Original article

The comparative assessment of awareness, perspective, and basic practice skills about the Saudi pharmacovigilance system among students of different health-care professionals of a Saudi Female University

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ABSTRACT

Introduction: The low reporting of adverse drug reactions (ADRs) in Saudi Arabia is prevalent among health-care professionals and is responsible for poor ADR signal detection. Therefore, all healthcare institutes connected with patient concern require joint and sustained efforts to strengthen ADR reporting by providing harmless and efficient medication.
Objectives of the study: The current study was performed to estimate the awareness corresponding to the knowledge, perspective, and basic practice skills about the Saudi pharmacovigilance system among students of different health-care professionals of a Saudi Female University.
Material & methods: A questionnaire was planned and standardized by a thorough literature review. Questions were classified: Group 1 had ten knowledge-based, group 2 five attitude-based, and group 3 four basic practice skills-based questions of pharmacovigilance (PV). Also, determinants that hindered them from becoming part of the pharmacovigilance program were reported. Such 600 questionnaires were distributed among the interns, final and prefinal year students of different health care professionals of Princess Nourah bint Abdulrahman University, Riyadh. The participants' awareness and practice skills were graded in 3 categories as unacceptable, inadequate, and adequate, depending upon the mean score along with identification of their type of perception towards PV. The data was interpreted by calculating the frequencies, one-way ANOVA, and by post-hoc Tukey-Kramer HSD multiple comparison test.
Results: Five hundred ninety-two questionnaires were statistically investigated. Students' awareness and basic practice skills of pharmacovigilance were found to be inadequate, but positive perception towards PV.
Conclusion: Our study showed that awareness and practice skills of PV among students of different health care professionals stand insufficient but favourable perceptions towards PV. Regular educative interventions can increase these parameters of pharmacovigilance.
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1. Background

Health-care services in the Kingdom of Saudi Arabia are a profound vital area of advancement, demanding constant developments. Therefore, the Saudi Government considers health-care services supremacy, as is apparent from the World Health Organisation (WHO) ranking of the Saudi health-care operation at 26 amongst 190 countries all across the world (Almalki, Fitzgerald, & Clark, 2011). Notwithstanding the persistent attempts of the administration, numerous segments are yet to be approached, such

as a deficiency of qualified health-care experts, incompetent health information systems, low utilization of digital health strategies, including less Adverse Drug Reactions (ADRs) recording (Almalki et al., 2011; L. M. Khan et al., 2012).

Pharmacovigilance (PV) is the science associating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem (World Health Organization, 2002). ADRs lead to drug-related patient morbidity by causing an extended period of hospital stay, greater economic difficulty, and sometimes fatality. They are a common and frequently preventable condition of hospital admission. Detection and monitoring of ADRs is of essential concern for patient safety, as more substantial than 50% of authorized drugs are linked with some type of adverse effects that are not recognized before their approval for clinical use (Rabbur & Emmerton, 2005). It intends to get the most desirable result from practice with medications (World Health Organization, 2012).

The objectives of pharmacovigilance are prompt identification of adverse drug events (ADE), incidence and pattern of ADRs among population groups, likely causal relationships between ADE and drug following initiation of a novel drug or new drug combination, appraisal of these signs to estimate causality and its clinical significance (World Health Organization, 2006). These goals compare the safety of different medicines, clearly identify the risk factors, and provide to the evaluation of both effectiveness and risk of drugs. It presents up-to-date information and guidance to governing officials, clinicians, and society. Therefore PV is a crucial part of patient concern and rational utilization of medications.

Also, 21st-century pharmacovigilance includes efforts to supervise the quality of medicines and the reporting of suboptimum therapeutic outcomes systematically. The pharmaceutical industry is accountable for the quality and can measure it. Drugs quality is a complex union of pre-market regulatory specifications, appropriate sourcing of constituents (active pharmaceutical ingredient, excipients, etc.), manufacturing processes, healthcare ecosystem communications, and regular and robust post-marketing risk-based investigations into the possible associations with unanticipated adverse events based on components other than a medicine's active pharmaceutical ingredient. In 2014, the USFDA opened the Office of Pharmaceutical Quality to supervise the safety, efficacy, and quality of medicinal products. The USFDA is sourcing active pharmaceutical ingredients and excipients to generate a risk-based strategy that includes data collected from manufacturing inspections, adverse event reporting, and substandard pharmaceutical cases (Pitts, Louet, Moride, & Conti, 2016).

WHO promotes PV at the country level. Saudi food and drug authority (SFDA) established the National Pharmacovigilance Center in March 2009 (Olsson, 2009). It is associated with the WHO Uppsala monitoring center (UMC), Sweden, which reports Saudi ADRs internationally. The NPC center accepts ADR reports from the citizens, health-care professionals (HCP), and pharmaceutical manufacturers through multiple methods of communication like through the online Vigibase reporting system, E-mail, registered mail, fax, or by telephone. Notwithstanding around a decade of the NPC's presence, PV is yet observed as a comparatively new thought in the country, with low levels of knowledge among health-care providers (AlShammari & Almoslem, 2018; Moinuddin et al., 2018).

Aljadhey et al. explored different challenges for practicing PV in Saudi Arabia through a qualitative study of 4 focus group discussions of healthcare professionals namely complicated ADRs reporting forms, lack in activating all pharmacovigilance activities by the SFDA, unrestricted access to medications from community pharmacies, shortage of collaboration between governing bodies and hospitals, and lack of drug manufacturers in the country (Aljadhey et al., 2015).

Recently, international experts in healthcare discovery and regulatory science addressed regulatory science concepts related to raising both the quality of medications and patient care in Saudi Arabia. They believed that there are gaps and asymmetries in how "quality" is both defined and maintained. There was a general recognition that an essential way to improve both the quality of medications and health outcomes is to update existing registration guidelines continuously, regular and risk-based bioequivalence studies to estimate the quality of marketed either generic or brand drugs, design and execute educational and collaborative programs about pharmaceutical quality issues along with intensifying communications between regulative agencies, healthcare professionals and patients to encourage more timely post-marketing records of adverse events and substandard pharmaceutical consequences. Also, Saudi 21st century pharmacovigilance practices must take into thought of providing patients with information written in layman's terms about the bioequivalence of generic drugs (Alhawassi et al., 2018).

To promote ADR reporting, various hospitals in Saudi Arabia have formed Medication Safety Units (MSUs) (Aljadhey et al., 2013) which operate under the division of pharmaceutical care services (Ali, Aboheimed, Al-Zaagi, & Al-Dossari, 2017). They receive ADR data and report them to the NPC for forwarding transmission to the WHO-UMC, Sweden (Moinuddin et al., 2018). A study conducted in 2013, revealed that around 30% of the hospitals in the country hold a medication safety committee, with just 9% possessing a medication safety officer (Aljadhey et al., 2013).

The present database of Saudi Pharmacovigilance is not sufficient to represent the population that consumes the drug or to which the drug has been prescribed for. Therefore, all healthcare institutes connected with patient concern require joint and sustained efforts to strengthen ADR reporting by providing harmless and efficient medication. Moreover, including pharmacovigilance courses in the education curriculum of all healthcare programs of medicine, dentistry, nursing, pharmacy, paramedical, etc. could create the practice of ADR reporting among growing scholars. Estimation of awareness of pharmacovigilance (PV) among these students is critical to know the status of the adverse drug reporting system in KSA. Thus the present study was executed.

2. Objectives of the study

Aim of the study: The assessment of awareness, perspective, and basic practice skills about the Saudi pharmacovigilance system among the interns, final and prefinal year students of different health care professions of Princess Nourah bint Abdulrahman University, Riyadh.

Specific Objectives:

1. To assess the awareness and knowledge of Pharmacovigilance among the interns, final and pre-final year students of medical, dental, nursing and pharmacy students of PNU
2. To assess perspective towards Pharmacovigilance of the interns, final and pre-final year students of medical, dental, nursing and pharmacy students of PNU
3. To assess the basic practice skills of Pharmacovigilance among the interns, final and pre-final year students of medical, dental, nursing and pharmacy students of PNU
4. To compare the results among the students of each health care profession and within three groups of students of every health care profession.

3. Materials and Methods:

The Study Design and Setting: It was a cross-sectional, non-interventional, questionnaire-based study, and was performed in Princess Nourah bint Abdulrahman University, Riyadh

Sample selection criteria:

Inclusion criteria: The non-probability convenience sample of interns, final and pre-final students of the healthcare profession, i.e., medical, dental, pharmacy, and nursing of Princess Nourah bint Abdulrahman University who gave their informed consent were included in the study.

Exclusion criteria: Students who did not give their consent were eliminated from the study.

Sample size calculation: Using G * power sample size calculator with a 5% allowance of error, 95% confidence level, the prevalence of KAP of PV from the literature between 20 and 30% (Hema and Bhuvana, 2012), the sample size required for this study was 462. Assuming a response rate of 70%, a larger sample size of 600 was considered.

Structure of a questionnaire:

A structured questionnaire designed based on the primary objective of the study after a detailed review of relevant literature was used (Abubakar and Ismail, 2015; Hema and Bhuvana, 2012). It covered both positive and negative questions to elude agreement prejudice. It was validated by six experts for its content validity. Questions having item content validity index (ICVI) less than 0.78 were removed from the questionnaire (Polit & Beck, 2006). The finalized questionnaire composed of 4 sections: Section-I contained demographic content. Section-II comprised ten awareness and knowledge-based questions created with yes or no possibilities and multiple-choice questions; a score of one was given to the right answer and nil to each wrong answer. Section-III consisted of attitude questions constructed into a 5-point Likert scale (5 = strongly agree, 4 = partly-agree, 3 = -neutral, 2 = partly-disagree, 1 = strongly-disagree). Finally, section-IV had practice skills questions, a score of one was assigned to the right answer, and zero to the incorrect answer. The survey was first pilot-experimented with 20 different health-care undergraduates who were not involved in the main questionnaire. Students' responses then statistically tested for validity and reliability, with overall Cronbach's alpha was determined as 0.76. The participants' awareness and practice skills were graded in 3 categories as unacceptable, inadequate, and adequate, depending upon the mean score, as shown in Table 1.

Data collection:

The study was carried between January and June 2019. Six hundred questionnaires were distributed among the interns, final and prefinal year students of different health care professionals of Princess Nourah bint Abdulrahman University, Riyadh, and their responses were obtained. 592 returned questionnaires were statistically analyzed, thus giving a higher response rate of 98.6%, similar to Almandil's study (Almandil, 2016).

Data analysis

The data were interpreted using the statistical software JMP®, Version 12, SAS Institute Inc., Cary, NC, 1989–2019. Descriptive statistics were conducted to estimate the awareness, knowledge, and practice skills score of the participant. ANOVA test was performed to determine if there was a difference in the mean knowledge and practice score between students studying medicine, dentistry, nursing, or pharmacy. It was followed by a post-hoc Tukey-Kramer HSD multiple comparison test. The statistical significance was determined at a p-value of 0.05 and a 95% confidence interval.

4. Results

Figs. 1–3 show descriptive statistics indicating that the mean knowledge and practice skills score of pharmacovigilance among study participants where the respondents are graded in 3 categories unacceptable, inadequate, and adequate depending upon the mean score and Fig. 4 depicts their perception responses.

Fig. 1 explains that the level of knowledge was inadequate in 74.6% of participants, unacceptable in 12%, and adequate in only 13.34% of participants. Their evaluation by college of medicine, dentistry, nursing and pharmacy showed that it was inadequate in 64%, 73%, 76% and 36% of students respectively. It was adequate in 51% of pharmacy students as depicted in Fig. 3. The basic practice skills score of pharmacovigilance was unacceptable in 70.9% of participants, inadequate in 23%, and adequate in only 6% of participants, as shown in Fig. 2. Their evaluation by college of medicine, dentistry, nursing and pharmacy showed that it was unacceptable in 84%, 75%, 78% and 53% of students respectively (Fig. 3).

Fig. 4 depicts these varied perception responses. 73.48% of participants strongly favored that ADR recording is necessary, and 64.7% were of the clear opinion that ADR reporting would benefit the patients. 47.3% of participants urged the explanation of PV to HCP students in detail, representing a positive attitude towards PV. Few (34.12%) of the respondents thought of the requirement of pharmacovigilance centers within every hospital.

Figs. 5 and 6 and Table 2 represents the ANOVA test for knowledge and practice skills score, Table 3 shows the 1-Way Test, ChiSquare Approximation and Tables 4–6 represents estimation of Post hoc Tukey-Kramer HSD multiple comparison test between the groups. While analyzing the determinants challenging them from being part of pharmacovigilance as seen in Fig. 7, the significant number of participants (56.59) responded that they do not know how to and where to report, followed by a deficit of knowledge in diagnosing ADRs.

The mean knowledge score of the students of pharmacy, nursing, medicine, and dentistry were 5.35, 4.85, 4.73, and 4.53, respectively. Only 34% of our study respondents were knowledgeable of the Saudi National Pharmacovigilance Program, and 27% could correctly define PV. Only 2% of the respondents identified the WHO ADR collection database, Vigibase. Several (96%) were lacking information about the national pharmacovigilance center officially launch the year of 2009 and Sweden as an international center for adverse drug reaction monitoring (94%). Results are shown in Fig. 8. Similar findings were seen in other study of India (Bepari, Niazi, Rahman, & Dervesh, 2019).

The mean practice score of the students of pharmacy, dentistry, nursing, and medicine were 2.45, 2, 1.91, and 1.75, respectively, and the majority were on the unacceptable scale. Only 32% of participants had contact with a tutorial session specifically about PV. The results are provided in Fig. 9.

5. Discussion

The Saudi National Pharmacovigilance Center received about 439 ADR reports accounting to only 6% in 2009, as not all ADRs were communicated to SFDA. During the timespan between 2009 and 2012, 2127 (15%) reports from Saudi hospitals were received, out of which pharmacists were the primary reporter for 1859 (12.6%) reports (Alshammari, Al-Kathiri, Le Louet, & Aljadhey,

Table 1
Knowledge and practice skills score range of pharmacovigilance.

Parameter	unacceptable	inadequate	adequate	Max score
Knowledge	0–3	4–6	7–10	10
Practice skills	0–2	3	4	4

2015). Despite the NPC's aims, the under-recording of ADRs is prevalent among the public as well as healthcare professionals. Potential explanations for the under-recording of ADRs are a lack of information on the process of ADR reporting, underestimation of ADRs' seriousness, ambiguity on the causal correlation between the ADR and the medication, and unavailability of ADR reporting forms (T. M. Khan, 2013; Mahmoud et al., 2014).

The effect and achievement of any pharmacovigilance policy depend highly on the interaction of all HCPs, degree of co-operation, and contact between the practitioners and medication
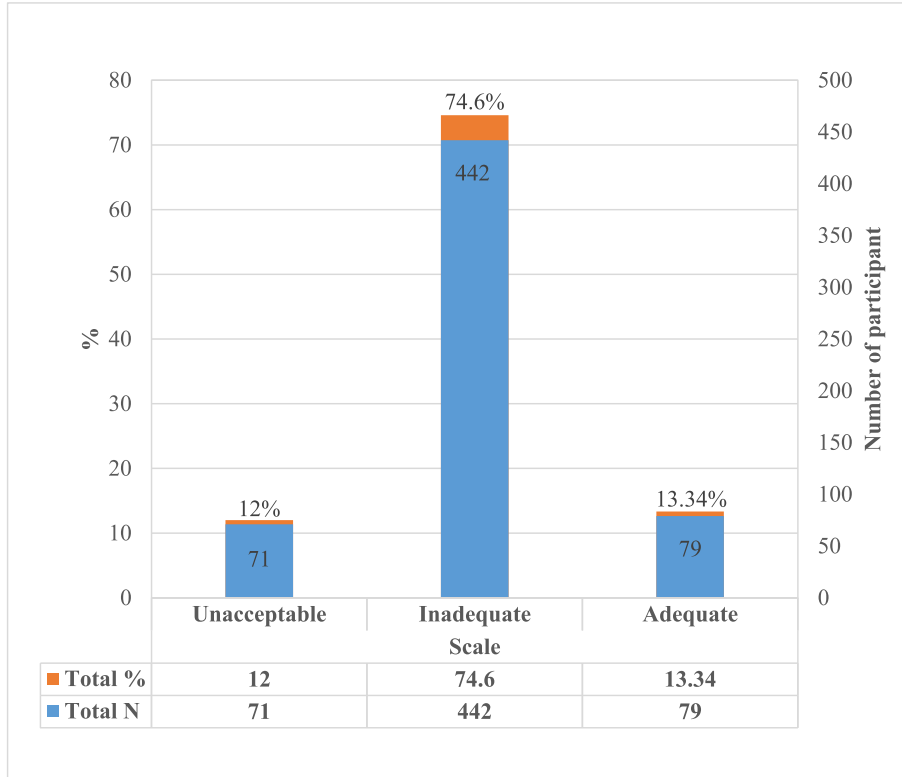

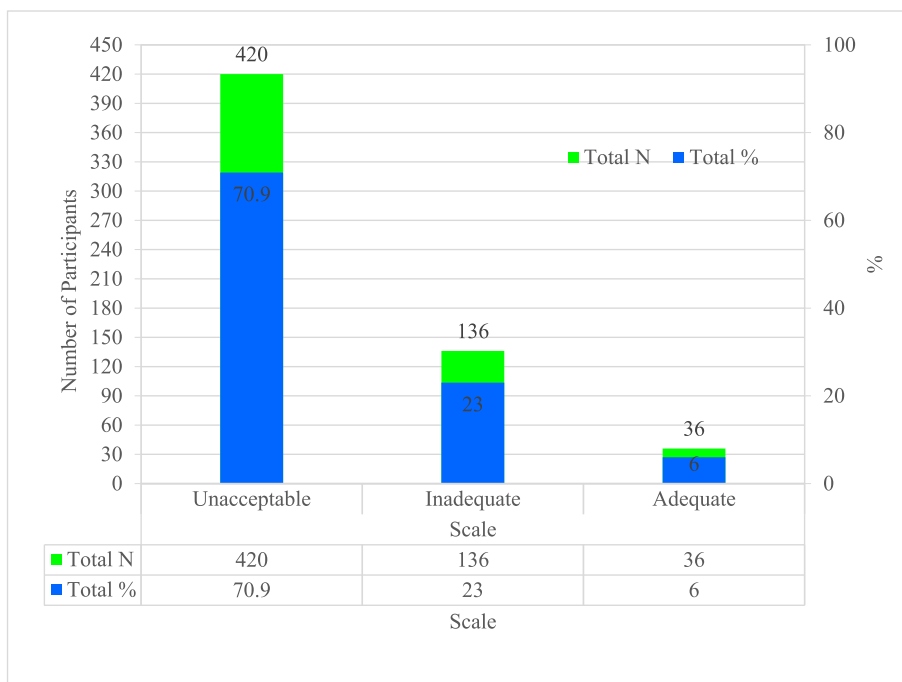**Fig. 1.** Scoring scale of the pharmacovigilance knowledge among study participants.

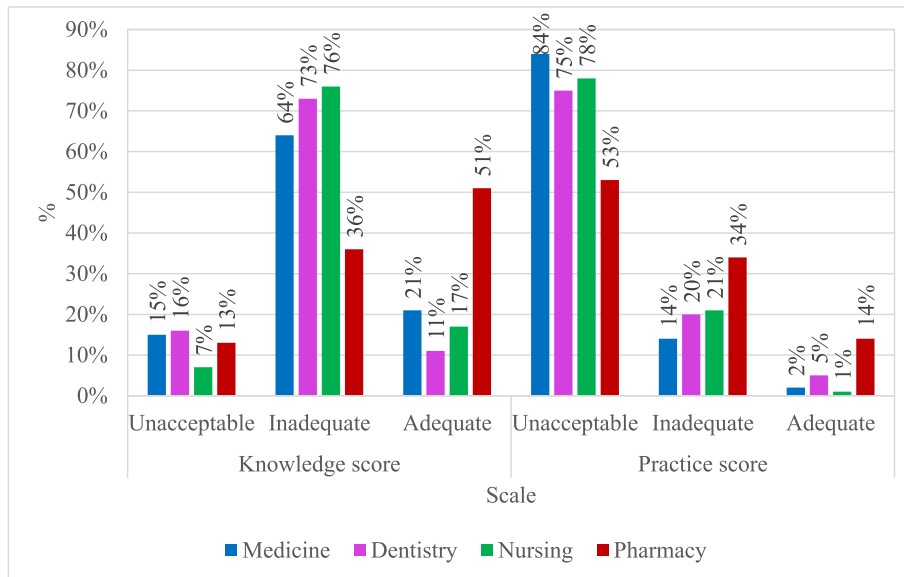**Fig. 2.** Scoring scale of the pharmacovigilance practice skills among study participants.

Fig. 3. Healthcare discipline-wise scoring scale of the pharmacovigilance knowledge & practice skills among study participants.
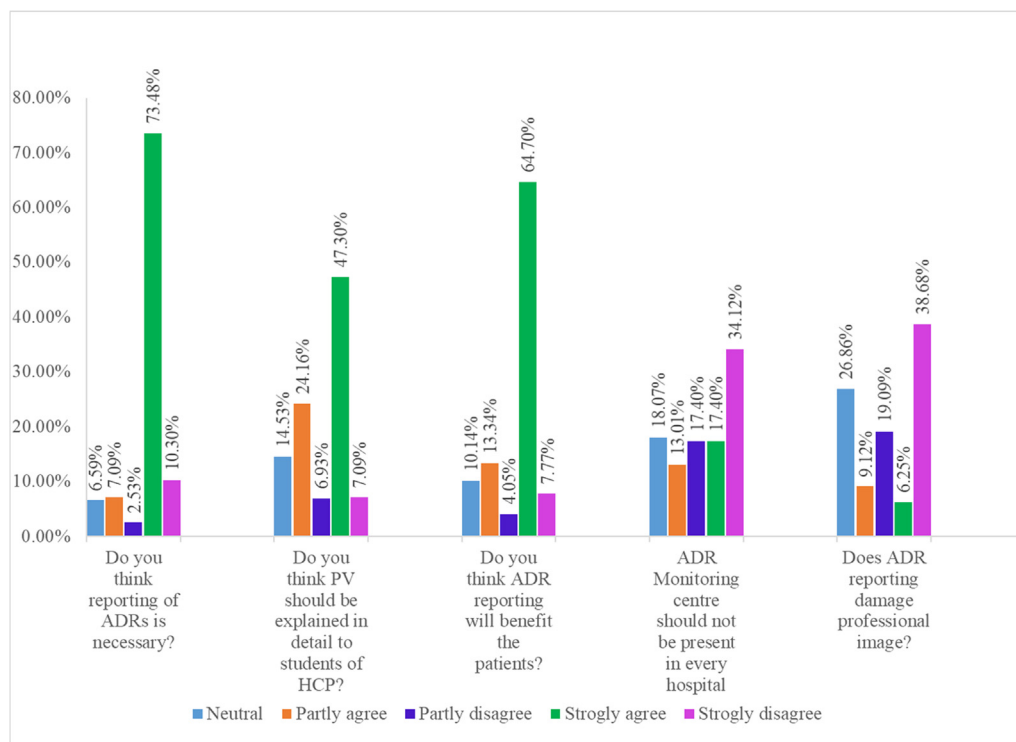

Fig. 4. Perception responses towards pharmacovigilance among study participants.

safety units. Thus, in this study, we estimated the knowledge, perception, and practice skills of pharmacovigilance amongst undergraduate students of medicine, dentistry, nursing, and pharmacy.

The mean knowledge score and basic practice skills were better in pharmacy students and statistically significant as depicted in Table no. 6 (<0.0001). This is similar to the study conducted by Noor B. Almandil, 2016, which showed that pharmacists and pharmacist technicians had the most substantial rate of PV awareness, followed by nurses and physicians (Almandil, 2016). As shown in Fig. 9, only one third of participants underwent a tutorial session specifically about PV and nearly half of participants supported

the need for information and full training of PV to HCP students, expressing a positive attitude towards PV. The major obstacles for getting involved in PV were that participants did not know how to and where to report, and deficient knowledge in diagnosing ADRs. Similar findings were seen in other studies (Adedeji, Ibraheem, & Fehintola, 2013; Almandil, 2016; Elnour, Ahmed, Yousif, & Shehab, 2009; S. A. Khan, Goyal, Chandel, & Rafi, 2013).

Our findings contribute a reason to enhance educational campaigns and awareness of pharmacovigilance to improve ADR reporting. Pharmacovigilance should be part of the educational program for all undergraduate health-care studies to provide
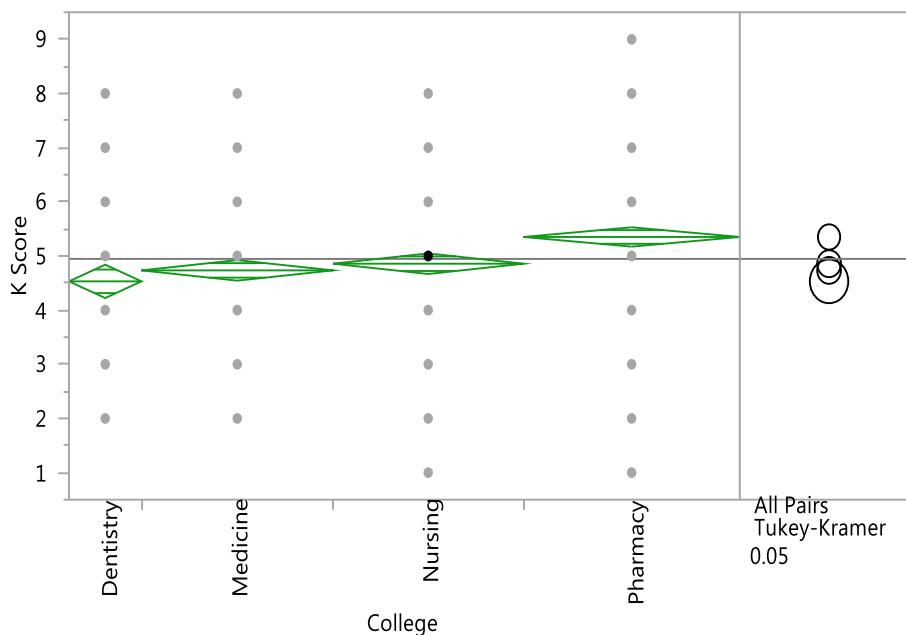
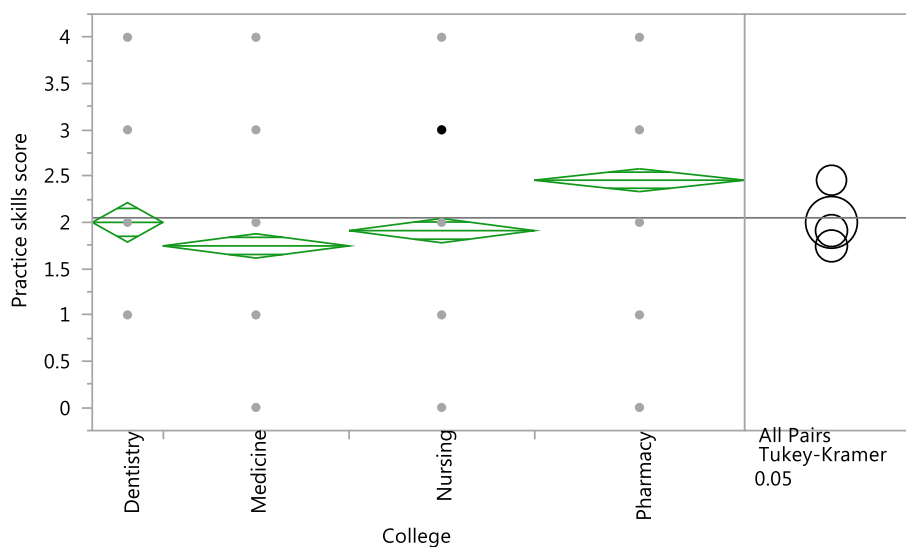**Fig. 5.** Oneway Analysis of Awareness Score By College-wise.

Fig. 6. Oneway Analysis of Practice skills score By College.

Table 2
ANOVA test of significance for comparison among the different healthcare college student groups.

	Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Mean_K_Score	College	3	51.24621	17.0821	10.8584	<0.0001*
	Error	588	925.02406	1.5732		
	Total	591	976.27027			
Mean_P_Score	College	3	50.48778	16.8293	22.3331	<0.0001*
	Error	588	443.09161	0.7536		
	C. Total	591	493.57939			

The * indicates the statistical significance

Table 3
1-Way test, ChiSquare approximation.

Parameter	ChiSquare	DF	Prob > ChiSq
Knowledge	37.8531	3	<0.0001*
Practice	56.8177	3	<0.0001*

The * indicates the statistical significance.

through postings in the Medication Safety Units during their studies.

Numerous studies have illustrated the positive influence of various intervention approaches on spontaneous ADR reporting among different healthcare professionals (Chang, Xi, Zhao, Zhang, & Lu, 2017; Pedros et al., 2009). Such interventions involve support with recording, routine prompts, revision of reporting tools and process, providing monetary considerations, and regular tutorial

well-prepared graduates in future practice. The practice of filling up of ADR reporting form and the ways for determining the causality through Naranjo's scale along with severity should be done

Table 4
HSD threshold matrix of awareness score: Abs(Dif)-HSD.

College	Pharmacy	Nursing	Medicine	Dentistry
Pharmacy	−0.33068	0.15183	0.27579	0.35280
Nursing	0.15183	−0.35259	−0.22865	−0.14879
Medicine	0.27579	−0.22865	−0.35154	−0.27182
Dentistry	0.35280	−0.14879	−0.27182	−0.57126

Positive values show pairs of means that are significantly different.

Table 5
HSD threshold matrix of practice skills score: Abs(Dif)-HSD.

College	Pharmacy	Dentistry	Nursing	Medicine
Pharmacy	−0.22886	0.13247	0.30822	0.47374
Dentistry	0.13247	−0.39537	−0.23925	−0.07383
Nursing	0.30822	−0.23925	−0.24403	−0.07851
Medicine	0.47374	−0.07383	−0.07851	−0.24330

Positive values show pairs of means that are significantly different.

sessions. The study of S. Ali et al. showed a notable rise in the incidence of ADRs reported following the initiation of the incentives that were principally driven by clinical pharmacists (Ali, Egunsola, Al-Dossari, & Al-Zaagi, 2018). In one study, a six-fold improvement in the average ADR reporting was observed through continuous multifaceted intervention, including both educational activities and financial incentives (Pedros et al., 2009). Varallo FR et al. study indicated that using multifaceted educational intervention with multidisciplinary teams for pharmacovigilance revealed a remarkable rise surpassing 100% in the total number of reports of drug-induced issues, their increased relevance, and enhanced medication error reporting (Varallo, Planeta, & Mastroianni, 2017).

The shortage of feedback from the governing bodies on the suspected ADRs was one of the hurdles reported by a new study (Ruud, Srinivas, & Toverud, 2010). Possibly this oversight will contribute to uncertainty in reporting ADRs in the prospect, recognizing that some health-care professionals might not have sufficient confidence to report ADRs (S. A. Khan et al., 2013; Ruud et al., 2010). The engagement of patients in ADR recording might perform an essential role in the improvement of pharmacovigilance
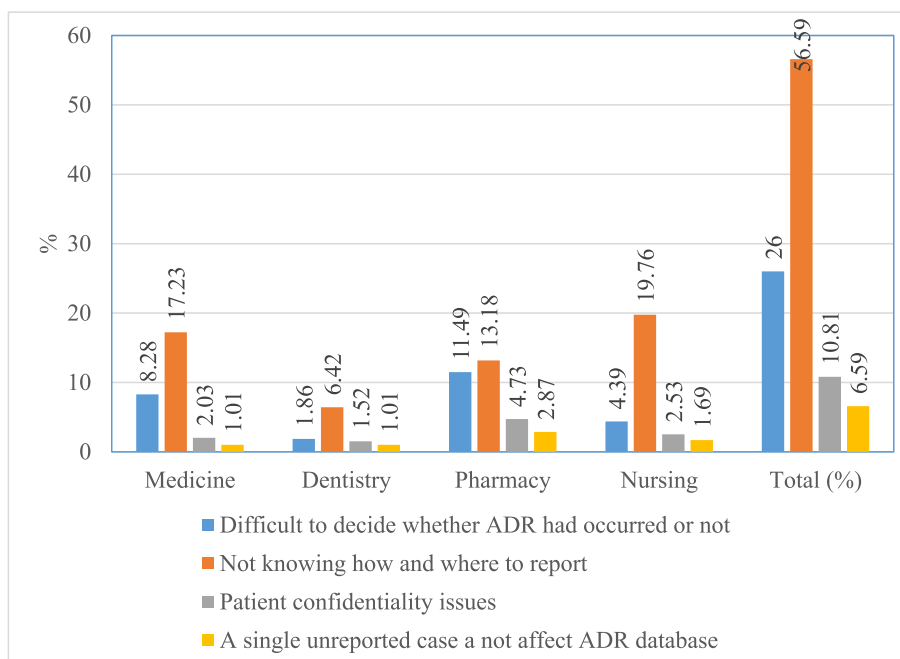
Table 6
Post-hoc Tukey-Kramer HSD multiple comparison test.

Dependent Variable	Level	Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Mean_K_Score	Pharmacy	Dentistry	0.8195353	0.1811554	0.352800	1.286271	<0.0001*
	Pharmacy	Medicine	0.6170575	0.1324583	0.275787	0.958328	<0.0001*
	Pharmacy	Nursing	0.4936425	0.1326673	0.151833	0.835452	0.0012*
	Nursing	Dentistry	0.3258929	0.1842414	−0.148794	0.800580	0.2895
	Medicine	Dentistry	0.2024778	0.1840910	−0.271821	0.676777	0.6897
	Nursing	Medicine	0.1234150	0.1366485	−0.228651	0.475481	0.8032
Mean_P_Score	Pharmacy	Medicine	0.7099353	0.0916747	0.473741	0.9461294	<0.0001*
	Pharmacy	Nursing	0.5447831	0.0918193	0.308216	0.7813499	<0.0001*
	Pharmacy	Dentistry	0.4554974	0.1253781	0.132469	0.7785263	0.0017*
	Dentistry	Medicine	0.2544379	0.1274098	−0.073826	0.5827013	0.1902
	Nursing	Medicine	0.1651522	0.0945747	−0.078514	0.4088181	0.3007
	Dentistry	Nursing	0.0892857	0.1275139	−0.239246	0.4178174	0.8970

The * indicates the statistical significance.

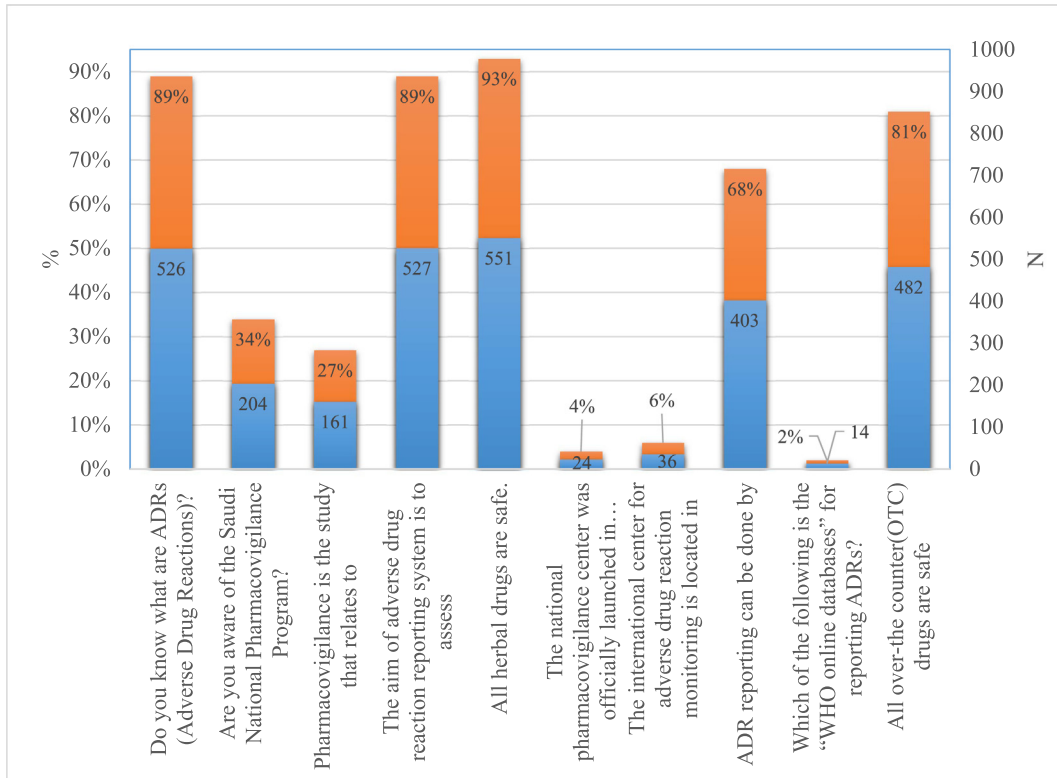**Fig. 7.** Factors discouraging to take part in pharmacovigilance program.

Fig. 8. Awareness and Knowledge related responses of pharmacovigilance from study participants.
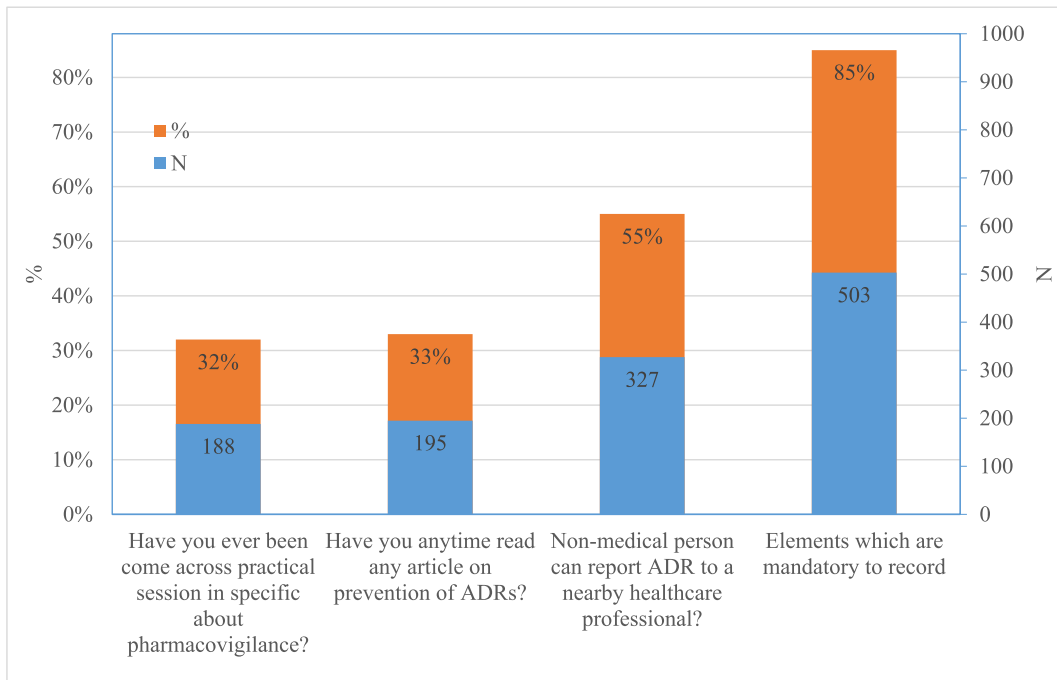

Fig. 9. Practice related responses of pharmacovigilance from study participants.

(de Langen, van Hunsel, Passier, de Jong-van den Berg, & van Grootheest, 2008) Nevertheless, the regulatory officials need to execute serious activities to increase the knowledge of society on ADR reporting. Health sciences colleges need to include pharmacovigilance programs in their syllabus to enhance prospective health-care providers' experience at an initial step in their careers.

6. Conclusion

Our study determined that there was profound unsatisfactory knowledge and poor basic practice skills but with good attitude towards pharmacovigilance among students of different healthcare profession colleges. Training to improve the knowledge through regular conferences, workshops and continued medical education (CME), and simplifying the reporting process with assistance will increase ADR reporting by healthcare professionals. Also, experiential learning about pharmacovigilance should start promptly in the professional education of healthcare professionals.

Acknowledgement

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