

2024 VIZIENT CONNECTIONS SUMMIT

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Drug Shortage and Oncology Stewardship: Ensuring Equitable Access to Medications

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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

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Yale New Haven Health Drug Shortage Management

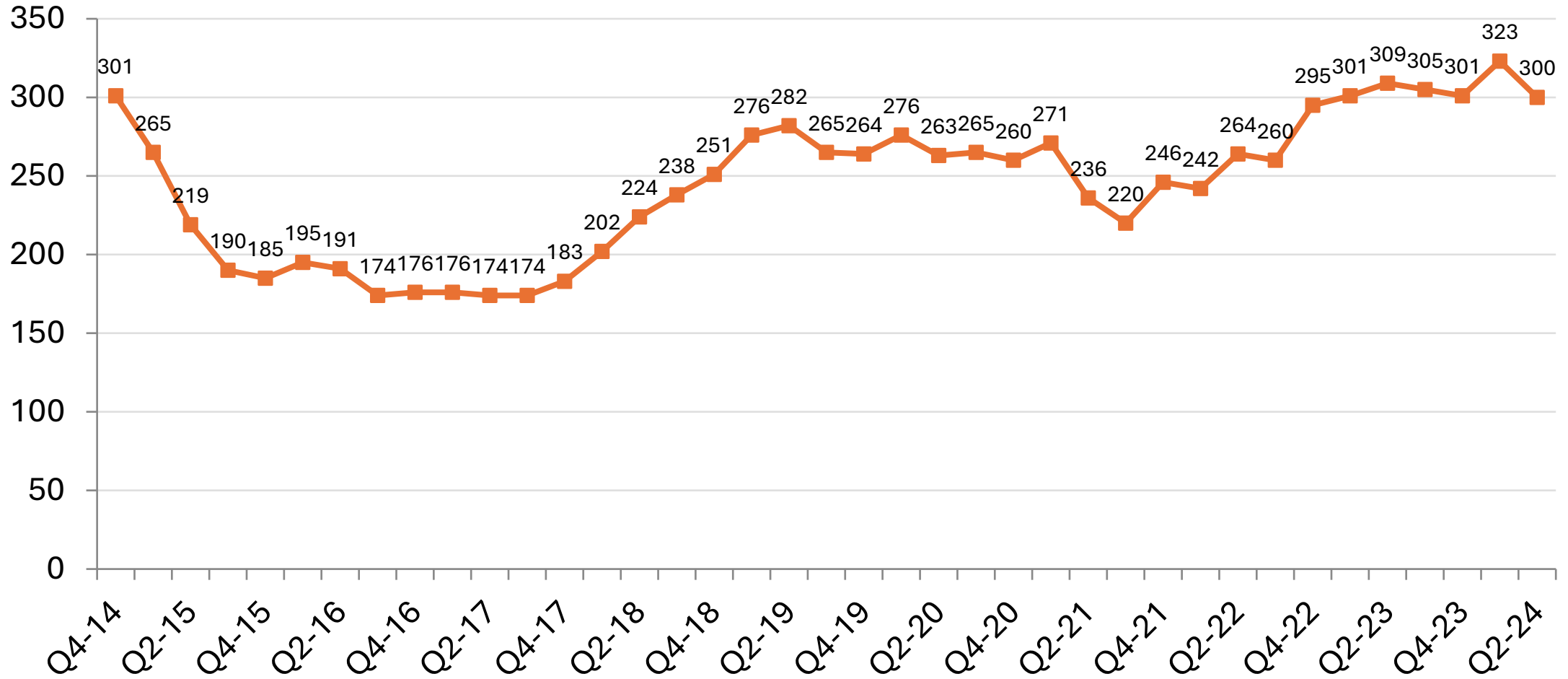


- Five Hospitals (2,681 licensed beds)
 - Yale New Haven Hospital
 - Bridgeport Hospital
 - Greenwich Hospital
 - Lawrence + Memorial Hospital
 - Westerly Hospital
- \$1.2B Pharmaceutical Expense
- Drug Shortage Management Program Established in 2011
 - System Oversight by Pharmacy Procurement Specialist
 - Multidisciplinary Team: Pharmacy Buyers, Clinical Pharmacy Specialists, Pharmacy Operations, P&T Committee, Digital Technology Services
 - Evaluation and continuous process improvement



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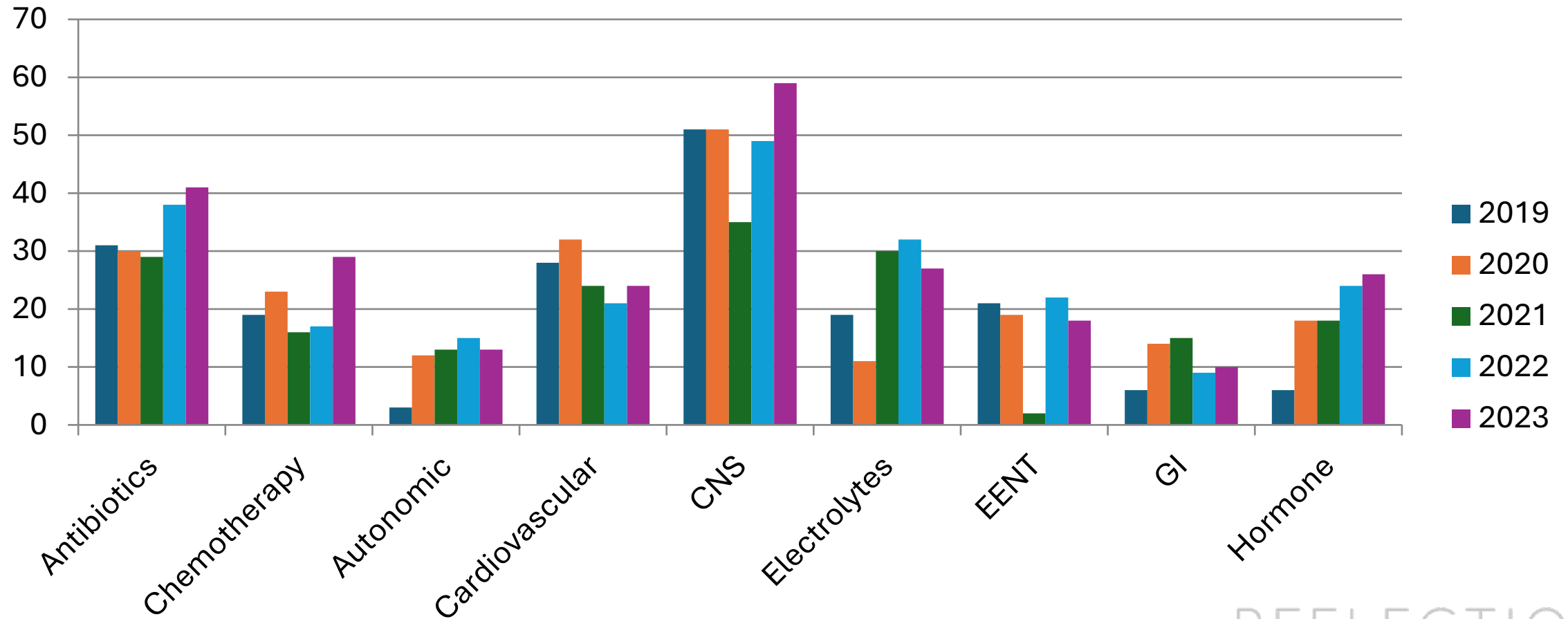
Drug Shortages Overview



University of Utah Drug Information Service

Common Drug Classes in Short Supply

5 Year Trend



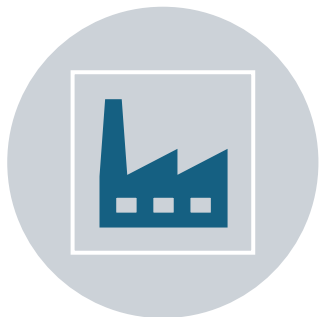
Major Drivers of Drug Shortages



Quality concerns/
regulatory agency
inspections



Limited drug suppliers and
manufacturer business
decisions

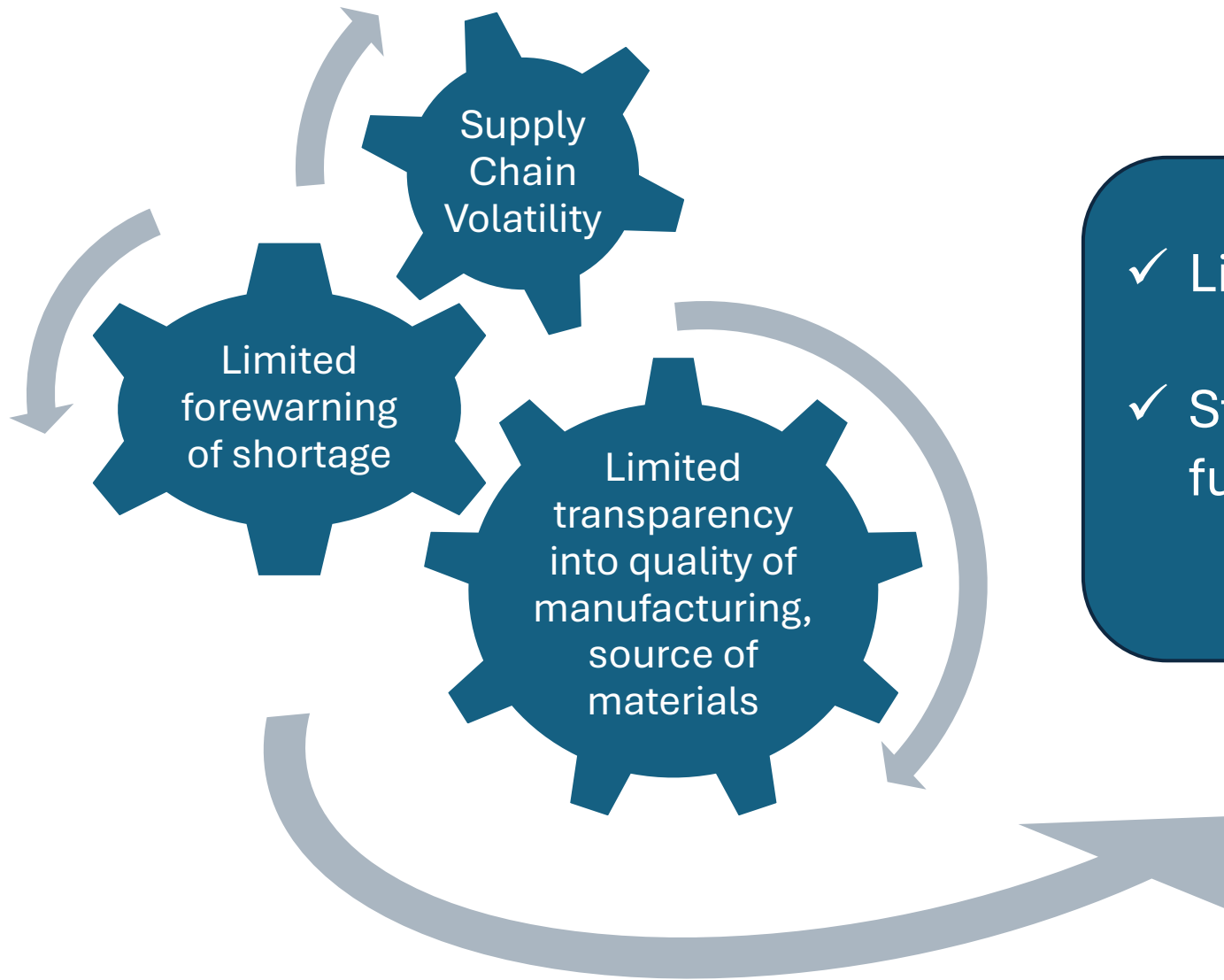


Inadequate supply of raw
materials



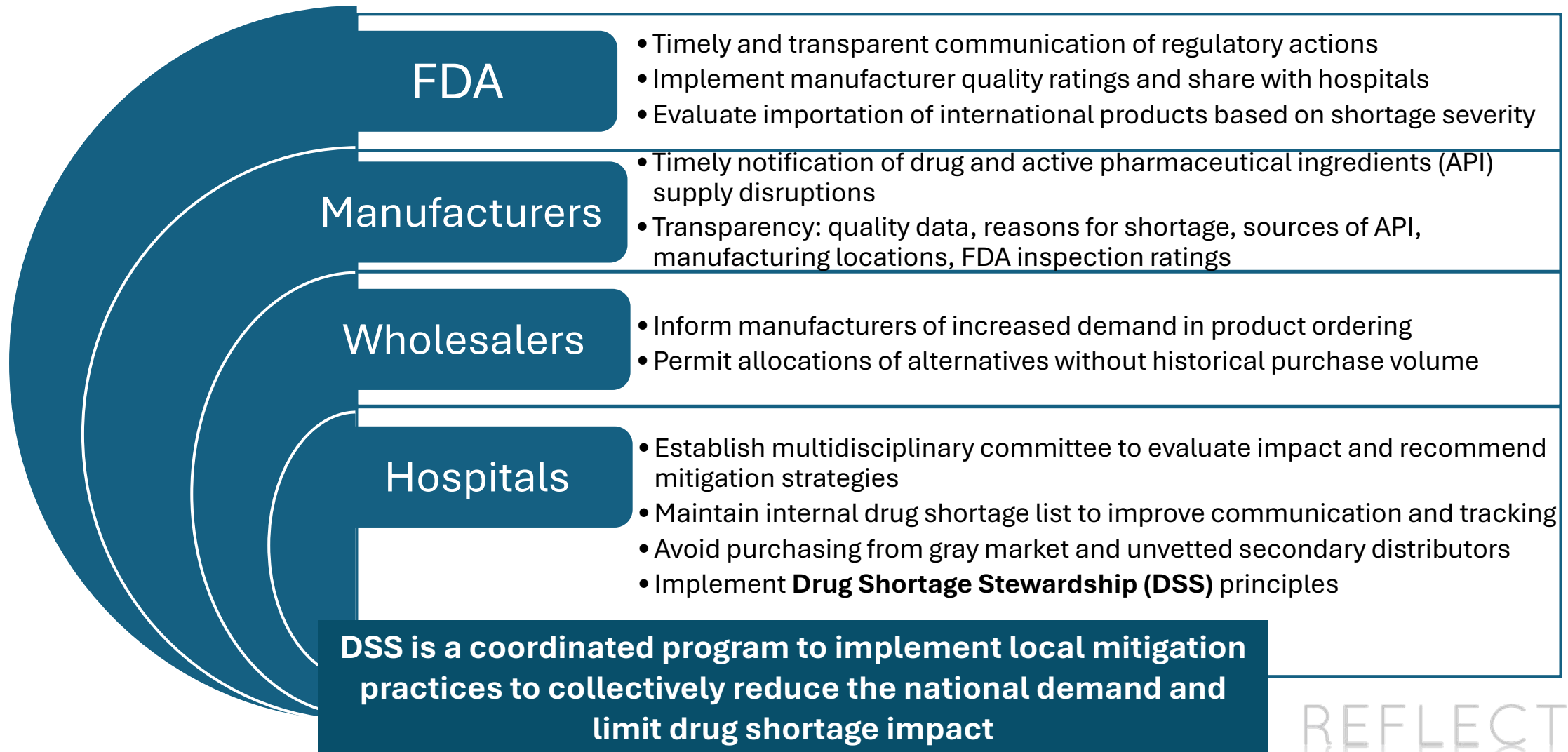
Demand/supply issues

Impact on Hospital Purchasing Practices

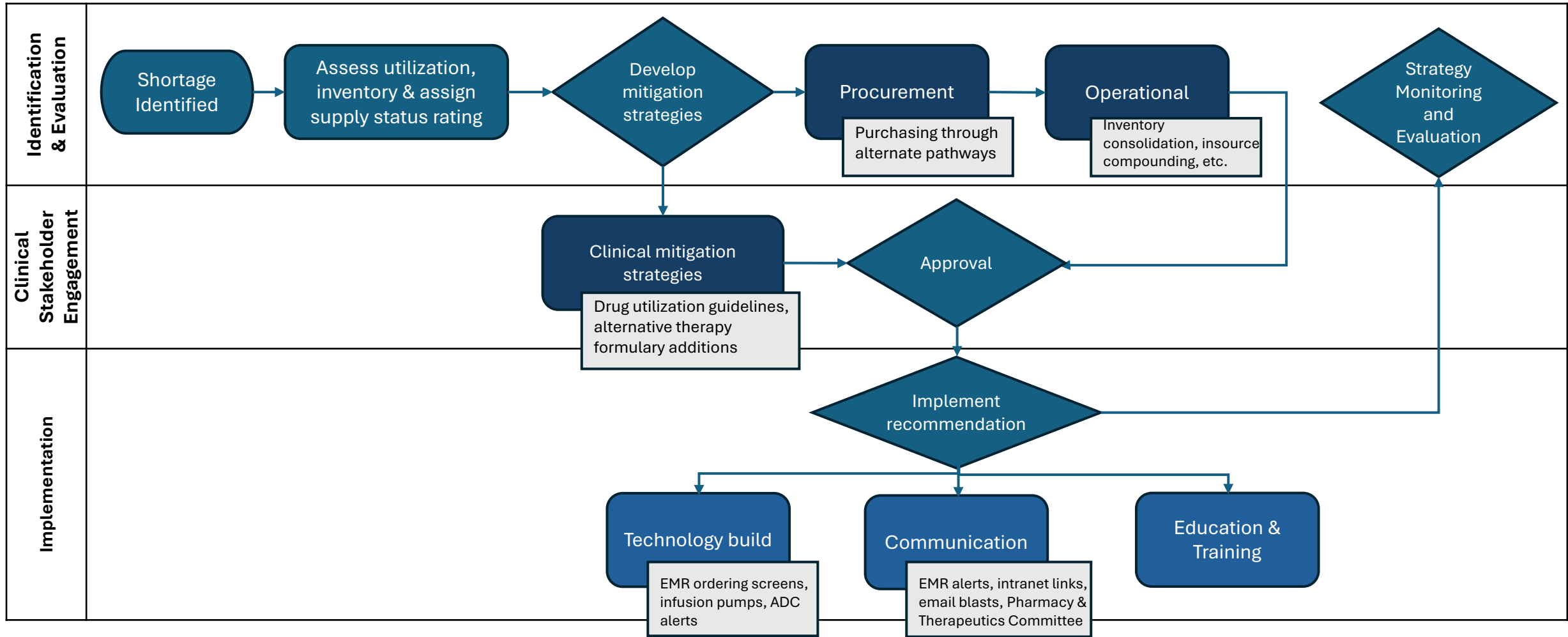


- ✓ Limited ability for predictive modeling
- ✓ Stockpiling/protective purchasing further aggregates supply challenges

What Can We Do?



YNHHS Drug Shortage Management Process



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YNHHS Drug Shortage Stewardship (DSS) Principles

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



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OHSU HEALTH

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

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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?

- Start by asking questions
 - Cause of scarcity?
 - Short-term or long-term?
 - Which patient populations are impacted?
 - Who are the stakeholders?
 - Protective purchasing?
 - Investigational therapies involved?
 - Alternate therapies?
 - Redirecting 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
 - 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

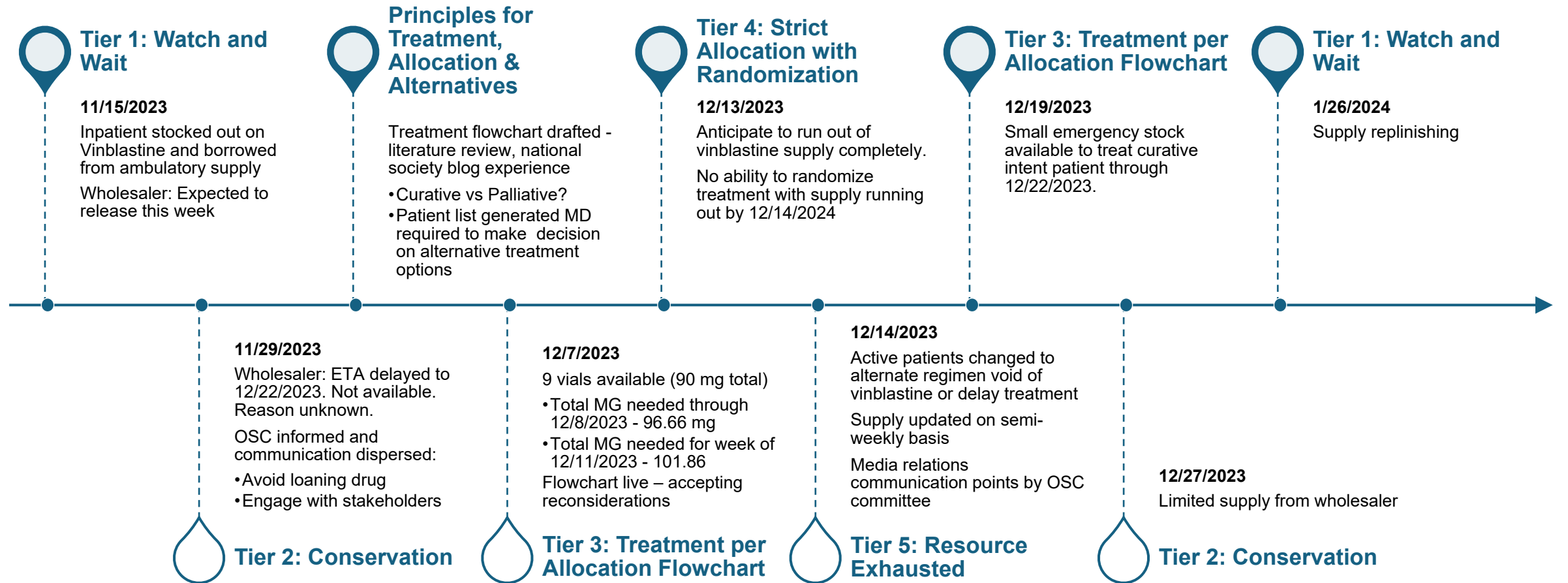
Condition: Supply unavailable

Inform all impacted groups

Remove from electronic health record

OSC ongoing monitoring

Vinblastine Shortage Nov 2023 – Jan 2024



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
 - 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.

Key Takeaways

- 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 scarce 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

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Questions?

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