Doesn’t Anyone Want to Make Drugs Anymore?  
Coping with the Drug Shortage Crisis  
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My Favorite Shortage  
• Empty evacuated containers  
• Shortage due to “increased demand and raw material constraints”

Overview  
• Drug shortage trends  
• Reasons for drug shortages  
• FDA involvement and strategy  
• Risk mitigation strategies and Children’s Mercy shortage action plans
• 10 medications on shortage greater than 50 times between 2001 and 2013
  – Dextrose, diazepam, epinephrine, fentanyl, lorazepam, morphine, ondansetron, nalbuphine, naloxone, promethazine

New Drug Shortages by Year

Active Drug Shortages by Quarter
January 2010 – June 2015
Summary of Trends

• Rate of new drug shortages is on the decline since 2011
• Active drug shortages are beginning to resolve
• Drug shortage situation is better, but still not good

Reasons for Drug Shortages

• Multi-factorial, complex problem
• Raw material shortage
  – Relatively rare cause of shortages
• Most are a combination of manufacturing quality and financial factors
• Not restricted to the United States
  – Imports can help, but are not the answer
  • Help us Canada!
Reasons for Drug Shortages

• Drug manufacturing is a business

$1.66

$1,000.00

Impact of Economics

• Less margin = less capital for quality improvements and infrastructure upgrades
• Generic facilities are aging and running 24/7 at capacity
• Forecasting
• 3 companies supply 71% of generic market

Quality of Manufacturing

• Manufacturing issues are complex and can take significant time to diagnose and fix
• FDA has increased auditing efforts to ensure manufacturers in U.S. and beyond are complying with good manufacturing practice requirements
**Role of the FDA**

- Prioritize medically necessary medications
- Exert regulatory discretion
- Allow imports in extreme cases
  - Propofol, IV fluids, thiotepa
- Through early notification efforts, work with other manufacturers to increase production
- Expedite reviews of new products, new manufacturing sites, and new raw material sources

**Outlook**

- May get worse…
  - FDA is increasing inspections in India and China
  - No new generic manufacturers on the horizon
  - Focus on biotechnology agents
- …but there is hope
  - Efforts toward prevention and early identification of manufacturing issues are working
  - Quality improvement efforts in manufacturing

**Dealing with Shortages**
CMH Shortage Definitions

- **Drug Shortage**
  - Diminished availability of a drug or product due to a variety of factors throughout the supply chain
- **Mild Drug Shortage**
  - Diminished availability of a drug or product has no impact on pharmacy services or patient care
- **Moderate Drug Shortage**
  - Diminished availability of a drug or product has implications on pharmacy services
- **Critical Drug Shortage**
  - Diminished availability of a drug or product has implications on pharmacy services and patient care

Pharmaceutical Pipeline

- Manufacturer A
- Manufacturer B
- Manufacturer C
- Wholesaler (Cardinal)
- Other Hospitals
- CMH

Identifying a Shortage

- Try to order it and discover that it’s not available
- List-serves
- Practitioners
What Happens When A Shortage is Identified?

- Pharmacy buyers validate shortage
  - Determine anticipated duration & reason for shortage
  - Contact wholesaler, manufacturer, other institutions
- Pharmacy buyers determine availability from other sources
  - Direct from manufacturer, other hospitals, etc.
- Pharmacy buyers determine how long our current supply might last
  - Supply on hand vs. estimated usage
- Pharmacy manager recommends action plan
  - Use of alternate products (if appropriate)
  - Restriction of use of current supply
  - Work with medical staff on options when necessary

CMH Shortage Action Plans

- Mild Drug Shortages
  - Buyers choose another product to purchase
  - May cost more, but no impact to pharmacy or patients
  - No notification to anyone necessary

- Moderate Drug Shortages
  - Pharmacy can purchase medication, but it comes in a different strength/size/package
  - Pharmacy repackages or manipulates, but the patient still receives the same medication
    - Example: UD cups are unavailable, and pharmacy has to pre-pack syringes from a bulk bottle
    - Example: 2 mg/2ml vials are not available, pharmacy has to purchase another strength (4mg/2ml) or size (1mg/1ml) or package (2mg/2ml ampules)
  - Notification to Pharmacy & sometimes Nursing if package size or look will be different
CMH Shortage Action Plans

• Critical Drug Shortage
  – Restrictions put in place to conserve supply
  • Example: antibiotics, cysteine, MWF Trace Elements
  – Alternate products utilized
  • Example: IV lansoprazole instead of IV pantoprazole
  – Electronic Alerts in Cerner
  • "Limited Availability" or "Unavailable"
  – Providers are notified
  • SBAR shortage email

Tools & Resources for Drug Shortages

• Internal
  – Weekly meeting with buyers to discuss status of ongoing shortages
  – CMH Drug Shortage Page on the SCOPE
  – SBAR Shortage Emails
  – 'Limited Availability' or 'Unavailable' tags in Cerner
• External
  – ASHP Drug Shortage Resource Center

Questions?