Original Research Article

Adverse drug reaction reporting by different categories of healthcare workers in Nnewi, Nigeria: Awareness, knowledge and attitudes

ABSTRACT

Aim: To determine the level of awareness, knowledge and attitudes among health workers in different settings of health care in Nnewi, Nigeria towards the reporting of adverse drug reactions (ADRs).

Methods: A descriptive cross-sectional study of 372 health workers in different health facilities in Nnewi North LGA of Anambra state, Nigeria was done. The participants were doctors, pharmacists and nurses, selected using multistage sampling technique. Datacollection employed pretested, self-administered structured questionnaires. Data was analysed using statistical package for social sciences version 17. Chi-square test for proportions was used to document statistical significance among variables. A p value of < 0.05 was considered significant.

Results: Two hundred and fifty five (68.5%) were females and 117 (31.5%) were males. This comprises 241 (64.8%) nurses/related cadres, 109 (29.3%) doctorsand22 (5.9%) pharmacists. Majority of them, 221 (59.4%) were not aware of the existence of the national ADR reporting scheme/guideline. The Pharmacists were more aware compared to other health professionals (P=.000). Respondents from tertiary health facility showed greatest awareness (43.2%). A total of 131 (35.2%) respondents have knowledge of the criteria for reporting ADR though it

does not have a relationship with profession (P=.71) and does not depend on the level of the health facility where one worked (P=.30).

Conclusions: This study showed poor awareness, knowledge gaps and poor attitude to ADR reporting across the professional groups. There is need for regular sensitization, training and retraining as well as attitudinal changes of health care providers to ADR reporting.

Keywords: Adverse drug reporting, awareness, knowledge, attitudes, health workers, Nnewi Nigeria

Introduction

High incidence of adverse drug reactions (ADRs) as well as the importance of effective ADR reporting in the achievement of patient safety has been documented by authors [1,2,3]. Direct patient reporting is viewed as important by those who have used the scheme, in order to provide the patient experience for the benefit of pharmacovigilance, as an independent perspective from those of health professionals [4]. Although the great relevance of spontaneous ADR reporting by patients has been emphasized in recent times, [4,5,6] the importance of objective reporting by healthcare professionals cannot be over emphasized [7,8].This is especially so in developing countries like Nigeria, where contrary to what obtains in developed climes of the world, poor enlightenment among health professionals and the lay public presents a daunting barrier to patients involvement in healthcare decision-making [9,10,11,12].

Health workers play an integral role in the success of safety surveillance of drugs by enhancing early detection of serious, unexpected and unusual ADRs. This requires high index

of suspicion, timeliness, teamwork and cooperation of various health professionals [13].Therefore, effective pharmacovigilance is achievable where a team with the requisite training, knowledge and responsibility for it is aware of its expected public health roles in that regard, and is willing, able and disposed to work together to perform it.

Though more pronounced in the developing countries, various studies conducted globally have revealed poor awareness of healthcare professionals to their various national adverse drug reactions reporting scheme/guideline [3]. Previous studies have also documented poor knowledge and poor attitude to ADR reporting among health care providers [3,14,15,16]. The World Health Organization has laid series of emphasis on pharmacovigilance [17]. Despite this and locally directed efforts such as the National ADR reporting scheme in Nigeria, there is still a high degree of under-reporting of ADRs world-wide [3,13,15,18,19]. Although similar studies have been carried out over the years in Europe [20], the United States [21], Asia and Australasia [22,23], and some parts of south-western and north-western Nigeria [3,15,16,19,24], not much has been reported in the south-eastern Nigeria. This is notwithstanding that this region has located in it, one of the largest open-air drug markets in Africa, notorious for the distribution of counterfeit and fake drugs [25,26]. This underscores the need to improve the level of awareness, knowledge and attitudes to ADR reporting among health care providers. Improving ADR reporting apart from reducing the incidence of adverse drug reactions and ensuring patients safety in health care delivery, will also lead to a reduction in health care costs. It is expected that the findings of this study will guide recommendations and serve as a basis for policy formulation, and putting in place appropriate intervention strategies toward the improvement of ADR reporting in Nigeria. With this backdrop, we designed our study to determine the level of awareness, knowledge and attitudes among health workers in different settings of health care in Nnewi, Nigeria towards the reporting of adverse drug reactions.

Methods

Description of Study Area

Nnewi North LGA (NNLGA) is one of the 21LGAs in Anambra, Southeastern Nigeria. It is a one town LGA that has an area dimension of 72km^2, an approximate total population of 391,222 people and a sex ratio of 1.02 male to female [27]

The health program of the LGA conforms to the National Health Policy and its goal to establish a comprehensive health care system, based on primary health care [28].Federal, State and Local Governments shall support, in a coordinated manner, a three-tier system of health care.The LGA has a number of health facilities; a federal teaching hospital, Nnamdi Azikiwe University Teaching Hospital, (NAUTH) Nnewi.There is no public secondary health facility in the LGA. There are about 114 private hospitals and clinics, 12 public primary health care centers and 12 health posts.

There is a total of 1,439 health workers in the LGA, grouped thus: 414 doctors {(142doctors from private hospitals) +275doctors (20 consultants + 176 registrars +79 house officers from tertiary hospital)} + 85 pharmacists (6 Assistant Director Pharmaceutical Services-ADPS) + 4 chief pharmacists + 7 principal pharmacists + 14 pharmacist I + 35 intern pharmacists from tertiary hospital and 20 community pharmacists) + 940 nurses and related cadres such as Community Health Extension Workers (CHEWS). There are alternative health care providers and patent medicine vendors.

Study Design

This was a cross-sectional descriptive study.

Study Population

This comprises all the health workers (doctors, pharmacists and nurses /related cadres) in NNLGA of Anambra state at the time of this study.

Sample Size Determination

The sample size was determined using the formula for the calculation of sample size in populations greater than 10,000, $n = z^2pq/d^2$ [29]. In a previous study in Nigeria, the proportion (p) of health workers aware of the ADR reporting scheme in Nigeria was 36.6% [16]. Therefore, p = 0.366 while n, the estimated minimum sample size required for the study was 371 health workers. Anticipating a response rate of 90%, an adjustment of the sample size estimate to cover for non- response rate was made by dividing the sample size estimate with a factor f, i.e. n/f, where f is the estimated response rate[29].Thus the calculated sample size =371/0.90 = 412. Then a conversion was made using the formula for the calculation of minimum sample size in populations less than 10,000, $nf = \frac{n}{1+\frac{n}{N}}$ [29], where N = target population = 1,439

nf = 320 health workers.

However, 420 questionnaires were distributed.

Sampling Technique

A multistage sampling technique was used. Firstly, the health workers were stratified thus: (Doctors, Pharmacists and Nurses/related cadres).

Secondly, proportionate allotment was done. The total number of health workers in NNLGA = 1,439 [Doctors = 414, Pharmacists = 85, Nurses/related cadre = 940, giving a ratio of 5: 1: 11].

Hence, total ratio = 17 and with a total sample required = 420, the allotment was done thus:

Sample of doctors required = 5/17 × 420 = 124.

Sample of pharmacists required = 1/17 × 420 =25.

Sample of nurses required = 11/17 × 420 = 272.

Thirdly, simple random sampling technique was used to select eligible and consenting respondents until the required number allotted to each cadre of health workers has been obtained. To ensure a fair assessment of the situation, only those health professionals who had had at least about a year's experience in practice were included in the study.

Data Collection Technique

Data collection in this study employed pretested, self-administered structured questionnaires to obtain data on the socio- demographics of the health workers, the level of awareness and knowledge on ADR reporting and the attitudinal stances of these health workers on ADR reporting. The questionnaire used was adapted and adopted from a study that assessed the ADR reporting practices of medical practitioners in the United Kingdom [30]. The questionnaire was pretested on health workers in Ekwulobia General Hospital to validate the research instrument.

On the administration of the questionnaires, time was taken to explain some of the questions to avoid ambiguity. Respondents who could not fill the questionnaires immediately were given a minimum of two days before collection. Reminding phone calls were also put up where necessary.

Data Management and Analysis

The data were scrutinized and entered into the computer. Data cleaning was done by carrying out range and consistency checks. Data were analyzed in respect to the socio- demographic characteristics of the respondents, level of awareness and knowledge on ADR reporting and attitudinal stances of health professionals on ADR reporting.

In analyzing the level of knowledge of standard ADR reporting guidelines, the responses of the respondents were assigned values (2 for the correct response, and 1 for the incorrect response). From these values, the maximum score was determined, based on which the level of knowledge was rated as Low, Moderate, or High, as appropriate. A similar value pattern

was used to analyze the attitudes of healthcare workers to ADR reporting. Descriptive and analytical statistics of the data were carried out using statistical package for social sciences (SPSS) Windows version17.0 [31].Tests of statistical significance were carried out using chi square tests for proportions**.** A p value of <.05 was considered significant. Descriptive data were presented as simple frequencies and percentages.

Results

A total of 420 questionnaires were sent out, 397 returned, and 23 not returned giving a response rate of 94.5%. Out of the 397 returned questionnaires, 25 were rejected due to incomplete filling and 372 (93.7%) were valid. The following analyses were based on inputs from the remaining 372 respondents.

Table 1 shows the socio-demographic characteristics and type of health facility of practice of the respondents. Two hundred and fifty five (68.5%) were females, and 117 (31.5%) were males. The modal age range (37.6%) was 31–40 years. Nurses/related cadres were in the majority with a total of 241 (64.8%), then doctors, 109 (29.3%) and pharmacists, 22 (5.9%). CHEWs made up only 5 % of the nursing sector population. Majority of them practice in private hospitals (46.2%) and tertiary hospital (41.7%). Community pharmacy and Health posts constituted the least (1.3% and 1.1% respectively) of the respondents studied.

Table 2 shows the level of awareness and knowledge on ADR reporting by the respondents. Majority of the respondents, 221 (59.4%) were not aware of the existence of the national ADR reporting scheme/ guideline. The Pharmacists weremore aware compared to other health professionals studied and the difference in awareness among these professions

was statistically significant ($\chi2$= 18.201, df = 2, P=.000). Respondents from tertiary health facility showed greatest awareness (43.2%) of the scheme and the reporting guideline while those from health post showed no awareness (0.0%). Nevertheless, this difference in awareness across the facilities was not significant ($\chi2$ =3.303, df = 4, P =.51).

A total of 131 (35.2%) respondents have knowledge of the criteria for reporting ADR. Only 35 (32.1%) out of 109 (100%) doctors studied have the knowledge of these criteria. The responses of those who have the knowledge were weighted and recoded into three categories – low, moderate and high knowledge of ADR reporting criteria for better presentation. None of the respondents have low knowledge. Among doctors with the knowledge, 26 (74.3%) have moderate knowledge and 9 (25.7%) have high knowledge. Twenty (90.9%) of pharmacists have the knowledge of ADR reporting criteria, 13 (65.0%) have moderate knowledge and 7 (35.0%) high knowledge while 76 (31.3%) nurses have the knowledge. However, the knowledge of these criteria has no relationship with profession ($\chi2$=0.674, df =2, P=.71). The health post reported complete lack of knowledge of ADR reporting criteria. However, the knowledge of ADR reporting criteria does not depend on the level of the health facility where one worked ($\chi2$=3.315, df =3, P=.30).

Table 3 shows attitudinal stances of health professionals on ADR reporting. The findings on the general tendencies among the health professional categories studied on five attitudinal stances on ADR. A total of 319 (85.8%) of respondents believe ADR reporting to be their professional responsibility. More pharmacists (90.9%) believed than nurses (85.3%) and doctors (83.5%) that reporting of ADR is their professional responsibility. While there was no statistically significant difference among the professions in their tendency to see ADR reporting as their professional responsibility ($\chi2$ =0.998, df =2, P =.61), nor in their tendency to report ADRs even if they were well known ($\chi2$=4.236, df =2, P=.12), they differed significantly in their tendency to report ADRs irrespective of their being sure that they were

caused by a given drug ($\chi 2$=19.295, df =2, P=.000). Although over two thirds of respondents were inclined to reporting ADRs if associated with either non-prescribed medications (72.4 %), or drugs prescribed by other or unknown physicians (73.8 %), there was no difference among the professional categories with respect to these inclinations ($\chi 2$=2.091, df=2, p=0.352); ($\chi 2$=1.989, df =2, P=.37).

Discussion

The response rate from our study is far higher than that reported in other studies [16,32,33].From this high response rate in our study, it can be adduced that with proper sensitization and information dissemination, there could be a massive improvement in the reporting of ADRs amongst the respondents. While there are many studies that have reported on the awareness, knowledge and attitudes of specific health professionals on ADR reporting, not much have studied various health professionals [16,34]. Even these few studies were not conducted among health workers in different levels of health care delivery.

This study revealed poor awareness of health care professionals (40.6%) in Nnewi, Nigeria to the National ADR reporting scheme/guideline. This finding is similar tothe finding in Nigeria which revealed that 63.4% of the respondents did not know about the existence of a Yellow Card reporting scheme [3]. In other parts of Africa, a study on the adverse drug reaction reporting by general medical practitioners and retail pharmacists in Harare, Zimbabwe, showed that 75% of the doctors had not known that a reporting scheme existed in Zimbabwe and none of the participants had ever sent in a report prior to the study [35]. Also among health professionals in Sudan**,** one of the main reasons for not reporting ADRs was lack of awareness about the existence of national or international reporting systems [36].This finding is consistent with findings of other studies in Jiangsu province, China where the health professionals were found to have poor awareness of pharmacovigilance[34]and in Malaysia,

where 40% of the health professionals were not aware of the existence of ADR reporting scheme [22]A study in India also identified that the awareness about pharmacovigilance program was very low among the doctors [37]. In a study where the knowledge of pharmacovigilance practice, reasons for not reporting ADR, and perceptions of the Iranian pharmacists on pharmacovigilance practice was evaluated, 29% of the respondents were not aware of the Iranian Pharmacovigilance Center [38].In a similar study on medical practitioners in Netherlands, even though majority of the respondents were aware of ADR reporting scheme, 18% were not aware of the need to report.These findings suggest the need for interventions to improve the awareness of the healthcare professionals on ADR reporting.

The present study showed that pharmacists were more aware of the scheme (81.8%) compared to the doctors (43.1%) and nurses (35.7%). The finding is similar to the finding of the study done in the United States of America, where majority of the reports come from pharmacists (38.8% and 34.8% by hospital and community pharmacists, respectively) while physicians' reports accounted for only 10.8% [39]. Contrary to these findings, some countries, such as France, Ireland, Malaysia, New Zealand, the Nordic countries, and the United Kingdom, have the largest contribution of ADR reports coming from the Physicians [39].Variations in drug use cum administration policies and implementation across countries may be the reason for these contrasting reports. Also the factors influencing under reporting may vary from one country to another.

Within each professional group, awareness of ADR reporting scheme was seen to be higher among the senior categories probably due to exposure from many years put into practice. This was contrary to the findings by John *et al.*, where among the clinicians who felt ADR reporting was necessary, the majority was clinicians with less than 10 years of experience [33]. A finding that was consistent with those reported by Bello *et al.*, in Sokoto Nigeria [24] and Bartels *et al.*, in Wisconsin United States of America [40]. They posited that there as on for

this finding could be that the younger clinicians are more aware of the existence of pharmacovigilance centers.

Across the health facilities, awareness of respondents were seen to be directly proportional to the level of the health facility- Health post (not aware), PHC (38.9%), private hospital (39.5), community pharmacy (40.0%), and tertiary health facility (43.2%). The finding is consistent with that from the study by the United States Health and Human services which revealed more awareness of large hospitals (71%) to the ADR reporting process compared to medium (58%) and small hospital (32%) [41]. This is understandable considering the caliber of personnel working in the tertiary health institutions and the fact that tertiary health institutions are in a better position to organize seminars, workshops and training for its workers.

As much as 64.8% of the health professionals studied was shown to lack the knowledge of the ADR reporting criteria. This finding is similar to that of a study to investigate the awareness and attitudes of healthcare professionals (doctors, nurses, and administrators) toward the ADR system in China, where 52.2% were reported to lack knowledge of the existence of a national ADR reporting system [42]. A survey among medical residents in France showed that the majority of them had a lower knowledge regarding pharmacovigilance [43].These findings are contrary to that of another study in Jiangsu province, China where the health professionals were found to have a good recognition of basic knowledge of ADR[34]. Perhaps this could be the reason why some respondents stated that they could not report because of uncertainty of reaction caused by drugs. If these respondents had the knowledge of these criteria, they may have known that they were required to report even when they were unsure that the drug in question was the actual cause of the reaction [44] In a research on the reporting of adverse drug reactions among health professionals in Sudan**,** one of the main reasons for not reporting ADRs was lack of

knowledge on how to report [36].Generally, pharmacists had better knowledge of this criteria (90.9%) compared to the doctors (32.1%) and then nurses (31.3%). For better understanding, the knowledge of the criteria was further categorized into low, moderate and high knowledge. Most of the respondents have moderate knowledge of ADR reporting, a clear indication of why most of the suspected ADR have gone unreported.

The study also revealed very poor attitude to reporting among the different health care professionals studied. Majority of the respondents (85.8%) actually believed ADR reporting to be their professional responsibility. John *et al*., [33] and Oshikoya*et al*., [3] reported about 30% and 60% of clinicians respectively, felt ADR reporting is a professional obligation. Clinicians are responsible for patient safety and ADR reporting eventually contributes to the aspect of medical ethics.

However, this study was limited by factors that are inherent to questionnaire-based self-reporting studies such as subjective response, accuracy of recall, personal bias and could also have affected, in some ways, the results of this study.

Conclusions: The investigation into the awareness, knowledge and attitude of ADR reporting revealed that there was generally poor awareness of ADR reporting among the health workers studied.There are knowledge gaps and poor attitude to ADR reporting across the professional groups. Pharmacists were more aware of as well as more knowledgeable on ADR reporting the scheme, compared to the doctors and nurses. Thus recommendations were made on the need for regular sensitization of all health care workers on the importance of pharmacovigilance through seminars, workshops, conferences on ADR reporting. There should be training and retraining of health care provider on ADR reporting as well as mandatory reporting of ADR. Attitudinal changes, whereby ADR reporting should be seen by health care providers as an integral part of health care delivery is also advocated.

Consent

All authors declare that written informed consent and co-operation of the respondents and the heads of the selecthealth facilities was solicited and obtained for the conduct and publication of this research study.

Ethical approval

All authors hereby declare that permission was obtained from the Anambra State Ministry of Health, and the NNLG PHC Department, while the study has been examined and approved by the Nnamdi Azikiwe University Teaching Hospital Ethical Committee (NAUTHEC), Nigeria and therefore has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

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Tables

Table 1: Socio-demographic characteristics of the respondents

Category	Number	Percentage (%)
Gender	**372**	**100**
Male	255	68.5
Female	177	31.5
Age (years)	**372**	**100**
21-30	92	24.7
31-40	140	37.6
41-50	100	26.9
51-60	33	8.9
>60	6	1.6
No response	1	0.3
Profession	**372**	**100**

Doctors	**109**	**29.3**
Consultants	20	18.3
General Practitioners	31	28.4
Resident doctors	33	30.4
House officers	25	22.9
Pharmacists	**22**	**5.9**
Assistant Director for Pharmaceutical Services (ADPS)	2	9.1
Chief Pharmacists	2	9.1
Principal Pharmacists	4	18.2
Pharmacist 1	5	22.7
Intern Pharmacists	9	40.9
Nurses/related health workers	**241**	**64.8**
Chief Nursing Officer (CNO)	48	19.9
Assistant Chief Nursing Officer (ACNO)	29	12.0
Principal Nursing Officer (PNO)	35	14.5
Senior Nursing Officer (SNO)	40	16.6
Nursing Officer I(NO I)	35	14.5
Nursing Officer II(NO II)	42	17.5
Community Health Extension Workers	12	5.0
Types of Health Establishment Surveyed	**372**	**100**
Health Post (H P)	4	1.1
Community Pharmacy	5	1.3
Primary Health Centre (PHC)	36	9.7
Private Hospital	174	46.2
Teaching Hospital	155	41.7

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436 **Table 2: Level of awareness and knowledge on ADR reporting of the respondents**

Assessment Criteria on ADR Reporting	**Assessment Categories**	**Health Professionals (%)**			**Statistic**	**Healthcare Facility (Practice Setting)**					**Statistic**
		Doctor	**Pharmacist**	**Nurse/ CHEWs**		**Health Post**	**Community Pharmacy**	**Primary Health Centre**	**Private Hospital**	**Teaching Hospital**	
Awareness Status (of the ADR	**Aware**	47 (43.1)	18 (81.8)	86 (35.7)	X^2= 18.201	0 (0.0)	2 (40.0)	14 (38.9)	68 (39.5)	67 (43.2)	X^2=3.303 df=4
	Not	62	4	155		4	3	22	104	88	

reporting Scheme/ Guideline)	**Aware**	(56.9)	(18.2)	(64.3	df=2 P =.000	(100.0)	(60.0)	(61.1)	(60.5)	(56.8)	P =.51
Level of Knowledge (of ADR reporting criteria)	**Moderate**	26 (74.3)	13 (65.0)	56 (73.7)	X^2=0.674 df=2 P =.71	-	3 (75.0)	13 (92.9)	38 (70.4)	41 (69.5)	X^2=3.315 df=3 P =.30
	High	9 (25.7)	7 (35.0)	20 (26.3)		-	1 (25.0)	1 (7.1)	16 (29.6)	18 (30.5)	

Table 3: Attitudinal stances of health professionals on ADR reporting

Attitudinal stance	**Healthcare Professionals**				**Total (%)**
	Doctors (%)	**Pharmacists (%)**	**Nurses (%)**	**Statistic**	
ADR reporting is my professional responsibility	91 (83.5)	20 (90.9)	208 (86.3)	X^2 =0.998, df=2, P =.61	319 (85.8)
Would report an ADR only if certain it was caused by drug	33 (33.0)	12 (75.0)	111 (56.9)	X^2=19.295 ,df=2, P=.000	156 (50.2)
Would report an ADR only if it was not well known	29 (29.0)	6 (37.5)	80 (41.2)	X^2=4.236, df=2, P=.12	115 (37.1)
Would be more inclined to report an ADR if associated with a drug prescribed by another/an unknown physician	86 (78.9)	15 (71.4)	172 (71.7)	X^2=2.091, df=2, P=.35	273 (73.8)
Would be more inclined to report an ADR if associated with a drug bought without a prescription	83 (76.1)	13 (61.9)	172 (71.7)	X^2=1.989, df=2, P=.37	268 (72.4)