

# A better future for pediatric care: How the Children's Hospital Coalition is addressing critical medicine shortages

Over the course of the previous year, pediatric essential medicines necessary to sustain life and conquer disease have reached critical shortage levels - an issue that health care professionals have faced for decades now exposed by the COVID-19 pandemic. The effects of medicine shortages have led to disproportionate workloads and costs in order to mitigate these issues and have put some patients at risk of receiving alternatives that are not the first treatment choice. Safety is a real concern since many medicines are not available in concentrations and package sizes appropriate for children. Hospitals are also grappling with shortages of supplies like sterile bags, vials, needles, and syringes. To address this crisis, children's hospitals are turning to collaboration and innovative partnerships.

## The impact of pediatric medicine shortages is felt at all levels of organizations

Pediatric essential medicines are particularly prone to supply issues. "There are not as many options for medications for pediatric patients, when it comes to a medication being short, there may be literature or options for adults that are simply not there in pediatrics" said Jared Cash, PharmD, Pharmacy Director for Intermountain Primary Children's Hospital in Salt Lake City.

Raj Mudahar, PharmD, Pharmacy Director at the Children's Hospital of Orange County (CHOC) in Orange, California, agreed. "The impactful products on the pediatric side are the ones that have been around for a long time. Most manufacturers probably are not making much money from them, but they are critical to our patient population."

Pharmacy teams in children's hospitals are on the front lines of the medicine shortage problem. One of the biggest challenges is identifying alternative products that clinicians can use as substitutes.

"We have a discussion every week about what is on the current drug shortage list," Dr. Mudahar said. "We develop a contingency plan internally and have it approved by front-line providers. Before implementing the plan, we must educate the team on the plan and implement IT changes that may be needed. When the drug shortage is resolved, the plan must be reversed."

In addition to the safety concerns associated with substitute medication, pharmacy teams are faced with added operational burdens that can lead to employee dissatisfaction and potential burnout. As Dr. Mudahar explained, "In any given week, I can spend up to 15 hours managing the numerous downstream facets of shortages." From a strategic perspective, hospital teams may lose sight of bigger-picture goals because they are constantly reacting to new shortages.

Medicine shortages also translate into increased costs for children's hospitals. There are costs associated with pharmacy overtime, additional staffing, wasted drug products, and higher-priced vendors. CHOC recently transitioned to an outsourcing facility for parenteral nutrition because it could not access critical electrolytes. This was a higher-cost alternative for the institution.



## **Collaboration is one of the best ways to address medicine shortages**

There are multiple levels where medicine shortage mitigation measures can be implemented. Within children's hospitals, teams are engaged in discussions to understand medicine usage patterns and alternative products. Wholesalers and manufacturers are launching initiatives like reserve programs. To date, no mitigation strategies have been deployed at the federal or national level.

To solve the problem of pediatric medicine shortages, stakeholders at all levels must collaborate as a unified ecosystem. "The worst thing we could do is to not cooperate with one another," Dr. Mudahar said.

Phlow, an essential medicines solutions company, has partnered with the Children's Hospital Coalition to take on the medicine shortage crisis. "Our founding mission is to solve for shortages at children's hospitals," said Dan Hackman, the Chief Business Officer at Phlow.

## **The Children's Hospital Coalition is rebuilding markets and getting medicines into clinicians' hands**

The Children's Hospital Coalition aims to ensure a reliable and affordable supply of high-quality essential medicines to help prevent pediatric medicine shortages. One of the ways they are addressing pediatric medicine shortages is by collaborating with member hospitals to identify and prioritize the most needed essential medicines, including sterile injectable medicines and potentially medications used to treat pediatric cancers and rare diseases. Member hospitals come together to ensure that the right products are prioritized, practice is standardized to an appropriate degree, volume is aggregated, and products are developed and distributed at a cost-competitive, sustainable level.



Over the last couple of years, the Coalition has focused its attention on quickly solving for medicine shortages. As a first step, the organization's members identified the top 25 medications in short supply that patients were in most critical need of. "[This] was done through a variety of MAC [Maximum Allowable Cost] mechanisms in which we factored in what our past histories of shortages have been, which ones have been more frequent or more severe, impacting more patients than others, [and] which ones are unique to the therapeutic side," said Dr. Cash, "the Children's Hospital Coalition members weigh in on different ranking factors and came up with the top 25 list."

Phlow is also working on the longer-term goal of developing novel pediatric essential medicines (NPEMs). These products are designed specifically for pediatric patients, so clinicians do not have to manipulate adult dosage forms and concentrations. "If you're not in pediatrics," Dr. Cash added, "you don't recognize that pediatric care-givers have to manipulate much more product than in the adult setting in order to get a pediatric patient an appropriate product. My last calculation compared to one of our sister adult hospitals is that pediatrics had four to five times as much manipulation." NPEMs are one of the aspects unique to Phlow and the Children's Hospital Coalition.

Phlow's role in the Children's Hospital Coalition has been as a founder, strategic pace-setter, convener, and facilitator. "We continue to believe that this needs to be a hospital-driven initiative, but Phlow brings business strategy, innovative ideas and significant development and manufacturing assets and capabilities to the table," Mr. Hackman said. "One of the unique aspects of the Coalition is that a manufacturer like Phlow is involved. That has given Coalition members a lot of optimism that we can significantly impact the shortages issues." The Children's Hospital Coalition aspires to continue to solve for pediatric medicine shortages and invest in the long-term goal of novel pediatric essential medicines.

## More work is needed to ensure future availability of pediatric medicines

While the Children's Hospital Coalition is making good progress in the battle against pediatric medicine shortages, continued vigilance and ongoing hard work are essential.

"A collaborative effort focused on long-term solutions is really important," Dr. Mudahar said. "We might be fixing the problem in the short term, but the future scares me. What will things look like one, five, or ten years out?"

Ongoing work must continue in four areas: awareness, collaboration and volume aggregation, data and analytics, and policy solutions. FDA priority and market exclusivity legislation for US-based pediatric essential medicines, similar to the Orphan Drug Act, are both areas that the industry needs to focus on.

"We need to think and act boldly when it comes to solving once and for all pediatric medicine shortages because this is a crisis that we can no longer tolerate," Mr. Hackman said. "We must innovate new solutions and no longer accept the status quo."

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