

# Evaluation and assessment of Knowledge, Attitude and Practice of Pharmacy students towards Pharmacovigilance in Saudi Arabia: A Cross sectional study.

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## Research article

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# Abstract

**BACKGROUND:** Pharmacovigilance is an important part of the health care system as it helps in the detection, assessment, reporting and prevention of Adverse Drug Reactions. Spontaneous reporting of adverse drug reaction plays a vital role in the success of Pharmacovigilance programs and pharmacy students are supposed to acquire sufficient knowledge and necessary skills required for practicing pharmacovigilance under different clinical settings. Hence, this study was carried out in the students of College of Pharmacy of a University in the Southern Province of Saudi Arabia to assess the Knowledge, Attitude and Practice (KAP) of undergraduate Pharmacy students towards Pharmacovigilance.

**METHODS:** A quantitative, prospective, cross-sectional online survey was carried out using a validated, self-administered questionnaire constituting 4 domains i.e. Demographics, Knowledge, Attitude and Practice of Pharmacovigilance among the pharmacy students of King Khalid University. **RESULTS:** The questionnaire was administered to 360 students out of which 329 responded (response rate of 91.3 %). The mean score of Level 7,8,9,10 and intern students for Knowledge was (3.03,5.37, 6.38, 6.19,6.42), Attitude (5.28,4.16, 5.62, 5.01, 5.29), and Practice (2.99, 3.25, 3.04, 3.43, 3.13) respectively. In addition, the findings indicated a significant difference in the mean score among different level of students for knowledge and attitude with a p-value of <0.0001, and 0.0002 respectively. The practice mean score showed there was no much significance among different level of students (p-value = 0.4108)

**CONCLUSION:** Our research findings revealed that the pharmacy students of the focused university have adequate knowledge and positive attitude towards adverse drug reaction. However, there is a dire need to understand and address concerns regarding real time practice patterns prevalent among Health Care Providers about pharmacovigilance under different clinical settings. **Keywords:** Pharmacovigilance, Knowledge, Attitude, Practice, Pharmacy students

## Background

Pharmacovigilance is an important part of the health care system as it helps in the detection, assessment, understanding and prevention of adverse drug reactions. It maintains the safety of the marketed medicines and primarily focusses on the adverse drug reactions and patient care. It also tries to heed on building healthy collaboration at different national and international levels, to deliver its complete benefits ("P V Chronicle - PV Jobs & Updates", 2018). At International level, World Health Organization (WHO) has an alliance with the Centre for International Drug Monitoring, Uppsala, to promote Pharmacovigilance whereas in Saudi Arabia the National Pharmacovigilance and drug safety center has been established under the charge of Saudi Food and Drug Authority which is responsible to promote Pharmacovigilance (Alshammari, Alshakka, Aljadhey, 2017). Adverse event reporting is a requisite for all the clinical research investigators, even if the side effects are only suspected. In other words, analyzing which side effects are worth the risk to patients compared with how effective they are at treating a disease. Spontaneous reporting of adverse drug reaction plays a prominent role in the success of Pharmacovigilance program (Muraraiah *et al.*, 2011).

As Pharmacovigilance is a subject of broad and current interest, significant studies have been carried out on this context globally Suyagh *et al.*, 2015, Alsaleh *et al.*, 2017, Gupta *et al.*, 2017 but limited studies have been carried out in this required domain in Saudi Arabia. So our aim was to widen it out and conduct a survey among the pharmacy students who are the future health care providers and being a pharmacy student they are supposed to acquire sufficient knowledge and necessary skills required for practicing pharmacovigilance under different clinical settings. This could result in an improvement in the Adverse drug reaction reporting in the future which will in turn reduce the health-care expenditures and costs associated with an adverse drug reaction and its treatment that goes beyond reach.

## Aim Of The Study

This study was carried out in the students of College of Pharmacy of a University in the Southern Province of Saudi Arabia to assess the Knowledge, Attitude and Practice (KAP) of undergraduate Pharmacy students towards Pharmacovigilance.

## Methods

*Study design and setting:* This prospective, cross-sectional descriptive online study was designed to assess the level of knowledge, attitudes and practices of Pharmacovigilance among the undergraduate students of College of Pharmacy, King Khalid University, Abha, Saudi Arabia.

*Target population, Sampling Criteria and Sample size:* The College of pharmacy of this university has a large group of students both male and female distributed in each level from Level-1 to Level-10. Each academic year comprises of 2 levels with a total of 5 years. Each level refers to a single semester of study. Later on they are subjected to a training period of one year in primary health care centers, and Pharmacies which is known as internship. This web-based survey was carried out on a sample of study participants constituting both male and female students who belonged to the fourth, fifth year students (Level-7,8,9,10) and those undergoing their internship during the study period (October 2018–November 2018). We excluded the students below Level-7 and the students who do not belong to the Pharmacy College.

We used a simple random sampling technique and our estimated sample size was 359 calculated by Raosoft method with a confidence interval of 99%. The online questionnaire link was given to the student leader of each level and they further forwarded the link to the students through their WhatsApp groups.

*Survey instrument development and Data collection:* Furthermore, a self-administered structured pre-validated questionnaire based on previous similar studies (Gupta, Sharma, Malhotra, 2017) was adapted. The questionnaire was then subjected to a review and validation process by experts from the members of the research team to ensure that the survey was sufficiently comprehensive and suitable to our study. A pilot study was then carried out to determine the validity, reliability and clarity of the questionnaire. The feedback was analyzed and a finalized questionnaire was developed accordingly.

The questionnaire constituted of 4 domains. The first section included the independent variables of the study i.e. details of participants like gender and level of education. The second section constituted of 11 closed-ended questions in a multiple choice format that intended to assess the Knowledge of students towards Pharmacovigilance. The third section constituted of 7 questions in Yes/No format to assess their attitude towards Pharmacovigilance, whereas the last section i.e. the fourth section included 6 questions pertaining to the practice of Pharmacovigilance in Yes/No format. The dependent variables of this study were Knowledge, Attitude, and Practice. The questionnaire was converted into a web-based format and was delivered to the study participants, with the data being collected from October to November 2018. Eligible participants were approached.

*Statistical Analysis:* The results were downloaded and stored in Microsoft excel spreadsheets. Data were analyzed using SPSS version 21.0 statistical software (IBM Inc., Chicago USA). Descriptive statistics (mean and standard deviation) were used to describe the categorical study and outcome variables. Unpaired student's t test, One way analysis of Variance and Bonferroni multiple comparison test were used to compare the mean score of the domains i.e Knowledge, Attitude and Practice between different gender and levels of students. A p-value of  $\leq 0.05$  and 95% confidence intervals was used to report the statistical significance and precision of results in the tables.

## Results

The online questionnaire constituting 3 dependent variables Knowledge, Attitude, Practice with a total score of 11, 7, and 6 respectively was self-administered to 359 participants, out of which 329 responded giving a response rate of 91.3 %. Seventy-seven percent (n = 254) of the students were based on the female campus, while the remaining 23% (n = 75) were based on the male campus.

*Gender wise comparison of mean scores for Knowledge, Attitude and Practice questions:*

The mean scores of the participant's knowledge was calculated which has been shown in Table-1. Unpaired student's t-test was carried out to compare the knowledge of the participants across different genders and it was estimated that the mean score of female participants was found to be  $6.2 \pm 2.1$ , whereas for the males it was  $5.79 \pm 2.25$  with an estimated two tailed p value of 0.1374 ( $<0.05$ ) which stated that the means were not significantly different.

Furthermore, Table-1 also shows the mean score of the participants towards attitude-based questions across different genders. Unpaired student's t-test was carried out to compare the attitude of the participants across different genders and it was estimated that the mean score of female participants was  $5.22 \pm 1.78$ , whereas for the males it was  $4.64 \pm 1.8$  with an estimated two tailed p value of 0.0131 ( $<0.05$ ) with a significant difference.

The students were also posed some basic questions which assessed their practice towards pharmacovigilance which has also been summarized in Table-1. Unpaired t-test was carried out to compare the practice of the participants across different genders and it was estimated that the mean

score of female participants was  $3.21 \pm 1.47$ , whereas for the males it was  $3.03 \pm 1.47$  with an estimated two tailed p value of 0.3459 ( $<0.05$ ) with no significant difference.

The mean score of knowledge of the participants were estimated and compared across different levels of both the genders. The mean score for Level-7,8,9,10 and the intern students was found to be  $3.03 \pm 1.47$ ,  $5.37 \pm 2.14$ ,  $6.38 \pm 2.21$ ,  $6.19 \pm 2.03$ ,  $6.42 \pm 2.31$  respectively. A one-way analysis of variance was carried out and the estimated p value was  $<0.0001$  ( $<0.05$ ) which showed there was a significant difference. A Bartlett's test for equal variances was also carried out with a p value of 0.0026 ( $<0.05$ ) which states that there was a significant difference between the groups. A bonferroni's multiple comparison test was also carried out across the different levels to know which group is more significant which has been clearly displayed in Table-2.

The mean score of the attitude of the participants were estimated and compared across different levels of both the genders. The mean score for Level-7,8,9,10 and the intern students was found to be  $5.28 \pm 1.82$ ,  $4.16 \pm 1.93$ ,  $5.62 \pm 1.56$ ,  $5.01 \pm 1.62$ ,  $5.29 \pm 1.76$  respectively. A one-way analysis of variance was carried out and the estimated p value was 0.0002 ( $<0.05$ ) which showed there was a significant difference. A Bartlett's test for equal variances was also carried out with a p value of 0.4716 ( $<0.05$ ) which states that there was no significant difference between the groups. A bonferroni's multiple comparison test was also carried out across the groups and the details have been summarized in Table-3.

The mean score of the practice of the participants were estimated and compared across different levels of both the genders. The mean score for Level-7,8,9,10 and the intern students was found to be  $2.99 \pm 1.53$ ,  $3.25 \pm 1.54$ ,  $3.04 \pm 1.56$ ,  $3.43 \pm 1.29$ ,  $3.13 \pm 1.42$  respectively. A one-way analysis of variance was carried out and the estimated p value was 0.4108 ( $<0.05$ ) which showed there was no significant difference. A Bartlett's test for equal variances was also carried out with a p value of 0.5233 ( $<0.05$ ) which states that there was no significant difference between the groups. A bonferroni's multiple comparison test was also carried out across the groups and the details have been summarized in Table-4.

## Discussion

From the findings of this study it was clear that the students of this university have adequate knowledge and positive attitude towards Pharmacovigilance which corroborates with the findings of (Abdel-Latif, Abdel-Wahab, 2015). In the findings of Abdel-Latif and Abdel-Wahab, 2015, the respondents were unable to correctly define the Pharmacovigilance term, but they were aware of ADRs whereas in our findings we could see that many students were able to define the term Pharmacovigilance correctly as well as they were very much aware about Adverse drug reactions and their reporting systems but most of them were not aware of the system followed in Saudi Arabia for reporting an Adverse drug reaction and also most of them had not seen the form used in Saudi Arabia. In a previous study conducted by Othman and colleagues among the Pharmacy students (Othman *et al.*, 2017), most of their respondents had a poor

knowledge on this concept which differs from the results of our university. There was another study conducted in Saudi Arabia in Dammam by Ali and his colleagues in which their respondents also had inadequate knowledge and poor attitude which differs from our results (Ali *et al.*, 2018). This difference in the findings of knowledge and attitude among different studies may be due to the differences in the teaching curriculum as well as the level of training received. Whereas regarding the practice of Pharmacovigilance, our study findings showed that the students required enough training to improve their skills. Many studies conducted previously among the student groups as well as those conducted among health care professionals by Suyagh *et al.*, 2015, Alsaleh *et al.*, 2017, Gupta *et al.*, 2017 stated that their study participants also had a poor practice which is in accordance with our findings.

Vora *et al.*, 2012, suggested that initiation of organized training programmes regarding Pharmacovigilance in undergraduate medical curriculum has to be mandatory if we wish to see better results in the future as these students are future prescribers in the society and also they suggested to provide an online and telephone line accesses to facilitate adverse drug reactions reporting system. This also implies to the students of our study because Pharmacy students are also future health care providers. So, conducting workshops in future to create awareness among them could be beneficial.

*Limitations:* This study is not without its limitations. The participants might have easily got the answers to the questions from their fellow-mates or through online access as we used a self-administered web-based questionnaire which could have affected the accuracy of our findings, particularly in the knowledge section, because this method does not allow us to have a look at the behavior of the participant while they complete the survey.

## **Conclusion**

Our research findings revealed that the Pharmacy students of this university have adequate knowledge and positive attitude towards adverse drug reaction reporting, however there is a dire need to understand and address concerns regarding real time practice patterns prevalent among Health Care Providers about Pharmacovigilance under different clinical settings. Educational intervention programs, like incorporation of this concept in undergraduate practical, Continuous medical education (CME), conducting workshop on pharmacovigilance may help in improving adverse drug reaction (ADR) monitoring and reporting skills.

## **Declarations**

### **ETHICS APPROVAL AND CONSENT TO PARTICIPATE:**

The study was approved by the Ethics Committee of College of Pharmacy, King Khalid University and all the respondents were asked for their verbal consent before participation in the study. Assessment of the responses was done blindly.

## CONSENT FOR PUBLICATION:

Not applicable

## AVAILABILITY OF DATA AND MATERIALS:

The data sets used during the current study are available from the corresponding author on reasonable request.

## COMPETING INTERESTS:

The authors declare that they have no competing interests.

## FUNDING:

The authors declare that they have not received any funding.

## AUTHORS' CONTRIBUTIONS:

<sup>A</sup>-Conceptualization, <sup>B</sup>-Formal analysis, <sup>C</sup>-Investigation, <sup>D</sup>-Methodology, <sup>E</sup>-Project administration, <sup>F</sup>-Resources, <sup>G</sup>-Supervision, <sup>H</sup>-Validation, <sup>I</sup>-Visualization, <sup>J</sup>-Writing—original draft, <sup>K</sup>-Writing—review & editing.

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## Tables

Table-1: Gender wise comparison of mean scores for Knowledge, Attitude and Practice questions

	Knowledge questions		Attitude questions		Practice questions	
	Females	Males	Females	Males	Females	Males
Mean	6.2	5.79	5.22	4.64	3.21	3.03
Std. Deviation	2.1	2.25	1.78	1.8	1.47	1.47
Std. Error	0.132	0.26	0.112	0.208	0.092	0.17
Lower 95% CI	5.95	5.27	5.04	4.29	3.06	2.74
Upper 95% CI	6.46	6.3	5.41	4.99	3.36	3.31

Table-2: Comparison of mean scores for Knowledge questions across different Levels of students

One-way analysis of variance					
P value	< 0.0001				
P value summary	***				
Are means signif. different? (P < 0.05)	Yes				
Number of groups	5				
F	36				
R squared	0.305				
Bartlett's test for equal variances					
Bartlett's statistic (corrected)	16.3				
P value	0.0026				
P value summary	**				
Do the variances differ signif. (P < 0.05)	Yes				
ANOVA Table	SS	df	MS		
Treatment (between columns)	598	4	149		
Residual (within columns)	1360	328	4.16		
Total	1960	332			
Bonferroni's Multiple Comparison Test	Mean Diff.	t	Significant? P < 0.05?	Summary	95% CI of diff
Level 7 vs Level 8	-2.34	6.54	Yes	***	-3.35 to -1.33
Level 7 vs Level 9	-3.36	9.27	Yes	***	-4.38 to -2.33
Level 7 vs Level 10	-3.16	9.32	Yes	***	-4.12 to -2.20
Level 7 vs In Training	-3.39	10.2	Yes	***	-4.33 to -2.46
Level 8 vs Level 9	-1.01	2.63	No	ns	-2.10 to 0.0756
Level 8 vs Level 10	-0.817	2.25	No	ns	-1.85 to 0.211
Level 8 vs In Training	-1.05	2.95	Yes	*	-2.06 to -0.0431
Level 9 vs Level 10	0.196	0.534	No	ns	-0.842 to 1.23
Level 9 vs In Training	-0.0392	0.109	No	ns	-1.06 to 0.981
Level 10 vs In Training	-0.235	0.697	No	ns	-1.19 to 0.719

Table-3: Comparison of mean scores for Attitude questions across different Levels of students

Table-3-Comparison of mean scores for Attitude questions across different Levels of students					
One-way analysis of variance					
P value	0.0002				
P value summary	***				
Are means signif. different? (P < 0.05)	Yes				
Number of groups	5				
F	5.82				
R squared	0.0668				
Bartlett's test for equal variances					
Bartlett's statistic (corrected)	3.54				
P value	0.4716				
P value summary	ns				
Do the variances differ signif. (P < 0.05)	No				
ANOVA Table	SS	df	MS		
Treatment (between columns)	70.8	4	17.7		
Residual (within columns)	990	325	3.04		
Total	1060	329			
Bonferroni's Multiple Comparison Test	Mean Diff.	t	Significant? P < 0.05?	Summary	95% CI of diff
Level 7 vs Level 8	1.12	3.62	Yes	**	0.245 to 1.99
Level 7 vs Level 9	-0.34	1.09	No	ns	-1.22 to 0.543
Level 7 vs Level 10	0.263	0.9	No	ns	-0.564 to 1.09
Level 7 vs In Training	-0.0117	0.0408	No	ns	-0.823 to 0.799
Level 8 vs Level 9	-1.46	4.43	Yes	***	-2.39 to -0.528
Level 8 vs Level 10	-0.856	2.75	No	ns	-1.74 to 0.0235
Level 8 vs In Training	-1.13	3.7	Yes	**	-2.00 to -0.267
Level 9 vs Level 10	0.604	1.92	No	ns	-0.285 to 1.49
Level 9 vs In Training	0.329	1.06	No	ns	-0.544 to 1.20
Level 10 vs In Training	-0.275	0.952	No	ns	-1.09 to 0.542

Table-4: Comparison of mean scores for Practice questions across different Levels of students

Table-4-Comparison of mean scores for Practice questions across different Levels of students					
One-way analysis of variance					
P value	0.4108				
P value summary	ns				
Are means signif. different? (P < 0.05)	No				
Number of groups	5				
F	0.994				
R squared	0.0121				
Bartlett's test for equal variances					
Bartlett's statistic (corrected)	3.21				
P value	0.5233				
P value summary	ns				
Do the variances differ signif. (P < 0.05)	No				
ANOVA Table	SS	df	MS		
Treatment (between columns)	8.53	4	2.13		
Residual (within columns)	697	325	2.15		
Total	706	329			
Bonferroni's Multiple Comparison Test	Mean Diff.	t	Significant? P < 0.05?	Summary	95% CI of diff
Level 7 vs Level 8	-0.26	0.999	No	ns	-0.993 to 0.474
Level 7 vs Level 9	-0.0503	0.192	No	ns	-0.792 to 0.691
Level 7 vs Level 10	-0.442	1.8	No	ns	-1.14 to 0.252
Level 7 vs In Training	-0.145	0.604	No	ns	-0.826 to 0.535
Level 8 vs Level 9	0.209	0.756	No	ns	-0.573 to 0.992
Level 8 vs Level 10	-0.183	0.7	No	ns	-0.922 to 0.556
Level 8 vs In Training	0.114	0.444	No	ns	-0.611 to 0.839
Level 9 vs Level 10	-0.392	1.49	No	ns	-1.14 to 0.354
Level 9 vs In Training	-0.0952	0.367	No	ns	-0.828 to 0.638
Level 10 vs In Training	0.297	1.22	No	ns	-0.389 to 0.983

## Supplementary Files

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