DRUG SHORTAGES: 0.9% NS 1000ML

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OBJECTIVES

• Understand “What is a Drug Shortage?”
• Know “Who is Affected?”
• Be aware of “What causes Shortages?”
• Evaluate “What are the Results of a Shortage?”
• Assess the Associated Costs of the 0.9% NS 1000mL shortage
• Know “How long will the Shortage last?”
• Discuss and Evaluate “What are some solutions to this shortage?”
WHAT IS A DRUG SHORTAGE?

• FDA definition
  – A situation in which “total supply of all clinically interchangeable versions of an FDA-regulated drug product is inadequate to meet the projected demand at the user level.”

WHO IS AFFECTED?

• Patients
• Patient’s family
• Physicians
• Pharmacists
• Nurses
• Healthcare systems
• Government (FDA)
WHAT CAUSES SHORTAGES?

• Increase in Demand
• Loss of Manufacturing sites
• Gray market suppliers – Buy product and stockpile to create shortages
• Shortages in other products – D5W, 0.45% NS, LRs, etc
• 2013-2014 Flu season
• FDA warning letters – Product Quality issues
• Shortage of raw materials
• GPOs
• Recession
• Delays/Capacity Problems
• Discontinuation of products – Baxter 0.9% NS 150mL

WHAT ARE THE RESULTS OF A SHORTAGE?

• ISMP survey of 1800 healthcare professionals
  – 1000 med errors related to shortages
  – 35% near misses, 25% actual error, 20% adverse outcomes
• Premier Survey of 300+ experts
  – 89% shortages may result in safety issues/errors in patient care
• AHA survey of CEOs of major hospitals
  – 99.5% reported one shortage in previous 6 months
  – 82% reported delays in therapy due to shortage
• Shortages in other IV fluid products
• Increased Compounding of sterile IV products = greater risk of contamination and concentration errors
  – 9 dead patients from Serratia contaminated PN formulations
  – Recent Fungus contaminated intrathecal steroid formulations
WHAT ARE THE RESULTS OF A SHORTAGE?

- Increased costs (alternatives/Labor) to everyone
- Increased Stress to patients, patient’s families, physicians, and hospital staff
- Delays/cancellations of care interventions
- Electrolyte disturbances
- Dehydration
- Rationing
- Medication errors
- Presidential Executive Order 13588 calls for government to counter shortage challenges
- Food and Drug Administration Safety and Innovation Act (FDASIA)

ASSOCIATED COSTS FROM NS 0.9% 1000ML

- Manufactured:
  - Baxter
    - $1.00/bag
  - Hospira
    - $1.46/bag
  - Average
    - $1.23/bag

- Compounded:
  - H2O 2000
    - $4.01/bag
    - Makes 2 bags
  - NaCl 4mEq/mL 100mL
    - $8.29/100mL
    - Makes 2.5 bags
  - Empty bag
    - $1.63/bag
  - Tech Labor
    - $2.53/bag

- Total Cost of 28 bags
  - $261.94
$34.44  VS.  $261.94

HOW LONG WILL THE SHORTAGE LAST?

- Hospira Letter 01/17/14: late February-March
- Baxter Letter 01/17/14: many weeks
- B Braun letter: tight supply till April
- Realistic Timeline: Shortages will probably continue till Summer or possibly early Fall.
**BE AWARE**

- NS solutions with no evidence of compatibility or clear evidence of incompatibility:
  - Amiodarone
  - Atropine
  - Diltiazem*
  - Fentanyl*
  - Ganisetron
  - Ondaneston*
  - Metoprolol*
  - Midazolam*
  - Naloxone
  - Vasopressin

*Trissels compendium notes these as compatible

**SOLUTIONS**

**WHAT ARE SOME SOLUTIONS TO THIS SHORTAGE?**

- Manage Inventory
  - Review availability of all IV products nationwide to see if other alternatives are more feasible
    - LR, 0.45% NS, Dextrose formulations
  - Keep staff updated when changing between products.
  - Contingency contracts with other suppliers

- Stockpiling
  - Not recommended
WHAT ARE SOME SOLUTIONS TO THIS SHORTAGE?

- Avoid gray market vendors
- Require manufacturers to have redundancies in process
- Keep track of shortages as soon as possible
  - Elect a technician or pharmacist to keep updated
- Communicate with and Educate physicians on shortage
  - Consider “safety huddles” with clinicians

WHAT ARE SOME RATIONING SOLUTIONS TO THIS SHORTAGE?

- Triage and Rationing
  - Assess every patient for indications/need for IV fluids
  - Provide fluids via oral route when feasible
  - Prioritize patients
  - Cancel elective surgeries/procedures if necessary
  - Assess for signs of electrolyte deficiencies specifically sodium deficiency:
    - headache, lethargy, disorientation, restlessness, nausea, vomiting, muscle cramps or weakness, depressed reflexes, seizures, coma, and death
WHAT ARE SOME RATIONING SOLUTIONS TO THIS SHORTAGE?

- Use minimum requirements per national guidelines
  - Ex. Minimum Fluid Maintenance therapy
- Pharmacists are to review the record/medication profile for exclusions and contact the prescriber to discuss possible treatment options and/or alternatives in these situations:
  - Fluid resuscitation (albumin may serve as an alternative in this case)
  - Diabetic ketoacidosis
  - hyperglycemic hyperosmolar syndrome (HHS),
  - dialysis
  - patients receiving blood transfusions

WHAT ARE SOME RATIONING SOLUTIONS TO THIS SHORTAGE?

- Halt investigational use during a shortage
- Consider switching NS compounding to night shift if cost effective and able
- Use smaller bag sizes with low infusion rates when 1000mL isn’t necessary
- Never use saline irrigation solutions for IV use
- Consider all shortage medications as high-risk for duration of shortage.
- Implement prioritization schemes
  - Utilize literature
• Assess patients for compounding needs
• Consider moving compounding to a single, standardized central location to decrease waste
  • FDASIA allows for this which would mean that a central location can supply a # of hospitals within one system

WHAT ARE SOME COMPOUNDED SOLUTIONS TO THIS SHORTAGE?

• Outsource to other institutions or compounding centers
• Implement and informed consent program for sterile compounded products
  – Makes patients aware
• Follow USP <797> for all compounding to reduce contamination risk
• Have advance shortage plans in place
  – Develop a Drug Shortage Task Force
    • Physicians, Pharmacists, Nurses
    • Should report to Pharmacy and Therapeutics Committee and other Hospital Administrative Committees
    • Involve physicians to help implement shortage protocols
    • Re-evaluate replacement algorithms and treatment protocols
    • Have demand projections and plan around them
  • Become involved and promote the Accelerated Recovery Initiative (ARI) launched by Generic Pharmaceutical Association (GPhA)

REFERENCES

8. Healthcare MLB. Sodium chloride 0.9% (normal saline) and 0.45% (half-normal saline) in 1000 ml bags for injection memo- adult hospitals2014:1.
REFERENCES

5. Healthcare MLB. Sodium chloride 0.9% (normal saline) and 0.45% (half-normal saline) in 1000 ml bags for injection memo- adult hospitals2014.

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