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Original Article

Knowledge, Attitudes, and Practices Toward Pharmacovigilance and Adverse Drug Reaction Reporting.

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ABSTRACT

Background: Pharmacovigilance is central to drug safety, as it detects, evaluates, and prevents adverse drug reactions (ADRs). Pharmacy students embody future front-line reporters of ADRs; hence, assessing knowledge, attitude and practice (KAP) towards pharmacovigilance is critical to reinforce systems of drug safety.
Objective: To determine the knowledge, attitude, and practice toward pharmacovigilance and ADR reporting among undergraduate pharmacy students at the College of Pharmacy, University of Al-Nahrain, Iraq, and determine factors associated with KAP outcomes.
Methods: A cross-sectional study was conducted among Stage 4 and Stage 5 undergraduate pharmacy students in the academic year between 2025–2026. Data were collected using a well-established, structured, self-administered electronic questionnaire to cover demographics and KAP domains. Knowledge and practice items were scored based on specific criteria and attitude was assessed using a 5-point Likert scale. All data were analyzed through JASP software. We tested normality using the Shapiro–Wilk test. Non-parametric tests, independent t-tests, Spearman correlation, and multiple linear regression analyses were used. The statistical significance was $p \leq 0.05$.
Results: The sample consisted of 222 students in total. Overall, students showed moderate degrees of knowledge and practice, and generally positive attitudes toward pharmacovigilance. Students were scored higher on mean practice and attitude if they had received formal pharmacovigilance instruction. The academic stage and formal instruction significantly predicted practice scores, whereas academic stage and gender predicted knowledge scores. Formal teaching also was the only major predictor of attitude. Regression models accounted for 4.1% of knowledge variance and 12.1% for practice scores.
Conclusion: Pharmacovigilance was acceptable knowledge and attitude, whereas practice varied among undergraduate pharmacy students. Formal instruction and learning progression greatly enhanced practical involvement. Introducing long-term, practice-based pharmacovigilance training in the pharmacy curriculum is suggested to improve ADR reporting behavior and medication safety outcomes.

Keywords: Pharmacovigilance; Adverse Drug Reaction; ADR Reporting; Knowledge Attitude Practice; Pharmacy Students; Drug Safety; Pharmacovigilance Education; Undergraduate Pharmacy.

INTRODUCTION

Adverse Drug Reactions (ADRs) represent a significant and pressing public health problem that poses serious challenges and risks to individuals and health systems. In response to this critical issue, regulatory authorities worldwide diligently monitor and evaluate the safety and efficacy of drugs that are currently available in the market (1). Pharmacovigilance (PV) is an important component of patient safety encompassing the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) and other problems related to drugs, such as drug-drug interactions, allergy-related problems, and side effects, also deals with communicating the safety of medicines through risk minimization strategies. It

constitutes the basic scientific knowledge about morbidity, mortality, and risk assessment of ADR detection, prevention, analysis, and improves peoples health at grassroots (2).

A 2019 published review article reported pharmacovigilance impact in the withdrawal of dangerous medications (e.g., Cisapride) from the market (3). Assessments of pharmacovigilance awareness and practices among health professions, especially emerging professionals, are scarce. Pharmacy students are unique in their need to possess pharmacovigilance awareness and share knowledge with other professions to protect the population and remain relevant in the pharmaceutical industry (4).

Pharmacovigilance systems are only as good as the regulatory frameworks, the knowledge, attitude, and practices (KAP) of healthcare professionals toward reporting an adverse drug reaction (ADR). Low levels of awareness, negative perceptions, and poor reporting behavior have been documented among healthcare providers as major barriers to effective pharmacovigilance. Hence, overcoming these barriers is important for improving ADR reporting and ensuring patient safety. In addition, with more drugs being approved, the population getting older and more people taking several medicines at once along with new health problems coming up, it is likely that ADRs will happen even more often (5).

Knowledge, Attitude and Practice (KAP) studies have emerged as the key check point of the intervention and prevention monitoring of public health (2). Evaluation of KAP has been undertaken in several health professionals and students, but limited on pharmacy students (6). Pharmacovigilance systems serve multiple purposes including regulation, hazard signal information collection, risk-benefit assessment, risk communication, and risk minimization (7).

In several countries, education and training significantly influence KAP among pharmacy undergraduates. Findings from a questionnaire-based study suggest education-related exposure is a pivotal KAP determinant. A colour-coded framework shows three variables linking educational exposure to pharmacovigilance KAP and emphasising the need for regulatory compliance to prevent drug safety issues. KAP literature features a limited focus on pharmacy students. Degrees and institutions differ in global pharmacovigilance KAP, sustaining demand for assessment as an educational intervention to enhance drug-safety behaviors (8).

Therefore, this study aimed to assess knowledge, attitude, and practice toward pharmacovigilance among undergraduate pharmacy students at Al-Nahrain University.

MATERIAL AND METHODS

Study Design and Setting

Study Design and Setting Conducted to investigate the knowledge, practice and attitude about pharmacovigilance among undergraduate pharmacy students at the College of Pharmacy, University of Al-Nahrain, Iraq, during the academic year [2025-2026].

Study Population and Sample Size

This study population included undergraduate pharmacy students study Stage 4 and Stage 5 undergraduate studies held at the College of Pharmacy, University of Al-Nahrain. Students who were willing to be involved, and who filled out the questionnaire, remained in the study. The final analysis excluded lecturers and incomplete answers in order to guarantee homogeneity of researchers' work group. A total of 222 questionnaires completed were included in the final analysis.

Data Collection Tool

Data were collected via a structured, self-administered questionnaire developed based on several previous papers that examined knowledge, practice and attitude towards pharmacovigilance (KPA). There were four primary sections of the questionnaire: Demographic Characteristics: gender, age group, and academic stage. Knowledge domain: five items (K1-K5) to assess knowledge; pharmacovigilance and adverse drug reaction (ADR) reporting. Practice domain: four items in the P1–P4 range on experience and behavior of ADR reporting. Attitude domain: four statements (A1–A4) were measured on a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5).

Face and Content Validity

he face and content validity of the questionnaire was verified before the data was collected. The first draft of the questionnaire was audited by a member of a panel comprising academic pharmacy and pharmacovigilance experts to assess the validity, specificity, and relevance of each item. Experts examined whether the items sufficiently addressed the main domains of knowledge, practice, and attitudes towards pharmacovigilance. Improvements were made to wording and clarity, as well as coverage of content based on their feedback. Final version of the questionnaire was deemed to show a satisfactory face and content validity.

Scoring System

Knowledge Items were assigned a Score of 1 for each correct answer and 0 for the wrong answer. One multiple-response knowledge item (K4) was scored by assigning one point for each correct option selected, with a maximum score of 3. Overall knowledge score varied from 0 to 7. Practice items were scored using predetermined criteria and higher scores corresponded to improved pharmacovigilance practice. The total score of practice ranged from 0 to 9. Items regarding attitude were scored from 1 to 5 on a Likert scale. An item that was negatively phrased was reverse coded before analysis. The attitude rating was on a scale of 4 to 20 with 4 being the lowest score and 20 the highest score representing a more positive attitude towards pharmacovigilance.

Data Collection Procedure

The questionnaire was administered electronically using Google Forms. Participation was voluntary, and electronic informed consent was taken from all participants prior to filling out the questionnaire. No personally identifying information has been gathered from respondents for the purpose of making responses anonymous and confidential.

Statistical Analysis

Data Analysis Data were analyzed using JASP software version [0.19.3.0 mac]. Demographic characteristics and KPA scores were presented with descriptive statistics. Continuous variables were represented as mean ± SD (standard deviation) and categorical variables as frequencies and percentages. The Shapiro–Wilk was used to show the normality of the distribution data. The significance of the data deviating significantly from normal distribution ($p < 0.05$) has led to a widespread reliance on non-parametric statistical tests for data analyses. To compare KPA outcomes, the Mann–Whitney U test was deployed between groups according to gender, academic stage, and receiving formal pharmacovigilance training. Due to the still relatively large sample size, independent samples t-tests were also performed for comparison. A Spearman's rank correlation coefficient was applied to test the link between knowledge, practice, and attitude scores. A multiple linear regression model was performed to identify independent predictors of key items in knowledge, practice and attitude assessments. Gender, status in terms of education and having been formally taught by the education system to keep vigilant for pharmacovigilance were added to the regression models. An average of $p = 0.05$ or less was considered a statistical significance.

Ethical Considerations

Ethical approval on the study was acquired from the Scientific and Ethical Committee of the College of Pharmacy, University of Al-Nahrain, Iraq. Participation was voluntary and electronic informed consent was received from all participants before data collection. The data were held Confidentiality and Anonymity was adhered throughout.

RESULT

Participant Characteristics

A total of 222 undergraduate pharmacy students from Stage 4 and Stage 5 at the College of Pharmacy, University of Al-Nahrain, were included in the final analysis. Females constituted the majority of participants (n = 150, 67.5%), while males accounted for 72 (32.4%). Most participants were from Stage 5 (n = 127, 57.2%). The distribution of participants according to receipt of formal instruction in pharmacovigilance is presented in Table 1.

Table 1. Demographic characteristics of participants (N = 222)

Variable	**n (%)**
Gender	
Male	72 (32.4)
Female	150 (67.6)
Academic stage	
Stage 4	95 (42.8)
Stage 5	127 (57.2)
Received formal instruction in pharmacovigilance	
Yes	175 (78.8)
NO	47 (21.2)

Descriptive Statistics of KPA Scores

Overall, participants demonstrated moderate levels of knowledge and practice, with generally positive attitudes toward pharmacovigilance. Students who reported receiving formal instruction showed slightly higher mean scores across all three domains compared with those who had not received formal instruction (Table 2).

Table 2. Descriptive statistics of Knowledge, Practice, and Attitude scores by formal instruction

Domain	Formal Instruction	Mean	SD
Knowledge	Yes	6.10	1.31
Knowledge	No	6.00	1.20
Practice	Yes	5.57	2.3
Practice	No	4.70	2.4
Attitude	Yes	13.88	3.3
Attitude	No	12.68	3.1

Normality Testing

The Shapiro–Wilk test demonstrated significant deviation from normality for K_total, P_total, and A_total ($p < 0.05$). Therefore, non-parametric statistical tests were prioritized for group comparisons.

Gender Differences

Using the Mann–Whitney U test, no statistically significant difference was observed between male and female participants in knowledge scores ($p = 0.061$) or attitude scores ($p = 0.161$). However, a highly significant difference was found in practice scores ($p < 0.001$), indicating that one gender group demonstrated significantly better pharmacovigilance practice than the other (Table 3).

Table 3. Comparison of KPA scores by gender (Mann–Whitney U test)

Domain	Male Mean	Female Mean	p-value	Interpretation
Knowledge	5.87	6.18	0.061	NS
Practice	5.51	5.32	<0.001	Significant
Attitude	13.87	13.50	0.161	NS

Effect of Formal Instruction

Independent samples t-tests showed no statistically significant difference in knowledge scores between students who received formal instruction and those who did not ($p = 0.628$). However, significant differences were observed for practice ($p = 0.025$) and attitude ($p = 0.029$), with higher scores among those who received formal instruction (Table 4).

Table 4. Independent samples t-test comparing KPA scores by formal instruction

Domain	t	df	p
Knowledge	-0.485	220	0.628
Practice	-2.250	220	0.025
Attitude	-2.200	220	0.029

Multiple Linear Regression Analysis

Predictors of Knowledge (K_total)

Multiple linear regression analysis showed that the overall model was statistically significant ($F = 3.09$, $p = 0.028$), explaining 4.1% of the variance in knowledge scores ($R^2 = 0.041$). Academic stage ($p = 0.013$) and gender ($p = 0.031$) were significant independent predictors of knowledge, whereas receipt of formal instruction was not significant after adjustment ($p = 0.691$) (Table 5).

Table 5. Multiple linear regression analysis for predictors of Knowledge (K_total)

Predictor	B	t	p
Gender	0.403	2.165	0.031
Stage	0.440	2.494	0.013
Instruction	0.083	0.398	0.691

Model statistics: $R^2 = 0.041$, $F(3,218) = 3.09$, $p = 0.028$.

Predictors of Practice (P_total)

The regression model for practice scores was highly significant ($F = 9.99$, $p < 0.001$), explaining 12.1% of the variance ($R^2 = 0.121$). Academic stage ($p < 0.001$) and formal instruction ($p = 0.033$) were significant predictors of practice scores, while gender was not a significant predictor ($p = 0.635$) (Table 6).

Table 6. Multiple linear regression analysis for predictors of Practice (P_total)

Predictor	B	t	p
Gender	0.071	0.475	0.635
Stage	0.912	4.909	<0.001
Instruction	0.331	2.151	0.033

Model statistics: $R^2 = 0.121$, $F(3,218) = 9.99$, $p < 0.001$.

Predictors of Attitude (A_total)

The regression model for attitude scores was not statistically significant overall (p = 0.102). However, formal instruction emerged as the only significant individual predictor of attitude (p = 0.033), while gender and academic stage were not significantly associated with attitude scores (Table 7).

Table 7. Multiple linear regression analysis for predictors of Attitude (A_total)

Predictor	p	Significance
Gender	>0.05	NS
Stage	>0.05	NS
Instruction	0.033	Significant

Model statistics: overall model p = 0.102.

Our study give a comprehensive evaluation of pharmacovigilance knowledge, practice, and attitude (KPA) between students, with a focus on the impact of study instruction, college stage, and gender. The findings illustrate that moderate levels of knowledge and practice, alongside generally positive attitudes, indicating good preparingor pharmacovigilance knowledge .

Knowledge of Pharmacovigilance:

The overall knowledge scores observed in our study were moderate, indicate that participants have a basic understanding of pharmacovigilance concepts with lack of more comprehensive knowledge. Academic stage playa significant predictor of knowledge, indicating that progression to the syllabus contributes good to pharmacovigilance knowledge. This finding is consistent with previous research showing that increased clinical stady and cumulative learning practice improve students' understanding about adverse drug reaction (ADR) reporting systems (9,10).

On other side, formal instruction did not demonstrate a significant independent effect on knowledge levels in the regression model. This indicate that isolated or short-term instructional study may be not enough to produce longterm improvements in pharmacovigilance knowledge. Similar conclusions have been noted in other studies, illustratethat pharmacovigilance study should be given in longitudinally rather than delivered as a single theoretical component (11).

Gender was also illustrate that a significant predictor of knowledge, which aligns with findings from some of studies but remains inconsistent with the literature. This differences may reflect contextual, educational, or cultural differences more than inherent gender-based disparities (12).

Pharmacovigilance Practice:

Practice scores were significantly influenced by both academic stage and formal instruction, with the decrease in model explaining a greater proportion of variance compared to the knowledge domain. These findings suggest that practical teaching in pharmacovigilance activities improves as students advance academically and receive targeted instruction.

Notice that, formal instruction had a stronger effect on practice rather than on knowledge, this indicating that structured educational interventions has more effective in shaping practical behavior than theoretical understanding alone. This supports by previous study demonstrating that workshops, case-based learning, and hands-on training can significantly improve ADR reporting practices (13,14).

The strong association between college stage and practice further improve the importance of experemental learning in clinical study, where students can notice that and participate in real-world pharmacovigilance processes.

Attitude Toward Pharmacovigilance

Participants generally reveal a good attitudes toward pharmacovigilance, reflecting a high level of awareness regarding patient safety and the importance of ADR reporting. Formal instruction hsd the only influnce predictor of attitude in the regression study, suggesting that educational play good affectonstudents' perceptions and motivation to follow in pharmacovigilance activities.

There is no significant differences by academic stage used that favorable attitudes may be established early in training and remain stable during academic progression.

This observation of the consistent with previous studies illustrate that attitudes toward pharmacovigilance are often good when knowledge and practice are suboptimal (15).

Statistical and Methodological Considerations:

Although normality assumptions were violated for several variables, the use of complementary non-parametric study supported the robustness of the results. The analysis between parametric and non-parametric results strengthens the finding in the observed associations.

Educational Implications:
Our study find the underscore the need for a longitudinal and practice-oriented pharmacovigilance curriculum. While formal instruction has good influences practice and attitude, its limited effect on knowledge this indicate that repeated reinforcement in academic stages is important. Embedding pharmacovigilance concepts within clinical training and assessment frameworks may give us to more meaningful and sustainable learning outcomes.

Limitations:
In our study there is limited by its cross-sectional study, which restricts causal inference. Additionally, searching on self-reported data may produce instructions bias. Future study employing longitudinal or interventional study will be recommended to evaluate the long-term effect of integrated pharmacovigilance education strategies.

REFERENCES

1. Ashok Wath D, Rathod P, Wadhwa S, Narlawar U. IJCM_245A: Beyond the Basics: Insights into Pharmacovigilance Literacy among Postgraduate Medical students: A Mixed-Methods study from central India.. 2024. ncbi.nlm.nih.gov
2. Mwakawanga DL, Kilonzi M, Philipo EG, Martine A, Mbilinyi T, Kileo NF, Mkinga B, Shonyella CJ, Mohamedi JA, Clement A, Mwasomola D. Pharmacovigilance and adverse drug reactions reporting: healthcare Providers' experiences from southern highland Tanzania. Advances in Pharmacological and Pharmaceutical Sciences. 2023;2023(1):5537592. wiley.com
3. Alomar M, Palaian S, Al-Tabakha MM. Pharmacovigilance in perspective: drug withdrawals, data mining and policy implications. F1000Research. 2019 Dec 16;8:2109.
4. Palaian S, Izham Mohamed Ibrahim M, Mishra P, Ravi Shankar P. Assessment of a Pharmacovigilance Module: An Interventional Study on Knowledge, Attitude, and Practice of Pharmacy Students. 2021. ncbi.nlm.nih.gov
5. 5.Batel-Marques F, Penedones A, Mendes D, Alves C. Outcomes from the first 6 years of operation of the Central Portugal Pharmacovigilance Unit. Journal of patient safety. 2020 Sep 1;16(3):e136-42.
6. Bepari A, Kalimulla Niazi S, Al-Otaibi A. The Efficiency of Multi-Faceted Educational Intervention on Knowledge, Perceived Behavior, and Practice Skills towards Pharmacovigilance among Undergraduate Pharmacy Students of India. 2019. ncbi.nlm.nih.gov
7. Sartori D, Aronson JK, Norén GN, Onakpoya IJ. Signals of adverse drug reactions communicated by pharmacovigilance stakeholders: a scoping review of the global literature. Drug safety. 2023. springer.com
8. Hasan HE, Jaber D, Al Tabbah S, Lawand N, Habib HA, Farahat NM. Knowledge, attitude and practice among pharmacy students and faculty members towards artificial intelligence in pharmacy practice: A multinational cross-sectional study. Plos one. 2024 Mar 1;19(3):e0296884. plos.org
9. Herdeiro MT, Figueiras A, Polónia J, Gestal-Otero JJ. Influence of pharmacists' attitudes on adverse drug reaction reporting. Drug Saf. 2012;35:493–503.
10. Sweileh WM, Abu-Hadeed HM, Al-Jabi SW, Zyoud SH. Pharmacovigilance knowledge, attitude and practice among healthcare professionals. Int J Clin Pharm. 2014;36:445–452.
11. AlShammari TM, et al. Pharmacovigilance education and ADR reporting. Saudi Pharm J. 2021;29:463–470.
12. Khan TM, Sulaiman SA, Hassali MA. Factors influencing adverse drug reaction reporting among healthcare professionals. J Patient Saf. 2019;15:e30–e35.
13. Backstrom M, Mjorndal T, Dahlqvist R, Nordkvist-Olsson T. Attitudes to reporting adverse drug reactions in Sweden. Eur J Clin Pharmacol. 2007;63:525–531.
14. Abu Hammour K, et al. Effect of educational intervention on ADR reporting. BMC Med Educ. 2017;17:200.
15. Gavaza P, Brown CM, Lawson KA, Rascati KL, Wilson JP, Steinhardt M. Influence of attitudes on pharmacists' intention to report serious adverse drug events. J Am Pharm Assoc. 2011;51:361–367