RESEARCH

Open Access

Assessment of pharmacovigilance activities among pharmacist interns in Nigeria: a cross-sectional study

Shadrach Chinecherem Eze^{1*}, Evaristus Chinonso Odoh², Kingsley Chinemerem Eze³, Wisdom Enyinnaya Arugo⁴, Gerald Obinna Ozota⁵, Ugomma Loveth Anyaji¹, Chidimma Elizabeth Mbakamma⁶, Collins Chukwuemeka Magbo⁷, Samuel Chijioke Ofili⁸, Victor Chikaodiri Amaechi⁹, Chimaobi Jude Nwiyi⁹, Joy Chekwube Onyesoro¹⁰, Uwakmfon Bassey Etukudo¹¹, Cornelius Chinedum Odoh¹², Loveth Onyinyechi Kalu¹⁰ and Caleb Febechukwu Eze¹⁰

Abstract

Background Pharmacovigilance (PV) and adverse drug reaction (ADR) reporting is at the core of the services and functions of a pharmacist. Pharmacist interns undergoing their one-year mandatory internship program are expected to be armed with this tool kit in order to provide adequate pharmaceutical services in all areas of pharmacy practice.

Objectives This study sought to assess the knowledge and perception of pharmacovigilance and adverse drug reaction reporting among pharmacist interns in Nigeria.

Methods This study was a cross-sectional study among pharmacist interns in their one-year mandatory internship program across Nigeria. The 32-item semi-structured questionnaires were administered online using simple random sampling with the snowballing technique to recruit the participants in the study. The results were analyzed with IBM SPSS version 25. Descriptive statistics were used to summarize the data. The Chi-square test and contingency coefficient were used to determine the association between knowledge of PV and the demographics of the participants.

Results A total of 450 pharmacist interns participated in this study. The participants' knowledge of pharmacovigilance and ADR is 92.5%. About 96.2% of respondents feel that responses to newly released pharmaceuticals must be recorded, compared to 79.1% for older drugs already on the market. There is a high correlation between the duration of the internship program and understanding of PV and ADR reporting among participants. More than fifty percent of respondents concur that ADR reporting is critical, while more than eighty percent concur that ADR reporting is required for pharmacists, the most significant health professionals in ADR reporting. The participants' length of participation in an internship program and their internship location significantly impact their opinion of ADR reporting. Seventy-four percent (74%) of respondents from tertiary hospitals say their internship center encourages ADR reporting.

Conclusion Most participants have a solid understanding of PV and ADR reporting, but perceptions of PV and ADR reporting are substantially correlated with internship location and program length. Active measures should be implemented to ensure that all pharmacy interns comprehend and embrace PV and ADR reporting as their exclusive duty.

*Correspondence:

Shadrach Chinecherem Eze

shadrachchinecheremeze@gmail.com

Full list of author information is available at the end of the article



© The Author(s) 2023. **Open Access** This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit http://creativecommons.org/licenses/by/4.0/.

Keywords Pharmacovigilance, Adverse drug reaction, Knowledge, Perception, Pharmacist interns, Nigeria

Background

Adverse drug reaction (ADR) is defined as a response to a medicinal product that is noxious, unintended, occurring at doses typically used in humans for the prophylaxis, diagnosis, or therapy of disease or the modification of a physiological function [1]. ADR is a subset of pharmacovigilance, involved in the detection, collection, assessment, monitoring, and prevention of adverse drug effects encountered with the use of pharmaceutical products [2]. Since 2012, the definition of ADR has included harmful reactions due to error, misuse, or abuse of medications, and from off-label use or unlicensed medications [3]. Researchers consider ADR a common manifestation in clinical practice; studies suggest that 5% to 10% of patients may suffer from an ADR as inpatient while being admitted or as an outpatient despite various preventive efforts [3]. ADRs can increase hospital visits, duration of stay (morbidity), financial burden, and a negative effect on the prescriber-patient relationship and even mortality. The clinical signs and symptoms of ADRs are often not recognized or, even when identified, may not be reported by health professionals, including intern pharmacists **[4**].

The primary process of reporting potential ADRs discovered through pharmacovigilance worldwide is 'spontaneous reporting' [3]. The National Pharmacovigilance Center (NPC) unit at National Agency for Food and Drug Administration Control (NAFDAC) coordinates pharmacovigilance activities in Nigeria [5]. ADR incidents are reported to the NPC using the ADR forms, called Yellow forms or Individual Case Safety Report (ICSR) forms. According to guidelines provided by NPC for detecting and reporting ADRs, all healthcare workers/providers are to report any suspected ADRs, and the guideline also stresses that it is their professional responsibility to do so [5]. All ADRs submitted to NPC are collated, analyzed, and submitted to the WHO Uppsala monitoring center. ADR report statistics are utilized in deciding post-marketing withdrawal of unsafe medicines; however, underreporting has been a major limiting factor of this process [5].

Pharmacists are in a better position than other health professionals to report ADR; however, in a recent study in Nigeria, more than half of the licensed pharmacists involved have never reported ADRs identified from patients [6]. Insufficient knowledge of pharmacotherapy in detecting ADRs (57.5%), unavailability of reporting forms (yellow form) (40%), and absence of a good professional environment to discuss issues relating to ADRs are some of the challenges facing spontaneous reporting [7].

According to the Pharmacy Council of Nigeria (PCN), the internship training program is designed to give recent pharmacy graduates a chance to perform all the skills and responsibilities of the profession under the close supervision of a fully licensed pharmacist [8, 9]. As a result, pharmacovigilance practices, including identifying and reporting ADRs, are now anticipated by intern pharmacists in training. Pharmacists and interns are easily accessible, work for long hours, and interact with numerous patients and thus are in an ideal position to undertake pharmacovigilance and identify and report adverse drug reactions (ADRs) [10]. Participation in pharmacovigilance exercises mostly depends on the pharmacist intern's understanding of what PV includes and the necessity of engaging in such activities. Numerous research has been undertaken to measure the knowledge and perspective of healthcare providers, including pharmacists, regarding pharmacovigilance; however, to the best of our knowledge, no large-scale investigation has included pharmacist interns [11]. This study evaluates the knowledge and perception of pharmacovigilance and adverse drug reaction (ADR) reporting among intern pharmacists in Nigeria.

Methods

Study technique and sampling technique

This cross-sectional study was conducted among pharmacist interns undergoing their one-year mandatory internship program across Nigeria. Simple random sampling involving the snowballing technique was used to recruit the participants in the study.

Study instrument and administration

The study instrument was a 32-item semi-structured questionnaire designed to obtain information on the respondents' knowledge and perception of pharmacovigilance and ADR reporting in Nigeria (attached in appendix III). The questionnaire consisted of four parts; the first included seven (7) questions on the pharmacist interns' sociodemographic variables, such as age, gender, place of internship, duration of the internship program, ethnicity, and religion. The second part consisted of nine (9) questions with three options 'yes,' 'no,' and 'do not know,' testing the pharmacist interns' knowledge of pharmacovigilance and ADRs. The third section measures knowledge of different ADRs to be reported with seven (7) questions. The fourth part consisted of 9 (nine) questions, each bearing a 5-point Likert scale of 'Strongly Agree to Strongly Disagree' measuring the respondents' attitude and perception toward pharmacovigilance and ADR reporting.

In developing the questionnaire, we first did a thorough literature review, from which we adapted the study instrument and modified it to suit our study context [1, 2]. Face validity, content validity by experts in the field were further used to validate the questionnaire. Test-retest validity was carried out using 10 intending respondents. The instrument's reliability was tested by conducting an alpha Cronbach's test. The alpha Cronbach's value of the scales in the instrument was between the ranges of 0.70–0.82 [2]. The questionnaire was distributed online via WhatsApp, Telegram, and Facebook to the target participants.

Duration of study

This study's data were collected over two months, from July 2022 to September 2022.

Inclusion/exclusion criteria

The questionnaire was shared only with fresh pharmacy graduates currently undergoing their one-year mandatory internship program across the country. Student pharmacists, post-intern pharmacists, and fully licensed pharmacists were all excluded.

Sample size determination

A minimum sample size of 430 was estimated using Fisher's formula. The assumed working proportion of 50% from the previous study was used at a 95% confidence level, and the desired accuracy level (from the confidence interval) was set at 0.05 [11].

sample size
$$=$$
 $\frac{z^2 p(1-p)}{d^2}$

where z = the z score from the distribution table with the confidence interval set at 95%

p = Knowledge level among youths from published literature

d = margin of error.

Then, using z=1.96 and p=0.5 (50%) and d=0.05 (5%),

Sample size =
$$\frac{1.96 \times 1.96 \times 0.5 \times 0.78}{0.05 \times 0.05} = 384 \text{ participants}$$

Accounting for nonresponse rate of 10%, the minimum number of sample size = 384/(1-0.1) = 430 responses.

The questionnaire was assessed for completeness, and only questionnaires with complete responses were subjected to analyses. The data were analyzed with the aid of SPSS version 23. Descriptive statistics such as frequencies and percentages were used to summarize the data. The association between the demographic variables of the respondents and their knowledge and perception of pharmacovigilance and ADR reporting were evaluated using the Chi-square test and contingency coefficients. The level of significance was set at p < 0.05.

The total score for the nine-item knowledge questions was classified as 'good' or 'poor' based on the total score for all questions in each domain. 'Yes' has a score of '1' while 'No' and 'Do not Know' both take a score of '0' for a positive question and vice versa for a negative question [2]. A total score equal to or greater than 6 (out of a maximum possible score of 9) was considered 'Good Knowledge, and a score of less than 6 (out of a maximum possible score of 9) was considered 'Poor Knowledge. The perception questions were stratified into 'Positive' (for Strongly Agree and Agree responses), Neutral (for Neutral response), and Negative (for Strongly Disagree and Disagree responses). A Chi-square test of association was done between the sociodemographic and the participants' knowledge and perception of PV and ADR reporting.

Ethical considerations

This study did not involve the use of human subjects, so an exception was sought and obtained from the Health Research and Ethics Committee of the University of Nigeria Teaching Hospital (Reference Number: NHREC/05/01/2008B-FWA00002458-1RB00002323). However, informed consent was obtained from all the participants.

Results

Sociodemographics of the participants

The survey was sent out to 500 pharmacist interns, and 450 interns filled in the survey, giving a total response rate of 90%. Table 1 depicts the sociodemographic characteristics of the participants. Nearly half (50%) of the respondents are between 26 and 30 years. There were more males (58.2%) than females (41.8%), with nearly all possessing a Pharm. B degree. More than half of the respondents (55.2%) have spent 7–9 months in their internship program, followed by those who have spent 4–6 months in their internship program (27.7%). Respondents undergoing a one-year mandatory internship program in a tertiary hospital account for (79.2%) of all the respondents, followed by participants in specialist

Table 1 Summary of the sociodemographic characteristics of study population (n = 450)

Sociodemographic variable	Frequency (n)	Percentages (%)	
Age (yrs)			
21–25	214	44.8	
26–30	236	50.0	
>30	25	5.2	
Gender			
Male	278	58.2	
Female	200	41.8	
Degree			
Pharm. B	474	99.2	
Pharm. D	4	0.8	
Duration into internship program			
<4 months	34	7.1	
4–6 months	133	27.7	
7–9 months	265	55.2	
>9 months	46	9.6	
Place of internship			
Tertiary hospital	380	79.2	
Specialist hospital	39	8.1	
Military hospital	20	4.2	
Community pharmacy	15	3.1	
Others	23	4.8	
Ethnicity			
Igbo	363	75.6	
Yoruba	14	2.9	
Hausa	17	3.5	
Others	84	17.5	
Religion			
Islam	20	4.2	
Christianity	456	95.0	
Others	2	0.4	

and military hospitals. The Igbo ethnic group represents a whopping 75.6% of the participants, followed by the Hausa (3.5%), while 95% of the respondents were Christians.

Knowledge of PV and ADR reporting among the participants

There was a positive response for most of the questions on the knowledge of PV and ADR reporting among the participants, as shown in Appendix I. The respondents know the definition of PV (yes=99.4%) and ADR (yes=99.4%) and the difference between ADR and adverse drug event (ADE). Eighty Seven percent of the respondents know the body regulating ADR reporting in Nigeria, while 76.4% know the tool for such reporting (yellow form). The essential purpose of PV is known by almost all the respondents (95.4%). The participants are divided on whether all severe ADRs of drugs are known before marketing the drugs as 49.8% of them responded 'yes' while 47.5% responded 'no.' Overall, as shown in Fig. 1, 92.5% of the participants had a good knowledge of PV and ADR reporting, while a 7.5% had poor knowledge.

Knowledge about types of ADRs to be reported

Figure 2 shows that 96.2% of the respondents believe that reactions to newly introduced drugs to the market need to be reported, while 79.1% believe so for old drugs already in the market. The respondents were favorable to reporting reactions leading to death (96.9%), reactions leading to persistent disability (95.0%), and reactions leading to hospitalization (97.5%). Just 61.7% believe that minor reactions such as vomiting and diarrhea should be reported.

There is a significant association (p < 0.01) between the knowledge score and genders, with the female gender having a higher knowledge score than the males. There is a strong association between participants' duration into the internship program and their knowledge of PV and ADR reporting. The association is significant (p < 0.01), as those with a duration of less than or equal to 9 months have a higher score than those with a duration greater than nine months. The participants' age, degree, place of internship, ethnicity, and religion had no significant association with their knowledge score (Table 2).

Perception toward PV and ADR Reporting

Appendix 2 depicts the participants' perception toward PV and ADR reporting in Nigeria. More than 50% agree that ADR reporting is critical, that their school curriculum covered the topics well, and that their present knowledge suffices to report any ADR they would face. More than 80% agree that ADR reporting is mandatory for pharmacists as they are the most critical health professionals in reporting ADR. Only a few agree that ADR reporting information is learned after the internship. The participants are favorable to later professional collaboration on ADR reporting.

Table 3 shows the association between the participants' duration into the internship program and their perception of PV and ADR reporting. The participants' internship program duration is significantly associated with many of the perception questions. Pharmacist interns who have spent at least seven months in their internship have the highest number of positive attitudes toward the 'importance of ADR' (57.6%), 'ADR reporting

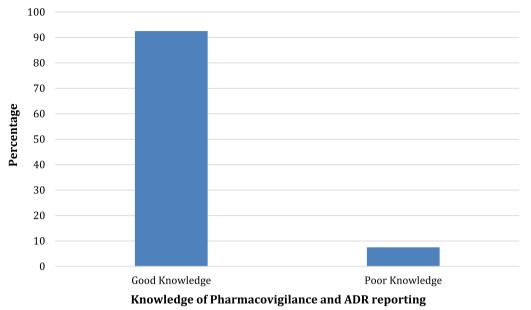
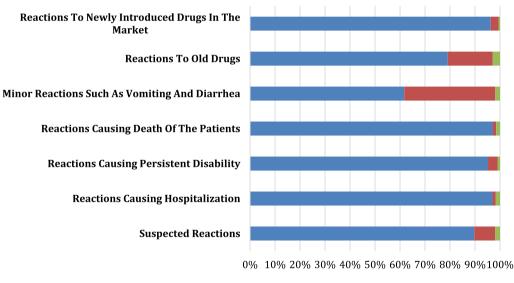


Fig. 1 Knowledge score of pharmacovigilance and ADR reporting among the participants (n = 450). 92.5% of the participants had a good knowledge of PV and ADR reporting, while a 7.5% had poor knowledge



ADR to be reported

■Yes ■No ■Don't Know

Fig. 2 Bar chart showing various ADR the participants believe should be reported (*n* = 450). 96.2% of the respondents believe that reactions to newly introduced drugs to the market need to be reported, while 79.1% believe so for old drugs already in the market. The respondents were favorable to reporting reactions leading to death (96.9%), reactions leading to persistent disability, and reactions leading to hospitalization (97.5%). Just 61.7% believe that minor reactions such as vomiting and diarrhea should be reported

being mandatory for all pharmacists' (56.6%), and 'their readiness to report any ADR they face with their present knowledge (56.2%). Participants who have spent less than four months (70.0%) and those who have spent 7–9 months (56.3%) are all positive about the idea that 'pharmacists are the most important healthcare professionals to report ADRs.' Regarding the question' information on ADR reporting is better learned after internship

Sociodemographic variable	Poor	Good	X ² (p value)	C (p value)	
Age (yrs)					
21–25	13 (6.1)	201 (93.9)	4.190 (0.123)	0.093 (0.123)	
26–30	23 (9.6)	216 (90.4)			
> 30	0	25 (100.0)			
Gender					
Male	31 (11.2)	247 (88.8)	12.5 (< 0.001**)	0.160 (< 0.001)	
Female	5 (2.5)	195 (97.5)			
Degree					
Pharm. B	36 (7.6)	438 (92.4)	0.329 (0.567)	0.026 (0.567)	
Pharm. D	0	4 (100)			
Duration into internship program					
<4 months	2 (5.9)	32 (94.7)	14.754 (<0.001**)	0.173 (0.002)	
4–6 months	8 (6.0)	125 (94.0)			
7–9 months	16 (6.0)	249 (94.0)			
>9 months	10 (21.7)	36 (78.3)			
Place of internship					
Tertiary hospital	35 (9.2)	345 (90.8)	7.982 (0.157)	0.128 (0.157)	
Specialist hospital	0	39 (100)			
Military hospital	0	20 (100)			
Community pharmacy	0	15 (100)			
Others	1 (4.3)	22 (95.7)			
Ethnicity					
Igbo	32 (8.8)	331 (91.2)	4.309 (0.230)	0.095 (0.230)	
Yoruba	0	14 (100			
Hausa	0	17 (100)			
Others	4 (4.8)	80 (95.2)			
Religion					
Islam	3 (15.0)	17 (85.0)	1.822 (0.402)	0.062 (0.402)	
Christianity	33 (7.2)	423 (92.8)			
Others	0	2 (100)			

Table 2 Association between knowledge score of participants and their Sociodemographic (n = 450)

 X^2 Chi-square test of association, C contingency doefficient

**Significant difference exist between groups (p < 0.01)

program,' there was a strong negative attitude highest among those who have spent 4–6 months (24.6%) and 7–9 months (57.6%) into their internship program. Participants who have gone less than four months (5.9%), 4–6 months (26.2%), 7–9 months (57.8%), or greater than nine months (10.1%) into their internship program have a strong positive attitude toward consulting colleagues and other healthcare professionals as very important in ADR reporting.

The place of the internship program of the participants has a strong positive association with many of the questions on their perception of PV and ADR reporting, as shown in Table 4. Tertiary hospitals have the highest number of positive attitudes among the participants toward most of the perception questions. Participants in tertiary hospitals (79.7%) and those in specialist hospitals (8.6%) believe that ADR reporting is essential and also assert their readiness to report ADR they will encounter with their present level of knowledge. Community pharmacy practice and military hospitals lagged in all the perception questions. Regarding the question, 'I believe that information on ADR reporting is better learned after internship,' tertiary hospitals have the highest positive attitude. Consulting colleagues and other healthcare professionals are very rampant in tertiary hospitals (79.0%) and specialist hospitals (8.7%) as they strongly believe that 'Consulting colleagues and other healthcare professionals is important in ADR reporting.'

Figure 3 shows the percentage of positive responses to 'My internship program center strongly encourages

Table 3 Association between participants' duration into internship program and perception of pharmacovigilance (n = 450)

Perception question		Positive n (%)	Neutral n (%)	Negative n (%)	X ² (p value)	C (p value)
I think ADR reporting is very important	<4 months	26 (6.1)	0	8 (21.6)	24.66 (< 0.001)**	0.221 (< 0.001)**
	4–6 months	114 (26.6)	3 (25.0)	16 (43.2)		
	7–9 months	247 (57.6)	6 (50.0)	12 (32.4)		
	>9 months	42 (9.8)	3 (25.0)	1 (2.7)		
With my present knowledge, I am prepared to report any ADR I	<4 months	21 (5.9)	1 (11.0)	4 (9.5)	15.284 (0.018)**	0.176 (0.018)**
would face	4–6 months	97 (27.4)	16 (19.5)	20 (47.6)		
	7–9 months	119 (56.2)	49 (59.8)	17 (40.5)		
	>9 months	37 (10.5)	9 (9.8)	1 (2.4)		
ADR reporting is mandatory for all pharmacists	<4 months	29 (7.4)	2 (4.9)	3 (7.0)	17.76 (0.007)**	0.087 (0.729)
	4–6 months	104 (26.4)	7 (17.1)	22 (51.2)		
	7–9 months	223 (56.6)	25 (61.0)	17 (39.5)		
	>9 months	38 (9.6)	7 (17.1)	1 (2.3)		
Pharmacist must advise their patients to immediately report any	<4 months	31 (6.9)	0	3 (13.6)	6.98 (0.323)	0.189 (0.007)**
ADR	4–6 months	112 (27.0)	2 (50.0)	9 (40.9)		
	7–9 months	255 (56.4)	1 (25.0)	9 (40.9)		
	>9 months	44 (9.7)	1 (25.0)	1 (4.5)		
Pharmacist are the most important healthcare professionals to	<4 months	28 (70.0)	3 (6.5)	3 (8.8)	8.87 (0.181)	0.120 (0.323)
report ADR	4–6 months	110 (27.6)	10 (21.7)	13 (38.2)		
	7–9 months	224 (56.3)	24 (52.2)	17 (50.0)		
	>9 months	36 (9.00	17 (50.0)	1 (2.9)		
I believe that information on ADR reporting is better learned after	<4 months	7 (9.3)	7 (6.6)	20 (6.7)	8.09 (0.281)	0.135 (0.181)
internship	4–6 months	23 (30.7)	37 (34.9)	73 (24.6)		
	7–9 months	37 (49.3)	57 (53.8)	171 (57.6)		
	>9 months	8 (10.7)	5 (4.7)	33 (11.1)		
Consulting colleagues and other healthcare professionals is important in ADR reporting	<4 months	25 (5.9)	6 (18.2)	3 (14.3)	19.36 (0.004)**	0.129 (0.231)
	4–6 months	111 (26.2)	11 (33.3)	11 (52.4)		
	7–9 months	245 (57.8)	13 (39.4)	7 (33.3)		
	>9 months	43 (10.1)	3 (9.1)	0		

ADR Adverse drug reaction, Chi-square test of association, C contingency coefficient

**Significant difference exist between groups (p < 0.01)

ADR reporting' among the participants from the various internship centers. 74.0% of those with positive responses are from participants in tertiary hospitals, followed by those in specialist hospitals (10%) and military hospitals (8%). Community pharmacy scored the least, with a positive response of 2%.

Discussion

This study assessed the knowledge and perception of pharmacovigilance and ADR reporting among pharmacist interns across Nigeria. To the best of our knowledge, this study is the first of its kind among pharmacist interns in Nigeria. Nearly all of the participants possess Pharm. B. degree since only two pharmacy schools in Nigeria currently offer the Pharm. D. program [12]. Fresh pharmacy graduates immediately go in for their internship program, as shown in the results where 55.2% of the respondents have already done 7-9 months in their internship program. Pharmacist interns in tertiary hospitals across the country account for over 79.0% of the participants. An explanation is that tertiary hospitals across the country have the highest intake of interns yearly since they have the capacity, in both finances and human resources, to train them. Tertiary hospitals in various countries receive the highest health funding from those countries' federal governments. This observation is also consistent with studies in Saudi Arabia, where 51.4% of the respondents are working in Ministry of Health (MoH) hospitals which are tertiary hospitals [2]. The considerable representation of the Igbo ethnic group (75.6%) and Christianity (95.0%) among the participants reflects the many pharmacy schools operating in the southern part of the country as opposed to northern Nigeria, which is predominantly Hausa and Islam.

Table 4 Association between participants' place of internship program and perception of pharmacovigilance (n = 450)

Perception question		Positive	Neutral	Negative	X ² (p value)	C (p value)
I think ADR reporting is very important	Tertiary hospital	342 (79.7)	12 (100)	26 (70.3)	15.63 (0.111)	0.198 (0.111)
	Specialist hospital	37 (8.6)	0	2 (5.4)		
	Military hospital	16 (3.7)	0	4 (10.8)		
	Community pharmacy	15 (3.5)	0	0		
	Others	18 (4.2)	0	5 (13.5)		
With my present knowledge, I am prepared to report	Tertiary hospital	275 (77.7)	66 (80.5)	39 (92.9)	14.72 (0.143)	0.173 (0.143)
any ADR I would face	Specialist hospital	30 (8.5)	9 (11.0)	0		
	Military hospital	20 (5.6)	0	0		
	Community pharmacy	12 (3.4)	3 (3.7)	0		
	Others	16 (4.5)	11 (4.9)	3 (7.1)		
My internship program center strongly encourage ADR	Tertiary hospital	183 (74.4)	112 (84.8)	85 (85.0)	29.77 (0.001)**	0.242 (0.001)**
reporting	Specialist hospital	25 (10.2)	10 (7.6)	4 (4.0)		
	Military hospital	19 (7.7)	1 (0.8)	0		
	Community pharmacy	5 (2.0)	3 (2.3)	7 (7.0)		
	Others	14 (5.7)	5 (3.8)	4 (4.00		
ADR reporting is mandatory for all pharmacists	Tertiary hospital	300 (76.1)	40 (97.6)	40 (93.0)	22.38 (0.013)**	0.211 (0.013)**
	Specialist hospital	39 (9.9)	0	0		
	Military hospital	20 (5.1)	0	0		
	Community pharmacy		0	3 (7.0)		
	Others	22 (5.6)	1 (2.4)	0		
Pharmacist must advise their patients to immediately report any ADR	Tertiary hospital	356 (78.8)	2 (50.0)	22 (100)	24.0 (0.008)**	0.211 (0.008)**
	Specialist hospital	39 (8.6)	0	0		
	Military hospital	20 (4.4)	0	0		
	Community pharmacy		0	0		
	Others	21 (4.6)	2 (50.0)	0		
Pharmacist are the most important healthcare profes-	Tertiary hospital	316 (79.4)		29 (85.3)	26.57 (0.003)**	0.229 (0.003)**
sionals to report ADR	Specialist hospital	36 (9.0)	1 (2.2)	2 (5.9)		
	Military hospital	20 (5.0)	0	0		
	Community pharmacy		6 (13.0)	0		
	Others	16 (4.0)	4 (8.7)	3 (8.8)		
I believe that information on ADR reporting is better	Tertiary hospital	66 (88.0)	77 (72.6)	237 (79.8)	22.74 (0.012)**	0.213 (0.012)**
learned after internship	Specialist hospital	3 (4.0)	9 (8.5)	27 (9.1)		
	Military hospital	1 (1.3)	11 (10.4)	8 (2.7)		
	Community pharmacy		3 (2.8)	11 (3.7)		
	Others	3 (4.0)	6 (5.7)	14 (4.7)		
Consulting colleagues and other healthcare profession-	Tertiary hospital	335 (79.0)	29 (87.9)	16 (76.2)	73.988 (<0.001)**	0,171 (0,153)
als is important in ADR reporting	Specialist hospital	37 (8.7)	0	2 (9.5)		
	Military hospital	19 (4.5)	1 (3.0)	0		
	Community pharmacy		3 (9.1)	0		
	Others	20 (4.7)	0	3 (14.3)		

ADR Adverse drug reaction, Chi-square test of association, C contingency coefficient

**Significant difference exist between groups (p < 0.01)

The percentage of pharmacist interns with good knowledge of PV and ADR reporting is 92.5%. This is consistent with reports by Alshayban [2], in which most of the study population knew the correct definition of pharmacovigilance. This high knowledge is likely due to a heightened emphasis on the pharmacist's role as steward of drug outcomes and effects. Strengthened curricula across the various pharmacy schools in the nation have contributed to such a level of knowledge and awareness. Practicing pharmacists in works by Emeka [13] also show high

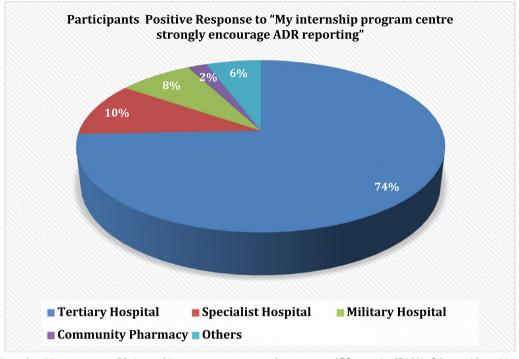


Fig. 3 Participants' positive response to 'My internship program center strongly encourage ADR reporting.' 74.0% of those with positive responses are from participants in tertiary hospitals, followed by those in specialist hospitals (10%) and military hospitals (8%). Community pharmacy scored the least, with a positive response of 2%

knowledge of PV and ADR reporting. Compared with other healthcare professionals, pharmacists always stand out as having a better knowledge of issues of pharmacovigilance and reporting ADR. In the study by Hussein et al. [1], pharmacists showed better adverse drug reporting knowledge than physicians and nurses. This is linked to the training of pharmacists who study in-depth medicines and their effects [14, 15]. Also, a study conducted in India identified shallow awareness of pharmacovigilance programs among doctors [16, 17]. Intern doctors, too, had lower knowledge of pharmacovigilance compared to the findings in this study, as reported by [10, 11, 18].

In this study, most participants believe that newly introduced drugs should be reported. This is consistent with the knowledge of post-marketing surveillance for drugs that have received approval after scaling the phase III clinical trials [11]. Such monitoring is essential as the most adverse effect of the drugs are not evident during the clinical trial phases. So, the duty is upon pharmacists and other healthcare professionals to identify these sudden reactions and inform further guidelines for use [19]. Only 61.7% of the respondents agree to report minor reactions such as diarrhea and vomiting which underscores the position healthcare professionals have placed these specific reactions on the ADR reporting list. In another study, Nurses are more concerned about reporting minor reactions to drugs, probably due to their lesser knowledge than pharmacists and physicians who report serious ADR, including reactions to newly introduced drugs in the market [1, 20]. There is a strong association between the participants' duration into the internship program and their knowledge of PV and ADR reporting. Pharmacist interns who have spent at least seven months have better knowledge than their peers. This is consistent with numerous studies indicating that the length of employment or number of years of experience influences the knowledge and practice of ADR reporting. As reported by Ezeuko [16], awareness of ADR reporting was higher among senior colleagues than among the lesser cadre. Possible explanations are the exposure due to the number of years of experience. Continuing professional development and in-house education are also the keys to these observations. Other studies refute these claims, as clinicians with less than ten years of experience had higher awareness of ADR reporting [21]. Similar studies by Bello in Sokoto [6], Nigeria, and Leone in Italy [22] hold similar views. Explanations for these are conflicting, and a general consensus is challenging.

Pharmacists' attitudes are considered pivotal for reporting an ADR; thus, a positive attitude and perception will encourage the prompt reporting of an ADR. So, knowledge and awareness alone are insufficient if intern pharmacists do not have a strong sense of obligation to report ADRs. More than 50% of the pharmacist interns agree that ADR reporting is essential and that their school curriculum covered the topics well and prepared them to report any ADR they would face. As already discussed above, this reflects the impact of quality and strictly regulated and unified pharmacy education in Nigeria on the quality of pharmacy graduates [23–25]. More than 80% agree that ADR reporting is mandatory for pharmacists as they are the most critical health professionals in reporting ADR. The findings are similar to many studies, where most pharmacists considered ADR reporting their professional responsibility [14, 26]. As reported by Alshayban [2], more interns, compared to pharmacists, believed that ADR reporting should be mandatory. Interns are the future pharmacists, and their positive perception is a sign that much improvement in pharmacovigilance practice is anticipated in the coming decades [27]. Only few of the participants agree that ADR reporting information is learned after the internship program. This is important as the internship period is the only full-time training period given to fresh graduates to learn the nitty-gritty of the profession before a full license.

The perception of the participants toward ADR reporting is associated with the duration of the internship program. This is significant as the experiences and practices of other licensed pharmacists easily rub off on the intern pharmacists during the internship period. The fully licensed pharmacist serve as role models, and the intern pharmacists would easily follow in their footsteps. Also, the fact that interns who have spent 7-9 months into their internship training had higher positive perceptions lends credence to the impact of the few months into the training on the perception of the intern. In a few months of training, new pharmacy graduates are turned into professionals passionate about pharmacovigilance and reporting ADR. Similar studies report the impact of work experience on attitude toward ADR reporting [1, 24]. The place of the internship training is critical in the attitude and perception of the interns toward pharmacovigilance and ADR reporting. Tertiary hospitals, trailed closely by specialist hospitals, have the highest positive attitudes among the participants toward most of the perception questions. These two classes of hospitals in Nigeria receive the highest funding from the federal government and have the best healthcare professionals to train and equip interns pharmacists [28]. Again, most of them are teaching hospitals or universities, which explains the high attitude toward ADR reporting among interns undergoing their internship training in these facilities. Interns in community pharmacies lagged on most of the perception questions. This is consistent with findings in similar studies in which pharmacists in hospitals perform better in all metrics of ADR reporting than community pharmacists [13]. Other reports showed that knowledge, perception, and involvement in ADR reporting was more by hospital pharmacists than community pharmacists [29]. This is likely because hospital pharmacists are better educated and better informed. Suyagh et al. [30] argued that the probable cause for high reporting among hospital pharmacists is the direct interaction they have with other healthcare professionals involved in identifying ADR.

Conclusion

This present study shows that most participants have a solid understanding of PV and ADR reporting, but perceptions of PV and ADR reporting are still below average. Perceptions of PV and ADR reporting is substantially correlated with internship location and program length. Active measures should be implemented to ensure that all pharmacy interns comprehend and embrace PV and ADR reporting as their exclusive duty.

Strengths and limitations of study

The major strength of this study is that it focused on an issue that has not been adequately studied, especially in Nigeria. The study also dug deep into the impact of the duration of the internship program and the place of the internship as independent variables. Another strength of this survey is that international readers could use the results as a base for comparison with similar studies carried out abroad.

However, there are some limitations. The main limitation of this study that it is a cross-sectional study, so the causality could not be warranted. Secondly, the study was based on a self-reported questionnaire, so personal bias may have affected the results. Also, the sociodemographic of our participants is a bit skewed as more data were not collected from the northern part of the country which influenced the ethnicity and religion distribution of the participants. Also only about two pharmacy schools in Nigeria are currently running Pharm D. program which also affected the distribution of degrees held by the participants.

Appendix I

See Table 5.

Table 5 Knowledge of pharmacovigilance and ADR reporting among the participants (n = 450)

Question	Yes N (%)	No <i>N</i> (%)	l don't Know <i>N</i> (%)
Definition of pharmacovigilance	475 (99.4)	3 (0.6)	
Definition of ADR	475 (99.4)		3 (0.6)
ADR and ADE are different	382 (79.9)	51 (10.7)	45 (9.4)
Yellow form is a tool for reporting ADR in Nigeria	365 (76.4)	5 (1.0)	108 (22.6)
Pharmacovigilance center, through NAFDAC, regulates ADR reporting in Nigeria	416 (87.0)	10 (2.1)	52 (10.9)
Classes of ADRs include (i) dose-related, (ii) allergic, and (iii) idiosyncratic	435 (91.0)	21 (4.4)	22 (4.6)
Most important purpose of PV is to ensure safety of drugs	456 (95.4)	8 (1.7)	14 (2.9)
All severe ADRs of drugs are known before a drug is marketed	238 (49.8)	227 (47.5)	13 (2.7)
ADRs previously documented by manufacturers need not be reported again	216 (45.2)	207 (43.3)	55 (11.5)

ADR Adverse drug reaction, PV pharmacovigilance, NAFDAC National Agency for Food and Drug Administration Control

Appendix II

See Table 6.

Table 6 Perception of participants toward pharmacovigilance and ADR reporting (n = 450)

Question	Strongly agree N (%)	Agree N (%)	Neutral N (%)	Disagree N (%)	Strongly disagree N (%)
The topic of PV was well covered in my pharmacy school curriculum	71 (14.9)	178 (37.2)	94 (19.7)	81 (16.7)	54 (11.3)
I think ADR reporting is very important	332 (69.5)	97 (20.3)	12 (2.5)	3 (0.6)	34 (7.1)
With my present knowledge, I am prepared to report any ADR I would face	127 (26.6)	227 (47.5)	82 (17.2)	20 (4.2)	22 (4.6)
My internship program center strongly encourages ADR reporting	98 (20.5)	148 (31.0)	132 (27.6)	51 (10.7)	49 (10.3)
ADR reporting is mandatory for all pharmacists	196 (41.0)	198 (41.4)	41 (8.6)	19 (4.0)	24 (5.0)
The pharmacist must advise their patients to report any ADR immediately	267 (55.9)	185 (38.7)	4 (0.8)	3 (0.6)	19 (4.0)
Pharmacist are the most important healthcare professionals to report ADR	205 (42.9)	193 (40.4)	46 (9.6)	5 (1.0)	29 (6.1)
I believe that information on ADR reporting is better learned after intern- ship	23 (4.8)	52 (10.9)	106 (22.2)	191 (40.0)	106 (22.2)
Consulting colleagues and other healthcare professionals is important in ADR reporting	193 (40.4)	231 (48.3)	33 (6.9)	3 (0.6)	18 (3.8)

ADR Adverse drug reaction, PV pharmacovigilance

Appendix III Questionnaire Sociodemographic of the participants

- 1. Age (21-25yrs; 26-30yrs; > 30yrs)
- 2. Gender (male; female)
- 3. Degree (Pharm. B; Pharm. D)
- 4. Duration into internship program (<4 months; 4–6 months; 7–9 months; >9 months)
- 5. Place of internship (tertiary hospital; specialist hospital; military hospital; community pharmacy; others)
- 6. Ethnicity (Igbo; Yoruba; Hausa; others)
- 7. Religion (Islam; Christianity; Others)

Knowledge of pharmacovigilance and adverse drug reactions (yes, no, don't know)

- 1. Pharmacovigilance is the science and activity relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-/ vaccine-related problem
- 2. Adverse drug reactions (ADRs) can be recognized as noxious, unwanted effects of drugs
- 3. ADR and adverse drug events (ADEs) are different
- 4. Yellow form is a tool for reporting ADR in Nigeria
- 5. Pharmacovigilance center, through NAFDAC, regulates ADR reporting in Nigeria

- 6. Classes of ADRs include (i) dose-related, (ii) allergic, and (iii) idiosyncratic
- 7. Most important purpose of PV is to ensure safety of drugs
- 8. All severe ADRs of drugs are known before a drug is marketed
- 9. ADRs previously documented by manufacturers need not be reported again

Perception toward pharmacovigilance and adverse drug reactions (strongly agree, agree, neutral, disagree, and strongly disagree)

- (1) The topic of PV was well covered in my pharmacy school curriculum
- (2) I think ADR reporting is very important
- (3) With my present knowledge, I am prepared to report any ADR I would face
- (4) My internship program center strongly encourages ADR reporting
- (5) ADR reporting is mandatory for all pharmacists
- (6) The pharmacist must advise their patients to report any ADR immediately
- (7) Pharmacist are the most important healthcare professionals to report ADR
- (8) I believe that information on ADR reporting is better learned after internship
- (9) Consulting colleagues and other healthcare professionals is important in ADR reporting

Abbreviations

PV	Pharmacovigilance
ADR	Adverse drug reaction
IBM	International Business Machine
SPSS	Statistical Package for Social Sciences
WHO	World Health Organization
NPC	National Pharmacovigilance Center
NAFDAC	National Agency for Food and Drug Administration Control
ICSR	Individual Case Safety Report forms
ADE	Adverse drug event
Pharm B.	Bachelor of pharmacy
Pharm. D	Doctor of pharmacy
МоН	Ministry of Health

Acknowledgements

Our profound gratitude goes to Pharm Anosike Chibueze of the department of Clinical Pharmacy and Pharmacy Management, University of Nigeria Nsukka for his guidance in this study. Special thanks also goes to Pharm Chijioke Modestus for his painstaking reviews. We will not fail to recognize all vital comments offered by anonymous reviewers and colleagues. Their various input have improved this work tremendously and saved us from numerous mistakes; those that remain are entirely our fault.

Author contributions

SCE conceptualized the idea, designed the study tools, analyzed the results, and wrote the "Results" section of the manuscript. ECO wrote the "Methods"

section of the manuscript and was involved in the analysis of results. GOO was involved in the study design and analysis of the results. WEA wrote the "Discussion" section of the manuscript. KCE was involved in the study design and data collection. ULA was involved in the study design and data collection. CEM was involved in data collection and wrote the "Methods" section of the manuscript. CCM wrote "Introduction" part of the manuscript and was involved in data collection. SCO, VCA, CJN, JCO, UBE, CCO, LOK, and CFE were involved in data collection. All the authors read and approved to the final manuscript.

Funding

The authors did not receive any funding for the work.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study did not involve the use of human subjects, so an exception was sought and obtained from the Health Research and Ethics Committee of the University of Nigeria Teaching Hospital (Reference Number: NHREC/05/01/2008B-FWA00002458-1RB00002323). However, informed consent was obtained from all the participants. The pharmacist interns were informed that participation in the study was voluntary and they were at liberty to withdraw from the study anytime without any consequences. Confidentiality, privacy, and anonymity were upheld following the Nuremberg code and Helsinki declarations.

Consent for publication

The authors declare no conflict of interest.

Competing interests

The authors declare no conflict of interest.

Author details

¹Department of Pharmacy, Federal Medical Centre Makurdi, Makurdi, Benue State, Nigeria. ²Department of Pharmacy, Federal Medical Centre Bida, Bida, Niger State, Nigeria. ³Department of Pharmacy, Federal Medical Centre Keffi, Keffi, Nasarawa State, Nigeria. ⁴Department of Pharmacy, Federal Medical Centre Keffi, Keffi, Nasarawa State, Nigeria. ⁴Department of Pharmacy, Federal Medical Centre Keffi, Keffi, Nasarawa State, Nigeria. ⁴Department of Pharmacy, Federal Medical Centre Keffi, Keffi, Nasarawa State, Nigeria. ⁴Department of Pharmacy, Iniversity of Nigeria Teaching Hospital, Ituku-Ozalla, Enugu State, Nigeria. ⁷Alex Ekwueme University Teaching Hospital, Abakaliki, Ebonyi State, Nigeria. ⁸Department of Clinical Pharmacy and Pharmacy Management, University of Nigeria, Nsukka 410001, Enugu State, Nigeria. ¹⁰Faculty of Pharmaceutical Sciences, University of Nigeria, Nsukka 410001, Enugu State, Nigeria. ¹¹Department of Pharmaceutical Technology and Industrial Pharmacy, Faculty of Pharmaceutical Sciences, University of Nigeria, Nsukka 410001, Enugu State, Nigeria. ¹²Department of Pharmacology and Toxicology, Faculty of Pharmaceutical Sciences, University of Nigeria, Nsukka 410001, Enugu State, Nigeria. ¹²Department of Pharmacology and Toxicology, Faculty of Pharmaceutical Sciences, University of Nigeria, Nsukka 410001, Enugu State, Nigeria.

Received: 28 November 2022 Accepted: 1 February 2023 Published online: 08 February 2023

References

- Hussain R, Hassali MA, Hashmi F, Akram T (2021) Exploring healthcare professionals' knowledge, attitude, and practices towards pharmacovigilance : a cross - sectional survey. J Pharm Policy Prac 14(5):1–13. https:// doi.org/10.1186/s40545-020-00287-3
- Alshayban D, Mahmoud MA, Islam MA, Alshammari S, Ansulaiman D (2020) Pharmacovigilance perception and knowledge among pharmacists and interns in Saudi Arabia. Risk Manag Healthc Policy 13:55–61
- Coleman JJ, Pontefract S (2016) Adverse drug reactions. Clin Med 16(5):481–485
- Adedeji WA, Adegoke AB, Fehintola FA (2021) Adverse drug reactions reporting practice and associated factors among community health

extension workers in public health facilities, Southwest. Nigeria Pan Afr Med J 17(40):165. https://doi.org/10.11604/pamj.2021.40.165.28574. PMID:34970407;PMCID:PMC8683451

- Ogundele S, Dawodu F, Ogunleye F (2012) Adverse drug reaction reporting among healthcare workers at a Nigerian Tertiary Hospital: a comparative cross-sectional survey of health care professionals. Glob Res J Med Sc 2:32–37
- Bello N, Atunwa SA (2018) Knowledge and practice of reporting of adverse drug reactions among community pharmacists in Ilorin, North-Central, Nigeria. J Pharm Res Dev & Pract 2(2):41–51
- Elkalmi RM, Hassali AM, Ibrahim MIM, Jamshed SQ, Al-Lela OQ (2014) Community Pharmacists' attitudes, perceptions, and barriers toward adverse drug reaction reporting in Malaysia: a quantitative insight. J Patient Saf 10:81–87
- 8. Oparah AC (2010) Essentials of pharmaceutical care, 1st edn. A Cybex Publication, Lagos
- Pharmacists' council of Nigeria (2016) http://www.pcn.org.ng. Accessed 25 Oct 2022.
- Shetti SA, Limaye RP (2021) An evaluation of knowledge, attitude and perception about adverse drug reactions and pharmacovigilance among intern doctors in a medical college teaching hospital of Sangli. Int J Basic Clin Pharmacol 10(6):714–719
- Korde RA, Radhika MS (2018) A KAP study of pharmacovigilance among junior residents and interns of a tertiary care hospital. Int J Basic Clin Pharmacol 7(11):2178–2183
- 12. Education and training [Internet]. Pharmacy Council of Nigeria (2021) [cited 2022 Nov 18]. Available from: https://www.pcn.gov.ng/educationand-training/
- Emeka PM, Badger-Emeka LI (2017) A study on the knowledge and barriers towards ADRs reporting among community pharmacists in Enugu and Nsukka areas, Souh-Eastern Nigeria. Pharmacol Tox Biomed Rep 3(1):1–6
- Su C, Ji H, Su Y (2010) Hospital pharmacists' knowledge and opinions regarding adverse drug reaction reporting in Northern China. Pharmacoepidemiol Drug Saf 19(3):217–222
- Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D (2004) Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions. Chin Med J 117(6):856–861
- Ezeuko A, Ebenebe U, Nnebue C, Ndu O (2015) Adverse drug reaction reporting by different categories of healthcare workers in Nnewi, Nigeria: Awareness, Knowledge and Attitudes. Br J Med Med Res 7(11):932–941. https://doi.org/10.9734/BJMMR/2015/17183
- Saxena K, Srivastava S (2021) Assessment of knowledge, attitude and practice of reporting of adverse drug reaction among family physicians in Surat city. Int J Basic Clin Pharmacol. 10:820
- Thakuria N, Deka D, Choudhury D, Ahmed N (2016) A cross sectional study to evaluate the knowledge, attitude and practices of healthcare professionals on pharmacovigilance at Silchar medical college and hospital, Assam. India Int J Basic Clin Pharmacol 5:1481–1489
- Usifoh S, Aika I, Odili V, Nwokoro J (2018) Community pharmacists knowledge, behaviours and practice of adverse drug reactions reporting in Lagos State, Nigeria. Indian J Phar Pract 11:07–13
- 20. Prakash S, Yadav P, Yadav K (2018) Perspectives of developing nursing education in Nepal. Nurs Care Open Access J 5(4):214–220
- John JL, Arifulla M, Cheriathu J, Sreedhara J (2012) Reporting of adverse drug reactions: a study among Clinicians. J Appl Pharm Sc 2(6):135–139
- Leone R, Moretti U, D'Incau P, Conforti A, Magro L, Lora R, Velo G (2013) Effect of pharmacist involvement on patient reporting of adverse drug reactions: first Italian study. Drug Saf 36:267–276
- 23. Showande JS, Fakeye TO (2013) The Concept of adverse drug reporting: awareness among pharmacy students in a Nigerian University. Int J Med Update 8(1):24–60
- 24. Oshikoya KA, Awobusuyi JO (2009) Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos. Nigeria BMC Clin Pharmacol 9(1):14
- National universities commission. (2016) http://www.nuc.edu.ng. Accessed 25 Oct 2022.
- Toklu HZ, Uysal MK (2008) The knowledge and attitude of the Turkish community pharmacists toward pharmacovigilance in the Kadikoy district of Istanbul. Pharm World Sci 30(5):556–562

- Aljadhey H, Mahmoud MA, Alshammari TM et al (2015) A qualitative exploration of the major challenges facing pharmacovigilance in Saudi Arabia. Saudi Med J 36(9):1097–1102. https://doi.org/10.15537/smj. 2015.9.12125
- 28. Alkali NH, Bello MR (2020) Tertiary hospital standards in Nigeria: A review of current status. Ann Afr Med Res 4:3(1). Available from: https://www.aamronline.org/aamr/article/view/108
- 29. Herdeiro MT, Figueiras A, Polonia J, Gestal-Otero JJ (2006) Influence of pharmacists' attitudes on adverse drug reaction reporting: a case control study in Portugal. Drug Saf 29(4):331–340. https://doi.org/10.2165/00002 018-200629040-00004;PMid:16569082
- Suyagh M, Farah D, Farha RA (2015) Pharmacist's knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting process. Saudi Pharm J 23(2):147–153. https://doi.org/10.1016/j.jsps. 2014.07.001

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Submit your manuscript to a SpringerOpen[®] journal and benefit from:

- Convenient online submission
- Rigorous peer review
- Open access: articles freely available online
- High visibility within the field
- Retaining the copyright to your article

Submit your next manuscript at > springeropen.com