Drug Shortages - Current Status & State Survey Results

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Disclosure

- I do not have a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity or any affiliation with an organization whose philosophy could potentially bias my presentation.

A shortage of everything except ERRORS

The FDA - Background Information & History

- FDA originated in 1906 first known as the "Pure Food and Drug Act"
- Good Manufacturing Practices (GMP) was developed by the FDA in 1938 – 73 years ago.
- GMP - Inspection of facilities in the last year (2010) has caused 43% of shortages in this country
- The FDA has received additional funding and increased their budget over the last two years (2010 – 2011)
- Current drugs shortages are mostly injections (80%) thus affecting hospitals much more than drug stores *From FDA Website

FDA - Staffing

Drug shortages occur due to the following:
- Lack of resources / ingredients – 10%
- Inspections by the FDA manufacturing problems – 43%
- Delays in shipping – 15%
- Fewer companies making the products - 8%
- Less money for generics - ? %
Drug Shortages Breakdown by FDA

Quality and Manufacturing Issues

Examples of Recent Quality and Manufacturing Issues Involving Sterile Injectables - 1

• Significant quality issues that have occurred
  – Sterility problems – including bacterial and mold contamination
  – Particles of foreign matter (glass, metal and fibers) in vials
  – Crystallization of the active ingredient
  – Precipitate formation (due to reaction with raw materials or container/stopper with the drug)
  – Newly identified impurities or degradants

FDA Inspections

• The FDA received additional funding and increased their budget in 2010 – 2011.
• Inspection of facilities in the last 2 years has caused 43% of shortages in this country.
• Current drugs shortages are mostly injections (80%) thus affecting hospitals much more than drug stores *From FDA Website
• The public is mostly unaware of the issue.
• Ramping up of inspections by the FDA in 2010 – 2011 drastically increased the warning letters sent to manufacturing facilities from 2010 to 2011 by 156%.

Total Drug Shortages Compared To Sterile Injectable Shortages

P&T Journal

Figure 1: National drug shortages from January 2001 to September 15, 2011. Each column represents the number of new shortages identified during that year. (From Fox ER, University of Utah Drug Information Service.)

PT > v.36(11): Nov 2011
From The FDA Website

- In 2010 there were 178 drug shortages - 132 were injectable drugs
- In 2011 there were 251 drug shortages - 183 were injectable drugs
- In 2012, there were 219 drug shortages
- In 2013, there are still 121 drug shortages

Breakdown of Shortages – The Real Meaning

- In 2013, there are still 121 drug shortages (one month into the new year)
- The 121 number mentioned above are classes of drugs. For example, 121 drug shortages in 2013:
  - Propofol is counted as 1 in the number above but includes 12 different products according to FDA
  - Hydromorphone is counted as 1 in the number above but include 27 different products according to FDA
  - Potassium chloride is counted as 1 in the number above and includes 45 different products according to FDA
  - Lidocaine is counted as 1 and the number of products and includes 57 different products according to FDA
- On the FDA website as of January 15, 2013, there are 822 drugs on backorder

Wholesaler Backorders, Shortages, & Discontinues

Our wholesaler reported the following on our vendor availability report:
- January 2012 – 4,242
- November 2012 – 4,283
- December 2012 – 4,336
- January 2013 – 4,147
- February 2013 – 4,167

U.S. House of Representatives
Committee on Oversight and Government Reform
Darrell Issa (CA-49), Chairman

Recommendations
- Proposals to allow drug companies to share information about each other’s manufacturing capability and product availability may have merit because of the extraordinary circumstances of the present drug shortage crisis. However, this type of information sharing potentially places consumers at risk as a result of collusion by the large manufacturers.
- “The committee has learned that FDA regulatory activity has effectively shut down 30% of the total manufacturing capacity at four of America’s largest producers of generic injectable medications”
- From their findings, the House Oversight Committee found that 58% of the drugs on the shortage list were produced at facilities cited by the FDA. They also found that the FDA’s warning letters increased 156% from 2010 to 2011.

Regulatory Issues for Hospitals

- Joint Commission recommends that hospitals standardize concentrations to minimize chance of errors – This is almost impossible due to shortages
- CMS (Center for Medicare Services) mission and vision it based on promoting quality care. Drug shortages can jeopardize quality due to manipulations and unavailable medications in the proper concentrations.
- USP (United States Pharmacopeia) set stability and sterility standards for injectable medications. There is a regulation that requires manufacturers to notify the FDA when drugs are in short supply
- Board of Pharmacy inspections for compliance with stability and sterility standards
Increased Cost to Hospitals

- In March 2011, Premier stated the cost of purchasing alternative therapy to those in shortage - $200 million
- ASHP estimated the additional labor cost to hospitals to manage shortages - $216 million

Problems with Drug Shortages – Safety Concerns Slide 1 of 2

1) Hospitals receive no warning when a product becomes unavailable
2) Alternative drugs must be used during shortages – Delays in treatment because of unavailability of drugs – it takes time to contact Physicians to change medications
3) Buying different concentrations of a medications leads to medication errors.
4) Pharmacy and Nursing staff are unfamiliar with drugs that are not normally stocked and thus do not take the time to review the literature prior to administrations.
5) Pharmacies must perform time consuming searches for life saving medications which sets us up for failure and places our patients at risk
6) Hospitals are having to dilute, manipulate, and relabel products that cannot be purchased in the most ready to use form. - increases the chance of errors significantly
7) Extended length of hospital stay due to lack of product availability. Creates unsafe conditions for our patients
8) New or alternative medications obtained must be added to bar code systems, pharmacy inventory systems, automated dispensing cabinets, hospital information systems, and computerized Physician Order Entry systems – time consuming process that is massive with drug shortages

Problems with Drug Shortages – Safety Concerns Slide 2 of 2

9) Hard to find companies have begun price gouging hospitals on prices for drug shortages.
10) Drug Shortages cause increased hospital costs and increased patient costs.
11) High prices for hard to find medications are still reimbursed at the same rate.
12) Manufacturing problems can cause drug recalls to occur – with so many recalls, notices are delayed in getting to hospitals to insure timely removal of product for our shelves
13) Multiple dose vials are used to draw up syringes because of shortages – increased chance of preparation errors and short dating of product required - 28 day expiration date (USP 797 Regulation)
14) Hospitals compete with each other for drugs that are in short supply
15) Hospitals buy all available of a product that is on backorder - stock piling
16) Emergency syringes (Sodium Bicarbonate and Epinephrine) are not available – We now make up a kit – very time consuming for care givers.
17) Increase chance of diversion when the only narcotic available is a 20 ml multiple dose vial of Fentanyl.

ISMP and AHA Statistics

- The ISMP Survey from 2011 reported over 1000 adverse events, 25% were medication errors, and 20% were adverse drug reactions.
- Alternative drugs must be used during shortages – Delays in treatment because of unavailability of drugs – it takes time to contact Physicians to change medications. The AHA July 2011 Survey found that 82% of hospitals reported delayed treatment and more than 50% said they could not provide some patients with the recommended therapy.

ISMP – Harm from Drug Shortages

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Not One Specific Area
Actual News Captions Due to Drug Shortages

1) Child cancer patient deals with drug shortage - Methotrexate
2) Chemo drug shortage to hit Hunter cancer hospital – Doxorubicin
3) Drug shortage looms over hospitals – Morphine & Fentanyl
4) Major drug shortage threatens lives & result in deaths– Propofol, Antibiotics, Cardiovascular agents, TPN solutions
5) Fake Pharmacies Create Drug Shortages
6) Drug shortage fixes can ready US for disasters
7) Drug shortage tied to cancer relapse in kids
8) Nearly All Anesthesiologists Report Drug Shortages
9) Drug shortages Persists in U.S., Harmig Care
10) Drug shortage fixes can ready US for disasters
11) Drug shortage tied to cancer relapse in kids
12) Drug Shortages Persist in U.S., Harmig Care

OMC Hospital Stats

- Oconee Medical Center had 60 open purchase orders - January 2012
- We currently have 45 open Purchase orders - January 2013
- Hard to find companies are charging OMC enormous amounts – on average a 395% more than our normal cost. We try our best not to use these companies. We have experienced as much as 1100% mark-up from one company.

Example of Price Gouging at Oconee Medical Center:

a. January 2012 – Promethazine injection backordered – Our cost is $21 / pack of 25
b. February 1, 2012 – 3:29 PM – Received email from Price Gouging Company - $25 / pack of 25 – 1100 %
c. February 1, 2012 – 3:47 PM – OMC responded “we cannot pay this”
d. February 1, 2012 – 3:49 PM – Special approval from Allied to sell for $195/ pack of 25 – 950 %
e. February 1, 2012 – 3:54 PM – OMC responded “still too high”
f. February 1, 2012 – 3:59 PM – Final offer from Allied - $175 / pack of 25 – 850 %

Examples of Hard to Find Drugs

Letter to Senator Graham

United States Senate
Embassy Gardens
South Carolina
Columbia

Letter to Senator Graham

January 14, 2013
Senator Graham
I am the Dean of Pharmacy at Oconee Medical Center. My daughter used

her phone to call me with the news that the drug Promethazine was

backordered in our hospital. I called our hospital and was told it was

backordered in all hospitals in the county. The drug Promethazine is a

vital drug for many patients in our hospital.

I have been speaking with one doctor at this hospital on this subject - SC Board of Pharmacy, SC Senate of Health

Services Subcommittee. Each has their own hospital and the news is the same.

Currently, the pharmacist has an inventory of the drug which will run low in a few days and will not be able to

order more. The hospital has been unable to find the drug from other pharmaceutical companies.

I urge you to take action on this matter. I have attached a letter to the pharmacist and the

hospital administration. The letter is attached.

Please feel free to contact me at the number I’ve listed above.

Sincerely,

L. Graham

Pharmacist
Follow-up Letter from Senator Graham

Drug Shortage Survey Results

- In 2012, a drug shortage survey was sent to all Hospital Pharmacies in SC, NC, Georgia, and Florida.
- In SC, Pharmacists responded that 47% of the time, drug shortages created unsafe conditions for patients and staff.
- The results of this survey follow.
Drug Shortages Require Additional FTE's

Manipulations and Syringe Preparation

Estimated Cost for Additional Syringe Usage

Additional Hours/Week For Added Syringe Preparation

Should Expiration Dates on Repackaging Be Extended Due to Drug Shortages? – Yes Responses

Suggested Extension of Expiration Date
% Hospitals That Track Exp Dates in ASM

Pulling Expired Drugs From ASM

Days in Advance Hospitals Pull Outdates from ASM

How Hospital Pharmacies Communicate Drug Shortages

Pharmacy Staff Time Required to Communicate Shortages

Maintenance of Information Systems
Standardized Concentrations?

Hospitals That Have Approved Auto-Subs

Chance of Errors Due to Manipulations

Open Purchase Orders at Facilities

Drug Recalls – Removed in Time?

No Safety When It Comes to Drug Shortages
Develop Strategies to Help With Shortages

• Determine the length of the shortage when possible
• Evaluate auto-subs for shortages thru P&T Committee & determine when to use.
• Contact not just the wholesaler, but also the manufacturer – sometimes shipments may be close or in transit.
• Initiate purchase orders at both sources & inquire how purchase order backorders are handled (ie new PO’s each week, 1 item received completes PO, etc)
• Tell manufacturer you are having supply problems – we found company shipped direct but because we had not called, they assumed we were fine.
• Determine if you should limit remaining stock to certain areas and specific patients.
• Dispense critical low amounts from drug shortages directly from central pharmacy – remove from ASM
• Inform P&T committee and send out newsletters
• Contact reputable compounding companies for assistance.

Summary

• Drug shortages are not getting any better
• Drug shortages require significant resources to manage
• Drug shortages have created unsafe conditions for patients & staff because of drug shortages.
• Support and understanding at the state & national level is needed to bring attention to what is actually happening in health care institutions

Websites

• Notify the FDA of shortages at drugshortages@fda.hhs.gov
• Gray market – FDA via Office of Criminal Investigations at http://www.accessdata.fda.gov/scripts/email/oci/contact.cfm
• Price concerns at the Federal Trade Commission at http://www.ftc.gov
• ISMP - A shortage of everything except errors: Harm associated with drug shortages

Thank you!!

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