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Drug shortages in Saudi Arabia: Root causes and recommendations

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ABSTRACT

Drug shortages are a multifaceted problem that has been recurring in Saudi Arabia over the past decade with its significant negative impact on patient care. However, there is a dearth of evidence about possible domestic reasons, if any, behind this recurring problem. Recently, the Pharmacy Education Unit at King Saud University College of Pharmacy has called for a meeting with multiple stakeholders from academia, pharmaceutical care, pharmaceutical industry, purchasing and planning, and regulatory bodies to unveil the root domestic causes of the drug shortages in the Kingdom. Four major topics were used to guide the discussion in this meeting, including: current situation of drug shortages in Saudi Arabia, major factors contributing to drug shortages, challenges and obstacles to improve drug supply, and stakeholders' recommendations to manage drug shortages. The meeting was audio-recorded and transcribed into verbatim by five authors. The text was then reviewed and analyzed to identify different themes by the first and third authors. Multiple causes were identified and several recommendations were proposed. The main domestic causes of drug shortages that were explored in this study included poor medication supply chain management, lack of government regulation that mandates early notification of drug shortages, a government procurement policy that does not keep pace with the changes in the pharmaceutical market, low profit margins of some essential drugs, weak and ineffective law-violation penalties against

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pharmaceutical companies and licensed drug importers and distributors, and overdependence on drug imports. The participants have also proposed multiple recommendations to address drug shortages. Policy makers should consider these factors that contribute to drug shortages in Saudi Arabia as well as the recommendations when designing future initiatives and interventions to prevent drug shortages.

1. Background

Drug shortages are a serious and complex health care issue that affects multiple classes of medications and have been noted in many countries (Fox et al., 2014). According to the United States Food and Drug Administration (FDA) drug shortage is "a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the patient level" (US Department of Health and Human Services, 2011). The importance of managing drug shortages stems from the fact that this phenomenon is associated with higher rates of medication errors and worse patient outcomes (Fox et al., 2014; Reis and Perini, 2008; Allen and Williams, 2012). Furthermore, the economic impact of drug shortages on different health care institutions such as lost work time among health care personnel and higher drug prices is significant (Gray and Manasse, 2012). However, what is more challenging when drug shortages occur is to deliver just health care with limited resources (Lipworth and Kerridge, 2013). Several studies have investigated the prevalence and causes of drug shortages in different countries and health care institutions (Pauwels et al., 2014; Balkhi et al., 2013; Pauwels et al., 2015; Alsheikh et al., 2016; Setayesh and Mackey, 2016). Although a few studies have investigated drug shortages in Saudi Arabia, most of these studies were based on questionnaires administered to hospital pharmacists to explore the prevalence of drug shortages and how their institutions are coping with them (Alshehri and Alshammari, 2016; AlRuthia et al., 2017). Nevertheless, the root causes of drug shortages in Saudi Arabia have not been fully investigated before mainly due to the unavailability of published data. Recently, there were some media reports of patients not having their prescription medications filled in different governmental hospitals. However, the perspective of the experts in pharmaceutical care, regulation, purchasing and planning, and industry on the current drug shortage problem was not covered. While drug shortages are largely believed to be a global issue that is mainly influenced by international factors (Fox et al., 2014; Gray and Manasse, 2012), many argue that domestic reasons may remarkably contribute to drug shortages. Therefore, in this study a qualitative approach was adopted to explore the domestic causes of drug shortages in Saudi Arabia, identify the challenges to improve drug supply, and provide recommendations to address them.

2. Methods

2.1. Study design

An exploratory qualitative analysis using stakeholder discussion for data generation was conducted. The discussion points were generated after conducting extensive literature review of similar studies (Fox et al., 2014; Reis and Perini, 2008; Gray and Manasse, 2012; Pauwels et al., 2014; Balkhi et al., 2013; Pauwels et al., 2015; Alsheikh et al., 2016; Setayesh and Mackey, 2016; Alshehri and Alshammari, 2016; AlRuthia et al., 2017; Food and Drug Administration Safety and Innovation Act, USC, 2012; Iqbal et al., 2017; Haaijer and Joncheere, 2003; WHO, 1988; MSH, 2009; The Selection, 2017; APICS, 2014; Rasooldeen, 2017; Barlas, 2013; Yang et al., 2016). The topics included to guide the discussion were: current situation of drug shortages in Saudi Arabia, major factors contributing to drug shortages, challenges and obstacles to improve drug supply, and stakeholders' recommendations for managing drug shortages.

2.2. Sampling and recruitment

In February 2018, the Pharmacy Education Unit in the College of Pharmacy at King Saud University called for a meeting to discuss the main reasons behind drug shortages in Saudi Arabia. In order to cover this important issue from different perspectives, a list of stakeholders representing different health care, academic, regulatory, and industrial sectors in Saudi Arabia was generated based on the first and last authors' recommendations and personal contacts. Then, an email or phone invitation was sent to those stakeholders to participate in a one-day meeting at King Saud University College of Pharmacy in Riyadh, Saudi Arabia.

2.3. Data generation/procedures

A semi-structured interview was used to explore the main domestic reasons behind drug shortages in the Kingdom. The meeting lasted for two hours and was moderated by one of the authors. In addition, representatives from the Saudi Food and Drug Authority (SFDA), pharmaceutical purchasing and planning departments in the health care services of the ministries of defense and interior as well as from King Faisal Specialist Hospital and Research Center were interviewed to better understand this phenomenon.

2.4. Data analysis

The meeting was audio-recorded and transcribed into verbatim by five authors. The text was then reviewed and analyzed to identify different themes by the first and third authors.

3. Results and discussion

3.1. Characteristics of participants

There were 19 interviewees who shared their perspectives on the domestic causes of drug shortages in the Kingdom as well as their recommendations to address this serious health care problem. The characteristics of the participants are displayed in Table 1.

Table 1
Baseline characteristics of participants.

Characteristics	N, (%)
Gender	
Male	19(100)
Areas of experience	
Academia	2(10.52)
Regulatory affairs	5(26.31)
Pharmaceutical purchasing and planning	5(26.31)
Pharmaceutical care services	3(15.79)
Pharmaceutical industry	4(21.10)

3.2. Main themes, challenges and potential solutions

Seven main themes were identified and several recommendations were provided. The identified domestic causes along with the recommendations to address drug shortages in the Kingdom were summarized in the followings:

3.2.1. Failure to notify the Saudi Food and Drug Authority (SFDA) in advance of anticipated drug shortages

According to the United States FDA Safety and Innovation Act (FDASIA), pharmaceutical companies must notify the FDA of any potential drug shortage at least 6 months in advance (Fox et al., 2014). This requirement was made effective since the enactment of FDASIA back in 2012 (Food and Drug Administration Safety and Innovation Act, USC, 2012). Unfortunately, there is no current regulation that requires pharmaceutical companies or the licensed importers and distributors of pharmaceutical products to notify the SFDA of any anticipated disruption in the supply of certain drugs that may lead to drug shortages in advance. Therefore, the SFDA should pass and enforce a regulation by which pharmaceutical companies and licensed pharmaceutical products importers and distributors are obliged to notify the SFDA about any potential disruption in the supply of their products at least 6 months in advance.

3.2.2. Poor supply chain management systems

In order to avoid any drug shortage or wastage in any health care institution, there ought to be an efficient medication supply management system (Iqbal et al., 2017). This entails having a proper selection policy of medications, accurate estimation of the needs, efficient procurement and distribution policies, and rational use of medications (Haaijer and Joncheere, 2003). While some hospitals in the Kingdom have well-functioning supply management departments, many hospitals do not. Therefore, selection criteria to purchase from any pharmaceutical vendor or wholesaler should be based on price, registration condition of the pharmaceutical product, dependability, returned product policy, terms and conditions, shipping times, packaging, and quality of service (Iqbal et al., 2017). These selection criteria should also be linked to evidence-based clinical guidelines that must be updated regularly (WHO, 1988). In addition, the process of quantifying or forecasting the health care institutions' needs of any particular pharmaceutical product should be based on medication prescription and utilization patterns, the average length of the procurement cycle, the frequency of stock-outs, the incidence rate of the disease, and the minimum and maximum stock levels (Iqbal et al., 2017). This would hopefully eliminate the need for a direct purchasing order of any pharmaceutical product before the end of the financial year (MSH, 2009). Furthermore, prioritization criteria should be set based on an essential list of medications such as the World Health Organization (WHO) essential list of medicines to help in an efficient allocation of resources (The Selection, 2017). Moreover, having an effective and transparent inventory system whereby the pharmacy can keep accurate records of its stocks of pharmaceutical products in terms of their expiration dates and quantities on hand via a computerized inventory program is imperative (APICS, 2014). Thus, providing training on inventory management and effective planning for pharmaceuticals for those in charge of inventory management and pharmaceutical planning is highly needed.

3.2.3. Lack of effective penalties against pharmaceutical companies and licensed pharmaceutical importers that do not comply with the government regulations

According to the Saudi government regulations, all pharmaceutical manufacturers and local licensed importers and distributors of international pharmaceutical companies must keep reserves of their pharmaceutical products regardless of the consumption rates and prices of their products should any government or private health institution need to place a second purchasing order within the same financial year. The SFDA is responsible for the oversight of different pharmaceutical entities in the Kingdom to ensure that they are adhering to the regulations that were set forth to prevent and manage any potential drug shortage. However, the SFDA relies on the Saudi Ministry of Health (MOH) in enforcing the laws and regulations that govern the local pharmaceutical market as penalties against pharmaceutical companies, local pharmaceutical importers and distributors who fail to comply with such regulations lie in the hands of the MOH. Once the MOH receives reports of noncompliance against any pharmaceutical company issued by the SFDA, it verifies them and then issues what it deems appropriate fines against these companies that violate the laws and regulations. Unfortunately, this complex and lengthy bureaucratic process, which takes years sometimes, are not effective so far in deterring pharmaceutical companies' misconducts. For example, the fines filed against a pharmaceutical company or licensed pharmaceutical importer that imported a shipment of a prescription drug with short expiry dates are only 2% of the total cost of that shipment for every week that passes by without replacing it with a new shipment, and the cumulative fines should not exceed 30% of the total cost of that shipment. Such minimal fines are considered by many as ineffective and contributing in one way or another to the drug shortage problem. Therefore, the fines against the pharmaceutical companies and licensed pharmaceutical importers and distributors should be high enough to deter them from violating the laws and regulations. Furthermore, the MOH should relinquish its authority in penalizing pharmaceutical companies, pharmaceutical importers, distributors, and community pharmacies to the SFDA to cut the red tape and bureaucracy.

3.2.4. Relatively long time in releasing some lots of biological medicinal products by the SFDA

The SFDA has made huge strides in ensuring the safety of food and pharmaceutical products in the Kingdom ever since its establishment. The SFDA requires all biological medicinal products such as vaccines and plasma-derived products to have a National Regulatory Authority (NRA) certificate for imported products, summary lot protocol documents, finished product certificate of analysis, and non-insert diluent or solvent certificate of analysis to release any of these products to the Saudi market. However, some planning and purchasing departments in several hospitals in the Kingdom had some complaints about the lengthy process that the SFDA takes to release biological products; it took more than two months in some instances according to some of the interviewees who represented different health care institutions. Therefore, both the SFDA and the different health care institutions should work closely together to expedite the process of releasing these vital biological medicinal products without jeopardizing patient safety.

3.2.5. Overdependence on prescription drug imports

Local pharmaceutical manufacturing has grown drastically over the past 10 years. Despite that more than 32 pharmaceutical manufacturing plants are registered, in which about 27 are operating, local manufacturers only cover 20–25% of the Kingdom's consumption of prescription drugs according to some estimates (Rasooldeen, 2017). Therefore, to meet the country's demand of essential prescription drugs, private and public investment in essential market segments of pharmaceutical manufacturing such as biologics, vaccines, and chemotherapeutics should be boosted. This can be achieved through partnership and joint ventures between local manufacturers and international pharmaceutical companies lured by different government sponsored schemes. Also, investment in pharmaceutical research and development

through academic, government, and private initiatives should increase.

3.2.6. Low-profit margins of some essential drugs

The continuous supply of any pharmaceutical product is subject to the market forces. When the profit margin of a product becomes extremely narrow, especially when it goes off-patent and generic or biosimilar manufacturers start to compete, many manufacturers cannot withstand low profit margins and may eventually be forced to cease producing a specific product turning it prone to drug shortage (Barlas, 2013). For example, strict price control was found to be one of the contributing factors to drug shortages in China (Yang et al., 2016). In Saudi Arabia, the SFDA is responsible for pricing all pharmaceutical products before their registration and release to the market. Therefore, reconsideration of SFDA stringent pricing policy to give higher profit margins to essential medications, such as antineoplastic and psychotropic medications that undergo frequent shortage is advised in order to avoid interrupted supply of these critical medications in the future.

3.2.7. Outdated procurement policy

The current government procurement policy is based on open tenders or competitive bidding process. The WHO Collaborating Center for Pharmaceutical Pricing and Reimbursement Policies defines tendering as "any formal and competitive procurement procedure through which offers are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous" (WHO, 1999). The ultimate goal of the tendering process should be to obtain the most effective and high-quality pharmaceutical products in the most favorable pricing (WHO, 2014). However, the existing government pharmaceutical procurement policy focuses mainly on the price and does not consider other important factors such as quality, safety, and effectiveness. Such policy that only considers price with very little emphasis on the quality of pharmaceutical product and service of the tenderer is one of the contributing factors to drug shortages (Management Sciences for Health, 2012; Dranitsaris et al., 2017). Moreover, many regulatory bodies around the world have recalled several pharmaceutical products from the market for safety concerns (Tawde, 2014; Ten Ham, 2003; Johnston and Holt, 2014). Therefore, the current government procurement policy for pharmaceuticals needs to be revised to include innovative payment arrangement such as outcome-based contracts (Adamski et al., 2010).

4. Conclusion

Drug shortages are a complex health care issue that involves both international and domestic factors. Although many international factors contributed to drug shortage phenomenon that the Kingdom has been experiencing over the last decade, several domestic factors have played a major role in the recent drug shortage problem. These domestic factors were explored in this study and multiple recommendations were proposed. Developing a new regulation that requires pharmaceutical companies, importers, and distributors to notify the SFDA of anticipated drug shortages, overhauling the supply chain management, reforming the procurement policy, establishing and enforcing a new penalty system against law-violating companies, boosting investment in pharmaceutical manufacturing, and revising the current pricing policy of pharmaceutical products were the main recommendations that this study has come up with to manage drug shortages in the Kingdom. Therefore, different regulatory bodies including the ministry of health, the Saudi Food and Drug Authority, the ministry of commerce and investment, and the ministry of finance should act swiftly to manage the drug shortage problem before it turns into a crisis.

Disclosure

Authors of this study have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this study.

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