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An analysis of communication-centered policy alternatives to address the anesthesia drug shortage

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Abstract
Provision of safe and effective anesthesia relies on an adequate and uninterrupted supply of anesthetic drugs and drugs used to manage complications throughout the perioperative period. The confluence of regulatory and communication barriers impede the ability of the pharmaceutical industry, government and healthcare institutions to effectively respond to anesthetic drug shortages. These impediments directly threaten the health and safety of patients undergoing surgical and diagnostic procedures in the United States. The most common causes of drug shortages are product or quality issues and manufacturing capacity issues.
This paper presents 2 policy alternatives directed towards the most common causes of drug shortages; an FDA-operated stakeholder communication center and a public/private partnership communication center. The feasibility of the 2 alternatives was assessed against 5 criteria including population benefit, ethics and equity, cost feasibility, administrative feasibility and political feasibility. Selection of the most favorable alternative was based on the final score from a decision matrix presenting evaluation criteria weighed against each proposed alternative.
The final result reveals the public/private communication center as the most feasible alternative. This is consistent with stakeholder agreement that early, accurate communication and coordination will help mitigate and prevent present and future shortages. Specifically, the public/private center will improve the current state of communication, protect proprietary information and provide stakeholders with information regarding manufacturing, supply, distribution, and business issues encouraging coordination of action to attack the root causes of drug shortages.

Introduction

Provision of safe and effective anesthesia relies on an adequate and uninterrupted supply of anesthetic drugs and drugs used to manage complications throughout the perioperative period. The United States Government Accountability Office (GAO) reports in November 2011 that 1190 drug shortages were reported to the University of Utah Drug Information Service between 2001 and mid-2011. The number of reported shortages escalated in 2006 and rose each year to a peak of 267 shortages in 2011. The GAO states anesthetic, oncology and anti-infectives are the drugs most often in short supply [1]. Over 30 anesthetic drugs and drugs used to manage complications are in short supply as of July 2013 [2].

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The confluence of regulatory and communication barriers impede the ability of the pharmaceutical industry, government and healthcare institutions to effectively respond to anesthetic drug shortages. These impediments directly threaten the health and safety of patients undergoing surgical and diagnostic procedures in the United States. Several policy alternatives have been proposed or enacted by the US Government to address anesthetic drug shortages. The results achieved by those alternatives have been minimal. The US Food and Drug Administration remains limited in their ability to respond to drug shortages. However, representatives from government, the pharmaceutical industry, distributors and healthcare providers agree that improved communication between all stakeholder groups may provide an "early-warning" system that may decrease the number and severity of drug shortages [3].

This paper presents 2 potential communication-centered policy alternatives directed towards resolving the most common causes of drug shortages; product quality issues and delays due to manufacturing capacity issues [3]. The first alternative is an FDA-operated stakeholder communication center discussed at an FDA stakeholder meeting in 2011 [3]. The second alternative is a public/private partnership communication center as proposed by the Generic Pharmaceutical Association [4]. Following presentation of background information regarding the anesthesia drug shortage problem, the feasibility of each policy alternative will be discussed. Each policy alternative will be competitively evaluated against specific criteria to determine the most feasible policy alternative.

Background

Anesthesia drug shortages create harmful effects on patients and their providers

The American Society of Anesthesiologists (ASA) conducted a survey in March 2012 reporting the responses of 3033 anesthesiologists across the US concerning the effects of anesthetic drug shortages. The results reported 97.6% of respondents were currently experiencing a shortage of at least 1 anesthetic drug, 96.3% of respondents reported use of alternative drugs, 52.8% modified the anesthetic procedure; 7% postponed cases and 4.1% canceled cases [5]. (See Table 1).

Anesthetic drugs most frequently reported in short supply included fentanyl, succinylcholine and propofol.

The impact on patients included, 66.7% of patients having a less than optimal outcome; such as post-operative nausea and vomiting, 52.8% of patients experienced prolonged recovery times, 27.5% of patients complained of untoward side effects and 6 patients reportedly died as a result of drug shortages. (See Table 2).

The Anesthesia Patient Safety Foundation (APSF) reported in 2012 drug shortages limit choices for drug therapy; many drugs do not have substitutes or substitutes may be less effective, increase the cost of drugs and personnel resources to manage shortages and increase the risk of medication errors and untoward patient outcomes. Drug shortages have caused frustration, anger and mistrust among providers and manufacturers, pharmacy and providers and patients and providers. Drug shortages have increased prices of drugs in short supply and of alternative drugs used to replace those in shortage. Use of alternative drugs depletes their supply causing shortages of those drugs as well [6].

Table 1 Effects of drug shortages on anesthesia providers.

Experiencing shortage of at least 1 anesthetic drug	97.60%
Resorted to use of alternative drugs	96.30%
Modified anesthetic procedure	52.80%
Postponement of surgical cases	7%
Cancellation of surgical cases	4.10%

Table 2 Effects of anesthesia drug shortages on patients.

Experienced less than optimal outcome	66.70%
Experienced prolonged recovery time	52.80%
Complained of untoward side-effects	27.50%
Number of deaths believed to be result of drug shortage	6

The APSF cited a survey conducted by the Institute for Safe Medication Practices reporting 25% of respondents acknowledged their facility experienced a medication error due to a drug shortage [6]. Many times these medication errors are due to lack of familiarity with substitute drugs or drugs that are only available in an unfamiliar strength [1].

Some healthcare institutions have resorted to purchasing drugs on the gray market, at exorbitant prices, placing additional financial burden upon healthcare institutions, insurers, patients and taxpayers. The shocking reality of purchasing drugs on the gray market is the origin of the drug may be unknown. Nor can it be assured the drug was stored or transported properly which may affect the performance of the drug once in the body potentially causing adverse or inadequate effects [1].

Another unforeseen effect of drug shortages includes healthcare institutions resorting to the use of compounding pharmacies. Compounding pharmacies are not legally authorized to prepare drugs that are copies of commercially available drugs. The use of compounding pharmacies has been linked to the 2012 outbreak of 438 cases of fungal meningitis in 19 states resulting in 32 deaths in interventional pain therapy patients [7].

The magnitude of the shortage of anesthetic drugs

The American Society of Healthcare Pharmacists drug shortage reporting system reveals over 30 anesthetic drugs across several classes are in short supply. These include anesthetic induction agents, opiate analgesics, local anesthetics, neuromuscular blocking agents, anti-nausea agents and resuscitation drugs [2].