

Medication Exchange and Sharing Network Program (MESNP) initiative to cope with drug shortages in the Kingdom of Saudi Arabia (KSA)

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Background: Drug shortages are a major public health concern and remain a persistent problem worldwide. At present, there are no unified existing strategies for managing medicine stocks in the Kingdom of Saudi Arabia (KSA). Here, the aim is to describe our experience with creating a non-profit voluntary national Medication Exchange and Sharing Network Program (MESNP) throughout the KSA.

Methods: A quality improvement process map method was used in this project. The baseline evaluation included a review of possible reasons and strategies for managing medication shortages and recognizing potential associated safety issues. To that end, at the national level, we developed MESNP as a novel project to cope with medication shortages using Telegram social media as the preferred program for connecting with the member institution.

Results: A total of 500 requests were received over one year. Three hundred and fifteen (315) constituted requests for drug supplies due to shortages while the number of reports indicating the availability of overstock drug for re-distribution is (185). Almost 98% of overstocking drug reports was re-distributed in which it covers 75% of drug shortage requests.

Conclusion: This novel project aims to use our current resources by facilitating the medication exchange and sharing between the organizations at national level. The optimistic goal is to proactively mitigate drug wastages and prevent drug shortages toward better patient care.

Keywords: medication exchange, sharing project, drug shortages

Introduction

Drug shortages are a major public health concern and remain a persistent problem worldwide.¹⁻¹⁵ In the United States, drug shortages are tracked by the Food and Drug Administration (USFDA) and the American Society of Health-System Pharmacists (ASHP) despite the fact that they each use a slightly different definition of the term.^{16,17} The USFDA defines drug shortage as “[a] period of time when the demand or projected demand for [a] drug within the United States exceeds the supply of the drug”.¹⁸ The ASHP, on the other hand, defines drug shortage 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.”¹⁹ Although certain drug classes such as oncology medications are more vulnerable to shortages than others, there are reports from various countries of drug shortages in terms of

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different types and classes of commonly used or essential drugs.^{20–22} In Europe, too, reports and studies have also highlighted the drug shortage problem and its effect on the European health care system.^{23–29}

Saudi Arabia is one of the richest and fastest growing populations in the Middle East. That said, Saudi Arabia's drug markets are not immune to drug shortages. Although exact figures about drug shortages in Middle Eastern countries in general and Saudi Arabia in particular are lacking, there is an emerging yet still limited number of reports about the occurrence of drug shortages.^{14,15} A study by Alageel et al (2010) reported that drug shortages resulted in prescription drugs not being dispensed to patients in 9% of the cases.³⁰ Alshaikh et al (2016) compared the respective patterns of drug shortages in selected hospitals in KSA and the USA with special focus on the contributing factors in each case. The study findings showed that there are significant differences in drug regulation, pharmaceutical sectors, and health care systems between the two countries; such differences exist even among hospitals located within the same country.¹⁴ AlRuthia et al (2018) investigated possible causes of drug shortages in large hospitals in Saudi Arabia using stakeholder meeting discussions as the main source of data collection, and found that seven main causes were associated with drug shortages, with Poor Supply Chain Management Systems cited as one of the causes.³¹ The lack of early warning systems has been recognized by the ASHP as one of the main causes of the drug shortage crisis.^{18,32} Unfortunately, this early warning system is only available in a limited number of countries and programs. Additionally, the criteria for what constitutes a medicine at high risk of shortage may differ from region to region and country to country.³³ Failure to monitor and trace the supply chain systems and improper management of pharmacy inventory are key indicators of suboptimal practice performance that puts patients at risk by not providing the appropriate drugs when it is urgently needed.^{4,34}

Some useful methods for alleviating and reducing the drug shortage problem include advance notice systems, which are usually managed by regulatory authorities and tend to be available only in high-income countries.^{35–37} Systems that can track and trace drugs and redistribution of supplies create opportunities to mitigate shortages in the short term.³⁶ Shortages of essential and chronic medications will put patient safety at risk. In such situations, providers are usually forced to look for alternative approaches which may not be as effective as the original treatment plan or may even delay or cancel

patient treatment altogether. The United States has made great effort to ensure an adequate drug supply, with the FDA mandating that manufacturers both send updated advance notification to the FDA of any potential shortage and make the information publicly available.^{36,37} Several reports highlight the role of drug authorities in tracking medicines; however, they still play a limited role when it comes to action, as they cannot compel a company to increase drug production. In Saudi Arabia, the Saudi Food and Drug Administration (SFDA) has yet to fully initiate and implement its role in tracking drug shortages, while the role of other regulatory bodies is either outdated or unknown.³¹

At present, there are no unified existing strategies for controlling and managing medicine stocks in the kingdom. Having a nationwide centralized program might help spotlight shortage trends and even spur on the sharing or redistribution of medications between institutions. In this paper, we describe our experience with creating a novel voluntary centralized collaborative medication exchange program at the national level aimed at overseeing and facilitating the medication redistribution between different institutions around the kingdom.

Materials and methods

We performed a thorough literature review to understand and identify the possible causes of drug shortages in Saudi Arabia, and then have those compared to other countries in terms of their significant negative impact on patient care. We used the process map tool^{38,39} to gain a clear understanding of national drug shortages and the key factors associated with them so as to identify possible intervention, action, and solutions. At the national level, we found that drug shortage is a multifaceted problem. As found in other local studies,^{30,31} there are significant differences in drug regulation, tendering process as the main drug procurement process (winner takes all), different allocated drug budgets, a simplified drug inventory policy (Min/Max) is applied to all drugs in the hospital regardless of the service level or different demand characteristics for a drug, different pharmaceutical sectors, and different health care systems that exist among hospitals located within the same region.^{31,40} For the purpose of this paper, we define drug shortage as any disturbance in the drug supply process that results in the unavailability of a drug, thereby leading to alteration in the pharmacy processes for obtaining that drug, hence directly affecting patient care in a negative way. We define drug overstock as stocking additional or extra inventory of a drug that is not commonly used in a particular hospital.

What has become clear is that no one can solve this problem alone. A group of voluntary practitioner pharmacists, friends, and colleagues from hospitals nationwide was assembled to study the process as a team. The group considered the country's need for an organization to serve as communication center using current resources. The various steps in the process, starting from when a drug is considered overstock to when there is a shortage, were recognized. After determining all these steps, the potential failures in each step as well as the potential causes of such failures were identified, and a number of recommendations were then discussed. It is of special concern that overstock is among the causes of drug shortages,⁴¹ an issue that should be addressed and investigated at the national level. The team highlights the need for adequate communication on drug shortages and a collaborative network center for medication reallocation and exchange between hospitals nationwide as an innovative solution for drug shortages. The process identified three high-level steps as the causes of medication shortages: corporate regulatory bodies' role and involvement, poor medication supply chain, and communication failure. It came to our team's attention that specialized hospitals have well-structured, integrated computerized systems for billing, finance, drug procurement, logistics, as well as a well-established medication exchange program between their branches and facilities such as the Ministry of National Guard Health Affairs Hospitals (MNGHA) and King Faisal Specialist Hospital and Research Center (KFSHrC), while others such as MOH hospitals still lack such a system. Due to different tender processes for drug purchasing between hospitals, we found that some institutions end up overstocking some medications while leaving other institutions with shortages. Based on the group's abilities, limited capabilities, and in view of a more efficient use of current resources, the group recommended the development of a novel MESNP at the national level, especially as a collaborative network program with the primary function of serving as a centralized communication system that collects data about available stocks and shortages, as well as being able to track, advice, communicate, and provide pharmacists with guidance for and assistance in the exchange and redistribution of medication stocks between institutions in the hope of mitigating and coping with shortages or preventing stock expiration.

Here is a brief description of the team. The Development of Pharmacy Career Voluntary group was set up in 2015 using Telegram as the preferred social media platform for group

creation and communication. This voluntary group is a non-profit association representing members of the pharmacy profession in the KSA. The idea behind the creation of this group emerged as a result of discussions between a small group of friends and colleagues who all work as pharmacists. The group considered the country's need for an organization or association aimed at setting standards for practicing their profession and of finding ways to develop the profession by raising the level of professionalism at the national level. Several small groups were created under the umbrella of the Development of Pharmacy Career group which included the following: the job-seeker pharmacist group, the group for the development of pharmacy students and residents, a Drug and Poison Information Channel within the group, and a medication exchange and sharing network program (MESNP) that was set up in November 2016 after a flowchart analysis. To be considered a member of MESNP, the interested pharmacist should first make sure s/he has leadership engagement, support, and commitment, in addition to obtaining verbal consent to share stock information (overstock or shortages). Furthermore, s/he should be aware of the available stock, pay attention to current shortage issues, and understand the ethical process for stock sharing and setting up a medication redistribution policy in their working area. The main focus of the group is to maintain high situational awareness. This dynamic work demands that the MESNP member, who works in the supply or material department of a hospital, be vigilant about the patients' need, supply, and stock shortages or availability in every participant hospital or center, and then make a request (shortage or overstock) at least weekly and have it uploaded to the MESNP channel group using the group template spreadsheet. The group administrator oversees the process on a daily basis, reviews all requests made, and identifies if the overstock request will cover the shortage request. Finally, the administrator facilitates the communication between the requestors. The requestor will be asked to further proceed with the medication exchange following his/her hospital logistic policy via an appropriate channel of commands and procedures. MESNP will only facilitate the communication between the requestor hospitals and will neither deliver the drugs nor communicate directly with the concerned hospital. Any additional requirements from the participants should strictly adhere to the group's mission, personal requests for drug supplies are not allowed; stock redistribution strictly follows formal, official requests from hospitals. Such requests should specify the type of requests (supply vs stock), the medicine's generic name, strength and dosage form requested, expiry date, quantity, hospital name, and city. Interested pharmacists will be invited

to participate in the group on the telegram social media platform after signing an electronic written agreement indicating assent to the group's participation criteria. The group also shares certain information publicly via social media services such as Twitter.

The group recognizes the ethical imperative of collaborative work. Furthermore, the MESNP framework recognizes that responses to the increased demand for drugs and their shortages constitute a continuum response from conventional to contingency efforts. For example, ASHP provides a three-phase strategy to manage drug shortages, starting with identifying the anticipated duration and determining whether a patient is at risk; this is followed by a contingency phase, and then the mandate to communicate the plan to the FDA, before being rounded off by the implementation phase.¹⁸ Three main elements ought to be met in MESNP:

1. Authority of each participating hospital involved in the program
2. Sharing stock availability between institutions
3. Sharing information about the drug shortage status

Results

A total of 500 requests were received by the MESNP group over a 1-year period (November 2016 to December 2017). Most of the requests (70%, 350/500) originated from the Ministry of Health (MOH) affiliated hospitals, while the remaining requests (30%, 150/350) were made by medical cities, specialized and university hospitals. A majority of the requests (63%, 315/500) were

for drug supply due to shortages, of which 75% (237/315) were effectively solved by reallocating the required supply, sharing the medications with the other institutions, and dispensing them successfully to their patients.

Chemotherapeutic drugs were among the top drug requests for supply which constituted 25% (79/315) of drug shortage requests received, while 75% (236/315) concerned other medications such as sodium bicarbonate injection, zinc sulfate oral, epinephrine intramuscular, and norepinephrine injection; a vital drug for treating patients with hypotension was among the requests for supplies. Norepinephrine shortages are associated with increased patient mortality.⁴²

The percentage of requests indicating medication overstock or a situation in which medications were in low demand for redistribution was 37% (185/500). Various medications involved in overstock or slow-moving drugs included tacrolimus 5 mg cap, everolimus 0.5 mg, and antibiotics. Almost 98% of overstocking drug requests were redistributed, covering 75% of drug shortage requests.

Table 1 provides a list of the most frequently reported medications related to drug shortages or overstock.

Discussion

According to the World Health Organization (WHO), the Saudi health care system is ranked 26th among the world's 190 health care systems.⁴³ This is because the Saudi Government has made the development of health care services at all levels a top priority, and the health care system has benefited from substantial investment over

Table 1 Frequently requested medications involved in drug shortages or overstock requests

Example of top 10 medications involved with drug shortage requests	Example of top 10 medications involved with drug overstocking/low demand requests
Analgesic, non-opioid, fentanyl injection, rectal diazepam Antimicrobial (abecet, vancomycin, meropenem, metronidazole, clindamycin injection, cefuroxime, cefotaxime), pyrimethamine, antiretroviral: ritonavir 100 mg Corticosteroids (prednisolone) Magnesium sulfate injection, sodium bicarbonate Recombinant factor viii, fibrinogen, protein c concentrate Clopidogrel Furosemide injection Iron products Chemotherapy: clofarabine, cladribine, azacitadine, irinotecan, fludarabine, methotrexate, asparaginase products Epinephrine intramuscular and norepinephrine injection	Everolimus, tacrolimus Antimicrobial (cefuroxime injection, erythromycin syrup, erythromycin eye ointment, flucloxacillin oral suspension, amikacin, moxifloxacin, teicoplanin), antiretroviral: efavirenz Fluticasone inhaler 250 mcg, budesonide nasal spray, citriline syrup Bumetanide, furosemide oral Recombinant factor viia, alteplase 50 mg injection Chloralhydrate solution Ethionamide oral Phenytoin 100 mg tablet Chemotherapy: cytarabine, ifosfamide, doxorubicin, ibrutinib Terbinafine

decades.⁴⁴ Nowadays, drug shortage has become the norm rather than the exception in pharmacy daily practices. Although specific and certain drug classes such as oncology medications are more vulnerable to shortages than others, there are reports from various countries indicating drug shortages of different types and classes involving common and essential drugs. In such situations, pharmacists and health care providers are forced to look for alternative approaches which may not be as effective as the original treatment plan. As specialized governmental hospitals (eg, MNGHA and KFSHrC) have a well-established medication exchange program between their branches and facilities, this could be the reason for the increased number of drug shortages and overstock requests from MOH hospitals. This finding is consistent with the recommendations raised by the respondents of a survey conducted by the Institute for Safe Medication Practices (ISMP) to mitigate drug shortages; these recommendations include regular meetings with pharmacy staff, use of a safe dose of alternative drugs, and restricting the use of drugs in short supply.⁴⁵ A previous study conducted in the MNGHA-Jeddah to examine public attitude towards medication disposal found that many patients tend to dispense and overstock the medications, which may be an additional reason for drug shortages in some institutions. In that study, we suggested organizing collaborative, nationwide awareness campaigns that utilize social media on how to properly deal with the leftover medication.⁴¹ Keeping health care providers updated and the general public informed about drugs that are in short supply at the national level will help individuals trust their health care providers and better understand the magnitude of drug shortage and what it means for their care plan.^{46,47} Currently in the KSA, there are no national guidelines or policy that addresses how drug shortages should be managed. The implementation of MESNP and the development of national guidelines that assess and guide institutions/hospitals nationwide on how to manage drug shortages as well as communicating internally and externally should be considered a high priority.

Practical implications: health care is one of the main focus-areas of Saudi Vision for the year 2030 which represents a comprehensive plan for the entire economic structure of Saudi Arabia. In order to ensure the Saudi vision 2030 becomes reality, we should focus on a more efficient use of our current resources.⁴⁴ To that end, we identified an innovated solution at the national level to cope with the current situation by developing a centralized MESNP.

Furthermore, the purpose of our innovated project is in line with the 2016 United Nations secretary-general's high-level panel reports where they call for supports of new approaches for health and to accelerate promoting innovation in health and technology to ensure access to medicine.⁴⁸

In Canada, led by the Canadian Generic Pharmaceutical Association (CGPA), they have developed best practice guidelines to notify, prevent, and manage drug shortages.⁴⁶ In European Union member-countries, the European Medicines Agency (EMA) assesses the drug shortage and provides its recommendation directly to all health care professionals and patients.⁴⁹ In the United States, the FDA mandates that manufacturers send updated advance notification to the FDA of any potential shortage and make the information publicly available.^{36,37,47} In Saudi Arabia, however, the policy for tracking and dealing with drug shortages or overstock is either unknown or outdated.³¹ Due to the lack of a national reporting system, having a precise indication or comparison of the extent of drug shortages nationwide is difficult. Having a systematic and standardized methodology for communicating and reporting drug shortages is especially needed. The involvement of the Saudi Food and Drug Administration (SFDA) in creating a centralized, accessible network and logistic system to oversee, share information about stock availability, anticipate drug shortages, and facilitate medication redistribution will certainly play a crucial role as well as helping to analyze the drug shortages. The SFDA's involvement appears to play a significant role in coping with this problem. Our report findings were limited by the small sample size of the received requests, and the fact that only motivated voluntary MESNP members who noticed a stock issue were able to raise and share their request through the MESNP channel, which we suspect might have been responsible for the substantial number of reports missing. We neither analyze the cost-saving nor the cost-waste associated with drug redistribution or overstock issues, which is an area for future improvement.

Conclusion

Despite these efforts, this problem is expected to persist as this initiative may not be feasible in all institutions without the involvement of a national centralized authority such as SFDA. To ensure that MESNP is able to maintain and treat all patients fairly without treatment interruption, we recommend implementing a

centralized ethical approach for dealing with fair drug redistribution in order to minimize overstocking and either prevent or cope with drug shortages. The findings in this paper include the proactive identification and development of a framework to collect data about national drug shortages so as to facilitate medication exchange and sharing between organizations by aiming to prevent, mitigate drug wastages and shortages toward a better patient care. Our intention is to provide a platform for tackling drug shortages which is an important public health and practice quality issue, as well as the creation of a national uniform policy for the sharing and exchange of medications to be overseen by a drug regulation authority to control overstocking, offer reallocation, prevent shortages, minimize medication expiration and wastages, and eventually to help minimize risks and improve patient safety.

Ethical consideration

This project received exemption (Voluntary, confidential, No human subject involve or participant identifiers) by Institutional Review Board (IRB) of King Abdullah International Medical Research Center (KAIMRC), Saudi Arabia.

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3. The 28th PPAG Annual Meeting Poster Abstracts Gallery (April 2019) <https://ppagannual.secure-platform.com/a/gallery?roundId=9>.

Author contributions

Both authors contributed to data analysis, drafting or revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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