

Knowledge, attitudes and practice of pharmacovigilance amongst community pharmacists: a case study of Ogun State, Nigeria

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ABSTRACT

Background: Medicinal products are among the accomplished successes of the modern health, providing society with enormous benefits. However, medicinal product's known or unknown adverse drug reactions are contributing to deterioration of quality health and wellbeing. Core medicine safety information is generated during clinical trial phase with limitations to the detection of all adverse drug reaction (ADR) due to its restricted period. Pharmacovigilance focuses on detecting and reporting ADRs; hitherto, community pharmacists, often the first point of patients' contact, are preeminent in detecting and reporting ADRs.

Objectives: To assess the knowledge, attitude and the application of pharmacovigilance amongst community pharmacists.

Methods: Cross-sectional survey was conducted among community pharmacists in Ogun State. Data were obtained with a 33 - item self-administered questionnaire and analyzed using descriptive and Chi-square statistics.

Results: Pharmacists' knowledge of pharmacovigilance and reporting of ADRs was adequate as 78.1 % soundly understood pharmacovigilance definition and 73.1 % are knowledgeable about reporting ADRs. The existence of pharmacovigilance centers was confirmed by 81.3 % respondents. The attitudes to pharmacovigilance were positive as 99.6 % believed that the role and utility of pharmacists in ADRs reporting is crucial to their practice. However, 51.9% had a challenge with time and 96.3 % claimed easy accessibility to reporting forms would facilitate reporting. Age and years of experience of respondents were statistically significant with the knowledge, attitude and practice of pharmacovigilance amongst pharmacists.

Conclusion: There was a relatively good knowledge of pharmacovigilance, and positive attitudes towards ADR reporting; however, time constraints and easy access to reporting forms were barriers to active reporting.

Keywords: Attitude, community pharmacist, knowledge, pharmacovigilance,

Connaissances, attitudes et pratiques en matière de pharmacovigilance chez les pharmaciens communautaires : une étude de cas dans l'État d'Ogun au Nigeria

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RÉSUMÉ

Contexte: Les produits médicaux font partie des succès réalisés dans le domaine de la santé moderne, apportant à la société d'énormes avantages. Cependant, les effets indésirables connus ou inconnus des médicaments contribuent à la détérioration de la qualité de la santé et du bien-être. Les informations essentielles sur la sûreté des médicaments sont générées au cours de la phase d'essai clinique, ce qui limite la détection de tous les effets indésirables des médicaments (EIM) en raison de sa durée limitée. La pharmacovigilance se concentre sur la détection et la déclaration des effets indésirables des médicaments ; jusqu'à présent, les pharmaciens communautaires, qui sont souvent le premier point de contact avec les patients, jouent un rôle prépondérant dans la détection et la déclaration des effets indésirables des médicaments.

Objectifs: Évaluer les connaissances, l'attitude et l'application de la pharmacovigilance chez les pharmaciens communautaires.

Méthodes: Une enquête transversale a été menée auprès des pharmaciens communautaires de l'État d'Ogun. Les données ont été obtenues à l'aide d'un questionnaire auto-administré de 33 questions et analysées à l'aide de statistiques descriptives et du chi carré.

Résultats: Les connaissances des pharmaciens en matière de pharmacovigilance et de déclaration des effets indésirables sont satisfaisantes, puisque 78,1 % d'entre eux ont bien compris la définition de la pharmacovigilance et 73,1 % savent comment notifier les effets indésirables. L'existence de centres de pharmacovigilance a été confirmée par 81,3 % des personnes interrogées. Les attitudes à l'égard de la pharmacovigilance étaient positives puisque 99,6 % estiment que le rôle et l'utilité des pharmaciens dans la déclaration des effets indésirables sont essentiels pour leur pratique. Cependant, 51,9 % des personnes interrogées ont eu du mal à trouver le temps nécessaire et 96,3 % ont déclaré qu'un accès facile aux formulaires de déclaration faciliterait la déclaration. L'âge et le nombre d'années d'expérience des personnes interrogées étaient statistiquement significatifs pour les connaissances, l'attitude et la pratique de la pharmacovigilance chez les pharmaciens.

Conclusion: Les pharmaciens ont une connaissance relativement bonne de la pharmacovigilance et des attitudes positives à l'égard de la déclaration des effets indésirables ; cependant, les contraintes de temps et la facilité d'accès aux formulaires de déclaration constituent des obstacles à la déclaration active.

Mots-clés: attitude, pharmacien communautaire, connaissance, pharmacovigilance

INTRODUCTION

Complexity of drug therapy and intrinsic potential of drugs to develop multi-morbidity actions, may result into adverse effects, most noticeable when people administered drugs.¹ Although, medicinal products are authorized after an assessment of their quality, safety and efficacy and a positive benefit-risk balance,² the detection of all adverse drug reaction (ADR) is limited at this stage. The core medicine safety information is generated during the clinical trial phase.^{3,4,5} In point of fact, most medicines will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals.^{3,4,5} The patients are often selected from specific groups of relatively homogeneous people that have only one disease being treated with limited medicines in clinical trials.^{3,4,5}

Be as it may, once a licensed medicine is placed on the market, it leaves the clinical trial setting of the controlled scientific environment. This licensed medicine is not later on taken in only selected patients who suffer from only one disease but also it is likely administered in many patients who are treated by different agents for their concomitant diseases.^{6,7} Therefore, it is imperative that the use of medicines is monitored for their ongoing effectiveness and safety. The information that can be obtained before placing a medicinal product on the market is limited hence a thorough understanding of the benefit-risk balance is required. Pharmacovigilance is the term used to describe the detection and collection of data regarding drug related problem issues.

Pharmacovigilance (PV), as defined by the World Health Organization (WHO), is the "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem".⁸ Pharmacovigilance as an integral part of the global healthcare system needs cooperation of many different professions. The primary goal of PV implementation is to ensure the safe use of drugs, protect patient safety, and preserve public health. However, pharmacists being custodians of drugs, work towards achieving a main goal of minimizing the risks associated with the drugs and maximizing their benefits and improve patient safety and quality of life. This places community pharmacists in a pivotal position to detecting any issue relating to medication therapy. Additionally, the public's easy access to community pharmacies also place them as the first groups of professional to have contact with patients.^{3,4,5}

In spite of a medication's therapeutic benefits, adverse drug reactions have been a major global burden for years.⁹ Due to these adverse drug reaction cases, numerous studies have demonstrated the extent of pharmacovigilance knowledge and practice by healthcare professionals,^{3,4,5} the results of which present significant challenge to ensuring the safety of medication therapy and the protection of patients' health at large. A robust PV practice provides the information that helps to refine the healthcare policies and strategies that protect public health.¹⁰ This prompted more studies on the pharmacovigilance knowledge, attitude, and practice among community pharmacists in Ogun State, Nigeria. Objectively, the study aimed at assessing the knowledge of pharmacovigilance among community pharmacists; evaluate the attitude of community pharmacists towards pharmacovigilance and to examine the levels of pharmacovigilance practice among community pharmacists in Ogun State.

METHODS

Study site

This study was conducted, from August to November 2023, in Ogun State, South West Nigeria.

Study design study population

The study was a cross-sectional survey conducted using questionnaire as the survey tool. The self-administrable questionnaire adopted for the survey was carefully structured, pre-tested and piloted for clarity and was distributed among randomly selected registered community pharmacists practicing in Ogun State.

Inclusion and exclusion criteria

Community pharmacists in Ogun state were included while hospital pharmacists were excluded.

Study size

Yamane's formula was used to determine the sample size as 272 from the total population of 640 registered community pharmacists practicing in Ogun State at the time of study. Simple random sampling technique was used to select the (272) respondents.

Instrument for data collection

The questionnaire with no names or contact information recorded on it, to maintain the participant's privacy and confidentiality was used as the survey tool. To ensure its validity, the questionnaire was pilot tested on 10 randomly chosen participants (who were excluded from

the study) and adjustments were made where necessary. The (33 item) questionnaire was divided into four sections; demographics, knowledge on pharmacovigilance among respondents, attitude of respondents towards pharmacovigilance and practice of pharmacovigilance among the respondents. The data obtained with the questionnaire were analyzed using descriptive statistics (percentage, mean and standard deviation) and Chi-square as the inferential statistics, using SPSS version 23.

RESULTS

Almost all (270 of 272) participants attended to and returned the questionnaire given to them (99.3 % response rate). As shown in Table1, 104 (38.5 %) of the respondents fell within 20-30 age groups. The male pharmacists [143(53.0 %)] slightly outnumbered the female [127(47.0 %)]. Also, 104(38.5 %) of the respondents had less than 5 years of practice experience. Furthermore, 197(73.0 %) of the respondents had B.Pharm as highest academic qualification. Details of the findings are presented in Table 1.

Table 1: Socio-demographic characteristics of the participants

Variable	Group	Frequency (n=270)	Percentage (%)
Age	20-30	104	38.5
	31-40	78	28.9
	41-50	51	18.9
	51-60	27	10.0
	>60	10	3.7
Sex	Male	143	53.0
	Female	127	47.0
Religion	Islam	77	28.6
	Christianity	190	70.6
	Traditional	1	0.4
	Others	1	0.4
Practice Experience (years)	<5	104	38.5
	5-10	75	27.8
	10-15	43	15.9
	16-20	29	10.7
	>20	19	7.0
Marital Status	Single	104	38.8
	Engaged	52	19.4
	Married	99	36.9
	Divorced	9	3.3
	Widowed	4	1.5
Academic Qualification	B.pharm	197	73.0
	Pharm.D	30	11.1
	FWPCPharm	23	8.5
	PHD	3	1.1
	Msc	17	6.3
Place of Study	Nigeria	261	96.7
	Abroad	9	3.3

Provided in Table 2 are insights into the community pharmacists' understanding, awareness, and confidence regarding pharmacovigilance and ADRs, showing strong consensus on certain aspects and variations in perceptions on others. Results in Table 2 revealed that respondents' knowledge of pharmacovigilance (PV) was really remarkable given that 78.1 % of the respondents strongly agreed to the correct meaning of PV. A significant (73.0 %) proportion strongly agreed that the primary aim of PV was to ensure drug safety. In respect of adverse drug reactions, 66.7 % of the respondents

correctly defined adverse drug reactions while 14.4 % strongly agreed that ADRs are dose dependent and easily predictable. An appreciable proportion (81.3 %) of respondents were aware of the existence of a PV program in Nigeria while 73.1 % were aware of applications available for reporting adverse drug reactions. Majority (90.7 % of the respondents) claimed to possess adequate knowledge about common adverse drug reactions for the medications they dispense, indicating confidence in their understanding of potential risks associated with medications.

Table 2a: Knowledge of Community Pharmacists on Pharmacovigilance (n = 270)

Variable	Frequency	Percentage (%)
<i>Pharmacovigilance is the science and activity relating to detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccinereLATED problem</i>		
Strongly agree	211	78.1
Agree	58	21.5
Disagree	1	0.4
<i>The main purpose of pharmacovigilance is to ensure safety of drugs</i>		
Strongly agree	197	73.0
Agree	71	26.3
Neutral	1	0.4
Disagree	1	0.4
<i>Adverse drug reaction (ADRs) is any response to a drug which is noxious and unintended and which occurs at doses used in man for prophylaxis, diagnosis, or therapy or for modification of physiologic function</i>		
Strongly agree	180	66.7
Agree	83	30.7
Neutral	2	0.7
Strongly disagree	4	1.5
Disagree	1	0.4
<i>Pharmacovigilance activities in Nigeria are being coordinated by the National Agency for Food and Drug Administration and Control (NAFDAC)</i>		
Strongly agree	114	53.3
Agree	75	27.8
Neutral	29	10.7
Strongly disagree	15	5.6
Disagree	7	2.6
<i>Pharmacovigilance prevents potential ADR's and Improves patients' quality of life</i>		
Strongly agree	178	65.9
Agree	87	32.2
Neutral	3	1.1
Strongly disagree	1	0.4
Disagree	1	0.4
<i>Pharmacovigilance helps in saving cost for the patient, the health care institution and reduce hospital visits or admissions</i>		
Strongly agree	133	49.3
Agree	90	33.3
Neutral	26	9.6
Strongly disagree	13	4.8
Disagree	8	3.0

Table 2b: Knowledge of Community Pharmacist about Pharmacovigilance (n = 270)

Variable	Frequency	Percentage (%)
<i>ADRs are dose-dependent and are easily predictable</i>		
Strongly agree	39	14.4
Agree	76	28.1
Neutral	57	21.3
Strongly disagree	59	21.9
Disagree	37	13.7
<i>Some morbidity or mortality cases are due to ADRs</i>		
Strongly agree	98	36.3
Agree	96	35.8
Neutral	39	14.4
Strongly disagree	19	7.0
Disagree	16	5.9
<i>Are you aware of the pharmacovigilance program in Nigeria</i>		
Yes	217	81.3
No	50	18.7
<i>Are you aware of any application for reporting adverse drug reactions (ADRs)</i>		
Yes	198	73.1
No	72	26.9
<i>Are you aware of the medicine safety application for adverse drug reaction reporting</i>		
Yes	187	69.0
No	83	31.0
<i>Do you have adequate knowledge about common adverse drug reactions for the medications you dispense</i>		
Yes	245	90.7
No	25	9.3

More than a quarter (38.5%) of the pharmacists found ADR reporting process time-consuming. Almost all (99.6%) of the pharmacists believed they have an essential role to play in reporting ADR and 98.5% found the ADR reporting and monitoring systems useful to their practice. Majority (98.9%) of the pharmacists believed that ADR reporting and monitoring systems would benefit patients and 33.0% believed that there may be foot-dragging approach to reporting ADRs due to fear of litigation. Majority (96.3%) of the respondents claimed they would be able to report ADRs if reporting forms were distributed within the pharmacy. Details of the findings are presented in Table 3.

Table 3: Attitude of Community Pharmacists towards Pharmacovigilance (n = 270)

Variable	Frequency	Percentage (%)
<i>Do you think ADR reporting process is time consuming</i>		
Yes	104	38.5
No	166	61.5
<i>Do you think community pharmacists have an essential role to play in ADR reporting</i>		
Yes	269	99.6
No	1	0.4
<i>Do you think ADR reporting and monitoring systems in your community pharmacy is useful for your practice</i>		
Yes	266	98.5
No	4	1.5
<i>Do you think that ADR reporting and monitoring system would benefit the patient</i>		
Yes	267	98.9
No	3	1.1
<i>Community pharmacists are usually unwilling to report ADR because of fear of crime</i>		
Yes	89	33.0
No	181	67.0
<i>Do you think there is lack of time to actively look on an ADR while at work</i>		
Yes	138	51.9
No	128	48.1
<i>Is pharmacist assistance in detection, reporting and management of ADR useful</i>		
Yes	244	92.1
No	21	7.9
<i>Will you be able to report an ADR if the reporting forms would be distributed into the pharmacy</i>		
Yes	260	96.3
No	10	3.7

Table 4 highlighted existing PV related practices among community pharmacists in Ogun State. Almost half (45.5%) of pharmacists always ask their patients about adverse reactions. Also, 35.6% of patients always inform pharmacists about ADRs while 58.5% of pharmacists encountered ADR incidents but did not report ADRs to the National Pharmacovigilance Center (NPC). Hitherto, most pharmacists used the NPC Yellow Form (67.0%) or guidelines obtained from training (33.0%) to report ADRs. Challenges encountered in reporting included uncertainty about where to drop the form after filling (42.6%), and an expectation that NPC officials would pick up the filled forms (30.9%).

Table 4: Existing Pharmacovigilance Related Practices among Community Pharmacists (n = 270)

Variable	Frequency	Percentage (%)
<i>Do you usually ask your patients about adverse reactions they experience when they come to the pharmacy</i>		
Always	122	45.5
Never	6	2.2
Sometimes	140	52.2
<i>Do patients usually inform you about adverse drug reactions they experience when they come to the pharmacy</i>		
Always	96	35.6
Never	2	0.7
Sometimes	170	63.4
<i>Have you ever encountered an ADR but did NOT report the incidence to the NPC</i>		
Yes	158	58.5
No	112	41.4
<i>Have you ever reported any ADRs as a community pharmacist</i>		
Yes	128	47.4
No	142	52.6
<i>Who did you report the ADRs to</i>		
The NPC	50	39.1
Drug Information Center (DIC) of the Association of Community Pharmacists in Nigeria (ACPN)	44	34.4
Pharma Company	15	11.7
Others	19	14.8
<i>How did you report the ADR</i>		
Used NPC Yellow Form	63	67.0
Used guidelines obtained from training	31	33.0
<i>Did you encounter any problem or difficulty in reporting the ADR to the pharmacovigilance center</i>		
Yes	68	25.2
No	202	74.8
<i>What Kinds of Problem did you encounter</i>		
Did not know where to drop the form after filling	29	42.6
Expected NPC Officials to pick up the forms	21	30.9
Did not know whom to submit to at the NPC	18	26.5

Chi-square test statistic showed that none of the socio-demographic characteristics of the respondents had significant association with their knowledge of PV. Details of the findings are presented in Table 5.

Table 5: Comparative assessment of Knowledge of the Participant

Variable	Adequate Knowledge	Inadequate Knowledge	χ^2	p-Value
<i>Age</i>				
20-30	67	37	6.4080	0.1710
31-40	59	19		
41-50	43	8		
51-60	18	9		
>61	6	4		
<i>Sex</i>				
Male	102	41	0.0030	0.9530
Female	91	36		
<i>Years of Experience</i>				
<5	71	33	8.5180	0.074
5-10	61	14		
10-15	33	10		
16-20	19	10		
>20	9	10		
<i>Academic Qualifications</i>				
B.Pharm	141	56	3.0340	0.5520
Pharm.D	25	5		
FWPCPharm	15	8		
PhD	2	1		
MSc	10	7		

Chi-square test statistic showed that respondents' age had significant association with respondents' attitude towards PV ($\chi^2 = 21.30$, $p < 0.01$). Details of the findings are presented in Table 6.

Table 6: Comparative assessment of Attitude of the Participant

Variable	Positive Attitude	Negative Attitude	χ^2	p-Value
<i>Age</i>				
20-30	62	42	21.3010***	0.0001
31-40	67	11		
41-50	45	6		
51-60	15	12		
>61	7	3		
<i>Sex</i>				
Male	104	39	0.19400	0.6600
Female	92	35		
<i>Years of Experience</i>				
<5	66	38	6.4160	0.1700
5-10	64	11		
10-15	30	13		
16-20	23	6		
>20	13	6		
<i>Academic Qualifications</i>				
B.Pharm	135	62	7.5040	0.1120
Pharm.D	27	3		
FWPCPharm	17	3		
PhD	2	1		
MSc	15	2		

Chi-square test statistic showed that respondents' age ($\chi^2 = 15.65$) and years of experience ($\chi^2 = 13.43$) had significant association ($p < 0.05$) with respondents' existing PV practices level. Details of the findings are presented in Table 7.

Table 7: Comparative assessment of Practice of the Participant

Variable	Poor Practice	Fair Practice	Good Practice	χ^2	p-Value
<i>Age</i>					
20-30	1	60	43	15.6490**	0.0480
31-40	1	37	39		
41-50	2	14	35		
51-60	1	14	12		
>61	1	2	7		
<i>Sex</i>					
Male	1	69	72	2.2740	0.3210
Female	5	58	64		
<i>Years of Experience</i>					
<5	1	54	49	13.4330**	0.0322
5-10	0	34	41		
10-15	1	14	27		
16-20	2	17	10		
>20	2	8	9		
<i>Academic Qualifications</i>					
B.Pharm	4	92	100	9.8000	0.2790
Pharm.D	0	15	15		
FWPCPharm	0	10	13		
PhD	0	2	1		
MSc	2	8	7		

DISCUSSION

Globally, researches have shown either poor or lack of better knowledge, attitude and practice of pharmacovigilance by pharmacists in different facets of pharmacy in the past.¹ However, there is a considerable change in recent times; for example, current researches on PV indicate improving knowledge, attitude and practice by pharmacists. By implication, an enhanced professional culture has been built by pharmacists accepting the fact that the profession is no more drugs centric but patients focused.

In this study, a general consensus on the definition and purpose of pharmacovigilance, reflecting a robust understanding of pharmacovigilance among the respondents was observed. There are varying perspectives on aspects like the predictability of adverse drug reactions, indicating divergence in understanding within the sampled group. This study established that

there is an adequate knowledge of the concept of pharmacovigilance but there is still room for further improvement. These findings were contrary to that of Oreagba *et al.*¹¹ study in Lagos which found there was poor knowledge about pharmacovigilance among pharmacists in the study group. A similar study in Ibadan by Adisa and Omitogun⁹ found that there was a poor knowledge of the concept of pharmacovigilance. A report by Adedeji *et al.*¹² on public health facilities of Oyo State also reported inadequate knowledge and poor reporting of ADRs. Better knowledge of pharmacovigilance in the present study may be attributed to daily awareness in the advancement of pharmacy practice among pharmacists.

The attitudes of community pharmacists toward ADR reporting and monitoring systems demonstrated a positive inclination, emphasizing the belief in the crucial role pharmacists play in reporting ADRs and the

perceived utility of these systems for patient benefit. Nevertheless, concerns about time constraints and fear influencing reporting behavior exist among a segment of pharmacists, reflecting potential barriers to effective reporting. The existing practices related to pharmacovigilance among community pharmacies reveal a mixed scenario. While a notable proportion of pharmacists inquire about ADRs and report them, a significant number encounter challenges in the reporting process, primarily logistical uncertainties and procedural obstacles. This suggests a need for more streamlined and accessible reporting mechanisms to facilitate smoother ADR reporting practices. This was the same conclusion by O'Donnell *et al.*¹³ study, which identified barriers and a need to improve the ADR reporting process to encourage reporting among respondents.

The assessment of knowledge, attitudes and practice among participants based on socio-demographic characteristics highlights statistically significant associations. For instance, age exhibited statistically significant association with pharmacists' attitude to PV, while years of experience showed significant associations with pharmacists' practice levels.

CONCLUSION

The study offers crucial insights into the socio-demographic characteristics, knowledge, attitudes, and practices of community pharmacists regarding pharmacovigilance and ADR reporting. It's evident that while there is a strong foundation of knowledge and positive attitudes toward ADR reporting, there are barriers such as time constraints and procedural uncertainties that impede active PV practice.

To significantly improve the pharmacovigilance practices among community pharmacists, some steps could be taken. These include enhancing knowledge through training and awareness, simplifying reporting procedures, ensuring access to reporting tools, and offering time-management support. Addressing these areas will likely foster a more robust and effective ADR reporting system within community pharmacies, consequently enhancing drug safety and patient care.

Ethical considerations

This study was approved by the ethical committee of the Olabisi Onabanjo University Teaching Hospital, Ogun State, Nigeria. (Ref No.: OOUTH/HREC/719/2023AP)

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CONFLICT OF INTEREST

We declare no conflicting interest.

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