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## 1. Introduction

It has been estimated that the global expenditure on medicines will reach US\$ 1.4 trillion by 2020 [1]. The rising cost of medicinal products compromising accessibility and affordability to healthcare presents as a major challenge to healthcare systems globally. Generic medicines by means of their cheaper price provide an opportunity to curtail the escalating costs of medicinal products and reduce the burden on healthcare expenditures [2]. The World Health Organization (WHO) defines generic medicine as " a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights"[3].

In order to ensure the drug availability, improve consumer access to generic medicines and to address the challenge of escalating pharmaceutical expenditures, generic substitution policy has been adopted and promoted in many healthcare systems around the globe [2,4,5]. The cost of generic medicines is, on an average, 80 to 85 % less than the branded product, therefore generic products can significantly reduce healthcare costs [6]. In the US, the use of Food and Drug Administration (FDA)-approved generics saved US \$158 billion in 2010 alone [7]. The health system savings rose to US \$ 254 billion in 2014 with generic prescriptions accounting for nearly 3.8 billion of the total 4.3 billion prescriptions dispensed [7]. Similarly in Europe, generic medicines constitute more than 56% of prescriptions dispensed but only account for only 22% of the total expenditure on medicines [8]. Generic substitution is defined as the act of substituting a branded medicine with an equivalent generic medicine [9].

Consequently, generic substitution policy allows pharmacists to dispense a generic medicine in place of a branded medicine except in situations where the prescriber

recommends a particular brand in patient's interest. Pharmacists, being the fundamental members of any health care system can also play an important role in spreading awareness about generic substitution policy. This is evident from the findings of a study conducted in Norway that suggested that patients, who had their medicine switched to an alternative generic medicine were reported to have received information from a pharmacist [2]. However, there are many challenges that hinder the promotion and use of generic medicines and one of these include the lack of understanding among physicians about the generic medicines' bioequivalence [10]. Not all branded medicines have a generic bioequivalent; but when they do, generic medicines cost much less than the branded medicine. However, if the branded medicine is cheaper, it needs to be dispensed.

### **1.1. Saudi Healthcare system and generic medicines use**

Saudi Arabia, one of the biggest oil producers in the Gulf, has a population of 27.4 million (30% expatriates), as of 2010 census, with a gross domestic product (GDP) US\$ 748.4 billion [11]. Two-thirds of the population (69 %) is covered by a public health service, public health insurance or social insurance and the rest is covered by private health insurance. Healthcare workforce predominantly consists of expatriates [12]. In 2010, the total pharmaceutical expenditure (TPE) was 13.5 billion SAR (US\$ 3.5 billion) accounting for 18% of their total healthcare expenditure and gigantic 2% of the GDP [11]. The TPE equates to per capita pharmaceutical expenditure of 500 SAR (US\$ 132). Public expenditure on pharmaceuticals represents 40 % of the TPE (per capita public expenditure 200 SAR (US\$ 53). Total private expenditure on pharmaceuticals was 8.2 Billion SAR (US\$ 2.1 billion) [12]. There are 19 manufacturers that are Good Manufacturing Practice (GMP) certified including 4 multinational pharmaceutical companies [12].

Saudi Arabia relies heavily on the import of pharmaceutical products and in 2012, domestic manufacturers held only 18% of the market share by value produced [13]. With the escalating pharmaceutical cost in Saudi Arabia, the need to have an alternative cheaper medicine is crucial in achieving cost effective healthcare outcomes for patients. Saudi Food and Drug Authority (SFDA) is the governmental body designated to set medicine prices. SFDA uses two pricing frameworks including External price referencing (EPR) and value-based pricing (VBP) to set medicine prices in the Kingdom [14]. Once the generic medicine becomes available, the prices of branded innovator drug is lowered by 20% of their original registered prices [14]. Prices are reviewed every five years at the time of renewal of product registration. The generic medicines substitution policy has been implemented in Saudi Arabia since 2005 [15].

A study conducted in Taif, Saudi Arabia suggested that there was a lack of awareness among the general public about generic medicines and generic substitution [16]. Furthermore, more than half of the participants of the study preferred branded medicine over their generic counterpart [16]. Similarly, another study that evaluated physicians' knowledge, perception, and attitude toward generic medicines in Riyadh, Saudi Arabia suggested that lack of knowledge about generic medicines among the prescribers was one of the major factors that were responsible for the low rate of generic medicine prescribing [17]. In a previous qualitative study conducted in Alahsa city (Eastern province), community pharmacists expressed concerns about the quality of generic medicines [18]

To the best of our knowledge, there has been no quantitative study using a structured questionnaire and systematic sampling technique has assessed community pharmacists' knowledge and practices towards generic substitution in Saudi Arabia

despite the fact that community pharmacists are 'central' in generic medicines substitution. Therefore, the aim of this study is to evaluate community pharmacists' knowledge, perceptions and opinions towards generic medicines and generic substitution, and to assess their current substitution practices.

## **2. Materials and methods:**

### **2.1. Study Design**

A cross-sectional survey using a 25-item self-completed, anonymised questionnaire was conducted in the Makkah region of Saudi Arabia between February and March 2016.

### **2.2. Questionnaire Design**

A questionnaire was developed in English language after extensive literature search and review [16,19-21]. Although Arabic is the first language of Saudi Arabia, English is widely spoken and understood among the multi-ethnic pharmacist community. The initial draft of the questionnaire consisted of 35 items. Based on the feedback received from two subject experts, the final questionnaire consisted of 25 items divided into four sections. The first section assessed the demographic data including age, country of graduation, terminal degree, years of experience working as a community pharmacist in Saudi Arabia, total years of experience, and the number of prescriptions dispensed by the pharmacists. The second section evaluated the pharmacists' knowledge of generic medicines and the national policies related to generic medicines substitution. For each knowledge question, pharmacists had to choose from yes, no or don't know options as appropriate. Each correct answer was given 1 point and a wrong or don't know answer was scored zero. The maximum knowledge score was 7 points. The third section assessed the pharmacists' opinions on generic substitution including its

role in improving patient's quality of life, amount of information given to the patients about generic medicines and impact of pharmaceutical companies-led advertisement on dispensing of medicines. The fourth and final section evaluated pharmacists' current generic substitution practices including most common generic substitution, type of information provided to patients at the time of generic substitution and reasons for recommending generic medicine. The face and content validity was done by two senior academics with expertise in questionnaire design and two community pharmacists. To improve clarity and comprehension, a couple of questions were reworded and/or reframed based on the feedback received by the community pharmacists. The final questionnaire was pilot-tested on ten community pharmacists, not included in the final analysis.

### **2.3. Sampling and Data Collection**

Saudi Arabia is divided into thirteen administrative regions. The present study was conducted in the Makkah region (province) located in the Western Saudi Arabia along the Red Sea coast. The Makkah region consists of 12 governorates and has a population density of 45/km<sup>2</sup>, the most populous region of Saudi Arabia.

Since no up-to-date list of community pharmacies was available to authors, a 4-step sampling approach, previously tested in another study [22], was used with an aim to ensure generalizability and minimize selection bias. Firstly, three most populous governorates, Makkah Al-Mukarrmah (capital city), Jeddah and Taif, were selected. Secondly, each of these governorates were divided into four zones (South, North, East, and West). Thirdly, a list of districts within each of these twelve zones (3 governorates x 4 zones) was compiled and six districts from each zone were randomly

selected using random numbers. Finally, community pharmacies were selected conveniently within each of the six randomly selected districts.

Five senior Pharm-D students who had received training in undertaking survey research visited selected pharmacies for data collection. The student explained the study purpose to community pharmacists and invited them to complete the questionnaire. If more than one pharmacist was working at a community pharmacy, both were requested to complete the questionnaire. The completed questionnaires were collected by the same student at a mutually agreed time.

#### **2.4. Data Analysis**

Data analysis was performed using SPSS for windows, version 20. Frequency and cross-tabulation were used for descriptive analysis. Chi-square and Fisher's Exact statistical tests were used to investigate association between pharmacists' responses and their demographic characteristics (country of graduation, age, experience, and employment position) as appropriate. Fisher's Exact test was used instead of Chi-square test when 20% of the cells have expected count less than 5. Student's T-test or One-Way ANOVA were used as appropriate to compare total knowledge score across various sociodemographic domains.  $P < 0.05$  was considered statistically significant.

#### **2.5. Ethical approval**

The study was approved by the Institutional Research Ethics Board (IRB), Umm-Al-Qura University, Makkah, Saudi Arabia. Verbal consent was obtained from the participants before entering the study. Only members of the research team had access to research data.

### **3. Results:**

One hundred and twenty-eight community pharmacists were approached in the study. Of these, 121 completed the questionnaire (response rate of 95%). Of the 121, 35 questionnaires were collected from Jeddah, 71 from Makkah and 15 from Taif.

#### **3.1. Demographics of participants**

The mean age of the participants was 33 years and most of them were working as staff pharmacists (70%). The vast majority of the participants 108 (89.3%) graduated from Egypt and 97 (80.2%) had BPharm degree as their highest qualification. More than half of the community pharmacists (57.9%) had more than 7 years of overall experience with 40% having 4-7 years of practice experience in Saudi Arabia. More than two thirds of the respondents (88%) were stocking generic medicines. Sixty seven (55.4%) of the participants were dispensing 10-30 prescriptions per day [Table 1].

#### **3.2. Total knowledge score of participants about generic substitutions**

Only 76 (63.3%) correctly believed that pharmacists are allowed to carry out generic substitution without consulting the physician. The vast majority of the pharmacists 109 (90.1%) and 113 (93.4%) correctly identified that generic medicines should be in the same dosage form and same dose as of branded counterpart. More than two thirds of the participants (79.3%) were aware that generic medicines are bioequivalent to the branded medicines. [Table 2]. No statistical significant difference was found in total knowledge score across different age groups ( $P = 0.75$ ), job descriptions ( $P = 0.92$ ), country of graduation ( $P = 0.51$ ), terminal degree ( $P = 0.27$ ), number of years in practice (overall) ( $P = 0.81$ ) and number of years in practice in Saudi Arabia ( $P = 0.77$ ) [Table 3]

### **3.3. Participants' beliefs about generic substitutions**

About two-thirds of the respondents (83; 68.5%) of the participants supported (agreed or strongly agreed) generic substitution and believed that it is a good practice and will improve patient's quality of life. A vast majority of the respondents (92; 76.1%) believed that patients should be given enough information about generic medicines in order to ensure they really understand about the medicines that they take. Seventy-three (60.3%) highlighted the need for more information on the issues pertaining to the safety and efficacy of generic medicines. [Table 4]

Both country of graduation ( $P = 0.01$ ) and experience of practicing in Saudi Arabia (0.02) were associated with respondents' support towards generic substitution. There was also significant association between respondents' current position (e.g. manager, staff pharmacist) and their belief about the influence of pharmaceutical companies-led advertisement and their future dispensing pattern (0.02) [Table 4]. No association was reported between the participants' demographics and their total knowledge score.

### **3.5. Current generic substitution practices**

More than two thirds of the respondents (79%) reported to have 'occasionally' dispensed generic medicines while 6% stated that had never dispensed generic medications in their practice. Some of the most common generic substitutions made were for antibiotics (40%) followed by analgesics (37%) and antihypertensive medicines (8%).

More than half (51%) of the respondents did not consult the physician before performing generic substitution. Some of the reasons for not contacting prescribers included; did not consider it necessary to contact (18%) and did not had the time to contact (16%) [Table 5].

Quality of the generic medicines (65%) and cost-saving (65%) were the two most important pieces of information provided to patients [Table 4]. The top two reasons for recommending generic medicines to patients included: medicine cost (67%) and patient's demand (58%) [Table 5].

#### **4.0 Discussion**

This was the first study to evaluate Saudi community pharmacists' knowledge, perceptions and opinions towards generic medicines, generic substitution and their current substitution practices. The findings of this study has highlighted knowledge gaps towards generic medicines among community pharmacists in Makkah region did not seem to possess sufficient knowledge about generic substitution that necessitates the need of creating more awareness about generic medicines and importance of generic substitution. The role of community pharmacist in Saudi healthcare setting in implementing generic medicines substitution policy remains very important as prescription only medicines including antibiotics are frequently sold without prescription [22]. Although illegal, selling prescription only medicines without prescription is a common practice among community pharmacists [22]. Therefore, by performing generic substitution, community pharmacists can significantly reduce medicines cost especially out-of-pocket expenditure on pharmaceuticals.

Over half of the participants (55%) of this study agreed that generic substitution is a good practice to implement. These findings are in line with the findings of a previous study conducted in Malaysia [19] where the authors reported that more than 80% of the study population were in favour of generic substitution. The relatively lower rate of support towards generic substitution reported by participants in this study indicates that generic substitution is still a new concept in this region. Furthermore, this study

also suggested a potentially significant association between the participants' country of graduation and their support towards generic substitution. This is evident from the fact that participants who graduated from Egypt were more aware of generic substitution due to the adoption of generic substitution policy in Egyptian healthcare system as opposed to their counterparts [23].

Majority of the participants (62%) believed that advertisements by the drug companies will influence their future dispensing pattern. Similar findings have also been reported by community pharmacists in Malaysia [19]. More than half of the participants of this study stated that they would not consult the prescribers at the time of performing generic substitution. One of the main factors that can help to improve generic medicines use is to promote their acceptability not only among patients but also prescribers [24]. Pharmacists being the expert of medicines can play an important role in promoting the utilization of generic medicines. Evidence from a previous study suggests that community pharmacists can help to increase the uptake of generic medicines by general prescribers [25]. In Europe, many countries encourage prescribers and pharmacists to engage in pharmaco-therapeutic discussions with the aim of improving the prescribing of generic medicines [26].

Besides engaging with the prescribers, detailed and relevant advice provided by pharmacists about generic medicines can help in gaining the confidence of patients about the consumption of generic medicines [27]. Participants of this study were asked about what type of information they would consider important to provide to patients when making generic substitution. In line with the findings of a previous study [16], reassurance about the quality of the generic medicines and potential cost-saving were the two most common pieces of information provided to patients by community pharmacist before performing generic substitution. Lower cost of generic medicines

was the main reason cited by pharmacists to recommend generic medicines to patients. A previous study conducted in Saudi Arabia [16] also reported lack of awareness or knowledge about generic medicines among consumers and their negative perceptions towards generic substitution. It is important to mention here that more than half of the pharmacists participating in this study also did not seem to be too convinced with the effectiveness of generic medicines in comparison with branded medicines. This lack of perceived awareness on part of pharmacists coupled with their poor overall knowledge score about generic medicines signifies the need to raise more awareness among both consumers and pharmacists required for the successful implementation of generic substitution policy in Saudi Arabia. One of the means to improve awareness about safety and quality of generic medicines and promote generic substitution can be inclusion of generic medicines topic in pharmacist registration examination, a mandatory examination for expatriate pharmacists to obtain licence to practice in Saudi Arabia. Since community pharmacies are predominantly managed by foreign trained pharmacists, including generic medicines in the registration test curriculum will help pharmacists to familiarise themselves with local policies and laws pertaining to generic medicines substitution. Similarly, in order to equip Saudi pharmacists with necessary knowledge and skills to carry out generic substitution, it has been proposed to include topics related to generic medicines substitution including governing policies, procedures for generic drug registration with SFDA, concept of bioequivalence and safety, efficacy and quality of generic medicines should be included in undergraduate pharmacy curriculum [28]. This is particularly important because pharmacy students' perceptions about effectiveness, safety, and economic value can influence their recommendation of either generic medicines or brand medicines in future practice [29].

This study had some limitations. One of these limitations was the issue of non-participation bias as the authors were unable to find any official list of community pharmacies in Makkah region. However, a 4-step systematic sampling approach was used to recruit community pharmacists to avoid non-participation bias. Another limitation of this study was the gender bias as only male pharmacists participated in the study. All participants of this study were male and majority of them expatriates (non-Saudis). Saudi pharmacists and females tend to work in hospital settings because of better salary structure and career progression. Since females do not work in community settings therefore non-exclusion is unlikely to affect study findings.

## **5.0 Conclusion**

The community pharmacists in Makkah region did not seem to possess sufficient knowledge about generic medicines substitution. These findings emphasize the role of Saudi Ministry of Health (MOH) and Saudi Food and Drug Authority (SFDA) in raising awareness about generic medicines among public in general and community pharmacists in particular in order to successfully implement the policy of generic substitution in Saudi Arabia. Given the high expenditure on pharmaceuticals both by the Saudi government and out-of-pocket, implementation of generic substitution policy can be an effective cost containment strategy to support Saudi economy, severely affected by low oil prices. Future work is required to assess the cost-effectiveness of generic substitution in Saudi Arabia.

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