

# Patient Safety

# Implications of Drug

# Shortages

Tricia Meyer PharmD, M.S., FTSHP, FASHP

Associate Professor of Anesthesiology

Baylor Scott & White Medical Center

Texas A&M College of Medicine

Temple, Texas

# Shortages were reported across all treatment categories

- **Emergency care** (87%)
- **Anesthesia care** (85%)
- **Pain management** (81%)
- **Infectious disease treatment** (71%)
- **Cardiovascular care** (68%)
- **Parenteral nutrition** (55%)
- **Obstetrics/gynecology** (33%)
- **Hematology/oncology** (33%)
- **Neurology** (18%)
- **Allergy/asthma care** (15%)
- **Psychiatry** (10%)
- **Endocrinology** (10%)
- **Ophthalmology** (5%)

Current ASHP drug shortage list of 191 medications, 73% of drugs are used in perioperative area/surgery/anesthesia



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**bupivacaine, lidocaine, chloroprocaine, cefazolin, ciprofloxacin, clindamycin, dexamethasone, dexmedetomidine, diphenhydramine, epinephrine, fentanyl, famotidine etomidate, heparin granisetron, hydromorphone, hydralazine, ketamine, ketorolac, lactated ringers, labetalol, meperidine, mepivacaine, metoclopramide, metoprolol, morphine, ondansetron, mupirocin, promethazine, protamine, rocuronium, ropivacaine, remifentanil, scopolamine transdermal, sufentanil, vecuronium, vancomycin**

# 2018 Headline Article – DRUG SHORTAGES continue to compromise patient care

- August through October 2017 national survey on drug shortages by Institute of Safe Medication Practices (ISMP)
- 300 respondents completed survey
- Respondents noted that *“the state of drug availability in the US is unacceptable”*
- Respondents felt *“inadequate planning during recent drug company mergers has led to many of the recent drug shortages”*
- Respondents are blaming *“drug manufacturers for limiting supplies to increase demands/bolster profits, noting that products in short supply return to the market are often more costly”*
- Respondents questioned *why drug shortages continue to occur at an alarming rate that make it nearly impossible to provide safe, high-quality patient care in a fiscally responsible manner*

# Results of survey

- Respondents provided approx. 100 errors as examples; 67% were associated with the wrong dose or concentration
- Few respondents reported receiving advanced notifications from drug manufacturers, wholesalers, distributors, group purchasing organizations, or FDA about impending drug shortages (12%), their causes (13%), or their duration (11%)
- 71% were unable to provide patients with the recommended drug or treatment for their condition due to shortages
- 47% thought that this resulted in patients receiving a less effective drug
- 75% stated that patient treatments had been delayed due to drug shortages
  - Ex.- involved delay in treating sepsis and acidosis using sodium bicarbonate that may have contributed to a patient's death
- 5% of respondents reported other types of adverse outcomes related to drug shortages, such as increased pain or discomfort during a procedure due to the unavailability of a required analgesic or sedation agent

# Sufentanil-Fentanyl mix-ups during shortages

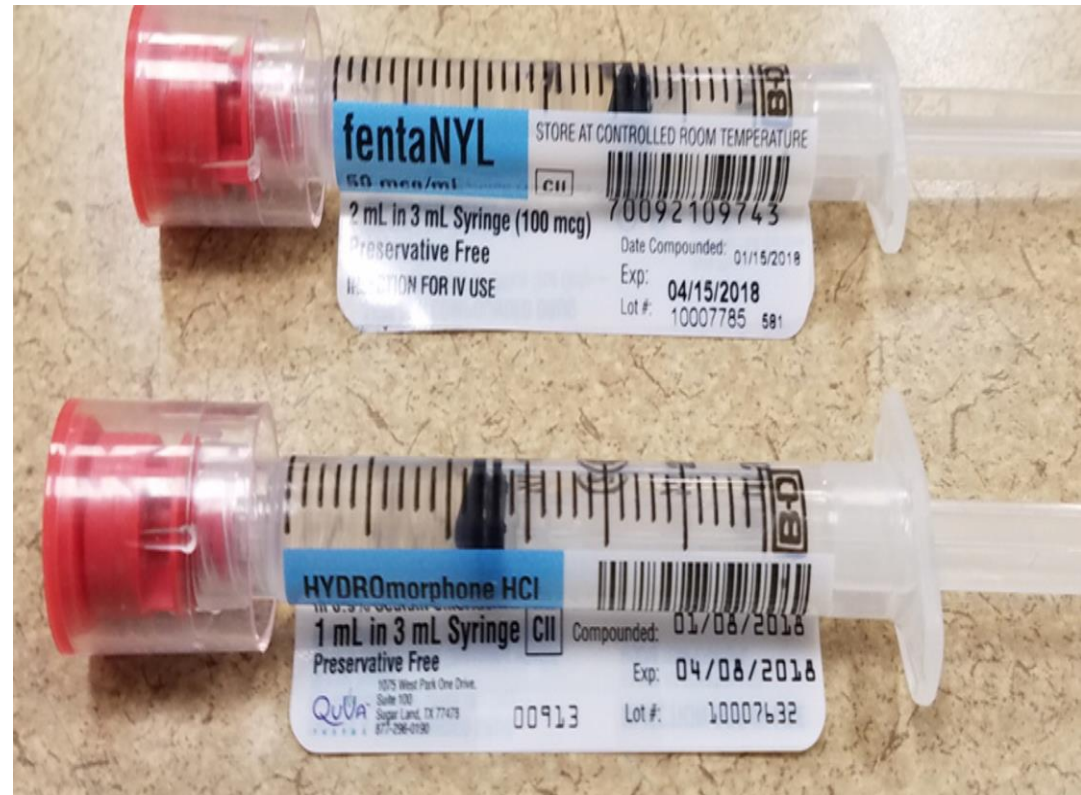
## Fentanyl shortage errors

- **Anesthesiologist administered 50 mcg of sufentanil intravenously (IV) instead of fentanyl-patient developed respiratory arrest and required intubation**
- **Pharmacist made a patient-controlled analgesia (PCA) solution with sufentanil instead of fentanyl using same concentration**
- **Nurse selected SUFENTA<sup>®</sup> (sufentanil) 50 mcg per mL instead of SUBLIMAZE<sup>®</sup> (fentanyl) 50 mcg per mL after typing “su” and choosing the wrong drug due to the mnemonics assigned to these drugs**

All of the involved patients became unresponsive and required supportive care but recovered



Drug shortages worsening the situation, as hospitals rely more on compounders they have not previously used to fulfill their needs.



503A/B Shortages – Need to assure safe labeling practices

# NEJM-July 18, 2018

Shortages of the 3 best-known parenteral opioids (morphine, hydromorphone, and fentanyl) may increase the risk for errors when we switch a patient to a less familiar drug or to opioid-sparing drug combinations

<b>Possible Clinical Measures to Address Shortages of Parenteral Morphine, Hydromorphone, and Fentanyl.</b>	
<b>Intervention</b>	<b>Limitations</b>
Oral opioids when possible	Delayed analgesia; many patients cannot take oral opioids
Transdermal fentanyl	Delayed analgesia; not available for morphine or hydromorphone
Custom-made methadone suppositories	Requires complex opioid rotation; safe only if administered by experts
Supportive and palliative care consult	Understaffed in most hospitals
EHR notification, alternative opioid and dose ratio immediately on prescription	Change in EHR expensive and slow
Nonopioids (cannabinoids, gabapentin, ketamine)	Limited evidence of efficacy, toxicity risk when combined with opioids
Less common parenteral opioids (nalbuphine, buprenorphine)	Limited evidence of efficacy, complex opioid rotation, and toxicity



# Carpject flawed but released due to shortages May 18, 2018

- Carpject glass syringes may have cracked needle hubs and/or contain particulate matter (separate issues)
- Certain strengths and sizes of heparin, labetalol, lorazepam, morphine, and hydromorphone
- Cracked hub could allow air to reach the outer cartridge (not the solution inside)
- To help reduce critical drug shortages, company has begun to release affected lots, which should reach wholesalers by mid-June.
- Provider should visually inspect to confirm there are no cracks to the needle hub or visible particulate matter or discoloration.

# Resource-intensive actions

- Add back-up inventory important drugs
- Change par levels on Pharmacy inventory
- Purchase more expensive brand, generic, or therapeutic alternative product from established wholesaler
- Purchase more expensive products from a new distributor/outsourcer
  - 15% of respondents admitted to purchasing drugs at greater cost from a secondary gray market
- Borrow or purchase from another health system
- Purchase directly from manufacturer
- Purchase different strengths/concentrations
- Compound

# Resource-intensive actions

- Ration/restrict drugs
- Establish criteria for using products
- Use drug in short supply outside its specific labeling to help extend its use and/or keeping expired products (without FDA approval/30% of respondents)
- Repetitive contacting wholesaler/suppliers for ETA's and placing backorders
- Multiple reviews daily of manufacturer/wholesaler ordering site
- Finance approval for large non-routine purchases
- Tracking direct orders
- Managing space for storage of larger quantity purchases
- Need full-time staff to manage drug shortages
- Compiling communications on shortages/fielding numerous questions

*Tasks associated with shortage process cut into time devoted to patient care & med safety*

# Recommendations to help prevent and mitigate shortages

1. **Manufacturers should provide FDA with more information on causes of shortages & expected durations**
1. **Health systems should establish best practices for high-alert drugs**
3. **FDA should require manufacturers to establish contingency plans**
4. **FDA should establish incentives to encourage manufacturers to produce drugs in shortage**
5. **FDA should provide information on quality of outsourcing facilities' compounding**
6. **Reconsider the purchasing process of 0.9% sodium chloride injection**
7. **Manufacturers need to be more transparent**
8. **Examine drug shortages as a national security initiative**
9. **Request EHR vendors to make changes to their systems to ease burden of making drug product changes.**
10. **FDA should establish a quality manufacturing initiative.**
11. **FTC should include the potential risk for drug shortages in its review of drug company merger proposals**