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RESEARCH ARTICLE

Gaps in pharmacovigilance education: Insights from pharmacy students in a Nigerian university

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Abstract

Background: Pharmacy students represent the future workforce in pharmacovigilance systems, yet gaps in their education persist, particularly in low- and middle-income countries. This study aimed to identify gaps in pharmacovigilance education and its determinants and examine specific barriers to ADR reporting among pharmacy students. **Methods:** A descriptive cross-sectional study was conducted among pharmacy students in a Nigerian university. Data were collected using a structured, self-administered questionnaire. Descriptive and inferential statistics were used to analyse the data. **Results:** The median (IQR) KAP scores were 6 (4–8), 6 (5–7), and 4 (2–7), respectively. While 78.5% of students correctly defined pharmacovigilance, only 5.9% identified the WHO monitoring centre. Positive attitudes were observed, with 90.0% supporting pharmacovigilance integration into the curriculum, but only 22.8% had ever reported an ADR. Determinants of poor knowledge included being in the third (AOR = 16.0, $p < 0.001$) and fourth (AOR = 15.1, $p < 0.001$) years of study. The most commonly reported barrier to ADR reporting was the lack of knowledge about reporting ADRs (78.0%). **Conclusion:** This study highlights significant gaps in pharmacovigilance education. The findings underscore the need for comprehensive curriculum reforms and practical training to enhance pharmacovigilance competency and prepare students for active roles in ADR reporting.

Introduction

Pharmacovigilance (PV) is an essential component of the healthcare system, aimed at monitoring, detecting, assessing, and preventing adverse drug reactions (ADRs) to ensure patient safety and improve therapeutic outcomes (World Health Organisation, 2002). The increasing complexity of pharmacotherapy and the rapid introduction of new drugs into the market underscore the importance of robust PV systems, particularly in low- and middle-income countries (LMICs) where systems for drug safety monitoring are often underdeveloped (Uribe et al., 2023).

Pharmacists, as frontline healthcare providers, play a pivotal role in PV and ADR reporting. Effective reporting relies not only on their clinical skills but also on their knowledge, attitudes, and practices (KAP) regarding PV (Oreagba *et al.,* 2011; Ahmad *et al.,* 2013). Pharmacy students represent the future workforce in this domain, and their training is critical to ensuring the sustainability and effectiveness of PV systems.

In Nigeria, ADR reporting is mandatory for healthcare professionals, and the National Agency for Food and Drug Administration and Control (NAFDAC) serves as the regulatory body overseeing PV and ADR reporting activities. Despite this mandate and the critical role of PV in ensuring medication safety, pharmacy students often encounter substantial barriers that hinder their active engagement in ADR reporting. These barriers can be categorised into systemic, educational, and practical challenges, each contributing to the underreporting of ADRs and limiting the effectiveness of PV efforts.

Systemic barriers stem from broader institutional, regulatory, and healthcare system limitations that restrict students' involvement in ADR reporting. A notable challenge is the lack of institutional support for PV, as many universities and healthcare facilities do not actively promote ADR reporting or provide structured

mechanisms for student participation (Farha *et al.,* 2015; Alshakka *et al.,* 2017). Weak PV infrastructure, particularly in LMICs, further exacerbates this issue, as inefficient, underutilised, or poorly integrated ADR reporting systems create obstacles to student engagement (Subish *et al.,* 2010). Regulatory gaps, including unclear guidelines, bureaucratic processes, and weak enforcement of PV policies, also lead to uncertainty among students regarding their role in ADR reporting (Eze *et al.,* 2022; Anbeo & Abacioğlu, 2023; Khan *et al.,* 2023; Nduka *et al.,* 2024). Furthermore, a limited reporting culture within healthcare institutions and academia means that faculty members and healthcare professionals often fail to emphasise or model ADR reporting (Eze *et al.,* 2022; Khuspe, 2024), reducing opportunities for students to gain practical experience.

Educational challenges primarily arise from deficiencies in pharmacy curricula and training methodologies (Showande & Oyelola, 2013). A significant limitation is the insufficient and inadequately structured PV education, which tends to focus more on theoretical concepts than practical applications (Osemene *et al.,* 2012). Many pharmacy programmes introduce PV late in the curriculum, reducing students' opportunities to develop a solid foundation in ADR reporting early on (Subish *et al.,* 2010; Farha *et al.,* 2015). Additionally, many programmes lack structured hands-on training, such as case-based learning, role-playing exercises, or supervised ADR reporting (Haridass *et al.,* 2017). The lack of integration of PV into clinical training further hinders student preparedness, as many students are not directly exposed to ADR reporting during internships or clinical placements (Eze *et al.,* 2022). Without real-world practice, the transition from theoretical knowledge to practical application remains challenging.

Beyond systemic and educational barriers, pharmacy students face practical challenges, which influence their willingness and ability to report ADRs. One of the most common issues is a lack of awareness regarding ADR reporting procedures, as students often do not know where, when, or how to submit reports (Tekel *et al.,* 2021; Islam Rasel *et al.,* 2023; Jarab *et al.,* 2023). This knowledge gap can make the reporting process seem complex or intimidating. Another significant challenge is fear—students may hesitate to report ADRs due to concerns about the accuracy of their observations, potential professional repercussions, or uncertainty about their authority to submit reports (Tekel *et al.,* 2021; Jarab *et al.,* 2023). Time constraints further compound the issue (Tekel *et al.,* 2021; Malla *et al.,* 2023), as students juggling coursework, internships, and other responsibilities may perceive ADR reporting as an additional burden rather than a professional obligation. Moreover, a perceived lack of impact associated with ADR reporting reduces motivation. Some students believe their reports may not lead to meaningful action or changes in medication safety policies, leading to disengagement from PV activities (Jarab *et al.,* 2023). Without feedback mechanisms or examples of how ADR reports contribute to public health improvements, student participation remains low.

Addressing these barriers is crucial for equipping pharmacy students with the necessary skills and confidence to engage in PV, ultimately improving drug safety and public health outcomes. In the last eight years, studies have assessed the knowledge and attitudes of pharmacy students toward PV and ADR reporting, noting deficiencies in both areas (Showande & Oyelola, 2013; Osemene & Afolabi, 2017). However, none of these studies have comprehensively investigated pharmacy students' practices and the determinants of PV knowledge, attitudes, and practices (KAP) adjusted for relevant confounders or the relationship between KAP and ADR reporting among pharmacy students.

This study aims to bridge these gaps by assessing pharmacy students' current KAP levels regarding PV and ADR reporting, identifying critical determinants of poor KAP and examining specific barriers preventing participation. It is guided by four questions:

1. What is the current KAP level regarding PV and ADR reporting among pharmacy students in Nigeria?

2. What are the determinants of poor KAP regarding PV and ADR reporting?

3. What specific barriers prevent pharmacy students from engaging in ADR reporting?

4. What strategies can enhance PV education and improve ADR reporting practices among pharmacy students?

This study provides a critical evaluation of the current state of PV education, highlighting gaps in students' understanding and engagement. The findings could drive curriculum reform by integrating more comprehensive training on ADR reporting, practical case studies, and hands-on PV exercises. Training improvements through workshops, simulations, and collaboration with regulatory bodies could enhance students' confidence and motivation to report ADRs. Strengthening these areas would better prepare future pharmacists for their crucial role in medication safety.

Building on previous research in Nigeria and other LMICs, this study uniquely focuses on pharmacy students' preparedness before entering professional practice. Unlike prior studies that primarily surveyed

practising pharmacists or physicians (Oshikoya & Awobusuyi, 2009; Joubert & Naidoo, 2016; Nisa *et al.,* 2018; Gordhon & Padayachee, 2020; Kumari *et al.,* 2020; Alam *et al.,* 2021; Asiamah *et al.,* 2022; Alwidyan *et al.,* 2025), this study examines the effectiveness of pharmacy education in fostering PV competencies at the undergraduate level. It also identifies unique barriers specific to Nigerian pharmacy students, such as curriculum deficiencies and the lack of practical training, informing targeted educational reforms.

This study could drive meaningful changes in PV training at universities and influence broader policy recommendations. It could prompt universities to revise pharmacy curricula and include structured PV training by identifying educational gaps and a lack of engagement in ADR reporting among pharmacy students. Strengthening collaborations with regulatory bodies such as Nigeria's NAFDAC could further provide students with real-world PV experience.

Beyond curriculum reforms, this study underscores the need for faculty training in PV. Universities may introduce specialised programmes and continuous professional development workshops to ensure educators remain updated on global PV standards, allowing effective teaching of ADR reporting. Integrating digital and technological tools, such as mobile applications, electronic reporting systems, and interactive e-learning modules, could also enhance student engagement and familiarity with PV practices.

On a national policy level, this study's findings could support mandating early PV education in pharmacy programmes, ensuring students are prepared to contribute to medication safety from the outset of their careers. Identifying PV training gaps at the student level could serve as a model for other LMICs facing similar challenges. Addressing these gaps could standardise pharmacy education globally, ultimately improving medication safety and public health outcomes.

Methods

Design

This descriptive cross-sectional study was conducted among pharmacy students in a Nigerian university.

Sample size determination

The minimum required sample size for the study was calculated using the Raosoft online sample size calculator. The calculation was based on a total population of 323 undergraduate pharmacy students in their third to fifth year at the University of Maiduguri during the 2023/2024 academic year, with a margin of error of 5.0% and a confidence interval of 95.0%. Thus, the recommended minimum sample size for the study was 176.

Study population and sampling

The study population consisted of undergraduate pharmacy students in their third, fourth, and fifth years of study. These groups were selected as they are more likely to have been exposed to pharmacological concepts and clinical experiences. All 323 eligible students participated in the study. Inclusion criteria included enrolment in the pharmacy programme and willingness to provide informed consent. Students in the first and second years of the pharmacy programme and those from other faculties were excluded.

Development of the data collection tool and validity and reliability analysis

A structured, self-administered questionnaire was developed based on similar studies (Elkalmi *et al.,* 2011; Farha *et al.,* 2015; Alwhaibi *et al.,* 2020; Tekel *et al.,* 2021), ensuring it aligns with international PV guidelines. The instrument was designed to assess (1) knowledge of PV and ADR reporting, (2) attitudes towards ADR reporting and its perceived importance, and (3) self-reported practices and barriers to ADR reporting. Three experts in PV, pharmacy education, and public health, respectively, reviewed and refined the questionnaire before administration to improve content validity. A pilot study was conducted with a small group of 30 second-year pharmacy students. This step was taken to ensure the questionnaire is clear and comprehensible, culturally and contextually appropriate, and reliable and valid for measuring the intended constructs.

Based on feedback from the pilot study of the original 37-item KAP instrument, specifically regarding the questionnaire's appearance, formatting, clarity, and ease of interpretation, necessary modifications were made to enhance its face validity. For reliability testing, response options in the knowledge domain were collapsed into "*correct*" and "*incorrect*" categories. The Cronbach's alpha values of 0.73, 0.68, and 0.75 were obtained for the knowledge, attitudes, and practices domains, respectively. Also, removing two items from the original 10-item attitude domain improved its Cronbach's alpha to 0.70, resulting in an overall mean Cronbach's alpha of 0.73, suggesting a good level of reliability for the instrument. The final version of the questionnaire comprised 35 KAP items divided into four sections:

Demographics: This section included age, sex, year of study, and previous undergraduate degrees.

Knowledge: fifteen items assessed awareness of PV concepts, tools, and reporting systems. Responses were based on the options provided.

Attitudes: eight items measured students' perceptions and beliefs regarding PV education and ADR reporting. Responses were on five point Likert scale (strongly agree, agree, neutral, disagree, and strongly disagree).

Practices: eleven items evaluated participation in ADR reporting activities and exposure to PV resources, with responses on three-point Likert scale (no, yes, and can't say). One item assessed barriers to PV and ADR reporting.

Data collection procedure

Data collection was conducted over eight weeks, from September to October 2024, to ensure adequate participation. The final version of the questionnaire was administered in paper-based formats. Surveys were distributed in lecture halls, and participants were given sufficient time to complete them. Completed questionnaires were collected on the same day to minimise the risk of response loss.

Data entry and transformation

Double data entry was implemented to minimise errors and enhance reliability. Responses from the paper-based questionnaire were entered independently by two individuals to cross-check for discrepancies. When there was a discrepancy, the original paper forms were reviewed to determine the correct entry.

Responses to the knowledge, attitudes, and practices (KAP) items were transformed using modified Bloom's cut-offs (Bloom, 1956) as follows:

Knowledge: Responses were categorised as "*correct*" (scored 1) or "*incorrect*" (scored 0). A total score of ≥ 60.0% (9–15 points) was classified as "*good knowledge*", while a score < 60.0% (1–8 points) was considered "*poor knowledge*".

Attitudes: Responses of the five-point Likert scale were dichotomised. "*Agree*" (strongly agree and agree) was scored 1, and "*disagree*" (neutral, disagree, and strongly disagree) was scored 0. A total score of ≥ 62.5% (5–8 points) was categorised as "*positive attitude*", and a score < 62.5% (1–4 points) as "*negative attitude*".

Practices: Responses of "*can't say*" were merged with "*no*". "*Yes*" responses were scored 1, and "*no*" responses were scored 0. A total score of ≥ 62.5% (7–11 points) was classified as "*positive practice*", while scores < 62.5% (1–6 points) were classified as "*negative practice*".

For logistic regression analyses, the dependent variables were dichotomised such that poor knowledge, attitudes, and practices were coded as 1, and good knowledge, attitudes, and practices were coded as 0.

These transformations enabled binary classification for statistical analysis.

Statistical analysis

Questionnaires with missing data were excluded from the statistical analysis. Data were analysed using SPSS version 25. The normality distribution of the data was checked by using the Kolmogorov-Smirnov test and a skewness test. As age and the total KAP score were not found to be normally distributed, a nonparametric test was applied. Comparisons of the total KAP of the participants were done based on their age, sex, and study years using the Mann-Whitney U-test for groups with two categories and the Kruskal-Wallis test for groups having more than two categories. Descriptive statistics, including frequencies, percentages, medians and interquartile range (IQR), were calculated to summarise respondents' demographics and KAP scores. Relationships between KAP scores were analysed using Spearman's correlation coefficient. Logistic regression analysis was performed to identify determinants of poor KAP with results presented as adjusted odds ratios (AOR) with 95% confidence intervals (CI). Statistical significance was set at $p < 0.05$.

Results

Basic characteristics of the respondents

All 323 third- to fifth-year undergraduate pharmacy students who participated in the study returned completed questionnaires. However, 34 questionnaires (10.5%) were excluded due to missing data. The remaining 289 questionnaires were included in the analysis. Table I presents the demographic characteristics of the respondents. Nearly half were aged 18–24 (49.8%), with a median age of 25 (interquartile range: 23–27). Slightly more respondents were male (55.4%) than female (44.6%). Most respondents were in their fifth year of study (47.1%), followed by those in their third (29.4%) and fourth (23.5%) years. The vast majority (93.4%) did not have a prior undergraduate degree.

Table I: Basic characteristics of the respondents

Variables	n (%)
Age group (years)	
18-24	144 (49.8)
25-31	124 (42.9)
32-38	21 (7.3)
Sex	
Male	160 (55.4)
Female	129 (44.6)
Study years	
Third	85 (29.4)
Fourth	68 (23.5)
Fifth	136 (47.1)
Previous undergraduate degree	
No	270 (93.4)
Yes	19 (6.6)

Knowledge of PV and ADR Reporting

Table II presents respondents' knowledge of PV and ADR reporting. The highest correct response rates were observed for the definition of PV (78.5%) and the belief that ADR reporting is a professional obligation (71.3%). Conversely, knowledge was notably low regarding the location of the international ADR monitoring centre (5.9%) and the identification of ADR examples with their causative drugs (8.0%). Overall, the respondents demonstrated limited knowledge, with a median score of 6 (interquartile range: 4–8) out of a maximum score of 15. Based on the scoring criteria, 66 students (22.8%) had good knowledge, while 223 (77.2%) had poor knowledge.

Table II: Knowledge categories of the respondents

Knowledge items	Knowledge categories	
	Correct n (%)	Incorrect n (%)
1. Healthcare professional(s) responsible for reporting ADRs	85 (29.4)	204 (70.6)
2. Definition of pharmacovigilance	227 (78.5)	62 (21.5)
3. The most important objective of Pharmacovigilance	88 (30.4)	201 (69.6)
4. Location of international center for ADRs monitoring	17 (5.9)	272 (94.1)
5. The commonly used scale for assessment of causality of ADR	53 (18.3)	236 (81.7)
6. The WHO online database for ADRs reporting	71 (24.6)	218 (75.4)
7. The phase of clinical trial which rare ADRs can be identified	138 (47.8)	151 (52.2)
8. An example of ADR and its causative drug	23 (8.0)	266 (92.0)
9. Class of ADRs	122 (42.2)	167 (57.8)
10. It is important to report ADRs leading to	176 (60.9)	113 (39.1)
11. The common method to monitor ADRs of new drugs once they are launched in market.	98 (33.9)	191 (66.1)
12. The type of ADRs to be reported	157 (54.3)	132 (45.7)
13. ADR reporting is a Professional obligation	206 (71.3)	83 (28.7)
14. Measures that should be taken when ADR is suspected	135 (46.7)	154 (53.3)
15. Government agency in Nigeria the case of ADRs is to be reported to	181 (62.6)	108 (37.4)

Subgroup analysis results of overall knowledge score

The present study revealed significant differences in knowledge scores across student subgroups. Table III shows a statistically significant association between age and knowledge scores (p = 0.008). Older students (25–31 years and 32–38 years) had higher mean ranks (158.84 and 166.81, respectively) compared to younger students aged 18–24 years (129.90). When knowledge was categorised into good and poor, only 30.3% of students aged 18–24 demonstrated good knowledge, compared to 57.6% of those aged 25–31 years and 12.1% of those aged 32–38 years (p = 0.001).

Table III: Subgroup analysis of the overall knowledge score

Variables	N	Ranks		*P* value
		Mean Rank	Sum of Ranks	
Age (years)				
18-24	144	129.9		0.008[a]*
25-31	124	158.84		
32-38	21	166.81		
Sex				
Male	160	143.49	22959	0.732[b]
Female	129	146.87	18946	
Study years				
Third	85	96.7		0.000[a]*
Fourth	68	140.93		
Fifth	136	177.22		

[a]Kruskal-Wallis Test; [b]Mann-Whitney Test; *Significant at $P < 0.05$

Significant differences were also observed by year of study ($p < 0.001$). Fifth-year students had the highest mean rank (177.22), followed by fourth-year (140.93) and third-year students (96.7). When classified by knowledge level, 89.4% of students with good knowledge were in their final year, compared to only 6.1% in third year and 4.5% in fourth year ($p < 0.001$) (Table IV).

Table IV: Subgroup analysis of the overall knowledge levels

Variables	Total (N=289)	Good knowledge (N=66)	Poor knowledge (N=223)	*P* value
	N (%)	n (%)	n (%)	
Age (years)				
18-24	144 (49.8)	20 (30.3)	124 (55.6)	0.001[a]*
25-31	124 (42.9)	38 (57.6)	86 (38.6)	
32-38	21 (7.3)	8 (12.1)	13 (5.8)	
Sex				
Male	160 (55.4)	33 (50.0)	127 (57.0)	0.318[a]
Female	129 (44.6)	33 (50.0)	96 (43.0)	
Study years				
Third	85 (29.4)	4 (6.1)	81 (36.3)	0.000[b]*
Fourth	68 (23.5)	3 (4.5)	65 (29.2)	
Fifth	136 (47.1)	59 (89.4)	77 (34.5)	

[a]Chi-Square test; [b]Fisher's Exact test, *Significant at $P < 0.05$

Attitudes towards PV and ADR reporting

Most participants believed that PV should be part of the pharmacy curriculum (90.0%) and that ADR reporting is a professional obligation (84.8%). However, only 46.0% considered PV as well covered in their curriculum. The distribution of respondents' overall attitudes towards PV and ADR reporting revealed a median attitude score of 6 (5–7) out of a maximum of 8 points; the majority (n = 220, 76.1%) demonstrated positive attitudes (Table V).

Table V: Pharmacovigilance and ADRs reporting attitudes of the respondents

Attitude items	Attitude categories	
	Agree n (%)	Disagree n (%)
1. Pharmacovigilance should be included as a core topic in undergraduate pharmacy curriculum in Nigeria.	260 (90.0)	29 (10.0)
2. I believe that the topic of pharmacovigilance is well covered in my pharmacy curriculum.	133 (46.0)	156 (54.0)
3. Pharmacy students can perform ADRs reporting during their clerkship.	238 (82.4)	51 (17.6)
4. I believe ADR reporting is a professional obligation for all healthcare providers.	245 (84.8)	44 (15.2)
5. Information on how to report ADR should be taught to pharmacy students.	245 (84.8)	44 (15.2)
6. Reporting of known ADR makes no contribution to the reporting system.	85 (29.4)	204 (70.6)
7. I believe that pharmacy profession is vital when it comes to reporting ADRs.	242 (83.7)	47 (16.3)
8. I believe that I have acquired enough knowledge to enable me to report ADRs.	151 (52.2)	138 (47.8)

Practices of PV and ADR reporting

Table VI presents respondents' practices related to PV and ADR reporting. While 73.7% expressed willingness to participate in PV education, actual reporting practices were low, with only 22.8% having ever reported an ADR. Additionally, only 28.4% had seen an ADR reporting form. The overall median practice score regarding PV and ADR reporting was 4 (2–7) out of a maximum score of 11 points, with 77 (20.6%) and 212 (73.4%) of students having positive and negative practices, respectively.

Table VI: Pharmacovigilance and ADRs reporting practices of the respondents

Practice items	Practice categories	
	Yes n (%)	No n (%)
1. Is pharmacovigilance well covered in your B. Pharm curriculum?	125 (43.3)	164 (56.7)
2. Are pharmacy students in your university trained on how to report ADR?	119 (41.2)	170 (58.8)
3. Have you ever attended a seminar or workshop on pharmacovigilance?	74 (25.6)	215 (74.4)
4. Have you read any article on prevention of ADRs?	125 (43.3)	164 (56.7)
5. Can pharmacy students in your university perform ADR reporting during their clerkship?	127 (43.9)	162 (56.1)
6. Do you feel adequately prepared to report ADR in your future practice?	154 (53.3)	135 (46.7)
7. If students in your university are offered an opportunity to undertake education in pharmacovigilance and ADR reporting system, will you be willing to participate?	213 (73.7)	76 (26.3)
8. Have you seen the ADR reporting form?	82 (28.4)	207 (71.6)
9. Have you ever come across any patient during your training that had ADR or sensitivity to any medication?	118 (40.8)	171 (59.2)
10. Have you ever reported an ADR?	66 (22.8)	223 (77.2)
11. Have you ever counselled a patient about possible ADRs of drugs?	110 (38.1)	179 (61.9)

Barriers to ADRs reporting among pharmacy students

Figure 1 illustrates the barriers to ADR reporting, as identified by the participants. The most frequently reported barrier was the lack of knowledge about how to report ADRs (78.0%), followed by the unavailability of ADR reporting forms (64.0%) and insufficient training on ADR reporting procedures (59.0%).

Additional barriers included the perceived complexity of ADR reporting processes (47.0%), the lack of time to complete reporting (42.0%), and fear of legal repercussions (31.0%). Some respondents also mentioned the lack of support from supervisors (26.0%) as a hindrance.

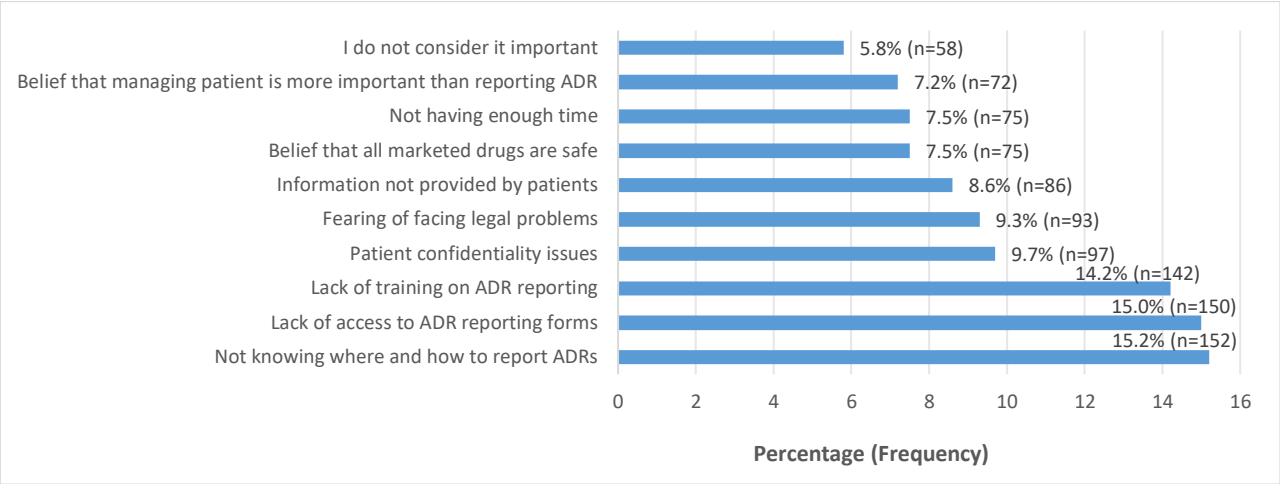

Figure 1: Barriers to ADR reporting among the respondents (Note that more than one responses were allowed)

Relationships between knowledge, attitudes, and practices

Table VII shows the correlation between knowledge, attitude, and practice scores. Knowledge was positively correlated with practice (r = 0.175, $p = 0.03$), while attitude had a stronger positive correlation with practice (r = 0.503, $p < 0.01$).

Table VII: Correlation between knowledge, attitudes, and practices of PV and ADR reporting (N=289)

		Knowledge	Attitude
Attitude	Spearman's Correlation(strength)	0.059 (weak)	-
	P value	0.319	-
Practice	Spearman's Correlation (strength)	0.175 (weak)	0.503 (Strong)
	P value	0.003*	< 0.001*

*Correlation analysis is significant at $p < 0.05$

Determinants of poor knowledge, attitudes, and practices

Table VIII presents the multivariate logistic regression analysis identifying determinants of poor knowledge, attitudes, and practices.

Respondents in their third and fourth years of study were significantly more likely to have poor knowledge compared to fifth-year students (AOR: 16.0, $p < 0.001$ and AOR: 15.1, $p < 0.001$, respectively).

Other factors, including age and sex, did not significantly influence attitudes or practices.

Table VIII: Multivariate logistics analysis of the predictors of poor knowledge, attitudes, and practices of PV and ADR reporting

	Knowledge		Attitude		Practice	
	AOR (95% CI)	***P* value**	**AOR (95% CI)**	***P* value**	**AOR (95% CI)**	***P* value**
Age group (years)						
18-24	5.3 (1.5-18.2)	0.008*	0.9 (0.3-2.6)	0.861	1.6 (0.6-4.4)	0.412
25-31	2.9 (0.9-9.6)	0.087	0.6 (0.2-1.8)	0.374	0.8 (0.3-2.3)	0.699
32-38	1.0 (Reference)		(1.0) Reference		(1.0) Reference	
Sex						
Male	1.3 (0.7-2.5)	0.379	0.8 (0.5-1.4)	0.376	0.9 (0.5-1.5)	0.634
Female	1.0 (Reference)		1.0 (Reference)		1.0 (Reference)	
Study years						
Third	16.0 (5.3-47.9)	<0.001*	1.5 (0.8-2.9)	0.188	1.5 (0.8-2.9)	0.222
Fourth	15.1 (4.4-51.5)	<0.001*	0.9 (0.4-1.8)	0.718	1.2 (0.6-2.3)	0.696
Fifth	1.0 (Reference)		1.0 (Reference)		1.0 (Reference)	

*Logistics regression analysis is significant at $p < 0.05$

Discussion

The study highlights critical gaps in KAP in PV and ADR reporting among pharmacy students in a Nigerian university. While attitudes were generally positive, significant deficits in knowledge and practices were identified. Primary findings indicate that a majority of respondents correctly defined PV but lacked knowledge about tools and international ADR reporting systems, with only a few knowing the location of the international monitoring centre. Although most students believed ADR reporting is a professional obligation, only a few had ever reported an ADR. Younger students (third and fourth years) exhibited significantly poorer knowledge than final-year students.

Findings from this study shed light on the current state of knowledge, attitudes, and practices surrounding PV and ADR reporting among respondents. While there is a foundational understanding of what PV is, as evidenced by slightly more than two-thirds of respondents correctly defining it, there are significant gaps in other areas that are crucial for effective ADR management.

For instance, the low awareness of the location of the international ADR monitoring centre and the limited knowledge of specific ADR examples and their causative drugs highlight a concerning gap in practical knowledge. This result aligns with findings from other studies (Asiamah *et al.,* 2022; Gordhon & Padayachee, 2020), which similarly reported that healthcare professionals often lack detailed and applied PV knowledge. This deficiency in practical knowledge suggests a broader trend in which theoretical understanding fails to translate into practical competence, highlighting a critical area for targeted educational interventions.

The present study revealed a concerning median knowledge score of 6 out of 15 in pharmacy students' understanding of PV and ADR reporting. This score highlights a significant knowledge gap that mirrors trends observed in Nigeria and other LMICs. For instance, previous studies among Nigerian pharmacy students reported a mean knowledge score of 4.3 out of 10 (Osemene & Afolabi, 2017) and poor PV and ADR reporting knowledge in approximately half of the participants (Ozota *et al.,* 2024). These findings indicate persistent inadequacies in PV education, emphasising the need for more robust and integrated coverage of PV concepts within pharmacy curricula.

Expanding the scope to other LMICs, a similarly troubling picture emerges. In Nepal, a median score of 5 out of 13 was recorded among healthcare students, including pharmacy students (Malla *et al.,* 2023). In Bangladesh, pharmacy students averaged 3 out of 5 (Islam Rasel *et al.,* 2023), while Jordanian pharmacy students achieved a mean score of 3.2 out of 6 (Jarab *et al.,* 2023). By comparison, Malaysian pharmacy students scored slightly higher, with a mean score of 6.9 out of 10 (Elkalmi *et al.,* 2011), and Ethiopian healthcare students scored a median of 6 out of 15 (Tekel *et al.,* 2021). These consistent findings point to systemic challenges in PV education across LMICs, highlighting a need for comprehensive curriculum reforms to strengthen drug safety monitoring knowledge.

Subgroup analysis revealed significant differences in PV knowledge based on age and year of study but not by sex. Older students (25–31 years) demonstrated significantly better knowledge than younger students (18–24 years), likely due to greater academic and clinical exposure, as observed in studies from India and Ethiopia (Agarwal *et al.,* 2017; Tekel *et al.,* 2021). Similarly, final-year students outperformed those in earlier years, underscoring the importance of clinical training in PV education. However, the low scores among third- and fourth-year students highlight inadequate early exposure, reinforcing the call for PV education to start earlier in the curriculum (Alkayyal *et al.,* 2017).

Contrary to some studies reporting better PV knowledge among female pharmacy students (Osemene & Afolabi, 2017; Jarab *et al.,* 2023), the present study found no significant sex differences, aligning with findings from Malaysia and Jordan (Elkalmi *et al.,* 2011; Farha *et al.,* 2015). Hence, PV training seems to be equally delivered across sexes in Nigeria. However, further qualitative studies could explore potential differences in knowledge.

Findings from this study indicate that while PV knowledge improves with age and progression in pharmacy training, early-stage gaps persist. Addressing this issue involves early PV education and hands-on ADR reporting exercises integrated throughout pharmacy programmes. Additionally, faculty training is essential, as lecturer expertise strongly influences student competence in PV (Khuspe, 2024). Enhanced PV training is crucial to preparing future pharmacists to safeguard patient health effectively.

Considering participants' attitudes towards PV and ADR reporting, a substantial majority believed PV should be integrated into pharmacy curricula. This finding is consistent with recommendations from the World Health Organisation, which emphasises the importance of incorporating drug safety into medical and pharmacy curricula (World Health Organisation, 2002). However, the disconnect arose when less than one-half of the students felt that the topic was adequately covered in

their curriculum. This discrepancy suggests that while students recognise the importance of PV, they may not be receiving sufficient training in this critical area, consistent with findings from other research that have similarly highlighted inadequacies in PV education (Elkalmi *et al.,* 2011; Osemene & Afolabi, 2017; Malla *et al.,* 2023; Islam Rasel *et al.,* 2023; Jarab *et al.,* 2023).

This study revealed that pharmacy students in Nigeria have a median attitude score of 6 out of 8 regarding PV and ADR reporting. This score indicates a generally positive disposition towards the importance of monitoring drug safety and reporting potential drug-related issues. When compared with previous studies conducted in Nigeria and other LMICs, similar patterns emerged. For instance, a study conducted in three pharmacy schools in Nigeria found that a significant proportion of students had a favourable perception of PV and ADR reporting (Osemene & Afolabi, 2017). Likewise, studies in southeastern Nigeria and Malaysia reported an overwhelming majority of pharmacy students expressing positive attitudes towards PV and ADR reporting (Elkalmi *et al.,* 2011; Ozota *et al.,* 2024). In Nepal, a recent survey among medical, dental, nursing, and pharmacy students reported an average attitude score of 27 out of 30, reflecting a strong inclination towards ADR reporting (Malla *et al.,* 2023).

These findings suggest that despite recognising the importance of PV, pharmacy students often face challenges that hinder effective ADR reporting. A common issue is the disconnect between students' positive attitudes and their practical engagement in ADR reporting due to inadequate knowledge, training, and experience, as highlighted by the present study. This challenge persists across different settings, underscoring the need for targeted interventions in PV education. Cultural and systemic factors may also influence these attitudes. In many low-resource settings, healthcare infrastructure may lack adequate support for PV initiatives, leading to a gap between students' theoretical understanding and real-world practice. Consequently, students may feel uncertain or underprepared to navigate the bureaucratic processes involved in ADR reporting.

Furthermore, emotional and psychological factors can shape attitudes towards ADR reporting. Students may feel overwhelmed by the responsibility of reporting ADRs, fearing repercussions or doubting the validity of their observations. Supportive environments, where one reports ADRs without fear of judgement, enable students to gain confidence and competence in this critical area.

Overall, the favourable attitudes observed are encouraging. However, they must be complemented by comprehensive PV education, practical training, and supportive systems to ensure that pharmacy students can effectively contribute to drug safety monitoring.

In terms of practice, the data reveal a stark contrast between willingness to engage in PV education (73.7%) and actual ADR reporting behaviours (only 22.8%). This gap could be attributed to several factors, including the lack of confidence in the reporting process or inadequate support from institutions, a notion supported by studies indicating that healthcare professionals often feel unprepared to report ADRs due to bureaucratic hurdles and lack of feedback (Eze *et al.,* 2022; Anbeo & Abacioğlu, 2023; Khan *et al.,* 2023; Nduka *et al.,* 2024). Furthermore, the fact that only 28.4% had seen an ADR reporting form suggests that awareness of the mechanisms for reporting ADRs is alarmingly low.

This study revealed a median practice score of 4 out of 11 for pharmacy students in Nigeria regarding PV and ADR reporting. This low score highlights a significant gap in practical competence and the need for targeted interventions to strengthen PV and ADR reporting practices. Notably, this study is the first to report on PV and ADR reporting practices of pharmacy students in Nigeria, providing crucial insights into an unexplored area.

The concerning practice score aligns with global trends observed in other LMICs, where gaps in practical training and awareness hinder effective ADR reporting. For instance, a study in India reported a considerably high proportion of pharmacy students with adequate ADR reporting practices (Sam *et al.,* 2023). However, this proportion decreased substantially when medical and nursing students were included, suggesting a need for more consistent training across healthcare disciplines. Similarly, a much lower median practice score than that of the present study was observed among medical, pharmacy, and nursing students in Ethiopia (Tekel *et al.,* 2021). These disparities highlight varying levels of preparedness across LMICs and emphasise the importance of strengthening PV education within pharmacy curricula.

One promising area for improvement is curriculum enhancement. Practical, hands-on experiences, such as role-playing scenarios, real-life case discussions, and ADR reporting simulations, can deepen students' understanding and confidence in PV practices. Integrating these active learning methods early in the curriculum and reinforcing them throughout the pharmacy programme would foster practical skills essential for real-world application. Additionally, creating a supportive environment where students can practice ADR reporting without fear of judgment or repercussions is crucial for developing competence.

The findings from this study call for a renewed focus on practical PV education in LMICs, emphasising early and continuous exposure to ADR reporting practices. By embedding PV training throughout the pharmacy curriculum and providing ongoing mentorship and support, future pharmacists can be better equipped to fulfil their role in medication safety. This approach is vital not only for individual professional development but also for strengthening healthcare systems and ensuring patient safety on a broader scale.

This study also indicates that the barriers to ADR reporting among pharmacy students are multifaceted, consistent with findings from previous research. The most cited barrier was the lack of knowledge on how to report ADRs, aligning with other studies (Alshakka *et al.,* 2017; Jarab *et al.,* 2023) showing that insufficient understanding of PV processes is a common global issue among health professional students. Enhancing training on ADR reporting could empower future healthcare professionals, including pharmacists.

The second most reported barrier—unavailability of ADR reporting forms—is particularly concerning. It indicates that even when students may want to report an ADR, systemic issues prevent them from doing so. Previous literature found similar challenges (Tekel *et al.,* 2021; Jarab *et al.,* 2023), emphasising the importance of accessible reporting mechanisms in encouraging ADR reporting. This problem points to a broader systemic issue that needs addressing at the individual level and within the healthcare infrastructure.

Additional barriers, such as the perceived complexity of ADR reporting processes, time constraints, fear of legal repercussions, absence of incentives, and lack of supervisory support, reveal the need for systemic changes in how ADR reporting is approached within pharmacy education and practice. These issues were also noted in prior studies, indicating a persistent challenge across various contexts (Tekel *et al.,* 2021; Khan *et al.,* 2023; Jarab *et al.,* 2023; Malla *et al.,* 2023). Addressing these barriers will require collaboration between educational institutions and regulatory bodies to create a more supportive environment for ADR reporting.

More than one-half of the participants reported insufficient training on ADR procedures, reinforcing the need to prioritise formal education and practical training. Studies have shown that targeted training can significantly improve ADR reporting knowledge (Palaian *et al.,* 2021). This prioritisation is particularly relevant given the correlation observed in the present study, which demonstrated a positive correlation between knowledge and practice. These results suggest that improving knowledge is not just a box to check; it translates directly into practice.

Interestingly, attitudes had an even stronger correlation with practice than knowledge did. This association suggests that fostering positive attitudes towards ADR reporting could be just as crucial as improving knowledge levels. Previous research has shown that a supportive reporting culture can enhance engagement (Potlog Shchory *et al.,* 2020). If students feel that ADR reporting is valued and encouraged, they may be more likely to engage in this practice.

Multivariate logistic regression analysis revealed that third- and fourth-year students had significantly poorer knowledge than their fifth-year counterparts. This somewhat alarming finding reinforces the univariate results and confirms a persistent shortfall in the early integration of pharmacovigilance and ADR reporting into the pharmacy curriculum. Previous studies have suggested that knowledge retention and application often improve with experience, which might explain why final-year students feel more equipped (Enakrire & Smuts, 2023).

These findings highlight a critical gap in pharmacy education and the need for comprehensive strategies to overcome barriers to ADR reporting. Knowledge-practice gaps in PV arise when pharmacy students and professionals possess theoretical knowledge about ADR reporting but fail to apply it effectively in real-world settings. Several factors contribute to this gap, including curriculum deficiencies, lack of practical training, fear of legal consequences, inadequate motivation, and weak institutional support for PV activities.

One probable reason for this gap could be that many pharmacy programmes focus heavily on theoretical instruction without providing sufficient hands-on training. While students may learn about PV principles in lectures, they often lack exposure to real-life ADR reporting scenarios, making them uncertain or hesitant when faced with actual cases. Additionally, many students may be unaware of the reporting procedures or systems in place, leading to low confidence in their ability to submit ADR reports correctly.

Another substantial barrier is the fear of making mistakes or facing legal consequences. Some students and even professionals may hesitate to report ADRs due to concerns about accuracy, potential repercussions, or a lack of clarity regarding their role in the PV system. Furthermore, lack of motivation and perceived irrelevance can hinder engagement. If students do not see the direct impact of ADR reporting on patient safety, they may not prioritise it as an essential responsibility.

Institutional barriers, such as weak regulatory enforcement, limited integration of PV in clinical practice, and lack of mentorship from faculty or professionals, further contribute to the knowledge-practice gap. Without a strong reporting culture or structured support systems, students may graduate without ever having participated in ADR reporting, making them less likely to engage in it professionally.

Several practical recommendations should be considered for curriculum reform to enhance PV education and ensure that pharmacy students are well-prepared for real-world practice. One primary recommendation is the introduction of mandatory PV modules as part of the pharmacy curricula. These courses should provide comprehensive training on the principles of PV, the importance of medication safety, and the ethical and legal responsibilities associated with adverse ADR reporting. Making these modules compulsory would ensure that all students receive the foundational knowledge that prepares them for their role in drug safety.

Beyond theoretical instruction, hands-on ADR reporting exercises should be incorporated into training. Pharmacy students would benefit from practical sessions where they complete ADR reporting forms used by regulatory bodies, such as Nigeria's National Pharmacovigilance Centre or the World Health Organisation's Uppsala Monitoring Centre. Role-playing exercises that simulate real-world reporting scenarios could also help students develop confidence in identifying and documenting ADRs. Additionally, integrating digital ADR reporting platforms into training would familiarise students with modern reporting systems, ensuring they are comfortable using electronic PV tools.

PV should be embedded within clinical rotations and internships to further strengthen students' practical exposure. During their placements in hospitals and community pharmacies, students should be encouraged to participate in ADR monitoring and reporting. By engaging in real-world PV under the supervision of experienced professionals, they would gain valuable hands-on experience that reinforces the importance of drug safety in patient care.

Collaboration between universities and drug regulatory agencies could also enhance PV training. Pharmacy schools should partner with national regulatory bodies to provide guest lectures from experts, hands-on workshops, and even internship opportunities at PV centres. This collaboration would ensure that students are exposed to the latest advancements in ADR monitoring and reporting.

Continuous assessment and certification should be introduced to assess students' understanding and reinforce their training. Regular evaluations, including quizzes, case study analyses, and practical ADR reporting assignments, would ensure that students retain essential PV concepts. Additionally, offering a certification upon completion of PV training could serve as an incentive for students to engage seriously with the subject.

Finally, universities should encourage student-led PV awareness initiatives. Organising workshops, seminars, and research projects focused on ADR reporting could promote a vigilance culture and proactive engagement with drug safety. By fostering an environment where students actively discuss and participate in PV efforts, universities can help instil a lifelong commitment to medication safety.

Implementing these recommendations would equip pharmacy students with the necessary knowledge, skills, and confidence to contribute effectively to PV efforts. This approach, in turn, would strengthen ADR reporting practices and improve overall medication safety, benefiting both patients and the broader healthcare system.

Strength and limitations

A notable strength of this research is its comprehensive assessment of knowledge, attitudes, and practices, providing a nuanced understanding of how well individuals grasp PV concepts, perceive its importance, and translate this understanding into action.

However, the study has some limitations. The reliance on self-reported data may introduce bias, as students may overestimate their knowledge or underreport barriers due to social desirability and recall bias. Social desirability bias was mitigated by anonymising responses and reassuring participants that their answers would remain confidential. Additionally, using neutral and non-judgemental wording in questions helped minimise pressure to provide socially acceptable answers.

Recall bias was addressed by focusing on recent and specific PV activities rather than general or long-term experiences, reducing the likelihood of inaccurate recall. Providing clearly defined response options (multiple-choice rather than open-ended recall-based questions) also helped standardise responses and minimise inconsistencies. These mitigation strategies— anonymisation, careful questionnaire design, and a focus on recent experiences— collectively enhanced the reliability of the study's findings and ensured a more accurate representation of pharmacy students' KAP regarding PV. Another limitation was the exclusion of first- and second-year students for feasibility reasons, which may have introduced selection bias.

Future research should assess their KAP for a more complete picture.

Additionally, investigating one Nigerian pharmacy school may limit the generalisability of the findings. Future research could benefit from a more diverse participant pool and perhaps a longitudinal design to track changes in KAP over time.

Conclusion

This study provides valuable insights into the KAP of PV and ADR reporting among pharmacy students in a Nigerian university, highlighting critical gaps that could inform curricular reforms and policy improvements. The findings underscore a disconnect between theoretical knowledge and practical application, emphasising the need for enhanced hands-on training, earlier integration of PV into pharmacy education, and stronger institutional support for ADR reporting. By identifying determinants of poor knowledge and barriers to ADR reporting, this study contributes to an in-depth understanding of the challenges faced by pharmacy students when engaging with PV.

Implications for practice

The implications of low PV knowledge are profound. Pharmacovigilance is critical for identifying, assessing, and preventing ADRs. Inadequate knowledge among future pharmacists could undermine patient safety, as poorly informed pharmacists may fail to recognise or report ADRs, leading to delayed safety interventions and compromised patient care.

The study's contributions to the field are significant in that it builds on existing research in Nigeria and other LMICs by offering new insights into the factors influencing PV competence among future pharmacists. Unlike previous studies,which primarily assessed knowledge and attitude levels, this research explores predictors of poor KAP towards ADR reporting and practical challenges faced by students, providing a more comprehensive perspective on the issue.

Given these findings, universities should consider:

- Mandatory PV modules that include real-world ADR reporting exercises.
- Earlier introduction of PV topics in the pharmacy curriculum to reduce knowledge-practice gaps.
- Stronger collaborations between academia and regulatory bodies to provide practical exposure to ADR reporting systems.
- Integrating PV into clinical training and internships to ensure that students gain firsthand experience in reporting ADRs.

Future longitudinal studies should be conducted to track students' KAP over time, assessing the long-term impact of educational interventions. Additionally, studies exploring faculty perspectives, institutional barriers, and the effectiveness of digital reporting tools in improving ADR reporting behaviour could further enrich PV education and policy.

By addressing these critical areas, pharmacy education can better equip students with the necessary skills and confidence to actively participate in PV, ultimately strengthening ADR reporting systems and improving medication safety in Nigeria and beyond.

Ethics approval and informed consent

Ethical approval was obtained from the Research Review Committee of the Faculty of Pharmacy, University of Maiduguri, Nigeria (approval number: FP/03/24-18/11/01/035) before data collection. The purpose of the study was explained to the participants, and informed consent was obtained. Participants' confidentiality was ensured by anonymising data, and participation was voluntary.

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Conflict of interest

The authors declare no conflict of interest.

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