EVALUATION OF THE FINANCIAL IMPACT OF MEDICATION BACKORDERS IN A TERTIARY CARE HOSPITAL

by

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ABSTRACT

Medication backorders and shortages may contribute to an increase in the overall cost of healthcare by increasing the cost to deliver care. Drug manufacturers face little regulatory pressure to provide immediate notice to the healthcare industry regarding anticipated supply issues. These supply issues impact the finances of hospitals and the care patients receive. Particularly, supply issues effecting life-saving medications, like antibiotics, are of public health relevance as they have the greatest potential to impact the delivery of healthcare. Although the public health impact is mostly understood, the exact financial impact of medication backorders is not well-defined. The purpose of this study is to quantify the financial burden of medication backorders and shortages to a large, tertiary care hospital in Pittsburgh, Pennsylvania.

Medication backorders and shortages have steadily increased in the past decade, requiring healthcare institutions to be proactive in order to prevent shortages from effecting patient care outcomes. The primary objective of this study is to determine the percent change in direct drug prices pre- and post-backorder. The secondary objectives are to evaluate the change in labor costs associated with preparing medication products and the overall percent change in costs (direct drug price and labor costs combined) pre- and post-backorder.

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1.0 PURPOSE

Medication backorders or shortages are defined by American Society of Health-System Pharmacists (ASHP) as "a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent."[1] The terms medication backorder and medication shortage will be used interchangeably throughout this paper because the net effect to a health-system is the same for each situation.

In the past decade, the number of medications effected by a backorder has steadily increased, increasing the amount of resources required to address gaps in care left by dwindling drug stock.[2] Many causes of medication backorders have been identified, including: raw or bulk material shortage, regulatory issues delaying manufacture of product, voluntarily medication recall by drug companies, formulation change requiring new production practices, manufacturer business decisions, unexpected increases in demand for drug, and natural disasters.[3]

It is estimated drug shortages are associated with an annual cost of $216 million in the United States and approximately $37,951 annually for hospitals with 200-399 beds.[1] Larger hospitals spend more time managing drug backorders compared to smaller hospitals.[1] At the study location, there is a medication backorder committee that tracks stock levels and creates recommendations on how to manage backorders when one arises.

Medication backorders are often inconvenient and have the potential to impact patient care and hinder cost containment efforts – making backorders and shortages of significant public health relevance.[4] Injectable products comprise about 80% of medication backorders, including life-extending chemotherapy agents and life-saving antibiotics.[5] These medication categories are of particular concern because availability issues of injectables may endanger patient lives.[5]

While the public health impact of shortages is recognized, the exact financial impact of medication backorders is not known. This project will estimate and summarize the financial impact of medication backorders at a tertiary care hospital in Pittsburgh, Pennsylvania by identifying factors that potentially increase drug costs as a result of medication backorders, including quantifying labor expenditures. It is expected that the cost to prepare a dose of medication effected by a backorder will be greater post-backorder than pre-backorder.

2.0 METHODS

This study is a single-center retrospective analysis of medications currently or recently on backorder within the past 24 months. The study methods were submitted to the Institutional Review Board and received exemption due to minimal risk identified.

In order to be included in the study analysis, an intervention must have been implemented as a result of a backorder and the medication had at least 20 charted doses in the computerized physician order entry (CPOE) system per month. Non-formulary medications and medications with an intervention lasting less than three months were excluded from analysis.

All medications provided by the pharmacy department have a potential to be effected by a medication shortage and thus had the potential to be included in study analysis. Most medications effected by a shortage at this specific institution, and nationally, are intravenous products. However, all products are tracked and evaluated by the medication backorder committee, including: topical agents, oral formulations, suppositories, ophthalmic solutions, otic solutions, etc.

A total of eight medications were evaluated for inclusion. Six medications were excluded and two were included in analysis. The most common reason for exclusion was an intervention which did not last for at least three months. Two evaluated medications met inclusion criteria and were included in analysis.

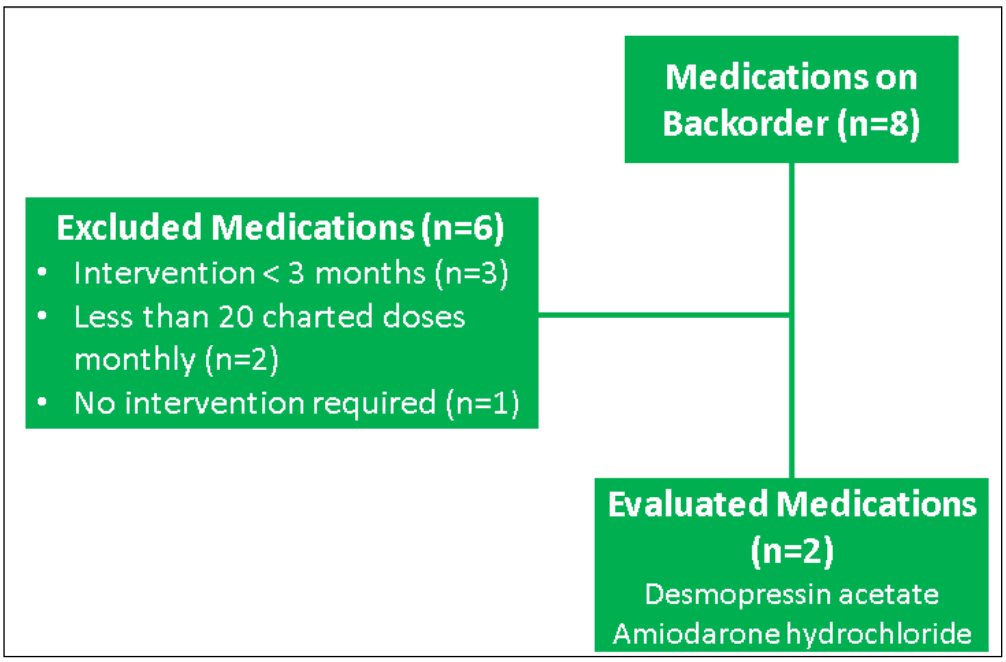

Figure 1. Inclusion Criteria

Pre- and post-backorder usage and pricing information was collected for a three month time period, before and after implementation of the backorder intervention, using the CPOE system and inventory records, respectively. Observation of current preparation times for identical delivery methods were used to extrapolate and determine pre- and post-backorder labor costs. For example, if a product was previously prepared using a needle-less sterile preparation product, that delivery method for another drug was observed, timed, and assumed to be equivalent to the pre-backorder preparation time. Additionally, CPOE documentation was utilized to determine pharmacist time required to ensure compliance with the medication backorder committee's intervention.

Monetary values were assigned to the labor times using national wage medians from the United States Bureau of Labor and Statistics. Descriptive statistics was generated from the collected data. Means and medians were used when appropriate. It was expected that post-backorder costs would be greater than pre-backorder costs.

3.0 RESULTS

Two medications met inclusion criteria: desmopressin acetate and amiodarone hydrochloride. For both medications, only the intravenous preparations met inclusion criteria. Data was evaluated individually for each medication and the backorder cost comparison is reported for each medication separately.

The manufacturer of desmopressin acetate ceased production of the 4 mcg vial used to prepare intravenous (IV) products. The hospital was forced to purchase a more expensive, brand only product which was also on backorder due to increased demand. The post-backorder average wholesale price (AWP) of one vial was $84/vial. The backorder committee proposed measures that would reduce overall use of desmopressin in order to minimize the increased costs associated with switching manufacturers.

The hospital Pharmacy and Therapeutics Committee approved the medication backorder committee's three-part intervention plan, which included: dosing based on patient's ideal body weight (instead of actual body weight), a maximum dose of 20 mcg, and rounding of all doses to the nearest vial size. These interventions were targeted at reducing use and waste of the drug.

Data collected for desmopressin acetate included usage data and pharmacist intervention time pre- and post-backorder. Monetary values were assigned to the pharmacist intervention time using national wage median ($57.20/hour).[6] Table 1 lists the percent change in institutional price

and cost of a medication dose pre- and post-backorder. The price and cost to prepare a single dose of desmopressin acetate was higher post-backorder. Applying these percentages to the AWP of a single vial, the cost increase was annualized.

Table 1. Desmopressin Acetate Results

Primary Objective		
	Pre-Backorder	**Post-Backorder**
Total Charted Doses	89	70
Median Dose (range)	23 mcg (10-40)	20 mcg (12-26)
Percent Change in Price per Dose (price increase)		**249% ($299.70[+])**
Secondary Objectives		
RPh Interventions*, n=22		$111.55
Percent Change in Cost per Dose		**252% ($301.29[+])**
Annual Cost Increase		**$84,361.20*[+]**

*5 min per intervention and salaries equivalent to national medians per US Bureau of Labor and Statistics
[+]Based on current Average Wholesale Price (AWP) of $84/vial per inventory records

Amiodarone hydrochloride intravenous (IV) drips were prepared using a sterile, needle-less connector which allowed the vial to be connected to a bag of diluent without mixing. This method enabled the product to be prepared in batches in the pharmacy and stored in automatic dispensing cabinets (ADCs). Nursing personnel would obtain the product from ADCs and activate the bag by enabling the mixing mechanism. The bag used with the needle-less preparation system went on backorder and was no longer available for hospital staff to order.

As a result of the backorder, preparation of amiodarone hydrochloride IV drips was moved to the IV Room where doses were compounded to fill patient-specific orders. Direct drug prices included all products required to prepare a single dose (diluent bag, drug, connectors, etc.). Labor costs were measured by observations of pharmacy staff preparing and checking drips

batched using a needle-less preparation system (pre-backorder method) and compounded IV drips (post-backorder method).

Price and cost to prepare a single dose of amiodarone hydrochloride drips were higher post-backorder. The AWP for a single dose post-backorder was $11.56 per dose and this data was used to annualize the cost increase.

Table 2. Amiodarone Hydrochloride Results

Primary Objective		
	Pre-Backorder	**Post-Backorder**
Total Charted Doses	699	498
Percent Change in Price per Dose		**67% ($4.09[+])**
Secondary Objectives		
Pharmacist Check*	0.23 min ($0.22)	0.89 min ($0.85)
Technician Preparation*	0.91 min ($0.25)	2 min ($0.56)
Labor Costs per dose (annual cost)	$0.47 ($1,314.12)	$1.41 ($2,808.72)
Percent Change in Cost per Dose		**78% ($5.03[+])**
Annual Cost Increase		**$10,019.76*[+]**

*Salaries based on values from US Bureau of Labor and Statistics[7]
[+]Based on current AWP of $11.56/dose for preparation products

The price and cost to prepare a single dose of amiodarone hydrochloride was higher post-backorder. Applying these percentages to the AWP of a single dose of the product, the cost increase was annualized.

4.0 CONCLUSION

One predominant limitation to this study was the small number of medications that met inclusion criteria and were ultimately evaluated. Another limitation is the study methods did not enable investigators to capture doses that were not charted as given in the computerized physician order entry (CPOE) system or wasted doses.

Additionally, the medication backorder committee's time, spent managing backorders and creating action plans in concert with key prescribers, was excluded from analysis. Lastly, data was collected from current labor efforts and assumed these times to be equivalent to pre-backorder preparation times.

Analysis of financial changes pre- and post-backorder of desmopressin acetate and amiodarone hydrochloride suggest that a medication backorder will lead to an increase in cost to prepare a medication. Factors contributing to increased costs include the price of the drug products and increased labor efforts to prepare the product.

This study supports the notion that drug shortages are a significant public health concern as shortages may hinder cost containment efforts of healthcare providers. Increases in drug costs ultimately increase the cost to provide patient care; these costs may eventually transfer to the patient in the form of higher premiums and deductibles.

The information obtained through this study will be incorporated into the analysis of future medication backorders within the study institution. By identifying factors contributing to increased drug costs and quantifying these increases, the most cost-effective or cost-neutral recommendation can be implemented. However, medication shortages pose a greater public health concern when patient care is rationed, delayed, or denied due to a specific medication not being available. Future investigations should be conducted to understand the impact of medication shortages on patient care and patient outcomes.

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