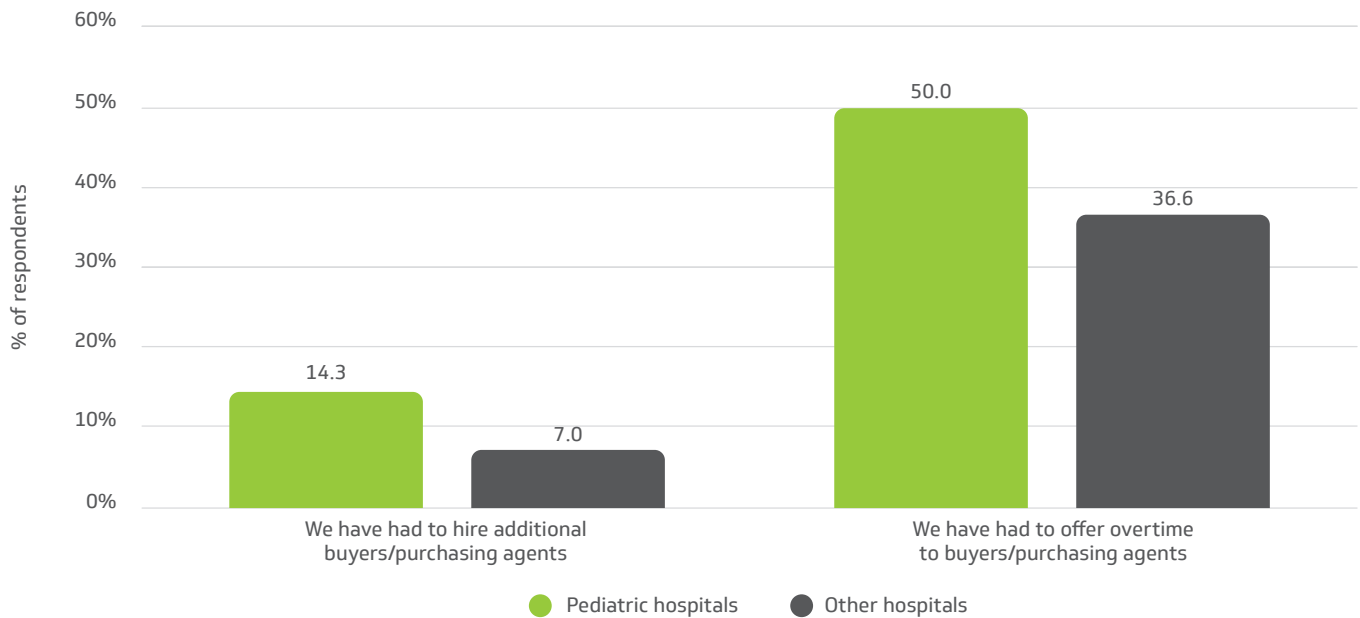
A member's perspective: the cost of one drug shortage

One of the largest, most established self-governed pediatric hospitals in the U.S. creates a drug shortage task list for each shortage that is reviewed and that requires action by its pharmacy team. The assessment/action plan for each shortage is broken down into discrete tasks (i.e., the task list); each task has an assigned employee and the time it takes to complete each task is documented.

Using the total hours by profession dedicated to managing a drug shortage along with employee wages, this hospital calculated the labor impact for one drug shortage — calcium gluconate. The labor associated with converting calcium gluconate to calcium chloride and then back to calcium gluconate resulted in nearly $50,000 in additional labor costs (Table 5).

This hospital has accounted for the impact to workflow outside of the time required to manage shortages from a managerial (administrative) perspective.

Table 5. The cost of one shortage: labor required for conversion from calcium gluconate to calcium chloride and back to calcium gluconate

Conversion step	Total hours	Hourly rate ($)	Labor cost ($)
Technician: conversion	164.0	31.50	5,166.00
Pharmacist: conversion	73.5	52.52	3,860.22
Administration: conversion	39.5	65.00	2,567.50
Administration: preparation and oversight	100.0	65.00	6,500.00
Technician: additional dose preparation	510.0	33.00	16,830.00
Pharmacist: additional dose verification	255.0	52.52	13,392.60
Pharmacist: dose reentry and reverification	10.0	52.52	525.20
Total	**1,152.0**	**--**	**48,841.52**

Source: Member-provided on-site materials.
[a] No *P* value remained statistically significant when Benjamini-Hochberg procedure was applied.

Drugs with a disproportionate impact on the pediatric population: sildenafil

Sildenafil

When investigating comparative drug spend for pediatric hospitals and other hospital members, one of the first drugs chosen for additional investigation was sildenafil. While sildenafil is often taken electively in the adult population, in the pediatric population it is used to prevent and treat pulmonary hypertension. The initial analysis for sildenafil revealed that pediatric hospital members had 11 times the spend of other hospital members, and over one-third of the market share on sildenafil 10-mg/mL oral suspension. Our pediatric hospital MAG confirmed that this is the preferred dosage form of this drug in the pediatric population, since many younger pediatric patients are unable to tolerate drugs in pill form.

As the sole supplier, Pfizer sets the price point for this drug in the market — one that is 400 times higher than that of an equivalent dose of the tablet formulation. Although the MAG revealed that the suspension is easy to compound from tablets in-house (and that this would indeed be preferred), members are unable to do so based on federal regulations that restrict the compounding of a commercially available product in the absence of a shortage.

In the case of a shortage, our members can compound the suspension in-house, at a much cheaper price point. However, published stability data currently only exist for the 2.5-mg/mL concentration. Thus, this is the concentration that is often compounded — at a fourfold difference from the commercially available product. This opens up patients to dosing errors, especially in the outpatient setting.

Summary

Through member feedback and the analyses performed for the PDSP, we have demonstrated that drug shortages appear to have a greater impact on self-governed pediatric hospitals. Overall, these types of hospitals experience a greater number of shortages, with related labor and budgetary impacts. Pediatric patients are a unique patient population, and the types of drug products that are available to them and that can be used are restricted. During shortages, we see a difference in terms of which shortage types have a higher impact. This becomes evident in safety considerations (particularly with compounding and administering dose-specific pediatric medications) and the labor and financial impact on these hospitals.

We compiled a list of 30 drug products; if a shortage occurs with any one of them, pediatric hospitals would be disproportionately impacted. We have developed a tool that enables on-demand monitoring of these drug products in the market and allows us to continually assess changes in demand and potential shortage risk. We have identified and begun implementing mitigation strategies to protect supply of these drugs — one of which is protection offered through the Novaplus Enhanced Supply Program.

In our assessment of member purchasing patterns, we determined that as members perceive a current or pending drug shortage, the quantity of drug ordered spikes — generally far beyond baseline values. This practice results in:

- Skewed communication of demand to manufacturers and distributors, which can impact stocking and allocation
- Some members receiving a disproportionately higher share of the drug in question, resulting in other hospitals being unable to obtain the drug and worsening perceptions about a shortage
- An apparently lower fill rate, which can also worsen perceptions of the shortage; however, in our investigation into the drugs of interest, we determined that the average quantity of drug supplied in times of a perceived shortage often remains steady and in some cases is even higher than that supplied prior to the perceived shortage, as manufacturers struggle to meet the new demand

Health care professionals need to be cognizant of the negative impacts of anticipatory purchasing and strive to improve in this area.

Lastly, through our on-site visits, we discovered many shared — and unique — strategies employed to manage and mitigate the impact of drug shortages. While hospitals must determine which strategies best suit them, here are some high-level recommendations:

- **Determine a way to more accurately keep track of drugs on hand.** Creating dedicated spaces for drugs, performing manual counts and having automated storage systems are all effective strategies. Even using a simple spreadsheet for drugs of importance that you can use to identify variances in supply can be helpful.

- **Standardize the evaluation of drug shortages.** Identifying the key parameters to be assessed for each drug in question and making sure these are addressed reduces the risk that something will be overlooked, or not anticipated or addressed.

- **Make sure you have a drug shortage task force or committee in place.** Having a task force or committee in place is recognized as a best practice by ASHP, and ideas on how to structure these committees are included in this paper. You can reduce the duration and frequency of meetings, limit the number of drugs you focus on and even communicate via email, if needed.

- **Be cognizant of sterility and stability and know how to compound in-house.** Knowing how to compound a product in-house before you outsource makes sense, since receiving a timely drug supply is never guaranteed. Remember that any change made to the base ingredients used in compounding can alter the stability (shelf life) of a drug. If you perform sterility and stability testing in-house, consider sharing the results with other pediatric hospitals.

- **Leverage your relationship with distribution representatives.** You have a choice when it comes to the distributor that you use and you should also have a dedicated representative assigned to your hospital. Inquire about perceived disruptions in the supply chain, possible causes, and product back order and availability timelines. Establish a means of communication that works best for you and determine what information and reports are available to you that you may not currently be receiving. Ensure that your demand is being accurately reflected in your ordering practices and that your allocation makes sense based on the size and demand of your hospital.

- **Take advantage, whenever possible, of the protections offered through Vizient contracts and Novaplus.** Vizient has the most leverage in resolving issues with the purchase of products when those products are on Vizient contract. We have quality and supply requirements with suppliers for any product that is on contract, and our distributors have mandatory stocking and fill rate requirements for contracted items.

- **Develop a policy for communicating drug shortage information.** Pediatric hospital members voiced a shared concern about alarming hospital staff in the event of a potential or known shortage. Establishing guidelines around the "who" (who needs to know), "when" (at what point) and "how" (best method of communication) to communicate with staff can go a long way toward managing fear and expectations.

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Appendices

Appendix A. Project overview

The PDSP was a yearlong project dedicated to studying the impact of drug shortages on pediatric hospitals. This project was deemed an "organic proposal," as it was determined that member data and feedback would provide insight into focal points and drive project deliverables and future actions. The PDSP used the following data sources, described in detail below:
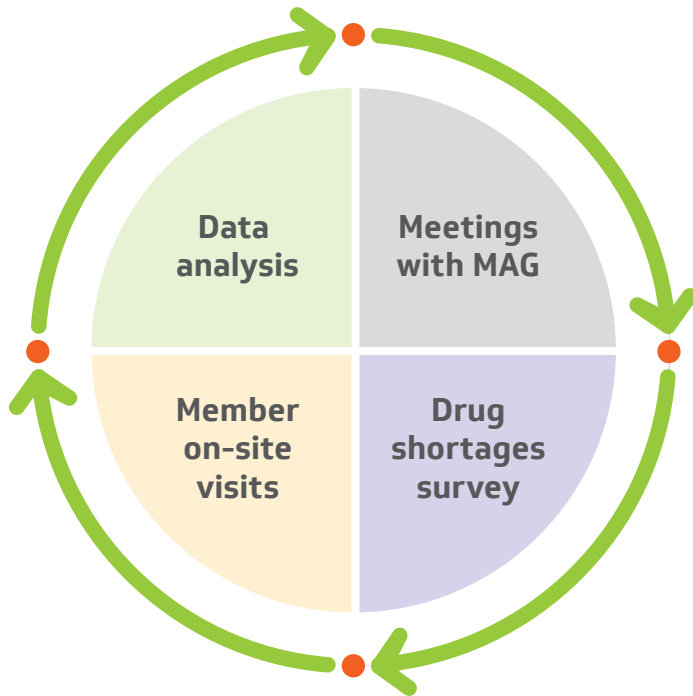
Data analysis

With access to member purchase data, Vizient has unique insights into supply and demand for drugs, key parameters such as drug prices, and supplier availability and reliability. Looking at trends in the data enabled the Vizient team to focus on "drugs of interest," which are of higher importance and pose a greater risk to our pediatric hospital members.

Meetings with the MAG

Monthly meetings were held with the MAG to review current findings and progress and to seek continual project guidance and approval. The Vizient team held additional ad hoc sessions with MAG members to gain insight into the potential impact of drug shortages and the mitigation strategies currently implemented at various institutions.

Drug shortages survey

To identify the impact of drug shortages on pediatric hospital members, Vizient conducted a drug shortages survey. This survey was distributed to all members of the Vizient Pharmacy Program, and enabled a comparator analysis to be performed between pediatric hospital and other hospital members to identify ways in which pediatric hospital members are uniquely and disproportionately impacted by drug shortages.

Member on-site visits

We performed on-site visits at four pediatric participating hospitals, deemed to be leaders within the pediatric space. The purpose of these on-site visits was to gain further understanding into the impact of drug shortages from labor, financial and safety standpoints, as well as to learn about the unique strategies that each hospital is employing to mitigate the impact of drug shortages. In an effort to drive thoughtful discussion around these parameters, proposed topics of discussion were sent to participating hospitals ahead of our on-site visits.

Project deliverables

It was decided at the onset of this project that many deliverables would be guided by data analysis and member input and would be elucidated throughout the course of this project. However, several prespecified deliverables were detailed in the Statement of Work, including:

- Investigating the impact of drug shortages on the pediatric population (including a member survey)
- Creating and maintaining a list of the top 20 to 30 critical pediatric products that, if a shortage occurred, would create significant disruption in pediatric patient care
- Providing insights and potential solutions intended to mitigate the drug shortage impact among the pediatric population
- Presenting project findings at CHA forum meetings and at other venues, as needed and agreed upon
- Providing a white paper describing results of this project

Appendix B. Additional survey findings

Based on your answers about strategies used to mitigate the impact of drug shortages, please rank the top three most helpful strategies, where 1 = most helpful, 2 = second most helpful and 3 = third most helpful.

Mean rankings were calculated for each strategy, for both pediatric hospital and other hospital members. These mean rankings were then compared, using a two-sample t-test with the alpha level set at 0.05 (Table 1 and Figure 1).

Pediatric hospital members ranked adjusting PAR levels statistically significantly more helpful than other hospital members, who ranked using the EHR to communicate information regarding drug shortages statistically significantly more helpful.

It is interesting to note that these mean rankings of helpfulness do not necessarily correlate with the usage of these strategies, as demonstrated above in Question 3. For example, pediatric hospitals actually had a higher usage — trending towards statistical significance — of using the EHR to communicate information regarding drug shortages compared to other hospitals. However, pediatric hospital members had a higher mean ranking for this strategy.

Table 1. Strategies members found most helpful in mitigating the impact of drug shortages

| Most helpful strategies	Mean rank by pediatric hospital members (n = 28)	Mean rank by other hospital members (n = 246-250)[a]	*P* value (95% confidence interval)
Implemented processes to restrict duration of therapy	1.00 (1)	1.50 (4)	N/A
Adjusted par levels[b]	1.43 (7)	2.07 (46)	.022 (–1.16 , -0.115)
Removed electrolyte/vitamin from TPN	1.50 (2)	3.00 (3)	N/A
Increased stock of (anticipated) short medications	1.50 (8)	1.60 (126)	.720 (-0.756 , 0.549)
Implemented drug shortage task force(s)/committee(s)	1.83 (6)	1.47 (17)	.430 (-0.687 , 1.41)
Removed drugs from floor/returned to central storage	1.93 (15)	2.01 (84)	.752 (-0.593 , -0.436)
Extended beyond-use dating for products	2.00 (1)	2.43 (14)	N/A
Used unit dosing to prevent waste	2.00 (1)	2.00 (6)	N/A
Compounded in-house	2.00 (1)	2.25 (32)	N/A
Implemented process to expedite updating electronic resources	2.00 (1)	2.60 (15)	N/A
Restricted use of short drugs to approved indications and populations deemed most in need	2.00 (9)	1.87 (61)	.680 (-0.556 , 0.818)
Purchased alternative presentations	2.10 (10)	1.86 (116)	.351 (-0.304 , 0.779)
Generated email communications to pharmacy department/ providers	2.25 (4)	2.53 (30)	.604 (-1.84 , 1.28)
Used EHR to communicate information regarding drug shortages to providers at time of order entry[b]	2.56 (9)	1.94 (35)	.046 (0.013 , 1.21)
Implemented a more aggressive IV to oral conversion	2.67 (3)	2.63 (24)	.918 (-1.50 , -1.58)
Outsourced compounding to a 503B-compliant manufacturer	2.67 (3)	2.34 (35)	.456 (-1.19 , 1.84)
Elected to use smallest appropriate volume IV product to prevent waste	3.00 (1)	2.00 (3)	N/A
Modified/amended P&T policies	3.00 (1)	2.15 (26)	N/A
Coordinated with other regional facilities (e.g., borrow/lend)	-- (0)	2.18 (28)	N/A

Most helpful strategies	Mean rank by pediatric hospital members (n = 28)	Mean rank by other hospital members (n = 246-250)[a]	P value (95% confidence interval)
Imported international product as approved by the FDA	-- (0)	2.00 (4)	N/A
Switched from automatic to manual order verification for drugs that are short	-- (0)	2.33 (3)	N/A
Increased "hang" time for continuous IV fluids	-- (0)	-- (0)	N/A
Transitioned meds from intermittent/continuous infusion to IV push, where applicable	-- (0)	1.86 (22)	N/A
Adjusted electrolyte replacement (e.g., raised threshold for ordering)	-- (0)	1.00 (1)	N/A
Altered/loosened patient's own medication policy	-- (0)	2.67 (3)	N/A

[a] Providing ranking was optional and n varied between rankings; n for "1" = 250, n for "2" = 248 and n for "3" = 246.
[b] P value less than 0.05.
Abbreviations: FDA = U.S. Food & Drug Administration; IV = intravenous; N/A = unable to perform t-test to assess for statistical significance (no response, n = 1, identical values, etc.); P&T = pharmacy and therapeutics committee; TPN = total parenteral nutrition.

Figure 1. Top-ranked drug shortage mitigation strategies among members
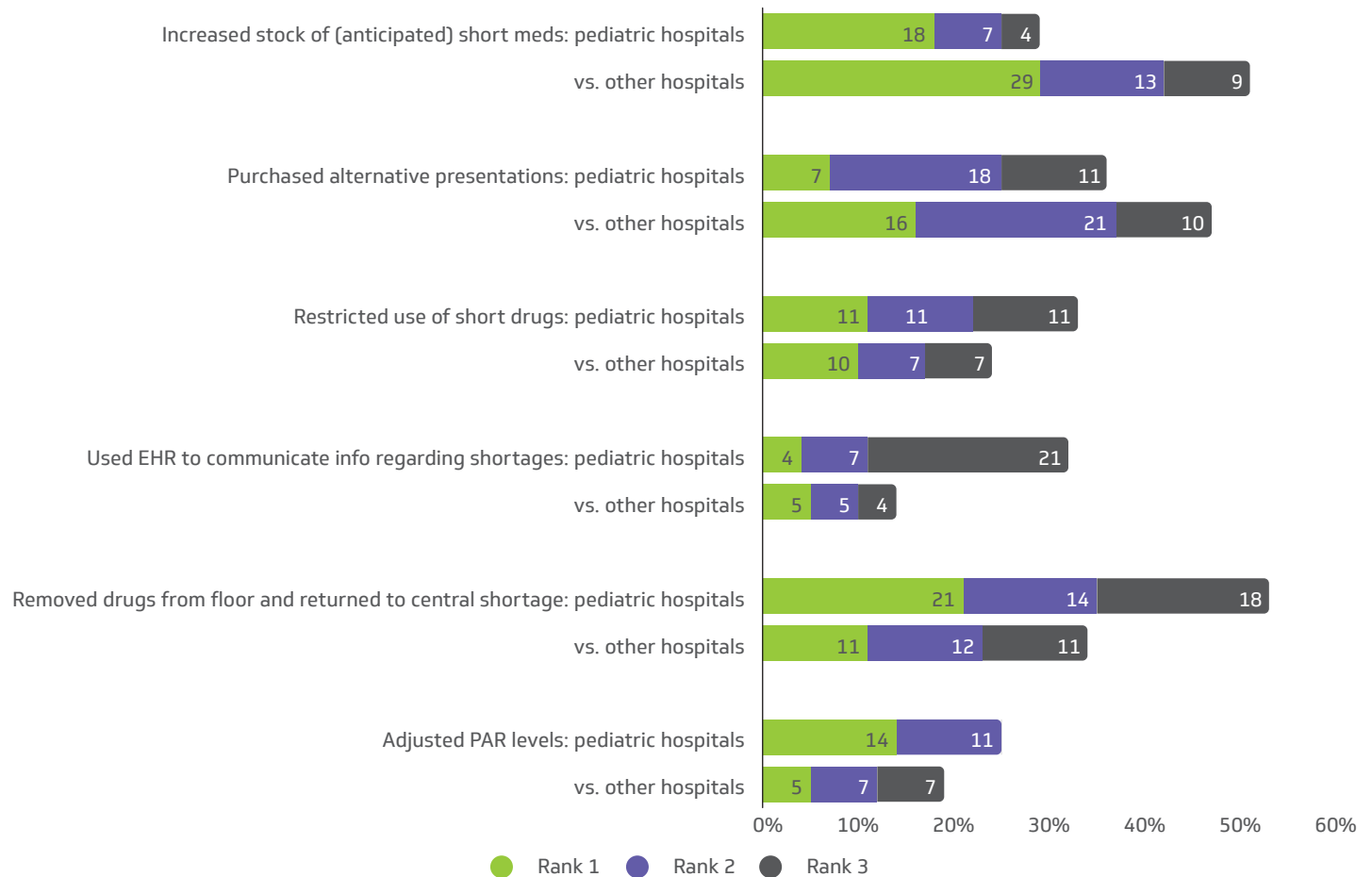
Abbreviations: EHR = electronic health record; PAR = periodic automatic replenishment.

Do you have a critical drug list?

By definition, a critical drug list is considered a listing of the top 10 to 20 most commonly used, life-sustaining therapies, deemed most critical to patient care.[1]

Pediatric hospital members were statistically significantly more likely to have a critical drug list, with 52% responding that they have a critical drug list, compared to only 33% of other hospitals (p = .043).

What were the primary reasons your facility was over budget? Select all that apply.

Chi-square or Fisher's exact tests were used, as appropriate based on expected value, to compare response rates between pediatric hospital and other hospital members for mitigation strategies used; the alpha level was set at 0.05.

Overall, pediatric hospitals had a higher rate for citing off-contract purchases as the reason for being over budget, with the response rate for off-contract purchases from a secondary distributor nearly double for pediatric hospitals compared to other hospital members (50% vs. 27.3%; p = .022) (Table 2).

Table 2. Primary reasons for members being over budget

Primary reasons for being over budget	Pediatric hospitals (n = 24) (%)	Other hospitals (n = 187) (%)	P value
Off-contract purchases from primary distributor	75.0	68.4	.513
Off-contract purchases from secondary distributor	50.0	27.3	.022
Off-contract purchases from 503B manufacturer	41.7	35.3	.540
More expensive alternative agents	91.7	86.1	.748
Increased labor needed to manage drug shortages	45.8	50.8	.647
Increased technology/ equipment needed to manage drug shortages	4.2	11.8	.484

What percentage of medication errors recorded during July through December 2018 were related to a drug shortage?

The ASHP defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer."

The percentage of medication errors related to a shortage was calculated for respondents in each category between pediatric hospital and other hospital members (Table 3).

Table 3. Percentage of medication errors related to a drug shortage

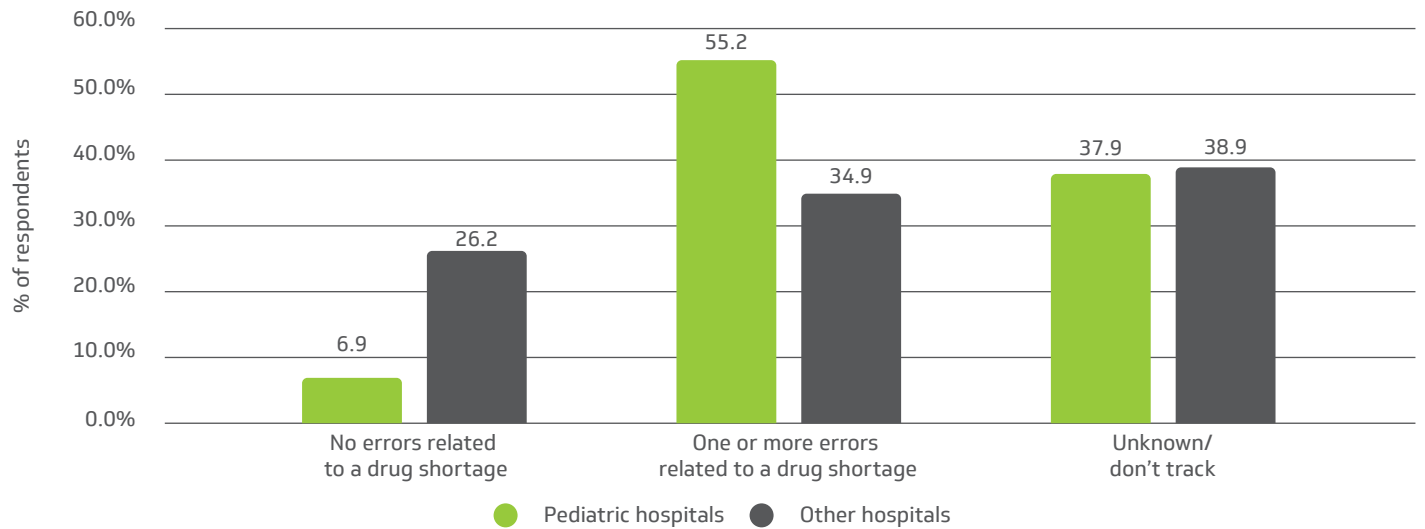| Percentage of medication errors related to a shortage	Pediatric hospitals (n = 29) (%)	Other hospitals (n = 252) (%)
None	6.90	26.2
1%-5%	51.7	30.2
6%-10%	3.40	3.20
11%-15%	0.00	0.40
Greater than 15%	0.00	1.20
Unknown	37.9	33.7
Do not track	0.00	5.20

Responses were then grouped into the categories of "no," "yes" or "unknown/don't track" regarding whether or not one or more medication errors were experienced related to a drug shortage. A chi-square test was then used to compare these categories, with the alpha level set at 0.05. With the caveat that just over one-third of both pediatric hospital and other hospital members (well matched between groups) answered "unknown/don't track," based on known errors, pediatric hospital members experienced a statistically significantly higher rate of medication errors compared to other hospital members (Table 4 and Figure 2).

Table 4. Medication errors related to a drug shortage

Was a medication error experienced that was related to a drug shortage?	Pediatric hospitals (n = 29) (%)	Other hospitals (n = 252) (%)	P value
No	6.9	26.2	.022
Yes	55.2	34.9	.032
Unknown/don't track	37.9	38.9	.920

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[1] Drug shortages roundtable: Minimizing the impact on patient care. *Am J Health Syst Pharm*. 2018;75(11):816-820. doi: 10.2146/ajhp180048.

Figure 2. Medication errors tied to a drug shortage

Figure 2. Medication errors tied to a drug shortage

Bar chart showing % of respondents. Pediatric hospitals (green) and Other hospitals (dark gray):
- No errors related to a drug shortage: Pediatric 6.9, Other 26.2
- One or more errors related to a drug shortage: Pediatric 55.2, Other 34.9
- Unknown/don't track: Pediatric 37.9, Other 38.9

Legend: ● Pediatric hospitals ● Other hospitals

Did any of these medication errors result in known harm to a patient (regardless of severity)? Optional.

Errors resulting in known harm to a patient appeared to be well-balanced between answer choices for pediatric hospital and other hospital members. Thus, statistical analysis was not performed for this question (Table 5).

Table 5. Medication errors resulting in known patient harm

Occurrence of medication error resulting in known harm	Pediatric hospitals (n = 26) (%)	Other hospitals (n = 182) (%)
Yes	3.80	3.80
No	30.8	33.5
Unknown	57.7	55.5
Prefer not to disclose	7.70	7.10

Which of the following have you experienced during July through December 2018 as a result of drug shortages? Select all that apply.

Chi-square or Fisher's exact tests were used, as appropriate based on expected value, to compare response rates between pediatric hospital and other hospital members for the impact of drug shortages presenting as delays, cancellations and/or disruption to care; the alpha level was set at 0.05 (Table 6).

Pediatric hospitals had a higher response rate for delaying and/or cancelling procedures or outpatient infusions, while other hospital members had a higher response rate for delays to immunization administration.

While two answer choices —"we have had to cancel one or more medical procedures (e.g., surgeries)" and "we have had to delay an immunization administration" — trended toward statistical significance, none met the criteria.

Table 6. Impact of drug shortages on patient care

Impact on patient care	Pediatric hospitals (n = 29) (%)	Other hospitals (n = 251) (%)	P value
We have had to delay one or more medical procedures (e.g., surgeries)	41.4	28.3	.144
We have had to cancel one or more medical procedures (e.g., surgeries)[a]	24.1	10.8	.064
We have had to delay an outpatient infusion	41.4	38.2	.743
We have had to cancel an outpatient infusion	27.6	15.9	.122
We have had to delay an immunization administration[a]	6.9	21.5	.062
It has disrupted our medication reconciliation program	3.4	9.2	.487
It has resulted in delays of medications in the inpatient setting	65.5	67.3	.487
It has resulted in a deferred or delayed admission	13.8	10.0	.519
None of the above	17.2	19.1	.806

[a] These categories trended toward statistical significance.

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