

Turning Lemons into Lemonade: The Upside of Drug Shortages

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MEDICINE *of* THE HIGHEST ORDER



Conflict of Interest/Financial Disclosures

Speaker has no conflicts of interest, commercial interests or financial interests to disclose.

Objectives

▪Pharmacist Objectives

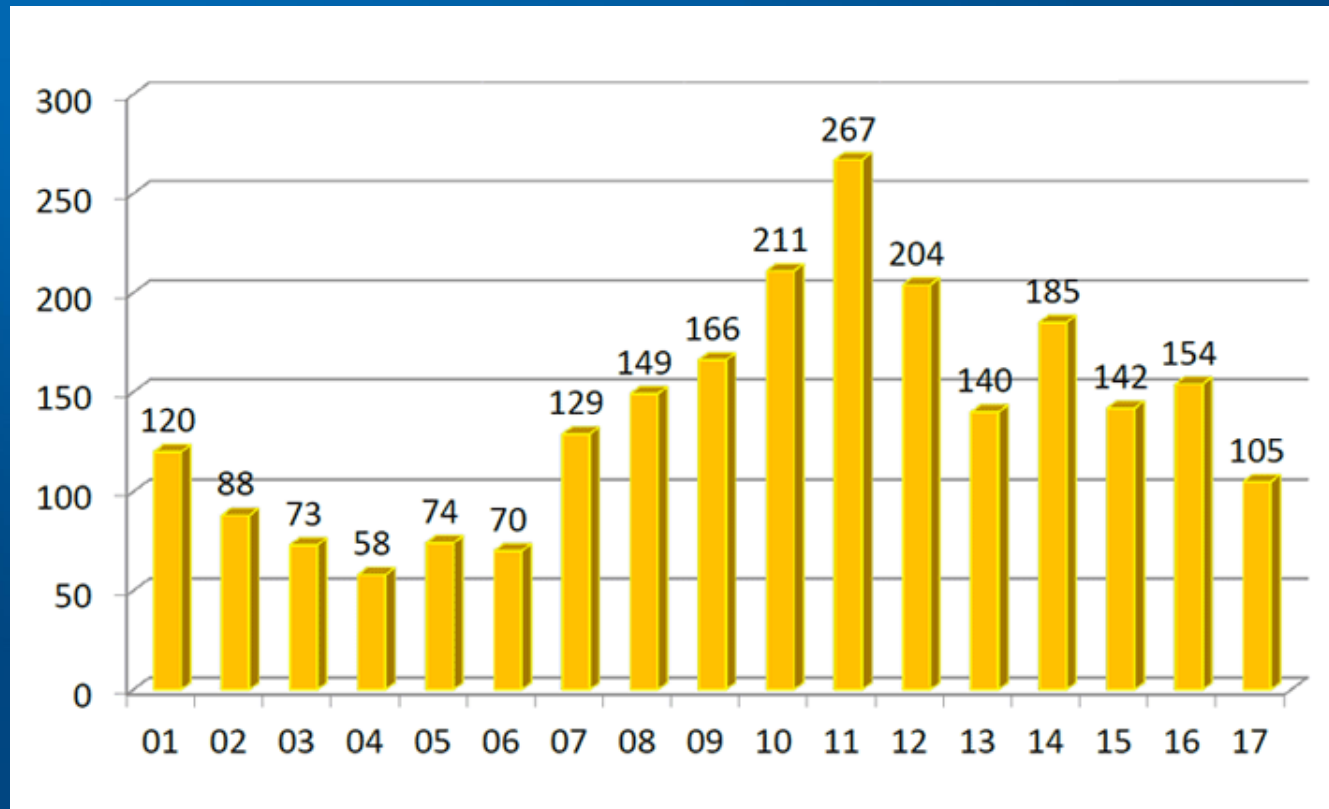
- To describe various business and clinical strategies for managing critical drug shortages.
- To explain how drug shortages have played an important role in improving communication and teamwork across multiple hospital departments.

▪Technician Objectives

- To outline various approaches to buying and managing inventory during critical drug shortages.
- To explain ways in which certain drug shortages have improved inventory management.

Background

National Drug Shortages: Annual New Shortages by Year
January 2001 to September 30, 2017



University of Utah Drug Information Service
Contact: Erin.Fox@hsc.utah.edu, [@foxerinj](https://twitter.com/foxerinj) for more information.

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Background

Timeline of response in US:



Impact *seems* to be felt hardest at local and health-system level

FDA Strategic Plan for Preventing and Mitigating Drug Shortages

<https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf>

Background

- The number of documented shortages each year has declined since its peak in 2011.
- The number ongoing shortages are declining
- The continued shortages involving antibiotics, electrolytes, IV solutions, opioids, etc. is what makes these so critical

Drug Shortages

Causes

- Raw material shortage
- Quality shutdowns
- Profitability
- Natural disasters
- Mergers & Acquisitions
- Increased Demand
- Unknown

Supply Chain Strategies

- Buy everything available!
- Alternate distributors/direct
- Alternate dosage forms
- Alternative clinical therapies
- Think ahead (domino effect)
- Maintain ongoing backorders
- Communicate regularly

Drug Shortages



Pfizer Inc.
275 North Field Drive
Lake Forest, IL 60045

July 10, 2017

Notification of Upcoming Pfizer Injectables Opioid and Non-Opioid Prefilled Syringe Shortage

Dear Valued Customer,

Pfizer Injectables is committed to providing information on supply shortages so that appropriate contingency plans can be made to facilitate patient care and safety. As such, this letter is to provide you with updated information on the supply status of opioid and non-opioid prefilled syringe (PFS) products. We anticipate that at the end of July we will not be able to meet market demand on opioid and non-opioid PFS products due to remediation efforts at our McPherson manufacturing facility. Although we will continue to manufacture and deliver select presentations throughout the remediation process, we anticipate product shortages and stock outs to begin as early as this month. We expect recovery of prioritized products by the end of Q1 2018.

Hospira-Emergency Syringes

3/31/2017

Unable to access Pfizer Sodium Bicarbonate, Atropine, Calcium Chloride Emergency Syringes

4/27/2017

Pfizer distributes supply disruption letter.

4/28/2017

UR facilities unable to access Dextrose 50% Emergency Syringes.

Pfizer Inc.

275 North Field Drive
Lake Forest, IL 60045

April 27, 2017

Notification of Emergency Syringe Supply Interruption

Dear Valued Customer,

Pfizer Injectables is committed to providing information on supply so that appropriate contingency plans can be made to facilitate patient care and safety. This letter is to provide you with updated information on the supply status of our Emergency Syringes.

Due to manufacturing delays and increased demand, we expect to experience backorders on multiple presentations of Emergency Syringes. We understand the importance and critical nature of these products and are working to resolve these delays.

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Hospira-Emergency Syringes

5/24/2017

On hand commercial supply of Dextrose 50% reaches critical levels.

5/31/2017

UR sites begin compounding Dextrose 50% syringes from Dextrose 50% 500 ml bags.

6/13/2017

Dextrose 50% commercial bags unavailable. Convert compounding process to using Dextrose 70% as source.

Dextrose-Supply Chain/Inventory Management

1. Assess market situation and access any high concentration dextrose formulations available.
 - D50W (500 ml bags), D70W (500 ml, 2000 ml), D20W (500 ml)
 - Other suppliers (IMS, ICU Medical, BBraun, etc.)
2. Think ahead; which products are going to see market pressures as a result of original shortage? Glucagon, oral forms, etc.
3. Evaluate existing inventory of D50W small volume forms (syringes, vials) and estimate days supply on hand.
4. Discuss current state with drug shortage management team and develop strategy to present to senior pharmacy leadership.
5. Communicate internally (pharmacy) and externally (nursing), and execute strategy.

Dextrose-Supply Chain/Inventory Management

▪Strategy:

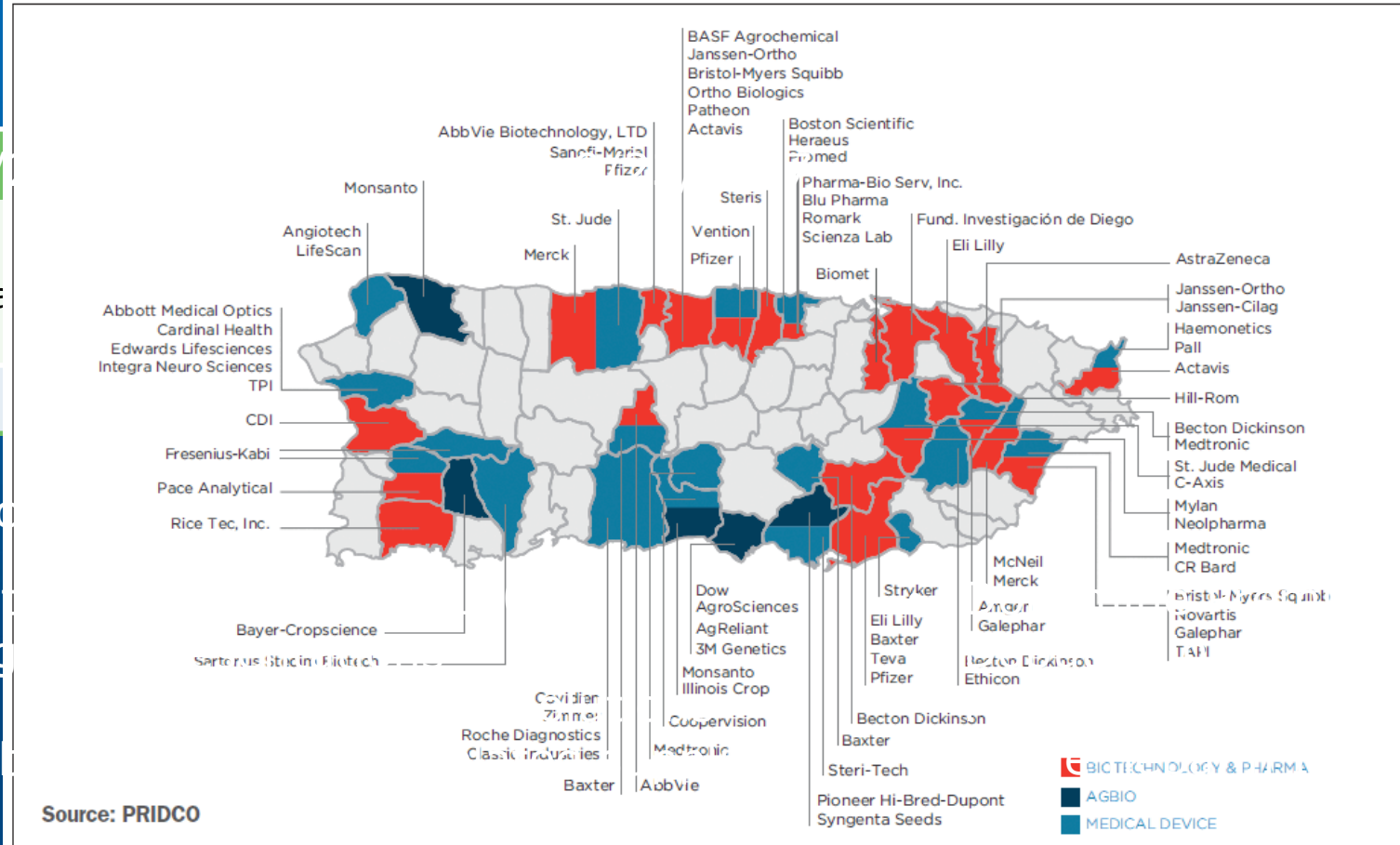
- Reduce unnecessary utilization of D50W through clinical efforts.
- Treat vials and syringes as interchangeable products from an inventory management/dispensing standpoint.
- Where possible, centralize and consolidate decentralized inventory (central pharmacy needs to be extremely prompt to handle urgent requests for D50W syringes).
- Compound from D50W bags (until exhausted), providing 9-day expiration under refrigeration.
- Compound from D70W bags, providing 9-day expiration under refrigeration.

▪ Communication

- Email
- Committees/Nursing Leadership
- Embedded communication in EMR
 - Updated order sets/protocols
 - Direct shortage communication (LMA)

Baxter IV solutions

Map of Puerto Rico's life science manufacturing facilities



9/19/2017
Hurricane
Puerto

Affected products

- All IV solutions
- All Minibags
- Potassium
- Empty IV

2017
distributes
cancellation that
is for impacted
are being
ted.

IV solutions
d IV solutions
d IV solution
olutions

Baxter IV solutions-Supply Chain/Inventory Management

- IV solutions shortage of this magnitude introduces complexities not seen with typical pharmaceutical shortages.
 - Extremely high volume (hundreds of cases/month).
 - In use in hundreds of locations (inpatient, OR, infusion centers, urgent care, onsite and off-site clinics, etc.).
 - Broadly used and therefore difficult to present cohesive reduction strategy.
 - Not primarily managed through pharmacy supply chain (pharmacy is heavy user of the affected items, but treated like a supply at UR and runs through materials management department).
- IV solutions market in US has been fragile for years
 - Commoditized market (low cost product, costly to transport, years of downward pressure on price, etc.)
 - Frequent outages at baseline (all products).
 - Suppliers reportedly making large investments to improve supply, but effects yet to be seen.
 - M&A has only had deleterious effects on this market (Hospira/Pfizer)

Baxter IV solutions-Supply Chain/Inventory Management

1. Engage stakeholders (Pharmacy and Materials Management) to understand impact
 - How much do we use of each affected product
 - Where are these items used
 - How much inventory is on hand (IOH in units and days)
 - What can we access right now to increase IOH
 - Summarize circumstances
2. Communicate to leadership
 - Shortage of this magnitude should reach highest levels of leadership as early as possible
3. Collectively devise strategy to reduce utilization and manage inventory
 - Requires all participate (Pharmacy, Materials Management, Nursing, Providers, Supply Chain, Facilities (storage/receiving), others).
 - Primary goal is to reduce utilization to the point of supply exceeding demand. Focused effort on increasing supply and decreasing demand.

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Baxter IV solutions-Supply Chain/Inventory Management

▪Strategy (non-clinical)

- Calculate supply/demand gap.
- Identify areas of high use for targeted reduction efforts.
- Seek storage space to accommodate monthly ordering schedule and manage solution (3PL, BRCC, receiving dock, etc.).
- Determine what MB+ items can be converted to alternative drug delivery formulations (e.g. Duplex, premix, frozen, AddVantage, compounded forms, etc.).
- Establish recurring meeting schedule between MM and Pharmacy to exchange information, maximize allocation and ensure appropriate product mix in purchase orders. Meetings to cover existing inventory, monthly demand changes, and reporting status on utilization reduction efforts.
- Educate ourselves on “Baxter language” (2B...) and gain flexibility on package types (single pack, quad back, bulk pack, etc.). Versatility in product selection is critical to maintaining product flow to UR.

Drug Shortages-An Upside

- An opportunity for our profession
 - Pharmacy is best equipped to manage shortages (not just pharmaceuticals!)
 - High visibility to senior leadership
 - Get engaged at the national level; share best practices
 - Need to do a better job of telling success stories
- Experience has made us better at planning
 - Buyers are more strategic and thoughtful about market dynamics
 - More efficient inventory management efforts
 - More judicious use of inventory on hand and improved skills relative to utilization reduction
 - Plan A, B, C, D, E, F, etc.

Drug Shortages-An Upside

- A change in perspective
 - Providers and other clinicians have become more accepting and understanding of drug supply disruptions
 - More willing to be engaged as active participants in strategy
 - Better focus on solutions rather than causes
- Increased system integration
 - Shortage management requires partnership across disciplines/departments
 - More frequent communication between hospital pharmacies across UR enterprise
 - *System strategy over hospital strategy*
 - More consistent execution and communication of plan
 - Reduced duplication of effort
 - Stronger position to maximize use of inventory and reduce impact on patient care across all sites

Drug Shortage Pearls

- Stay current with communications from multiple sources regarding supply.
 - GPOs, manufacturer representatives, wholesaler ordering site, networking, other sources.

ALT	QTY	STOCK STATUS	CIN	NDC/UPC	GENERIC NAME	STRENGTH	FORM	SIZE
+	<input type="text" value="0"/>		2965341	63323-0411-10	MIDAZOLAM HCL	1MG/ML	MDV	10X10 ML
+	<input type="text" value="0"/>		3536166	63323-0411-25	MIDAZOLAM HCL	1MG/ML	MDV	25X5 ML

Medication	Average Daily Usage	Stockroom	Pyxis	IVA	Code Tray Rm	Dudsters	Total	Projected Days-on-hand	Status
Atracurium 10mg/ml	4	170					170	42.5	all cin available early July release date
Atropine 0.1mg/ml 10ml	5	193	150		23	3	369	73.8	unavailable at Cardinal, Pfizer June release Cardinal says October
Calcium Chloride 100mg/ml 10ml	17	1572	50		15	281	1918	112.8	unavailable at Cardinal, Pfizer late May/June release Cardinal says late October
Dextrose 50% abbj	4	34	123		26		183	45.8	unavailable at Cardinal, Pfizer May release Cardinal says late August
Dextrose 50% sdv	17	0	220			4	224	13.2	unavailable at Cardinal no re-release dates
Epinephrine 0.1mg/ml 10ml	11	542	229		21	23	815	74.1	unavailable at Cardinal, Pfizer August release dates

Drug Shortages-Continued Challenges

- Transparency from industry is currently the biggest problem we face. Early notification or advanced warning that a shortage will happen rarely occurs, and often is communicated after we've been impacted.
- Ongoing Updates are difficult to attain and resolution times are almost never provided.
- Long-term and short-term planning is still very difficult.
- Defensive buying still an issue.
- Frequent dilemma with regard to communication strategy
 - Who, what, when, where, why, how...different with each shortage
- Despite governmental efforts, drug shortages are here to stay...

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Questions/Comments

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