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## **Perspective of Saudi undergraduate pharmacy students on pharmacovigilance and adverse drug reaction reporting: A National Survey**

### **ABSTRACT**

**Objective:** To evaluate Saudi undergraduate pharmacy students' knowledge, attitude and readiness towards pharmacovigilance and reporting of adverse drug reactions (ADRs).

**Methods:** A cross-sectional survey was conducted between January 15, 2016 and February 18, 2016 using a structured, validated and pilot-tested questionnaire among senior (year 4, 5 and 6) undergraduate pharmacy students enrolled at a governmental or private university/college. Students completed an online 27-item questionnaire developed using Google Forms™. The questionnaire consisted of four sections: demographics; knowledge about pharmacovigilance and ADR reporting; attitudes towards ADR reporting; and pharmacy students' readiness towards ADR reporting.

**Results:** Two hundred and fifty-nine students completed the questionnaire. Most of the participants were females (n = 174, 67.2%) and were year 4 (n = 128, 49.4%) students. Out of a total possible score of seven, the mean knowledge score (SD) was 4.15 (1.1). Multiple linear regression showed that after adjusting for gender and program of study (BPharm/PharmD), year of the study was found to be an independent predictor (P =0.03) of the total knowledge score. More than half of the respondents (n = 166, 64.1%) acknowledged that they do not know how to report ADRs to the relevant authorities in Saudi Arabia. The majority (n = 213, 82.2%) of respondents believed that information on how to report ADRs should be taught to senior pharmacy students.

**Conclusion:** This study highlighted wide knowledge gaps about pharmacovigilance and ADR reporting among senior pharmacy students. There is a clear need to put more emphasis on theoretical and experiential aspects of ADR reporting in pharmacy curriculum.

### **Keywords:**

Pharmacovigilance; Adverse drug reaction, Saudi Arabia; Pharmacy; Curriculum; Pharmacist

**Conflict of interest:** None declared

**Financial disclosure:** No funding was obtained from any governmental or private agency for this study.

### **Specific Contribution to Literature:**

This study further builds on existing evidence highlighting the issue of deficiencies in pharmacy undergraduate curriculum pertaining to pharmacovigilance and ADR reporting, especially in countries where patient-centered pharmacist role has not yet fully evolved. This is the first study that has assessed pharmacy students' knowledge, attitudes and readiness towards ADR reporting in Saudi Arabia. Our findings can partly explain poor ADR reporting practices by pharmacists reported by previously conducted studies in Saudi Arabia. In addition, this study has tested the feasibility of using web-based social media applications in recruiting participants for academic research. We have shown that recruitment through social media is possible, efficient and economical. We hope that future researchers will use this approach for recruitment especially in instances where participants are widely distributed geographically.

### **Introduction**

While medications are used globally to achieve desired therapeutic outcomes, they may also cause undesirable side effects.<sup>1</sup> An adverse drug reaction (ADR) is defined by the World Health Organization (WHO)<sup>2</sup> as "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function." ADRs are a common cause of morbidity and mortality in both hospital and community settings.<sup>1</sup> ADRs have been estimated to affect 2.2 million people worldwide and are responsible for a 100,000 deaths yearly.<sup>3</sup> Furthermore, the economic burden associated with ADRs has been estimated at 136 billion United States Dollars annually.<sup>1,4-6</sup> Studies have reported that 5- 20% of all hospital admissions are attributable to ADRs.<sup>5,7</sup>

Pharmacovigilance (PV) is defined as the "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem".<sup>8,9</sup> Prompt reporting of suspected ADRs is fundamental in the post-marketing surveillance of medicines and is considered to be the mainstay of pharmacovigilance.<sup>2</sup> A large proportion of ADRs can be prevented by improved drug prescribing, administration and through consistent and prompt recording and reporting.<sup>2</sup> The present study will focus only on the prevention of adverse effects component of pharmacovigilance.

Post marketing surveillance, initiated in the 1960s by the WHO after the 'thalidomide' crisis, is practiced by more than 70 countries worldwide for early detection and prevention of ADRs using the

spontaneous adverse drug reaction reporting system (SADRRS).<sup>1,10,11</sup> In March 2009, the Saudi Food and Drug Authority (SFDA) established National Pharmacovigilance Center (NPC) and launched its national pharmacovigilance program in order to prevent and detect ADRs at an early stage.<sup>12</sup>

Pharmacists, being drug experts, have a central role in ensuring safe and effective use of drugs by detecting and reporting ADRs.<sup>13-18</sup> In Malaysia, more than half of the total ADR reports received by their National Pharmacovigilance Center were submitted by pharmacists.<sup>19</sup> A number of studies conducted internationally as well as in Saudi Arabia have suggested a lack of awareness among both community and hospital pharmacists about ADR reporting systems and guidelines.<sup>20-24</sup> Lack of emphasis and training on pharmacovigilance and ADR reporting during undergraduate pharmacy degree may contribute to the lack of awareness and negative attitudes towards ADR reporting among hospital and community pharmacists documented in earlier studies. As future pharmacy practitioners, pharmacy students need to be well educated and trained on how to document, distinguish and report ADRs. Proper assessment must be made to determine whether pharmacy graduates are well educated and trained to report ADRs.<sup>26</sup> Internationally a number of studies have been conducted to evaluate pharmacy students' awareness about pharmacovigilance and ADR reporting.<sup>25-28</sup> However, no national study has been conducted in Saudi Arabia assessing pharmacy students' knowledge, attitudes and readiness towards ADR reporting. The present study was designed to evaluate Saudi pharmacy students' knowledge, attitude and readiness towards ADR reporting.

## **Methods**

A cross-sectional study was conducted in Saudi Arabia from January 15 to February 18, 2016 for a period of four weeks.

### **Ethical approval**

The ethical approval was obtained from the ethics committee at the College of Pharmacy, Umm-Al-Qura University. In addition, permission was also obtained from respective Facebook™, Twitter™ and WhatsApp™ page administrators before publishing the survey link on a particular page.

### **Questionnaire design**

The initial draft of the online questionnaire was developed based on the information obtained from an extensive literature search and review about ADR reporting among pharmacy students.<sup>25-28</sup> 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 pharmacy schools across the Kingdom. The face and content validity of the questionnaire was undertaken by two experienced pharmacy academics (one Assistant Professor and one Professor) and two senior pharmacy students. The questionnaire was then piloted on a sample of 10 pharmacy students. Based on students' feedback and discussion with experts, three questions were dropped and the final version consisted of 27-items that were divided into four sections. The first section consisted of 5 items about student demographics, such as age, gender, academic year, pharmacy program, and current university. The second section (10 questions) was designed to assess pharmacy students' knowledge towards pharmacovigilance and ADR reporting. For each question in this section, students were asked to choose yes, no or don't know options. A score of 1 was given for each correct answer and 0 for each wrong answer. The maximum possible score was 7 and the minimum was 0 as only 7 out of 10 questions were deemed suitable for scoring. The third section consisted of 5 items designed to evaluate the attitude of pharmacy students toward pharmacovigilance activities and ADR reporting. The questions were framed into a 5-point Likert-scale format (1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, and 5 = strongly disagree). In order to avoid affirmation or agreement bias, both positive and negative statement-based items were included within each section. The fourth section included 7 items and was designed to evaluate pharmacy students' readiness towards ADR reporting and coverage of these topics in their respective curricula. Like the previous section, a five-point Likert scale was used to elicit students' responses. The questionnaire was developed and distributed using Google Forms™.

#### Sampling and recruitment

Pharmacy students were approached and recruited through social networking websites (Facebook™, Twitter™, and WhatsApp™). Social networking websites were used for recruitment as they offer convenient, effective, economical, and fast method to recruit participants. The sampling frame consisted of all full-time senior undergraduate pharmacy (4, 5 and 6 year) students enrolled at a governmental or private university/college in Saudi Arabia in either BPharm or PharmD program. Both BPharm and PharmD are considered entry-level qualifications in Saudi Arabia. BPharm is typically a five year program and PharmD is a six year program. The final year of PharmD program involves clinical clerkship/training year for PharmD students. The questionnaire link was posted on 20 different social media pages which were identified

through an online search and using a snow balling technique (a type of non-probability sampling technique where existing subjects help researchers to identify new subjects).<sup>29</sup> The survey links were posted on colleges' official social media pages. If official social media pages could not be retrieved the links were posted on unofficial (run by student groups) social media pages. An invitation letter outlining the aims of the study was attached to the questionnaire. All information collected from this study was kept confidential. Consent for participation was implied by completion and submission of the survey. The survey link was reposted every week for four weeks during the study period on each of the social media pages.

#### Statistical analysis

Data were analyzed using SPSS version 18. Descriptive statistics, frequencies and percentages were used to summarize data. Since data were not normally distributed, the Mann-Whitney test or the Kruskal-Wallis test were used as appropriate, to compare total knowledge score across various respondent demographics. The Chi-square test was used to assess association between respondents' attitudes and demographic characteristics. Fisher's Exact test was used instead of the Chi-square test if 20% or more of the cells in the table had expected frequencies of less than 5. Multiple linear regression analysis was used to determine the predictors of good knowledge score.  $P < 0.05$  was considered statistically significant.

#### Results

A total of 259 students completed the study. The mean (SD) age of the students was 22 (1.6) years. Most of the students ( $n = 174$ , 67.2%) were female and year 4 students ( $n = 128$ , 49.4%). The vast majority ( $n = 217$ , 83.8%) of the students could not identify the correct definition of pharmacovigilance. However, more than two thirds ( $n = 179$ , 69.1%) of the students correctly identified the definition of an ADR. Only 59.1% of the students were aware that SFDA is the national organization responsible for collecting ADRs in Saudi Arabia. More than two thirds (81.5%) of the students incorrectly stated that it is necessary to establish the association between an ADR and suspected drug before reporting it (Table 1).

The total mean (SD) knowledge score for pharmacovigilance and ADR reporting was 4.15 (1.14). A statistically significant difference was found in the total mean knowledge score across year of study with year 6 students achieving a higher knowledge score compared to year 4 and 5 students ( $P = 0.02$ ). However, there was no significant difference in the total mean knowledge score by gender (male vs female) ( $P = 0.38$ ) and program of study (BPharm vs PharmD) ( $P = 0.79$ ) (Table 2). Multiple regression analysis

found that after adjusting for gender and program of study (BPharm/PharmD), year of the study was found to be an independent predictor ( $P = 0.03$ ) of total knowledge score.

More than two-thirds ( $n = 166, 64.1\%$ ) of the students either agreed or strongly agreed that they do not know how to report ADRs to the relevant authorities in Saudi Arabia. Consequently, the majority ( $n = 213, 82.2\%$ ) of the students either agreed or strongly agreed that information on how to report ADRs should be taught to senior pharmacy students (Table 3). Over two-thirds ( $n = 205, 79.1\%$ ) of the students either agreed or strongly agreed that the pharmacovigilance concept should be included as a core topic in pharmacy curriculum. Only one third of the students ( $33.9\%$ ) agreed or strongly agreed that they had received training on ADR reporting during their clinical clerkship. Less than half ( $44.4\%$ ) of the students stated that they are capable of reporting ADRs (Table 3).

The majority ( $87.3\%$ ) of the students believed that pharmacists are one of the most important healthcare professionals for reporting ADRs and  $69.4\%$  agreed or strongly agreed that ADR reporting should be made compulsory for pharmacists. Almost  $80\%$  of the students ( $n = 207$ ) expressed willingness to report ADRs in future practice (Table 4).

## **Discussion**

To the best of our knowledge, this is the first cross-sectional study that evaluated knowledge and attitude of undergraduate pharmacy students towards reporting of ADRs in Saudi Arabia. Our study builds on previous international studies highlighting the need to strengthen knowledge and skills related to ADR detection and reporting in pharmacy curriculum.<sup>25-28</sup> It highlights wide knowledge gaps about pharmacovigilance and ADR reporting among senior pharmacy students in Saudi Arabia. This calls for a thorough review of national pharmacy curriculum involving all stakeholders with an aim to improve knowledge and skills required to detect and report ADRs.

More than two-thirds of the students stated that they were unaware of the methods to report ADRs to relevant authorities in Saudi Arabia. These results indicate that, irrespective of the study program (BPharm or PharmD) and the university offering such programs, students seem to lack awareness about pharmacovigilance and reporting of ADRs. It was further evident by the fact that majority ( $73.7\%$ ) of the students confirmed they had never seen the official ADR reporting form. Similar findings have also been reported previously involving pharmacy students in Malaysia.<sup>25-26</sup> Well designed educational training

programs and workshops on pharmacovigilance may clarify and enhance the knowledge of both students and healthcare professionals about the requirements of ADR reporting.<sup>25,28,30</sup>

There were also some misconceptions on the type of ADRs that are required to be reported. The majority of students mistakenly believed that establishing association between ADR and the suspected drug is compulsory before reporting it. Additionally, more than two-thirds (86.1%) of the students believed that ADRs associated with herbal products should not be reported. These findings are consistent with those of similar reports about healthcare professionals.<sup>26,32,33</sup>

The majority (87.3%) of the students agreed or strongly agreed that the pharmacist is one of the most important healthcare professionals who report ADRs. These findings are consistent with the findings of other studies for healthcare professionals.<sup>27,35</sup> Importantly, majority (79.9%) of the students considered reporting ADRs as their moral obligation and expressed a positive attitude toward pharmacovigilance and the importance of reporting ADRs. Furthermore, there was a major consensus (79.1%) among the students that pharmacovigilance should be included as a core topic in the curriculum of pharmacy. These results reinforce the results of previous studies conducted internationally (outside Saudi Arabia) involving pharmacy students.<sup>26-28</sup>

The present study results emphasize the importance of providing explicit education and training on reporting ADRs to pharmacists at both undergraduate and professional levels. Previous studies aimed at investigating the extent of pharmacovigilance education provided to medical and pharmacy students suggested need for more time to be spent on pharmacovigilance education.<sup>35</sup> Research indicates that training is associated with an increased likelihood to ADR reporting.<sup>36,37</sup> A recent study in Denmark demonstrated positive impact of a community pharmacy internship program on improving clinical competencies of pharmacy students to identify and report ADRs.<sup>38</sup> Furthermore, pharmacists who receive specific educational training on ADR reporting are more likely to report ADRs.<sup>39</sup>

#### Limitations

There are some limitations to the findings of the present study. First, questionnaire based studies are subject to recall bias. Second, the low survey response rate from the students was unexpected. Although the authors are not aware of the total number of pharmacy students enrolled in governmental and private institutes, it can be safely assumed that the response rate was quite low. However, all efforts were made



to maximize the response rate such as the inclusion of all universities/colleges offering pharmacy program in the study and the use of 20 different social media pages to post the online questionnaire. Finally, the reliability of using social media applications for research purposes is not known. It is possible that some students might have responded more than once and/or sought external help in completing the questionnaire. Future research in this topic should explore the views of recent pharmacy graduates as well with the aim of identifying not only curriculum needs and gaps but also instruction methods to teach pharmacovigilance topic.

### **Conclusion**

The results of this national study highlight wide knowledge gaps among senior pharmacy students with regards to pharmacovigilance and ADR reporting in Saudi Arabia. The students perceived a clear need to review the current pharmacy curriculum with more emphasis should be laid on both theoretical and experiential aspects of ADR reporting. All graduating pharmacists should be able to identify and report ADRs in their future clinical practice, thus optimizing patient safety.

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