

# Evaluation of knowledge and perception of students studying health related courses in Saudi universities regarding generic medicines and generic substitution: A cross-sectional study

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## Abstract

**Objectives:** To evaluate knowledge and perceptions of students studying healthcare related courses at Saudi universities about generic medicines and generic substitution in Saudi Arabia.

**Methods:** A cross-sectional study using a validated and pilot-tested 19-item questionnaire was conducted between January and March 2017. Senior undergraduate students studying medicine, dentistry or pharmacy were eligible for participation.

**Results:** Two hundred and fifty-two students completed the questionnaire. Of these 252, 138 were male and 114 were female. Overall, students had poor knowledge with no statistically significant differences across study discipline or year of study. Over half (54%) of the participants correctly responded that generic medicines are bioequivalent to the brand-name medicines. Merely, less than half (43%) correctly stated that both brand-name medicines and generic medicines should have the same dose.

**Conclusion:** Healthcare students had poor knowledge about generic medicines and generic substitution suggesting a need to improve content and delivery of topics related to these areas in the curricula to ensure better understanding among future practitioners about generic medicine and generic substitution.

**Keywords:** *Generic Medicines, Generic Substitution, Knowledge, Perceptions, Saudi Arabia*

## Introduction

The World Health Organisation (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” (WHO, 2012). Generic substitution is referred to the replacement of a prescribed branded drug with an alternative that contains the same active ingredient (Posner & Griffin, 2011). It is expected that the universal expenditure on medicines will reach nearly \$1.5 trillion in 2021 with annual growth of 4-7%

(Quintiles IMS Institute, 2016). This huge expenditure on medications alone imposes a significant cost burden on healthcare systems globally. Generic medicines by virtue of their affordable and competitive prices can lessen the financial burden on healthcare systems (Kirking *et al.*, 2001; Haas *et al.*, 2005), encouraging healthcare authorities worldwide to adopt a policy of generic medicine substitution (Suh, 1999; Haas *et al.*, 2005; Kjoenniksen *et al.*, 2006). For example, in the year 2010 alone, the use of FDA-approved generics saved US\$158 billion, an average of US\$3 billion every week (General Pharmaceutical Association, 2011).

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Saudi Arabia with a population of 27.4 million has witnessed substantial growth in the use of prescription medicines in the recent years. It has been estimated that the total expenditure on medicines exceeded by 1.6 billion US dollars in the year 2006 contributes to 10% of the total healthcare cost in Saudi Arabia (Alghasham, 2009). It is further expected that the prescription medicines market will reach 11.5% by 2020 (Business Monitor International, 2013). The escalation in the prescription medicines market in Saudi Arabia can be attributed to several reasons such as the increased prevalence of chronic medical conditions including diabetes mellitus, hypertension (Al-Qurashi *et al.*, 2008; Al-Turki, 20011) as well as growth in population. It is expected that the Saudi population will reach 39.8 million by 2025 and 54.7 million by 2050 (Al-Malki *et al.*, 2011). Given the fact that both Saudi and expatriates working in the public sector are entitled to a free of charge healthcare service (Bawazir *et al.*, 2013), the provision of a sustained and affordable healthcare service to a growing population is becoming a challenge for Saudi health authorities.

Although generic medicine prescribing has gained importance in the recent past, there are still some concerns regarding the bioequivalence, quality, and safety of generic medicines among healthcare professionals including prescribers and pharmacists (Brand *et al.*, 1995; Birkett, 2003). Some of these concerns may be attributed to lack of awareness and understanding about generic medicines (Hassali *et al.*, 2008). For example, a study conducted in Saudi Arabia suggested that a lack of prescribers' knowledge about generic medicines was found to be an independent predictor of a lower prescribing rate of generic medicines (Salhia *et al.*, 2015). Similarly, another study reported community pharmacists' concerns about the quality of generic medicines in Saudi Arabia (Al-Badr & Khan, 2015). However, to the authors' knowledge, no study has been conducted in Saudi Arabia that has assessed the knowledge and attitude of healthcare students towards generic medicines and generic medicines' substitution. Furthermore, it is imperative to gain an insight into the knowledge and perceptions of senior healthcare students about generic medicines as it may influence their future prescribing or dispensing practices. This study, therefore, aims to evaluate senior healthcare undergraduate students' knowledge, perceptions and opinions towards generic medicines and generic substitution in Saudi Arabia. A second objective was to assess association between various demographic characteristics and total knowledge score.

## Methods

A cross-sectional study using a structured 19-item online questionnaire was conducted in Saudi Arabia between January and March 2017. Ethical approval was obtained from the ethics committee of the Umm-al-qura University Saudi Arabia (UQU-COP-EA# 143629). All

information collected from this study was kept strictly confidential. Consent for participation was understood by completion and submission of the survey.

## Sampling

A universal sampling approach was adopted. Undergraduate students studying medicine, dentistry or pharmacy enrolled at a major government or private institution across the Kingdom of Saudi Arabia (Kingdom) were approached and recruited through social networking websites (Facebook, Twitter, and WhatsApp). Students were eligible to participate if they were in Year 4, 5 or 6 of their undergraduate programme enrolled in any one of the five participating universities/higher education institutes. The password protected survey links were posted on participating schools/faculties official social media pages. Participants completed the survey electronically on a voluntary basis. An introductory paragraph outlining the aims and objectives of the study as well as instructions to complete the questionnaire were posted alongside the survey. The limitations of using social media for recruitment are discussed below.

## Questionnaire development and administration

A 19-item structured questionnaire was developed using the style and format of a questionnaire used in a previous study conducted in Saudi Arabia (Alkhuzae *et al.*, 2016). The questionnaire was designed to evaluate students' understanding and perception towards generic medicines and generic substitution, and an assessment of their future training needs (see Appendix A). Although Arabic is the national language of Saudi Arabia, the questionnaire was developed in the English language as it is the official medium of instruction at all healthcare colleges across the Kingdom. The questionnaire was piloted among a small number of undergraduate students (n=5). The face and validity of the questionnaire was undertaken by an experienced academic and five senior pharmacy students. The 19-item questionnaire consisted of four sections. Section one (five-items) collected demographic data including age, gender, year of study and name of the institution along with study discipline. Section two included eight items and was designed to evaluate students' in-depth knowledge about generic medicines' substitution. The knowledge questions were designed based on a 5-point Likert-scale format (1=strongly agree, 2=agree, 3=neutral, 4=disagree and 5=strongly disagree). Positive statements were scored on a scale of 5 to 1 with 'strongly agree' responses scoring '5' and 'strongly disagree' responses scoring '1'. Similarly, negative statements were scored on a scale 1 to 5 with 'strongly disagree' responses carrying a maximum score of '5'. The maximum obtainable knowledge score was 40. Section three comprised of four items and was aimed to gather students' perception towards generic medicines' substitution. Section four comprised of two items and was aimed to evaluate students' experience of generic substitution practices, if any. The questionnaire was developed and distributed using Google Forms.

**Data Analysis**

Data were analysed using SPSS version 20. Descriptive statistics, frequencies and percentages were used to summarise data. Ordinal linear regression was used to determine association between various sociodemographic characteristics and total knowledge score. For all statistical tests,  $p < 0.05$  was considered statistically significant.

**Results**

Two hundred and fifty-two participants completed the questionnaire (approximate response rate around 50%; assuming a total of 500 students were enrolled in participating institutes and were social media user). Of these 252, 138 were male and 114 were female. More than half (55%) of the participants were 23-24 years old. Majority (81%) of the participants were studying in public universities (see Table I for demographics of participants).

**Table I: Participants demographics**

Variables	Frequency (%)
<u>Age</u>	
18-20	17 (6.7)
21-22	90 (35.7)
23-24	139 (55.1)
>25	2 (0.8)
<u>Gender</u>	
Male	138 (54.7)
Female	114 (45.2)
<u>Type of institution</u>	
Public	204 (80.9)
Private	48 (19.0)
<u>Study discipline</u>	
Pharmacy	112 (44.4)
Medicine	76 (30.1)
Dentistry	64 (25.3)
<u>Study year</u>	
4	76 (30.1)
5	105 (41.6)
6	71 (28.1)

In general, overall, students had a poor knowledge about generic medicines and generic substitution. There was no significant difference in the total knowledge score across

different genders, type of institution, study discipline and year of study (Table II). The ordinal regression analysis did not report any association between age of participants ( $p=0.24$ ), gender ( $p=0.06$ ), study discipline ( $p=0.83$ ) and year of study ( $p=0.13$ ) and their total knowledge score. Just over half (54%) of the participants correctly responded that generic medicine are bioequivalent to the brand name medicines, while less than half (43%) correctly stated that both brand name medicines and generic medicines should have the same dose (Table III).

**Participants' opinions and perceptions towards generic medicine substitution**

Over half (56%) of the participants agreed that generic substitution is an efficient and good practice that should be promoted to improve patients' quality of life. A further, (59%) of the participants believed that adequate information about generic medicines should be provided to patients to help them improve their understanding about generic medicines thus helping them in making better informed choices about their medicines. Similarly, around half (53%) of the participants suggested that their future prescribing or dispensing practices would be influenced by the advertisements of pharmaceutical companies. Finally, 34% of the participants considered new prescription items as the most appropriate substitution for generic medicines followed by 23% for refill prescription items and 20% for non-prescription items.

**Table II: Total knowledge score of participants about generic medicines and generic substitution**

Demographic characteristics	Total knowledge score Mean (SD)
<u>Gender</u>	
Male	20.91 (3.8)
Female	21.12 (3.9)
<u>Type of institution</u>	
Public	21.19 (3.8)
Private	20.96 (3.8)
<u>Study discipline</u>	
Pharmacy	20.74 (3.5)
Medicine	21.14 (4.2)
Dentistry	21.33 (4.1)
<u>Study year</u>	
4	19.77 (2.7)
5	20.56 (4.3)
6	18.66 (4.7)

**Table III: Percentage of participants with correct responses about generic medicines**

Question	Correct responses N (%)
<i>Generic medicines are bioequivalent to brand name medicines</i>	137 (54%)
<i>Generic medicines should have the same dosage form as brand name medicines</i>	126 (50%)
<i>Both brand name medicines and generic medicines should have the same dose</i>	119 (43%)
<i>Generic medicines are as effective as brand name medicines</i>	102 (40%)
<i>Generic medicines are as safe as brand name medicines</i>	104 (41%)
<i>Generic medicines should meet the same safety standards as brand name medicines</i>	88 (34%)
<i>Generically substituted medicines can be administered in any route</i>	94 (37%)
<i>Any brand name medicine can be switched to a generic medicine</i>	47 (18%)

### ***Experience of participants about generic substitution practice***

Just over half, (54%) of the participants reported to have witnessed a healthcare professional making a generic medicine substitution during their clerkship period (undergraduate training). Of these 54% participants, 42% participants identified patient request or patient satisfaction as the reason for making a generic medicine substitution. Availability of the generic medicine (22%); quality (21%) and cost (14%) were some of the other reasons reported by participants for making the generic medicine substitution.

### **Discussion**

This is the first study that has evaluated the knowledge, perception and opinion of senior students studying healthcare related courses in various Saudi universities towards generic medicines and generic substitution. The study has identified huge knowledge gaps among healthcare students about generic medicines and generic substitution. The students across all study disciplines including pharmacy, medicine and dentistry did not seem to have adequate knowledge about generic medicines and generic substitution that suggests the need to update the current educational curricula across all healthcare programmes to include content related to generic medicines and the importance of generic substitution

Just over half (54%) of the included participants correctly agreed that generic medicines are bioequivalent to the brand name medicines. While it can be expected that the topic of bioequivalence is covered in pharmaceuticals modules taught to the undergraduate pharmacy students (Nandita & Sudip, 2001), it is less likely that medical and dentistry students are introduced to this topic. However, the expected variations in the undergraduate curricula did not seem to reflect in the responses of the students included in this study with no significant differences reported in their total knowledge scores. The lack of exposure of medicine and dentistry students to the topic of bioequivalence signifies the need to integrate this topic into their respective curricula. Furthermore, given the complexity of this topic, these authors recognise that there is also a need to simplify some of the concepts of bioequivalence taught to pharmacy students to improve their understanding about the bioequivalence of generic medicines with brand name medicines.

More than half (60%) of the participants of this study expressed their concerns about the quality and safety of generic medicines when compared to brand name medicines. Such concerns about quality and safety of generic medicines have also been previously expressed by qualified healthcare professionals including prescribers and pharmacists (Brand *et al.*, 1995; Birkett, 2003; Al-Badr & Khan, 2015). The lack of perceived awareness on the part of participants coupled with their negative perceptions about the quality and safety of generic medicines suggests the need to educate future prescribers in order to improve their acceptability of generic medicines. The significance of providing explicit education to healthcare students has also been supported by the Saudi Food and Drug Authority (SFDA) that has proposed the inclusion of generic medicine-specific topics including bioequivalence, quality and safety into the undergraduate pharmacy curriculum (Al-Rasheedi *et al.*, 2014). Improvement in the knowledge and perceptions of pharmacy students would positively influence their future behaviours with regards to their recommendation of generic medicines (Holmes & Dennison, 1992). An educational intervention consisting of an interactive lecture, a booklet and a drug list has been shown to improve doctors' knowledge about bioequivalence and safety of generic medicines but failed to improve generic medicines' prescribing, in a study conducted in Malaysia (Hassali *et al.*, 2014). Future work is required to assess the impact of an educational intervention on the knowledge of healthcare students about generic medicines and generic substitution.

With regards to the participants' opinions towards generic substitution, more than half (56%) of the participants believed that generic substitution is an efficient and good practice that should be promoted to improve patients' quality of life. However, the support rate of participants towards generic substitution reported in this study is lower in comparison to a previous study where more than 80% of the participants expressed their support towards generic substitution (Chong *et al.*, 2010). Considering the rising cost of pharmaceutical

expenditures in Saudi Arabia, the Saudi health authorities can successfully implement the policy of generic substitution by further building on the positive perceptions of healthcare professionals about generic substitution.

This study has some limitations. Firstly, no power calculations were undertaken prior to the commencement of this study. However, it may be argued that this study was a descriptive study with no hypothesis testing. Secondly, in this study, participants were recruited on their willingness and ability to engage with social media. Students who had not engaged with the schools'/faculties' social media pages were automatically excluded. Finally, all questionnaire-based surveys are subject to recall bias.

### Conclusion

Overall, healthcare students across all study disciplines had poor knowledge about generic medicines and generic substitution. The Saudi ministry of education together with SFDA should take the required steps to update the curricula to ensure better understanding for future practitioners about the use of generic medicine and generic substitution.

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**Appendix A**

**Umm Al – Qura University**  
**Faculty of Pharmacy**  
**1438-2017**

**Thank you for taking time to complete this questionnaire.**

**As a group of 5th year Pharm D students, we are conducting a research project as a part of our Pharm D degree under the supervision of Dr Ejaz Cheema (MPharm, PhD, UK) Assistant professor of clinical pharmacy – faculty of pharmacy , Umm Al-Qura university .**

**The aim of this study is to evaluate senior healthcare undergraduate students’ knowledge, perceptions and opinions towards generic medicines and generic substitution in Saudi Arabia.**

**Ethics approval has been obtained from college of pharmacy – Ethics Approval Committee.**

**All your response will be kept anonymized confidential. Data will only be used for research purposes.**

**Please provide your answers based on your current knowledge only.**

**This questionnaire has FOUR sections. Please complete all questions. For each question, please click only one box for your answer. The questionnaire will only take 5-7 minutes to complete.**

Section 1: Demographics of the student:

Age :  
 18-20     21-22     23-25

2- Gender:  
 Male     Female

3- Place of study:  
 Makkah     Jeddah     Riyadh     Other

4- Name of College: College of pharmacy umm-al qura university, college of medicine umm

5- Study year:  
     4     5     6

Section 2 : Knowledge about generic substitution :

1- A generic medicine is bioequivalent to a brand name medicine:  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

2- A generic medicine must be in the same dosage form (e.g. tablet, capsule) as the brand name medicine :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

3-A generic medicine must contain the same dose as the brand name medicine :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

4- Generic medicines are less effective as compared to brand name medicines :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

5- Generic medicines cause more side effects compared to brand name medicines :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

6- Brand name medicines are required to meet higher safety standards than generic medicines :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

7- Generically substituted medicines can be administered in any route :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

8- Any brand name medicine can be switched to generic medicine :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

Section 3: Opinions on Generic substitution

1- Generic substitution is an efficient and good practice that will improve patient's quality of life and I support it :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

2- I think patients should be given enough information about generic medicines in order to make sure they really understand about the medicines they take :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

3- I believe advertisement by the drug companies will influence my future dispensing/ prescribing/ administering pattern :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

4- Most suitable substitution in your opinion :  
 New prescription only     Refill prescriptions only     Any prescription     non – prescription items

5- More information on the issues pertaining to the safety and efficacy of generic medicines should be added to our curriculum :  
 Strongly agree     Agree     Neutral     Disagree     Strongly disagree

Section 4: Experience about generic medicine substitution :

1. Did you witness a healthcare professional making a generic substitution in a hospital/pharmacy/ medical Centre during your summer training or placement?  
 Yes     No

2. If yes, what was the reason for making the generic medicine substitution? (Rank them from 1 to 5 with 1 being the most significant and 5 being the least significant)

Patient request     Availability of generic medicine

Quality of the generic medicine     Patient's satisfaction

Cost saving

Profit margin and incentives from the manufactures

Brand name medicine was not available