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Drug shortage management in Alabama hospital pharmacies

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Key words: drug shortage, pharmacy, hospital, Alabama

Abstract

Purpose: The purpose of this study is to identify effective strategies used by Alabama hospitals to manage drug shortages. Moreover, this study aims to determine if there are any relationships among hospital size, utilization of a standard policy for drug shortage management and perceived usefulness of standard procedures for drug shortages.

Methods: A paper survey was mailed to 129 hospital pharmacies in Alabama (per the Alabama Hospital Association directory). The survey consisted of 5 demographic questions, questions involving perception of current medication shortages, sources of information about shorted drugs, and frequency of discussion at P&T committee meetings. Most importantly, the survey contained questions about the use of a standard policy for handling drug shortages, the effectiveness of the policy if one is used, and an open-ended question asking the recipient to describe the policy being used.

Results: A response rate of 55% was achieved as 71 surveys were completed and returned. Approximately 70% of the survey respondents described the current drug shortage issue as a top priority in their pharmacy department. The pharmacy distributor served as the primary source of information regarding drug shortages for 45% of the facilities. There is a direct relationship between size of hospital and likelihood of utilization of a standard policy or procedure for drug shortage management among the sample. The smaller facilities of the sample perceived their management strategies as effective more frequently than the larger hospitals.

Conclusion: Common components of effective management strategies included extensive communication of shortage details and the ability to locate alternative products. The use of portable technology (e.g., Smart phones and tablets) along with mobile applications may emerge as popular means for communicating drug product shortage news and updates within a facility or healthcare system.

The manufacturing and supply chain problems of the pharmaceutical industry have ballooned in recent years. In 2010 alone, the United States Food and Drug Administration (FDA) recognized 178 new shortages of products that are deemed medically necessary, not including vaccines, immunoglobulin products, and other biologics.^{1,2} This figure is up from 61 reported shortages in 2005, an approximate 300% increase.² Many have postulated causes for the lack of prescription pharmaceuticals, and the main issue is probably a composite of the following: lack of raw and bulk materials, voluntary recalls, manufacturing difficulties, product formulation changes, increased regulation of manufacturing practices, manufacturers' production decisions, shifts in clinical practice, drug product distribution/ allocation restrictions, natural disasters, industry consolidations, increased demand, stockpiling by end-users, and non-traditional distributor usage (gray market).³

There have been a few genres of medications that have been affected most heavily by the recent problems. Some of those classes include oncology medications, emergency drugs, anti-

infective products, anesthetic medications, electrolytes and CNS-targeted treatments.⁴ A list of the drugs that are currently in short supply or on backorder can be found on the FDA's website.⁵

The effects of the medication shortages are widespread and run deep into the operations of almost every health system in the United States. American health care institutions spend countless hours and millions of dollars trying to manage inventories of drugs in limited supply. Additionally, in 2010, American health systems spent an estimated \$200 million due to inflated inventory costs.⁶ Along with increased financial burdens, medication shortages cause increased labor needs focused on managing inventories and evaluating alternative therapy. One survey claimed that, on average, hospitals had to allocate 17-18 full-time employee hours per week- mostly pharmacists and technicians- to manage the current state and plan for the future state of drug supplies.⁸ The health systems' median annual labor cost associated with the shortages has been reported to total \$216 million.⁸

Although the labor and financial burdens have placed increased stress on health care systems around the country, arguably the most significant danger of medication shortages is the increased risk of harm to patients. Shortages have been linked to increases in medication errors.⁹ This correlation stems from the use of unfamiliar alternative treatments or different concentrations or dosage forms of

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high-risk drugs. For example, hydromorphone 1mg/mL and 2mg/mL ampules have been commonly backordered and shorted products.⁹ Thus, hospitals must stock higher concentrations of 4mg/mL or 10mg/mL to accommodate for the indicated pain control.⁹ Subsequently, the risk of a potentially fatal overdose has increased due to the use of more potent formulations, and there have been reported medication errors and near misses.¹⁰

Medication scarcity is not a new phenomenon, and therefore, policy and procedure recommendations for handling such problems have been established by entities such as ASHP, ISMP, USP and FDA. The ASHP encourages health care professionals to immediately assess the situation once a drug shortage is identified.⁴ From an operational standpoint, the facility needs to validate the shortage, inventory the stock on hand, find potential alternative sources, analyze the purchase and use history compared to current usage, estimate how long the problem might last and possibly find a supply of alternative drug products.⁴ From a therapeutic perspective, alternative drug therapies should be identified along with the primary patient population that will be affected.⁴ Then, in the optimal setting of a meeting with representation from multiple health care disciplines, the impact of the medicine's unavailability should be discussed, addressing the changes to therapeutic, prescribing, in-house distribution and administration processes.⁴ Also, the financial repercussions of the changes should be considered. Once a consensus has been reached regarding the proper actions to be taken, mass communication and implementation should follow.⁴ Another source places high emphasis on communication during a shortage and encourages alerts and notices to be visible in key areas of the hospital, such as dictation rooms, employee parking garages, medical staff lounges and other high traffic areas.¹¹ Also, drug shortages should be addressed and evaluated at every Pharmacy and Therapeutics (P & T) committee meeting held by a facility.¹¹

There is a lack of state-specific data that identify if the previously mentioned standard management strategies are being utilized in Alabama to mitigate the problems associated with drug shortages. Also, new and innovative methods being used could be identified and made known to other facilities. The purpose of this study is to identify effective strategies used by Alabama hospitals to manage drug shortages. Moreover, this study plans to determine if there exists any relationship between hospital size, utilization of a standard policy for drug shortage management and perceived usefulness of the standard procedure.

Methods

A 12 question paper survey was mailed out to Alabama inpatient pharmacies (n=129), on October 8, 2012 (See Appendix A.). The survey was sent along with a cover letter and a self-addressed, stamped envelope for the return of the document. The survey was comprised of questions relating to demographics, perceptions of drug shortages, sources of information, drug shortage policy, and one open ended question to describe the policy. The Samford University Institutional Review Board approved this study.

The demographic questions included the position in the pharmacy of the person completing the survey, the size of the hospital by number of inpatient beds, the number of full-time pharmacists employed by the hospital, and presence of a designated purchasing agent as well as clinical pharmacy staff. The next question inquired about the overall perception of the drug shortage issue on a scale of "top priority" being the most emergent to "not a problem" as least emergent. The following question surveyed the primary source used to gain information about drug product shortages with options including, the FDA website, ASHP website, pharmacy distributor, manufacturers, and an open ended option. The frequency that medication shortages are discussed in P&T committee meetings was gauged using a scale of always, often, sometimes, seldom or never. Questions nine, ten and eleven determined the use of a standard procedure for managing drug shortages, and asked the participant to characterize and describe the policy if there was one in place at the facility. Finally, a question was posed regarding interest in obtaining information about new or innovative drug shortage management strategies.

The completion and return of the survey by October 26, 2012 was incentivized with a chance to win a \$100 gift card that was randomly selected by an uninvolved third-party. Each survey was labeled prior to distribution with a number, 1 through 129, in the top left corner of the page. The number on the survey corresponded with the same number on a master list of the facilities with addresses. Upon receipt of the completed survey, the envelope was kept unopened until the survey could be de-identified by an established third party. The numbers were kept until the deadline, and then one number was blindly selected from the container. The chosen number was referenced by the master address list, and that entity was awarded the gift card.

Survey variables were nominal and ordinal with one open-ended response. All survey item selections were transformed into numerical variables to allow for the calculation of statistics. The data was then transferred to an Excel

workbook, with the exception of the free text entered for the open-ended responses to question eleven.

A frequency table was constructed for the responses of each question, and the results were displayed in both raw numbers and percentages of total responses. The size of hospitals was also cross-tabulated against the use of a standard policy or procedure for managing drug product shortages and against the degree of efficacy of the policy. Spearman's rank correlation coefficient was calculated for both relationships to determine dependence between the variables. A systematic approach to analyzing the open-ended responses was established by identifying the policy descriptions that were characterized as effective and looking for common phrases or steps. The same process was performed with the responses that were characterized as only "working sometimes". Finally, a general review of all of the responses was performed to identify extremely common phrases (occurring in more than 75% of the responses) and extremely unique phrases (occurring in less than 5% of the responses).

Results

Of the 129 mailed surveys, 71 were returned completed, lending a response rate of 55%. An overwhelming majority, 94.4% (n=67), of the participants were directors of pharmacy, or held a comparable position. The distribution of responses by hospital size was skewed to the right, but this would be expected, as there is a larger quantity of smaller facilities in the state versus hospitals with 400 beds or more. A 50-99 bed facility was the most common size that responded with 22 participants (31.0%). The complete breakdown can be found in Table 1. Forty-six of the seventy-one facilities represented employed between one to five full-time pharmacists. There were 62.0% (n=44) and 60.4% (n=43) of the participants that claimed to have a designated drug-purchasing agent and designated clinical pharmacist or staff, respectively.

The overall perception of the drug shortage situation was categorized as a "top priority" by 70.0% (n=49) of the pharmacy departments, and 17 (24.3%) others viewed the issue as "somewhat important". About one-half (n=32) of the respondents used their distributor as the primary source of information about drug product shortages. The second most common source of information was the ASHP website, which was listed by 28.6% (n=18) of the participants as their primary resource for drug shortage news and updates. There were five responses regarding primary source of information that were listed as "other" and then described in free text. Those answers included corporate emails, an iPhone app called Rx Shortages, the group purchasing organization (GPO) and a third party that monitors the FDA and ASHP information and

gives daily updates. Drug Shortages were always discussed in P&T committee meetings by 57.8% (n=41) of the hospitals and often discussed by 29.6% (n=21) of the hospitals. Only one hospital claimed that drug product shortages were seldom topics of discussion at their facility's P&T committee meetings.

There were 41 hospitals (57.7%) that responded as having a standard policy or procedure for managing drug shortages. The number of facilities with standard policies was also analyzed by corresponding facility size. Figure 1 provides a graphic describing those results. There appeared to be a correlation between size of the hospital and use of a standard procedure. Only 31% (5 of 16) of smaller hospitals (< 50 beds) utilized a drug shortage management policy, whereas, 63% (5 of 8) and 67% (4 of 6) of larger hospitals (250-399 beds and >300 beds, respectively) had standard procedures implemented. Spearman's rho (ρ), which is a rank correlation coefficient, for this comparison was 0.7, where hospitals were ranked in size from largest to smallest and percentages of perceived effective policies were also ranked from largest to smallest.

The responses to question 10 are displayed in Figure 2 based on percentages of total responses categorized by facility size. The highest percentages of respondents who classified their standard procedure for drug shortage management as effective were associated with facilities with <50 beds (40%) and 100-249 beds (38%). Neither of the two largest hospital size categories had any respondent to classify their policy as effective. The data for this comparison was ranked in order largest hospital size to smallest and largest percentage of effective policies to smallest. Spearman's rho (ρ) for this comparison was -0.825.

Analysis of the open-ended responses associated with the policies that were perceived as effective by respondents revealed a few common characteristics. First, communication with physicians through various means (memos, emails, phone calls, faxes, P&T meetings, etc) was a staple among the responses. Also, locating alternative supplies or finding a therapeutic alternative was listed in multiple responses. Finally, prioritizing the use of remaining stock of the shorted drug was mentioned as part of a few of the standard procedures.

The policies that were deemed to only be successful sometimes were also analyzed and found to have no unique descriptors to differentiate their policy from the others that were described. An evaluation of all the responses resulted in discovering three characteristics that were frequently listed as a part of the drug shortage management strategies.

Once again, communication of the status of the shortage and therapeutic plan resonated throughout the responses. The vehicle for communication varied among the answers, but it appears that notification to prescribers and other members of the healthcare team is paramount when dealing with medication shortages. The ability to systematically select a therapeutic alternative and find a supply source was the second most common feature among all the responses. Finally, working in a committee setting, such as a P&T or Medical Staff committee, was used in 26 out of 41 policies to develop and implement the specific plan for each specific shortage. A few of the unique elements that were recognized include placing notices on the machines, the clinical pharmacist vs. pharmacists working directly with the pharmacy buyer to control and locate inventory, and using automatic formulary substitution protocols.

In response to the last question on the survey, approximately 93% (n=63) of the participants indicated interest in gaining information on new and innovative strategies for managing drug shortages.

Discussion

As a novel project relating to the subject matter of drug shortages in Alabama hospital pharmacies, a lot was learned about the sample. It was no surprise that the vast majority of participants served as the director of pharmacy because the letter was addressed to director. The top priority rating given by 70% of the respondents is a solid indicator that the issue of drug shortages is still a relevant topic for investigation. Survey results published by ASHP in October 2011 claimed that the ASHP website was the most widely utilized source of information about drug product shortages followed by the wholesaler website, then the group purchasing website and FDA website. The Alabama hospital pharmacy directors who completed this survey portrayed the use of the distributor (wholesaler) as the primary source of information for news and updates. Inpatient pharmacies are in frequent contact with their distributor every week; thus, this relationship seems to serve as the most pragmatic source of information. One extremely interesting response to this survey explained that one facility uses a mobile application, called Rx Shortages, as its main source of information on shorted medications. This application pulls information from both the ASHP website and FDA website, and it compiles it into a database. With the rise in use of smart phones and tablets in the medical and pharmacy fields, a mobile application could serve as an effective means of internal communication regarding drug shortages for an institution or health system.

The function of standing committees in healthcare institutions, such as P&T and Medical Staff committees is

multifaceted. Moreover, it is important that operational issues, such as medication shortages, are discussed at these multi-disciplinary meetings. As portrayed through the results of this study, 41 of the 71 respondents always discuss medication shortages at their P&T meetings and also understand that the committees are appropriate for deciding the course of action and initiating the communication pathways. This is also consistent with the recommendation made by ASHP, the FDA, and ISMP.

Another characteristic of the Alabama inpatient institutions that responded was the strong positive relationship between facility size and the presence of a standard management policy. The correlation was supported by a Spearman's coefficient calculation. This observation could occur in part to the higher level of structure and organization that comes along with larger operations. With small facilities, the personnel may fill multiple roles which simplify decision-making processes and lines of communication; therefore, a standard policy may not always be necessary because one or two clinicians may handle every portion of the management process.

Even though a higher percentage of larger hospitals followed a set policy, the percentage of smaller facilities with established guidelines that classified their operations as effective was higher. This inverse correlation was supported with a strongly negative Spearman's coefficient. Smaller facilities may be more apt to effectively manage drug shortages due to having smaller inventories to control and having a more intimate work environment among pharmacists, physicians and other healthcare professionals.

Although it was not possible to identify any new strategies that could be directly applied to increased success in managing drug shortages, there were common themes throughout the open-ended policy description responses. Common components of effective management strategies included the ability to extensively communicate the details of the shortage and the ability to locate therapeutic alternatives.. Both of these strategies are key pieces of the standard guidelines that were published by the ASHP, FDA and ISMP.

The limitations associated with this study include the lack of objective criteria to define efficacy in the survey. Also, there is a possibility of measurement bias when evaluating the open-ended responses.

Conclusion

Due to the severity of drug product shortages over the past few years and the publicity that has been gained, the federal government and the FDA have made strides to alleviate the burden on healthcare institutions.^{13,14} This is accomplished by requiring manufacturers to identify drugs that could be prone to shortages and report any fluctuation in production or inventory. However, it is not enough for hospitals to rely on external means for managing shortages. Proper procedures and methods need to be used internally to control the risks and costs associated with drug shortages. However, not every healthcare facility or system operates exactly the same. Some hospitals have adapted recommended guidelines for drug shortage management to fit their healthcare model. It is important to continually reassess the efficacy and practicality of these strategies.

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Table 1.

Demographic Results	
Demographic	No. (%) of Respondents
<u>Position in Pharmacy</u>	
Director of Pharmacy	67 (94.4%)
Assistant Director/Clinical Director	3 (4.2%)
Staff Pharmacist	---
Clinical Pharmacist	1 (1.4%)
Buyer/ Purchasing Agent	---
Technician	---
<u>No. of Beds in Facility</u>	
<50	16 (22.5%)
50-99	22 (31.0%)
100-249	18 (25.4%)
0-399	9 (12.7%)
>399	6 (8.4%)
<u>No. of Full-time Pharmacists</u>	
1-5	46 (64.8%)
6-10	8 (11.3%)
11-20	7 (9.8%)
>20	10 (14.1%)
<u>Designated Purchasing Agent Employed</u>	
Yes	44 (62.0%)
No	27 (38.0%)
<u>Designated Clinical Pharmacist(s) Employed</u>	
Yes	43 (60.6%)
No	28 (39.4%)

Figure 1.

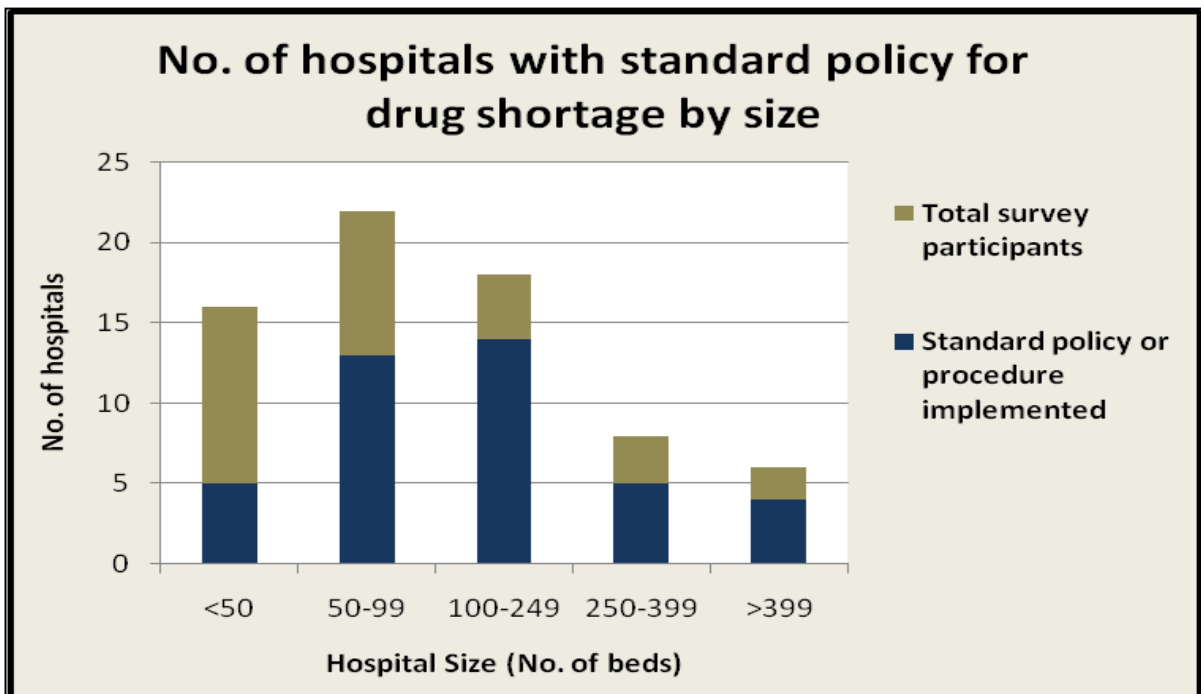
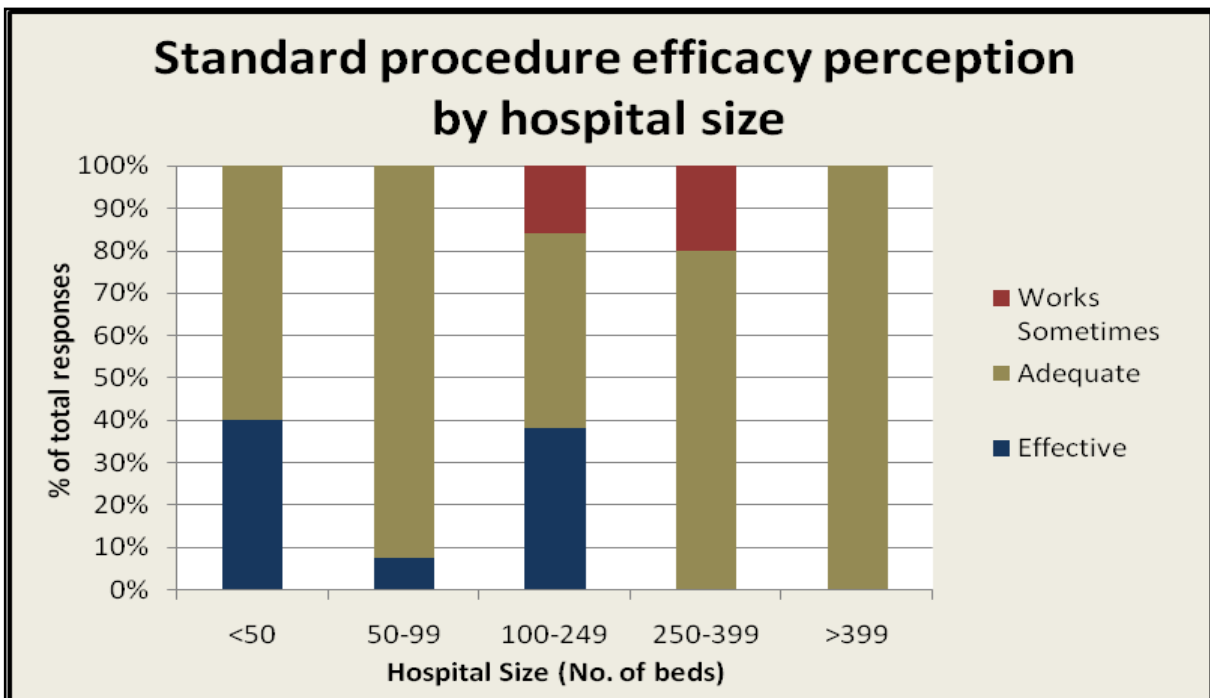


Figure 2.



Appendix A.
Drug Shortage Management in Alabama Hospital Pharmacies

Please circle ONE response unless instructed otherwise

1. Which answer best describes your role/position in the pharmacy?
 - a. Director of Pharmacy
 - b. Assistant Director/ Clinical Pharmacy Director
 - c. Staff Pharmacist
 - d. Clinical Pharmacist
 - e. Buyer/ Purchasing agent
 - f. Technician

2. Please, choose a bed range that describes your facility:
 - a. <50 beds
 - b. 50-99 beds
 - c. 100-249 beds
 - d. 250-399 beds
 - e. ≥400 beds

3. How many full time pharmacists are employed at your facility? (including central and clinical staff)
 - a. 1-5
 - b. 6-10
 - c. 11-20
 - d. >20

4. Does your facility have a designated purchasing agent?
 - a. Yes
 - b. No

5. Does your facility have a clinical pharmacy staff?
 - a. Yes
 - b. No

6. What is your pharmacy department's perception of the recent drug shortage issue?
 - a. Top priority
 - b. Somewhat important
 - c. Just a part of operations
 - d. Not a problem

7. What source is primarily used for gaining information regarding the shortage of a drug?
 - a. FDA website
 - b. ASHP website
 - c. Distributor
 - d. Manufacturer
 - e. Other _____

8. How often are drug shortages discussed in the P&T committee meetings at your facility?

- a. Always
 - b. Often
 - c. Sometimes
 - d. Seldom
 - e. Never
9. Does your facility have a standard policy or procedure when a drug shortage has been identified?
- a. Yes
 - b. No
10. If you answered yes to question 9, how would you characterize the current policies and procedures for dealing with drug shortages?
- a. Effective
 - b. Satisfactory
 - c. Flawed
 - d. Useless
11. If you answered yes to question 9, would you please explain your current policy for managing drug shortages (Do you/how do you communicate shortages, Do you/how do you select alternative medications and prioritize use of drugs in short supply)?
12. Would you be interested in obtaining information regarding other new or innovative strategies for the management of drug shortages based upon the feedback of other Alabama hospital pharmacies?
- a. Yes
 - b. No