

Does the drug shortage in the united states have implications on the health care system, if it really exists?

Short communication

The U.S. Food and Drug Administration in 2010 have reported 178 drug shortages, 132 of which involved sterile injectable drugs. In 2011, the drug shortage continued to show an increase. The drugs that were in shortage are cancer drugs, anesthetics used for patients undergoing surgery, drugs needed for emergency medicine, and electrolytes needed for patients on IV feeding.¹ Drug shortages are tracked by the American Society of Health-System Pharmacists (ASHP) and the FDA as well as the Drug Information Service at University of Utah Health Care (UUHC) partners with ASHP. The Drug Information Service at University of Utah Health Care (UUHC) have tracked a total of 211 drug shortages in 2010 which had been reported as the highest number since 2001. The ASHP tracked 224 drug shortages between January 1996 and June 2002. Additionally, the Premier Healthcare Alliance in March 2011 found that around 240 drugs were in short supply or completely unavailable in 2010 and more than 400 generic medications had been back-ordered for five days or more. The ASHP/UUHC reported 70 drug shortages in 2006, 129 in 2007, 149 in 2008, 166 in 2009, and 210 in 2011.²

The problems that might arise because of shortage affecting health care system are several. One of which is by raising the cost of delivering patient care because of increased drug acquisition and personnel expenditures. Operational adjustments are required to adapt to the product change which needs additional labor. There might be substitution of one drug for another that might have reduced efficacy or cause side effects. The effects of drug shortage extend to cancellation of procedures, or the use of alternative treatments that have a worse safety profile, are more expensive, or are more prone to overdoses or medication errors. An additional problem is that some cancer patients will have an altered or delayed chemotherapy for another patient who might have a better prognosis.³ This will eventually lead to an imbalance in treatment options and thus one patient might suffer on the expense of the other.

One of the FDA divisions is the Center for Drug Evaluation and research (CDER) which established the Drug Shortage Program (DSP). Through communication, facilitation and negotiation, the DSP works with internal and external stakeholders to prevent, mitigate and resolve shortage situations. A website had been created by the FDA (fda.gov/drugs/drugsafety/drugshortages) which lists the most recent drug shortage in the market which and at times might release reasons of shortage since manufactures are reluctant to report the reasons of shortage, the duration and other information related to drug shortage supply to the FDA.⁴ Lots of publications had emerged due to the increasing problem of drug shortage and its effect to the health care system across different countries. Different government agencies and healthcare providers are working hard to resolve the scarcity of drugs affecting patient care delivery.

Drug shortage can affect patients that rely on medicine like

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oncology and cardiac patients. Drug shortages have a big impact on delivering patient care; it may threaten patient safety, delay medical treatments especially for emergency cases and may affect the quality of care provided by health professionals.

What are the most common causes for drug shortage?

- a. Recession and economic slowdown has affected manufacturing companies which make them. These companies have either left the market or closed down or had merged with other companies, thus resulting in fewer companies making drugs across the board. Manufacturers business decisions contribute to the shortage and other factors are based on insufficient profits, introduction of generic products, market share, anticipated clinical demand, patent expiration, drug approval status, regulatory compliance requirements, and expense to correct manufacturing problems.
- b. Manufacturing difficulties is another contributing factor
 - I. Shift of companies' resources from manufacturing to research and development, loss of production and compliance personnel
 - II. Changes in product's formulation and limited production capabilities can also delay product availability
 - III. Manufactures often use the same manufacturing equipment for other drug products thus limiting the capacity of producing certain drugs
 - IV. FFDA sometimes approves a specific manufacturing line to produce specific drugs in a specific facility thus delay setting up production
 - V. Antitrust laws may also prevent companies from sharing manufacturing information
 - VI. Disruption in supply of raw or bulk materials is frequently

responsible for drug shortages. Even if there are multiple manufacturers of a certain drug, there may be only one producer or raw material that is used in producing drug.

- VII. Major drug recall can have rapid and significant effect on the availability of a product, especially when it is produced by a sole manufacturer which sometimes develops because of minor problems in manufacturing that are not governed by FDA regulations.
- VIII. Natural disaster can profoundly affect drug product availability. Finished drug product or supplies can be affected by fires, hurricanes, tornadoes and floods.
- IX. Quality control is monitored by FDA and due to limited resources of the FDA it impedes the timely inspection and recertification of manufacturing sites after a noncompliance shutdown.
- X. Supply chain and distribution methods and health care systems practices can contribute to the shortage of drugs.⁵

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Conflict of interest

The author declares no conflict of interest.

References

1. <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>
2. <http://www.ashp.org/DrugShortages/Current/>
3. Ventola L. The Drug Shortage Crisis in the United States. Causes, Impact, and Management. *P T*. 2011;36(11):740–742, 749–757.
4. Strategies. *PT*. 2011;36(11):740–757.
5. James C, Robinson. Value-Based Purchasing For Medical Devices. A misalignment of information and incentives between hospitals and surgeons blocks the path to value-based purchasing. *Health Affairs*. 2008;27(6):1523–1531
6. http://www.nytimes.com/2010/04/21/business/21device.html?_r=1&pagewanted=all