



APHON Position Paper on Drug Shortages

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The Association of Pediatric Hematology/Oncology Nurses affirms that all children have a right to the highest standard of physical and mental health and the right to treatment that maximizes their survival and well-being.

Shortages of essential drugs compromise the health and well-being of all children, especially those diagnosed with cancer and blood disorders, who are among the most vulnerable members of society and require added protection.

Background

Since 2001, the number of drug shortages in the United States has risen. The American Society of Health-System Pharmacists (2019) has reported between 174 and 320 active drug shortages each quarter since 2014.

The causes of drug shortages are multifactorial and include limited availability of raw materials; quality problems in manufacturing that create production delays; a limited number of manufacturing companies; and manufacturers' business decisions, restricted distribution methods, and inventory practices. The U.S. Food and Drug Administration (2019) reports that economic forces are the root cause of drug shortages in the United States.

Impact

In pediatric oncology, drug shortages have a particularly serious impact. Childhood cancer treatment relies on the use of sterile injectable generic agents, which make up the majority of scarce medications and which manufacturers have limited economic incentives to produce. Furthermore, no adequate substitutes or alternative drugs are available to treat these pediatric patients during a shortage. In 2019, a critical shortage of the drug vincristine was felt throughout the childhood cancer population because of its widespread use in the treatment of many different types of childhood cancer. In the case of acute lymphoblastic leukemia, the most common childhood cancer accounting for nearly one-quarter of all children with cancer, a shortage of a critically important drug like vincristine means that the current 90% 5-year event-free survival rate for 3,000 U.S. children affected each year may be compromised.

Beyond their immediate effect on clinical care, drug shortages may negatively affect enrollment in clinical trials and the results, because the drugs that are scarcest are those that serve as the backbone in childhood cancer clinical trials. These clinical trials are vital and have led to a dramatic improvement in childhood cancer survival over the past 5 decades.

Positions and Recommendations

The Association of Pediatric Hematology/Oncology Nurses supports the following efforts:

- promoting awareness of drug shortages through reliable information sharing
- advocating for strategies that minimize the impact of drug shortages on the quality of care
- cooperating and collaborating with health-care institutions, consortiums, professional organizations, policy makers, and stakeholders in prioritizing the prevention and management of drug shortages
- advocating for federal, local, and institutional policy changes that address drug shortages and reduce their frequency and impact on patients and families
- developing institutional policies that
 - describe the institution's approach to the management of drug shortages
 - include ethical principles of decision making on drug allocation
 - ensure explicit and transparent communication with patients and families about drug shortages



- using evidence-based strategies to minimize the impact of drug shortages by maximizing efficiency and eliminating waste through interventions such as
 - grouping patients receiving the same therapy into cohorts to share vials during drug preparation
 - reducing advance preparation of drugs that may lead to waste
 - using safe dose-rounding practices to eliminate waste
 - evaluating drugs' expiration times and shelf life to extend the period of safe drug use
- developing institutional interdisciplinary drug allocation committees that
 - include physicians, pharmacists, nurses, social workers, members of institutional ethics committees, and patient representatives
 - apply ethical decision-making principles
 - explore reasonable therapeutic drug alternatives
 - make prioritization decisions that are applied equitably to patients affected by drug shortages
 - provide an appeal process for patients and families who have been affected by drug allocation decisions
- showing respect for patients and caregivers by informing them about drug shortages and the process by which allocation decisions are made.

The Association of Pediatric Hematology/Oncology Nurses does not support

- unethical practices (such as drug hoarding or discrimination based on patients' age, developmental level, ability to pay, race, ethnicity, disability, or immigration status) that violate the principle of justice

- unsafe strategies of waste reduction, such as those that violate infection prevention protocols (e.g., re-using drugs, administering expired drugs) or compromise quality of care.

The Association of Pediatric Hematology/Oncology Nurses recommends that nurses

- become informed both about the causes and impact of drug shortages and about current recommendations to prevent or reduce the impact of drug shortages on public health
- advocate for and participate in institutional drug shortage and allocation committees
- ensure that families receive current and reliable information about drug shortages and the subsequent management plan for their child's care
- refrain from implementing individual strategies (e.g., drug hoarding) that, although well-intentioned, may compromise the delivery of safe, ethical, and high-quality care
- acknowledge the distress that clinicians experience when forced to implement drug allocation decisions that negatively affect individual patients and families
- provide support and therapeutic communication to patients and families whose treatment is altered because of an insufficient drug supply
- become involved in public policy advocacy that strives to minimize drug shortages.



References

- American Society of Health-System Pharmacists. (2019). Drug Shortages Statistics. Retrieved from <https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics>
- U.S. Food and Drug Administration. (2019). Drug Shortages: Root Causes and Potential Solutions. Executive Summary. Retrieved from <https://www.fda.gov/media/131130/download>

