

Experts issue 'blueprint for action' to combat shortages of life-saving drugs

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A group of prominent healthcare experts including bioethicists, pharmacists, policymakers and cancer specialists have proposed concrete steps for preventing and managing a nightmare scenario that is becoming all too common: shortages of life-saving drugs.

In a consensus statement published in the journal *Pediatrics*, the experts say they sought to move away from the current strategy of reaction to shortages once they have occurred and focus instead on prevention. Using the example of shortages of [chemotherapy drugs](#) used for treating children with cancer—therapies proven to have high survival rates for the most common childhood cancers—the group developed "a comprehensive blueprint for action" they say is critical for managing and preventing future drug shortages.

"Although our recommendations were developed with pediatric oncology in mind, and serve as a blueprint for preventing children with cancer from lacking access to essential life-saving medications, we believe that they apply more broadly across medicine to include pediatrics and adult medicine in general," says Yoram Unguru, a pediatric hematologist/oncologist at the Herman and Walter Samuelson Children's Hospital at Sinai and faculty member at the Johns Hopkins Berman Institute of Bioethics. Unguru, a coauthor of the consensus statement, was the principal organizer of meetings that led to its creation, bringing together representatives from the Food and Drug Administration (FDA), leadership of the Children's Oncology Group and The American Society of Pediatric Hematology/Oncology, patient

advocacy groups, legal scholars and clinicians.

Some recommendations would represent new norms for healthcare practice, including the sharing of scarce drugs between healthcare institutions and not giving preferential access to patients participating in research studies.

"This statement is significant both for the consensus found by such a diverse group of experts, and for being the first to take seriously the ethical rationale to prevent shortages in the first place," says Matthew DeCamp, a Johns Hopkins professor at the Berman Institute of Bioethics and Division of General Internal Medicine, and lead author of the [consensus statement](#).

Included in the statement's six recommendations is a call to develop policies that give equal priority to patients regardless of whether they are participants in research. The authors acknowledge this "may be controversial," due to the sentiment that fairness requires giving research participants high-priority access to drugs because of their contribution to medical knowledge and future patients. However, the statement's authors explain 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."

For each recommendation the statement also includes potential barriers to its implementation. A centralized information source of drug supply information, for instance, faces the risk that such information will encourage hoarding of existing supplies, including so-called "gray market" suppliers that sell scarce drugs for inflated prices. The statement calls for new policies for both reporting and avoiding these markets, though acknowledges the temptation of healthcare providers to use them in a shortage, when their patients are in need.

The authors also note the marketplace economy as an obstacle to implementing their recommendations and preventing drug shortages. Drug manufacturers do not like to disclose manufacturing problems that lead to shortages, nor are competitive healthcare institutions accustomed to cooperating to share resources. Nonetheless, the statement calls for an exploration of "ways to facilitate interinstitutional and interstate transfer of drugs, especially during shortages," as well as the ethical obligation to patients inside vs. outside a healthcare institution when there is a drug shortage.

"The reasons for [drug shortages](#) are complex, but we must not lose sight of the fact that without access to these life-saving drugs, children and adults with cancer will almost certainly die," Unguru says. "It is untenable for this situation to continue any longer. We have a clear moral obligation to act to address this critical issue."

Provided by Johns Hopkins University School of Medicine

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