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Original Research Article

Knowledge and Perception of Pharmacovigilance and Adverse Drug Reactions Reporting among Healthcare Professional Students

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Abstract

This study aimed to assess knowledge and perception of pharmacovigilance in addition to identifying the plausible barriers for employing an effective ADRs reporting system from the perspective of healthcare students. A questionnaire-based survey was conducted among randomly selected students from five healthcare colleges. The overall knowledge score of 367 respondents was 5.1±2.1 (out of 10) that reflects substantial knowledge deficits in principles of pharmacovigilance and ADRs reporting. College of Pharmacy students and students in the third and fourth academic years demonstrated relatively significant higher knowledge scores (7.3±1.6, 5.5±2.1 and 6.2±2.1, respectively) compared to other students. On the other hand, 99.5% of respondents expressed a pronounced negative perception towards pharmacovigilance with an overall mean score of 22.0±3.9 (out of 50).Although, the vast majority of respondents had unanimously agreed on the importance of ADRs reporting, most of them felt unconfident, because they were either uncertain or unprepared to do so. The major recognized barriers for employing an effective ADRs reporting system were knowledge deficits and insufficient training received during academic and internship stages. In conclusion, this study revealed significant knowledge deficits and negative perception among most healthcare students owning to the lack of awareness and deficiencies in the colleges' program curricula.

Keywords: Knowledge, Perception, Pharmacovigilance, Adverse Drug Reactions

INTRODUCTION

Although drugs are indispensable tool for treating and sometimes for preventing illnesses, they have been always associated with numerous adverse effects and toxicities. According to WHO, an adverse drug reaction (ADR) is a noxious and unintended response to a medication which often occurs at normal doses (World Health Organization 2002). Several studies have confirmed substantial morbidity and mortality due to these unwelcomed ADRs that substantially increase treatment costs and hospital admissions due to the administered drugs (Pirmohamed, James et al., 2004; Alexopoulou, Dourakis et al., 2008). These detrimental effects can eventually affect patients' quality of life and disturb the therapeutic outcomes of used drugs. These ADRs may occur in any healthcare setting regardless of the taken precautional measurements.

Reporting ADRs is a fundamental and crucial responsibility of all healthcare professionals. Monitoring of these ADRs is a pivotal aspect of any healthcare system in order to recognize and probably minimize or prevent these deleterious adverse effects. Despite the positive attitude of healthcare professionals, most studies reported unsatisfactory ADRs reporting practice (Rehan, Sah et al., 2012; Abdel-Latif and Abdel-Wahab, 2015). The identified barriers for employing an effective ADRs reporting system were mainly due to inadequate knowledge of pharmaco-vigilance, unavailability of reporting system, incompetency of healthcare professionals or common misconceptions (Elkalmi, Hassali et al., 2014; Suyagh, Farah et al., 2015).

Many studies have taken placed to assess the knowledge, attitude and practice of healthcare professional towards pharmacovigilance and ADRs reporting (Hajebi, Mortazavi et al., 2010; Umar, Bello et al., 2016; AlShammari and Almoslem, 2018). However, few studies have been conducted to explore the knowledge **and** perception of ADRs reporting system among undergraduate healthcare professional students, the future healthcare providers (Rajiah, Maharajan et al. 2016; Limaye, Shah et al., 2018). Thus, the main aim of the present study was to evaluate knowledge and perception of various healthcare professional students towards pharmacovigilance and ADRs reporting.

STUDY DESIGN

A cross-sectional survey was carried out at King Saud Bin Abdulaziz University for Health Sciences (KSAU-HS) in Riyadh, Saudi Arabia, using a validated questionnaire adopted with permission to reproduce from Rajiahet al. (2016) (Rajiah, Maharajan et al., 2016). The questionnaire was reviewed and slightly modified according to the University relevance and to suite the local society. An online-based questionnaire was prepared using Google Forms. The survey questionnaire consisted of 23 structured items, which addressed participants' demographic data, and their knowledge and perception of ADRs reporting system. The questionnaire reliability was assessed in a pilot sample of 20 students. The attained Cronbach's alpha value was 0.71. The questionnaire was then shared with potential participants through the KSAU-HS e-mail service to randomly selected undergraduate students from colleges of medicine, dentistry, pharmacy, nursing and applied medical sciences. The sample size was estimated based on an expected response rate of 50% and 5% margin of error with two-sided confidence limits and a precision of 0.05% using the Rasoft® sample size calculator to be 320 students.The study population include healthcare professional students in different academic years. This study was reviewed and approved by the Institutional Review Board at King Abdullah International Medical Research Centre, Riyadh, Saudi Arabia (Reference no. IRBC/1492/18).

Descriptive and data analysis were done using SPSS software package version 21.0 [Release 21.0.0.0, IBM, USA]. Results were presented as percentages or as means with standard deviations. Statistical analyses of the data were performed using Student's t-test, one-way ANOVA, or Pearson's chi-squared test ($\chi 2$). Statistical significance was considered at p-values less than 0.05.

RESULTS

A total of 367 healthcare professional students participated in the current survey study that represents a response rate of 73.4%. Table-1 displays the general profile of respondents and their distribution in the corresponding colleges and academic years. Participants were undergraduate students from five healthcare professional colleges at KSAU-HS, namely College of Medicine (COM), College of Dentistry (COD), College of Pharmacy (COP), College of Nursing (CON) and College of Applied Medical Sciences (CAMS)with a distribution of 29.7%, 9.3%, 17.7%, 20.2%, and 23.2%, respectively. The majority of participants were female students (69.2%). The higher number of female among respondents was owing to the CON, which enrolls female students only.

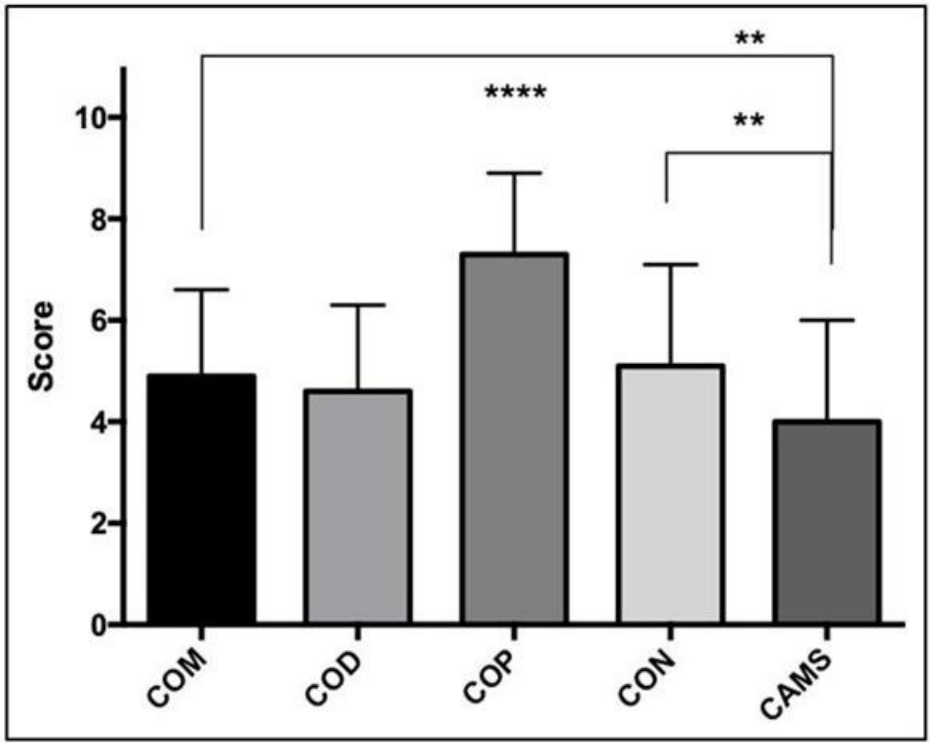
The scores of respondents in knowledge part of the survey were estimated out of 10, based on 'YES' / 'NO' - questions assessing the participants' basic knowledge in pharmacovigilance and ADRs reporting. Student who scored less than 5 were regarded as knowledge deficient, whereas, a score equals to or more than 5 was considered as sufficient knowledge. The overall mean score value of all respondents was 5.1± 2.1 (median=5; min=0; max=10).

The knowledge scores of female students were comparatively higher than those of male students. However, statistical analysis of the knowledge scores did not show a significant difference between respondents by gender. Nonetheless, there were noteworthy significant differences in the knowledge scores among students from different colleges (Figure-1 A) or academic years (Figure-1 B). Students at COP showed a prominent higher mean knowledge score (7.3 ± 1.6) than students at other colleges (p-value < 0.0001). Students at COM and CON showed mean knowledge scores of 4.9 ±1.7 and 5.1 ± 2.0, respectively, which are significantly higher than CAMS students only, with p-values equal to 0.009 and 0.007, respectively. Moreover, students in the third and fourth professional academic years demonstrated significantly higher knowledge scores (5.5 ± 2.1, and 6.2 ± 2.1, respectively) than students in other academic years (p-value = 0.002).

Table 1. Profile of participating healthcare professional students, n = 367

Variable	Value n (%)
Gender	
Male	113 (30.8%)
Female	254 (69.2%)
College of	
Medicine	109 (29.7%)
Dentistry	34 (9.3%)
Pharmacy	65 (17.7%)
Nursing	74 (20.2%)
Applied medical sciences	85 (23.2%)
Academic year	
First professional year	99 (27.0%)
Second professional year	96 (26.2%)
Third professional year	86 (23.4%)
Fourth professional year	29 (7.9%)
Fifth professional year	57 (15.5%)

A)



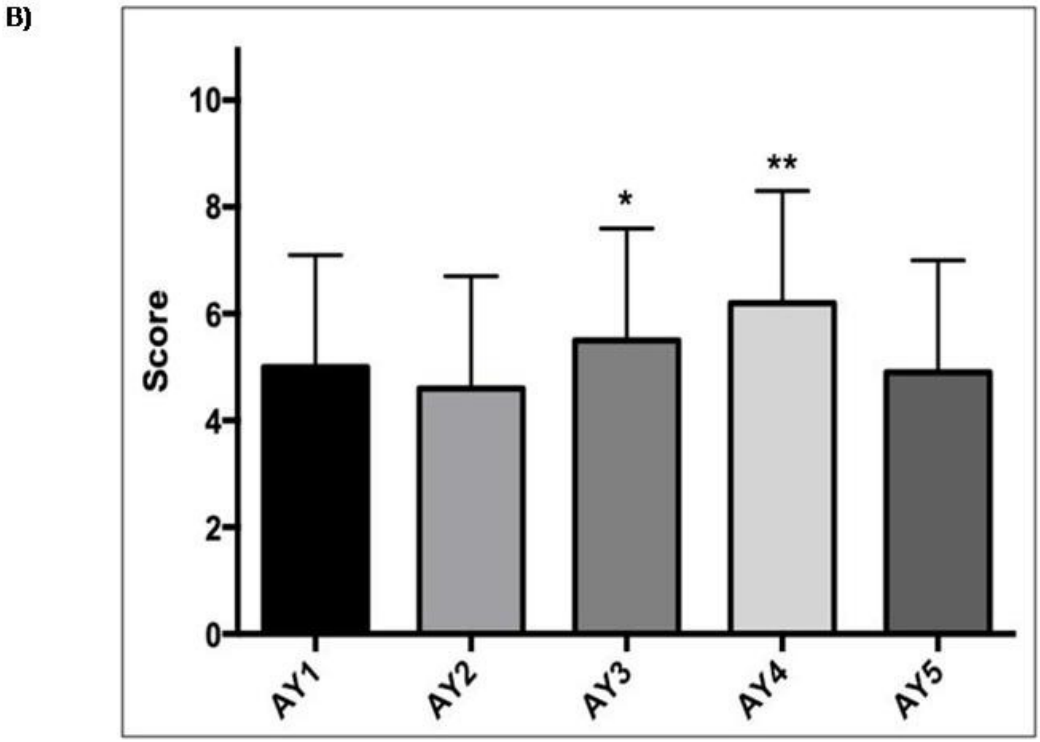


Figure 1. Knowledge scores, out of 10, of pharmacovigilance and ADR reporting among participants in (A) different healthcare colleges and (B) professional academic years. Where, COM: College of Medicine; COD: College of Dentistry; COP: College of Pharmacy; CON: College of Nursing; CAMS: College of Applied Medical Sciences; AY: academic year.

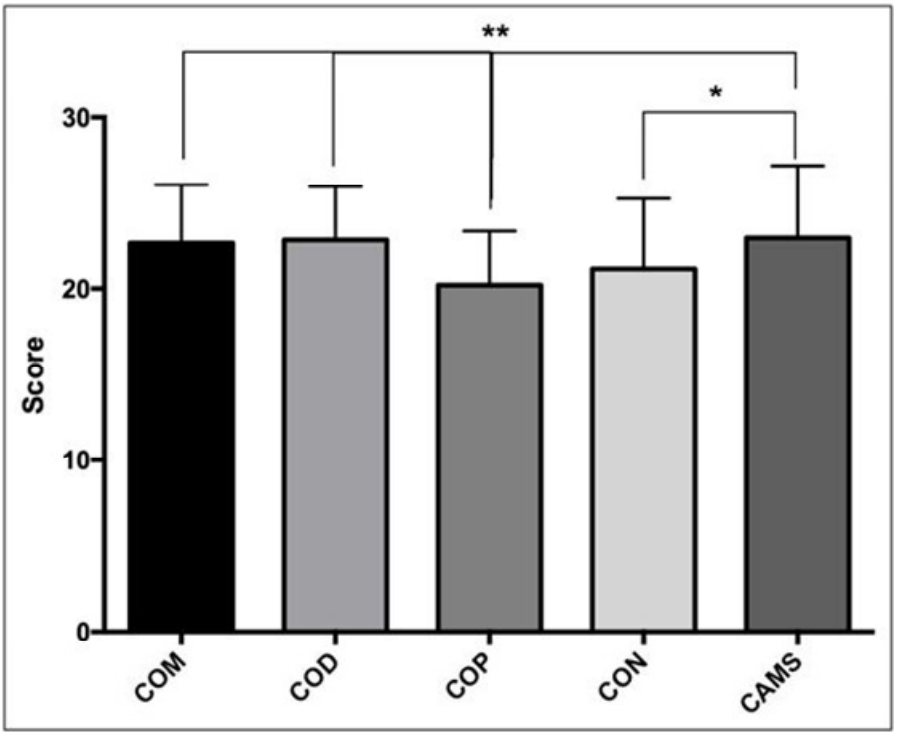
Table-2 summarizes responses to the questions that assessed participating students' knowledge of pharmacovigilance and ADRs reporting. More than two-third of respondents (66.5%) expressed a lack of awareness about how to report ADRs to the relevant authorities in Saudi Arabia, especially students at COM and CON (76.5% and 78.8%, respectively, data not shown). Peculiarly, slightly more than half of the respondents (52.6%) believed that healthcare professional students can report ADRs during their clerkship/internship, especially female students and students at COM and COD. Noticeably, the majority of respondents, except for students at COD, stated that pharmacovigilance topic is not well covered in their studying curricula. The vast majority of respondents (86.9%), particularly females (89.4%), appreciated the importance of reporting of known ADRs to contribute to the reporting system. More than three quarts of respondents (76.5%-86.2%) also recognized that hypersensitivity reactions are related to ADRs. Similarly, most respondents (57.3%-81.7%) identified the difference between ADRs and the adverse events. Although, more than 64% of respondents comprehend various types of hypersensitivity reactions, students at CON and CAMS and students in the earlier academic years were significantly less knowledgeable than their counterpart colleagues (p-values are <0.0001 and 0.0003, respectively). Nonetheless, students at COD and COP and students inthe third and fourth professional academic years were more knowledgeable about the post-marketing surveillance of drugs than other students (p <0.0001). However, 61.0% of respondents were explicitly concerned that they do not know ADRs classifications, mostly male students (69.9%) in addition to students in COM (64.7%), COP (74.3%) and CON (82.4%). Furthermore, 88.3% of participants disclosed deficits in the knowledge of how causality assessment of ADRs is done in Saudi Arabia (up to 92.9% in males and 94.1% in CON students).

On the other hand, the next ten questions in the survey were pertaining to the perception of participants towards pharmacovigilance and ADRs reporting using a 5-point Likert scale. The score was estimated, based on the student responses, out of 50. A score of less than 30 was considered as a negative perception; whereas, a score equals to or more than 30 was considered as positive perception. The results revealed an immense negative perception (99.5%) towards pharmacovigilance and ADRs reporting as the overall mean score value of participants was 22.0± 3.9 (median=22; min=10; max=32). There were no significant differences between scores by gender or among students in different professional academic years. Although, there is a slight, but statistically significant, higher perception on

Table 2. Students' responses to questions assessing their knowledge of pharmacovigilance and ADRs reporting, n = 367

Questions	Answer (%)		p-value		
	Yes	No	Gender	College	Academic year
I have an idea of how to report ADRs to the relevant authorities in Saudi Arabia	33.5	66.5	0.0997	<0.0001	0.8613
Students can perform adverse drug reactions reporting during their clerkship/internship	52.6	47.4	0.0097	0.0002	0.1515
The topic of Pharmacovigilance is well covered in my curriculum	32.4	67.6	0.1730	0.0002	0.8833
Reporting of known ADRs makes a significant contribution to the reporting system	86.9	13.1	0.0370	0.0885	0.5494
I know the different classifications of ADRs	39.0	61.0	0.0200	<0.0001	0.7357
Hypersensitivity reactions are related to ADRs	77.1	22.9	0.5653	0.1410	0.2256
There is a difference between ADR and the adverse events	66.5	33.5	0.6102	0.0198	0.0623
I know the different types of hypersensitivity reactions	64.3	35.7	0.0276	<0.0001	0.0003
I know what post-marketing Surveillance is	46.6	53.4	0.0957	<0.0001	<0.0001
I know how causality assessment of ADRs is done in Saudi Arabia	11.7	88.3	0.0654	<0.0001	0.3479

A)



B)

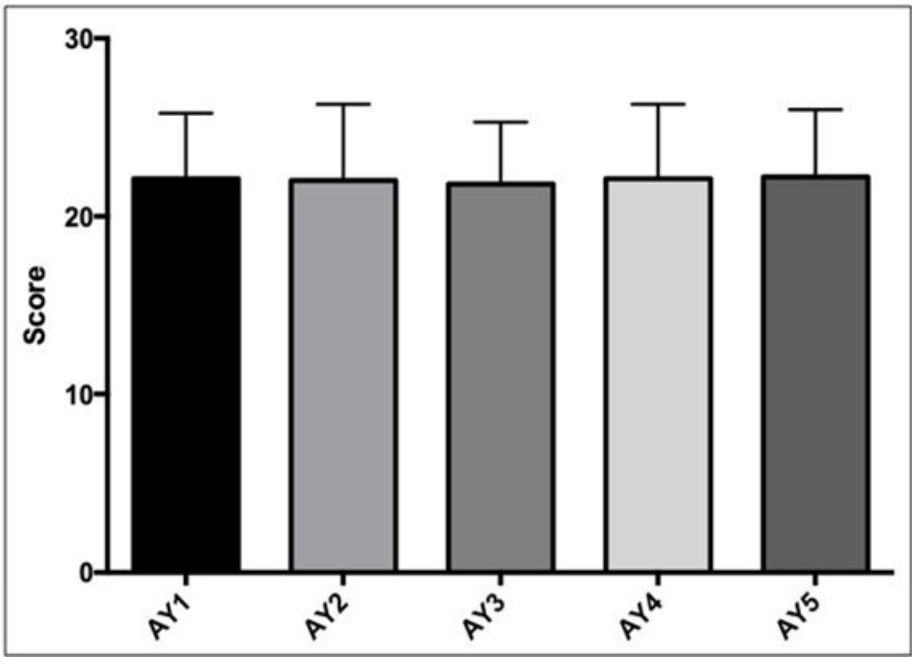


Figure 2. Perception scores, out of 50, on pharmacovigilance and ADRs reporting using 5-point Likert scale among participants in (A) different healthcare colleges and (B) professional academic years. Where, COM: College of Medicine; COD: College of Dentistry; COP: College of Pharmacy; CON: College of Nursing; CAMS: College of Applied Medical Sciences; AY: academic year

Table 3. Students' responses to questions assessing their perception on pharmacovigilance and ADRs reporting, n = 367

	Answer (%)			p-value		
Questions	**Strongly agree/ Agree**	**Neutral**	**Disagree Strongly/ disagree**	**Gender**	**College**	**Academic year**
ADRs reporting should be made compulsory for healthcare professionals	75.5	21.5	3.0	0.0825	0.0004	0.5362
Information on how to report ADRs should be taught to students	86.1	12.0	1.9	0.2253	0.0007	0.0220
I am very well prepared to report any ADRs noticeable in my future practice	29.2	25.3	45.5	0.0155	<0.0001	0.9239
Healthcare is one of the most important professions to report ADRs	91.3	8.4	0.3	0.5403	0.1434	0.1987
Serious and unexpected ADRs that are not fatal or life-threatening during clinical trials must not be reported	13.4	7.9	78.7	0.2013	<0.0001	0.1748
The purpose of ADRs spontaneous reporting system is to measure the incidence of ADRs	59.7	31.6	8.7	0.9948	0.0057	0.0375
Any ADR (serious or non-serious) should be reported spontaneously	86.9	10.1	3.0	0.6365	0.1259	0.0863
Reason for not reporting a suspected ADR is due to the uncertainty of its association with drugs	49.9	39.2	10.9	0.6941	0.1535	0.2962
Patients should be counseled about ADRs every time their medications are dispensed	79.8	14.2	6.0	0.3352	0.1701	0.5102
Female patients should be asked if she is pregnant when dispensing medications to them	92.9	6.3	0.8	0.8081	0.2648	0.7106

Table 4. Summary of knowledge and perception scores of participants, n = 367

Variable	Value n (%)	Knowledge mean score[a] ± SD	Perception mean score[b] ± SD
Gender	113 (30.8%)	4.8 ± 2.0	22.4 ± 3.9
Male	254 (69.2%)	5.2 ± 2.2	21.9 ± 3.8
Female			
College of	109 (29.7%)	4.9 ±1.7	22.7 ± 3.4
Medicine	34 (9.3%)	4.6 ± 1.7	22.9 ± 3.1
Dentistry	65 (17.7%)	7.3 ± 1.6	20.2 ± 3.2
Pharmacy	74 (20.2%)	5.1 ± 2.0	21.2 ± 4.1
Nursing	85 (23.2%)	4.0 ± 2.0	23.0 ± 4.2
Applied medical sciences			
Academic year	99 (27.0%)	5.0 ± 2.1	22.1 ± 3.7
First professional year	96 (26.2%)	4.6 ± 2.1	22.0 ± 4.3
Second professional year	86 (23.4%)	5.5 ± 2.1	21.8 ± 3.5
Third professional year	29 (7.9%)	6.2 ± 2.1	22.1 ± 4.2
Fourth professional year	57 (15.5%)	4.9 ± 2.1	22.2 ± 3.8
Fifth professional year			

[a]Score out of 10; [b]Score out of 50.

pharmacovigilance and ADRs reporting among COM, COD and CAMS, they were still exhibiting pronounced negative perception (Figure-2).

Table-3 displays responses of participants to questions assessing perception towards pharmacovigilance and ADRs reporting. The vast majority of the respondents had unanimously agreed on the importance of spontaneous ADRs reporting by healthcare professionals and its impact on the patients' therapeutic outcomes. However, most of them felt unconfident to report ADRs, because they either uncertain or unprepared to do so. A few disagreements were revealed on a number of perception items, particularly among those respondents in different healthcare professional colleges. Table-4 summarizes the knowledge and perception scores of participating healthcare professional students of pharmacovigilance and ADRs reporting according to the gender, healthcare professional colleges and academic years.

DISCUSSION

Drug interventions of diseases have always been associated with a number of unintended ADRs (Aronson 2013). Identifying and/or predicating of those ADRs are pivotal in optimizing the therapeutic outcomes of used drugs (Giardina, Cutroneo et al., 2018). Previous studies have reported a under-reporting of ADRs by healthcare professionals due to a various reasons including lack of awareness, knowledge deficits, time constrains and others (Tandon, Mahajan et al., 2015; Gahr, Eller et al., 2017; Haider and Mazhar 2017; Güner and Ekmekci, 2019). A number of studies have been already examined the knowledge and perceptions of the healthcare professional students and practitioners, which highlighted the need for enhancing their awareness of for the importance of spontaneous reporting of ADRs (Gavaza and Bui 2012; Rajiah, Maharajan et al., 2016; AlShammari and Almoslem, 2018). Hence, the present study aimed, in addition to exploring the knowledge and perception, to identify the plausible barriers for employing an effective ADRs reporting system from the healthcare professional students' perspective. This study is a descriptive cross-sectional study that surveyed 367 students from various healthcare professional colleges in different academic years.

The results showed that the vast majority of respondents have appreciated the importance of ADRs reporting system. However, most of them, especially male participants, displayed substantial deficiencies in the fundamental knowledge of pharmacovigilance owning to the lack of awareness of those students about the ADRs reporting system in Saudi Arabia. This serious deficit could be attributed to the absence or insufficient coverage of topics pertaining to the drug safety and ADRs in the college programs curricula or during the clerkship/internship stage as clearly stated by most surveyed students. This allegation is consistent with a number of studies from diverse countries that reported similar findings (Elkalmi, Hassali et al., 2011; Alkayyal, Cheema et al., 2017; Othman, Ibrahim et al., 2017; Limaye et al., 2018). COP students in the present study demonstrated a significant higher knowledge than other students. This may reflect a fairly good comprehension of pharmacy students of pharmacovigilance principles due to the inclusion of certain educational activities about ADRs in their program curriculum. Yet, their scores were far less than the anticipated aspiration from the prospective drugs experts. Additionally, students at higher academic levels, i.e., at the third and fourth professional years demonstrated slightly, but statistically

significantly, higher knowledge scores than students in their earlier academic years.

On the other hand, the surveyed participants expressed an immensely pronounced negative perception towards pharmacovigilance and ADRs reporting. Despite their substantial negative attitudes, the vast majority of them expressed consistent agreement on the importance of spontaneous ADRs reporting by healthcare professionals due to the direct impact of ADRs on the patients' therapeutic outcomes. However, the majority of participants were unconfident to report any suspected ADR, because they were either uncertain or unqualified. This could be also attributed to their inadequate training or knowledge deficits.

Therefore, it is crucial to emphasis on importance of pharmacovigilance and ADR Reporting in the healthcare professional students' curriculum throughout all their academic years and during their clerkship/internship schedule in order to ensure a translation of their knowledge into a clinical practice. Moreover, it is necessary to develop an effective strategy to minimize such knowledge deficits by implementing a series of continuous educational and training programs to all healthcare professionals to improve quality their clinical skills and to promote their confidents in ADRs reporting.

CONCLUSION

Despite the undisputed agreement among the surveyed participants about the importance of identifying and reporting of ADRs in the clinical practice, most of respondents demonstrated significant knowledge deficits and negative perception towards pharmacovigilance and ADRs reporting. The utmost recognized barriers for employment of an effective ADRs reporting system were knowledge deficits, lack of awareness and insufficient training and support.

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