ADDRESSING PEDIATRIC DRUG and **SUPPLY SHORTAGES**

Children's hospitals depend on a reliable and safe drug and supply chain to provide life-saving treatments to their pediatric patients. We support efforts to strengthen and stabilize the nation's supply chain to forestall shortages and ensure that our nation's most vulnerable patients have access to safe and effective health care. We ask federal policymakers to place a strong emphasis on research, development, procurement strategy and guidance that can ensure timely access to sufficient pediatric-appropriate equipment, medications, and supplies.

In the face of both long-term and shorter-term shortages, the Children's Hospital Association (CHA) collaborates with suppliers, industry associations and government agencies to mitigate the impacts of drug and supply shortages on our patients and to ensure that all available supply is shared, as appropriate, with children's hospitals. At the same time, the nation's children's hospitals are working to identify and leverage data that can help them reduce supply spend, advance supply chain efficiencies, improve organizational effectiveness, and strengthen educational opportunities for clinical staff so pediatric caregivers have high-quality products, services, and analytics.

Unique Implications for Children's Health

A drug or supply shortage is particularly challenging in pediatric health care as drugs and supplies intended for children are unique. There are fewer manufacturers of pediatric supplies which means it is easier to disrupt the supply chain. A recent report1 finds that more than half of pediatric drugs had only one to two manufacturers currently supplying the dosage form most used by pediatric hospitals. Of the essential medication manufacturers utilized by children's hospitals, only 15% of them are pediatric-only suppliers.

- Pediatric care requires specialized medications, therapeutics, and equipment. For example, many pediatric drugs come in specific formulations that support safer dosing, and with practical methods for appropriate delivery for growing children, such as altered concentrations or formats (e.g., oral liquids, etc.). These pediatric products are not used as frequently as "adult-sized products," leading manufacturers to place less of a priority on them for supply chain planning. As a result, pediatric products are often the first affected by shortages.
- When drugs or supplies are in or nearing a shortage, important patient procedures may be delayed or even canceled. Sometimes the location of care must abruptly change—care intended to be provided in a community setting close to a child's home may have to be moved to a setting further away, requiring parents to take off work and children to miss school.
- Shortages can also impact care protocols when drugs or supplies must be changed to alternatives, or worse yet, delayed or canceled all together. An appropriate substitute specifically geared for pediatric patients might not be as readily available as an adult product. Drug and supply shortages can lead to adverse clinical outcomes for pediatric patients, such as increased rates of drug errors and possible disease relapse, with potentially detrimental impacts on their long-term health and well-being.

Impact on Children's Care

Children's hospitals have long faced shortages of critical drugs and supplies that child patients rely on for treatment and recovery.

¹ 2020 Pediatric Drug Shortage Trends and Best Practices for Mitigation Strategies Report https://www.childrenshospitals.org/drugshortagesreport



SUPPLY SHORTAGES

Supply shortages also uniquely, and more profoundly, affect children's health care compared with adult care facilities:

- Children's hospitals experience shortages of pediatric supplies earlier than adult hospitals because manufacturers and
 distributors consider pediatric utilization to be less profitable. Products dedicated to a small, specific patient population do
 not provide the same return on investment as adult products, leading manufacturers to place less of a priority on those
 products in supply chain planning.
- Shortages are more likely to impact pediatric essential supplies, including infant feeding, dialysis kits, pediatric-sized syringes, TPN compounding supplies and small volume solutions.
- Children's hospitals supply chain teams spend considerable resources on supply shortages, often devoting substantial time to locating multiple substitute products that are safe, effective and reliable for pediatrics.

DRUG SHORTAGES

A recent analysis finds children's hospitals are disproportionately impacted by drug shortages, compared to non-pediatric hospitals.² Children's hospitals spend more hours managing shortages than non-children's hospitals—51 hours compared to 36 hours per drug shortage. This additional time is often dedicated to compounding replacement products into safe pediatric dosage forms and as a result, they are more than twice as likely to hire additional staff. Children's hospitals report that, on average, the cost to manage one drug shortage from onset to correction is approximately \$50,000, in addition to the actual cost of the drug itself.

Ongoing shortages affect the following pediatric essential drugs:

- Lifesaving electrolytes, including calcium chloride, magnesium, potassium, sodium, and certain acids, which are
 essential for maintaining the health of nerves and muscles, including those in the brain, heart, lungs, and other vital
 organs.
- Total Parenteral Nutrition (TPN), a method of feeding that bypasses the gastrointestinal tract when someone can't or shouldn't receive feedings or fluids by mouth.
- Antineoplastics and plasma products used to treat critical conditions such as sepsis, cancer, and immune deficiencies.

Policies to Address Drug and Supply Shortages

CHA and our children's hospitals advocate for solutions to prevent and mitigate pediatric drug and supply chain shortages:

- Ensure manufacturer and distributor transparency throughout the supply chain, including the location of
 production, as well as an immediate and clear timeline on product availability. The absence of this timely
 information hinders proactive steps that providers can take to prevent and mitigate shortages—especially
 during natural disasters and other emergencies.
- Adjust the FDA drug shortages list to provide a timely and accurate accounting of pediatric populations and pediatric drug formulations, including the potential for regional shortages.
- Reduce the risk of pediatric drug and supply shortages by encouraging "readiness to supply," or proactive shortage mitigation plans and/or competition in production of pediatric products that are often solesourced or under-resourced.
- Strengthen funding support for research and development on pediatric drugs, supplies procurement, and strategy.

² 2020 Pediatric Drug Shortage Trends and Best Practices for Mitigation Strategies Report https://www.childrenshospitals.org/drugshortagesreport



Contact Us: Elizabeth Brown | elizabeth.brown@childrenshospitals.org Natalie Torentinos | natalie.torentinos@childrenshospitals.org