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Knowledge, attitude and participation of hospital pharmacists in adverse drug reaction monitoring and reporting in Ibadan, southwest Nigeria

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ABSTRACT

Background: Pharmacists as a significant member of healthcare team are expected to play a pivotal role in adverse drug reaction (ADR) detection, monitoring and reporting. However, pharmacists have been found to inconsistently engage in this practice, thereby underscoring the need for periodic evaluation of their participation in core-aspects of ADRs.

Objective: To assess knowledge, attitude and participation of pharmacists in 11-public hospitals in Ibadan, southwestern Nigeria in ADR detection, monitoring and reporting.

Method: This was a questionnaire-guided cross-sectional survey among pharmacists in the 11-selected hospitals. Demographic information, general knowledge in ADRs, as well as attitude and participation in ADR detection, monitoring and reporting were assessed. Data were summarised using descriptive statistics, while categorical variables were evaluated using Chi-square ($\chi 2$) test at $p<0.05$.

Results: All the 37 participants completely responded to the question-items. Twenty-one (56.8%) had 1-10 years' practice experience and 24 (65.0%) had prior ADR-related training. Overall, 17 (45.9%) had 'adequate' knowledge, 28 (75.1%) demonstrated 'positive' attitude, and 17 (45.9%) showed 'high' level of participation in ADR detection and monitoring. Prior training in ADR-reporting significantly influenced knowledge ($\chi 2=4.220$, $p=0.04$) and attitude ($\chi 2=9.489$, $p=0.004$).

Conclusion: The general knowledge of hospital pharmacists about ADRs and reporting is relatively moderate. Approximately three-quarters show positive attitude towards ADR reporting, and nearly half exhibit high level of participation. There is generally a need for consistent training and re-training of hospital pharmacists in the core-concept of ADRs and ADR-reporting, as this may help in bridging the knowledge and practice gaps to enhance reporting rate.

Keywords: Adverse drug reaction reporting, Hospital pharmacists, Knowledge and attitude, Nigeria

Connaissance, attitude et participation des pharmaciens hospitaliers au suivi et à la déclaration des effets indésirables des médicaments à Ibadan, dans le sud-ouest du Nigéria

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RESUME

Contexte : Les pharmaciens, en tant que membre important de l'équipe de soins de santé, devraient jouer un rôle central dans la détection, le suivi et la déclaration des effets indésirables des médicaments (EIM). Toutefois, on a constaté que les pharmaciens s'engagent de façon incohérente dans cette pratique, ce qui souligne la nécessité d'une évaluation périodique de leur participation aux aspects fondamentaux des EIM.

Objectif : Évaluer les connaissances, l'attitude et la participation des pharmaciens dans 11 hôpitaux publics d'Ibadan, dans le sud-ouest du Nigéria, à la détection, au suivi et à la déclaration des EIM.

Méthode : Il s'agit d'une enquête transversale guidée par questionnaire auprès des pharmaciens des 11 hôpitaux sélectionnés. Les informations démographiques, les connaissances générales sur les effets indésirables (EIM) ainsi que l'attitude et la participation à la détection, au suivi et à la déclaration des effets indésirables ont été évaluées. Les données ont été résumées à l'aide de statistiques descriptives, tandis que les variables catégorielles ont été évaluées à l'aide du test du chi carré (?2) à p <0,05.

Résultats : Tous les 37 participants ont répondu à toutes les questions. Vingt-et-un (56,8%) avaient entre 1 et 10 ans d'expérience dans la pratique et 24 (65,0%) avaient reçu une formation préalable liée aux EIM. Dans l'ensemble, 17 (45,9%) avaient des connaissances " adéquates ", 28 (75,1%) ont fait preuve d'une attitude " positive " et 17 (45,9%) ont montré un niveau " élevé " de participation à la détection et au suivi des effets indésirables. Une formation préalable à la notification des effets indésirables a eu une influence significative sur les connaissances (?2 = 4,220, p = 0,04) et l'attitude (?2 = 9,489, p = 0,004).

Conclusion : Les connaissances générales des pharmaciens hospitaliers sur les effets indésirables et la déclaration sont relativement modérées. Environ les trois quarts affichent une attitude positive à l'égard des notifications sur les EIM, et près de la moitié affichent un niveau élevé de participation. Il y a généralement un besoin de formation et de recyclage uniforme des pharmaciens hospitaliers sur le concept de base des effets indésirables et de la déclaration des effets indésirables, car cela peut aider à combler les lacunes en matière de connaissances et de pratique afin d'améliorer le taux de déclaration.

Mots-clés : *Déclaration des effets indésirables des médicaments, pharmaciens hospitaliers, connaissances et attitude, Nigéria*

INTRODUCTION

Adverse drug reactions (ADRs) is a major global concern that adversely impact patient safety and health outcomes.[1,2] In both developed and developing countries, ADRs have been identified as significant cause of morbidity and mortality,[2-4] as well as increased healthcare costs[5] and patient dissatisfaction with treatments.[1,2] Spontaneous ADR reporting, which is the cornerstone of pharmacovigilance relies largely on healthcare professionals who are expected to report all ADRs regardless of uncertainty about a causal relationship.[6] In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) stipulates that healthcare providers including pharmacists should report all suspected adverse reaction that is considered of clinical importance as soon as it is detected, to the National Pharmacovigilance Centre (NPC) using the ADR report form popularly referred to as 'yellow form'.[7] In addition, NAFDAC introduced a toll-free short message service (SMS) alert system tagged 'Pharmacovigilance Rapid Alert System for Consumer Reporting (PRASCOR)'. The SMS short code alert system is designed for prompt report of ADRs directly to the NPC.[7,8] Despite the obvious advantages of spontaneous reporting system, underreporting of ADRs remain a foremost problem hindering progressive achievement in pharmacovigilance activities.[9-12] A systematic review of the determinants of underreporting of ADRs among healthcare professionals based on Inman's seven sins of underreporting revealed that ignorance was the greatest determinant of underreporting.[13,14] Also, the voluntary nature of spontaneous reporting of ADRs in most countries including Nigeria does not help the situation.[15,16]

Adverse drug reaction monitoring is a process of continuous observing of undesirable effects suspected to be associated with the use of medicinal products.[17] The essential components include information about the patient, description of the ADRs, the suspected drug(s) and the reporter.[17] Hospital pharmacists, by virtue of their routine practice are in regular contact with patients, thus, they are in a key position to monitor, detect and report ADRs.[17-19] However, studies have indicated that pharmacists in many low-income countries including Nigeria have not been reporting ADRs to their full potentials.[20-22] Factors responsible for underreporting and low level of involvement of healthcare providers including pharmacists in ADR reporting have been identified as inadequate knowledge about ADRs, workload and time constraints to report,[23-28] as well as lack of remuneration[29-31] among others. On the other hand, in some developed countries, it has been confirmed that increased participation of pharmacists in pharmacovigilance activities can play a significant role to improve underreporting of ADRs.[32,33] This study therefore generally aim to explore the knowledge and level of participation of hospital pharmacists in ADR detection, monitoring and reporting. Specifically, we assessed the knowledge, attitude and participation of hospital pharmacists working in 11 public secondary healthcare facilities in Ibadan, southwestern Nigeria in ADR monitoring and reporting. Opinion on factors that can either motivate or hinder reporting of ADRs among the participants was also explored.

Ethics approval

Ethics approval was obtained from the Research Ethics Review Committee in the Ministry of Health, Oyo state with approval number AD 13/479/673. Permission was also obtained from the Head of Pharmacy department of each hospital.

METHOD

Study site

All the 11-state government-owned healthcare facilities in Ibadan, Oyo state were used as study sites. This comprised Ring Road State Hospital (6 pharmacists), General Hospital Moniya (5 pharmacists), Adeoyo Maternity Hospital, Yemetu (4 pharmacists), Jericho Nursing Home (4 pharmacists), Oni Memorial Children's Hospital (4 pharmacists), General Hospital Aremo (3 pharmacists), Mother and Child Hospital, Apata (3 pharmacists) Jericho Specialist Hospital (3 pharmacists), Jericho Chest Clinic (2 pharmacists), State Secretariat Clinic (2 pharmacists) and State High Court Clinic (one pharmacist). These public hospitals offer in-patient and out-patient services, as well as generally cater for the healthcare needs of the people within and outside the state.

Study population

Pharmacists working in the 11 selected hospitals, with at least one-year post-qualification practice experience.

Study design

This was a cross-sectional questionnaire-guided survey among hospital pharmacists in all the selected public healthcare facilities.

Inclusion and exclusion criteria

Pharmacists working in the selected hospitals, who had at least one-year post-qualification practice experience

were enrolled, while pharmacist-internee who are undergoing pre-registration training were excluded.

Sample size determination

The record available from Oyo State Hospital Management Board as at 2018, showed that a total population of 37 registered pharmacists were working in public secondary care hospitals within Ibadan metropolis. Based on the estimated number, at 95% confidence level and 5% margin of error, a representative sample size of 34 was obtained using the Raosoft® sample size calculator.[34] Incorporating a 10% attrition rate gave a target sample population of approximately 37 to guide enrollment of participants.

Data collection instrument

Questionnaire for the study was developed by the investigators following extensive review of relevant studies,[23,26,31,35] as well as previous practice experience. The questionnaire consisted of five sections.

Section A captured demographic characteristics, as well as information on prior training in ADR reporting. Section B contained 10-question-items that evaluated general knowledge of ADRs. Section C comprised 14-item statements that evaluated attitude towards ADR reporting, using a 5-point Likert scale ranging from strongly agree (5), agree (4), undecided (3), disagree (2), and strongly disagree (1) for positive statements (items 1-5), and reversed ranked score for the negative statements (items 6-14). Section D contained questions that evaluated the extent of participation in ADR detection and monitoring. Section E contained item-statements that explored factors that can either motivate or hinder ADR reporting among the participants.

Pretest and validation of questionnaire

The questionnaire was assessed for content validity by two academic scholars who were expertise in the field of pharmacovigilance, to ascertain the comprehensiveness of the item-statements in the questionnaire vis-à-vis the study objectives. A pretest of the questionnaire was subsequently done among five pharmacists randomly chosen from the pharmacy department of the University College Hospital, Ibadan, who were not part of the main study. This was to ascertain the ease of comprehension of the question-items by would-be respondents. Minor modifications included rephrasing of the previously designed dichotomous Yes/No response options for item-statements on extent of participation in ADR detection and monitoring, as ranked variables for better clarification of opinion.

Recruitment and sampling procedure

Eligible participants were visited in their respective practice site, objectives of the study were explained to individual participant, after which verbal informed consent was obtained to signify intention for participation. Total sampling of consented hospital pharmacists was done. The questionnaire which took about 20 minutes to complete, was self-administered by individual participant and returned to the principal investigator, who subsequently checked for completeness of response to the question-items.

Data analysis

Data were analysed using SPSS version 23.0 software. Descriptive statistics including frequency, percentage and median score were used to summarise the data.

Binary categorisation of overall scores into > 80% versus < 80% was developed as cut-off to establish the level of knowledge, attitude and participation in ADR detection, monitoring and reporting. The cut-off point was adapted following review of relevant studies.[36-38] Percent score > 80 indicates 'adequate' knowledge, 'positive' attitude and 'high' participation versus score < 80% which signifies 'inadequate' knowledge, 'negative' attitude and 'low' participation. Pearson Chi-square or Fischer's exact test as appropriate was used to evaluate associations among participants with or without additional postgraduate qualification, prior training in ADR reporting, as well as years of practice experience and the binary categorisation of overall scores in knowledge, attitude and participation domains. Mann-Whitney-U test was used to investigate associations among participants with or without prior training in ADRs and additional postgraduate qualification, in respect of their response to specific attitude statements. Also, Kruskal-Wallis (K-W) test was used to investigate association between participants' years of practice experience and response to each attitude statement. Level of significance was set at $p < 0.05$.

RESULTS

The response rate was 100%. There were 20 (54.1%) female participants, 22 (59.5%) had Bachelor of Pharmacy degree alone, and 21 (56.8%) had 1-10 years practice experience as hospital pharmacist. A total of 24 (65.0%) had prior training in ADR reporting, and majority (17; 70.8%) had the training within the last 1-5 years prior to this study (Table 1).

Table 1: Demographic characteristics of participants

Variables		Frequency (%)
Gender	Male	17 (45.9)
	Female	20 (54.1)
Age (years)	21-30	9 (24.3)
	31-40	12 (32.4)
	41-50	11 (29.7)
	51-60	5 (13.5)
Period of pharmacy qualification (year)	1-10	17 (45.9)
	11-20	7 (18.9)
	21-30	11 (29.7)
	31-40	2 (5.4)
Educational qualification	Bachelor of Pharmacy (B. Pharm) alone	22 (59.5)
	B. Pharm + Postgraduate degree	15 (40.5)
Years of experience as hospital pharmacist	1-10	21 (56.8)
	11-20	10 (27.0)
	21-30	6 (16.2)
Pharmacists' rank/cadre	Youth corps pharmacist (1 year)	9 (24.3)
	Pharmacist grade1 (=1-3 years)	12 (32.4)
	Principal pharmacist (>6 -9 years)	4 (10.8)
	Chief pharmacist (>9 – 12 years)	1 (2.7)
	Assistant director (>12 – 15 years)	2 (5.4)
	Deputy director (> 15 years)	9 (24.3)
Previous training in ADR reporting	Yes	24 (64..9)
	No	13 (35.1)
Period/length of the training in ADR reporting (years)	1-5	17 (70.8)
	6-10	7 (29.2)

ADRs = Adverse drug reactions

Participants' knowledge about ADRs and reporting

Majority, 36 (97.3%) understand that ADRs can occur at normal therapeutic doses, but 12 (32.4%) accurately cited that an adverse drug event is not the same as an ADR. Overall, 17 (45.9%) participants had score > 80% indicating 'adequate' knowledge of ADRs and reporting (Table 2).

Table 2: Item analysis of participants' general knowledge about adverse drug reactions and reporting

10-items knowledge test question	**Response options**	
	Yes n (%)	**No n (%)**
1. Adverse drug reactions(ADRs) are responses to drugs which are harmful and unintended	34 (91.9)*	3 (8.1)
2. Adverse drug reactions can occur at normal therapeutic doses	36 (97.3)*	1 (2.7)
3. Adverse drug reactions can cause temporary or permanent disability	33 (89.2)*	4 (10.8)
4. Adverse drug reactions can cause death	34 (91.9)*	3 (8.1)
5. An adverse drug event is the same as an adverse drug reaction	25 (67.6)	12 (32.4)*
6. ADR should stop immediately once the suspect drug is discontinued	15(40.5)	22 (59.5)*
7. A true test of causality of ADR is that the reaction stops when the suspect drug is discontinued	22 (59.5)	15 (40.5)*
8. A blue and yellow form is used in reporting adverse drug reactions	24 (64.9)	13 (35.1)*
9. Completed ADR forms should be submitted to the NAFDAC office	35 (94.6)*	2 (5.4)
10. Patients can report adverse drug reactions through SMS short code	30 (81.1)*	7 (18.9)
Overall percent cut-off score	**Frequency (%)**	**Remark**
< 80	20 (54.1)	Inadequate
= 80	17 (45.9)	Adequate
Which of the following statement describe a serious ADRs?:		
An ADR that do not either require discontinuation of suspect drug or change in treatment	6 (16.2)	
An ADR whose treatment require discontinuation/change of suspect drug while no other treatment is required	3 (8.1)	
An ADR whose treatment require discontinuation/change of suspect drug and /or other treatment is required	2 (5.4)	
An ADR that causes hospitalization or increased length of hospitalization and whose treatment requires discontinuation of suspect drug or change and/or other treatment required	26 (70.3)*	

*= Correct answer. Maximum obtainable score = 10; % individual score = score obtained by an individual ÷ total obtainable score x 100. A total score of at least 8 out 10 (i.e. > 80%) indicates 'adequate' knowledge, while score < 8 suggests 'inadequate' knowledge. ADR = Adverse drug reaction, NAFDAC = National Agency for Food and Drug Administration and Control, SMS = Short message service

Participants' attitude to ADR reporting

All the participants (37; 100%) believed that reporting of ADRs is part of their professional duties as a pharmacist. Only eight (21.6%) opined that it is cumbersome to look out for ADRs in patients. Overall, 28 (75.7%) had scores >80 suggesting "positive" attitude towards ADR reporting (Table 3).

Table 3: Item analysis of participants' attitude towards adverse drug reaction reporting

Statement	SA & A n (%)	U n (%)	D & SD n (%)	Median score
1. I believe that reporting of ADR is important in ensuring drug safety	37 (100.0)	0 (0.0)	0 (0.0)	5.00
2. Reporting ADR is part of the professional duties of a pharmacist	37 (100.0)	0 (0.0)	0 (0.0)	5.00
3. I report an ADR to get more insight into post-marketing surveillance of drugs	32 (86.5)	2 (5.4)	3 (8.1)	5.00
4. I report ADR to show the patients their concern is being taken seriously	30 (81.1)	0 (0.0)	7 (18.9)	4.00
5. I will report ADR because it is part of pharmaceutical care	36 (97.3)	0 (0.0)	1 (2.7)	5.00
6. I have to be sure that the ADR is related to the implicated drug before reporting	25 (67.6)	3 (8.1)	9 (24.3)	2.00
7. Consulting the physician is important before reporting an ADR	8 (21.6)	7 (19.0)	22 (59.5)	4.00
8. I believe it is cumbersome to look out for ADRs in patients	8 (21.6)	2 (5.4)	27 (73.0)	4.00
9. ADR reporting by pharmacist may not be necessary once the drug is prescribed by a physician	1 (2.7)	0 (0.0)	36 (97.3)	5.00
10. It is the physician's duty to report ADR, since he/she has the full clinical information regarding the reaction	6 (16.2)	4 (10.8)	22 (59.5)	5.00
11. Cases of adverse drug reactions are not common in my place of practice	1 (2.7)	11 (29.7)	20 (54.1)	4.00
12. I can't look for the ADR form	1 (2.7)	4 (10.8)	32 (86.5)	4.00
13. I don't believe reporting ADRs will make any difference in pharmacovigilance	0 (0.0)	0 (0.0)	37 (100.0)	5.00
14. I believe only serious reactions need to be reported	3 (8.1)	4 (10.8)	30 (81.1)	4.00
Overall percent cut-off score		**Frequency (%)**	Remark	
< 80		9 (24.3)	Negative	
= 80		28 (75.7)	Positive	

Maximum obtainable score = 70; %individual score = score obtained by an individual ÷ by total obtainable score x 100. Total ranked score of at least 56 out of 70 (i.e. > 80%) indicates 'positive' attitude, while ranked score < 56 suggests 'negative' attitude. Statements 1 to 5 are positive attitude items, with strongly agree (SA) = 5, agree (A) = 4, undecided (U) = 3, disagree (D) = 2, strongly disagree (SD) = 1; statements 6 to 14 are negative attitude items with reversed ranked score of strongly agree = 1, agree = 2, undecided = 3, disagree = 4, strongly disagree = 5. ADR = Adverse drug reaction

Practice and extent of participation in ADR detection and monitoring

Twenty (54.1%) of the participants reported to have ADR reporting form available in their place of practice, while most (23; 62.2%) had no standard operating procedure for ADR monitoring and reporting. A total of 32 (86.5%) participants reported to regularly inform patients of effects that could occur with the drug(s), while 25 (67.6%) claimed to take note of vulnerable patients who may be at risk of ADRs on a regular basis. Overall, 17 (45.9%) had score > 80% suggesting 'high' participation in ADR detection and monitoring (Table 4).

Table 4: Item analysis of practice and extent of participation in adverse drug reaction detection and monitoring

Response on practice	Yes (%)	No (%)	Don't know (%)
1. Are ADR reporting forms available in your pharmacy?	20 (54.1)	12 (32.4)	5 (13.5)
2. Is there a standard operating procedure for ADR monitoring and reporting in your pharmacy?	8 (21.6)	23 (62.2)	6 (16.2)
3. Is there an instituted pharmacovigilance committee in the hospital where you practice?	8 (21.6)	24 (64.9)	5 (13.5)
If "Yes" to (3), does the committee oversee ADR documentation? (n = 8)	6 (75.0)	2 (25.0)	0 (0.0)
4. Have you come across an ADR in the last 3 months?	7 (18.9)	30 (81.1)	0 (0.0)

Response on extent of participation	Always/ Most times n (%)	Sometimes n (%)	Rarely n (%)	Never n (%)	Median score
1. Do you consider whether any new symptom a patient is experiencing could indicate an ADR?	15 (40.5)	21 (56.8)	1 (2.7)	0 (0.0)	3.0
2. Do you take note of patients at risk of ADRs (elderly, children, pregnancy etc.)	25 (67.6)	10 (27.0)	2 (5.4)	0 (0.0)	4.0
3. Are you particularly alert for ADRs or unexpected events with new medicines?	24 (64.9)	9 (24.3)	2 (5.4)	2 (5.4)	4.0
4. Do you check with/probe patients for history of drug allergies?	23 (62.2)	12 (32.4)	2 (5.4)	0 (0.0)	4.0
5. Do you ask the patient if they are taking other medicines; OTCs and herbal medicines?	29 (78.4)	7 (18.9)	1 (2.7)	0 (0.0)	4.0
6. Do you inform patients of effects that could occur with their drugs?	32 (86.5)	4 (10.8)	1 (2.7)	0 (0.0)	4.0
7. Do you check whether there are any specific monitoring requirements with respect to the patients' medications and ensure that they are carried out?	20 (54.1)	14 (37.8)	3 (8.1)	0 (0.0)	4.0
8. Do you ensure appropriate dosage form and regimen for patients with compromised ability to use medicines?	28 (75.7)	8 (21.6	1 (2.7)	0 (0.0)	5.0

Overall percent cut-off score	Frequency (%)	Remark
< 80	20 (54.1)	Low participation
> 80	17 (45.9)	High participation

Maximum obtainable score = 40; %individual score = score obtained by an individual ÷ total obtainable score x 100. Total ranked score of at least 32 out of 40 (i.e. > 80%) indicates 'High' participation, while score <32 suggests 'Low' participation. Always = 5, Most times = 4, Sometimes = 3, Rarely = 2, Never= 1. ADR = Adverse drug reaction, n = number. OTC = Over-the-counter

Factors affecting ADR reporting among participants

Participants largely agreed that occurrence of serious reaction (36; 97.3%), as well as reaction(s) to a new drug (35; 94.6%) constitute factors that can stimulate reporting of ADRs. Believe that the reports made by patients were known side effects of the drug (19; 51.4%), lack of reimbursement, in respect of transport fare to submit the completed ADR forms (16; 43.2%), as well as expenses incurred in scanning and mailing of the forms (15; 40.5%) to the NAFDAC office, were mostly cited as barriers to reporting (Table 5).

Table 5: Opinion on factors affecting adverse drug reaction reporting among participants

Motivating factors for ADR reporting	**SA & A n (%)**	**U n (%)**	**D & SD n (%)**	**Median score**
Unusual reaction to a well- known drug	34 (91.9)	1 (2.7)	2 (5.4)	1.0
Serious reaction	36 (97.3)	1 (2.7)	0 (0.0)	1.0
Reaction to new drug	35 (94.6)	1 (2.7)	1 (2.7)	1.0
Known ADR to the drug	30 (81.1)	3 (8.1)	4 (10.8)	2.0
Unknown ADR to the drug	34 (91.9)	3 (8.1)	0 (0.0)	1.0
ADR reporting being a professional obligation	35 (94.6)	1(2.7)	1 (2.7)	1.0
Need to add to the medical knowledge of the drug	32 (86.5)	3 (6.1)	2 (5.4)	1.0
Being the pharmacist assigned to report ADR in my place of practice	14 (37.8)	13 (35.1)	10 (27.0)	3.0
Limiting factors/barriers to ADR reporting	**SA & A, n (%)**	**U, n (%)**	**D & SD, n (%)**	**Median score**
1. Too many patients to attend to and lack of time for filling the forms	15 (40.5)	4 (10.8)	18 (48.6)	3.0
2. Lack of reimbursement for the transport fare to submit the forms at the NAFDAC office	16 (43.2)	5 (13.5)	16 (43.2)	3.0
3. Lack of reimbursement for scanning and mailing the completed ADR forms	15 (40.5)	4 (10.8)	18 (48.6)	3.0
4. Inability to ascertain the drug that caused the reaction	4 (10.8)	7 (18.9)	26 (70.3)	4.0
5. Patients are inpatient to wait to make reports	10 (27,0)	6 (16.2)	21 (56.8)	4.0
6. The reports made by patients are known side effects of the drug	19 (51.4)	6 (16.2)	12 (32.4)	2.0
7. Inadequate knowledge of pharmacovigilance to determine whether an ADR has occurred	4 (10.8)	5 (13.5)	28 (75.7)	4.0
8. Lack of sensitization of pharmacists by the pharmacovigilance officials/regulatory authorities on ADR reporting	15 (40.5)	6 (16.2)	16 (43.2)	3.0
9. Absence of pharmacovigilance committee to oversee the ADR reporting	12 (32.4)	5 (13.5)	20 (54.1)	4.0
10. Fear of negative impact of ADR reports on the manufacturer or marketer of the drug	6 (16.2)	4 (10.8)	27 (72.0)	4.0
11. Non-availability of ADR form on site	9 (24.3)	6 (16.2)	22 (59.5)	4.0
12. Incomplete information from the patients	17 (45.9)	6 (16.2)	14 (37.8)	3.0

Strongly agree (SA) =1, agree (A) = 2, undecided (U) = 3, disagree (D) = 4, strongly disagree (SD) = 5, ADR = Adverse drug reaction, NAFDAC = National Agency for Food and Drug, Administration and Control

There were no statistically significant differences among participants in respect of years of practice experience, as well as possession of additional postgraduate qualification and the binary categorisation of their overall scores in knowledge, attitude and participation domains ($p > 0.05$). However, more of the participants with prior training in ADR reporting had significantly better knowledge ($\chi2 = 4.220$, $p = 0.04$), positive attitude ($\chi2 = 9.489$, $p = 0.004$), and high level of participation in ADR detection and monitoring ($\chi2 = 0.452$, $p = 0.501$) compared to those without training (Table 6).

Table 6: Relationships between relevant demographic characteristics of participants and the binary categorisation of overall scores in knowledge, attitude and participation domains

	ADR general knowledge		**Attitude towards ADR reporting**		**Participation in ADR detection and monitoring**	
Variables	**Adequate (score > 80%) n (%)**	**Inadequate (score < 80%) n (%)**	**Positive (score > 80%) n (%)**	**Negative (score < 80%) n (%)**	**High (score > 80%) n (%)**	**Low (score < 80%) n (%)**
Qualification						
Bachelor of Pharmacy alone	12 (70.6)	10 (50.0)	15 (53.6)	7 (77.8)	8 (47.1)	14 (70.0)
Bachelor of Pharmacy + PG	5 (29.4)	10 (50.0)	13 (46.4)	2 (22.2)	9 (52.9)	6 (30.0)
	$\chi2$ =1.616	p = 0.204*	$\chi2$ = 1.656	p = 0.262^	$\chi2$ = 2.006	p = 0.157*
Years of experience as hospital pharmacist						
1-10	9 (52.9)	12 (60.0)	14 (50.0)	7 (77.8)	8 (47.1)	13 (65.0)
11-20	6 (35.3)	4 (20.0)	9 (32.1)	1 (11.1)	5 (29.4)	5 (25.0)
21-30	2 (11.8)	4 (20.0)	5 (17.9)	1 (11.1)	4 (23.5)	2 (10.0)
	$\chi2$ = 1.269	p = 0.660^	$\chi2$ = 1.943	p = 0.441^	$\chi2$ = 1.640	p = 0.437^
Previous training in ADR reporting						
Yes	14 (82.4)	10 (50.0)	22 (78.6)	2 (22.2)	12 (70.6)	12 (60.0)
No	3 (17.6)	10 (50.0)	6 (21.4)	7 (77.8)	5 (29.4)	8 (40.0)
	$\chi2$ = 4.220	**p = 0.040***	$\chi2$ = 9.489	**p = 0.004^**	$\chi2$ = 4.452	p = 0.501*

$\chi2$ = Chi-square test, *Pearson Chi-square, ^ Fischer's Exact Test, Level of significance at $p < 0.05$, ADR = Adverse drug reaction, PG = Postgraduate

In respect of specific attitude statement, participants with prior training in ADR reporting were those who mostly disagreed that it is cumbersome to look out for ADRs in patients (MW-U p = 0.012), they also disagreed that only serious reactions need to be reported (MW-U p = 0.013), compared to those without training (Table 7).

Table 7: Association among participants with or without prior training in adverse drug reaction reporting and item analysis of attitude towards reporting

Statement	Prior-ADR-training	N	Mean Rank	MW-Up-value
1. I believe that reporting of ADR is important in ensuring drug safety	Yes	24	19.23	0.863
	No	13	18.58	
2. Reporting ADR is part of the professional duties of a pharmacist	Yes	24	20.00	0.460
	No	13	17.16	
3. I report an ADR to get more insight into post-marketing surveillance of drugs	Yes	24	20.15	0.387
	No	13	16.88	
4. I report ADR to show the patient that their concern is being taken seriously	Yes	24	19.92	0.499
	No	13	17.31	
5. I will report ADRs because it is part of pharmaceutical care	Yes	24	18.54	0.742
	No	13	19.85	
6. I have to be sure that the ADR is related to the implicated drug before reporting	Yes	24	19.71	0.604
	No	13	17.69	
7. Consulting the physician is important before reporting an ADR	Yes	24	21.29	0.083
	No	13	14.77	
8. I believe it is cumbersome to look out for ADRs in patients	Yes	24	22.25**	0.012*
	No	13	13.00*	
9. ADR reporting by pharmacist may not be necessary once the drug is prescribed by a physician	Yes	24	21.25	0.089
	No	13	14.85	
10. It is the physician's duty to report since he/she has full clinical information regarding the reaction	Yes	24	22.73**	0.003*
	No	13	12.12*	
11. Cases of adverse drug reactions are not common in my place of practice	Yes	24	20.17	0.387
	No	13	16.85	
12. I can't look for the ADR form	Yes	24	22.13	0.016*
	No	13	13.23	
13. I don't believe reporting ADRs will make any difference in pharmacovigilance	Yes	24	21.88	0.028*
	No	13	13.69	
14. I believe only serious reactions need to be reported	Yes	24	22.21	0.013*
	No	13	13.08	

N = number, ADR = Adverse drug reaction. For positive statements 1-5, higher mean rank indicates those who mostly agreed with the corresponding statement, while lower mean rank signify those who least agreed/disagreed with the corresponding statement. For negative statements 6-14, Lower mean rank indicates those who mostly agreed with corresponding statement and higher mean rank suggests those who least agreed/disagreed with the corresponding statement. *Significant difference with Mann-Whitney U (MW-U) test. Level of statistical significance, $p < 0.05$

Also, those with practice experience within 21-30 years largely disagreed (mean rank [MR] = 27.00) that it is cumbersome to look out for ADRs in patients, compared to those with 11-20 (MR = 23.90) and 1-10 years' experience in practice (MR = 14.38), K-Wp = 0.006. Similarly, participants with additional postgraduate qualification least agreed (MR = 25.87) that it is cumbersome to look out for ADRs in patients compared to those with Bachelor of Pharmacy alone (MR = 14.32) MW-U p = 0.001.

DISCUSSION

In this study, nearly half of the participants had adequate general knowledge of ADRs and reporting, with the strength of knowledge largely residing in the basic definitions of ADRs. Many had knowledge deficit in information relating to causality assessment, as well as follow-up process whenever an adverse reaction occurs. Specifically, most participants believed that ADRs should stop immediately once the suspect drug is discontinued.

Also, about 60% opined that a true test of ADR causality indicates that the reaction stops whenever the suspect drug is withdrawn. The low knowledge gap is consistent with previous studies that reported lack of knowledge of ADRs and pharmacovigilance generally among healthcare workers.[25,38-40] As a matter of fact, there is no foolproof method of ascertaining a true test of causality between a suspect drug and the reaction. All the available assessment criteria ranging from Naranjo ADR probability scale[41] to the WHO-Uppsala Monitoring Centre causality criteria[42] are based on likelihood and predictions, with their own limitations.[41,42] Nonetheless, the NAFDAC stipulates that healthcare providers should report all suspected ADRs of clinical importance once it is detected to the National Pharmacovigilance Centre, either manually using the 'yellow form' or through the SMS alert short code.[7,8]

Thus, there is a need to clarify some of these knowledge gaps among healthcare professionals including hospital pharmacists, whenever an intervention training in pharmacovigilance and ADR is being envisaged by concerned authorities. Interestingly, participants who had prior training in ADR reporting had significantly better knowledge compared to those without training. This seems consistent with previous studies which reported that respondents who had attended on job-training in ADRs reporting and monitoring had a good level of knowledge, as well as positive attitude towards reporting of ADRs than those who had not.[26,43,44]

In this study, approximately three-quarters demonstrate positive attitude towards ADR reporting, while all the participants strongly believed that reporting of ADRs is part of their professional duties as a pharmacist. The relatively higher number of participants with perceived positive attitude to ADR reporting is encouraging, and the findings are in agreement with studies by Almandil (2016)[40] whose participants including pharmacists largely believed that ADR reporting is their professional obligation, and Oreagba *et al* (2011)[25], where a larger proportion of respondents believed that the role of pharmacists in ADR reporting is important. The emerging role of pharmacists as a key player in value-added healthcare delivery encompass patient-centred activities such as ADR detection, prevention, monitoring and reporting.[45,46] These are essential services that are useful in ensuring medicine use safety, which is a core mandate of pharmaceutical care that need to be upheld by every pharmacist irrespective of the areas of practice. Interestingly, participants with prior training in ADR reporting, as well as those with additional postgraduate qualification significantly disagreed that it is cumbersome to look out for ADRs in patients, compared to those without ADR-related training or Bachelor of Pharmacy degree alone. Studies have shown that participation in relevant pharmacovigilance and ADR-related training can enhance knowledge, as well as reinforce positive attitude and participation in ADR reporting.[31,35,43,47] Thus, there may be a need for the various institutions to embrace consistent training and re-training of hospital pharmacists in their respective institution in pharmacovigilance and ADRs, as this may assist in enhancing reporting rate.

Essentially, it may be expected that having a positive attitude towards ADR reporting should largely translate to better involvement in ADR detection, monitoring and reporting. However, in this study, nearly 46% demonstrates 'high' level of participation in ADR detection and monitoring. Participants focused largely on information on direction for dosage regimen, with less attention paid to probing questions that will reveal history of drug allergies, as well as new symptom(s) that could indicate an ADR. Worthy of note to mention is the fact that approximately 81% of the participants had not come across an ADR case within three months prior to the time of this study. This is similar to the study that reported about 90% of healthcare workers comprising physicians, pharmacists and nurses, who had never

reported, submitted or identified any ADR, while about 74% did not know where to obtain the ADR form.[40] The non-encounter of ADR case by majority of the participants in our study specifically may in part be linked to the possible deficiency in questioning skills to unfold the existence of any ADR that the patients might have likely experienced. On the other hand, most participants mentioned occurrence of serious reactions (98%), as well as reaction(s) to a new drug (95%) as factors that largely motivate them to report. Nevertheless, the use of appropriate questioning style that will help in exploring the likelihood of suspected reactions, should be the prime focus of therapeutic counseling during patient-pharmacist encounters. Early reporting of ADRs is fundamental to pharmacovigilance and it is the best method for detection and prevention of adverse events.[9,10] Concerned authorities may however need to closely look at some of the factors hindering ADR reporting among the participants including non-reimbursement of transport fare for submission of completed forms, so as to generally facilitate reporting rate.

Notably, there were mixed feelings of agreement and disagreement among participants with respect to statement relating to whether too many patients to attend to and lack of time for filling the ADR form are limiting factors to reporting. A study conducted among community pharmacists in Australia indicated that lack of time was the most significant barrier to ADR reporting.[48] Thus, the challenge of time constraints should not be totally disregarded, considering the emerging role of hospital pharmacists which required them to provide a number of value-added services in addition to their traditional role of dispensing and supplying of medicine.[18,45]

Despite the useful information provided by our study, it is however limited by small but representative sample size. This coupled with its cross-sectional nature, as well as recruitment of only the pharmacists working in public secondary healthcare facilities in a metropolitan city. Thus, there may be a need for caution in making a wide-spread generalisation of the study findings to entire hospital pharmacists in the region.

CONCLUSION

From this study, it can be concluded that the knowledge of hospital pharmacists about adverse drug reactions and reporting is relatively moderate. Approximately three-quarters demonstrate positive attitude towards adverse drug reaction reporting, but nearly half show 'high' level of participation in adverse drug reaction detection and monitoring. Thus, there is generally a need for consistent training and re-training of hospital pharmacists in the core concept of adverse drug reactions and reporting, as this may help in bridging the knowledge and practice gaps to enhance reporting rate.

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