

The Multidisciplinary Impact of Drug Shortages in an Acute Care Setting

A presentation for HealthTrust members

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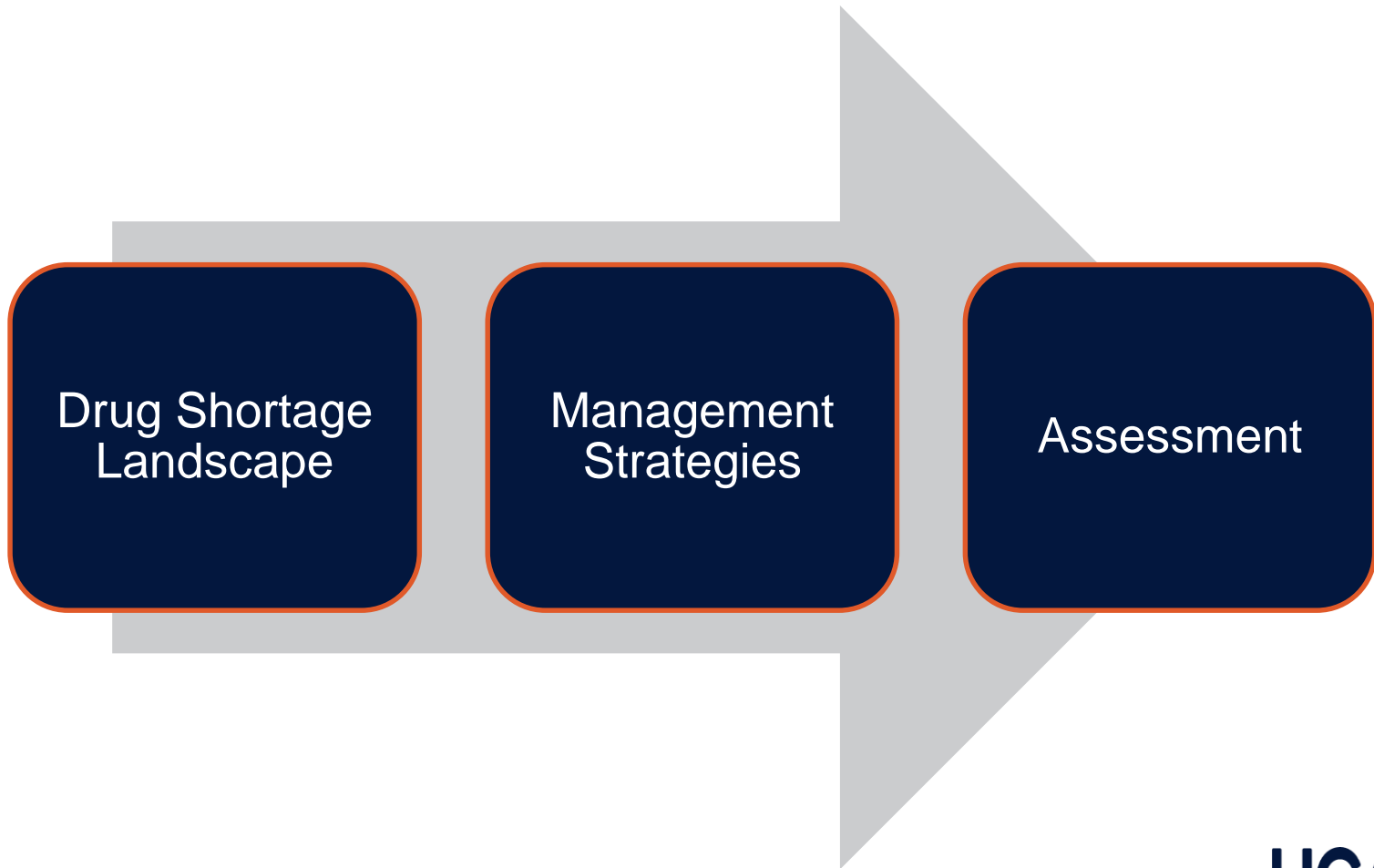
Pharmacist & Supply Chain Objectives

- Describe the impact of drug shortages on a multidisciplinary team
- Identify management strategies to mitigate the operational, clinical and financial outcomes
- Assess the state of current practice to determine potential gaps

Pharmacy Technician Objectives

- Define the drug shortage landscape and the impact that it has on the acute care setting
- Recall strategies to help minimize the impact of drug shortages on the acute care setting

Roadmap



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Drug Shortage Landscape & Impact

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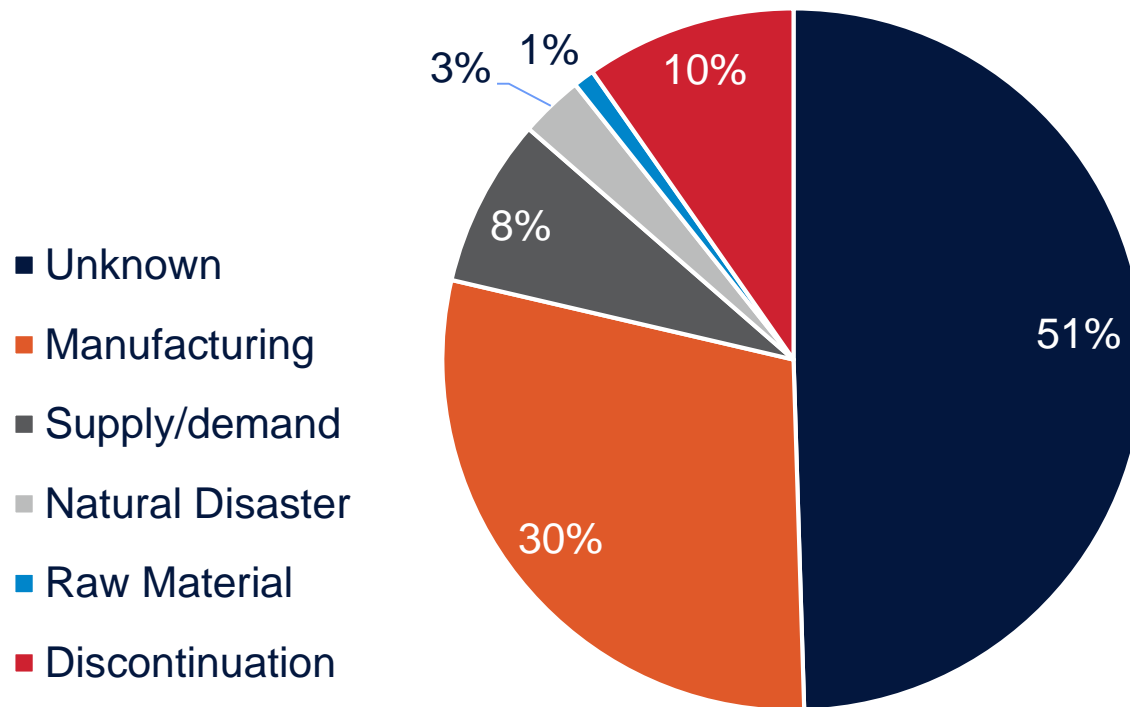
Drug Shortage

- Definition
 - Supply issue that affects preparation or dispensing
 - OR
 - Prescribing an alternative agent due to a shortage which influences the care of a patient

Factors Affecting the Drug Shortage	
Manufacturing:	Production of raw material
Production delays	Restricted distribution
Quality concerns	Inventory practices
Lack of capacity	Regulators
Business decisions	Distributors/wholesalers

Reasons for Drug Shortages

Reasons for Drug Shortages as reported by manufacturers



Source: <https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics>

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Drug Shortages – State of the Union

- 2018 ISMP Survey with nearly 300 respondents representing various types of inpatient settings
 - 56% community, 21% teaching, 9% critical access & 10% specialty hospitals
- More than half of respondents reported at least 20 drugs were involved with shortages in the preceding 6 months
- Shortages were reported across all treatment categories:
 - Emergency, anesthesia, pain management, infectious diseases & cardiovascular
 - More than half of respondents experienced drug shortages affecting parenteral nutrition (55%)
 - OB/GYN & Hematology/Oncology service lines were also commonly affected

Sources: <https://www.ismp.org/resources/drug-shortages-continue-compromise-patient-care>

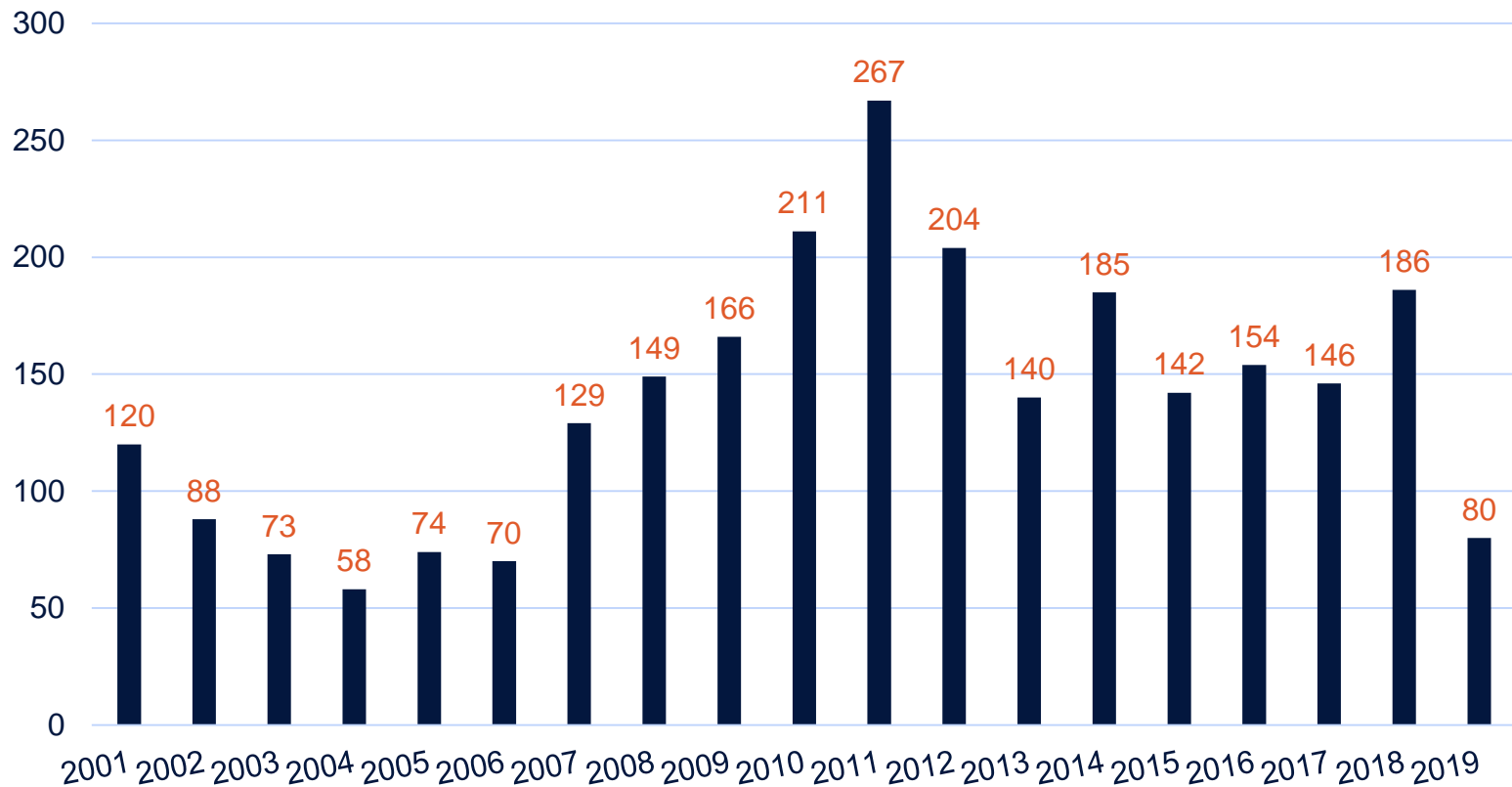
ISMP: Institute for Safe Medication Practices

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Drug Shortages – By the Numbers

Annual New Shortages by Year
(2001 through June 30, 2019)

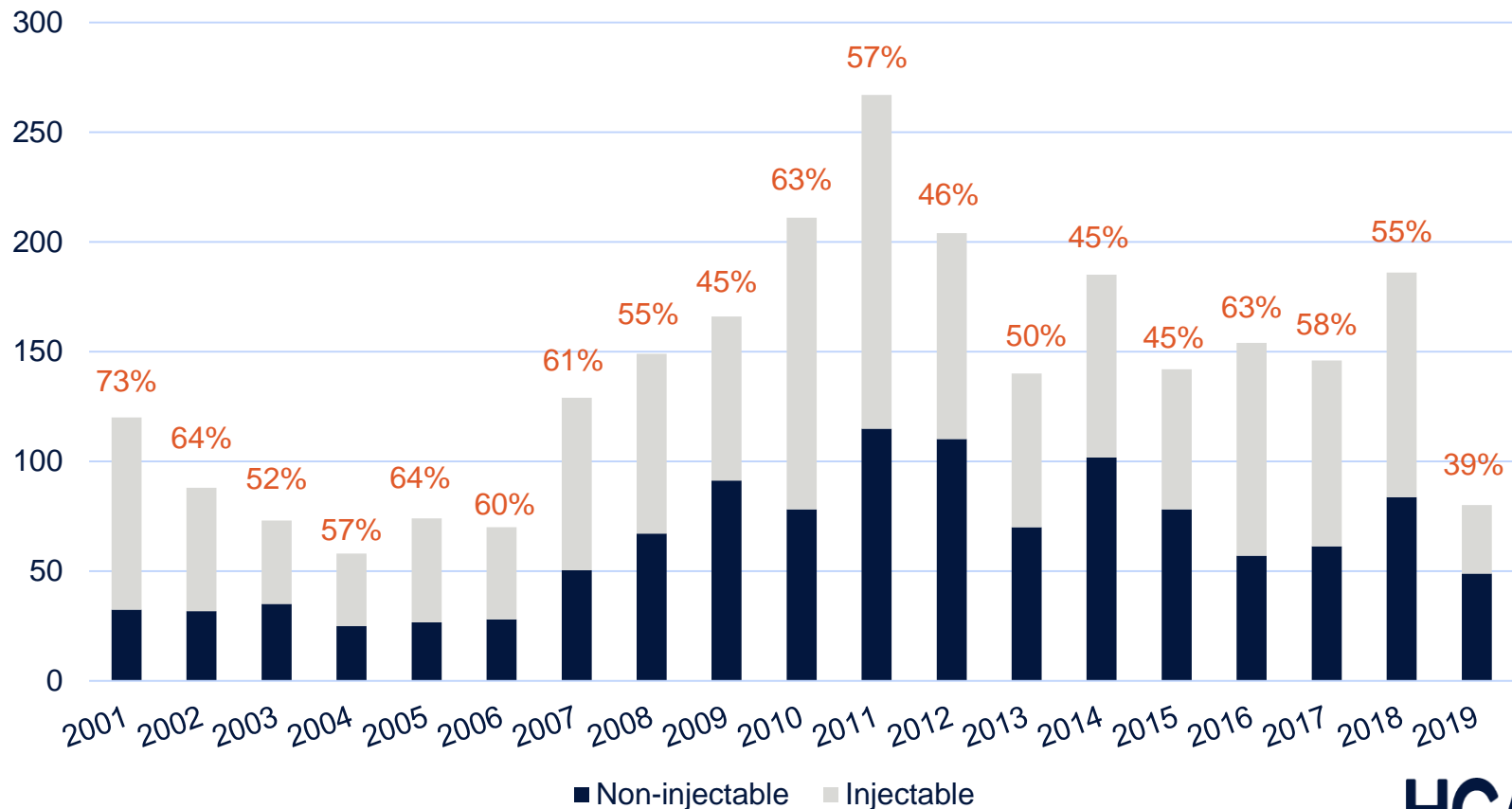


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Drug Shortages – By the Numbers

Annual New Shortages by Year – Percent Injectable
(2001 through June 30, 2019)

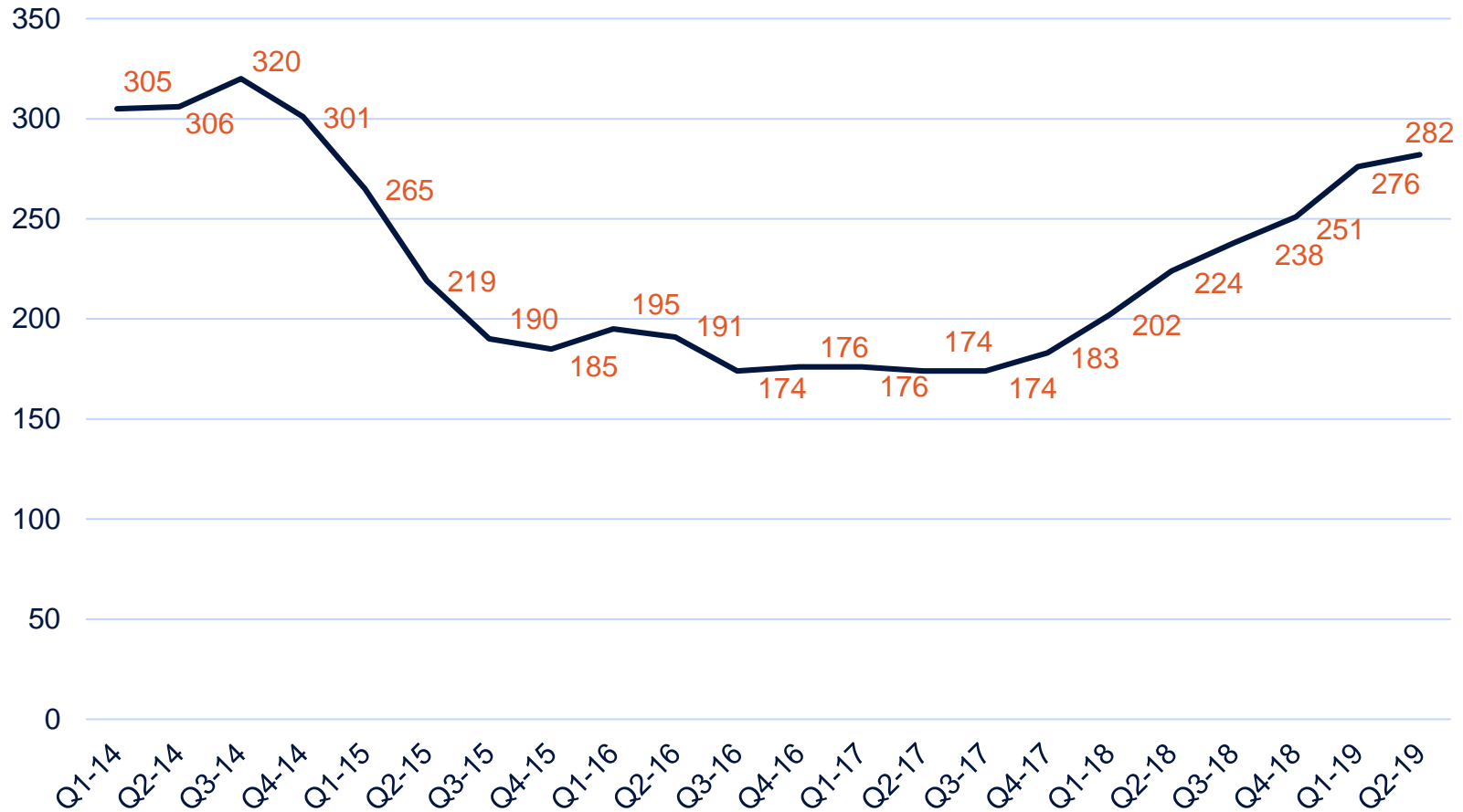


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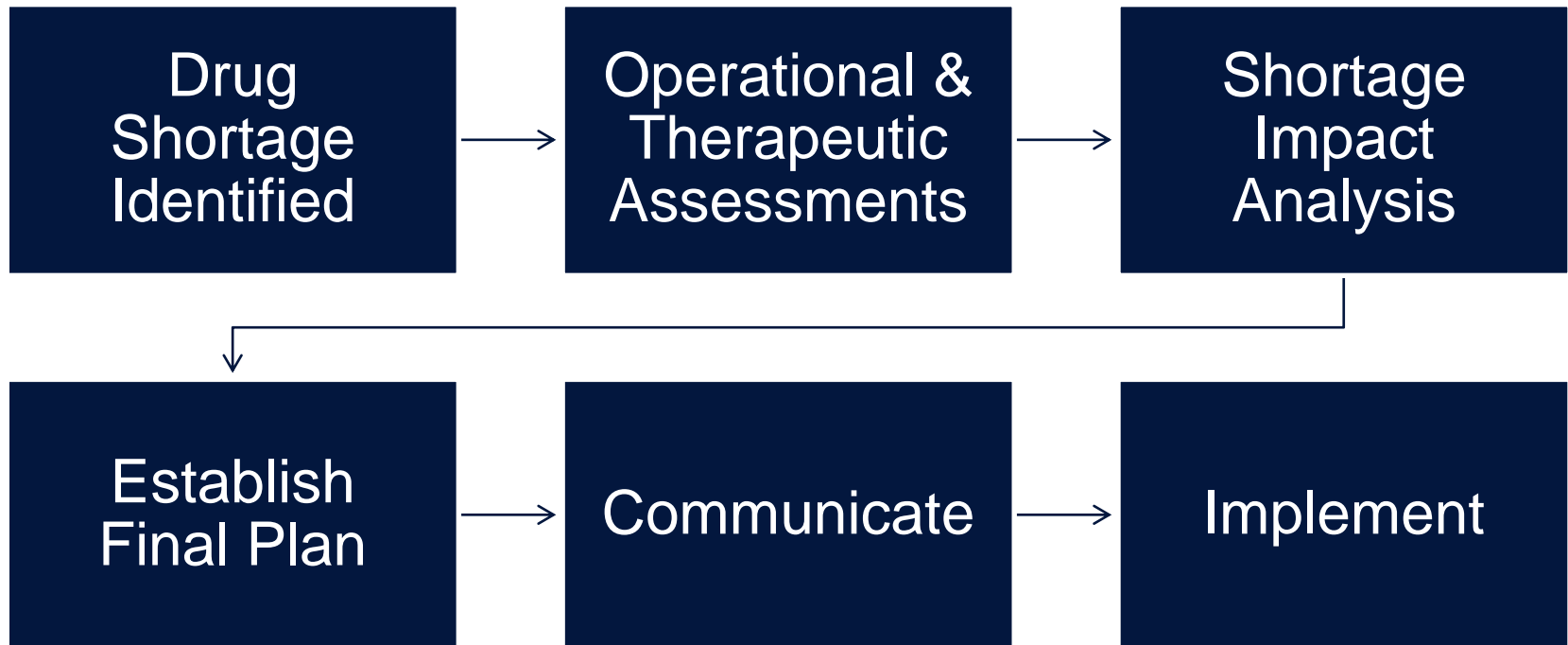


Drug Shortages – By the Numbers

Active Drug Shortages by Quarter



Decision Making Process



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Management Strategies: Operational

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Management Strategies

- Establishment of a Drug Shortage Team
 - Multidisciplinary
 - Include key stakeholders
 - Activities
 - Data gathering
 - Monitoring
 - Storage and preparation considerations
 - Dispensing procedures
 - Conservation strategies
 - Technology changes
- Develop a process for approving alternative agents

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Management Strategies



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Management Strategies

- Validate details
 - Determine details and the shortage duration
 - The team may contact distributors, manufacturers, Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC)
 - The status of a shortage may change quickly
 - Frequent communication with manufacturers may be required
- Determine stock
 - Assess the on-hand inventory
 - Estimate the time period the drugs will cover

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Management Strategies

- Purchase history
- Estimate impact
 - Estimate the time for the drug shortage to impact the facility
 - Convert counts of inventory into common measurements such as days of therapy or common dose
- Alternative sources
 - Quantify the supply from other predetermined alternative sources
- Alternative agent
 - Determine alternative drug products' supply

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Management Strategies

- Therapeutic assessment
 - A therapeutic assessment should be done at the same time as the operation assessment
 - Identify the patient population(s) being affected
 - Identify therapeutic alternatives
 - Assess inventory to assure the supply meets the new demand
 - Establish a process for expediting formulary additions, if needed

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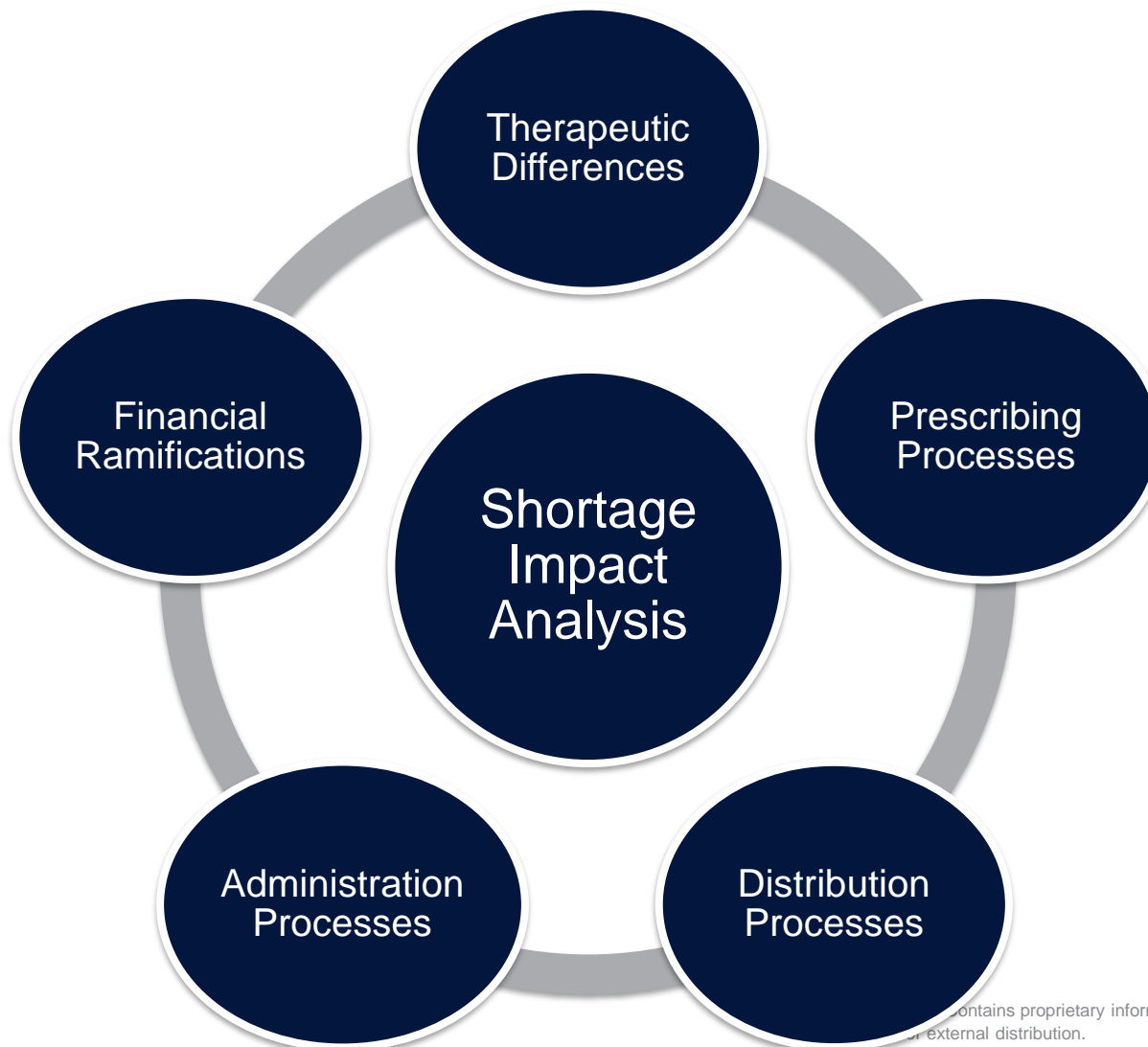
Management Strategies

- Conduct a shortage impact analysis to determine the impact on patient care
 - Analysis evaluates all factors pertinent to the shortage
 - Duration
 - Inventory
 - Medical necessity
 - Patient populations affected
 - Alternative therapies

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Management Strategies

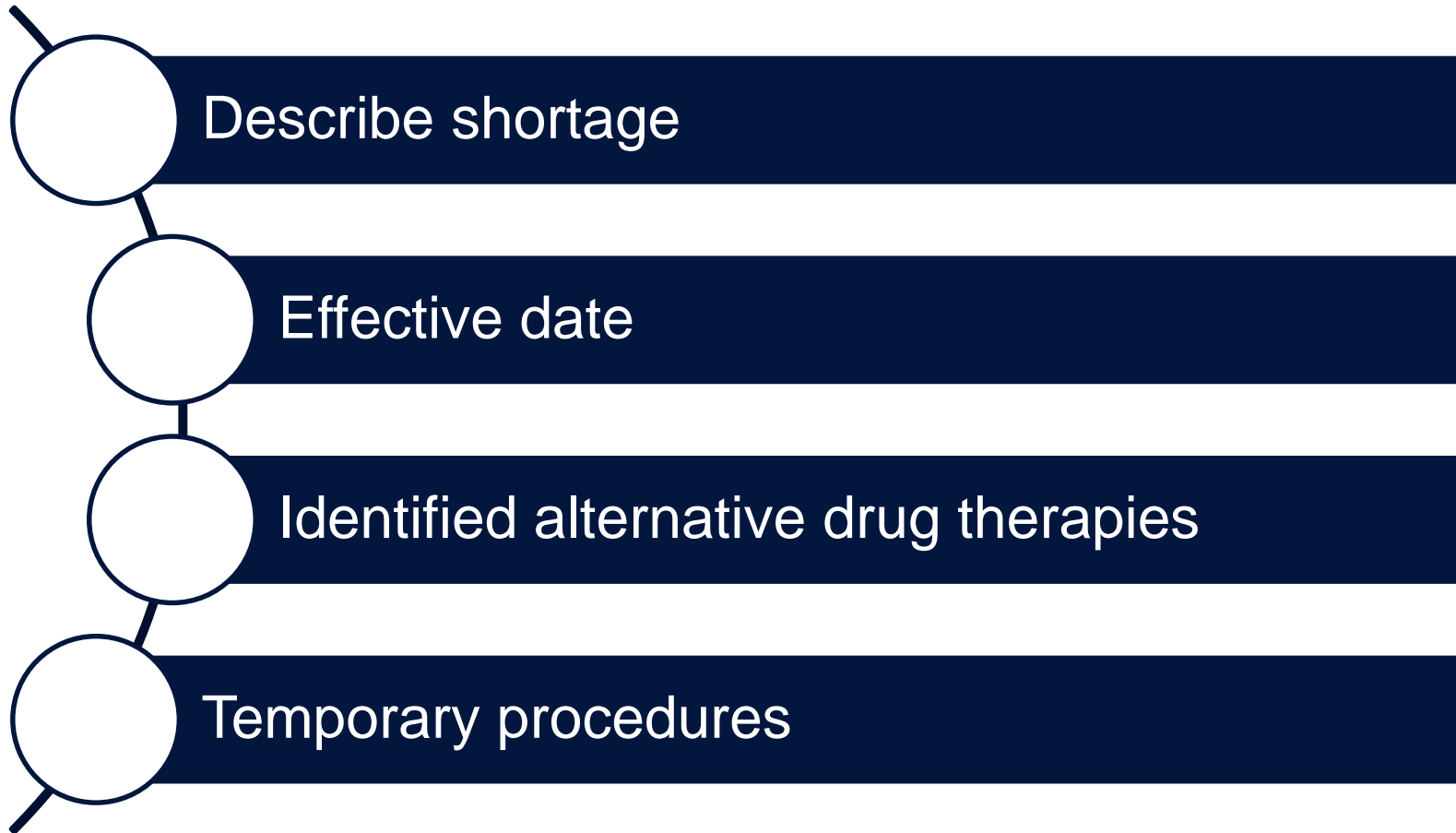


²¹ Source: *Am J Health-Syst Pharm.* 2018; 75:e593- 601.

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Communication

Clear communication with affected clinicians



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Communication

- Multiple communications versus one communication is better
- Electronic Health Records (EHRs) may be able to assist in communication with prescribers at the time of drug ordering
- Prospectively share both confirmed and anticipated drug shortages to allow appropriate preparation
- All shifts should receive the same communication

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Communication

Providers

- Face-to-face
- Physician Lounge
- Email/Fax blasts
- Routine touchpoints

Nursing, Supply Chain, Clinical Staff

- Shortage alerts or memos
- Huddles
- Staff meetings
- Leadership meetings
- E-mail

Pharmacy

- Shortage alerts or memos
- Staff meetings
- Huddles
- E-mail

Administration

- Shortage alerts or memos
- Shortage meetings
- Status reports
- Staffing needs

Management Strategies: Clinical

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Therapeutic Assessment: What is it?

- Occurs simultaneously with the operations assessment
- Integral part of the communication you will have with the key stakeholders
- Identify primary patient population(s) affected by the drug shortage
- Research conservation strategies & potential alternatives
- Prepare for resistance

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Therapeutic Assessment



Patient Safety Impact

- Shortages impact patient care in a real way
 - 71% of respondents believed patients were unable to get the recommended drug due to shortages
 - 47% of respondents felt this resulted in patients receiving a less effective drug
 - 75% reported delays in treatment due to drug shortages
- Shortages predispose healthcare personnel to participate in unsafe medication practices
 - Due to changes in ordering, preparing, dispensing & administering

Patient Safety Impact

- Drug shortages contribute to medication errors

EPINEPHrine 1 mg/mL vial was used to prepare and administer an IV dose; the drug was not diluted, and wrong dose was administered

A multiple dose vial with a preservative was used to prepare an epidural infusion when preservative-free bupivacaine with EPINEPHrine was unavailable

1 mL vials of morphine 10 mg were dispensed when 2 mg vials were unavailable; 10 mg IV was administered in error

Patient received no treatment when a drug known to be unavailable was ordered verbally and the nurse did not notify the pharmacy about the order or request an alternative

Potassium chloride small volume piggybacks were prepared at the wrong concentration and administered

Patient Safety Impact



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Capitalize on Opportunities

Failed attempts to implement a new clinical initiative

Drug shortage necessitates implementation of a clinical initiative to preserve available supply

Continue with the initiative after the shortage has resolved

Fixed Dose 4F- PCC Implementation

- FDA-approved dosing is based on patient weight and INR values¹

Pretreatment INR	2 to <4	4 to 6	>6
Dose (units Factor IX activity)/kg body weight	25	35	50
Maximum Dose (units Factor IX activity)	2500	3500	5000

- Literature suggests that lower doses may be similarly effective for warfarin reversal²⁻⁵
 - 1000 – 1500 units (up to 2000 units maximum)

Sources:

1. Kcentra [package insert], CSL Behring
2. Am J Emerg Med. 2015;33(9):1213-8
3. J Am Coll Cardiol. 2017;70(24):3042-3067.
4. J Emerg Med. 2018;54(6):861-866.
5. J Thromb Thrombolysis. 2018;45(2):300-305.

4F-PCC: 4-Factor Prothrombin Complex Concentrate
INR: International Normalized Ratio

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Next Steps

- Check whether or not any policies and procedures need to be modified to accommodate the plan for the shortage
- Ensure orders and order sets are modified
- Develop any necessary education

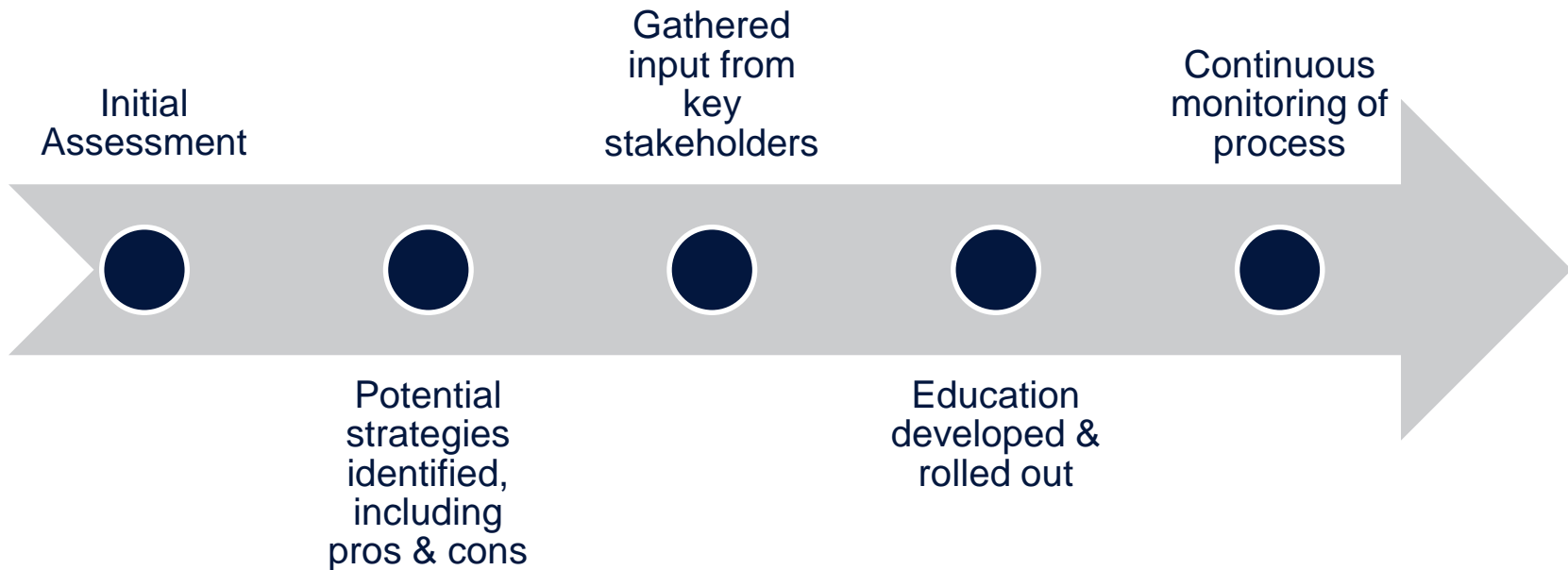
Emergency Syringe Shortages

- Early 2019: Epinephrine 1 mg/10 mL abboject syringes go on shortage
 - Step 1: Assess indications for use, patient population(s)/nursing units/physician groups affected
 - Step 2: Identify potential management strategies
 - Step 3: Get input from key stakeholders
 - Step 4: Develop & roll out education
 - Step 5: Continuous monitoring of proposed solution



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Therapeutic Assessment Steps



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Management Strategies: Financial

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Off-contract options

Alternative agents may be more expensive

Labor of drug shortage team

Labor to modify technology

Direct Costs

Indirect Costs

Increased Costs

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Labor Costs

\$359 million/year

Expand access
to medications

Research
strategies

Attend shortage
meetings

Review
alternatives

Redistribute
medications

Update EHR

Update infusion
pumps

Communication

Sources: Lagasse, J. (2019, June 26). Drug shortages cost hospitals close to \$360 million annually in labor expenses. Retrieved from: <https://www.healthcarefinancenews.com/news/drug-shortages-cost-hospitals-close-360-million-annually-labor-expenses>

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Time Spent

- 8.6 million hours spent on labor

Hours spent each week (average)	
Buyers	12 hours
Pharmacists	9.3 hours
Pharmacy technicians	7.6 hours
Informatics pharmacists	3.8 hours
Nurses	1.7 hours
Physicians	1.4 hours
Financial office	1.3 hours

Sources: Lagasse, J. (2019, June 26). Drug shortages cost hospitals close to \$360 million annually in labor expenses. Retrieved from: <https://www.healthcarefinancenews.com/news/drug-shortages-cost-hospitals-close-360-million-annually-labor-expenses>

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Financial Impact of Drug Shortages

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Drug shortages cost hospitals close to \$360 million annually in labor expenses

Controlled substances, local anesthetics and antibiotics are among the most common drug categories where shortages had an impact.



Jeff Lagasse, Associate Editor



Sourcess: Lagasse, J. (2019, June 26). Drug shortages cost hospitals close to \$360 million annually in labor expenses. Retrieved from: <https://www.healthcarefinancenews.com/news/drug-shortages-cost-hospitals-close-360-million-annually-labor-expenses>

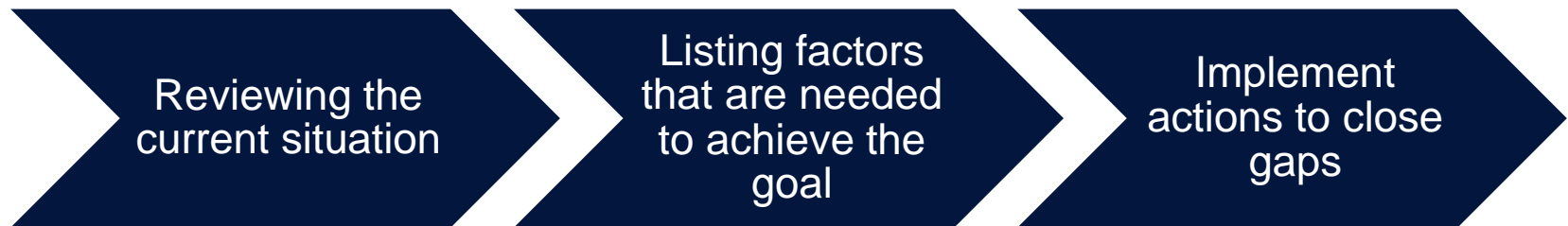
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Gap Analysis

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Gap Analysis

- Determines the steps that are needed in order to move to the desired goal
- Gap analysis consists of:



Source: *Business Dictionary*. 2019.

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Example: Gap Analysis

Objective	Opportunity (Y/N)	Actions	Comments
Has a Drug Shortage Team been developed?			
A process exists for identifying a drug shortages.			
Operational assessments are performed when a drug shortage is identified.			
A therapeutic assessment is performed when a drug shortage is identified.			
A drug shortage impact analysis is performed when a drug shortage is identified.			
An implementation plan includes new procedures, system and technology changes.			
A communication plan is developed when there are drug shortages.			

Source: *Am J Health-Syst Pharm.* 2018; 75:e593- 601.

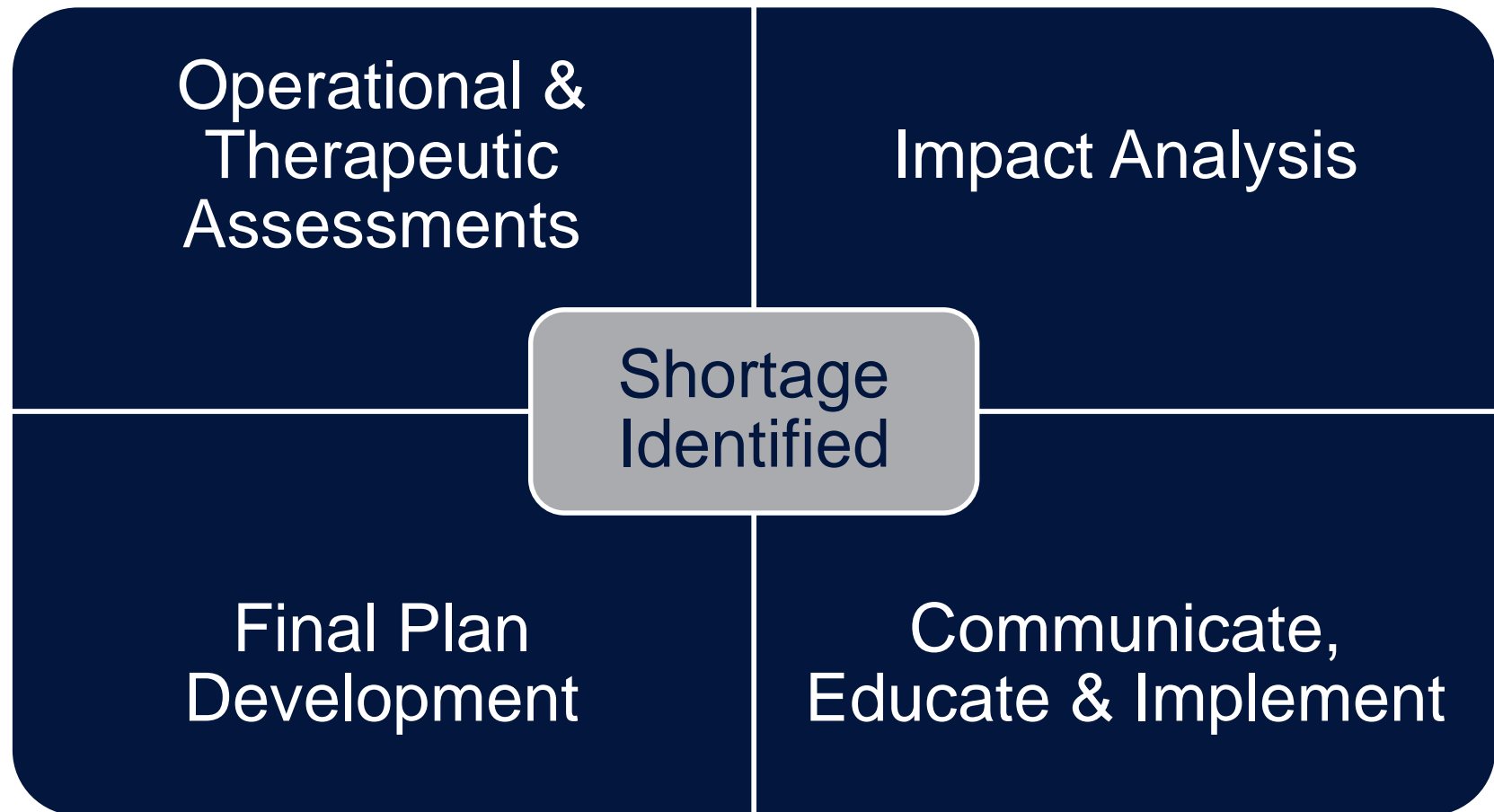
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Management Example – IV Opioid Shortage

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IV Opioids



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Operational Assessment

Validate Details: Decreased availability of injectable opioids (morphine, fentanyl, and HYDROmorphone) due to multiple factors

Determine Stock: Compare with historical usage to figure out how many days on hand are available

Alternative Sources: 503b Compounding facility? In-house compounding?

Estimate Impact: Projected to be a major impact affecting almost every service line

Technology Impact: Need to update orders to guide prescribers to concentrations on hand, ensure smart pumps have correct volumes/concentrations programmed

Therapeutic Assessment

Populations affected: Almost all hospitalized patients

Available Alternatives: PO opioids, non-opioid analgesics, alternative parenteral opioids (e.g., SUFentanil)

Conservation Strategies: Reserve on-hand parenteral opioids for which patient populations? Palliative care, OB/GYN, critical care, surgical services

Patient Safety Concerns: Varying concentrations of opioids, nurses have limited familiarity with alternative agents

Impact Analysis

Therapeutic Differences: Potency concerns, bioavailability concerns

Prescribing Processes: Alerts in the EHR to communicate what concentrations are available & what restrictions exist, if any

Distribution Processes: Ensuring diligent checks when new/multiple concentrations of a product exist within the healthcare system

Administration Processes: Facilitating double checks of different concentrations of opioids?

Financial Ramifications: Increased costs associated with outsourced products, increased labor costs associated with in-house compounding/batching, human resources devoted to managing the shortage

Communication,
Education, &
Implementation

Communication: Face-to-face, huddles, EHR alerts, ongoing to keep team aware of what was on hand and what challenges were being faced

Education: Multidisciplinary partnership, education on new concentrations/presentations of medications, policy & procedure updates

Implementation: Encouraged oral utilization whenever possible, weekly communications with affected service lines, updated IV to PO policy to include opioids, patient-specific dosing to conserve existing stock

Key Points

- Drug shortages frequently affect health care systems
- Establishing infrastructures can mitigate effects of drug shortages
- Success may be found in teamwork by assessing options and the ability to change rapidly
- Communication with the healthcare team such as providers, nursing, administrations and the pharmacy team are vital

Test Your Knowledge: Question 1

- Which of the following are management strategies for drug shortages?
 - A. Compounding
 - B. Dose Optimization
 - C. IV to Oral Conversion
 - D. Utilization of Alternative Agents
 - E. All of the above

Test Your Knowledge: Response 1

- Which of the following are management strategies for drug shortages?
 - A. Compounding
 - B. Dose Optimization
 - C. IV to Oral Conversion
 - D. Utilization of Alternative Agents
 - E. All of the above**

Test Your Knowledge: Question 2

- Within a healthcare facility, providers, nursing, administration and pharmacy should all be notified regarding all drug shortages.
 - A. True
 - B. False

Test Your Knowledge: Response 2

- Within a healthcare facility, providers, nursing, administration and pharmacy should all be notified regarding all drug shortages.
 - A. True**
 - B. False**

Test Your Knowledge: Question 3

- Drug shortages represent a patient safety issue
 - A. True
 - B. False

Test Your Knowledge: Response 3

- Drug shortages represent a patient safety issue
 - A. True**
 - B. False

Test Your Knowledge: Question 4

- A gap analysis should identify opportunities that exist within a process at your organization in order to move toward a more optimal state
 - A. True
 - B. False

Test Your Knowledge: Response 4

- A gap analysis should identify opportunities that exist within a process at your organization in order to move toward a more optimal state

A. True

B. False

References

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Thank You!

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