West African Journal of Pharmacy (2026) 37 (2) 183 - 190 **DOI:** https://doi.org/10.82351/wajp.vol37no2.498

Pharmacovigilance at the National Orthopaedic Hospital Igbobi Lagos Nigeria: Knowledge and Attitude of the Healthcare Workers

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ABSTRACT

Background: Pharmacovigilance encompasses drug safety monitoring and adverse drug reactions (ADR) reporting. There is currently no literature on the knowledge of ADR monitoring and reporting amongst professional healthcare workers of the National Orthopaedic Hospital, Igbobi, Lagos.

Objectives: To determine healthcare workers' knowledge and attitude towards pharmacovigilance at the National Orthopaedic Hospital, Igbobi, Lagos.

Methods: A cross-sectional study was conducted at the centre. A questionnaire with focus on the knowledge and attitudes of healthcare workers towards pharmacovigilance was administered to Pharmacists, Physicians, Nurses, Physiotherapists, Medical Laboratory Scientists and Radiographers; and retrieved accordingly after the healthcare workers had completed the filling of the questionnaire.

Results: The result indicated a satisfactory knowledge of drug safety monitoring and adverse drug reactions as shown by a mean score of 36.24 $\pm$ 5.25 in 74.7 % of respondents. The attitude towards adverse drug reaction reporting was also satisfactory with a mean score of 22.29 3.83 in 88.8 % of respondents. However, uncertainty about drug reaction and drug relationship (3.79 $\pm$ 0.61 in 71 $\pm$ 6 % of respondents) is the main barrier towards ADR reporting. Fear of legal consequences (3.28 $\pm$ 0.58 in 88.8 % of respondents) was the least of the barriers. Lack of time (3.56 $\pm$ 0.59 in 65.9 % of respondents), lack of adequate knowledge (3.59 $\pm$ 0.60 in 65.8 % of respondents), lack of access to reporting tools (3.58 $\pm$ 0.59 in 64.0 % of respondents), were also recognized as factors that may act as barriers towards effective adverse drug reaction reporting.

Conclusion: Health care workers in NOHIL have a satisfactory knowledge of pharmacovigilance. Their knowledge of pharmacovigilance has an important influence on their attitude towards ADR reporting.

Keywords: Drug safety monitoring, adverse drug reaction, knowledge, attitude, reporting

 DOI: https://doi.org/10.82351/wajp.vol37no2.498

Pharmacovigilance à l'hôpital orthopédique national d'Igbobi, Lagos, Nigéria : connaissances et attitudes des professionnels de santé

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RÉSUMÉ

Contexte : La pharmacovigilance englobe la surveillance de la sécurité des médicaments et la notification des effets indésirables des médicaments (EIM). À l'heure actuelle, aucune donnée n'est disponible concernant les connaissances des professionnels de santé de l'Hôpital orthopédique national d'Igbobi, à Lagos, en matière de surveillance et de notification des effets indésirables.

Objectifs : Déterminer les connaissances et l'attitude des professionnels de santé en matière de pharmacovigilance à l'hôpital orthopédique national d'Igbobi, à Lagos.

Méthodes : Une étude transversale a été menée au sein de l'établissement. Un questionnaire portant sur les connaissances et les attitudes des professionnels de santé en matière de pharmacovigilance a été administré aux pharmaciens, médecins, infirmiers, physiothérapeutes, techniciens de laboratoire et manipulateurs en radiologie ; les questionnaires ont été récupérés une fois remplis par les participants.

Résultats : Les résultats indiquent une connaissance satisfaisante de la pharmacovigilance et des effets indésirables des médicaments, comme en témoigne un score moyen de 36,24 ± 5,25 obtenu par 74,7 % des répondants. L'attitude à l'égard de la notification des effets indésirables des médicaments était également satisfaisante, avec un score moyen de 22,29 ± 3,83 obtenu par 88,8 % des répondants. Cependant, l'incertitude quant aux réactions médicamenteuses et aux interactions médicamenteuses (3,79 ± 0,61 chez 71,6 % des répondants) constitue le principal frein à la notification des effets indésirables. La crainte de conséquences juridiques (3,28 ± 0,58 chez 88,8 % des répondants) représente le moindre frein. Le manque de temps (3,56 ± 0,59 chez 65,9 % des répondants), le manque de connaissances adéquates (3,59 ± 0,60 chez 65,8 % des répondants), le manque d'accès aux outils de signalement (3,58 ± 0,59 chez 64,0 % des répondants) ont également été reconnus comme des facteurs pouvant constituer des obstacles à une notification efficace des effets indésirables des médicaments.

Conclusion : Les professionnels de santé du NOHIL possèdent des connaissances satisfaisantes en matière de pharmacovigilance. Ces connaissances influencent fortement leur attitude face à la notification des effets indésirables des médicaments.

Mots-clés : Surveillance de la sécurité des médicaments, effets indésirables des médicaments, connaissances, attitudes, notification

INTRODUCTION

Pharmacovigilance is the pharmacological science of detecting, assessing, understanding, and preventing adverse drug effects or other medicines-related problems. It is relevant that we identify possible risks related to drugs, as lack of safety monitoring has led to unfortunate events in the past, such as death caused by using anesthesia and congenital malformation from the use of thalidomide.[1] The assessment and detection of the safety of drugs in clinical trials are limited due to the duration of the study and controlled population. The controlled population involved in drug clinical trials represents a small portion of the real-life users that will use the drug once it is in the market. This assessment continues through post-marketing surveillance that relies on the active participation of healthcare providers and consumers to provide data for pharmacovigilance and meaningful engagement to support drug safety during use in a large number of the population.

The collection of data for drug safety monitoring and adverse drug reactions reporting is the responsibility of federal regulations and the manufacturer of the medications.[2] The data collected is forwarded to WHO approved national pharmacovigilance centers (NCPs) which is then stored in the WHO global database, VigiBase which is maintained by Uppsala Monitoring Centre in Sweden.[3]

With adverse drug reaction being the fifth cause of death in hospitalized patients, under-reporting has been a major challenge as it is estimated that 90-94 % of cases are unreported which had been traced to the knowledge of the health professionals as it relates to pharmacovigilance and reporting of adverse drug reactions.[4] This has led to delays in activating warning signals and as a ripple effect, affect the public hence, the economy.[4] Knowledge and attitude of healthcare workers about pharmacovigilance play a part in their reporting of adverse drug reaction. In a study to evaluate the knowledge, attitudes, and practices of pharmacovigilance among healthcare professionals at a tertiary hospital in Sudan, it was found that while knowledge was adequate and attitude favourable, practical reporting rates was low. Targeted training as well as streamlined reporting mechanisms and Policy interventions were recommended.[5] In another similar study, insufficient knowledge about pharmacovigilance among healthcare workers was found to correlate with significant underreporting.[6] Studies to assess the knowledge and attitude of healthcare professionals about pharmacovigilance have not been carried out at the National Orthopaedic Hospital Igbobi Lagos thereby making this research work necessary. This study specifically seeks to assess the healthcare workers' knowledge of and attitude towards pharmacovigilance at the hospital.

METHODS

Setting

The study was conducted at the National Orthopaedic Hospital Igbobi Lagos. The hospital is the largest and foremost orthopaedic healthcare facility in Nigeria for the management of orthopaedic, trauma and accident cases. It is a 450-bed tertiary health facility serving Lagos metropolis residents and people living predominantly in the southwestern part of the country either on an in or outpatient basis.

Ethical approval for this research was obtained from the hospital's research ethics committee before conducting this research (Reference Number: NOH/HREC/01/23, Approval Date: 23/07/2024).

A 23-item questionnaire was administered to healthcare professionals who work in the hospital. The healthcare professionals included in the study includes pharmacists, physicians, nurses, physiotherapists, medical laboratory scientists and radiographers.

Data analysis

The retrieved questionnaires were analysed using descriptive statistics with the aid of SPSS statistical package version 29. Test for statistical significance of the association between knowledge of pharmacovigilance amongst healthcare workers at NOHIL and their attitude towards ADR reporting was determined with the Chi-square test at 5 % significance level and 95 % confidence level. In the section of the questions that dealt with the assessment of the healthcare workers knowledge of pharmacovigilance, nine questions were asked on a Likert scale response with strongly agree corresponding to score of 5 and strongly disagree corresponding to a score of 1. Respondents who picked a strongly agree response for all the nine questions will have a total maximum score of 45 and those who picked strongly disagree will have a total maximum score of 9. A logical average point was assumed to be 27 after summing up the two scores to obtain 54 and then dividing the summed-up score of 54 by 2. Since the summated score correlated with the healthcare workers' knowledge

about pharmacovigilance and adverse drug reactions, scores above 27 were taken as positive indicators of adequate knowledge of pharmacovigilance and adverse drug reaction.

The standard deviation was calculated as a measure of item variability from the mean. Any low standard deviation indicated a cluster of responses to the mean while high standard deviation reflected a high variability of opinion from the mean. The percentage performance was the number of respondents who scored above the critical or neutral point on the rating scale (4 or 5). Association between healthcare professionals' knowledge of pharmacovigilance and attitude towards adverse drug reaction reporting respectively was determined using the Chi-square test statistic at 5% significance level and 95% confidence level.

RESULTS

Demographic distribution of the respondents

Table 1 shows the demographic distribution of the respondents as well as their professional distribution.

Table 1: Demography of the respondents

Item	Frequency	Percentage %
Gender		
Male	33	27.3
Female	87	71.9
Non- response	1	0.8
Age (Years):		
18-24	1	0.8
25-35	34	28.1
36-45	33	27.3
46-55	26	21.5
56-60	25	20.7
Non - response	2	1.7
Profession		
Pharmacist	16	13.2
Physician	22	18.2
Nurse	58	47.9
Physiotherapist	15	12.4
Medical laboratory scientist	8	6.6
Radiographer	2	1.7
Years of work experience		
Less than 5 years	19	15.7
Between 5-15years	47	38.8
Between 16-25years	32	26.4
Between 26-35years	23	19.0

Knowledge of adverse drug reactions

Table 2 shows the analysis of the healthcare workers' knowledge of adverse drug reactions.

Table 2: Item analysis of responses to knowledge of adverse drug reactions

Item	Mean	Standard Deviation	% Performance
ADR is a noxious reaction to a drug occurring at normal doses	4.64	0.44	98.3
ADR could be classified as Type A, B, C, D, E or F reaction	3.83	0.53	62.0
National Pharmacovigilance Centre Under NAFDAC is responsible for ADR monitoring in Nigeria	4.21	0.69	86.0
Drug induced abnormal laboratory test result is also a case of ADR	4.07	0.66	81.0
Abnormal reaction to contrast media during CT Scan is also a case of ADR	4.04	0.69	76.9
Abnormal skin reaction to creams, ointments, lotions and pastes is also a case of ADR	4.18	0.69	84.3
An ADR can be reported by the use of the Individual Case Report Form (Yellow Form)	3.83	0.63	69.4
Med Safety App and NAFDAC Website also provides for on-line reporting of suspected ADR	3.80	0.60	66.1
All suspected ADRs are entered into a local database in Nigeria, analysed and then sent to Uppsala in Sweden for review	3.64	0.32	47.9
Mean Total	**36.24**	**5.25**	**74.7**

Mean: Average response score of the respondents to each of the questions about knowledge of pharmacovigilance

Attitude towards adverse drug reaction reporting

Table 3 shows the analysis of the respondents' attitude towards adverse drug reaction reporting.

Table 3: Item analysis of attitudes toward the reporting of ADR

Item	Mean	Standard deviation	%
How important do you think ADR reporting is for patient safety?	4.77	0.84	96.7
Healthcare workers have a professional responsibility to report ADRs	4.66	0.81	97.5
The ADR reporting system of NOHIL has been effective in reducing incidence of ADRs in the hospital	3.87	0.62	64.4
The ADR reporting system of NOHIL is beneficial to the patients, the healthcare professionals and the NOHIL healthcare system as a whole	4.39	0.75	88.3
Healthcare professionals must show interests in pharmacovigilance to improve efficiency and effectiveness in ADR reporting.	4.60	0.81	97.5
Mean Total	**22.29**	**3.83**	**88.8**

Mean: Average response score of the respondents to each of the questions about attitude towards ADR reporting

Association between knowledge of pharmacovigilance and attitude towards adverse drug reaction reporting

The analysed chi-square statistical association between knowledge of pharmacovigilance and attitude towards adverse drug reaction reporting is shown in Table 4. A statistically significant association was established between knowledge of pharmacovigilance and attitude towards reporting of adverse drug reactions.

Table 4: Chi-square statistical analysis of association between knowledge of ADR and attitude towards ADR reporting

Knowledge of ADR reporting	Positive attitude	Negative attitude	Total
Adequate	25	31	56
Inadequate	16	49	65
Total	**41**	**80**	**121**

$\chi^2 = 5.386$, $P < 0.05$

DISCUSSION

The result of this study is in agreement with the result of a similar study conducted in South Africa, where more than 50 % of the respondents knew about adverse drug reaction and reporting of adverse drug reaction.[7] The benefits of reporting by enhanced continuous professional development in pharmacovigilance was encouraged.[7] In another similar study, a cross sectional survey conducted in Nigeria, a moderate knowledge of pharmacovigilance and ADR reporting was however reported.[8] In another similar study conducted in a Northwestern state in Nigeria, however, a low level of knowledge of adverse drug reaction and reporting using the yellow card-reporting scheme was reported amongst healthcare workers. The need for regular training and reinforcement of guidelines for ADR reporting amongst healthcare personnel as well as the inclusion of nurses more in the ADR reporting process was recommended.[9]

The knowledge of pharmacovigilance and adverse drug

reaction reporting is important for its effective integration into a healthcare system.[12] In a study of community pharmacists' knowledge, attitude and practice towards pharmacovigilance, knowledge was found to be very poor as only 11 % of participants had adequate knowledge of pharmacovigilance.[8] Similar studies revealed inadequate knowledge of pharmacovigilance and ADR reporting.[11] Possible reasons adduced for the inadequate knowledge of pharmacovigilance and ADR reporting include lack of knowledge of where to report a suspected ADR to, the non-making of ADR report mandatory in their institution as well as the perception that ADR reporting is non-essential.[12]

The result of this study revealed that healthcare workers at NOHIL have a positive attitude towards ADR. The result of this study is in agreement with a similar study conducted in Sudan which showed a favourable attitude of healthcare workers towards pharmacovigilance though practical reporting rate was found to be low.[5] Another study conducted in a tertiary healthcare institution in Malaysia in contrast revealed a 40.7 % positive attitude towards ADR reporting. Those with greater knowledge of pharmacovigilance were found to however, have lesser negative attitude towards ADR reporting. Our result is also in agreement with a similar study of attitude of healthcare workers in a healthcare institution which revealed good attitude towards ADR reporting as shown by a mean score of 85 ± 15.3 in 72.2 % of respondents.[13] In a systematic review of 35 articles on healthcare workers attitude towards pharmacovigilance and ADR reporting, many were found to have positive attitude ADR reporting though with significant knowledge deficit particularly regarding how to report ADR. This was responsible subsequently to the underreporting of ADRs noticed in the systematic review.[14]

The result of this study revealed a statistically significant association between knowledge of pharmacovigilance amongst healthcare workers at NOHIL and their attitude towards ADR reporting ($\chi^2 = 5.386$, $P < 0.05$). Our finding is in agreement with the result of a similar study which also revealed a statistically significant association between healthcare workers knowledge level of pharmacovigilance and attitude towards ADR reporting (, $P = 0.02$, Cramer's $V = 0.27$, $\chi^2 = 7.6$).[5]

In reporting of ADR as part of pharmacy practice, this study revealed that uncertainty about adverse reaction and drug relationship (3.79 ± 0.61 in 71.6 % of respondents) was the main barrier that affects ADR reporting amongst healthcare workers. Fear of legal consequences (3.28 ± 0.58 in 88.8 % of respondents) was identified as the least barrier that affects ADR reporting amongst healthcare workers. Other barriers such as lack of adequate knowledge (3.59 ± 0.60 in 65.8 % of respondents), and fear of lack of time (3.58 ± 1.138 in 65.9 % of respondents) negatively affected the reporting of ADR. A lack of access to reporting tools (3.58 ± 0.59 in 64.0% of respondents) was also identified as a barrier towards effective ADR reporting by many of the respondents. These findings are in agreement with a similar study about the barrier to effective reporting of ADR conducted in a tertiary health facility in India where ADR reporting was identified as a time-consuming process. Fear of liability, a lack of understanding of ADR reporting mechanism, the complicated nature of the ADR reporting form, as well as the lack of motivation for ADR reporting were also identified as barriers to ADR reporting in the facility. Differences, however, exist in the degree to which each of the barriers affected each of the health profession group.[15] Another similar study corroborated our findings where lack of time and the pharmacist perception that the ADR was not serious enough were identified as barriers to ADR reporting.[16]

CONCLUSION

Knowledge of pharmacovigilance is satisfactory amongst healthcare workers at the National Orthopaedic Hospital Igbobi. Their knowledge has an important influence on their attitude towards ADR reporting.

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