

## Drug shortages in large hospitals in Riyadh: a cross-sectional study

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**BACKGROUND:** Drug shortages are a serious and complex issue in any healthcare system. We conducted this study because the prevalence of drug shortages in Saudi Arabia is largely unknown, while there have been reports of shortages.

**OBJECTIVE:** To explore the prevalence and characteristics of drug shortages as well as identify strategies to minimize their impact on patient care and safety in large hospitals.

**DESIGN:** Questionnaire-based cross-sectional study.

**SETTING:** Pharmacy departments in secondary and tertiary care hospitals in the city of Riyadh.

**SUBJECTS AND METHODS:** Pharmacists in ten hospitals, categorized as Ministry of Health [MOH], MOH-affiliated medical cities, and non-MOH, were recruited using convenience sampling. The European Association of Hospital Pharmacists drug shortage questionnaire was administered to survey pharmacists about drug shortages in their hospitals.

**MAIN OUTCOME MEASURES:** Percentages of drug class shortages, characteristics, and strategies to minimize impact on patient care and safety across each hospital sector.

**RESULTS:** Of 200 pharmacists invited to participate, 120 pharmacists completed the questionnaire (60% response rate). Twenty-four percent were from MOH hospitals, 32% from MOH-affiliated medical cities, and 44% from non-MOH hospitals. A significantly higher percentage of pharmacists from MOH-affiliated medical cities (42.11%) reported encountering drug shortages on a daily basis compared to 13.79% and 15.09% of participants from MOH-hospitals and non-MOH hospitals, respectively ( $P=.001$ ). The top three drug classes that  $\geq 25\%$  of participants reported having shortages of were cardiovascular, antineoplastic, and endocrine drugs. The two most common strategies that were reported to minimize the impact of drug shortages on patient care by more than 70% of participants were informing prescribers and recommending alternative drugs, and alerting hospital staff about the presence of drug shortages using new communication tools.

**CONCLUSIONS:** The relatively high reported rates of drug shortages in some hospitals should encourage health policymakers to address this serious public health problem.

**LIMITATIONS:** The generalizability of the study's findings were limited by the small sample size, convenience sampling technique, self-reported data, and the fact that only pharmacists were invited to participate.

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**D**rug shortages are a global problem and a major threat for any health care system as shortages negatively affect the health of patients, potentially increasing the risk of medication errors, and imposing an economic burden on patients, providers, and health care systems.<sup>1</sup> Drug shortage is defined by the United States Food and Drug Administration (FDA) as "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".<sup>2</sup> Therefore, providers may prescribe a more expensive, less effective and safe alternative drug in times of drug shortage.<sup>1,3</sup> Pharmacists must also deal with drug shortages, spending many hours in communication with drug manufacturers and suppliers to address this problem.<sup>2</sup> Drug shortages can lead to

treatment delays, which might harm patients, especially those with critical conditions where no alternative drugs are available.<sup>4</sup> In the United States, many healthcare institutions have reported a vast increase in their operating costs due to drug shortages.<sup>5</sup>

The number of reported drug shortages has increased worldwide over the last decade.<sup>6,7</sup> All therapeutic classes have been affected by drug shortages.<sup>7-10</sup> There are multiple contributing factors to drug shortages including a shortage of raw materials, increased demand, strict manufacturing quality standards, pharmaceutical policies that hinder new generic manufacturers from entering the marketplace, and supply chain disturbances.<sup>2,11,12</sup> Although these factors significantly contribute to drug shortages, they account for less than 50% of the potential causes of shortages.<sup>2,11,12</sup> Other factors are ambiguous.<sup>13</sup>

The root causes of drug shortages vary across different countries.<sup>14</sup> For example, in the United States it was reported that the list of drugs in shortage has increased from 60 drugs in 2005 to more than 200 in 2010.<sup>13,15,16</sup> A 2012 survey conducted by the European Association of Hospital Pharmacists (EAHP) across the European Union countries found that 99% of participating hospitals experienced drug shortages on a weekly and sometimes daily basis.<sup>17,18</sup> In Saudi Arabia, drug shortages have affected both hospitals and community pharmacies. A study conducted in the city of Riyadh to explore the number of prescriptions not dispensed from an outpatient pharmacy in a tertiary care hospital, found that 9% of the prescribed drugs were not dispensed due to drug shortages.<sup>19</sup> Another study conducted in one of the tertiary care hospitals in the city of Riyadh to explore pharmacist's awareness of drug shortages, showed that most of the surveyed pharmacists reported that they learn of a drug shortage when the stock of that particular drug becomes zero, suggesting that improved communication systems may help resolve this problem.<sup>20</sup> Drug shortages do not affect hospitals alone. In a study that explored the scarcity of commonly prescribed psychotropic drugs, almost 50% of more than 240 community pharmacies in different regions in Saudi Arabia reported drug shortages.<sup>21</sup> Although drug shortages represent a significant global issue to many healthcare systems, there is a dearth of studies on the prevalence and causes in Saudi Arabia.<sup>19,22</sup>

The primary objectives of this study were to explore the prevalence and characteristics of essential drug class shortages as well as to identify determine the different strategies used to minimize the impact of drug shortages on patient care and safety in large hospitals in the city of Riyadh. The secondary objective was to ex-

plore different proposed policy solutions to drug shortages from the perspective of the hospital pharmacist.

## SUBJECTS AND METHODS

A questionnaire based cross-sectional study was conducted in 10 large hospitals in the city of Riyadh selected to represent the main sectors of healthcare. The hospitals were categorized based on their Ministry of Health (MOH) affiliation, size of health care institution, and whether or not they have an independent budget from the MOH as follows: MOH hospitals, which included Al Yammah, Al-Iman, King Salman, and Prince Muhammad bin Abdulaziz hospitals; medical cities affiliated with the MOH, which included King Fahad Medical City and King Saud Medical City; and non-MOH hospitals, which included the Security Forces Hospital, King Faisal Specialist Hospital and Research Center, Prince Sultan bin Abdulaziz Humanitarian City, and the National Guard Health Affairs. Participants were practicing pharmacists at the hospitals.

We used the European Association of Hospital Pharmacists (EAHP) drug shortage questionnaire, which consists of 27 questions about the prevalence and duration of drug shortages, the classes of drugs in shortage, type of drugs in shortage (e.g., brand or generic), the impact of drug shortages on patient safety and care, strategies used to minimize the impact of drug shortages on patient safety and care, and proposed policy solutions to drug shortages.<sup>7,23</sup> Furthermore, sociodemographic information (e.g., age, education, gender, and years of experience) was collected. The EAHP drug shortage questionnaire was distributed to pharmacists in the hospitals.

Convenience sampling was used due to constraints on time and resources. The minimum sample size was estimated to be 88 participants at an alpha of 0.05,  $\beta$  of 0.2, and medium effect size ( $W=0.3$ ).<sup>24</sup> To ensure sample adequacy, 200 copies of the questionnaire were manually distributed to pharmacists in the 10 hospitals by four pharmacy interns. The questionnaire was explained to pharmacists who agreed to participate. Cronbach's alpha method was used to assess the reliability of the EAHP drug shortage questionnaire.<sup>25</sup> Descriptive statistics were used to compare the opinions of participants about drug shortages in the three hospital categories using the t-test, chi-square test, or Fisher's exact test, as appropriate. Statistical significance was determined at an alpha of 0.05. All statistical analyses were performed using SAS version 9.2 (SAS Institute, Inc., Cary, NC, USA). The study was approved by the Institutional Review Board (IRB) of the College of Pharmacy at King Saud University in January 2016.

Data collection started in January 2016 and ended in May 2016.

## RESULTS

Of the 200 copies of the EAHP drug shortage questionnaire that were distributed to the pharmacists in the 10 hospitals, 120 copies were completed and returned (60% response rate). The reliability of the questionnaire was acceptable (Cronbach's alpha= 0.738). The participants were distributed in the three hospital sectors as follows: 29 (24.2%) from the MOH hospitals, 38 (31.66%) from the MOH-affiliated medical cities, and 53 (44.2%) from non-MOH hospitals. The majority of the participants were female (63.3%) and aged between 20 and 39 years (88.3%). Most of the participants (63.3%) reported having a Bachelor of Science in Pharmacy (BSc.Pharm) as their highest educational degree. More than 50 percent of the participants reported working in their hospitals for more than 2 years. Participants were mostly pharmacists working in outpatient or inpatient pharmacies (61.7%), followed by inpatient or outpatient pharmacy managers (21.7%), clinical pharmacists (10.8%), and directors of pharmaceutical care services (5.8%) (**Table 1**).

**Table 2** shows the responses to questions about drug shortages in the three hospital sectors. The percentage of participants who reported that drug shortages in their hospitals compromise the quality of patient care, was significantly higher in the MOH-affiliated medical cities (94.7%) compared to 72.4% and 58.5% of participants from MOH and non-MOH hospitals, respectively ( $P=.0006$ ). Similarly, a significantly higher percentage of participants from MOH-affiliated medical cities (42.1%) reported that drug shortages in their hospitals are encountered on a daily basis compared to 13.8% and 15.1% among participants from MOH and non-MOH hospitals, respectively ( $P=.001$ ). More than 50 percent of participants reported that drug shortages usually last for less than a month. The longest duration of drug shortages that most participants (58.3%) could recall was one to three months. The majority of the participants (65.83%) reported that the most common drugs in shortage are the generic drugs with a significantly higher percentage of participants from MOH-affiliated medical cities (81.6%) compared to 72.4% and 50.9% among participants from MOH hospitals and non-MOH hospitals, respectively ( $P=.005$ ). A significantly higher percentage of participants from non-MOH hospitals (26.42%) reported shortages in branded drugs compared to 20.7% and 18.4% among participants from MOH hospitals and MOH-affiliated medical cities, respectively ( $P=.005$ ). Similarly, a significantly

higher percentage of participants from non-MOH hospitals (22.6%) reported shortages of unlicensed drugs compared to 6.9% and 0% among participants from MOH hospitals and MOH-affiliated medical cities, respectively ( $P=.005$ ). The vast majority of participants (91.7%) reported that on average 1 to 10 hours per week of their time at work is wasted trying to resolve drug shortage problems. Nearly 16% of participants from MOH-affiliated medical cities reported spending over 15 hours to address drug shortages in their hospitals per week compared to only 3.5% and 3.8% from MOH and non-MOH hospitals, respectively ( $P=.014$ ). Approximately 84% of participants reported providing therapeutic equivalents in their hospitals on some occasions without a major disruption to patient care in times of drug shortage. Almost 62% of participants did not know which external drug supplier (e.g., generic manufacturers, wholesalers, innovators, special orders for unlicensed drugs) their hospitals most frequently encounter problems with sourcing-specific required drugs.

**Table 3** shows the frequency of reported drugs in shortage for different drug classes across the three hospital sectors. A significantly higher percentage of participants from MOH-affiliated medical cities (52.6%) reported shortages of cardiac drugs compared to 35.9% and 17.2% among participants from non-MOH and MOH hospitals, respectively ( $P=.011$ ). Likewise, a significantly higher percentage of participants from MOH-affiliated medical cities (27.5%) reported shortages of antineoplastic or anticancer drugs compared to 18.9% and 17.2% among participants from non-MOH and MOH hospitals, respectively ( $P=.004$ ). Moreover, participants from MOH-affiliated medical cities reported a significantly higher percentage (34.2%) of shortages in hematology drugs compared to 18.9% and 6.9% among participants from non-MOH and MOH hospitals, respectively ( $P=.021$ ). A significantly higher percentage of respiratory drugs (22.6%) were reported to be in shortage among participants from non-MOH hospitals compared to 13.2% and 0% among participants from MOH-affiliated medical cities and MOH hospitals, respectively ( $P=.018$ ). Endocrine, antimicrobial, and pediatric drugs were reported to be in shortage among 25.0%, 23.3%, and 20.0% of participants, respectively. The other drug classes were reported to be in shortage among less than 20% of participants.

**Table 4** shows the different reported strategies to minimize the impact of drug shortages on patient safety and care. More than 70 percent of participants reported that they either 1) informed prescribers about the drugs in shortage and recommend therapeutic alternatives or 2) created new communication systems and

**Table 1.** Baseline characteristics by hospital sector.

Characteristics	Hospital Sector			P value	Total (n=120)
	MOH hospitals (n=29)	MOH-Affiliated medical cities (n=38)	Non-MOH hospitals (n=53)		
<b>Age (years)</b>					
20-29	15 (51.72)	21 (55.26)	23 (43.40)	.821	59 (49.17)
30-39	10 (34.48)	13 (34.21)	24 (45.28)		47 (39.17)
40-49	4 (13.79)	3 (7.89)	5 (9.43)		12 (10.00)
≥50	0 (0.00)	1 (2.63)	1 (1.89)		2 (1.67)
<b>Gender</b>					
Male	13 (44.83)	11 (28.95)	20 (37.74)	.399	44 (36.67)
Female	16 (55.17)	27 (71.05)	33 (62.26)		76 (63.33)
<b>Highest educational degree</b>					
Bachelor of Pharmacy (BSc. Pharm)	22 (75.86)	20 (52.63)	34 (64.15)	.063	76 (63.33)
Doctor of Pharmacy (Pharm.D.)	6 (20.69)	12 (31.58)	6 (11.32)		24 (20.00)
Other (e.g., MPharm, postgraduate diploma)	0 (0.00)	0 (0.00)	3 (5.66)		3 (2.50)
Master of Science (MSc.)	1 (3.45)	6 (15.79)	8 (15.09)		15 (12.50)
Doctor of Philosophy (PhD.)	0 (0.00)	0 (0.00)	2 (3.77)		2 (1.67)
<b>Length of time in the workplace</b>					
< 6 months	4 (13.79)	3 (7.89)	8 (15.09)	.913	15 (12.50)
6 months to <1 year	3 (10.34)	6 (15.79)	5 (9.43)		14 (11.67)
1-2 years	5 (17.24)	8 (21.05)	9 (16.98)		22 (18.33)
>2 years	17 (58.62)	21 (55.26)	31 (58.49)		69 (57.50)
<b>Position</b>					
Pharmacist	21 (72.41)	22 (57.89)	31 (58.49)	0.290	74 (61.67)
Clinical pharmacist	0 (0.00)	7 (18.42)	6 (11.32)		13 (10.83)
Pharmacy manager (e.g., inpatient or outpatient)	7 (24.14)	6 (15.79)	13 (24.53)		26 (21.67)
Director of pharmaceutical care services	1 (3.45)	3 (7.89)	3 (5.66)		7 (5.83)

Values are number (percentage). MOH= Ministry of Health. Number of pharmacists within each sector.

tools to alert prescribers and other hospital staff about drugs in shortage and the need to replace them with therapeutic alternatives. A significantly higher percentage of participants from non-MOH hospitals (52.8%) reported informing prescribers about drugs in shortage without recommending therapeutic alternatives compared to 39.5% and 24.1% among participants

from MOH-affiliated medical cities and MOH hospitals, respectively ( $P=.039$ ). Approximately 18 percent of participants reported substituting drugs in shortage without consulting prescribers or patients. A significantly higher percentage of participants from non-MOH hospitals (52.8%) reported determining when the supply would be restored and planning their stocks

**Table 2.** Responses to questions about drug shortages by hospital sector.

EAHP drug shortage questionnaire's questions	Hospital Sector			P value	Total (n=120)
	MOH hospitals (n=29)	MOH-Affiliated medical cities (n=38)	Non-MOH hospitals (n=53)		
<b>Do drug shortages compromise the quality of patient care in your hospital?</b>					
No	8 (27.59)	2 (5.26)	22 (41.51)	.0006	32 (26.67)
Yes	21 (72.41)	36 (94.74)	31 (58.49)		88 (73.33)
<b>How often does your hospital experience drug shortage?</b>					
Occasionally (e.g., 2-3 times/year)	5 (17.24)	4 (10.53)	19 (35.85)	.001	28 (23.33)
Monthly	11 (37.93)	5 (13.16)	15 (28.30)		31 (25.83)
Weekly	9 (31.03)	13 (34.21)	11 (20.75)		33 (27.50)
Daily	4 (13.79)	16 (42.11)	8 (15.09)		28 (23.33)
<b>How long do drug shortages usually last in your hospital?</b>					
A number of days (e.g., <7 days)	6 (20.69)	11 (28.95)	8 (15.09)	.549	25 (20.83)
A number of weeks (e.g., less than a month)	15 (51.72)	19 (50.00)	28 (52.83)		62 (51.67)
A number of months (e.g., ≥ a month)	8 (27.59)	8 (21.05)	17 (32.08)		33 (27.50)
<b>What was the longest drug shortage duration that you recall in your hospital?</b>					
1-3 months	18 (62.07)	25 (65.79)	27 (50.94)	.489	70 (58.33)
3-6 months	8 (27.59)	9 (23.68)	18 (33.96)		35 (29.17)
6-12 months	3 (10.34)	2 (5.26)	3 (5.66)		8 (6.67)
>1 year	0 (0.00)	2 (5.26)	5 (9.43)		7 (5.83)
<b>Which type of drugs is commonly in shortage?</b>					
Generic	21 (72.41)	31 (81.58)	27 (50.94)	.005	79 (65.83)
Brand	6 (20.69)	7 (18.42)	14 (26.42)		27 (22.50)
Unlicensed drugs (e.g., special orders)	2 (6.90)	0 (0.00)	12 (22.64)		14 (11.67)
<b>In an average week in your hospital, how much time (staff working time) do you estimate is diverted because of drug shortage problems?</b>					
Less than an hour	7 (24.14)	4 (10.53)	24 (45.28)	.014	35 (29.17)
1-5 hours	15 (51.72)	18 (47.37)	20 (37.74)		53 (44.17)
6-10 hours	6 (20.69)	9 (23.68)	7 (13.21)		22 (18.33)

**Table 2** cont. Responses to questions about drug shortages by hospital sector.

EAHP drug shortage questionnaire's questions	Hospital Sector			P value	Total (n=120)
	MOH hospitals (n=29)	MOH-Affiliated medical cities (n=38)	Non-MOH hospitals (n=53)		
11-15 hours	0 (0.00)	1 (2.63)	0 (0.00)		1 (0.83)
>15 hours	1 (3.45)	6 (15.79)	2 (3.77)		9 (7.50)
<b>How often do you provide a therapeutic equivalent or near equivalent medicine, without major disruption to their treatment?</b>					
Never	0 (0.00)	1 (2.63)	3 (5.66)	.289	4 (3.33)
Rarely	4 (13.79)	3 (7.89)	8 (15.09)		15 (12.50)
Sometimes	17 (58.62)	18 (47.37)	19 (35.85)		54 (45.00)
Most of the times	6 (20.69)	11 (28.95)	21 (39.62)		38 (31.67)
Always	2 (6.90)	5 (13.16)	2 (3.77)		9 (7.50)
<b>Which category of external supply does your hospital most frequently encounter problems with sourcing specific required medicines?</b>					
I do not know	18 (62.07)	23 (60.53)	33 (62.26)	.469	74 (61.67)
Generic manufacturers	1 (3.45)	5 (13.16)	2 (3.77)		8 (6.67)
Innovators (brand companies)	4 (13.79)	4 (10.53)	5 (9.43)		13 (10.83)
Unlicensed drugs suppliers (e.g., special orders)	4 (13.79)	3 (7.89)	3 (5.66)		10 (8.33)
Wholesalers	2 (6.90)	3 (7.89)	10 (18.87)		15 (12.50)

Values are number (percentage). EAHP= European Association of Hospital Pharmacists. MOH= Ministry of Health.

accordingly compared to 29.0% and 20.7% among participants from MOH-affiliated medical cities and MOH-hospitals, respectively ( $P=.006$ ). Forty percent of participants reported reassigning staff work profiles and job descriptions to include dealing with drug shortages as one of their employed strategies to minimize the impact of drug shortages on patient care. Almost 41% of participants reported readjusting budget plans due to additional expenditures caused by drug shortages. Approximately 18% of participants reported cancelling practice improvement and development initiatives due to resources having to be reassigned to dealing with the drug shortages. Only 5.8% of participants reported that no changes were required to tackle drug shortages in their hospitals.

**Table 5** shows policy solutions proposed by participants. Around 56% suggested creating a comprehen-

sive database for drugs in shortage run by the SFDA and the MOH; 39.17% suggested establishing a high-level investigation into the root causes of drug shortages led by the SFDA; 36.67% suggested having a greater legal clarity about the responsibility of drug manufacturers; and 35% suggested publishing a national annual report on drug shortages by the SFDA.

## DISCUSSION

Although multiple studies have explored the prevalence and root causes of drug shortages in the United States and Europe,<sup>2,7,8,10,13</sup> very few studies have been conducted addressing this serious problem in healthcare systems in the Middle East.<sup>19-22</sup> This study investigated the prevalence of drug shortages in 10 large hospitals in the city of Riyadh, Saudi Arabia, using the EAHP drug shortage questionnaire, which showed acceptable reli-

**Table 3.** Classes of the drugs reported in shortage by hospital sector.

Drug class	Hospital Sector			P value	Total (n=120)
	MOH hospitals (n=29)	MOH-affiliated medical cities (n=38)	Non-MOH hospitals (n=53)		
Antineoplastic agent/ anticancer drugs	5 (17.24)	18 (47.37)	10 (18.87)	.004	33 (27.50)
Antimicrobial agents	6 (20.69)	5 (13.16)	17 (32.08)	.101	28 (23.33)
Renal drugs	0 (0.00)	3 (7.89)	1 (1.89)	.207	4 (3.33)
Urological drugs	0 (0.00)	1 (2.63)	1 (1.86)	.696	2 (1.67)
Hematology drugs	2 (6.90)	13 (34.21)	10 (18.87)	.021	25 (20.83)
Immunosuppressants	3 (10.34)	5 (13.16)	1 (1.89)	.078	9 (7.50)
Gastrointestinal drugs	2 (6.90)	6 (15.79)	7 (13.21)	.567	15 (12.50)
Topical agents	5 (17.24)	2 (5.26)	10 (18.87)	.159	17 (14.17)
Orphan drugs	0 (0.00)	0 (0.00)	4 (7.55)	.152	4 (3.33)
Respiratory drugs	0 (0.00)	5 (13.16)	12 (22.64)	.018	17 (14.17)
Pediatric drugs	5 (17.24)	12 (31.58)	7 (13.21)	.088	24 (20.00)
Endocrine drugs	9 (31.03)	6 (15.79)	15 (28.30)	.273	30 (25.00)
Preventive drugs (e.g., vaccines)	1 (3.45)	2 (5.26)	3 (5.66)	.904	6 (5.00)
Anesthetics	0 (0.00)	3 (7.89)	7 (13.21)	.089	10 (8.33)
Cardiac drugs	5 (17.24)	20 (52.63)	19 (35.85)	.011	44 (36.67)
Emergency drugs	5 (17.24)	8 (21.05)	6 (11.32)	0.442	19 (15.83)

Values are number (percentage). MOH= Ministry of Health.

ability among the study sample.<sup>25</sup> The hospitals were categorized into three sectors based on the structure of the Saudi health care system where governmental hospitals differ in their affiliations and sources of funding.<sup>21</sup> The Ministry of Health (MOH) has a separate budget where it funds all hospitals that fall under its authority. Although some medical cities belong to the MOH, they enjoy more autonomous governmental funding channeled through the MOH. Therefore, these health institutions were categorized as MOH-affiliated medical cities and not MOH hospitals. The third category included hospitals that receive funding from other governmental entities such as the Ministries Of National Guard And Interior.

The findings of this study show the high prevalence rates of drug shortages of major drug classes in three hospital sectors in Saudi Arabia. The percentage of participants from MOH-affiliated medical cities who reported that drug shortages in their hospitals compromised the quality of patient care, was the highest

compared to participants from other hospital sectors. A higher percentage of participants from MOH-affiliated medical cities reported that they encounter drug shortages in their hospitals more frequently than participants from the other hospital sectors. In addition, the percentage of participants who reported that 6 or more hours per week of their hospitals' staff work time is diverted because of drug shortage problems, was the highest among participants from MOH-affiliated medical cities compared to participants from the other hospital sectors. Generic drugs are cost effective alternatives to many of the highly priced branded drugs, and their shortage makes the drug shortage problem even worse.<sup>7,9,17</sup> Unfortunately, generic drugs were reported to be in shortage more often than branded or unlicensed drugs especially among participants from MOH-affiliated medical cities. This indicates that the drug shortage problem in the MOH-affiliated medical cities is more prevalent and serious compared to MOH and non-MOH hospitals, and emphasizes the impor-

**Table 4.** Strategies used to minimize the impact of drug shortages on patient safety and care by hospital sector.

Strategy	Hospital Sector			P value	Total (n=120)
	MOH hospitals (n=29)	MOH-affiliated medical cities (n=38)	Non-MOH hospitals (n=53)		
Substitute (without consultation with the prescriber/the patient)	6 (20.69)	8 (21.05)	8 (15.09)	.716	22 (18.33)
Inform prescriber and recommend an alternative drug	17 (58.62)	28 (73.68)	42 (79.25)	.132	87 (72.50)
Inform the prescriber of the drug shortage	7 (24.14)	15 (39.47)	28 (52.83)	.039	50 (41.67)
Investigate when supply will be restored and plan stock accordingly	6 (20.69)	11 (28.95)	28 (52.83)	.006	45 (37.50)
Attempt to source the medicine from an alternative supplier (including another hospital)	5 (17.24)	11 (28.95)	21 (39.62)	.105	37 (30.83)
Change the formulary based on the information provided	4 (13.79)	0 (0.00)	3 (5.66)	.036	7 (5.83)
Reassign staff work profiles and job descriptions (e.g., devote staff resources more specifically to dealing with shortages)	12 (41.38)	15 (39.47)	21 (39.62)	.984	48 (40.00)
Create new communication systems and tools to alert prescribers and other hospital staff about the presence of shortages and the need to substitute replacement therapies	21 (72.41)	29 (76.32)	41 (77.36)	.879	91 (75.83)
Readjust budget plans due to additional expenditure caused by shortages (e.g., needing to use more expensive replacement therapies)	14 (48.28)	13 (34.21)	22 (41.51)	.505	49 (40.83)
Cancel practice improvement and development initiatives due to resources having to be reassigned to dealing with the shortages problem	7 (24.14)	4 (10.53)	10 (18.87)	.3273	21 (17.50)
No changes required	2 (6.90)	3 (7.89)	2 (3.77)	.690	7 (5.83)

tance of carrying out a thorough investigation into this issue to minimize any impact on patient safety and care. Fortunately, most participants, regardless of the hospital sector, reported that drug shortages usually last for less than a month. Although pharmacists should know the different sources of drugs, most participants (e.g., >60%) did not know which external sources of drug supply that were problematic. This may be attributable to poor communication between the pharmacists and pharmacy managers or directors of pharmaceutical care services in their hospitals.<sup>7,12,20</sup>

Cardiac drugs such as beta blockers and renin-angiotensin blocking agents were reported to be in shortage

by more than one third of participants. The drug shortage prevalence of such an important class of drugs is alarming given the huge impact of these drugs on controlling serious medical conditions such as hypertension and heart failure, where shortages could lead to unfavorable consequences such as higher rates of hospitalizations and mortality if left untreated.<sup>1,4,22</sup> Shortages of antineoplastic drugs is another serious public health issue that was reported by nearly half of participants from MOH-affiliated medical cities.<sup>9</sup> Endocrine drugs such as antidiabetics were also reported to be in shortage by one fourth of participants, which is as equally alarming as the shortage of cardiac drugs.<sup>9</sup>

**Table 5.** Proposed policy solutions to drug shortages by hospital sector.

Proposed policy solution	Hospital sector			P value	Total (n=120)
	MOH hospitals (n=29)	MOH-affiliated medical cities (n=38)	Non-MOH hospitals (n=53)		
Greater legal clarity about the responsibility of drug manufacturers	14 (48.28)	11 (28.95)	19 (35.85)	.262	44 (36.67)
Comprehensive database, run by the Saudi FDA and the MOH, of all drugs reported to be in shortage	12 (41.38)	20 (52.63)	35 (66.04)	.088	67 (55.83)
High level investigation into the root causes of drug shortages led by the Saudi FDA	10 (34.48)	10 (26.32)	27 (50.94)	.050	47 (39.17)
A national annual report on drug shortages by the Saudi FDA	7 (24.14)	14 (36.84)	21 (39.62)	.357	42 (35.00)

Values are number (percentage). MOH= Ministry of Health. Saudi FDA= Saudi Food and Drug Authority.

Participants reported a range of different strategies to minimize the impact of drug shortage on patient safety and care.<sup>15,17,23</sup> More than two-thirds reported that they inform prescribers of any existing drug shortages and recommend therapeutic alternatives, which is consistent with the findings of other studies.<sup>20,23</sup> The recommendation to improve communication among pharmacists and create better communication tools to enable pharmacists to act swiftly, should drug shortages exist, is one the strategies in use.<sup>20</sup> Sourcing drugs in shortage from other hospitals was reported by around one-third of participants compared to only 2-9% of European pharmacists in another study, who reported sourcing or referring patients to other hospitals as a strategy to minimize the impact of drug shortages on patient care.<sup>23</sup> Drug shortages may lead to a shortfall in the pharmacy budget due to the need to buy more expensive drugs as replacements or substitutes for drugs in shortage,<sup>5-7,14</sup> which was reported by more than 40% of participants in our survey. Furthermore, drug shortages may lead to cancelling essential staff training and improvement programs due to budget constraints and reallocation of resources to deal with this serious and urgent healthcare issue,<sup>13,14,17</sup> which was reported by around 18% of participants in our survey. Changing the formulary by adding therapeutic alternatives or deleting backordered medications may negatively affect the pharmacy budget and patient care if the alternatives are not as effective as the drugs in shortage.<sup>4,5,23</sup> Fortunately, this was only reported by around 6% of participants. Devoting more staff time to manage the

drug shortage problem is an issue that many hospitals are struggling with, and the Saudi hospitals are no exception.<sup>19,23</sup>

The findings of this study have multiple practical implications. Addressing drug shortages cannot be resolved using institutional level solutions,<sup>1,3</sup> and therefore require national and sometimes require the engagement of international health and regulatory bodies.<sup>2,13,15,18</sup> The relatively high estimates of drug shortages for multiple drug classes should raise the alarm among healthcare policy makers to act urgently to resolve this serious healthcare issue. The participants proposed multiple policy solutions to this serious healthcare issue such as clarifying the role that pharmaceutical manufacturers play regarding their responsibility in drug shortages, and creating a comprehensive database of drugs in shortage under the oversight of the SFDA and the MOH. However, there are other solutions and recommendations that were reported in the literature and used in different countries to address this issue.<sup>26-28</sup> For example, establishing a national drug shortage program similar to the one in the United States that was established by the U.S. FDA, in collaboration with the American Society of Health-System Pharmacists (ASHP), to trigger an advance notice of drug shortages in different healthcare institutions to minimize the impact on patient care is one of the workable recommendations of the program.<sup>28</sup> Starting a strategic national medical stockpile by the SFDA in collaboration with other governmental healthcare entities using the Strategic National Stockpile

(SNS) that was established by the Department of Health and Human Services in the U.S. as an example is essential in order to address any future drug shortage and minimize its impact on patient care.<sup>27</sup> The Accelerated Recovery Initiative (ARI) that was launched by the Generic Pharmaceutical Association (GPhA) in the U.S. is another potential solution to address the drug shortage problem, whereby generic drug manufacturers inform the U.S. FDA of any potential drug shortage at least three months in advance to enable the FDA to act swiftly to minimize its impact on patient care.<sup>27</sup> The main objective of the Saudi economic vision 2030 is to move the country away from its heavy reliance on oil and diversify its economy. Therefore, supporting generic drug manufacturers in the country is important for a multitude of reasons. First, strengthening the local production of essential generic drugs, such as cardiac and antineoplastic medications, will create hundreds if not thousands of jobs, and will ensure supplies of these essential drugs.<sup>28</sup> However, local generic drug manufacturers should have higher markups on their products than their international competitors in a form of government subsidy until they firmly establish themselves in the market, and to avoid the issues that other pharmaceutical markets faced which consequently led to drug shortages.<sup>25</sup> Furthermore, encouraging healthcare providers such as pharmacists to find solutions to this problem is important given their direct contact with patients as well as their awareness of the significance of this problem.<sup>23</sup> The role that private health insurance plays in the drug shortages should not be underestimated.<sup>27,28</sup> Health insurance companies usually cover drugs listed in their formularies with the most favorable prices. Therefore, when certain drugs go off-patent many generic drug manufacturers scramble to enter the market. As more drug manufacturers enter the market the prices of generic drugs decrease until they reach a point where the profit margin is not high enough for certain generic companies to keep manufacturing these drugs.<sup>27</sup> Hence, many generic drug manufacturers exit the market when it becomes unprofitable for them keep manufacturing certain generic drugs, thus contributes to drug shortages.<sup>28</sup> Therefore, a fair drug-pricing policy for both purchasers and drug manufacturers should

be established.<sup>28</sup>

Although this study is the largest to our knowledge in Saudi Arabia that explores the prevalence of drug shortages and the proposed policy solutions, it has several limitations. First, the study may suffer from the limitations of convenience sampling.<sup>29</sup> Second, the prevalence of drug shortages was based on self-report data instead of official hospital reports on drug shortages due to the difficulty in obtaining such data. Third, although the response rate in this study (60%) is comparable to other survey studies and the pharmacy departments from all the surveyed hospitals were represented by a group of pharmacists,<sup>30</sup> the risk of nonresponse bias still exists. Fourth, the participants were asked about the shortage of anatomical therapeutic classes of drugs rather than specific drugs so it is hard to determine which drugs are in shortage. Fifth, there may be other reasons behind drug shortages, which were not reported in the study due to its design. Sixth, the study included an uneven number of participants from the three hospital sectors. Finally, although pharmacists are believed to be the most knowledgeable healthcare providers about drugs and their availability, the inclusion of other healthcare providers such as nurses and physicians would have made the findings more robust and representative. Therefore, it is hard to generalize the findings of this study to other cities and hospitals in Saudi Arabia. Suggestion for future studies include implementing a mixed methods approach, whereby different themes regarding drug shortages can first be identified using qualitative research methods, and then a questionnaire could be developed to examine the prevalence and root causes of drug shortages quantitatively.

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#### **Conflict of interest**

*The authors have declared that no competing interests exist.*

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