Drug Shortages: what can we do?

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I have no conflict of interest to disclose.
Goals and Objectives

1) Understand the causes of nationwide drug shortage.
2) Identify strategies for substitution of available drugs during times of shortage.
3) Understand pitfalls or risks in using alternative drugs with associated medical and legal ramifications
Steps contributing to kinks in the process

1. Raw Materials
2. Manufacturer Process
3. Distribution Chain
4. Societal wrenches
Raw material

- Supply shortages
  - Active ingredients
  - Excipients, inert material
  - Weather occurrences
- Transportation
  - Natural disasters
  - Strikes
  - Other interruptions
Manufacturer Process

Dedicated assembly Line (lane)

Priority

FDA Mandate
Manufacturer Decision

Voluntary Recall

Economic
Distribution

Hoardings

Natural Disasters
Societal issues

Supply/Demand

3rd Party & payer issues
Dealing with shortages requires a two-pronged approach:

1. Secure product—either alternative drug, manufacturer or dose
2. Assure safe use with adequate education of all healthcare providers
Securing product can mean:

- Conserving available product,
- Changing wholesalers
- Changing manufacturers
- Using a therapeutic alternative
Conserving available product

- Prepack in smaller units in a sterile environment
- Restrict use to specific services or procedures
- Restrict ready access
Selecting alternative therapy

- Multi-disciplinary team
- Review dose differences and possible monitoring differences
- Educate nurses, physicians, and any healthcare provider about differences
- Plan for resource use changes
  - If time for recovery is longer, nursing staffing and bed utilization will be altered.
Educating affected staff in all disciplines

- Actual change being made
- Dose calculation changes
- Vial size changes
- Criteria for restricted use
- Monitoring requirements including:
  - Side effects and what to look for
  - Expected onset and duration of effect
  - Safety window after which intense monitoring isn’t necessary
Safety Measures to Back-up Reading

- Clear labeling of stock
  - ****New formulation*****
- Color alert and/or font changes from norm
  - *Epinephrine 1mg/ml NEW dose=1ml NOT 10ml*
- Warning memo with potential risks
  
  “epinephrine 1mg/10ml (1:10,000) is no longer available. New product is 1mg/ml (1:1000) or 10 times more potent. Please dose accordingly.”
Steps to planning strategies for dealing with specific shortages

- Identify early
- Plan conservation; prioritize use
- Engage pharmacist and key prescribers for formulation of an alternative plan
- Consider differences in monitoring, interactions, and doses and dosing intervals in alternatives.
- Educate staff and physicians
- Create easy to use ‘cheat sheet’ to reinforce
Conservation and distribution

- Should storage be centralized?
  - Inventory may be more closely monitored
  - Areas with low utilization are not ‘hoarding” supply
- How is it determined who gets limited supply?
- What is the basis for choosing the recipients?
  - Disease state?
  - VIP status of physician or patient?
  - Guidelines or pathways?
  - Available adequate alternatives?
  - Severity of illness?
Setting priorities fairly

- Severity of condition
- Alternative options are available
  - Base on disease
  - Base on age
  - Base on ability to take alternatives
- Indications are clear
  - FDA indications are followed
  - National guidelines are given priority
- Parameters fit the sunshine rule
One Institution’s Approach to Ethical Allocation of Limited Drug Supply

- **Transparent**
  - Any stakeholder can review

- **Relevance**
  - Decision is based on clinical evidence
  - Parameters are rational
  - Hospital population is considered

- **Appeal process**
  - Process built in to appeal a decision which is felt to be unfair

- **Enforced**
  - Eliminates “VIP” or “special consideration”

- Rosoff, Philip et al; “Coping with Critical Drug Shortages”, *Archives of Internal Medicine, 172*(19) 10/22/2012;1494-1498
Dealing with shortages requires different approaches depending on type of medication.
Succinylcholine shortage and one institution’s plan

- Notify affected area (i.e.) anesthesiology
- Identify therapeutic alternatives
  - Use is primarily for performing rapid sequence intubation
  - Alternatives are rocuronium, vecuronium, cisatracurium
- Identify significant properties of alternatives
  - Delayed onset (minutes compared to seconds)
  - Increases duration of monitoring as effect lasts longer (under 10 minutes to over 30 minutes)
- (adapted from UCI plan, 10/2012)
Succinylcholine shortage and one institution’s plan

- Point out dosing differences
  - (i.e.) succinylcholine 0.3-1.1 mg/kg
  - (i.e.) cisatracurium 0.15-0.2 mg/kg
- Identify special population risks
  - Liver/renal patients use cisatracurium
- Educate all parties on alternatives and their properties
  - Pharmacists
  - Nurses
  - Surgeons
  - Hospitalists
  - (adapted from UCI plan, 10/2012)
Consider utilization pathways upstream and downstream too

- Succinylcholine and shortages
  - What are your alternative neuro-muscular blockers?

- Furosemide shortage
  - Should you use medication with potential rhabdomyalgia?

- Sodium bicarbonate shortages
  If you get into trouble (Malignant hyperthermia) can you reverse it?
Strategies for Conserving Injectable Loop Diuretics

1. use stepwise dosing-start low and assess results
2. substitute oral dosage forms in appropriate patients
3. consider supplementing moderate loop diuretic dose with thiazide diuretic such as metolazone or chlorthalidone in lieu of larger loop diuretic dose
4. pre-pack or unit dose from a bulk vial
5. limit automated continuous orders for injectables to a short period of time – re-evaluate efficacy of dose early
Strategies for dealing with injectable narcotic shortages

- Remove decentralized stock from all areas without emergent need
  - i.e. epidurals are likely emergent in OB but probably not in chronic pain or orthopedics
- Change doses to oral if patient can eat
- Provide conversion charts to staff
  - Significant source of errors are hydromorphone/morphine dose conversions
- Consider topical dosage forms for patients who meet criteria (not naïve patients) and who cannot take orals
- Consider non-narcotic pain management
Strategies for dealing with Propofol shortages

- Pre-pack smaller volumes—use one for two
  - Only if done in sterile environment by pharmacy
- Reduce rate of infusion
  - Can you do so and achieve the same level of sedation?
- Substitute benzodiazepine (i.e.) lorazepam or midazolam
  - Benzodiazepines can ‘stack’
- Reserve for ICU sedation
Besides changing options, what other effects do shortages have?
Electronic age problems

- Automated pathways and order sets need revision
- NDC billing codes need correcting to new product
- Standardization leads to a lack of familiarity of *anyone* with the alternative agent(s)
- Limited formulary options need programming
Economic impact

- Staff time and redirection from other priorities
- Cost differences of alternative agents compared to previously determined most cost effective treatments
- Reimbursement and co-pay changes
- Special contract incentives become difficult to meet
- Elective procedures and/or non-emergent treatments postponed or cancelled
- Possibly increased recovery time or monitoring parameters
Safety issues -

- Internal
  - Inaccurate dosing
  - Incorrect route
  - Prolonged monitoring
  - Drug interactions
- External
  - Authenticity of grey market products
Ideas to remember

- Drug shortages necessitate multi-disciplinary, all stakeholder involvement when formulating plans.
- Hospitals should have an outline of steps needed to completely implement a shortage plan.
  - As much as creating a plan, remembering to notify IT, or alter pre-printed lists, etc needs to be formalized.
- Education, information and forewarning should be forthcoming.
- Evaluating plan should be done during and after to access appropriateness, efficacy and perhaps a better alternative to status quo.
Summary

- Shortages have different causes.
- Plans need to be made by stakeholder providers from all disciplines.
- Safety issues as well as practice/monitoring changes need to be identified and communicated as well as the change itself.
- Clarity and specificity increase chances for a safe transition.
- Evaluation of plan can reveal options for future care.
Do you have a


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