

IMPACT OF DRUG SHORTAGES ON MEDICATION SAFETY

August 20, 2019

Emily Messing, PharmD, BCPS

emessing@montefiore.org

Clinical Pharmacy Manager

Montefiore Medical Center

OBJECTIVES

- Discuss drug shortage patterns over the last decade
- Compare top medication classes involved in shortages
- Assess impact of drug shortages on patient safety and hospital resources
- Review recommendations on managing drug shortages

DEFINITIONS

Drug shortage:

- “A supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent” (ASHP)
- “A period of time when the demand or projected demand for a medically necessary drug in the United States exceeds its supply” (FDA)

Resolved drug shortage:

- “When all suppliers either have all products back in stock, or have discontinued those products” (ASHP)

WHO DO SHORTAGES IMPACT?

- Pharmacists
- Pharmacy technicians
- Buyers
- Nurses
- Doctors
- IT
- Patients

*List is not comprehensive



CAUSES OF DRUG SHORTAGES

Causes:

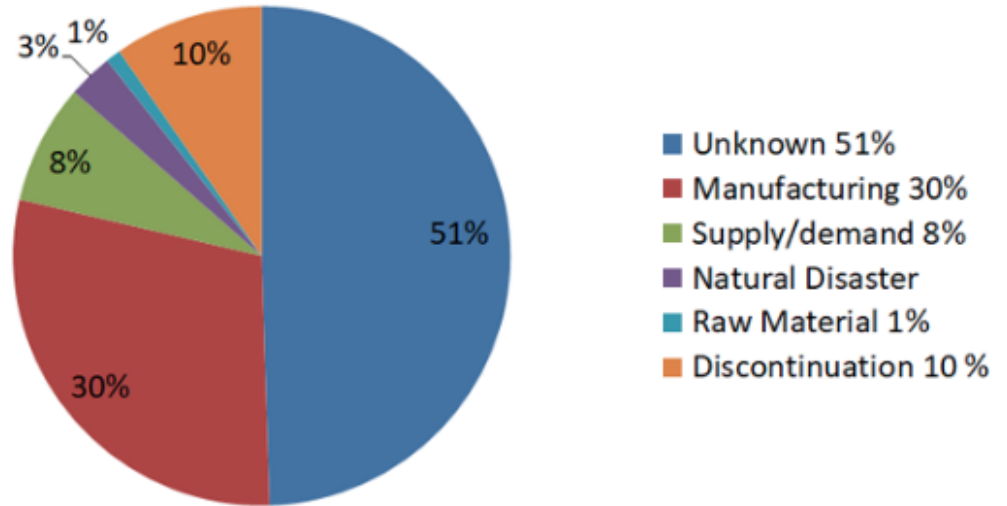
- Natural disasters
- Lack of available raw or bulk material
- Manufacturing difficulties
- Regulatory issues or recalls of affected or related products
- Changes in product formulations
- Superficial shortages

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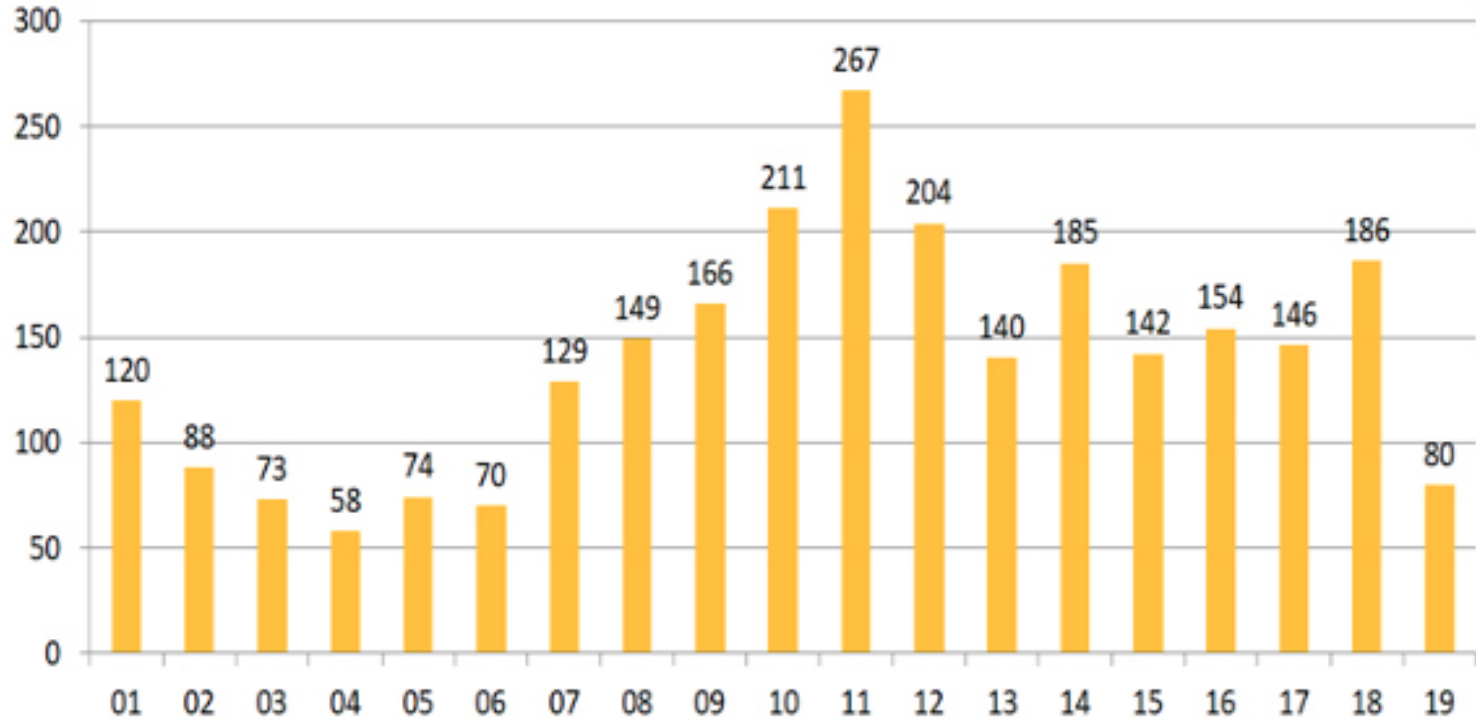
Reasons for Shortages* — 2018



NATIONAL DRUG SHORTAGES

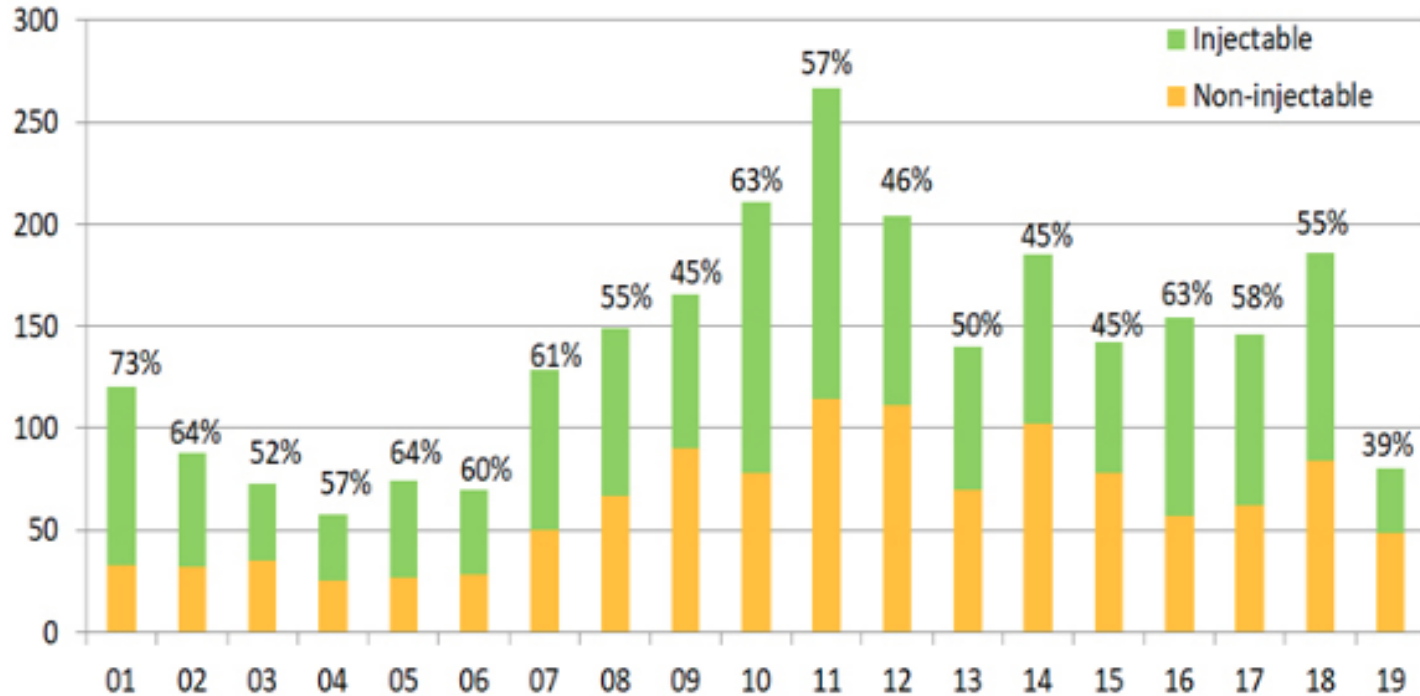
NUMBER OF NEW DRUG SHORTAGES

January 2001 to June 30, 2019



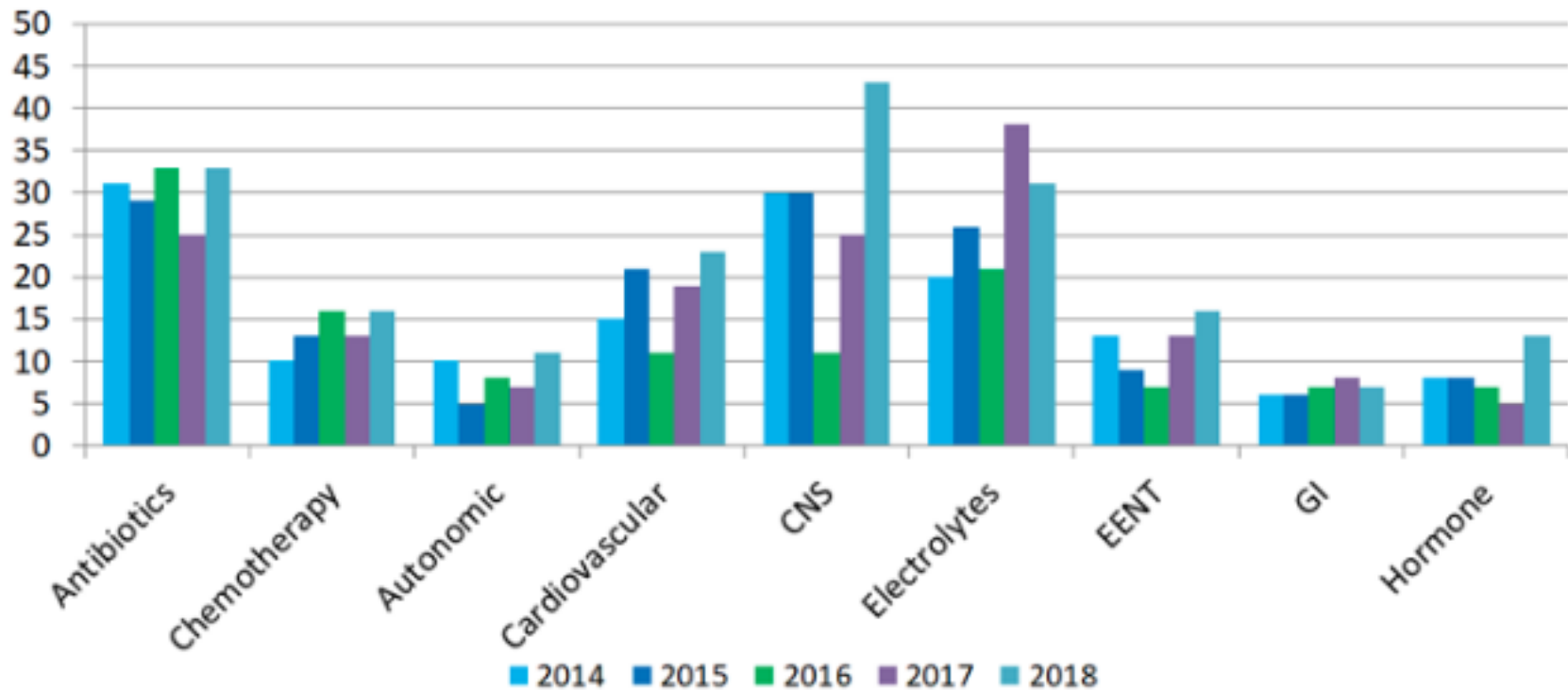
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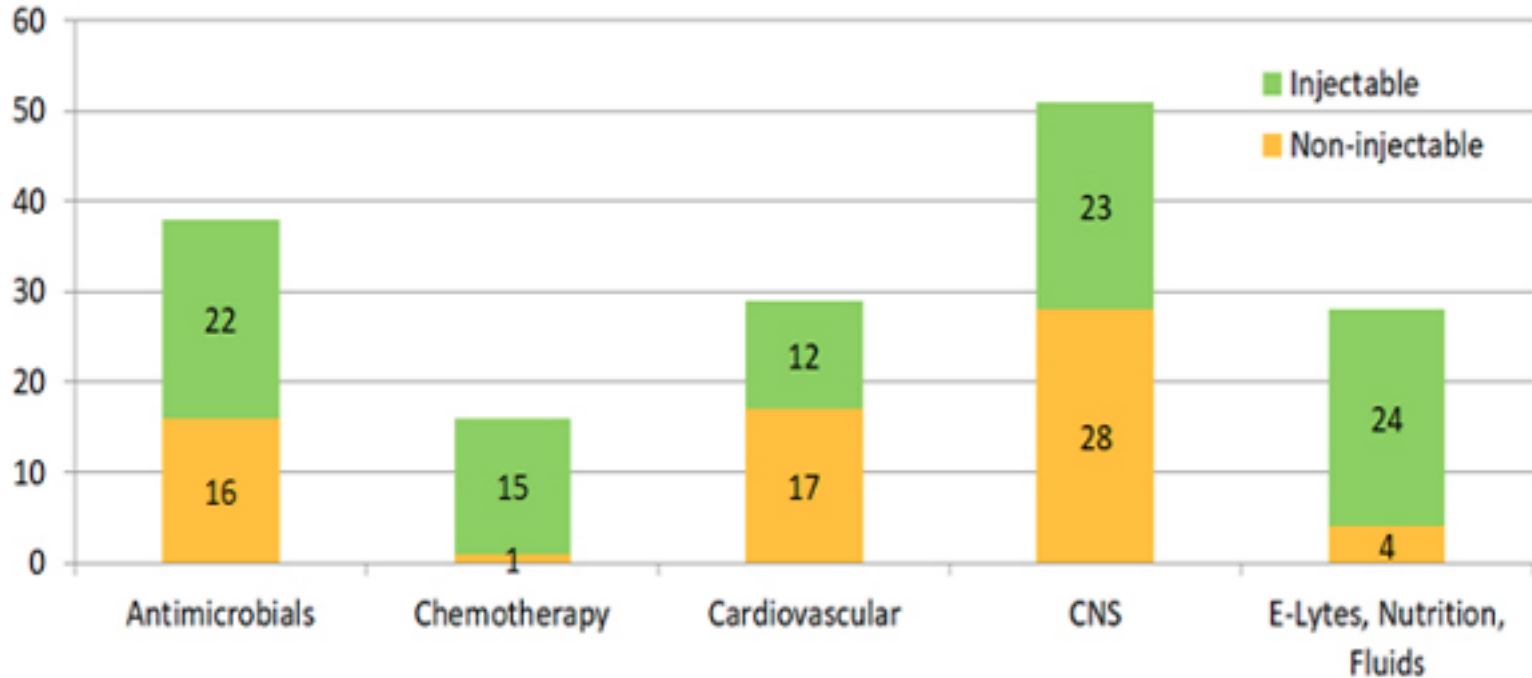
COMMON DRUG CLASSES

New Shortages Reported: 2014–2018



ACTIVE SHORTAGES – TOP 5 DRUG CLASSES

Active Shortages June 30, 2019



SHORTAGES: ANTIMICROBIALS

The Impact of Anti-infective Drug Shortages on Hospitals in the United States: Trends and Causes

Milena M. Griffith,^{1,2,3} Alan E. Gross,^{1,2,3} Sarah H. Sutton,^{3,4} Maureen K. Bolon,^{3,4} John S. Esterly,^{2,3,5} Jean A. Patel,^{2,3} Michael J. Postelnick,^{2,3} Teresa R. Zembower,^{3,4} and Marc H. Scheetz^{1,2,3}

¹Department of Pharmacy Practice, Midwestern University Chicago College of Pharmacy, Downers Grove, Illinois; ²Department of Pharmacy and ³Antimicrobial Stewardship Program, Northwestern Memorial Hospital, ⁴Division of Infectious Diseases, Department of Medicine, Northwestern University Feinberg School of Medicine, and ⁵Department of Pharmacy Practice, Chicago State University College of Pharmacy, Illinois

SHORTAGES: ANTIMICROBIALS

Drug (Date of Shortage Onset)	Reason for Shortage	Impact
Acyclovir injection (2010)	Manufacturing issues	Only therapy recommended for HSV/VZV encephalitis
Aztreonam injection (2008)	Raw material shortage	First-line agent for patients with b-lactam allergy who required gram-negative b-lactam coverage
Ciprofloxacin injection	Raw material shortage; noncompliance with GMPs	Empiric therapy selection in many national guidelines for a variety of infections
Piperacillin-tazobactam injection (2005)	Manufacturing issues; formulation change; increased demand; natural disaster	First-line anti-infective for many serious nosocomial infections
Polymyxin B injection (2008)	Increased demand	Often last-line therapy for serious multidrug-resistant gram-negative infection
Sulfamethoxazole-trimethoprim (2010)	Manufacturing issues	First-line treatment for <i>Pneumocystis jirovecii</i> pneumonia and <i>Stenotrophomonas maltophilia</i> infections

SHORTAGES: CHEMOTHERAPY



The NEW ENGLAND JOURNAL *of* MEDICINE **The Shortage of Essential Chemotherapy Drugs in the United States**

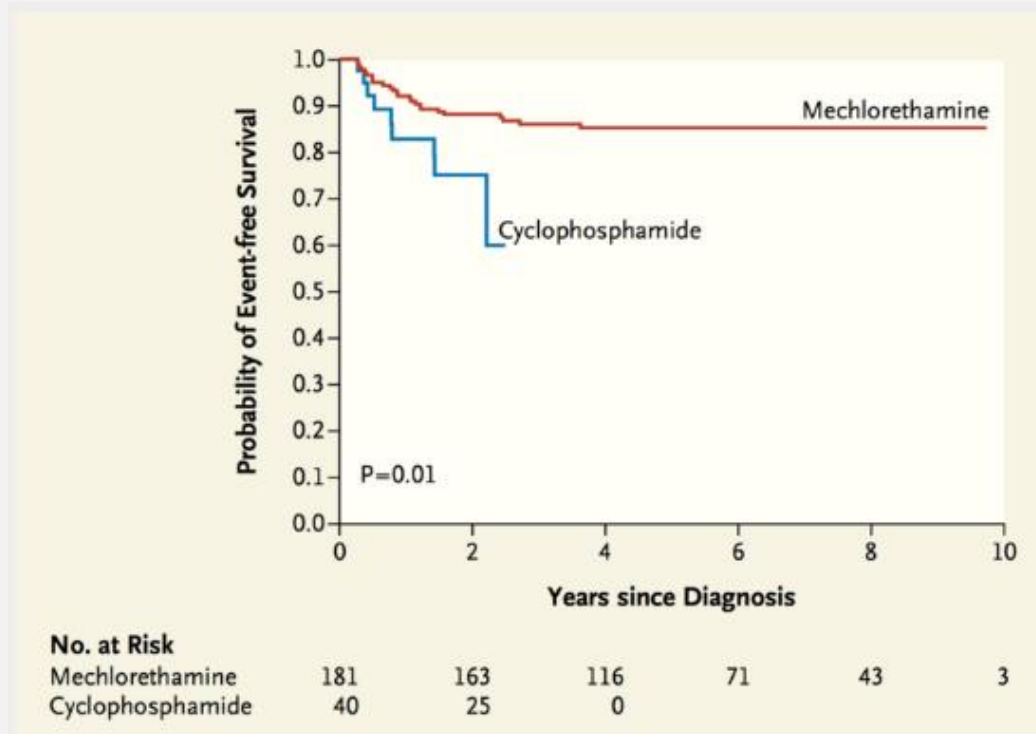
Mandy L. Gatesman, Pharm.D., and Thomas J. Smith, M.D.

Perspective
DECEMBER 27, 2012

For the first time in the United States, some essential chemotherapy drugs are in short supply. Most are generic drugs that have been used for years in childhood leukemia and curable cancers —

the increased time and work required to manage drug shortages.² A gray market for essential drugs — an unofficial alternative market of drugs obtained by vendors outside the usual distribution net-

MECHLORETHAMINE VS. CYCLOPHOSPHAMIDE



EFFECT OF ONCOLOGY DRUG SHORTAGES

National survey on the effect of oncology drug shortages on cancer care

ALI MCBRIDE, LISA M. HOLLE, COLLEEN WESTENDORF, MARGARET SIDEBOTTOM, NIESHA GRIFFITH, RAYMOND J. MULLER, AND JAMES M. HOFFMAN

- 34-question survey from September-October 2011 sponsored by HOPA
- Confirmed that oncology drug shortages occurred frequently in 2011
 - Delays and changes in chemotherapy regimens occurred frequently
 - Shortages are resulting in increased costs
 - Near-misses or actual medication errors as a result of shortages was reported by respondents

EFFECT OF ONCOLOGY DRUG SHORTAGES

Medication Errors and Shortage-Associated Adverse Outcomes, as Reported by Survey Respondents

Event	No. (%) Respondents ^a
Near-miss medication error (<i>n</i> = 39)	
Wrong drug	11 (28)
Wrong dosage conversion	10 (26)
Wrong drug concentration	8 (21)
Delayed or omitted drug	3 (8)
Inadequate supply to prepare dose	3 (8)
Details unknown	4 (10)
Medication error that reached a pt (<i>n</i> = 15)	
Wrong drug	2 (13)
Wrong dosage conversion	7 (47)
Wrong drug concentration	3 (20)
Delayed or omitted drug	1 (7)
Extra dose	2 (13)
Adverse pt outcome (<i>n</i> = 40)	
Increased toxicity	20 (50)
Disease progression	6 (15)
Cardiac event	2 (5)
Emotional stress	1 (3)
Details not disclosed	11 (28)

^aFor each item, percentage denotes proportion of respondents who reported and provided details on event.

EFFECT OF ONCOLOGY DRUG SHORTAGES

Effects of Selected Chemotherapy Shortages on Patient Care, as Reported by Survey Respondents (n = 243)^a

Effect	No. (%) Respondents Reporting Effect for Cancer Type and Drug in Shortage			
	Metastatic Ovarian Cancer (Liposomal Doxorubicin)	Breast Cancer (Paclitaxel)	Colorectal Cancer (Fluorouracil)	AML (Cytarabine)
Changed to another regimen	84 (34) ^b	49 (20) ^c	78 (32) ^d	29 (12) ^e
Sent patient to another institution for treatment	16 (7)	8 (3)	4 (2)	25 (10)
Omitted drug without substitution	42 (17)	12 (5)	18 (7)	12 (5)
Converted to another form of drug for treatment	66 (27)	NA	NA	NA
Reduced dosage of drug for treatment	NA	9 (4)	23 (9)	28 (12)
Obtained drug from another institution	18 (7)	28 (12)	19 (8)	40 (16)
Obtained drug, no effect on practice	30 (12)	138 (57)	131 (54)	113 (47)
Unknown or did not treat	63 (26)	36 (15)	25 (10)	54 (22)

SHORTAGES: CNS MEDICATIONS

CME

Shortage of Perioperative Drugs: Implications for Anesthesia Practice and Patient Safety

Gildasio S. De Oliveira, Jr., MD, Luke S. Theilken, MD, and Robert J. McCarthy, PharmD

Several medications used in clinical perioperative medicine are currently cited on the national shortage list. Medication shortages may be attributed to lack of raw materials, manufacturing issues, and discontinuation of production. Medication shortage has a substantial impact on patient care, and is responsible for creating an environment conducive to an increase in medication errors. Anesthesiologists should be taking an active role with the pharmacy and hospital management to alert caregivers and help to prevent adverse effects on patient care and safety. (Anesth Analg 2011;113:1429–35)

SHORTAGES: CNS MEDICATIONS

Table 1. Intravenous Drug Shortages Affecting Anesthesia Practice in 2010²

Drug class	Drug shortage resolved (yes/no)	Major cause for the shortage
Hypnotics		
Propofol	No	Manufacturer recall
Ketamine	Yes	Increased demand
Etomidate	Yes	Increased demand
Thiopental	No	Manufacturing issues
Benzodiazepines		
Midazolam	No	Manufacturing issues
Diazepam	No	No reason provided
Lorazepam	No	Manufacturing issues
Opioids		
Morphine	No	Increased demand
Hydromorphone	No	Increased demand
Fentanyl	No	Manufacturing issues
Nalbuphine	No	Manufacturing issues
Meperidine	No	No reason provided
Muscle relaxants		
Succinylcholine	No	No reason provided
Vecuronium	No	Manufacturing issues
Rocuronium	No	Manufacturing issues
Pancuronium	No	Manufacturer recall
Atracurium	Yes	No reason provided
Cisatracurium	Yes	Manufacturing issues
Opioid antagonist		
Naloxone	No	Manufacturer discontinuation

Table 3. Type of Medication Errors Attributed to Medication Shortages Between 2004 and 2005

Type of error	No. of cases	Percentage
Prescribing error	271	34.1
Improper dose/quantity	204	25.7
Omission error	176	22.2
Wrong administration timing	84	10.6
Unauthorized/wrong medication	47	5.9
Wrong drug preparation	43	5.4
Wrong dosage form	21	2.6
Expired product	15	1.9
Extra dose	11	1.4
Wrong patient	9	1.1
Wrong route	5	0.6
Deteriorated product	3	0.4
Wrong administration technique	1	0.1

Table was reproduced from Quantros MEDMARXSM (<http://www.quantros.com/medmarx.htm>). Copyright permission to reproduce the table was obtained.

SHORTAGES: ELECTROLYTES, NUTRIENTS, FLUIDS

FDA Statement

Statement by FDA Commissioner Scott Gottlieb, M.D., on efforts to address impact of IV fluid shortages following hurricane destruction and resolve manufacturing shortfalls

- temporarily allowing the importation of IV saline products from facilities outside of the U.S.;
- encouraging the expansion of production at existing facilities to meet shortfalls; and
- expediting our review of new product applications that will help address this shortage.

DRUG SHORTAGES IN THE HOSPITAL

Drug Shortages: A Complex Health Care Crisis

Erin R. Fox, PharmD; Burgunda V. Sweet, PharmD; and Valerie Jensen, RPh

Abstract

National tracking of drug shortages began in 2001. However, a significant increase in the number of shortages began in late 2009, with numbers reaching what many have termed crisis level. The typical drug in short supply is a generic product administered by injection. Common classes of drugs affected by shortages include anesthesia medications, antibiotics, pain medications, nutrition and electrolyte products, and chemotherapy agents. The economic and clinical effects of drug shortages are significant. The financial effect of drug shortages is estimated to be hundreds of millions of dollars annually for health systems across the United States. Clinically, patients have been harmed by the lack of drugs or inferior alternatives, resulting in more than 15 documented deaths. Drug shortages occur for a variety of reasons. Generic injectable drugs are particularly susceptible to drug shortages because there are few manufacturers of these products and all manufacturers are running at full capacity. In addition, some manufacturers have had production problems, resulting in poor quality product. Although many suppliers are working to upgrade facilities and add additional manufacturing lines, these activities take time. A number of stakeholder organizations have been involved in meetings to further determine the causes and effects of drug shortages. A new law was enacted in July 2012 that granted the Food and Drug Administration additional tools to address the drug shortage crisis. The future of drug shortages is unknown, but there are hopeful indications that quality improvements and additional capacity may decrease the number of drug shortages in the years to come.

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DRUG SHORTAGES IN HOSPITAL

- Particularly complex
 - Treating patients with acute and/or emergency conditions
 - Use a significant number of medically necessary or single-source products
- Goal: provide safe and therapeutically equivalent drug therapy preferably at comparable costs
- Without standardized protocols for allocating limited supply of a medication →
 - Susceptible to arbitrary judgements → revealing preformed bias
 - Medication errors

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 - ***Medication errors***

IMPACT OF DRUG
SHORTAGES ON
MEDICATION SAFETY

PATIENT SAFETY

- Medication errors are more likely to occur when
 - Pharmacy alters how a product is ordered, prepared or dispensed
 - When prescribing practices change to less-familiar alternative agents
 - Less efficacious, worse adverse effect profile, require unusual or difficult dosing regimen

January 11, 2018 ■ Volume 23 Issue 1

ISMP

Acute Care

ISMP Medication *Safety Alert!*[®]

Educating the Healthcare Community About Safe Medication Practices

Drug shortages continue to compromise patient care

***SAFETY* briefs**

- National survey from August-October 2017
- Confirmed that drug shortages continue to be a daily struggle
 - Lifesaving drugs without viable alternatives
 - Shortages lasting longer
 - Unsafe practices, compromised care, harmful errors

ISMP: ADVERSE PATIENT OUTCOMES

- Majority felt that drug shortages compromised patient care
- 71% were unable to provide patients with recommended drug/treatment for their condition because of shortage
 - 47% reported that this resulted in patients receiving less effective drug
- 75% reported patient treatment delays
- 5% reported other types of adverse outcomes
- 21% were aware of at least one medication error related to drug shortage in the 6 months prior to the survey

ISMP: ADVERSE IMPACT ON ORGANIZATIONAL RESOURCES

- Not directly queried in survey
- More than 33% of respondents provided comments
 - Unsafe practices that increased risk of error
 - Extensive human and financial resources required to manage drug shortages
 - Needed full-time staff to manage drug shortages
 - Time spent managing shortages cut into patient care

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ISMP: ADVERSE IMPACT ON ORGANIZATIONAL RESOURCES

- Examples of unsafe practices:
 - Dispensing medications in vials to patient care units so they can be prepared and administered via IV push administration
 - Administering IV push medications rapidly when they should be administered more slowly via a syringe pump
 - Diluting or reconstituting medications in saline flush syringes on patient care units due to shortages of normal saline
 - Compounding products in the pharmacy and in the operating room that were previously available as premixed solutions or injectables
 - Providing medications in concentrations that differ from what was typically used for direct injectables

THE IMPACTS OF MEDICATION SHORTAGES ON PATIENT OUTCOMES: A SCOPING REVIEW

Phuong JM, Penm J, Char B, Oldfield LD, Moles R (2019) The impacts of medication shortages on patient outcomes: A scoping review. PLoS ONE 14(5): e0215837. <https://doi.org/10.1371/journal.pone.0215837>



**RESOURCES NEEDED
TO MANAGE DRUG
SHORTAGES**

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TIME SPENT MANAGING SHORTAGES

Hospital Characteristic	Median No. Hours per Week (Interquartile Range)			
	Pharmacists	Pharmacy Technicians	Physicians	Nurses
Overall	9 (5–20)	8 (3–17)	0.5 (0–2)	0 (0–2)
Size (no. beds)				
<100 (n = 87)	8 (5–12.5)	5 (2–11)	0 (0–1)	0 (0–1)
100–199 (n = 54)	9 (5–19.75)	9 (3–17.5)	0.5 (0–2.25)	0 (0–2)
200–399 (n = 79)	9 (5–27.5)	10 (5–20)	1 (0–2)	1 (0–2)
≥400 (n = 64)	12 (8–28.5)	13 (6–21)	1 (0–4)	1 (0–4.5)
<i>p</i> ^a	0.028	<0.0001	<0.0001	0.003
No. shortages experienced				
<10 (n = 36)	4.5 (2.25–10)	2.75 (0.6875–6)	0 (0–0.5)	0 (0–0.875)
10–20 (n = 116)	8 (4.25–20)	6 (2.25–12)	0 (0–1)	0 (0–1.5)
21–30 (n = 84)	11 (5.75–26)	10 (5–21)	1 (0–3.5)	1 (0–2.75)
≥30 (n = 95)	10.5 (6.12–23.75)	13 (6–21.5)	1 (0–2.75)	0.125 (0–2)
<i>p</i> ^a	<0.0001	<0.0001	<0.0001	0.034
Level of automation (no. automated systems present)				
0 (n = 53)	4.5 (1.13–22.5)	1.63 (0–22.25)	0 (0–1.25)	0 (0–2.5)
1–4 (n = 74)	7 (4.5–17)	5 (2–10)	0 (0–1)	0 (0–1)
5–8 (n = 115)	10 (5–19.25)	8.5 (3.25–15.75)	0.5 (0–2)	0 (0–2)
9–12 (n = 92)	10 (5–26.5)	12 (5–21)	1 (0–2.5)	1 (0–3.5)
13–16 (n = 19)	14.29 (9.5–28.5)	14 (6.5–18.25)	1 (0–5)	0 (0–3.25)
<i>p</i> ^a	0.024	<0.001	0.002	0.022

^aKruskal–Wallis analysis for association between time spent managing shortages and increasing bed capacity, number of shortages, and level of automation.

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ESTIMATED COST OF SHORTAGES

- Estimated cost of shortages in 2013: \$209 million
 - Cost of purchasing more expensive substitutes
- Excludes other costs
 - Managing multiple pharmacy automation systems

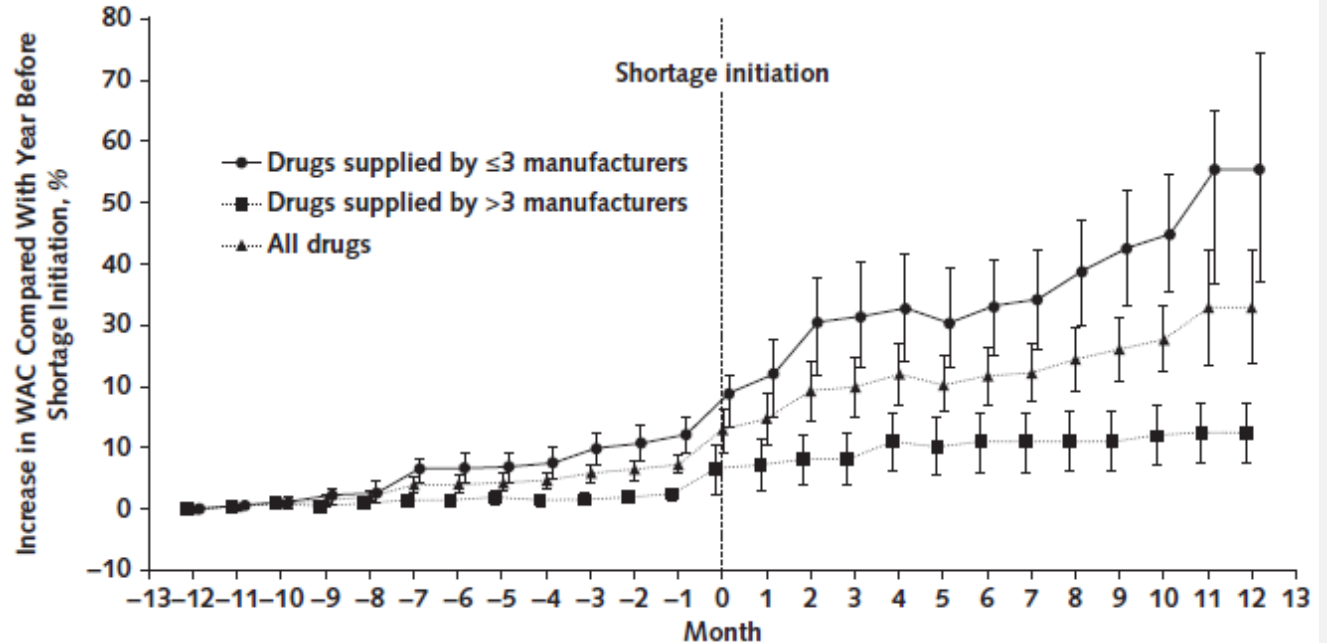
EXAMPLES: ESTIMATED COST OF SHORTAGES

Average Wholesale Prices (AWPs) of Selected Oncology Drugs in Short Supply and Their Potential Alternatives.*

Shortage Drug	AWP per Dose \$	Alternative Drug	AWP per Dose \$
Paclitaxel (breast, lung, ovarian cancer)	312	Docetaxel (Taxotere)	3,519
		Paclitaxel, protein-bound (Abraxane)	5,824
Leucovorin (pediatric cancers, colon cancer)	32	Levoleucovorin (Fusilev)	1,284
Doxorubicin (breast and ovarian cancers, leukemia)	120	Epirubicin	960
		Liposomal doxorubicin (Doxil)	5,789

EXAMPLES: ESTIMATED COST OF SHORTAGES

Figure 1. Observed increases in WACs in the 12 mo before and after the shortage began.



POSITIVES OF DRUG
SHORTAGES?

POSSIBLE POSITIVE OUTCOMES

- IV to PO programs
- Less waste
 - IV push
 - Standardized concentrations
 - Lowering PAR levels
- Cost savings?

**LEGISLATION: WHAT HAS
BEEN DONE TO COMBAT
DRUG SHORTAGES?**

LEGISLATION AND FDA RESPONSE

2011: Preserving Access to Life-Saving Medications Act

2012: FDA Safety and Innovation Act (FDASIA)

2013: FDA's Strategic Plan released

2017: FDA Drug Round Table

2018: FDA Shortages Summit

PRESERVING ACCESS TO LIFE-SAVING MEDICATIONS ACT

- Requires a prescription drug manufacturer to notify the Secretary of Health and Human Services (HHS) of:
 - A discontinuance, interruption or other adjustment of the manufacture of a drug that would likely result in a shortage of such drug

FOOD AND DRUG SAFETY AND INNOVATION ACT OF 2012

- Industry required to supply information to the FDA
- Wholesalers voluntarily supply inventory interruptions
- Public notification via email

- Who is not required to report supply data?
 - Repackagers
 - Secondary wholesalers/distributors
 - Compounders

STRATEGIC PLAN FOR PREVENTING AND MITIGATING DRUG SHORTAGES-2013

Strategic Plan for Preventing and Mitigating Drug Shortages

Executive Summary

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA).¹ Among other things, Title X of FDASIA directs the Food and Drug Administration (FDA or the Agency) to establish a task force on drug shortages to develop and submit to Congress a Strategic Plan to enhance FDA's response to preventing and mitigating drug shortages.

DRUG SHORTAGES ROUND TABLE 2017



Drug Shortages Roundtable: Minimizing Impact on Patient Care

Held November 6, 2017, at ASHP Headquarters, Bethesda, MD

- (1) examining drug shortages over the past five years and assessing what has worked in terms of preventing and mitigating shortages as well as what could be improved
- (2) whether there have been notable changes in the causes of drug shortages, in the trends in the types of shortages, or in the marketplace dynamics that impact supply

FDA DRUG SHORTAGES SUMMIT 2018

The Task Force

In July 2018, FDA Commissioner Scott Gottlieb, M.D. established the Agency Drug Shortages Task Force to identify the root causes of drug shortages and advance potential long-term solutions in a report to Congress.

Stakeholder Participation

In response to strong stakeholder interest, the task force is providing three ways for stakeholders to participate:

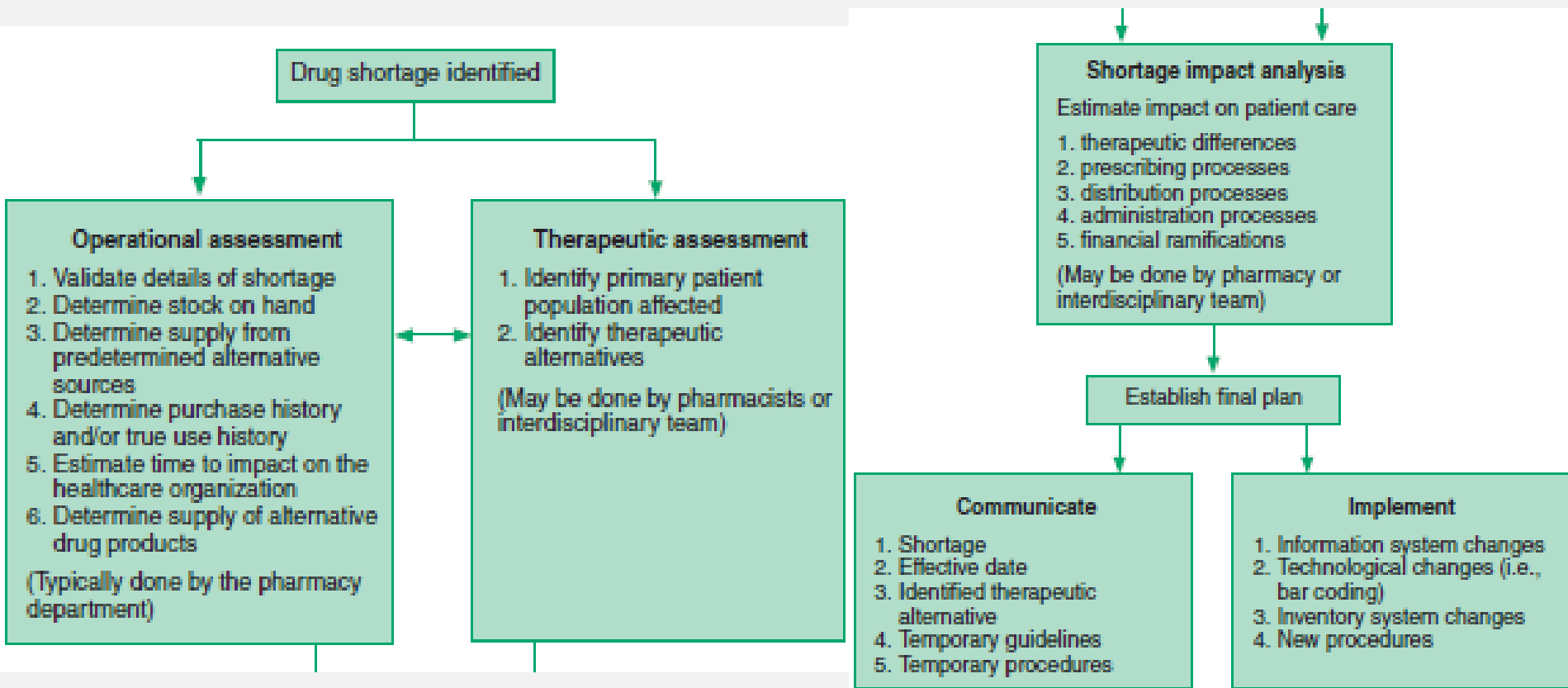
- **Public Meeting.** The task force, under a cooperative agreement with the Robert J. Margolis, MD, Center for Health Policy at Duke University, will host a public meeting on November 27, 2018, in Washington, D.C. Dr. Mark McClellan, Director of the Duke-Margolis Center and former FDA Commissioner and CMS Administrator, will moderate the meeting. The agenda will include opportunities for open discussion and audience participation.
- **Stakeholder Listening Sessions.** The task force held a series of stakeholder listening sessions in September and October 2018. Due to resource constraints, participation was by “invitation only.” The sessions brought together small groups of nationally recognized experts on the drug supply chain and leaders of organizations representing broad segments of the health care system.
- **Public Docket.** FDA has opened a docket to receive comments from stakeholders about the root causes of drug shortages and potential enduring solutions. The docket will remain open until January 11, 2019, to provide ample time for contributions.

ASHP RECOMMENDATIONS

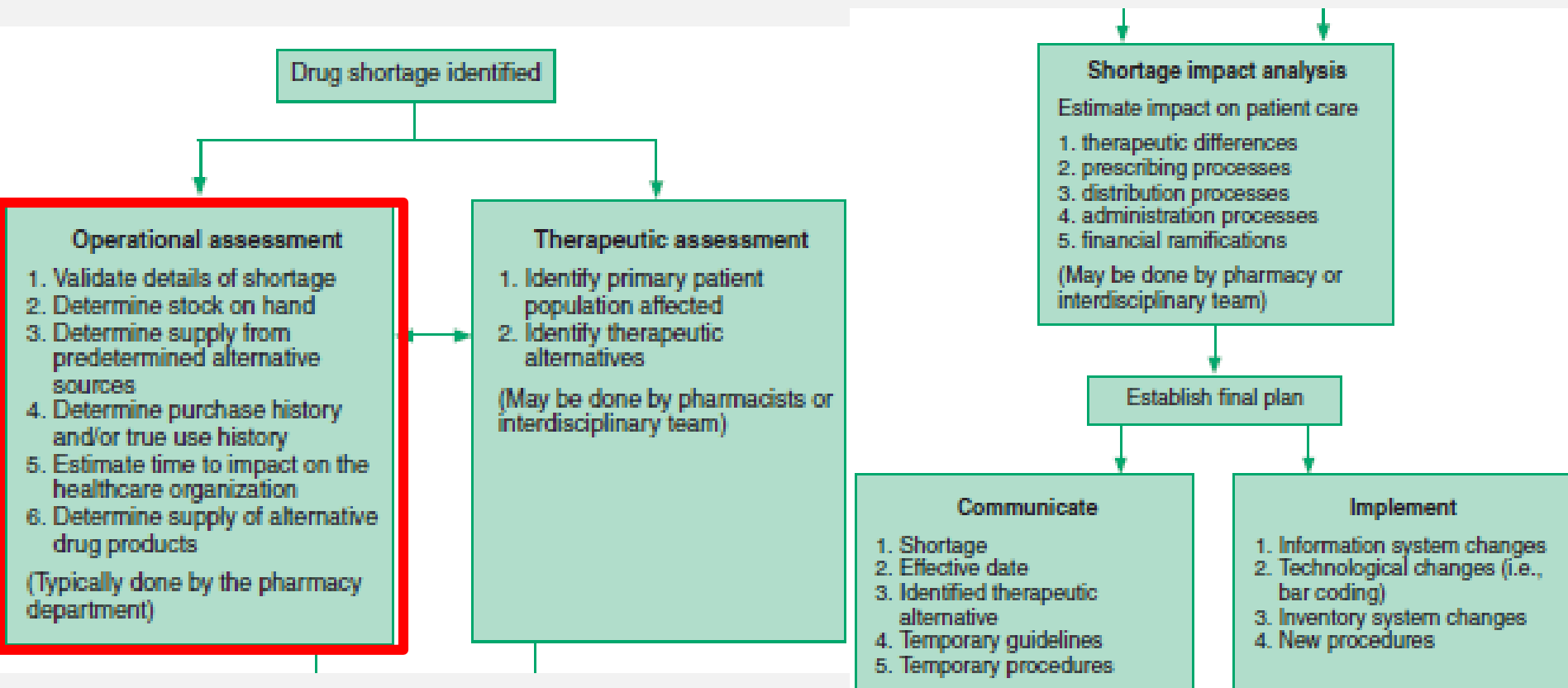
ROLE OF PHARMACY IN MANAGING SHORTAGES

- Ensure organization has the necessary infrastructure and well-defined management strategy in place before a shortage occurs
- Provide education to all members of the healthcare team and organizational leadership
- Communication
 - Informing practitioners of shortages and providing recommendations on alternative agents
- Ensure safe and effective use of therapeutic alternatives
- Restrictions, allocations, alternatives

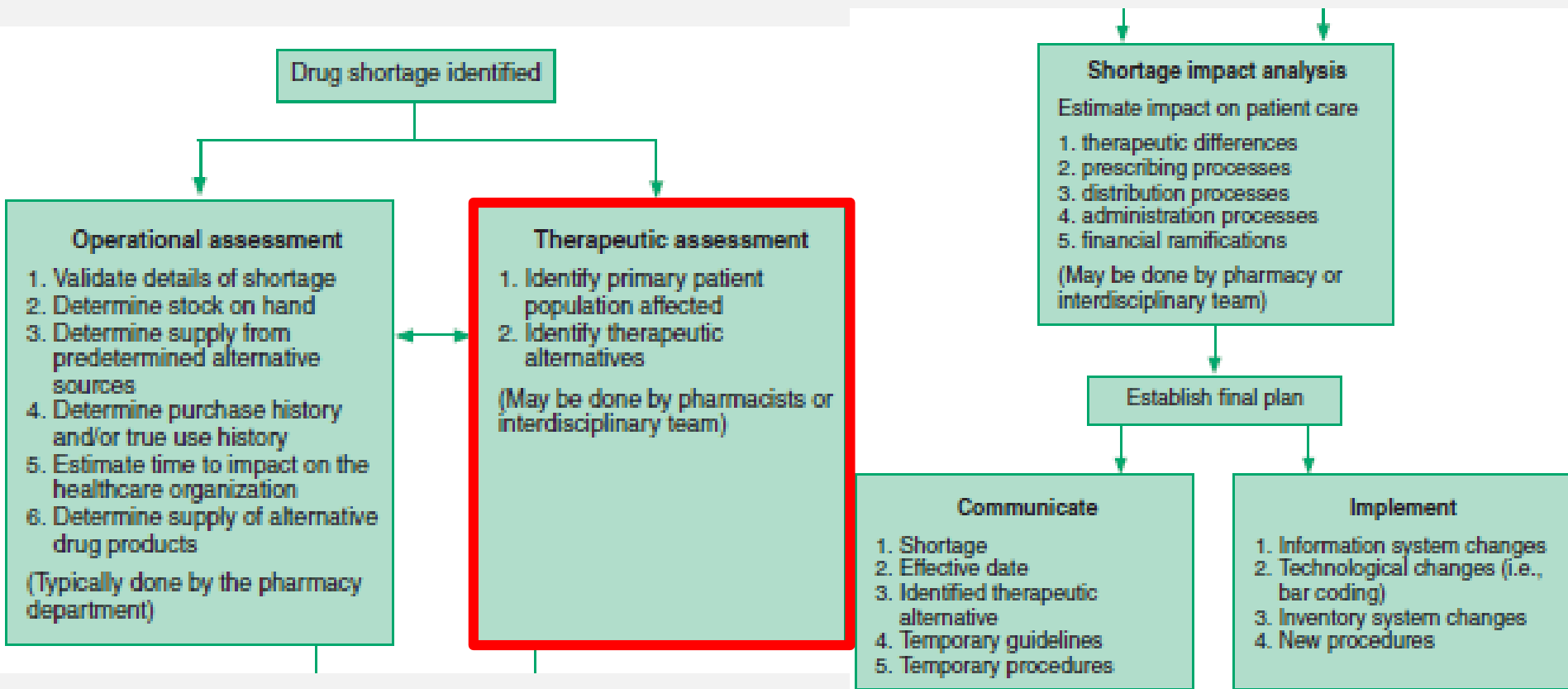
DECISION-MAKING MANAGEMENT OF SHORTAGES



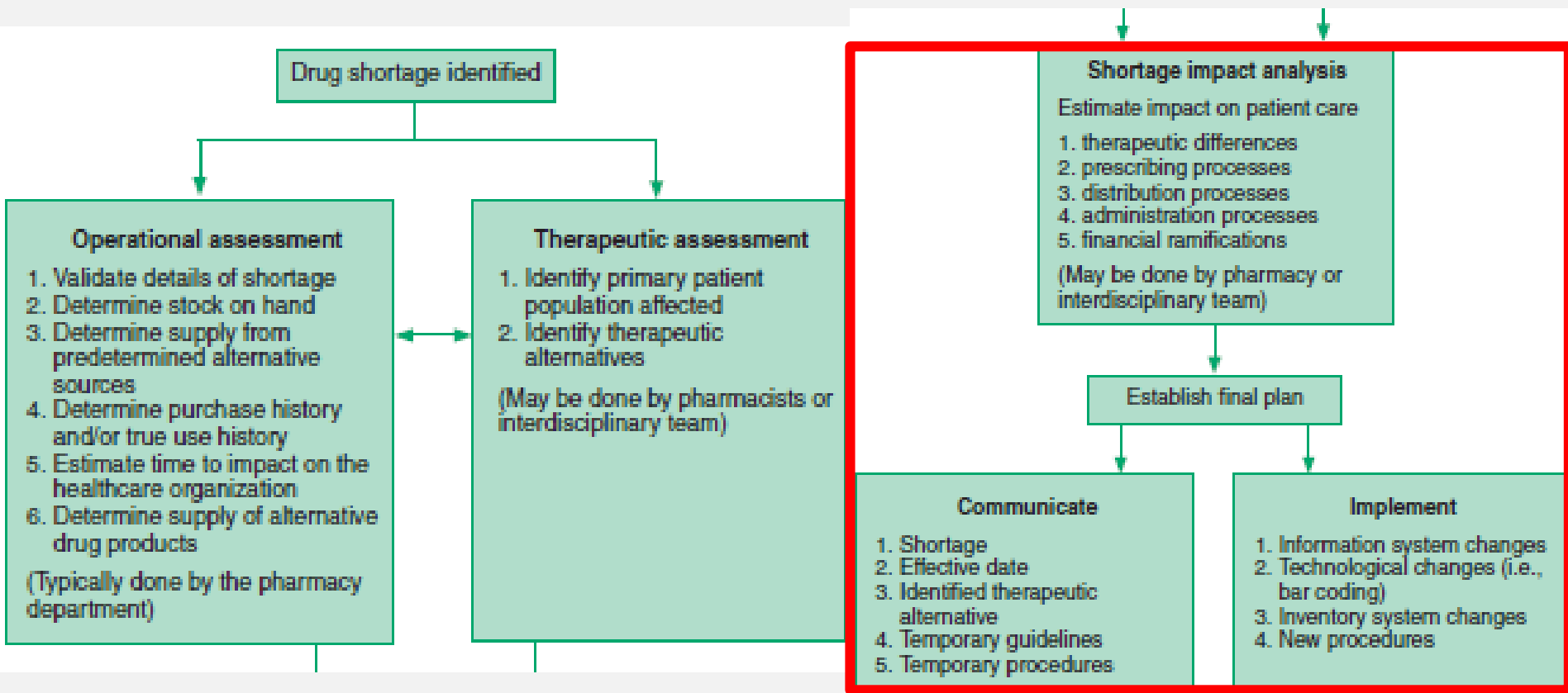
DECISION-MAKING MANAGEMENT OF SHORTAGES



DECISION-MAKING MANAGEMENT OF SHORTAGES



DECISION-MAKING MANAGEMENT OF SHORTAGES



RESOURCES

RESOURCES

- ASHP (<https://www.ashp.org/drug-shortages/current-shortages>)
 - Report a shortage
 - List of current, discontinued, resolved shortages
- FDA Drug Shortages Page (<https://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>)
 - Drug shortage database
 - List of drugs with extended use dates

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Emily Messing, PharmD, BCPS

emessing@montefiore.org

Clinical Pharmacy Manager

Montefiore Medical Center