



 **pshp** ANNUAL ASSEMBLY

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Creating Something Out of Nothing: Strategies to Mitigate Drug Shortages

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Disclosures

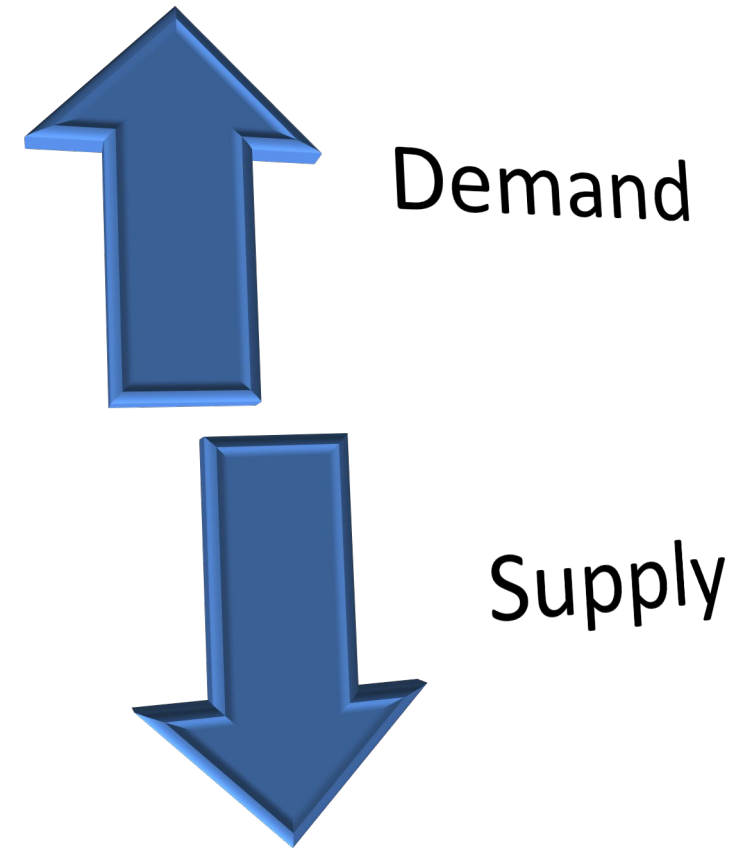
I have no relevant financial or nonfinancial relationships to disclose.

Learning Objectives

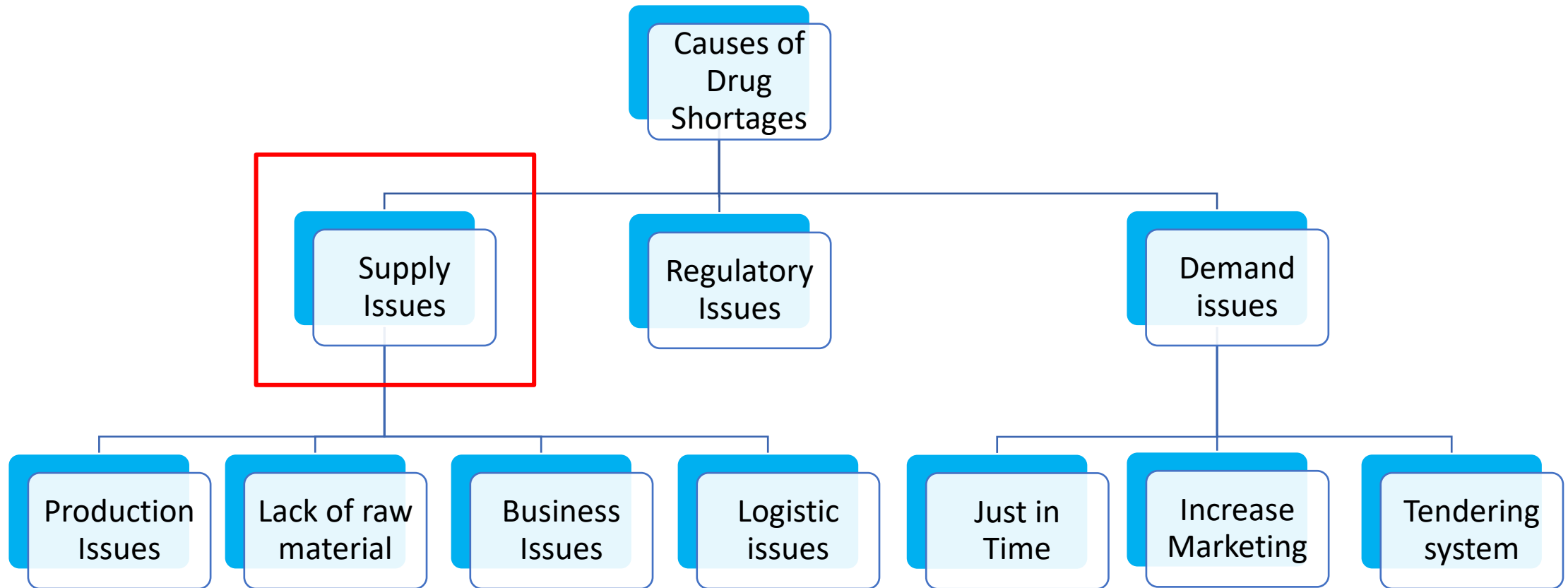
- Explain reasons for medication shortages
- Discuss implications of medication shortages on a health system
- Outline strategies to mitigate medication shortages

Drug Shortage Definition

- When the supply of medication is not able to meet the demand
- Anytime the supply affects how a medication is prepared, dispensed, or an alternative has to be used



Causes of Drug Shortages



Supply Issues

- Production Issues
 - Manufacturing and Quality Problems
 - Causes the majority of shortages
 - Failure of quality management

Supply Issues

- Shortages of APIs or Raw Materials
 - Inability to source APIs or raw materials
 - Other shortage causes can lead to this

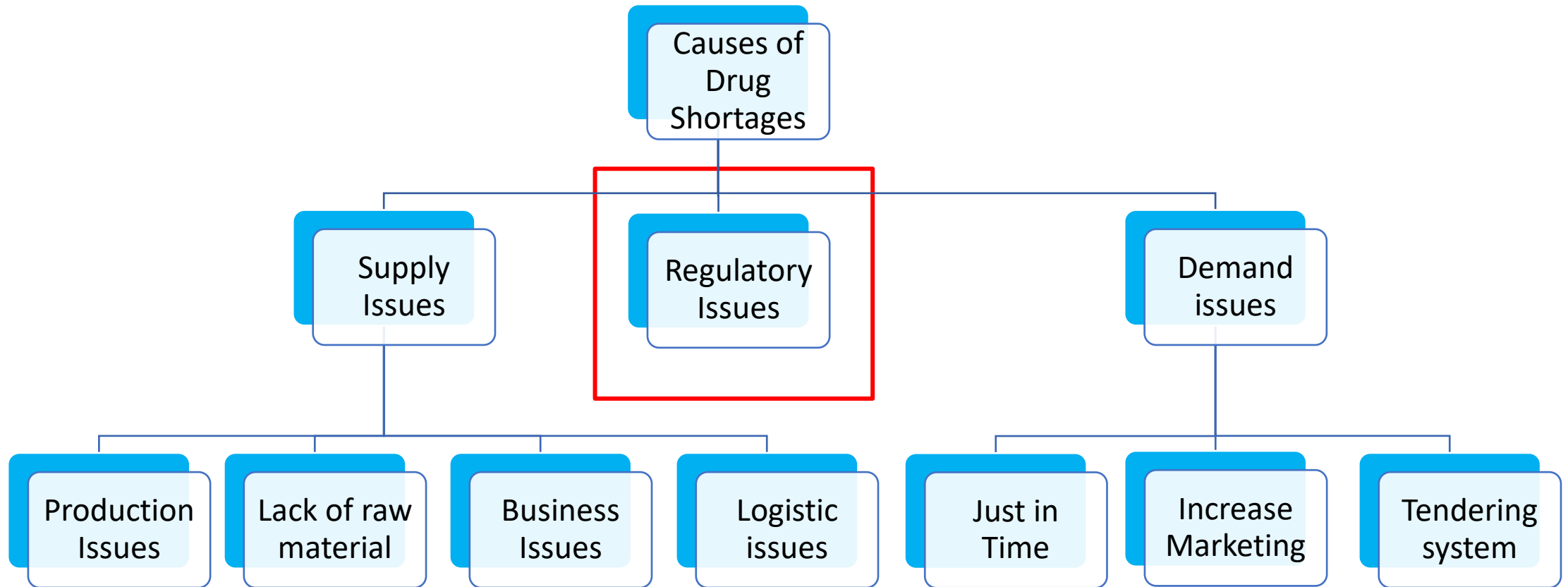
Supply Issues

- Manufacturer Business Decisions
 - Will a company continue to produce a medication
 - Availability of generic products
 - Market size
 - Patent expiration
 - Anticipated clinical demand

Supply Issues

- Logistic Issues
 - Production Delays and Lack of Capacity
 - Manufacturing capacity issues or delays

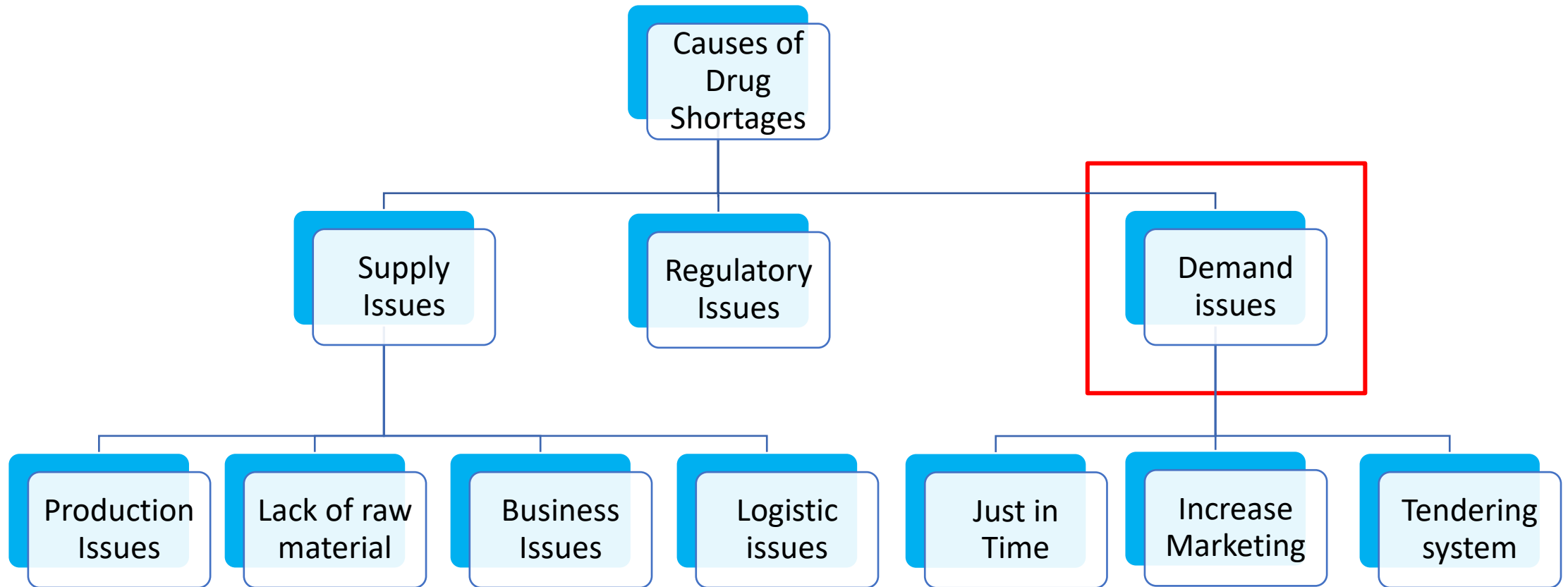
Causes of Drug Shortages



Regulatory Issues

- Regulatory Issues
 - Delay in certifications
 - Regulatory compliance requirements
 - Drug approval status

Causes of Drug Shortages



Demand Issues

- Just in time
 - Drugs are made just in time to meet demand
 - 503B companies

Demand Issues

- Increasing Market
 - Unexpected increase in demand for a medication due to guideline

Demand Issues

- Inventory Practices
 - Inventory reductions permitted by advanced communication and transportation efficiencies within the supply chain may amplify the effects of a shortage on healthcare organizations

Active Learning Question 1

What cause of medication shortages is related to supply issues?

- A. Raw material shortage
- B. New FDA restrictions
- C. Discontinuation of Product
- D. New guidelines causing an increase in demand

Staying Up to Date

Where to monitor for updates

- Manufacturer website
- FDA (U.S. Food and Drug Administration)
- ASHP (American Society of Health-System Pharmacists)
- Wholesaler updates

Manufacturer website

- Larger manufacturers are able list out product availability on website

SUPPLY AVAILABLE	Levetiracetam Injection, USP	1 SKU(s) in product family Unit of Sale NDC numbers for low inventory or out of stock SKUs 00409-1886-02	☆
SUPPLY AVAILABLE LIMITED SUPPLY	Levofloxacin in 5% Dextrose Injection	3 SKU(s) in product family Unit of Sale NDC numbers for low inventory or out of stock SKUs 00409-0528-15 00409-0528-25 00409-0528-35	☆
SUPPLY AVAILABLE	Levophed™ (Norepinephrine Bitartrate Injection, USP)	1 SKU(s) in product family Unit of Sale NDC numbers for low inventory or out of stock SKUs 00409-3375-04	☆
DEPLETED	Lidocaine Hydrochloride and Epinephrine Injection, USP (Lidocaine and Epinephrine 1:100,000)	6 SKU(s) in product family Unit of Sale NDC numbers for low inventory or out of stock SKUs 00409-3178-01 00409-3178-02 00409-3178-03 00409-3182-01 00409-3182-02 00409-3182-03	☆

Retrieved from: <https://www.pfizerhospitalus.com/products>

FDA

- Drug Shortages | FDA

Current and Resolved Drug Shortages and Discontinuations Reported to FDA

[Report a Drug Shortage](#) | [Contact Us](#) | [FAQ](#) | [Background Info](#) | [Get Email Alerts](#) | [Download Current Drug Shortages](#)

Search by Generic Name or Active Ingredient:

Current/Resolved Shortages

Discontinuations

Therapeutic Categories

New and Updated

A drug receives Resolved status when the Drug Shortages Staff (DSS) determines that the market is covered, based on information from all manufacturers. The market is considered covered when supply is available from at least one manufacturer to cover total market demand. However, some manufacturers may not have all presentations available. DSS monitors the supply of products with Resolved status. For the most current supply information, contact the manufacturers.

Show entries

Search:

Generic Name or Active Ingredient	Status
	Currently in Shortage
Acetazolamide Injection	Resolved

Retrieved from: <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>

ASHP

Drug Shortages List

[VIEW RELATED LINKS](#) ↓

ALL DRUG SHORTAGE BULLETINS

Entries:

Search:

GENERIC NAME	SHORTAGE STATUS	REVISION DATE
0.45% Sodium Chloride Injection Bags	Resolved Shortages	May 26, 2016
0.9% Sodium Chloride 10 mL, 20 mL, and 50 mL Preservative Free Vials and Syringes	Resolved Shortages	Aug 19, 2019

Retrieved from: <https://www.ashp.org/shortages>

Wholesaler updates

- Will list estimated release of more product
- Allocation to equally distribute supply
- Having a primary and secondary wholesaler may be needed

Active Learning Question 2

Where can you find up to date shortage information?

- A. FDA website
- B. ASHP website
- C. Directly from manufacturer
- D. All of the above

Creating a system to monitor and implement change

Overall Monitoring

- Create a monitoring system
- Meet with purchaser
- Electronic monitor inventory system to detect any issues

Mitigation Strategies

- Management of current medication shortages
- Improvement of operations
- Changes in government policies
- Education and training

Management of current shortages

Restrictions on use

Use products with minor defects

Increase expiration date

Redistribute available stock

Waste Management

Improvement of operations

Increase communication

Use of reporting/tracking

Obtain from multiple suppliers

Manufacture own supply

Changes in Policy

Changes in government programs

Advance notification systems

National guidance

Pricing

Expedited drug review

Educational and Training

Internal education

Updating EMR

Tracking previous changes

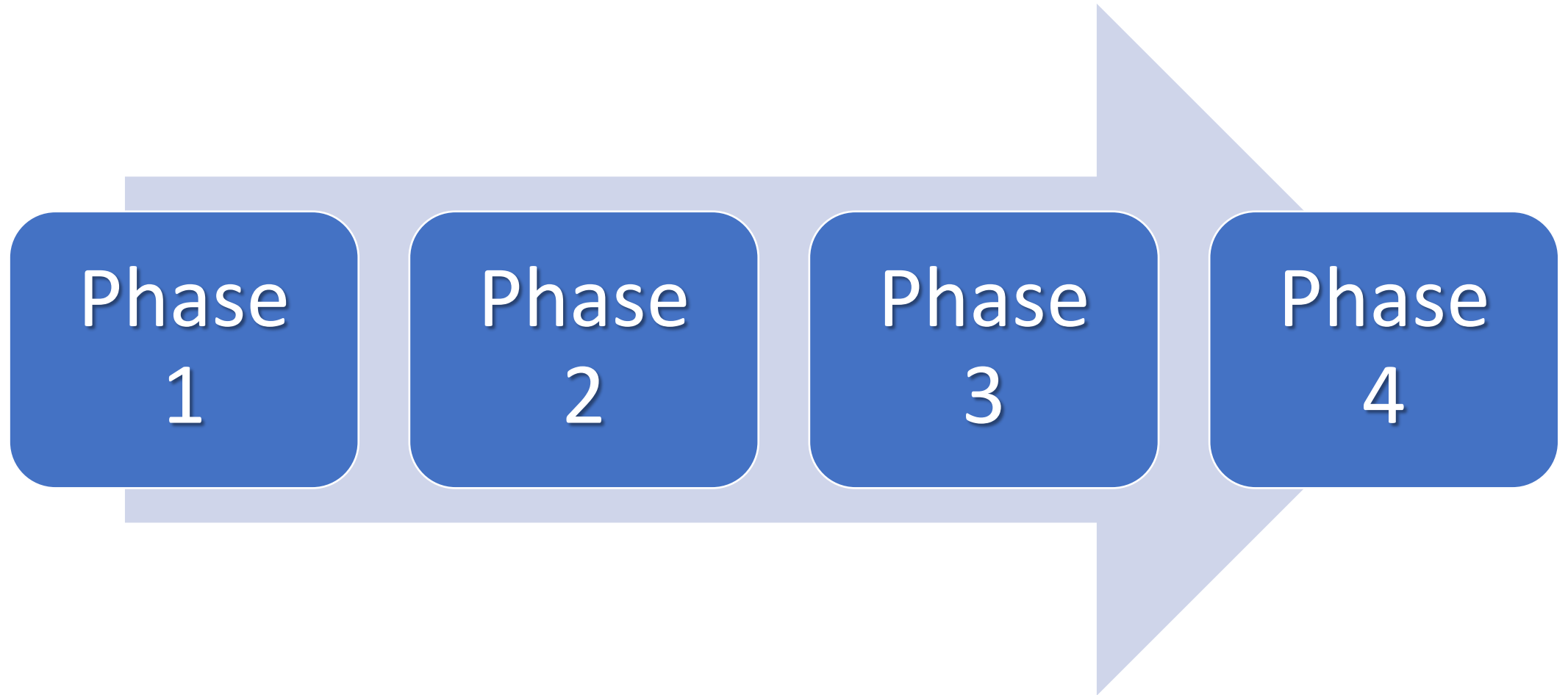
Dispersing information

Active Learning Question 3

Do you meet regularly at your institution to discuss medication shortages?

- A. Yes
- B. Yes, but not regularly
- C. No

Planning in Phases



Phase 1

- Potential shortage identified
- Start monitoring for upcoming and emerging medication shortages
- Pharmacy quantifying supply on hand and usage

Phase 2

- Notify the identified clinical leads in affected areas
 - Occurs when 4-6 weeks of supply remaining
- Begin to strategize a reduction of use and
- Identify alternatives
- Research and design strategy to maintain clinical operations

Phase 3

- Reduction of use or alternative agent plan should be implemented
 - Occurs when 4 weeks of supply remaining
- Clear communication to frontline clinicians and departmental leadership likely to be affected by the shortage
- Communication should continue regularly until supply is restored

Phase 4

- Critical Shortage Phase
- 2 weeks of supply remaining
 - Further mitigation and reduction strategy
- Restrict access to supply



Helpful Tips

Helpful Tips

- Communication is key
 - The earlier everyone is aware, the better the outcome
- Use internet resources to track information
- Consider formulary alternatives

Helpful Tips

- Consider adding therapeutic alternatives to the formulary.
- Order medications from more than one source
- Order as early as possible

Helpful Tips

- Look at all the available options when ordering online
- When changing remember to thoroughly review the new product
- Consider obtaining medications from another facility

Summary

- Know where to look
- Create a clearly outlined monitoring system
- Make sure you are planning for the worse case
- Communication is Key!



Questions

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