



ORIGINAL RESEARCH

Healthcare Workers Knowledge and Practice about Adverse Drug Reaction Reporting and Pharmacovigilance in Zaria, North-West Nigeria

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ABSTRACT

Background: Pharmacotherapy aims to optimize patient care by increasing drug efficacy and reducing drug toxicity. However, this goal is not always achieved particularly when adverse drug reaction (ADR) occurs. Globally, knowledge and practice of pharmacovigilance has enhanced health-care systems in recent times. Despite this, there are limitations in some regions.

Objectives: The study aimed to investigate the knowledge and practice about adverse drug reaction reporting and pharmacovigilance among health workers in healthcare facilities in Zaria, North-west Nigeria

Methods: A descriptive cross-sectional survey was conducted using structured questionnaires. These were distributed among 453 health workers in two tertiary hospitals, two secondary hospital, twelve primary health-care centers and twenty-three community pharmacies. The results were analyzed using descriptive and inferential statistical analysis.

Results: Of the 453 respondents, male/female ratio was 1:1.1, 62% had heard of pharmacovigilance though only 29% correctly defined it. Participants were mainly Nurses (39.5%) and Doctors (25%). About 75% knew the meaning of ADR reporting, 54% knew about existence of pharmacovigilance in Nigeria and 35.32% agreed that all workers should report ADRs. Only 40% agreed that there was an existing reporting system and 65% send reports to pharmacists. A significant difference in knowledge and level of practice of ADR reporting ($P = 0.0001$) exists. Ignorance (63%) and negative perception (46%) by the professionals were the main reasons for low ADR reporting.

Conclusion: The results showed that an appreciable number of respondents had sufficient knowledge and practice of pharmacovigilance. The study recommends that stakeholders should intensify efforts in strengthening pharmacovigilance practice.

Keywords: Pharmacovigilance; ADR Reporting; Knowledge and Practice; ADRs, Zaria, Nigeria, Healthcare facilities

INTRODUCTION

One of the goals of pharmacotherapy is to optimize patient care by increasing drug efficacy and reducing drug toxicity¹. This goal

is not always achieved particularly in cases of adverse drug reaction (ADR) event. An ADR is defined as ‘a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the

prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function¹. ADRs are a leading cause of mortality and morbidity globally². It is reported that, in Europe, 20% of ambulatory patients on drug therapy experience ADRs while drug-related problems also account for 10 – 20% of geriatric hospital admissions³. It is therefore of utmost importance that strong medication monitoring systems are put in place to protect patients from the harmful effects of medications. Reporting of ADRs constitutes an integral part of the pharmacovigilance (PVG) process. Pharmacovigilance (PVG) has been defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems⁴. Spontaneous Reporting Systems (SRSs) are the commonest means of reporting suspected ADRs in the majority of developed countries and some developing countries⁵. Spontaneous reporting can help in detecting serious and unusual adverse effects previously undetected during clinical trials³. However, under-reporting remains a challenge even in developing countries like Nigeria. The international database on adverse drug reaction reports is kept by the Uppsala Monitoring Centre (UMC, WHO), Sweden. Only an estimated 6-10% of all ADRs are reported to this global database⁶. There have been instances where drugs with potential harmful effects have been withdrawn from the market due to spontaneous reporting. This has great financial implications for the pharmaceutical industry³. In most countries, health-care professionals like medical doctors, nurses and pharmacists are responsible for reporting ADRs to their national Pharmacovigilance (PVG) centres. Patients are however able to directly report ADRs to the SRS in some countries like the United States. According to a report in Africa⁷, self-medication is rampant with easy access to both Over the counter (OTC) medications and prescription-only medicines (POMs) in most community pharmacies. Irrational medicine use is rife among both healthcare providers and

consumers, further increasing the risk of drug-related harm. Most of these reactions resulting from the use of these drugs are still not reported routinely, most especially in Nigeria. The study aims to investigate the pattern of ADR reporting and PVG practice among health workers in two tertiary hospitals, two secondary hospital, twelve primary health-care centers and twenty three community pharmacies in Zaria, North-western Nigeria.

METHODS

Study location and population

The study was conducted in Zaria, North-west Nigeria. Zaria was conveniently selected because it is a town where many health institutions and community pharmacies are located and therefore appropriate for the intended sample size. The study involved health professionals working in different health care centers and community pharmacies in Zaria North-western Nigeria.

Study design and sample size

The design of the study was cross sectional descriptive. Sample size was calculated using formula adopted from standard protocol in pharmacovigilance studies⁸. The estimated sample size from the formula was 100. The resulting minimum sample size after calculation was 433. However, more respondents (480 samples) were invited to the study to give better reliability. This was spread among two tertiary hospitals, two secondary or general hospital, twelve primary health care centers and twenty-three community pharmacies.

Inclusion and exclusion criteria

The health workers in the study sites willing to participate and could complete the questionnaire were recruited for the study while health workers that were critically ill, always inaccessible or not willing to participate were excluded from the study.

Data collection tool and administration

Data were collected by using self-administered questionnaires. Prior to the

study, a pilot testing of questionnaire's validity was carried out by interviewing 40 health workers from 5 selected health centers and 4 community pharmacies to fine tune the questionnaires. The final questionnaire comprised of three parts containing 38 questions. The first part consisted of six questions which covered demographics and continuing education information. The second part contained twenty- three questions which were used to assess respondents' knowledge towards ADRs reporting in terms of the meaning of ADRs reporting; profession required to report; where to report; which reactions to be reported and how to report ADRs. A knowledge scale was prepared as a guiding tool in assessment of knowledge level, whereby one point was awarded for each correct answer. Respondents' knowledge was then categorized into two categories, whereby those who answered correctly 16 or more questions were categorized as having good knowledge and those answered less than 16 questions were categorized as having poor knowledge. The third part contained eight questions which assessed practice towards ADRs reporting in terms of adherence to the Guidelines for ADRs monitoring and reporting. One and zero scores were merited for adherence and non-adherence respectively. The last part had one question meant to establish barriers against ADRs reporting and education needs to strengthen ADRs reporting system. During the survey, the purpose of the study was explained to participants both verbally and by covering letter which was attached with a consent form and an ethical clearance. Health workers who agreed to participate in the study were requested to complete the questionnaire and hand it back immediately. For those that were too busy at the time, the questionnaires were left behind and picked up after a maximum of two working days. Returned questionnaires were checked for completeness, consistency and clarity before collection.

Ethical considerations

The study received ethical clearance from Kaduna State Ministry of Health and Human

Services ethical committee of research and publication with ethics number *ADM/P45//345*. Permission to do the study was granted by the medical directors of different health institutions and superintendent pharmacists of community pharmacies after receiving request letter to conduct the study. Consent for health workers participation was sought from health workers themselves and confidentiality of their information was highly maintained.

Data analysis

The cleaned data were entered into Microsoft Excel (2010) spread sheet and subsequently transferred into Statistical Package for Social Sciences (SPSS) version 23 (Inc., Chicago, IL, USA) for descriptive and inferential statistical analysis. The categorical variables were compared using Chi-square test. *P* values < 0.05 were regarded as significant.

RESULTS

Demographic Characteristics and Knowledge about ADR Reporting/pharmacovigilance

Out of 480 administered questionnaires, 453 adequately filled questionnaires were returned resulting in a response rate of 94.4%. Out of the 453 respondents, male/female ratio was 1:1.1. The highest proportion of ages was between 30-50 years (51.21%) and 179 (39.51%) were nurses (Table 1).

Table 2 shows that about 80% of the respondents had heard about adverse drug reaction reporting in Nigeria. Mass media (35.10%) and Nigerian medical books (30.02%) were the main sources of information. About 62% of the respondents had heard of PVG while only 29% could define it correctly. Existence of PVG in Nigeria was known by 54%, though only 35% agreed that all workers should report ADRs and 34% agreed that it could be reported in the hospital pharmacovigilance center. About 75% of the respondents agreed that known and un-known reaction types of ADR should be reported.

Table 1: Demographic Characteristics of the Respondents (n=453)

Characteristics	Frequency	Percentage
Sex		
Female	218	48.12
Male	235	51.18
Marital Status		
Single	164	36.20
Married	262	57.78
Divorced	9	1.99
Separated	6	1.32
Widowed	12	2.65
Age in years		
<30	167	36.87
31-50	232	51.21
>50	54	11.92
Profession		
Pharmacists	69	15.23
Doctors	63	24.90
Nurses	179	39.51
Laboratory Scientists	57	12.90
Pharmacy Technicians and Assistants	18	3.97
Others*	67	14.79
Years of Practice		
5 years and below	190	41.94
6 to 15 years	173	38.19
More than 15 years	90	19.87

* Others included administration staff, Nurse Assistants, radiographer, record staff and ward attendants.

Table 2. Knowledge of ADR Reporting and pharmacovigilance

Items	Frequency	Percentage
Known the meaning of ADRs reporting	339	74.83
Heard of ADRs reporting in Nigeria	364	80.35
Source of information about ADR		
Nigerian medical handbook	139	30.02
Mass media	159	35.10
Define Pharmacovigilance		
Correctly	133	29.36
Wrong	320	70.64
Know the existence of ADR reporting system in Nigeria		
Yes	243	53.64
No	210	46.36
Seen the form for spontaneous reporting of ADRs (Yellow form)		
Yes	220	48.57
No	233	51.43
Health workers required to report ADRs		
Doctors only	90	19.87
Pharmacist only	127	28.04

Nurses only	57	12.58
All health workers	160	35.32
Don't know	17	3.75
Where to report ADRs		
Hospital PV center	154	33.99
National/Zonal office PV centers	117	39.07
Federal ministry of health	37	0.17
Manufacturer of the product	9	1.99
Others	10	2.21
Types of ADRs to be reported		
Known reactions	141	31.13
Unknown reactions	200	44.15
Life threatening reactions	180	39.74
Reactions to new products	130	28.70
Reactions to Herbal and traditional medicines	75	16.56
Reactions to vaccines and blood products	76	16.78
Training on Pharmacovigilance and ADR Reporting		
Yes	101	22.30
No	352	77.92
ADR forms		
Know the form used in reporting	142	31.35
Able to mention the form	181	39.96
Know how to report ADRs on the form	89	19.65
Able to explain correctly	137	30.24

Training about pharmacovigilance

About 64% of the respondents had good training in pharmacovigilance and ADR reporting. Male respondents (60.43%) had statistically significantly different results to the females while those aged 30 – 50 years had statistically significantly different results

than those below and above this range (74.14%) about ADRs reporting. In addition, statistically significant different results exist in the ADR reporting and pharmacovigilance knowledge of the different health care workers ($P = 0.0001$) as in Table 3.

Table 3. ADR Reporting Knowledge and Pharmacovigilance (n=453)

Variables	Good	Poor	Total	P value
Sex				
Male	142 (60.43)	93 (39.57)	235	0.0001
Female	108 (49.54)	110 (50.46)	218	
Age (Year)				
Below 30	62 (37.13)	105 (62.87)	167	0.0001
30-50	172 (74.14)	63 (27.16)	232	
Above 50	28 (51.85)	26 (48.15)	54	
Profession				
Pharmacists	61 (88.41)	8 (11.59)	69	0.0001
Doctors	48 (76.19)	15 (23.81)	63	
Nurses	74 (41.34)	105 (58.66)	179	
Lab. Scientist	29 (50.88)	28 (49.12)	57	
Pharm. Tech and Assistants	7 (38.89)	11 (61.11)	1	
Others	12 (19.35)	50 (80.64)	67	
Years of practice				

5 years and below	82 (43.16)	108 (56.84)	190	
6 to 15 years	135 (78.03)	38 (21.96)	173	
More than 15 years	28 (31.11)	62 (68.89)	90	0.0001
Training on PV and ADRs				
Yes	65 (64.35)	36 (35.64)	101	
No	91 (25.85)	261 (74.15)	352	0.0001

ADR Reporting Practices and reasons for low reporting of ADRs

With regards to their practice, 62.47% had heard about ADR reporting systems, 39.96% agreed that there was an existing reporting system, 64.68% send reports to pharmacists while 38.85% reported using yellow form. Reports were made by 44.80% in the hospital pharmacovigilance center and 56.95% reported all serious ADR. This indicates that only 39.96% of respondents have a system of monitoring and reporting adverse drug reactions in their hospital or pharmacies.

Low reporting system was mainly due to heavy work and lack of time among 225 (49.62%) and 214 (47.24%) claimed unavailability of reporting form and 284 (62.69%) had ignorance of reporting procedure and how the forms could be obtained. Ignorance of ADRs reporting procedure and how to obtain the reporting form account for the highest reasons (62.69%) given the respondents for low rate of ADRs reporting. The level of knowledge and practice about ADR (Table 4).

Table 4. Responses to Question Assessing the Practice towards ADRs Reporting (n=453)

Items	Frequency	Percentages
Is there a system of monitoring and reporting ADRs?	181	39.96
Ever reported ADRs cases?	169	37.31
Who do you send ADRs report to?		
Pharmacist-in-charge	293	64.68
Prescribing Doctor	81	17.88
Pharmaceutical company	8	1.77
Meetings	9	1.98
NAFDAC	62	13.69
How are ADRs Reported?		
Telephone	71	15.67
E-mail	63	13.91
Informing senior colleagues	94	20.75
Filling ADR		
Yellow form	176	38.85
Others	49	10.82
Are the forms for spontaneous reporting of ADRs available?		
Ever seen ADR in patient?	171	3
Ever reported an ADR?	169	37.31
Where did you report ADRs? (n=221)		
Hospital PVG	99	44.80
Zonal/National PVG	22	9.95
FMH	16	7.24
Manufacturer	27	12.22
Head of Department	48	21.72
Others	9	4.07
Types of ADRs reported		
Serious reactions	258	56.95

All reactions	173	38.19
Life threatening reactions	228	50.33
Disability	185	40.84
Hospitalization	181	39.96
Others	8	1.77
Reasons for Low ADRs Reporting (n=453)		
Heavy workload and lack of time	225	49.67
Unavailability of reporting forms	214	47.24
Ignorance of reporting procedure and how forms can be obtained	284	62.69
Ignorance about the need to report ADRs	198	43.71
Inability to recognize ADRs	165	36.42
Fear of being legally accused of administering the wrong medication	155	34.22
Lack of confidence in the reporting system	175	38.63
Fear of the negative impact on the drug manufacturing company	100	22.08
Fear of negative publicity for the profession	98	46.22
Consumers who suffer an ADR should be responsible for reporting it	71	15.67
Lack of reward or incentive	122	24.72
Not part of my professional responsibility to report ADRs	77	16.99
Others	13	2.86

Knowledge and Practice about ADR reporting and PVG.

Reporting and PVG was seen to vary in the centers. This indicates that majority (64.39%) of health workers at the tertiary health care

system had good knowledge of ADRs reporting and pharmacovigilance. The practice of ADRs reporting and pharmacovigilance was poor among health workers in all the facilities surveyed (Table 5).

Table 5. Knowledge and Practice of ADR Reporting and Pharmacovigilance at the centers

	THC	SHC	PHC	CP	P value
Reporting and PV					
Poor	73 (35.61%)	32 (54.24%)	78 (81.25%)	64 (68.82%)	
Good	132 (64.39%)	27 (45.76%)	18 (18.75%)	29 (31.18%)	
Total	205 (100%)	59 (100%)	96 (100%)	93 (100%)	P=0.0001
Level of Practice of ADRs					
Poor	87 (42.44%)	38 (64.40%)	80 (83.33%)	82 (88.17%)	
Good	118 (57.56%)	21 (35.60%)	16 (16.67%)	11 (11.83%)	
Total	205 (100%)	59 (100%)	96 (100%)	93 (100%)	P<0.05

THC: Tertiary Hospital Center. SHC: Secondary Hospital Center, PHC: Primary Health-care Center and CP: Community Pharmacies.

DISCUSSION

Despite the existence of pharmacovigilance system in the past 10 years in Nigeria, this is the first detailed study in Zaria, Northwest Nigeria to assess the knowledge, practice and attitude of health workers across different levels of health care and community

pharmacies in ADRs reporting pattern and pharmacovigilance practice. The findings of this study suggest that there may be several recommendations to curb the poor reporting of ADRs among health workers in various health facilities. The high proportion of participants in the age category showed the age-class of professionals that participated in

the study which is a reflection of the active group in service in pharmacovigilance activities. The study findings indicate that there is poor knowledge towards ADRs reporting among health workers in the primary health centers, secondary health centers and community pharmacies. The study showed variation in knowledge among the participants in ADRs reporting. This is a reflection of the order of institutional framework showing tertiary health centers as the highest hierarchy which should be well equipped with pharmacovigilance facilities for reporting. Those claiming full definition of ADR and pharmacovigilance concept correctly may be very much abreast with and may have had the training of pharmacovigilance under the auspices of the National Agency for Food Drug Administration and Control⁹ and the Federal Ministry of Health (FMOH). The Federal Ministry of Health (FMOH) in collaboration with the National Agency for Food Drug Administration and Control (NAFDAC) in 2011 conducted a train-the-trainer program in the six-geo-political zones of the country. A similar result was obtained in a previous study among pharmacists in Saudi Arabia, Iran and Malaysia¹⁰. It is acknowledged that the media and publicity are essential in achieving awareness among healthcare professionals. The general poor knowledge about ADR reporting and PVG in this study can be attributed to non-participation in the training and re-training of health personnel. It is a common practice that most health centers and hospitals in Nigeria that many health professionals perceive pharmacovigilance and ADRs reporting as solely pharmacy activities, but this study has shown that the concept has been adopted by all stakeholders in the health care delivery. Moreover, attendance of pharmacovigilance training was shown to significantly increase the ADRs reporting knowledge of health workers at the different level of health care, as observed in pharmacy, nursing and medical professionals. The importance of pharmacovigilance training in promoting ADR reporting was shown in a previous study¹¹. In addition, a study in the

UK concluded that pharmaceutical personnel require continuing education on ADR in order to raise further the profile of their role in reporting of suspected ADRs to their national pharmacovigilance program¹². A study conducted in India to investigate attitudes and perception of medical practitioners on ADR reporting showed that improvement of continuous PVG training among the healthcare professionals enhanced ADR monitoring and reporting¹³. Lack of knowledge on what is to be reported, who should report, when to report, how to report where to report, together with unavailability of ADRs reporting forms may have influenced the practice towards ADRs reporting among health workers in this study. This poor practice is similar to the findings by previous studies among community pharmacists in Malaysia. In Turkey pharmacists send ADR reports to their National pharmacovigilance center¹⁴. The study revealed that the health system is not adequately equipped with necessary guidelines and tools to guide and facilitate dispensers in monitoring and reporting of ADRs at their working places. This is contrary to the claimed efforts of National Agency for Food and Drug Administration and Control⁹ that much effort was undertaken to disseminate these tools¹⁵. Since the practice is not the case of all institutions, availability of appropriate guidelines and reporting forms are expected to provide proper guidance and procedures to be followed by health workers during reporting of ADRs to ensure adequate and standard practice. NAFDAC position in ADR reporting say all ADR could be reported by all professionals and non-professionals⁹. All reports should be channelled to the pharmacovigilance centers that are cited in private and public institution. The present study revealed a number of barriers that prevent health workers in the primary, secondary, tertiary health centers and community pharmacies from reporting ADRs effectively. The barriers observed in this study are similar that reported^{2,3,7,13}; hence may have contributed to the poor reporting in some of the centers as in Table 5. Therefore

concerted efforts should be made by individuals and corporate bodies in ensuring that these barriers do not hinder effective reporting the healthcare system. This study had revealed that ignorance of the reporting procedure and poor knowledge in obtaining the spontaneous reporting forms (yellow form) as the main reasons for low rate of ADR reporting. Meanwhile NAFDAC had emphasized the prompt collection and the use of yellow form as instrument for standard reporting⁹ in any healthcare system. Some of the barriers noted can be resolved through proper management and advertising of pharmacovigilance program such as disseminating of reporting forms and appropriate guidelines thus making them widely available; and creating a closer relationship between health workers and ADR reporting centers by strengthening feedback of pharmacovigilance activities to reporters⁹. In order to facilitate the ADR reporting, the reporting system should be reviewed from time to time to become user friendly. For example instead of using only the approved yellow forms which have been proved to be unavailable in most areas, there should be flexibility in using other means such as electronic yellow forms that can be retrieved online^{4,9}. Lack of knowledge among health workers can be addressed through intensive training and workshops about the concept of ADRs reporting and pharmacovigilance practice in Nigeria. The government and its various stakeholders should strive to ensure that the health care system is sufficiently staffed with qualified personnel and appropriate tools of pharmacovigilance to ensure effective ADR reporting. NAFDAC should provide continuous and regular education and training on ADR reporting and PVG to all health workers across different levels of health care and community pharmacies in order to improve their ability to identify and report ADRs. Also, NAFDAC should strengthen the existing PVG system by advocating an active rather than passive monitoring system of PVG in Nigeria. The new system should provide feedback to healthcare personnel on reported ADRs so as

to encourage and motivate them to report more. In addition, NAFDAC should make ADR reporting a regulatory requirement for establishment and running a hospital or community pharmacy. The Federal Ministry of Health in collaboration with the Federal Ministry of Education and relevant stakeholders should find measures to improve the output of medical and pharmacy professionals from Universities in order to increase the current ratios of medical professionals per population to meet up with the pharmacovigilance activity demand. An increased number of medical professionals would ultimately replace non-medical cadres in hospitals, and community pharmacies whose number and knowledge is not sufficient for ADRs reporting. Furthermore, there is also a need to review medical, pharmaceutical and all other health related profession curriculum at all levels to incorporate adverse drug reaction reporting system and pharmacovigilance practice for enhanced knowledge and practice.

CONCLUSION

The results showed that most of the health workers surveyed had poor knowledge and practice about ADR reporting and pharmacovigilance with those in tertiary hospitals showing somewhat better results. It is therefore recommended that the government through its national regulatory authorities and other relevant stakeholders should ensure that there is an improved pharmacovigilance practice in hospitals and community pharmacies. More successes can be achieved by routine training and retraining of all stakeholders in the healthcare system.

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