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## **Abstract**

**Aim:** The main objective of this study was to explore community pharmacists' knowledge on substandard and falsified medicines (SFs).

**Method:** A descriptive cross-sectional study was conducted with community pharmacists in the Kingdom of Saudi Arabia using a pre-validated electronic survey.

**Results:** Ninety-two community pharmacists participated in this study. Many of the respondents (68.5%) had no experience with identifying SFs. We identified a concerning trend of under-reporting SFs ( $p < 0.003$ ). Respondents reported that SFs constitutes 1-5% of medicines, with weight loss medicines being the most targeted for falsification. Most of the respondents had a low level of awareness about the newly implemented anti-counterfeit system in Saudi Arabia called the "Drug Track and Trace System" (28.3% not really, 23.1% not at all). Respondents showed low levels of knowledge about technologies available to detect SFs ( $p < 0.01$ ).

**Conclusion:** Community pharmacists' self-reported awareness and knowledge of SFs in Saudi Arabia was inadequate; this deficiency may affect their ability to protect their patients from potential harm by combating SFs. As a regulatory body responsible for issues related to SFs, the Saudi Food and Drug Authority should develop an action plan to equip community pharmacists with training in SFs to enhance their ability to respond to SFs.

**Keywords:** Counterfeit drugs, falsified medicines, substandard medicines, community pharmacists.

## Introduction

The use of substandard and falsified medicines (SFs) is an old practice that has threatened the pharmaceutical industry for many years. (1) Beyond the negative impact of SF medicines in endangering patient health, SFs also threaten the healthcare sector as a whole. (2) The term ‘Falsified’ has been identified by World Health Organization as ‘those that are deliberately and fraudulently mislabelled with respect to source and/or identity. They can apply to both branded and generic products and they may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of ingredient(s) or with fake packaging’. (3) The term ‘substandard medicine’, on the other hand, refers to any authorized drug that does not meet specific criteria, such as the requirements imposed by the European or US pharmacopeia and the manufacturers’ dossier. (4) However, the exact definition of falsified medicine has been under debate.

Past research has indicated that the prevalence of SFs has increased globally, not only in low- to middle income countries but also in high income nations with strong regulations and laws. (5) The precise global scope of the trade is difficult to estimate due to the stakeholders (e.g., pharmaceutical industry, insurance providers, regulators) which are often reluctant to be transparent about the magnitude of the problem due to the political and social sensitivity of the issue. (1) Yet the WHO has estimated that in developed countries, 10 to 15% of medicines are falsified, while in low- to middle income countries, such as Africa and parts of Asia, this number is 50%. (5, 6) A study conducted in 2005 in Saudi Arabia revealed that the percentage availability of SFs was approximately 34%, which increased to 49% a year later during the al Hajj (Al hajj means in Islam where pilgrims travel from several Islamic countries to the holy city of Mecca in Saudi Arabia to perform Hajj, which is the fifth of fundamental Muslim practice called Five Pillars of Islam). (7) The same study (n=2940 unique samples across two years) pointed that this increase was likely caused by the high number of people traveling from different parts of the world to Saudi Arabia to perform Hajj. Cross-border travel may increase the prevalence of SFs within the Kingdom of Saudi Arabia due to differences in medication regulations in different countries such as India, Egypt, Pakistan and other Islamic countries. (7)

Since this study focused entirely on SFs, we will highlight the intervention that the Saudi Food and Drug Authority (SFDA) ‘an independent governmental medicines agency in Saudi Arabia that launched in 2003’ has implemented to combat SFs. (8) To illustrate this, in 2018 the SFDA established the Drug Track and Trace system, also called “RSD”, as an anti-counterfeit system. This new system was designed and implemented to ensure the safety of medicines. This is achieved by tracking and tracing each medicine as it progresses from the manufacturing process to patient delivery. By ensuring that medicines transfer is quality assured before reaching consumers, the medicines market in Saudi Arabia should be protected from penetration by counterfeiters or unregulated medicines. (9-11)

Community pharmacists, who form the front line of defence against the spread of SFs since they dispense prescriptions, play a valuable role in ensuring patient safety by limiting the prevalence SFs.

Thus, community pharmacists knowledge about SFs can significantly increase public awareness by promoting a broader understanding and harms. Several studies investigating community pharmacists' perceptions of SFs globally revealed a low level of knowledge, which was reported by most of the participants. (12-14) The main findings of these studies are that community pharmacists strongly believe they have a crucial role in combating the availability of SFs, however, they lack the required knowledge, which emphasises the importance for the need of a variety of education and training programs to be able to respond to any SFs. Nonetheless, to our knowledge, no similar body of work examining pharmacists' knowledge has been conducted in Saudi Arabia. Therefore, the aim of this study was to examine the knowledge and practices of a sample of community pharmacists on SFs among different regions in the Kingdom of Saudi Arabia.

## Methods:

The study design was a cross-sectional survey among pharmacists currently working in community settings in Saudi Arabia.

The foundation of the survey's content was obtained from a previous study which was published in the Journal of Pharmacy & Pharmacognosy Research and BMJ because these two studies validate the same survey instrument in different sample sizes across time using statistical techniques. (12, 15) These were adapted for Saudi Arabia in collaboration with the original author of the survey. The survey consisted of 18 questions divided into demographics, questions to examine the level of knowledge, and questions to evaluate participants' awareness of the Saudi vigilance service, technologies, and training program to combat SFs. In Saudi Arabia, Arabic is the national language, however, pharmacy education is exclusively delivered and assessed in English, this means all pharmacists are competent in English. To ensure the face validity of the survey for the Arab pharmacist audience where English is a second language, two external community pharmacists in Saudi Arabia examined and approved the entire content of the survey. The final survey is available for free and wide use in Supplement 1, with appropriate reference to this paper.

The study was conducted throughout all regions of Saudi Arabia with pharmacists registered in the Saudi Commission for Health Specialties working at different community pharmacies and retail settings, were invited to participate in this study. Registered pharmacists working in other industries such as hospitals, research institutions, and academia were excluded from the study. The general public, including patients, other healthcare workers, and individuals under age 18 were not involved in this study. Participants were recruited through several methods; one method utilised was snowballing or chain referral sampling, in which all pharmacists employed by Al-dawaa, and Alnahdi pharmacies, two of the biggest chain community pharmacies in Saudi Arabia, were emailed the survey by the marketing coordinator of the pharmacies and invited to participate in this study. The second method was through social media, in which the survey was distributed across different social media platforms targeting community pharmacists. To maintain the anonymity and confidentiality of participants, no personally identifiable data was required to participate. Thus, withdrawal was not possible, which participants were informed about in the participant information sheet (Supplement 2). Participants were recruited from June 2021 to July 2021.

Latest Ministry of Health figures for 2020 show that of the 27,529 registered pharmacists, 20,411 represented predominately community pharmacists working in the private sector, with 4,358 employed in Ministry of Health offices and 2,760 in Hospital. Sample's calculation was not appropriate for this preliminary study because no previous studies had been conducted in Saudi

Arabia on this topic. As a result, the study used convenience sampling. A post-hoc sample size calculation was done which demonstrates sample size of 80, means 80 or more measurements/surveys are needed to have a confidence level of 95% that the real value is within  $\pm 11\%$  of the surveyed participants (Confidence Level:95%, Margin of Error:11, Population Proportion:50, Population Size:27,529). This means that a sample survey response is above 80 would be consider representative of the whole pharmacists' population.

In this study, the quantitative data were analysed using the Statistical Package for the Social Sciences (SPSS) v.26. Descriptive statistics was also used to summarise the findings, hypothesis testing including use of binomial test or bernoulli trial which assess the statistical significance of dichotomous outcome e.g. heads or tails in a coin toss. (16, 17) For the qualitative data of the open-ended questions, thematic analysis was used, which involved categorizing the data into major and minor themes. (18) The number of missing data points are clearly identified e.g. if all but one respondent fail to answer question X, this noted in the result.

The study proposal was reviewed and ethically approved by the local bioethics committee of Aljouf University, Saudi Arabia on 5<sup>th</sup> April 2021 (Reference number: 08-07-42). Written informed consent was obtained from participants prior to completing the survey.

## Results

In total, 92 participants completed the survey and were included in the analysis. This response rate meets the sample size threshold of a minimum of 80 participants, making findings generalizable across the Kingdom of Saudi Arabia. The first two questions related to respondents gender and years of experience, which shows an approximately even male and female split, with nearly 77% of respondent having less than 5 years of registered experience, and 10% of respondents having more than 20+ years of experience as shown in Table (1).

### Identification and reporting of substandard and falsified medicines

Respondents were asked if they or their patients had ever identified SFs. Most of the respondents said no 63 (68.5%), and 29 (31.5%) said yes ( $p < 0.001$ , one-sample binomial test). Respondents who said yes were asked if they informed the Saudi Food and Drug Authority (SFDA) after identifying SFs; 49 (68.1%) said no, whereas 23 (31.9%) said yes ( $p < 0.003$ , one-sample binomial test). Reasons for not contacting the SFDA are summarized in Table 2.

### Drug Track and Trace System "RSD"

The level of knowledge about the recently implemented Drug Track and Trace (RSD- is the official acronym used by the Saudi Food and Drug Administration) program was investigated. A standard five-points Likert scale was used to assess readiness to implement the RSD and the options were as follows: Not at all, Not really, Undecided, Somewhat, Very much **Strongly Disagree, Disagree, Uncertain, Agree, Strongly Agree**. Findings of RSD readiness show: 26 (28.3%) indicated 'Not really', 22 (23.9%) said 'Somewhat', 21 (23.1%) said 'Not at all', 13 (14.1%) said 'Very much', and 6 (6.5%) were undecided. We next asked the pharmacists if they had adequate equipment to be able to operate the system, including computer terminals, scanners, compliance software, initial set-up costs, IT, both software and hardware, and ongoing operational costs. 20 (22%) said 'Not at all', 20 (21.7%) said 'Very much', 18 (19.6%) said 'Somewhat', 18 (18.5%) said 'Not really', and 12 (13%) were undecided.

## **General knowledge about substandard and falsified medicines**

First, when asked for their beliefs about the prevalence of SFs in the Kingdom of Saudi Arabia, 32 (34.8%) of respondents believed that the percentages of SFs to be between 1 and 5%, 24 (24.2%) said <1%, 20 (21.7%) said from 6 to 10%, 10 (10.9%) indicated 11-20%, and only 3 (3.3%) said >21%.

The participants were then asked what percentage of SFs they believed came from online sources; their responses are represented in Figure 1. Following this, participants were invited to identify the most common sources of SFs. Approximately half of respondents 46 (50.5%) said foreign registered Internet pharmacies, 28 (30.4%) said Saudi registered Internet pharmacies, 24 (26.1%) of respondents indicated it might be from the professional falsifier/illicit trade, and 9 (9.8%) said other (of which one said social media, while another participant commented, “Some pharmacies bring supplements from China, East Asia, or Egypt that contain medicines such as those used for weight gain or for sex” – Implying the use of anabolic steroids and erectile dysfunction medications.

Following this, participants were asked to indicate what type of SFs they believed to be commonly prevalent in Saudi Arabia. Weight loss medication was the most frequently indicated 50 (54.3%) of participants, followed by erectile dysfunction medication at 15 (16.3%), anti-cholesterol medicines at 10 (11%), other at 8 (8.7%), and cancer and heart medication at the lowest with 5, and 4 (5.4% and 4.3%), respectively. Of the participants who indicated other medicines; **nutraceuticals**, vitamins, antibiotics, food supplements, herbal medicines, and over-the-counter medicines were identified.

## **The ability to recognise substandard and falsified medicines**

What makes pharmacist suspect that a medicine is falsified or substandard was examined. As shown in Figure 2, 23 (25%) reported that a different product composition (e.g., ingredients including excipients) indicated as the first item in the list makes them suspicious, 18 (19.6%) answered a different source (e.g., a different manufacturer or country of origin), 17 (18.5%) reported different labelling, 15 (16.3%) said different packaging to original packaging, 10 (11%) said a different distribution route, and 9 (9.8%) said ‘other’. For the participants who indicated ‘other’ reasons, repeatedly explained that if the medicine did not work properly or did not produce the therapeutic effects as expected. After visual identification, participants were asked to indicate which national agency they would inform, see Figure 3. Fortunately, most respondents could correctly identify the SDFA.

## **Awareness of the Saudi vigilance service, technologies, and training program to combat substandard and falsified medicines**

Of the 92 individuals who completed the survey, just over half 48 (52.2%) reported that they had never used the Saudi vigilance service for reporting falsified medicines before; of these, the reason behind not using the service was explained as either having no knowledge and awareness about the service or not experiencing any incident that would require using the service. Approximately the same percentage 47 (51.6%) indicated ‘No’ when asked if they were aware of any technologies to detect falsified medicines. Regarding involvement in any training program for identifying falsified medicines, almost two thirds of the participants 58 (63.7%) said ‘No’, and 33 (36.3%) said ‘Yes’ (p<0.01, one-sample binomial test)

## **Pharmacists' role in minimizing the spread of substandard and falsified medicines**

Pharmacists were asked about their strategies in combating the availability of SFs. The results of this question were thematic analysed and represented in Table 2. The qualitative themes were developed from a raw data and were not pre-specified. The coding was independently done by two researchers. Emergent major themes included appropriately contacting the SFDA, no harm experience by patient after seeking guidance from pharmacists, no experience of harm from Covid-19 related online medicines use, increasing public awareness and education and the importance of pharmacovigilance reporting.

## **Discussion**

A total of 92 community pharmacists participated in this study. Mainly respondents had not identified SFs, and those who had did not always report to the SFDA. The study found that low numbers of respondents have sufficient knowledge about the Drug Track and Trace program of the Kingdom of Saudi Arabia. Most pharmacists believed that the percentage of falsified medicines were between 1-5%, predominately originating from foreign registered internet pharmacies. Weight loss and erectile dysfunction medication will likely to be most falsified. Different compositions and packaging alerted pharmacists of potential risk of SFs. Pharmacists have an important role in combating SFs.

In this study, only 14% of the respondents were aware of the recently launched Drug Track and Trace program of the Kingdom of Saudi Arabia. This high percentage of pharmacists with insufficient knowledge of the drug tracking system is concerning since pharmacies are a critical element of the system that connects manufacturers, public and private hospital, and warehouses in securing the supply chain and ultimately reducing the spread of SFs. (11). This finding indicates the urgent need to raise awareness and educate pharmacists to thwart the spread of SFs.

Most of respondents of the current study estimated that SFs from online sources constitute 21 to 40% of medicines, which is consistent with surveys conducted by WHO indicating that the sale of pharmaceutical medicines over the internet has increased significantly. (19) A possible explanation for this increase might be the affordability of buying medicines from online websites; in addition, the frequent advertisement of medicines on social media might influence consumers. (20) Several researchers indicated that despite the benefits of purchasing medicines through online sources, the possibility of obtaining SFs from these sources is significantly high and can subsequently affect patient safety. (20-23) Furthermore, respondents believed that authorized foreign online pharmacies are the source for SFs ; although these pharmacies may operate legally, differences in the regulations and the laws against SFs in different countries mean that legal regulations are subverted from the perspective of individual pharmacist and affected patient. Weight-loss and erectile dysfunction medications were most commonly believed to be falsified, which is in line with findings from previous studies conducted in the UK and Egypt. (12, 14) In contrast, life-saving medications such as antibiotics and antimalaria are among the most frequently detected as SFs worldwide according to the WHO. (4)

The fact that over half of respondents had not used the only existing reporting system in the kingdom of Saudi Arabia for detecting SFs is worrying especially, giving 31.5% who detected SFs, did not report them. This under-reporting might obfuscate the magnitude of problem , preventing the problem from being recognised and solved. (24) Indeed, the WHO has stated that failure to report SFs will

prevent accurate records of the global size of the crisis, which prevents estimates of the prevalence of SFs globally. (19)

Pharmacists strongly agreed on the importance of their role in minimizing public harm, as they can quickly investigate and detect the presence of SFs. Several studies have shown that detecting SFs can be potentially done through reporting of incidents, raising awareness, communicating with patients, being vigilant and well trained. (24-26)

As the use of SFs continues to spread globally and endanger both the health systems and patients' lives, it is critical to understand pharmacists' knowledge of SFs since pharmacists can help identify and reduce their prevalence.

### Strengths

This novel 'first of its kind' study in the Kingdom of Saudi Arabia, is the first comprehensive research study to assess pharmacists' knowledge and **practice** on SFs and how they directly impact patient safety. This study captures evidence of change in practice in response to governmental policy. This study could form the basis for future governmental policy changes.

### Limitations

The main weakness of this study was the paucity of respondents with a long work tenure; as a result, the findings of this study were based mainly on young pharmacists with approximately 5 years of practice experience, which might affect the generalisability of the study. Seventy-seven percent of the respondents in this study had between 0 and 5 years of work experience (mostly young pharmacists); this number is relatively low but may be explained by the government decision in 2019 to increase the number of Saudi community pharmacists by 30% to increase employment rates. (27) Thus, the number of foreign community pharmacists (not Saudi national) with a higher degree of experience working in Saudi Arabia has been gradually decreased as a result of the decision. To illustrate this, according to the annual report from the Ministry of Health, the percentage of Saudi pharmacists in 2018 working in community pharmacies and the private sector was 6.4%; this number dramatically increased to 16% in 2020 after the implementation of the decision. (28) The results of this study demonstrate the governmental policy change has translated into the demographics skew we observed in this study. An additional limitation was that the survey language was limited to English, which participants might respond differently to if there were an Arabic version of the survey. Future studies could consider involving community pharmacy customers or patients in understanding their knowledge and practices of SFs, especially during Hajj. Larger studies should be conducted using this survey and a new adapted version in the Arabic language should be piloted. Qualitative interviews and focus groups should be also conducted to gauge the depth of understanding and truthfulness of responses.

### Conclusion

This study found that pharmacists have a fair level of knowledge regarding SFs. Surprisingly, pharmacists were not completely aware of the availability of important systems developed by the SFDA to combat SFs i.e. the Drug Track and Trace System. Lacking adequate knowledge will ultimately affect the ability of pharmacists to identify and report SFs, potentially endangering the safety of patients. Therefore, it is clear that while the SFDA has ensured that most pharmacists know about the agency and its mission, they have not equipped pharmacists with sufficient training to be able to respond to issues involving SFs.



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