Collaborating with the FDA to Manage Drug Shortages

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Webinar Goal
Through awareness and understanding of the overall scope of the issue, nurses will be able to develop and implement guidelines for best practices in collaborating with the FDA and pharmacy in the management of drug shortages

Session Topics
- Overview of Drug Shortage Staff: Roles
- Drug Shortages: Sources and Data
- FDA and Manufacturer Roles
- Nursing Role: Collaboration and Communication
Definition of a Drug Shortage

A change in the drug supply that has the potential to compromise patient care.

Medical Necessity

A *medically necessary drug product* is a product that is used to treat or prevent a serious disease or medical condition for which there is no other alternative drug available in adequate supply, that is judged by medical staff to be an adequate substitute.
U.S. Food and Drug Administration (FDA)
Who we are and what we do

Patient care is the #1 concern
- Gets involved when informed
- Seeks ways to prevent and mitigate shortages
- Only some shortages can be prevented
- Some can be addressed quickly while others require more time
Overview of the Drug Shortage Staff (DSS)
Drug Shortage Staff

Mission: To prevent, mitigate, and help resolve shortages

- Outreach to professional organizations, patient groups, the public and other stakeholders
- Part of the Center for Drug Evaluation and Research (CDER)
  - DSS began in 1999
  - Today have 13 full-time staff
Drug Shortage Staff: Role

DSS facilitates prevention and resolution of shortages by working with key stakeholders from the FDA, other government agencies, industry, and the public.

Within the FDA, DSS works closely with:
- Office of New Drugs (OND)
- Office of Pharmaceutical Quality (OPQ)
- Office of Generic Drugs (OGD)
- Office of Compliance
- Office of Regulatory Affairs Field Inspectors
Drug Shortages Data
Drug Shortages Data Sources

- Current shortage information updated daily at http://www.fda.gov
- Reporting shortages is encouraged
  - Contact from the public about existing shortages
  - Contact from industry about potential shortages
  - Executive order to require early notification (2011)
  - Food and Drug Administration Safety and Innovation Act (FDASIA) legislation (2012)
Polling Question

Which of the following most closely represents your institution’s current ability to manage drug shortages?

- Not at all prepared
- Somewhat prepared
- Very prepared with an informal process in place
- Extremely well prepared with formal policies, committee, communication with pharmacy
Supply Chain Management
Drug Supply Chain
1st Tier

SUPPLIER → MANUFACTURER → WHOLESALER → PHARMACY/HOSPITAL → PATIENT/HEALTHCARE PROVIDER

Inventory/Production Data:
Voluntarily Supplied
Supply Interruptions:
Voluntarily Supplied

Inventory/Supply Interruptions:
Voluntarily Supplied

Sales/Market Share Data:
Reported to FDA via IMS

Public Notifications:
FDA Drug Shortages email account

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Drug Supply Chain

2nd Tier

SUPPLIER → MANUFACTURER → WHOLESALER → PHARMACY/HOSPITAL → PATIENT/HEALTHCARE PROVIDER

Very limited to no data available to FDA regarding these 2nd tier supply sources.

REPACKAGER → SECONDARY WHOLESALER/DISTRIBUTOR → COMPOUNDER
Polling Question

Which of the following types of drugs is most often in short supply when there is a shortage in your facility?

- Anesthesia drugs
- Antibiotics
- Critical-care drugs
- Chemotherapy drugs
- Intravenous nutritionals
Why Do Drug Shortages Occur?
Reasons for Drug Shortages: 2013

- **Quality**: Delays/Capacity
- **Quality**: Manufacturing issues
- Discontinuation
- Raw Materials (API)
- Shortage of Component
- Increased Demand
- Loss of Manufacturing Site

CDER Drug Shortages

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Drug Shortages Cannot Always Be Prevented

- **Unanticipated events** occur
  - Manufacturing line breakdown or natural disaster (Tsunami)
- Sometimes manufacturer may not make up **production shortfall**
- If **systemic issues** present, the plant may have to close to repair

**Goal:** The FDA and the manufacturer can work together to encourage smart distribution
Shortages and the FDA Response
Drug Shortages Data

- **251** shortages reported in 2011
- **117** shortages reported in 2012
- **44** shortages reported for both 2013 and 2014

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Drug Shortages Data

- A high percentage are sterile injectables
  - Chemotherapy, anesthesia, injectable nutritional medications, and other acute meds
  - Highly specialized manufacturing processes
  - High risk to patient if process is not meticulous
- When there are quality or production problems for sterile injectables, the result is almost always a shortage
Shortages and FDA Response

What FDA CAN require:
- Notification by manufacturers (FDASIA)
  - Supply disruptions
  - Delays
  - Discontinuations
  - Notification of manufacturing changes

What FDA CANNOT require:
- A company to make a drug
- A company to make more of a drug
- How much and to whom the drug is distributed

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Role of Industry and Manufacturer
Role of Industry and Manufacturer

- Communicate early about potential shortages
- Provide shortage information for posting on FDA website when shortage unavoidable
- Provide short-term and long-term plans for preventing and addressing shortages while maintaining and improving quality
- Work with FDA to minimize shutdowns or slowdowns that will lead to shortages
Collaborative Role: Nursing and Pharmacy

1. AWARENESS OF ISSUE
   Understanding and Managing Drug Shortages

2. PLAN IN PLACE

3. COMMUNICATION

4. IMPLEMENTATION
Summary

- Focus on industry commitment to a culture of quality manufacturing
- We can only prevent shortages if problems are reported
- Public communication of existing shortages
- Be on the “get notified list” (see FDA drug shortage app free download via App Store for Apple devices and Google Play Store for Android devices; search for “FDA Drug Shortages 2”)
- Join your organization’s pharmacy and therapeutics committee if invited
- Seek out information via the FDA website if you see a trend
Questions?
AACN Implementation
Tools and Resources

Designed to help you apply these practices in your environment

- **Tools and Tactics**: Blueprint for Education and Collaboration while Managing a Drug Shortage
- **Bridging the Gap**: A Gap Analysis to Evaluate Staff Awareness and Collaboration during a Drug Shortage
- **Resources to Manage a Drug Shortage**: Resources and References to Guide Your Practice
- **FDA Drug Shortages Mobile Application**
- **FDA and ASHP Comparison List**

Find these tools on the Managing A Drug Shortage webinar information page at [www.aacn.org/webinars](http://www.aacn.org/webinars)

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Collaborating with the FDA to Manage Drug Shortages

1. Download the Implementation Tools. Find them on the: Collaborating With the FDA to Manage Drug Shortages webinar information page at www.aacn.org/webinars

2. Discuss the tools and recommended practices with your colleagues

3. Implement practices that are suitable for your unit
References


References
