Oncology Drug Shortage Op-Ed

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Empty IV bags: How we got to a national shortage of cancer drugs

In 2022, the American Cancer Society (ACS) issued a new report showing <u>marked decreases in fatality</u> risks from cancer — a promising trend for this constellation of diseases that saw <u>more than 1.6 million</u> <u>new cancer diagnoses</u> in the U.S. and over 600,000 deaths in 2020 alone. One of the factors attributed to the reduced death rate in the ACS's report was the growing use of chemotherapy after surgeries for breast and colon cancer.

Today, accessing that potentially life-saving treatment is more difficult than ever due to a nationwide <u>shortage of chemotherapy medications</u>.

Drug shortages are at an all-time high across the U.S., with more than 300 shortages as of June 2023. Earlier this spring, the nebulizer form of albuterol called albuterol sulfate — a life-saving drug relied on by more than 17 million patients to treat chronic and acute respiratory conditions — was <u>rationed by</u> <u>hospitals</u> because of a critical shortage caused by supply chain disruptions. The shortage of albuterol sulfate was particularly perilous for both patients and the health care industry, as the nebulizer formula is vital for treating those in acute respiratory distress — often older patients, infants and children. Similarly, there is also currently a <u>shortage of penicillin</u> impacting patient care and the health care industry.

The shortage of chemotherapy medications stands to be equally disruptive for health care systems and devastating for patients. In particular, <u>cisplatin</u> and <u>carboplatin</u> are of significant concern. The <u>National</u> <u>Comprehensive Cancer Network</u> (NCCN) surveyed its member institutions across the country and found that <u>93% of centers are currently experiencing shortages of carboplatin</u> and 70% of centers are experiencing shortages of carboplatin. This <u>ongoing shortage is causing doctors</u> to delay, modify or find alternative treatment plans — an impossible position for physicians and an uncertain prospect for patients.

Compounding the patient-facing impacts of the shortage is the fact that the two primary drugs — cisplatin and carboplatin — are often used as substitutes for each other in treatment protocol. Cisplatin can be used in place of carboplatin and vice versa. This interchangeability has been a strength in the past, allowing treatment plans to shift between the two if needed due to a low supply of one or the other. However, when both drugs fulfill the same role, <u>finding alternatives for both cisplatin and</u> <u>carboplatin</u> is increasingly difficult.

While the cause of drug shortages is often matrixed, the scarcities we're facing today are in part driven by a combination of manufacturing disruptions and policy implementation that crosses national borders. In 2022, the Food and Drug Administration (FDA) identified massive quality issues linked to <u>Accord</u> <u>Healthcare Inc.</u>, which holds a large market share when it comes to manufacturing and supplying both cisplatin and carboplatin. This injunction by the FDA led to the shutdown of Accord's manufacturing facility in India, effectively halting production. Other manufacturers of the drugs, including Fresenius Kabi, Hikma, Teva, Eugia and Pfizer, also experienced shortages as they were unable to fill the gaps left behind by Accord's manufacturing delays. Even with increased focus on production, the estimated release dates for both cisplatin and carboplatin vary between each manufacturer, with shipments estimated between June and September 2023.

Since late May 2023, the <u>FDA has been working with a Chinese-based pharmaceutical company</u> — Qilu Pharmaceutical Co. Ltd. (Qilu), in conjunction with Apotex Corp. — to increase the availability of cisplatin in the U.S. The FDA has also initiated temporary importation of the drug into the U.S. market to help alleviate the shortage.

These developments, combined with the manufacturer-supplied drug delivery timeframes above, are cause for hope. However, further delays in manufacturing and delivery could further extend the timeline for both getting drugs to patients and replenishing national stockpiles. Should such a delay occur, disruptions to patient care will continue and possibly worsen as the remaining drug supply dwindles. Furthermore, availability of other cancer drugs — particularly those providers have turned to as substitutes for products in low supply — may be threatened if shortages linger.

But there is more that can be done. As the executive director of Healthcare Ready, a nonprofit organization that serves as a public-private nexus to prevent patient care disruptions amid crises like natural disasters, pandemics and drug shortages, I see the following as non-negotiable changes we in the health care system must implement now to ensure we're addressing this crisis today while mitigating future shortage risks going forward:

- 1. Improve early warning systems for predicting shortages by building stronger relationships with and across providers, distributors, and manufacturers. The current systems developed for COVID-19 are too narrowly focused, inefficient and incredibly labor intensive.
- 2. Government agencies should partner with the private sector to identify single points of failure in supply chains, especially for less common and/or critical drugs.
- 3. Government agencies should incentivize manufacturers to invest in additional and/or "warm base" capacity essentially, latent capacity that can be activated quickly to manufacture products when they are needed for products that have been identified as at risk of single points of failure.

The above recommendations are a start, but not the totality of the solution. Such shortages will continue to happen if we don't change how we approach coordination today. An enduring strategy to eliminate drug shortages will require ongoing collaboration between community-based organizations, governmental agencies at all levels, medical supply manufacturers and supply chain stakeholders. These collaborations are crucial for responding to not only drug shortages but also to natural disasters, where first responders and frontline providers depend on access to supplies that need to be rerouted from other geographic hubs to support impacted communities.

Ultimately, the oncology drug shortages we're seeing today are the result of a confluence of factors. But it is also only through coordination and collaboration across preparedness, crisis response, and policy domains that we will safeguard access to such life-saving therapies for every person in every community across the country.

<u>HcR Drug Shortage Webpage</u> <u>Oncology Situation Report 1</u> <u>Oncology Situation Report 2</u> <u>Penicillin Situation Report</u> Tom Cotter, MPH, serves as executive director of Healthcare Ready, a nonprofit organization established in 2007 to help strengthen the U.S. health care system and assist all communities in planning for, responding to, and recovering from disasters and disease pandemics. Over his 15-year career as a public health and emergency management professional, he has piloted and launched innovative international strategies to localize emergency response operations and build equitable response functions worldwide. Most recently, he served as the director of emergency response and preparedness for Project HOPE, a renowned global health and humanitarian relief organization. Prior to that role, he developed and managed public health and emergency response programs in several countries for nonprofit organizations. He has a Master of Public Health degree from Boston University School of Public Health. He also served as an emergency response coordinator on the Incident Management Team of the U.S. Department of Health & Human Services between 2013 and 2022.