Oklahoma Association of Nurse Anesthetists
Fall Meeting
River Spirit Casino and Resort

September 29-30, 2018

Dealing with Anesthetic Shortages

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What to expect for today?

- What is a drug shortage?
- What causes a drug shortage?
- Impact on Patient Care
- Avoiding / Minimizing Impact of Drug Shortages
- What can be done (on a multitude of fronts) to protect your patients and protect yourself?
What is a drug shortage?

Food and Drug Administration ("FDA"):
We define shortages as a period of time when the demand or projected demand for a medically necessary drug in the United States exceeds its supply.

American Society of Health-System Pharmacists ("ASHP"): A drug product shortage is defined as 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.
How does a patient define a drug shortage?
National Drug Shortages

- Drug shortages risk of patient harm and cost of healthcare.
- In a recent survey, 98% of hospital pharmacists reported moderate to severe shortages of key opioids: morphine, fentanyl, hydromorphone.
- Without their first-choice drugs for certain conditions, many healthcare professionals must make the best of what they have on hand, and these drugs may be less effective and have more side effects, Augustine said.
- Current shortages include opioid pain medications, certain anesthetics and various antibiotics.
- The US Food and Drug Administration is forming a Drug Shortages Task Force to look into the country's persistent drug shortages and find long-term solutions.
So what causes a Drug Shortages?

- Manufacturing (30%)
- Supply and demand (8%)
- Lack or resources (raw or bulk materials) (2%)
- Natural disasters (3%)
- Product discontinuation (4%)

The Remaining 53%...?
We don’t know...
What could be some other causes?

- Group Purchasing Organizations?
  - Decreasing prices and driving generics out of the market
  - Collapse of competition

- Flow of Information
  - What drug did Michael Jackson take?
  - New England Compounding Center 2013
  - Can only increase production if on FDA shortage list

- Manipulation of Supply and Demand to Increase Profits?
Most Common Drug shortages

- Common classes of drugs affected by shortages:
  - Anesthesia medications (85%)
  - Antibiotics
  - Pain medications (81%)
  - Nutrition and electrolyte products
  - Chemotherapy agents
Current Number of Shortages Reported by the FDA
What about local drug shortages?
Who Still Does Not Care?

The patient on the table…
So what do you do?
Ok.... No disrespect...

I

DIDN’T REALLY

NEED A LAWYER

TO TELL ME THAT!
What are the healthcare risks?

• Substitution of drugs yields increased risk
  – Unknown conversion factors
  – Intermixing single use v. multi-use vials
  – Identifying the right alternative
  – Applying the right protocol / dosage etc.
  – Increase / Differing risk factors
    • (informed consent)
Drug shortages can impact patient care

- Are drug shortages impacting patient care? **YES!**

- Propofol shortage produced abrupt changes in clinical practice
  
  - Before propofol shortage: 80% of surgical patients received propofol (n=2830)
  - During propofol shortage: 81% received etomidate (n=3066) (600% increase)
  - Notable increase in use of Methohexital (rarely used prior to shortage)

**Question:**

- *Were all practitioners sufficiently familiar with these substances?*
- *Were there patients?*
How drug shortages may have impacted patient care

• Shortage of norepinephrine led to increased in-hospital mortality by 3.7%.
  — Phenylephrine was most commonly used as a replacement vasopressor.

• Shortages (increased cost of) Epi-Pen led to patients using expired drug.
  — Increases in anaphylaxis-related diagnoses or hospitalizations, representing “increased demand” and lack of competition with other companies, led Mylan to raise the price, "gouging" customers, the government and insurers.

• Shortages in anesthetic medications have led you to practice in a non-usual manner.
  — Different drugs have different potencies, increasing the chance of a medication error.
  — Ex: Sufentanil: 1,000 times more potent than morphine; patient went apneic after receiving.
  — Two patients died from overdoses during the opioid shortage in 2010.

• Shortages in opioids have led to cancer patients receiving less potent drugs.
Other Possible Impacts

– Medication errors
  • More likely to occur when a pharmacy alters how a product is ordered, prepared or dispensed
  • More likely to occur when prescribing practices change to less-familiar alternative agents
  • Substitutions may lead to a drug that is less efficacious or requires an unusual or difficulty dosing regimen

– Substituting with a drug that may have more or worse side effects
  • Example: Substituting hydromorphone with morphine
    – Hydromorphone commonly used due to fast onset and outstanding side effect profile
    – Morphine has many side effects, including histamine release, N & V
    – Morphine now short, so going to even older drugs (meperidine)
What is the fallout of this?

- Rationing or restricting drugs
- Using drugs outside of labeling
- Compromising care
  - Unable to provide treatment for a specific condition
  - Patients getting a less effective drug
  - Delays in care
- Changes to drug storage / pharmacy practice
  - (good and bad)
Oh.... And just wait until the lawyers figure this out!

And God saw that everything was good ... and then the lawyers appeared...
So what can we do about this?

Focus on:
- Patient Safety
- Preparation
- Documentation
- Communication
- Follow through and Follow up
Patient Safety

- One large single use vial
- Three patients / procedures
- What do you do?
Preparation

• Pay attention to what is going on in the world

• What are the most likely problems you will encounter?

• What are your contingency plans?

• Do you have policies and procedures in place?
Failing to think about it yields making it up as you go along

Good for theater… bad for patients.
From a big picture perspective

- Assess the situation
- Prepare for the situation
- Have Contingency Plans in Place
- Know what needs to be done to Implement
What can the Pharmacy do to Manage Drug Shortages?

- Add a back up supply for critical drugs
- Change minimum inventory levels
- Purchase excess amounts
- Buy a more expensive brand
- Use an alternative supplier or outsourcing
- Use a secondary market
- Pharmacy prepares from bulk ingredients as needed
What can anesthesia providers do to help in a shortage?

• Cautiously substitute other medications, hoping they won’t become short.

• Do not hoard medications if a shortage is predicted.
  – Stockpiling can cause artificial shortages, is costly, and may not be absorbed by normal usage if shortages do not occur as anticipated.

• Plan ahead to use alternative therapies with information on how to appropriately use and dose the medication.

• Stay informed on available alternatives and have a plan in place (and know how to execute it, too!)
What can anesthesia providers do in the current environment?

- Use a multimodal approach to combat the shortage of IV fentanyl, hydromorphone and morphine, including regional anesthesia.

- Considered “best practice”.
  - Utilize regional blocks when possible
    - Local anesthetics, such as bupivacaine, lidocaine and ropivacaine, are also in short supply.
  - Use other agents such as NSAIDS, acetaminophen, gabapentin, antidepressants to avoid using opioids that are in short supply
    - Consider meditation, physical therapy, occupational therapy
Documentation

• Damned if you do…

• Damned if you don’t…

• So do… and do it right.
Implementing a well thought out plan is better (for you and the patient) and more defensible then winging it!

But policies on a shelf are useless if the people responsible for implementing them are not aware of them and trained on how to effect them.
Communication

“FAILURE TO COMMUNICATE IS THE SHORTEST PATH FROM BAD TO WORSE”

Who said this?
That would be...... Me!
Follow up and Follow Through

“THOSE WHO CANNOT REMEMBER THE PAST ARE CONDEMNED TO REPEAT IT.”

George Santayana
Philosopher, essayist, poet, and novelist.
(Born: December 16, 1863 in Madrid, Spain and died September 26, 1952 in Rome, Italy)
Other challenges you are facing?
Summary

• Drug shortages are a frequent problem impacting the anesthesia provider, pharmacy, and patients.

• You cannot prepare for every potential shortage, but proper planning can reduce adverse effects on patient care and can prevent problems from escalating into crises.

• Know what you are doing, know why you are doing it, and document-document-document.

• Protect your patient, protect yourself, positive results will follow.
Thank you to Lynn Reede @ the AANA

(For anyone who read a few of these slides and thought… WOW! For a lawyer… he really understands the specifics of CRNA practice…. It’s good to have friends in high places!)

• This is also a plug – when dealing with practice issues or challenges --- the AANA is an incredible resource for identifying solutions and avoiding problems!
Don’t need me...
But I’m here if you do!

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