Chemotherapy Drug Shortages in Pediatric Oncology: A Consensus Statement

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KEY WORDS
antineoplastic agents/supply and distribution, resource allocation, health care rationing, ethics, medical, bioethics, coordination, pediatric oncology

ABBREVIATIONS
ASHP—American Society of Health-System Pharmacists
COG—Children’s Oncology Group
FDA—Food and Drug Administration
FDASIA—FDA Safety and Innovation Act of 2012
WG—Working Group on Chemotherapy Drug Shortages in Pediatric Oncology

Dr DeCamp made substantial contributions to the conception and design of the study and drafted the initial manuscript; Drs Fernandez, Joffe, and Faden made substantial contributions to the conception and design of the study and reviewed and revised the manuscript; Dr Unguru conceptualized and designed the study and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the institutions with which they are affiliated, including their academic institutions, the Children’s Oncology Group, the American Society of Pediatric Hematology/Oncology, and the National Institutes of Health. Individuals from the Food and Drug Administration were present and provided technical input only.

www.pediatrics.org/cgi/doi/10.1542/peds.2013-2946
doi:10.1542/peds.2013-2946

Accepted for publication Nov 26, 2013

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From 2005 to 2011, the number of drug shortages in the United States nearly quadrupled to include >250 drugs. Most involved sterile injectable drugs, including generic chemotherapeutic agents, antibiotics, intravenous nutrition, anesthetics, and sedatives. Shortages of critical drugs are likely to continue for multiple reasons, including unreliable or uncertain sources of raw materials, manufacturing quality problems, regulatory actions, limited economic incentives for generic drug production, and increased consumer demand.

Emerging evidence suggests that shortages have resulted in adverse patient outcomes; some related to use of substitute therapies and delayed clinical trials. Managing shortages costs valuable time and resources, with annual estimates as high as $416 million. Drug shortages also raise ethical issues: most notably, ensuring a fair distribution of available supplies.

The impact of shortages on pediatric oncology is particularly evident. Many affected drugs are generics, sourced or manufactured by single companies with limited manufacturing redundancy, that comprise the backbones of standard chemotherapeutic regimens. These regimens are potentially curative, and effective alternatives are frequently unavailable. Over the past 10 years, 8 of the 10 drugs used in treating the most common childhood cancer, acute lymphoblastic leukemia, were temporarily unavailable. These drugs account for the 90% 5-year event-free survival of the 3000 US children afflicted each year.

Compared with other specialties, childhood cancer therapies are characterized by greater reliance on generic, sterile injectable agents, smaller markets, and unparalleled integration with research via the Children's Oncology Group (COG), other research consortia, and institutional trials. For >50 years, cooperative clinical trials have advanced outcomes in pediatric cancer; historically, nearly two-thirds of children have enrolled in a trial during their treatment. Although this cooperative context poses special ethical challenges (eg, whether children participating in research should receive priority access to scarce drugs), it may also facilitate potential solutions.

**METHODS**

In response to a charge from the leadership of the COG, and with the support of the Johns Hopkins Berman Institute of Bioethics, the authors (the "steering committee") convened a 1-day Working Group on Chemotherapy Drug Shortages in Pediatric Oncology (WG) in January 2013. The interdisciplinary and multiinstitutional WG included practicing pediatric hematologist-oncologists, nurses, hospital pharmacists, bioethicists, experts in emergency management and public policy, legal scholars, patient/family advocates, and leaders of COG and the American Society of Pediatric Hematology/Oncology (see Acknowledgments). WG members were identified by their expertise and national leadership in pediatrics, drug shortages, health policy, and/or bioethics. Before the meeting, the steering committee reviewed the literature on drug shortages, identified 127 articles in ETHXWeb and PubMed published between 1985 and 2012, and distributed an annotated bibliography of the 55 most relevant articles to the WG. The steering committee charged the WG with 2 tasks. The first task was to define the ethical challenges raised by managing pediatric oncology drug shortages within individual institutions. Recognizing substantial previous work on this aim, the WG's second aim (reported here) focused on how stakeholders might coordinate efforts related to drug shortages. The steering committee synthesized recommendations from the face-to-face meeting and iteratively circulated these to the WG for comment, modification, and approval. Here we describe the steps that stakeholders can take, working collaboratively, to prevent and mitigate drug shortages, along with the ethical rationales for and potential barriers to those steps. Although the present recommendations focus on childhood cancer, they require coordination and integration with pediatric and adult specialties beyond pediatric oncology.

**RECOMMENDATIONS**

The obligation to prevent and manage drug shortages is based on 2 fundamental values: the need to maximize the benefits of highly effective drugs and the obligation of fairness (ie, ensuring equitable access across patients and patient groups). Although these values may sometimes be in tension, incorporating multiple values into principles of allocation is widely accepted. These basic principles led the WG to offer 6 specific recommendations (Table 1).

1. **Support Current Measures (and Develop Innovative New Ones) to Prevent Future Drug Shortages at the National Level**

**Ethical Rationale**

Although there is disagreement about what justice in health care requires, any plausible account must include reasonable access to drug treatments for potentially curable life-threatening diseases. This ethical mandate requires that laws, regulations, reimbursement schemes, and policy instruments minimize the economic, political, and manufacturing barriers that contribute to drug shortages. Patients, providers, pharmacists, health system leaders, payers, and policymakers have an obligation to engage in policy activities to prevent shortages of drugs that are critical to the effective management of serious illness.

**Background**

Although national policy was not the main focus of the WG, members recognized...
TABLE 1 Recommendations of the WG

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<td>1. Support current measures (and develop innovative new ones) to prevent future drug shortages at the national level</td>
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<td>2. Optimize and efficiently use supplies to reduce the likelihood and mitigate the effects of future shortages</td>
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<td>3. Develop explicit policies that give equal priority during a drug shortage to evidence-based use of chemotherapy agents whether patients are receiving treatment within or outside a clinical trial</td>
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how efforts since 2011 have prevented some drug shortages. In 2011, Executive Order 13588 directed the Food and Drug Administration (FDA) to deploy its full complement of legal and administrative tools to prevent shortages.22 This directive included requiring drug manufacturers to report planned discontinuation of production, expediting review of new drug suppliers and manufacturers, and working with the Department of Justice to report hoarding or exorbitant pricing. The FDA Safety and Innovation Act of 2012 (FDASIA) extended reporting requirements to all manufacturers of FDA-approved products (including biological agents, if the FDA so interprets the regulations). The FDA can also publicly issue noncompliance letters to manufacturers who fail to report. Additionally, FDASIA requires that the FDA submit an annual drug shortage and amelioration efforts report to Congress. FDASIA required the FDA to establish a task force to develop and implement a strategic plan, released in October 2013, for enhancing responses to drug shortages.23

**Action Items**

The WG supports the full implementation of existing legislative efforts, regulatory capabilities, and systematic studies of drug shortages as described in FDASIA. However, the approach to shortages remains primarily reactive by relying upon reporting of shortages as they occur. We therefore recommend the following additional actions by the relevant legislative and regulatory bodies to help prevent drug shortages in pediatric oncology:

1. create a critical drug and critical drug shortage list for pediatric oncology, in coordination with pediatric oncologists, pharmacists, and industry (congruent with a proposed, although not enacted, 2012 Drug Shortage Prevention Act24);
2. implement a proposed FDA quality metric to incentivize and reward high-quality manufacturing practices25;
3. explore the likelihood that production will be stimulated by amending the Medicare Prescription Drug Improvement and Modernization Act of 2003 to allow greater price increases for generic oncology drugs on the critical drug list;
4. examine the feasibility of a national stockpile of critical drugs, analogous to the Centers for Disease Control and Prevention’s Strategic National Stockpile, as previously considered by the National Cancer Institute26; and
5. explore international agreements to allow rapid access to international suppliers of ingredients or drugs during a shortage, with attention to expeditiously registering these drugs domestically to facilitate their reimbursement.

**Barriers**

The WG recognized the government’s inability to require manufacturers to produce specific products in a market economy. Notwithstanding this hurdle, the following additional barriers must be addressed to achieve these action items:

- potential disagreement about which drugs are “critical” for specific diseases;
- the unproven effectiveness of new incentives, such as manufacturing quality metrics, which will require evaluation before full implementation;
- recognition that modification of existing legislation requires political will and significant time before implementation;
- the need to ensure, in coordination with international regulatory agencies, the quality of drugs (or ingredients) obtained internationally;
- the need to avoid exporting shortages due to increased US demand; and
- the need to address drug shortages across the spectrum of health care needs beyond pediatric oncology.

2. Optimize and Efficiently Use Supplies to Reduce the Likelihood and Mitigate the Effects of Future Shortages

**Ethical Rationale**

During routine operations, high-value health systems should base clinical decisions on rigorous evidence and optimal resource utilization to deliver high-quality, efficient care.27 These values are even more important during a drug shortage.

**Background**

The WG discussed several examples where institutions and health systems optimized their local supplies to mitigate the effects of ongoing shortages.
For example, during the 1997–1998 intravenous immunoglobulin shortage, intensive and timely efforts were made to review the clinical evidence base supporting intravenous immunoglobulin use. Elimination of uses lacking substantial evidence effectively mitigated the shortage. More recently, the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services clarified the permissibility of repackaging unopened vials for multiple patients within a hospital to reduce wastage. WG members also described information technology innovations that use standard computer software to optimize drug supply use. For example, with appropriate safeguards, scheduling patients to receive infusions of scarce injectable drugs on the same day can reduce wastage. Finally, the WG discussed how some institutions, in an effort to increase effective supplies, have turned to "gray" (sometimes called "parallel") market suppliers: wholesalers that operate outside normal distribution channels and stockpile drugs for later resale, often at exorbitant prices.

Action Items

The WG recommends that institutions and health systems, individually and collectively, do the following:

1. review proactively, in a standardized manner, the evidence-based indications for drugs at risk for shortage, which is a task best achieved through multiinstitutional collaboration and the involvement of relevant professional societies;

2. support collection of data necessary for creating and maintaining this evidence base, both to facilitate prioritization of uses of drugs in shortage and to support identification of safe and effective substitutions (eg, those recommended by COG), as part of a learning health system;

3. develop and disseminate strategies, including novel applications of existing software programs, to optimize use of supplies; and

4. create policies to identify, report, and avoid gray market suppliers, due both to concerns over their potential to exacerbate shortages and to questions about supply chain documentation.

Barriers

Optimizing supplies poses challenges, including the following:

- inadequate evidence for many treatments in medicine, particularly in pediatric oncology, where off-label drug use is common;
- the political and public context of treatments, especially for rare or life-threatening diseases or diseases for which few alternatives exist, as a result of which prioritization efforts are likely to be controversial;
- disagreement about how to prioritize needs between divisions and departments, and between pediatric and adult patients, particularly when comparing evidence bases is difficult;
- the strong desire of clinicians, pharmacists, and institutions (motivated by concern for patient well-being) to use gray market suppliers in the short-term, notwithstanding these drugs’ questionable pedagogies and the gray market's contribution to, or exacerbation of, shortages; and
- the absence of regulatory barriers to (1) prevent use of gray market suppliers (eg, laws or regulations that deny reimbursement or penalize institutional use of such supplies, although some proposals exist) or (2) minimize the gray market’s impact (eg, laws or regulations that prohibit reselling drugs above a specified mark-up threshold).

3. Develop Explicit Policies That Give Equal Priority During a Drug Shortage to Evidence-Based Use of Chemotherapy Agents Whether Patients Are Receiving Treatment Within or Outside a Clinical Trial

Ethical Rationale

Most families of children with cancer are approached about research participation. Fairness requires sharing the benefits and burdens of research equitably, and ensuring that the decision to participate in research is free from coercion or undue inducement. During a shortage, tension might exist between use of a chemotherapy agent within a trial (which has the potential to benefit future patients as well as the children in the trial) and its use to treat children outside a trial.

Background

Nearly two-thirds of all children with cancer enroll in clinical trials, often via consortia such as COG. Childhood cancer research is rightly credited with tremendous gains in cancer survival over the past 50 years. Detailed prioritization discussions were not the principal focus of this statement; however, the unique collaborative context of pediatric oncology motivated the WG to address prioritization in this discrete area. We therefore considered whether institutions might justifiably prioritize clinical trial participants over nonparticipants during a drug shortage. The WG considered 2 situations: (1) the scarce drug is the investigational agent in a clinical trial and has not yet been shown to be effective (or more effective than the alternatives) for the indication under study and (2) the scarce drug is part of a well-established standard backbone within a clinical trial, such that patients would likely receive the drug...
regardless of whether they were participating in the trial.  

**Action Items**  
The WG recommends that research consortia such as COG work with member institutions to  
1. prioritize accepted and evidence-based uses of drugs over experimental uses during a drug shortage; and  
2. develop and endorse policies giving equal priority to patients receiving standard, evidence-based treatment with a chemotherapy agent, regardless of whether the patient is being treated within or outside a clinical trial.  

**Barriers**  
Not affording research participants priority during a shortage may be controversial. The most significant barrier to this recommendation, rooted in a sense of reciprocity for these children’s contribution to the generation of new knowledge and to future patients, is the viewpoint of some that trial participants deserve priority access to drugs. Ultimately, however, the WG concluded that concerns over undue inducement, public perception, and the imperative to use drugs for indications for which evidence of benefit exists outweigh arguments for giving priority access to research participants.  

4. Create an Improved, Centralized Clearinghouse for Sharing Information About Drug Availability and Shortages  

**Ethical Rationale**  
The WG endorsed the value of fairness, understood as equitable access to drugs across as well as within institutions. During a shortage, if some health systems and institutions are less able than others to manage drug shortages, their patients could experience unfairly diminished access. In some cases, these patients might be members of disadvantaged groups due to socioeconomic status, race/ethnicity, or immigration status. Fairness, therefore, requires developing strategies to facilitate cooperation across institutions.  

**Background**  
WG participants described the importance of accurate information about drug shortages, including expected duration and severity, as a prerequisite for effective management. For example, the FDA and the American Society of Health-System Pharmacists (ASHP) both maintain Web sites related to current and past drug shortages. These valuable resources have limitations, including inaccurate or unreliable information about expected duration, inconsistent reporting requirements, and differences in Web site content. Many limitations relate to inadequate information provided to the FDA or the ASHP. Pharmacists therefore spend significant resources locating information about drug availability and shortages, often via informal personal contacts and social networks. Despite COG’s invaluable role in facilitating such networks, contacts are not uniform, and some hospitals or health systems are less able than others to identify and manage impending shortages.  

**Action Items**  
Recognizing the ad hoc, inefficient nature of current strategies for sharing information related to drug shortages, the potential for inequitable information access by health systems and patients, and the limitations of current online resources, the WG recommends that institutions, health systems, and industry work with the FDA and ASHP to  
1. develop an accurate, comprehensive, controlled-access clearinghouse that is centrally managed and made available to health institutions and systems for sharing drug shortage information (including expected duration, available alternatives and sources, and contacts);  
2. develop a coordinated and authoritative system to declare when a drug is in short supply, perhaps building on the critical drug shortage list (see recommendation 1);  
3. design an active notification system, thereby preemptively informing pharmacists and providers about drug shortages and the location of existing supplies; and  
4. coordinate sharing drug shortage information, where possible, with similar initiatives internationally.  

**Barriers**  
A dedicated information clearinghouse will face several challenges. The WG specifically discussed the following:  
- the proprietary nature of drug shortage information, because manufacturers seek to maintain competitive advantage by withholding information about manufacturing problems;  
- the absence, aside from public non-compliance letters, of penalties for manufacturers that fail to provide accurate and timely information;  
- critical implementation questions regarding the cost of such a clearinghouse, its relationship to existing databases at the FDA and ASHP, and what organization(s) might host, support, and/or manage it; and  
- the risk that increased availability of information about actual or threatened shortages might facilitate hoarding by some stakeholders, including gray market suppliers.  

5. Explore Voluntary Sharing of Drugs at the State, Regional, and National Levels  

**Ethical Rationale**  
Drug supplies may be unevenly distributed during a shortage, with some institutions having a relative surplus...
whereas others experience scarcity. In the setting of maldistribution, sharing of drugs between institutions might maximize health outcomes for patients while minimizing inequities across patients and patient groups. Sharing thus upholds the principle of distributive justice.

**Background**

Existing prioritization plans repeatedly call for coordination between institutions in the face of shortages. However, no systematic, detailed, or widely publicized plans exist for sharing drugs, and interinstitutional and interstate transfer remains logistically and legally problematic. Regional systems exist for sharing resources in other contexts, such as the United Network for Organ Sharing or the Regional State Health Emergency Management Coalitions, motivating the WG to consider drug sharing in oncology. The WG recognized that sharing should not require 1 institution to deplete its supply to the detriment of its own patients, which raises questions of how to define “detriment,” “duration of responsibility,” and whether the depletion applies only to existing patients or anticipated ones. Nevertheless, a drug-sharing plan might reduce the degree to which maldistribution of supply exacerbates a drug shortage.

**Action Items**

Implementing a drug-sharing plan would be a lengthy process, but the WG agreed that it deserves urgent attention, particularly by pharmacists, state boards of pharmacy, institutions, and health systems. These and other stakeholders should

1. join with legal specialists to examine state drug pedigree laws and pharmacy board rules to identify ways to facilitate interinstitutional and interstate transfer of drugs, especially during shortages;
2. support ongoing federal efforts to establish a national “track and trace” authentication system that might support interstate transfer;
3. thoroughly examine the ethical obligation of institutions to prioritize “their own” patients over those at other institutions, including the relevance of this obligation during drug shortages and its relationship to institutional economic pressures; and
4. consider under what circumstances, if any, to centralize drug supply at a single regional center to minimize wastage, recognizing that this step would require patients to travel to the designated institution to receive the drug and that the need to travel might disadvantage vulnerable populations.

**Barriers**

Practical and ethical barriers make sharing drugs challenging. The WG discussed the following barriers:

- different thresholds among institutions for what counts as “adequate” reserve, and whether these thresholds must be standardized and publicized in the clearinghouse;
- whether or to what degree institutional and health system optimization and prioritization schemes must be standardized (eg, to avoid rewarding institutions that prioritize uses, such as those supported by lesser evidence, that are deemed less defensible by the community);
- the need to account for changing demand across institutions over time, due to variations in diagnosis, volume, and other aspects of patient need;
- the need for cooperation among institutions that ordinarily compete to attract patients, including questions about whether institutions’ sharing (or receiving) drugs might negatively affect patients’ confidence in these institutions;
- the need for cooperation among pediatric and adult specialties that use the same drugs (eg, medical and pediatric oncology, rheumatology);
- how to manage liability if shared products are later found to have quality problems; and
- whether sharing mechanisms must be mandated (ie, by federal or state agencies or by payers) to be successful.


**Ethical Rationale**

There are multiple justifications for engaging stakeholders, including procedural (as part of a fair process to involve affected individuals and groups), substantive (because engagement can contribute tangibly to improved plans), and practical (as a means to improve commitment to and implementation of a plan). Fundamentally, the ethical value of respect is demonstrated by ensuring that stakeholders have the opportunity to be informed about the problem and are invited to contribute to the solution.

**Background**

The WG emphasized that engagement with a comprehensive set of stakeholders, including patients and patient advocacy groups, is critical to the above recommendations. For example, widespread awareness and support of ongoing legislative efforts is necessary for the success of recommendation 1. Stakeholder engagement, particularly with patients and patient advocacy groups, will be similarly crucial for navigating the difficult context of evidence review in recommendation 2.
Recommendation 3 requires communication between hospitals and the academic research enterprise, in situations where these operate more independently. Patient representatives will have a role in the information clearinghouse proposed in recommendation 4. Finally, sharing of drug between institutions in times of shortage (recommendation 5) will require recognition not only of institutional ethical obligations but also of stakeholder views on this issue. WG members viewed successful examples of engagement in other areas, such as pandemic influenza planning, research, and resource allocation, as foundations for engagement in drug shortage management plans.

**Action Items**

The WG recommends that industry, institutions, organizations, health systems, and relevant government agencies commit to meaningful stakeholder engagement on management of drug shortages by

1. emphasizing transparency as a value in planning processes, including financial analyses;
2. developing concrete strategies to engage patients and advocacy groups during all phases of planning for current and future drug shortages;
3. including patients and patient advocacy groups in research to provide a patient-centered and evidence-based rationale for shortage management; and
4. creating mechanisms (including an appeals process) for managing disagreement and arriving at reasonable decisions given their likely controversial nature.

**Barriers**

Barriers to stakeholder engagement include the following:

- the unpredictability and time-sensitivity of drug shortages,
and Therapeutics, The Children’s Hospital of Philadelphia, and Chair, COG; Brooke Bernhardt, Clinical Pharmacy Specialist, Texas Children’s Hospital, and Group Pharmacist, COG; Lisa Bomgaars, Associate Professor of Pediatrics, Baylor College of Medicine; I. Glenn Cohen, Professor, Harvard Law School; Kenneth Cohen, Clinical Director, Division of Pediatric Oncology, and Associate Professor, Oncology and Pediatrics, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins; Eduvigis Cruz-Arrieta, Assistant Clinical Professor, Columbia University College of Physicians and Surgeons, and Chair, Minority Affairs Committee, COG; Alix A. Dabb, Clinical Pharmacy Specialist, Pediatric Oncology, Sidney Kimmel Comprehensive Cancer Center at The Johns Hopkins Hospital; Christine Grady, Chief, Department of Bioethics, National Institutes of Health; Howard S. Gwon, Senior Director, Office of Emergency Management, Johns Hopkins; Mekdes Kassa, Oncology Pharmacy Operations and Clinical Manager, Alvin & Lois Lapidus Cancer Institute, The Herman and Walter Samuelson Children’s Hospital at Sinai; Jennifer C. Kesselheim, Assistant Professor, Harvard Medical School, and Associate Ethicist, Dana-Farber Cancer Institute; Eric Kodish, Director, Cleveland Clinic Center for Ethics, Humanities and Spiritual Care; Revonda Mosher, Nurse Practitioner (retired), Division of Pediatric Hematology/Oncology, The Herman and Walter Samuelson Children’s Hospital at Sinai; Rebecca D. Pentz, Professor of Hematology and Oncology in Research Ethics, Emory School of Medicine; W. Nicholson Price II, Academic Fellow, Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School; Alan Regenberg, Senior Staff Member and Research Manager, Johns Hopkins Berman Institute of Bioethics; A. Kim Ritchev, Professor and Vice Chair for Clinical Affairs, Department of Pediatrics, University of Pittsburgh School of Medicine, and President, American Society of Pediatric Hematology/Oncology; Philip Rosoff, Director of Clinical Ethics and Professor of Pediatrics and Medicine, Duke University Medical Center; Carol Taylor, Senior Research Scholar and Professor of Nursing, Kennedy Institute of Ethics at Georgetown University; Joseph M. Wiley, Chief, Division of Pediatric Hematology/Oncology, and Chairman of Pediatrics, The Herman and Walter Samuelson Children’s Hospital at Sinai; Catherine L. Woodman, Associate Professor and Institutional Review Board Co-chair, University of Iowa Carver College of Medicine.

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