



**ONCOLOGY DRUG SHORTAGES:
TEACHINGS FROM RECENT INCIDENTS AND COPING STRATEGIES**

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FLASCO FALL 2023

Agenda



Reason for Shortages



Where to Find Information



How to Address
Monitoring/Implementation

The New York Times
How the Shortage of a \$15 Cancer Drug Is Upending Treatment
Older generic chemotherapy drugs remain scarce, forcing doctors to put a priority on the patients who have the best chance of survival

CNN health
BREAKING NEWS Audio Live TV Log In
Cancer experts demand action to end ongoing drug shortage: 'People's lives are really at stake'
By Jacqueline Howard, CNN
Published 12:01 AM EDT, Wed September 13, 2023

THE WHITE HOUSE
SEPTEMBER 12, 2023
Strengthening the supply chain for cancer drugs

Pharmacy Times
News Media Conferences Publications Clinical Events CME/CE Resources Subscribe
As Chemotherapy Drug Shortage Continues, Unimaginable Decisions
July 24, 2023

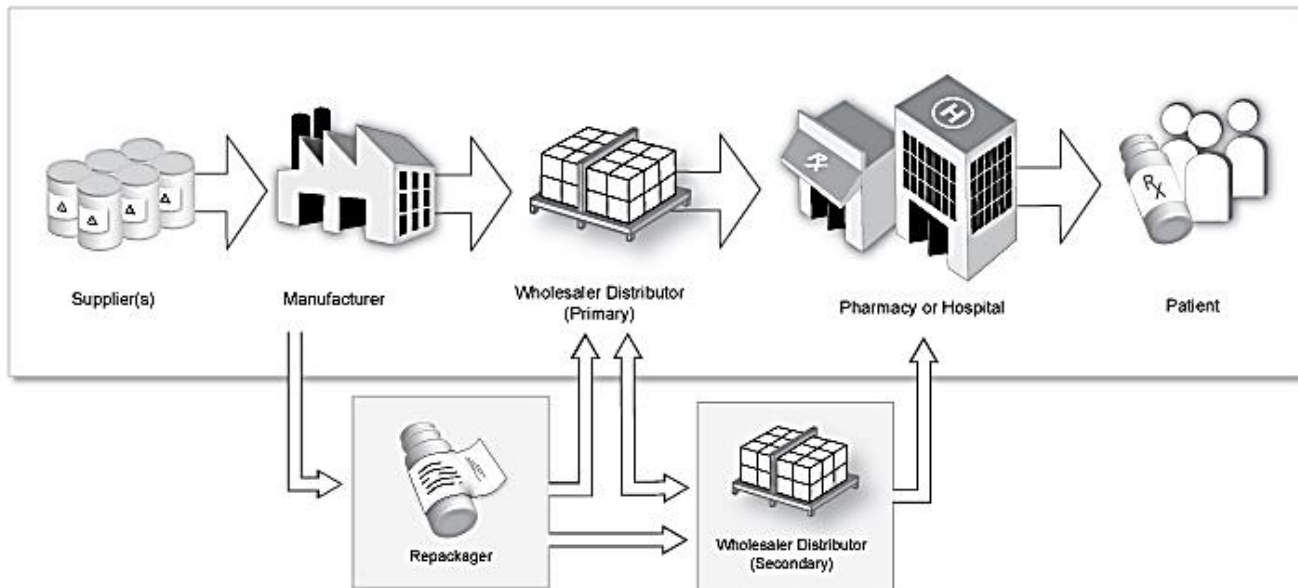
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Drug shortages are creating instances for some patients

abc NEWS VIDEO LIVE SHOWS ELECTION 2024 538
Cancer drug shortage is forcing doctors to decide which patients get treatment
At least 11 cancer drugs are currently in short supply, FDA data shows.

NEWS LIVE: ISRAEL AT WAR POLITICS U.S. NEWS WORLD WATCH LIVE
HEALTH NEWS
1 in 3 U.S. hospitals severely affected by drug shortages, survey finds
Many hospitals say they've skipped, delayed or rationed medications, including critical cancer drugs, as the crisis across the country continues.

SURVEY: 99% OF HOSPITAL PHARMACISTS EXPERIENCING DRUG SHORTAGES
ANALYSIS | BY **CHRISTOPHER CHENEY** | AUGUST 14, 2023



<https://www.fda.gov/drugs/drug-shortages/graphic-drug-supply-chain-example>

| Regional Distribution of Facilities Manufacturing Finished Dosage Forms and Active Pharmaceutical Ingredients in 2018. | | |
|--|-----------------|-----------------|
| Region | FDF MANUFACTURE | API MANUFACTURE |
| Canada | 4% | 0% |
| China | 8% | 14% |
| EU | 18% | 31% |
| India | 24% | 31% |
| Latin America | 0% | 2% |
| Rest of World | 10% | 11% |
| USA | 37% | 12% |
| Total | 100% | 100% |

Why are there so many shortages?

- Supply chain issues with raw materials
- Production delays
- Generic manufacturing lines cancelled
- FDA regulatory citations
- Supply chain disruptions
 - Hurricanes, tornados, pandemics

Where can I find information?



ASHP Drug Shortages Resource Center



HOPA Forum



FDA Alerts/Recalls



Wholesaler Announcements



MVP: Pharmacy Buyer(s)



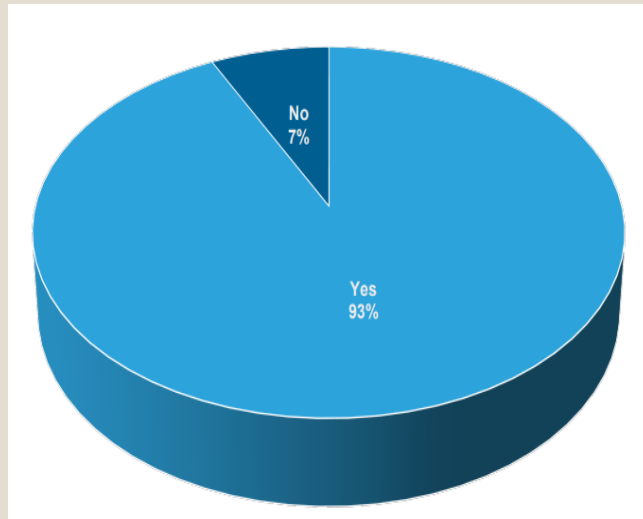
NCCN and other societies (ex. SGO)



NCCN Survey

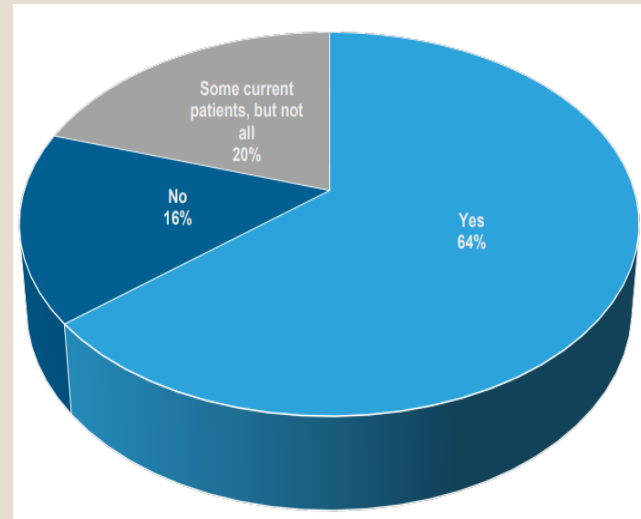
(Collected May 23 – 31, 2023)

CARBOplatin shortage?



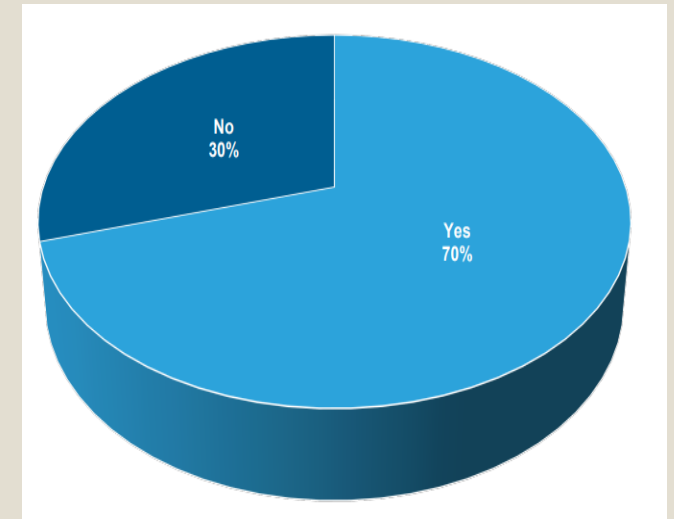
n = 27

Able to treat all patients according to the intended dose and schedule?



n = 25

CISplatin shortage?



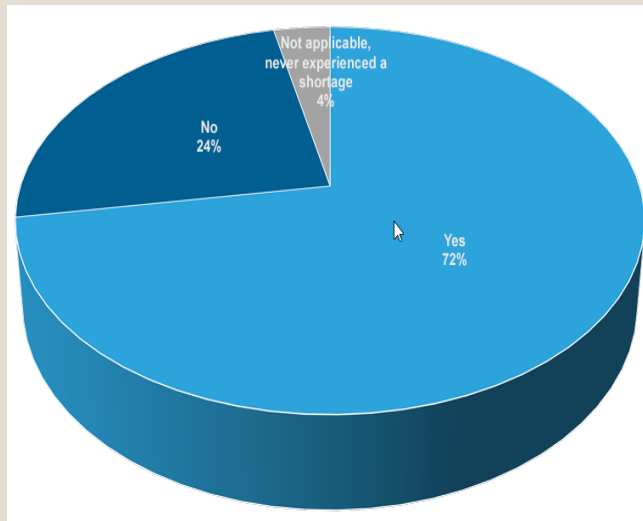
n = 27

National Comprehensive Cancer Network (2023). NCCN Best Practices Committee Carboplatin & Cisplatin Shortage Survey Results. Retrieved from: <https://www.nccn.org/docs/default-source/oncology-policy-program/NCCN-Drug-Shortage-Survey.pdf>

NCCN Survey Follow-up

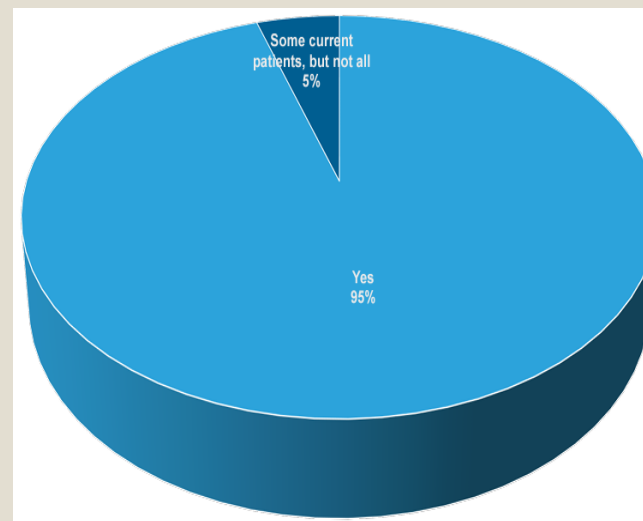
(Collected September 6 – 27, 2023)

Still experiencing
CARBOplatin shortage?



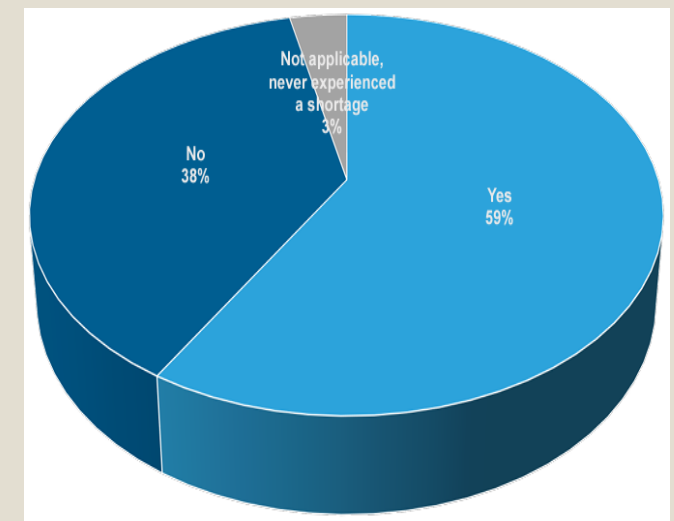
n = 27

Able to treat all patients
according to the intended
dose and schedule?



n = 21

Still experiencing
CISplatin shortage?



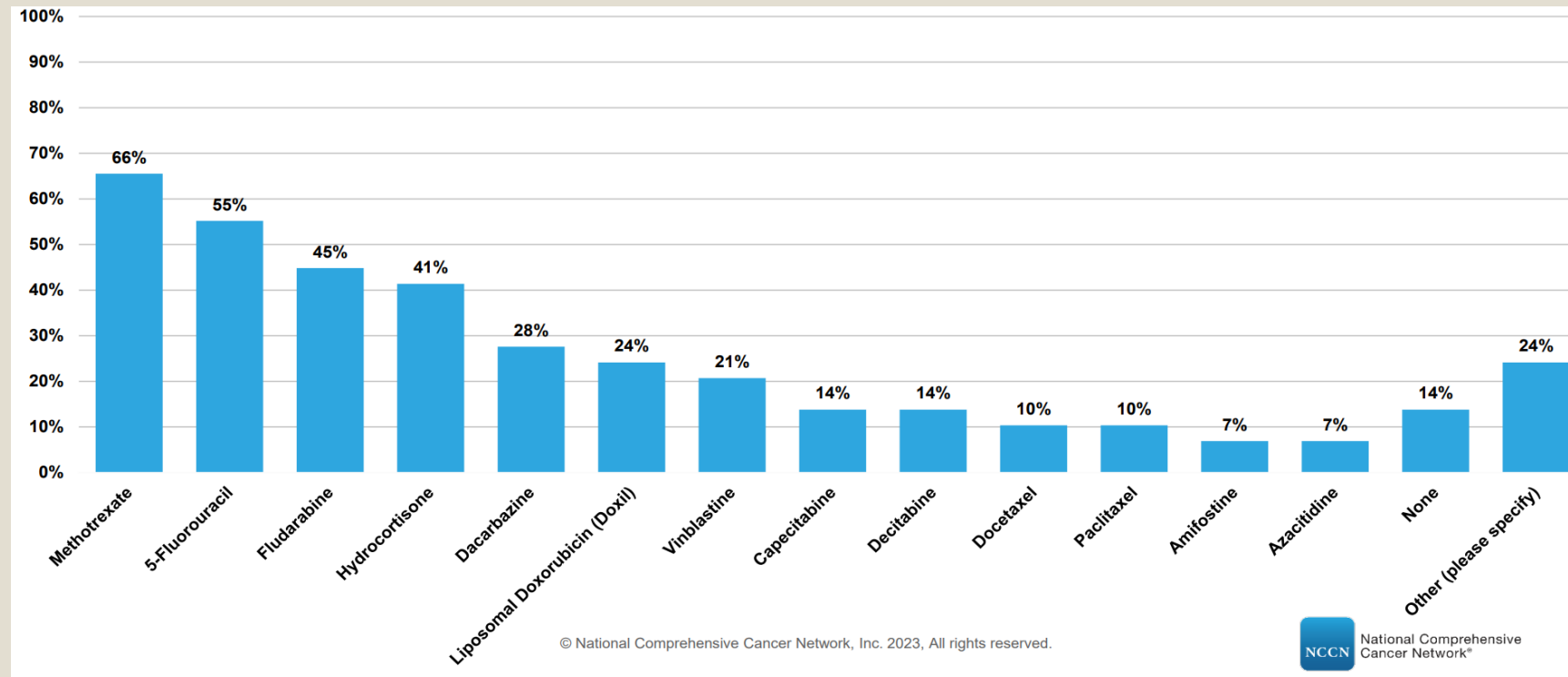
n = 29

National Comprehensive Cancer Network (2023). NCCN Best Practices Committee Carboplatin & Cisplatin Shortage Survey Results. Retrieved from: https://www.nccn.org/docs/default-source/oncology-policy-program/Drug-Shortage-Follow-Up-Survey_Deidentified-Placeholder.pdf

NCCN Survey Follow-up

(Collected September 6 – 27, 2023)

Other shortages?



n = 29

National Comprehensive Cancer Network (2023). NCCN Best Practices Committee Drug Shortages Follow-Up Survey Results. Retrieved from: <https://www.nccn.org/docs/default-source/oncology-policy-program/NCCN-Drug-Shortages-Survey-Update.pdf>

Shortage Mitigation Strategies



Monitor, monitor, monitor



Ability to pull quantity on hand (QOH),
quantities dispensed, upcoming patient doses



Drug/disease specific mitigation strategies



Borrow/buy agreements



Sourcing – 1ry, 2ry distributors



Centralize compounding



FLORIDA CANCER

S P E C I A L I S T S

& Research Institute



Miami Cancer Institute

BAPTIST HEALTH SOUTH FLORIDA

FRAMEWORK

Case 1: Platinum agents

- CARBOplatin and CISplatin both on shortage
- Various strategies:
 - 1. Prioritization** of curative intent patients and/or specific disease states (i.e., curative GYO patients with no alternatives)
 2. Use of **alternatives** (i.e., alternate platinum where equivalent and available)
 - 3. Sequencing**
 - TNBC Keynote-522 patients
 - Changing sequence of PACLitaxel/CARBOplatin/pembrolizumab to AC portion first
 - New start TCHP patients – Switched to AC THP
 - 4. Clinical trials:** Communicate to sponsors for enrollment hold into arms that contain drugs on shortage or request drug supply
 - 5. Increase interval** between treatments where appropriate

Case 2: Leucovorin

- Cyclical shortages
- Minimize waste inpatient: use 50 mg vials
 - If 50mg needed and only 100mg vial available, mix 2 doses at a time
- Removal of leucovorin dose in a regimen withOUT IV Push fluorouracil (except in curative intent regimens)
- Various strategies:
 1. If IV Push fluorouracil present, Pharmacy driven adjustment of the leucovorin dose for a 50% reduction and rounding down to nearest 100 mg
 2. Pharmacy-led dose rounding 5-10%



Case 3: Fluorouracil

- Pharmacy-led dose rounding
- Consider alternatives
 - Challenges when alternatives are also on shortage



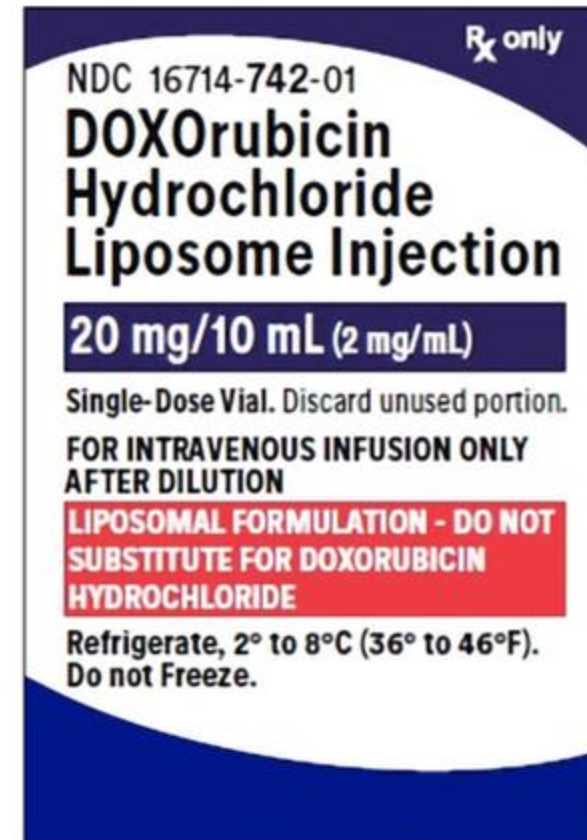
Case 4: Taxanes

- Different concentrations
- Consider alternative agents
- Criteria for use



Case 5: LIPOSOMAL DOXOrubicin

- Assess disease state and volumes
 - Sarcoma
 - Breast
 - Hodgkin's Lymphoma
 - Ovarian
- Criteria for use



Case 6: vinBLASTine

- Prioritization of patients
- Consider alternatives
- Dose rounding, when possible



Case 7: Methotrexate

- Different practices, different issues
 - Shortage of preservative free vs. standard
- Prioritization
 - Conserve larger vials for high dose methotrexate patients with active CNS disease
- Dosing
 - MR-CHOP – consider 2 g/m² instead of 3.5 g/m²
- Alternatives
 - intraTHECALs
 - Use alternatives where appropriate (cytarabine, thiotepa, topotecan)
 - Other indications for methotrexate:
 - Ectopic and molar pregnancies
 - CMF in breast cancer
 - MVAC in bladder
 - Metastatic H&N - methotrexate may be option



Audience Clinical Pearls



Other strategies



Other affected drugs

Ethical Concerns



STOCK PILING



PRICE GOUGING



PATIENT
PRIORITIZATION

Audience Experience

- How are ethical concerns managed?

Summary



Supply chain resiliency continues to be a concern



Multidisciplinary approach necessary for strategies



Collaboration imperative in communication and plans