





Drug Shortage and Oncology Stewardship: Ensuring Equitable Access to Medications

Marina Yazdi, PharmD, BCPS

Director, Pharmacy Business Strategy and Supply Solutions
Yale New Haven Health

Susie Jiing, PharmD, BCOP

Clinical Manager
Oregon Health and Science University



Disclosure of Financial Relationships



Vizient, Inc., Jointly Accredited for Interprofessional Continuing Education, defines companies to be ineligible as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

An individual is considered to have a relevant financial relationship if the educational content an individual can control is related to the business lines or products of the ineligible company.

No one in a position to control the content of this educational activity has relevant financial relationships with ineligible companies.

Learning Objectives



- Discuss drug stewardship program strategies to support informed decision-making for health systems.
- Explain how an oncology stewardship committee navigates through critical decision-making processes for scarce or high-cost medication resources.





Drug Shortage and Oncology Stewardship: Ensuring Equitable Access to Medications

Marina Yazdi, PharmD, BCPS

Director, Pharmacy Business Strategy and Supply Solutions
Yale New Haven Health

Susie Jiing, PharmD, BCOP

Clinical Manager
Oregon Health and Science University



Yale New Haven Health Drug Shortage Management



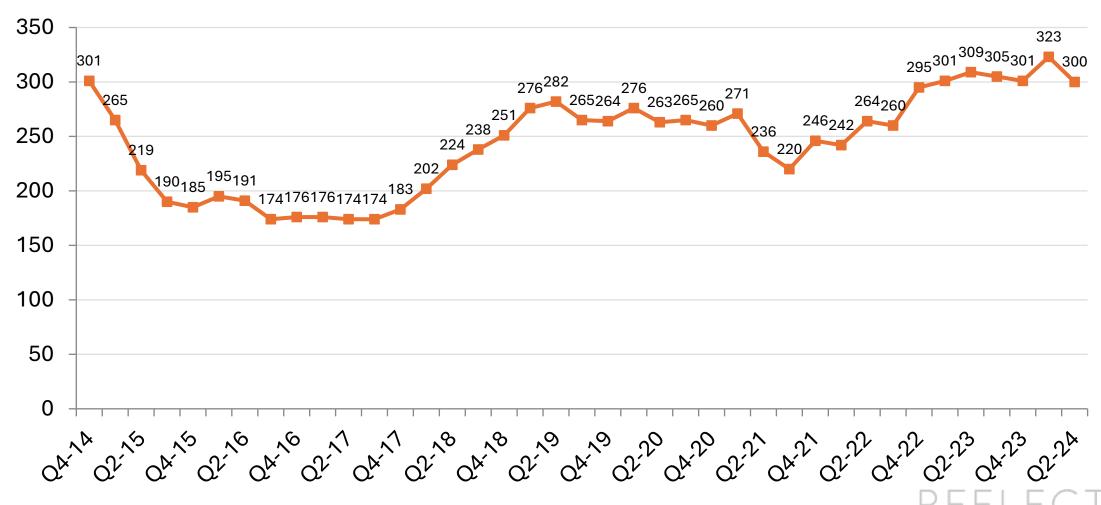
- Five Hospitals (2,681 licensed beds)
 - Yale New Haven Hospital
 - Bridgeport Hospital
 - Greenwich Hospital
 - Lawrence + Memorial Hospital
 - Westerly Hospital
- \$1.2B Pharmaceutical Expense

- Drug Shortage Management Program Established in 2011
 - System Oversight by Pharmacy Procurement Specialist
 - Multidisciplinary Team: Pharmacy Buyers, Clinical Pharmacy Specialists, Pharmacy Operations, P&T Committee, Digital Technology Services
 - Evaluation and continuous process improvement



Drug Shortages Overview

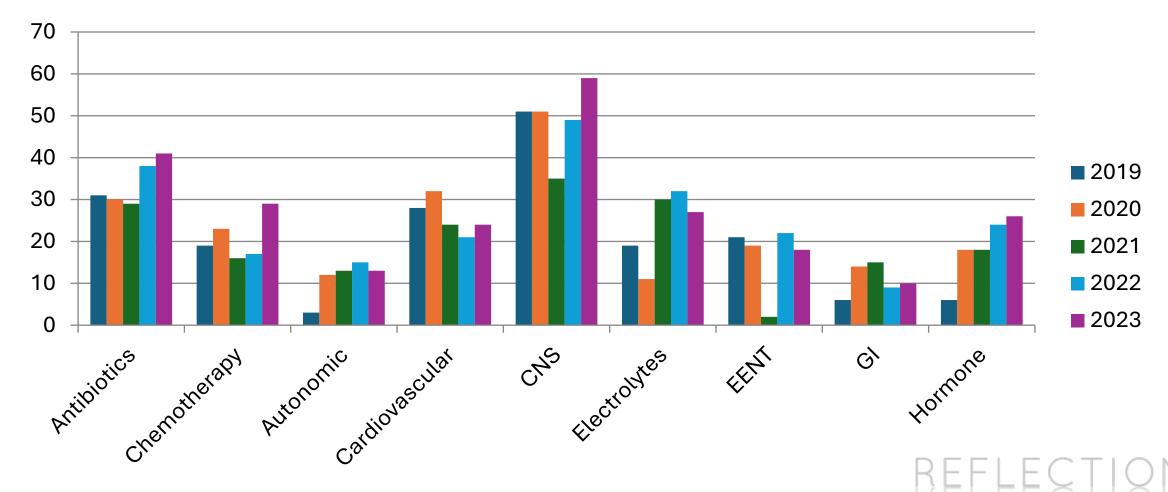
vizient.



University of Utah Drug Information Service

Common Drug Classes in Short Supply 5 Year Trend

vizient.



University of Utah Drug Information Service

Major Drivers of Drug Shortages





Quality concerns/ regulatory agency inspections



Limited drug suppliers and manufacturer business decisions



Inadequate supply of raw materials



Demand/supply issues

Impact on Hospital Purchasing Practices





- ✓ Limited ability for predictive modeling
- ✓ Stockpiling/protective purchasing further aggregates supply challenges

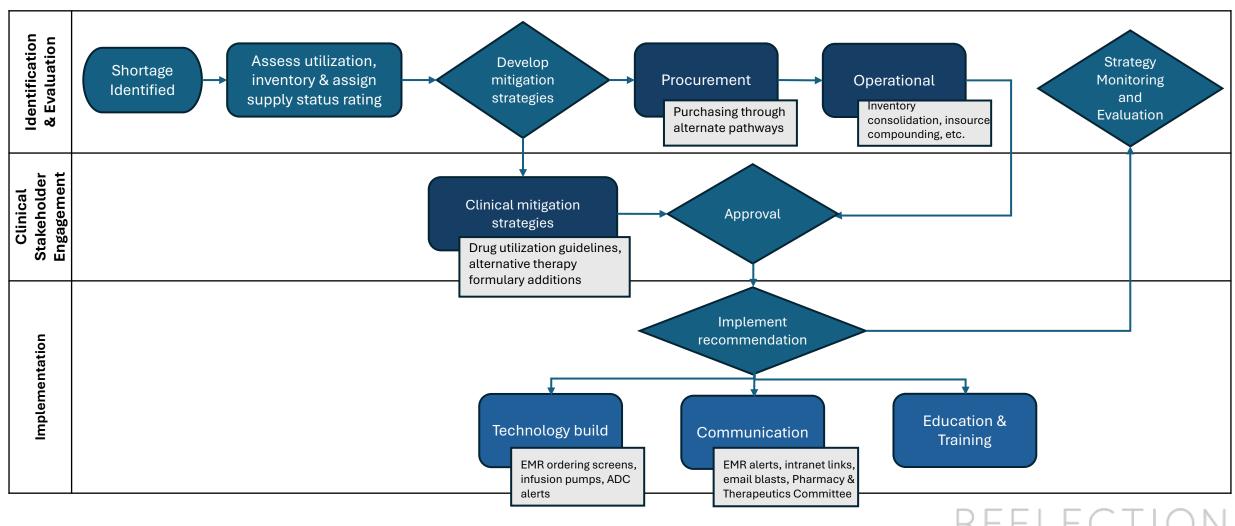
What Can We Do?



• Timely and transparent communication of regulatory actions **FDA** • Implement manufacturer quality ratings and share with hospitals • Evaluate importation of international products based on shortage severity Timely notification of drug and active pharmaceutical ingredients (API) supply disruptions Manufacturers • Transparency: quality data, reasons for shortage, sources of API, manufacturing locations, FDA inspection ratings Inform manufacturers of increased demand in product ordering Wholesalers • Permit allocations of alternatives without historical purchase volume • Establish multidisciplinary committee to evaluate impact and recommend Hospitals mitigation strategies Maintain internal drug shortage list to improve communication and tracking Avoid purchasing from gray market and unvetted secondary distributors • Implement Drug Shortage Stewardship (DSS) principles DSS is a coordinated program to implement local mitigation practices to collectively reduce the national demand and limit drug shortage impact

YNHHS Drug Shortage Management Process





BEFLESTION

YNHHS Drug Shortage Stewardship (DSS) Principles

vizient.

Responsible Protective Purchasing

Avoidance of anticipatory purchasing beyond routine patient needs

Partnership with GPO, wholesaler, manufacturers on supply reserve programs

Judicious Use of Essential Medications

Continuous
evaluation of
use of low-cost
medications
commonly on
shortage, even
when supply is
available

Contracting Strategy

Inclusion of supply guarantees/ failure to supply language

Strategic Partnerships

Participation on 503B and manufacturer clinical advisory committees

Education and Advocacy

C-suite education on drug shortages and mitigation efforts

Collaboration with State Legislators

Involvement in National Organizations





vizient.

OHSU HEALTH SYSTEM OVERVIEW

- Only academic health center in the state of Oregon
- Regional resource to SW Washington, Idaho, Montana, Alaska and northern California
- Four healthcare facilities:
 - OHSU Hospital
 - OHSU Doernbecher Children's Hospital
 - Hillsboro Medical Center
 - Adventist Health Portland
 - Future Legacy Health merger
 - Licensed beds: 572 (OHSU and Doernbecher)
- Knight Cancer Institution and Community Oncology Clinics

REFLECT

Oncology Scarce Drug and Its Impact on Patient Care



- Oncology drug supply chain disruptions
 - Backbone treatment for various oncology disease states with curative intent
 - Maziarz RT, Diaz A, Miklos DB, Shah NN. Perspective: An International Fludarabine Shortage: Supply Chain Issues Impacting Transplantation and Immune Effector Cell Therapy Delivery. Transplant Cell Ther. 2022 Aug 6:S2666-6367(22)01518-4. doi: 10.1016/j.jtct.2022.08.002. Epub ahead of print. PMID: 35940526.
- Alternatives are not better, sometimes worse
- Ethical dilemma on who to treat or redirect treatment and document justification on decision making process



How does a healthcare system navigate through scarce resources?

vizient.

- Start by asking questions
 - o Cause of scarcity?
 - Short-term or long-term?
 - O Which patient populations are impacted?
 - Who are the stakeholders?
 - OProtective purchasing?
 - o Investigational therapies involved?
 - O Alternate therapies?
 - ORedirecting patient care needs?



Benefits of an Oncology Stewardship Committee



- Standardize process to make key decisions
- Prioritization of therapy
- Anticipatory planning for critical decision points
- Transparency and communication
- Improves transition of care
- Senior executive awareness
- Media relations



OHSU Oncology Stewardship Charter



- Purpose: Stewardship Committee to plan and steward scarce oncology drugs while maintaining transparency, fairness and consistency
- Scope and Oversight: Oncology drugs
- Goals:
 - Identify and communicate to OHSU healthcare workers regarding oncology drugs in short supply and create a process whereby drugs are managed in a fair, consistent and transparent way
 - In collaboration with key stakeholders, supports final decision-making regarding alternative treatment options or allocation of scarce resources
 - o Provide standard structure to offer an opportunity for MDs to appeal decisions
- Membership: Oncology Division Head, Oncologists, Social Workers, Pharmacists, Nurses, Palliative Care Ethicist

Standard Work for Scarce Resources Oncology Agents



Tier 1: Watch and Wait

Condition: Supply Chain on Notice

Supply available for all patients

Communication to all impacted providers

Tier 2: Conservation

Condition: Loss of routine restock of drug supply

Supply is available for all patients

Communication to impacted providers and study teams of Tier 2 status

Adjustment to pharmacy operations

Engage stakeholders to create allocation flowchart for Tier 3

Tier 3: Treatment per allocation flowchart

Condition: Supply chain sporadic replenishment of drug, nationwide impact

Supply allocated to patient following treatment flowchart

Open request for exceptions consideration reviewed by Onc Stewardship Committee (OSC)

Tier 4: Strict Allocation with Randomization

Condition: Supply unstable

Declaration to randomize access

Eligible patients for randomization:

- •All patient who qualified in Tier 3
- •Open request for exceptions reviewed by OSC

Randomization
performed and providers
informed on outcome of
randomization for their
requested patient

Tier 5: Resource Exhausted

Condition: Supply unavailable

Inform all impacted groups

Remove from electronic health record

OSC ongoing monitoring

Vinblastine Shortage Nov 2023 – Jan 2024





Tier 1: Watch and Wait

11/15/2023

Inpatient stocked out on Vinblastine and borrowed from ambulatory supply

Wholesaler: Expected to release this week



Principles for Treatment, Allocation & Alternatives

Treatment flowchart drafted - literature review, national society blog experience

- Curative vs Palliative?
- Patient list generated MD required to make decision on alternative treatment options



Tier 4: Strict Allocation with Randomization

12/13/2023

Anticipate to run out of vinblastine supply completely.

No ability to randomize treatment with supply running out by 12/14/2024



Tier 3: Treatment per Allocation Flowchart

12/19/2023

Small emergency stock available to treat curative intent patient through 12/22/2023.



Tier 1: Watch and Wait

1/26/2024

Supply replinishing

11/29/2023

Wholesaler: ETA delayed to 12/22/2023. Not available. Reason unknown.

OSC informed and communication dispersed:

- Avoid loaning drug
- •Engage with stakeholders

Tier 2: Conservation

12/7/2023

9 vials available (90 mg total)

- •Total MG needed through 12/8/2023 96.66 mg
- •Total MG needed for week of 12/11/2023 101.86

Flowchart live – accepting reconsiderations

Tier 3: Treatment per Allocation Flowchart

12/14/2023

Active patients changed to alternate regimen void of vinblastine or delay treatment

Supply updated on semiweekly basis

Media relations communication points by OSC committee

Tier 5: Resource Exhausted

12/27/2023

Limited supply from wholesaler

Tier 2: Conservation

REFLESTION

Vinblastine Shortage Nov 2023 – Jan 2024



What's next?

- Root cause still unknown
- New Vinblastine Shortage announced June 2024
 - NCCN Best Practice Committee New Information and Survey Results from June 2024 57% reported shortage of vinblastine
 - Accessed: July 31, 2024 https://www.nccn.org/docs/default-source/oncology-policy-program/nccnbestpracticesdrugshortagesurvey.pdf?sfvrsn=b081351e-6

OHSU Oncology Stewardship Committee Vinblastine Shortage Statement Media Relations



Key Points

- Critical backbone to curative treatment of many disease states
- Timeline of shortage notification and why
- Current state impact to patients on treatment
- Standard work efforts underway to inform oncologist and informing patients
- Management strategies taken place
 - Avoidance of new starts
 - Changing of regimen
 - Direct care with patient including support of social workers
 - o Pharmacist supporting oncologist with treatment plan alterations



Lessons Learned



- Multidisciplinary standard work is critical to managing drug shortages.
- Transparency and frequent communication sets expectations for patient care.
- Incorporation of drug stewardship shortage principles allowed YNHHS
 to implement responsible protective purchasing practices and
 enhanced the ability to manage drug shortages.



- All pharmaceutical supply chain stakeholders are interconnected and play a critical role in reducing drug shortages.
- The creation of an oncology stewardship committee supports a process of equitable access to anti-cancer treatment in a transparent, fair and consistent way.
- Moving beyond policy and into real-time conversations with clinicians creates a system built on trust and ultimately creates a culture to successfully manage scare resources.

Thank You



- Kyle Hoelting, PharmD, BCPS
- Molly Leber, PharmD, MBA, BCPS, FASHP
- Members of the Vizient Member Drug Shortage Mitigation Group
- Members of the OHSU Oncology Stewardship Committee



Questions?







Contact:

Marina Yazdi, PharmD, BCPS, marina.yazdi@ynhh.org

Susie Jiing, PharmD, BCOP, jiings@ohsu.edu