



Factors Associated with the Reporting of Adverse Drug Reactions by Health Workers in Nnewi Nigeria

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ABSTRACT

Background: Under-reporting of adverse drug reactions (ADRs) by the prescribers is a common public health problem. Monitoring of factors that influence ADR reporting will reduce risks associated with drug use; improve patients care, safety and treatment outcome. The aim of this study was to determine the factors associated with the reporting of ADRs by health workers in Nnewi Nigeria.

Methods: A cross-sectional study of 372 health workers in different health facilities in Nnewi North Local Government Area of Anambra state, selected using multistage sampling technique was done. Data collection employed pretested, self-administered structured questionnaires. Data were analyzed using Statistical Package for Social Sciences version 17. Tests of statistical significance were carried out using Chi-square tests for proportions. A $P < 0.05$ was considered significant.

Results: Out of the 372 respondents studied, 255 (68.5%) were females, and 117 (31.5%) were males. The modal age range (37.6%) was 31–40 years. Factors related by the respondents to influence ADR reporting include: Unavailability of electronic reporting (83.6%), unavailability of reporting forms (66.4%) and ignorance (58.2%). The difference among medical practitioners who related unavailability of electronic reporting process as obstacle to ADR reporting was not significant ($P = 0.18$).

Conclusions: The study results revealed the factors associated with the reporting of ADRs among health workers in Nnewi Nigeria. It is desirable to initiate electronic reporting process, training programs on ADR reporting and make reporting forms/guidelines available to relevant health workers.

Keywords: Adverse drug reporting, determinants, health workers, Nnewi Nigeria

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INTRODUCTION

Spontaneous reporting of adverse drug reactions (ADRs) by healthcare workers remains an important method of ADRs detection. Such monitoring and reporting system contributes to signal detection of unsuspected and unusual ADRs previously undetected during the initial evaluation of a drug.^[1,2] It encourages documentation of

ADRs as well as provides a mechanism for monitoring the safety of drug use in high-risk patient populations. This system also stimulates the education of health workers regarding potential ADRs.^[3] In spite of these benefits, under-reporting remains a major drawback of spontaneous reporting.^[2,4]

The Nigerian system for monitoring drug safety is coordinated by the National Agency for Food, Drug Administration and Control (NAFDAC). All healthcare professionals including doctors, dentists, pharmacists, nurses, traditional medicine practitioners and other health professionals are requested to report all suspected adverse reactions to drugs including orthodox medicines, X-ray contrast media, medical devices, cosmetics, traditional and herbal medicines.^[5]

Studies have reported potential barriers for the spontaneous reporting of ADRs to include: Lack of index of suspicion of an ADR, belief of doctors that it is necessary to confirm ADRs before reporting, lack of knowledge of pharmacovigilance program, lack of yellow cards or forms for reporting, absence of a pharmacovigilance feedback system and methodology for identifying warnings.^[6,7] Time constraint, the notion that the forms are too cumbersome to fill, increase in work load, and other clinical priorities have also been documented.^[8] Several doctors have reported the potential of ADRs to attract legal actions and liabilities, possible judicial claims against them and the problems of confidentiality with patients' data as obstacles.^[6-9]

In addition, education and training have been reported as the only positive predictor in influencing health workers practice of ADRs reporting.^[9] In Nigeria, training of health workers on ADR is very poor. Among 120 doctors surveyed in Lagos State University Teaching Hospital, Nigeria, only one respondent had received training on how to report ADR with a Yellow Card.^[9]

In order to strengthen this system, the World Health Organization in 1968, created the International Drug Monitoring Program for the purpose of collecting information about ADRs that were not observed during clinical drug trials.^[10] It is, therefore, worrisome that ADRs are still under-reported worldwide, and are much more under-reported in Nigeria compared to the developed countries of the world.^[9] Also, most studies in the study area were on knowledge, attitude, practice and perception of physicians toward ADR reporting.^[9,11-13] Not much was done on other health workers or on factors influencing the reporting of ADRs by these health workers. 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. This study was, therefore, conducted to determine the factors associated with the reporting of ADRs by health workers in Nnewi Nigeria.

METHODS

Study design and participants

Description of study area

Nnewi North Local Government Area (NNLGA) is one of the 21 Local Government Area (LGAs) in Anambra, South-Eastern Nigeria. It is a one town LGA that has an area dimension of 72 km² and an approximate total population of 391,222 people with a sex ratio of 1.02 male/female.^[14]

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 that is promotive, protective, preventive, restorative and rehabilitative to every citizen of the country within the available resources so that individuals and communities are assured of productivity, social well-being and enjoyment of living.^[15] Federal, State and Local Governments shall support, in a coordinated manner, a three-tier system of health care. Thus, the LGA has a number of health facilities; a federal teaching hospital, Nnamdi Azikiwe University Teaching Hospital, Nnewi and the College of Health Sciences of the Nnamdi Azikiwe University. 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.^[14]

There is a total of 1,439 health workers in the LGA, grouped thus: 414 doctors ([142 doctors from private hospitals] +275 doctors [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, $n = z^2pq/d^2$.^[16] In the previous study in Nigeria, the proportion (p) of health workers aware of the ADR reporting scheme in Nigeria was 36.6%.^[9] 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 was made 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, n_f , 320 health workers.^[16] 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 = $5/17 \times 420 = 124$.

Sample of pharmacists required = $1/17 \times 420 = 25$.

Sample of nurses required = $11/17 \times 420 = 272$.

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.

Ethical consideration

Approval to conduct the study was obtained from the Nnamdi Azikiwe University/Teaching Hospital Ethical Committee, while permission was obtained from the State Ministry of Health, and the>NNLG PHC Department. Informed consent was sought and obtained from the respondents and the heads of the select health facilities.

Data collection and study instruments

Data collection in this study employed pretested, self-administered structured questionnaires to obtain data on the sociodemographics of the health workers and factors affecting reporting. The questionnaire used was adapted and adopted from a study that assessed the ADR reporting practices of medical practitioners in the United Kingdom.^[17] The data collection tool was pretested on health workers in Ekwulobia General Hospital to validate the research instrument.

Statistical 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 demographic characteristics of the respondents,

factors influencing ADR reporting by health care professionals, distribution of respondents who stated unavailability of electronic reporting as obstacle to reporting, distribution of respondents with training on ADR reporting, suggested ways to improve ADR reporting in Nigeria. Descriptive and analytical statistics of the data were carried out using International Business Machine, Statistical Package for Social Sciences (SPSS) Windows version 17.0.^[18] Tests of statistical significance were carried out using Chi-square tests for proportions. A $P < 0.05$ 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. Table 1 shows the sociodemographic variables of respondents. Out of the 372 respondents studied, 255 (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%).

Table 2 highlights factors related by the respondents to be associated with ADR reporting. These include: Unavailability of electronic reporting (83.6%), unavailability of reporting forms (66.4%) and ignorance (58.2%). Others are bureaucratic reporting process (39.9%), no incentives (32.5%), legal implication of reports (26.6%) and time factor (20.4%). The

Table 1: Sociodemographic variables of respondents

Variables	Frequency	Percentage
Gender		
Male	225	68.5
Female	177	31.5
Total	372	100.0
Age		
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
Total	372	100.0
Profession		
Doctors	109	29.3
Pharmacists	22	5.9
Nurses/related cadres	241	64.8
Total	372	100.0

difference among factors related by the respondents to be associated with ADR reporting was not significant ($\chi^2 = 0.00777$, $df = 4$, $P = 0.93$).

Table 3 summarizes the distribution of respondents who stated unavailability of electronic reporting as obstacle to reporting. With the exception of the most senior cadres of pharmacists studied (ADPS and chief pharmacists), other cadres believed entirely that unavailability of electronic reporting process has a negative influence to reporting of ADRs. The difference

among medical practitioners who related unavailability of electronic reporting process as obstacle to ADR reporting was not significant ($\chi^2 = 4.945$, $df = 3$, $P = 0.18$). However, this factor was significant among categories of nurses - Nursing Officer II, Nursing Officer I, Senior Nursing Officer, Principal Nursing Officer, Assistant Chief Nursing Officer, Chief Nursing Officer ($\chi^2 = 17.418$, $df = 6$, $P = 0.008$).

Table 4 shows the distribution of respondents with training on ADR reporting. Training on ADR was

Table 2: Factors influencing ADR reporting by health care professionals

Factors	Frequency (%)	Profession (%)			Total (%)
		Doctors	Pharmacists	Nurses/related cadre	
No electronic reporting process	311 (83.6)	90 (82.6)	19 (90.5)	202 (84.2)	311 (84.1)
No reporting forms	247 (66.4)	89 (89.9)	10 (62.5)	148 (75.9)	247 (79.4)
Ignorance of how to report	181 (58.2)	59 (59.0)	4 (25.0)	118 (60.5)	181 (58.2)
Bureaucratic reporting process	124 (33.3)	44 (44.0)	6 (37.5)	74 (37.9)	124 (39.9)
No incentives	101 (27.2)	23 (23.0)	8 (50.0)	70 (35.9)	101 (32.5)
Fear of litigation	99 (26.6)	21 (21.0)	5 (31.3)	73 (37.4)	91 (31.8)
Time consuming	76 (20.4)	22 (22.0)	5 (31.3)	49 (21.4)	76 (21.4)

$\chi^2=0.00777$, $df=4$, $P=0.93$

Table 3: Distribution of respondents who stated unavailability of electronic reporting as obstacle to reporting

Profession	Rank (%)	Unavailability of electronic reporting		Total (%)
		Yes (%)	No (%)	
Doctors	House officers	21 (84.0)	4 (16.0)	25 (100.0)
	Resident doctors	24 (72.7)	9 (27.3)	33 (100.0)
	General practitioners	29 (93.5)	2 (6.5)	31 (100.0)
	Specialists	16 (80.0)	4 (20.0)	20 (100.0)
	Total	90 (82.6)	19 (17.4)	109 (100.0)
$\chi^2=4.945$, $df=3$, $P=0.18$				
Pharmacists	Interns	9 (100.0)	0 (0.0)	9 (100.0)
	Pharmacist I	14 (100.0)	0 (0.0)	4 (100.0)
	Principal pharmacist	4 (100.0)	0 (0.0)	4 (100.0)
	Chief pharmacist	1 (50.0)	1 (50.0)	2 (100.0)
	ADPS	1 (50.0)	1 (50.0)	2 (100.0)
	Total	19 (90.5)	2 (9.5)	21 (100.0)
$\chi^2=9.395$, $df=4$, $P=0.052$				
Nurses and related cadres	CHEWS	10 (83.3)	2 (16.7)	12 (100.0)
	NO II	39 (95.1)	2 (4.9)	41 (100.0)
	NO I	26 (74.3)	9 (25.7)	35 (100.0)
	SNO	39 (97.5)	1 (2.5)	40 (100.0)
	PNO	25 (71.4)	10 (28.6)	35 (100.0)
	ACNO	22 (75.9)	7 (24.1)	29 (100.0)
	CNO	41 (85.4)	7 (24.1)	29 (100.0)
	Total	202 (84.2)	38 (15.8)	240 (100.0)

$\chi^2=17.418$, $df=6$, $P=0.008$

NO II=Nursing Officer II, NO I=Nursing Officer I, SNO=Senior Nursing Officer, PNO=Principal Nursing Officer, ACNO=Assistant Chief Nursing Officer, CNO=Chief Nursing Officer, ADPS=Assistant Director Pharmaceutical Services, CHEWS=Community Health Extension Workers

generally poor among the health workers studied, but pharmacists had an appreciable training on ADR reporting (50.0%) than nurses (19.5%) and the doctors (13.8%). The difference in training among the health workers was not significant ($\chi^2 = 5.187, df = 3, P = 0.16$).

Table 5 summarizes the suggested ways to improve ADR reporting. Three hundred and sixty-eight (98.9%) respondents gave suggestions on how to improve ADR reporting. The suggestions include: Awareness and provision of reporting forms/guideline, electronic reporting process. The difference among suggested ways

Table 4: Distribution of respondents with training on ADR reporting

Profession	Rank (%)	Training on ADR (%) reporting		Total (%)
		Yes (%)	No (%)	
Doctors	House officers	4 (16.0)	21 (84.0)	25 (100.0)
	Resident doctors	5 (15.2)	28 (84.8)	33 (100.0)
	General practitioners	1 (3.2)	30 (96.8)	31 (100.0)
	Specialists	5 (25.0)	15 (75.0)	20 (100.0)
	Total	15 (13.8)	94 (86.2)	109 (100.0)
$\chi^2 = 5.187, df = 3, P = 0.16$				
Pharmacists	Interns	5 (55.6)	4 (44.4)	9 (100.0)
	Pharmacist I	3 (60.0)	2 (40.0)	5 (100.0)
	Principal pharmacist	1 (25.0)	3 (75.0)	4 (100.0)
	Chief pharmacist	1 (50.0)	1 (50.0)	2 (100.0)
	ADPS	1 (50.0)	1 (50.0)	2 (100.0)
	Total	11 (50.0)	11 (50.0)	22 (100.0)
$\chi^2 = 1.311, df = 4, P = 0.86$				
Nurses and related cadres	CHEWS	0 (0.0)	12 (100.0)	12 (100.0)
	NO II	10 (23.8)	32 (76.2)	42 (100.0)
	NO I	9 (25.7)	26 (74.3)	35 (100.0)
	SNO	6 (15.0)	34 (85.0)	40 (100.0)
	PNO	9 (25.7)	26 (74.3)	35 (100.0)
	ACNO	5 (17.2)	24 (82.8)	29 (100.0)
	CNO	8 (16.7)	40 (83.3)	48 (100.0)
	Total	47 (19.5)	194 (80.5)	241 (100.0)
$\chi^2 = 5.981, df = 6, P = 0.43$				

NO II=Nursing Officer II, NO I=Nursing Officer I, SNO=Senior Nursing Officer, PNO=Principal Nursing Officer, ACNO=Assistant Chief Nursing Officer, CNO=Chief Nursing Officer, ADPS=Assistant Director Pharmaceutical Services, CHEWS=Community Health Extension Workers

Table 5: Suggested ways to improve ADR reporting in Nigeria

Suggested ways to improve ADR reporting	Profession (%)			Total (%)
	Doctors	Pharmacists	Nurses/related cadre	
Awareness through workshops and mass media	62 (58.5)	15 (68.2)	153 (63.8)	230 (62.5)
Provision of reporting guidelines and reporting forms by NAFDAC	18 (17.0)	2 (9.1)	22 (9.2)	42 (11.4)
Legislation and incentive	11 (10.4)	1 (4.5)	20 (8.3)	32 (8.7)
Decentralization of reporting centers	6 (5.7)	2 (9.1)	11 (4.6)	19 (5.2)
Drugs to be handled by only trained personnel	1 (0.9)	0 (0.0)	18 (7.5)	19 (5.2)
Reporting by cell phones, fax E-mails	5 (4.7)	2 (9.1)	3 (1.3)	10 (2.7)
ADR monitoring by NAFDAC	17 (2.8)	0 (0.0)	7 (2.9)	10 (2.7)
Rational prescribing	0 (0.0)	0 (0.0)	5 (2.1)	5 (1.4)
Prompt response by NAFDAC	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.3)
$\chi^2 = 0.84682, df = 4, P = 0.36$				
Total	106 (100.0)	22 (100.0)	240 (100.0)	368 (100.0)

ADR=Adverse drug reaction, NAFDAC=National Agency for Food, Drug Administration and Control

to improve ADR reporting by the respondents was not significant ($\chi^2 = 0.84682$, $df = 4$, $P = 0.36$).

DISCUSSION

The findings of our study showed factors related by the respondents to influence ADR reporting to include: Unavailability of electronic reporting, unavailability of reporting forms, ignorance, bureaucratic reporting process, lack of incentives, legal implication of reports and time factor. This result tallies with the findings of other authors.^[11,12,19-22]

Unavailability of electronic reporting was related as obstacle to reporting. This agrees with the findings of Kamtane *et al.*^[22] When doctors and other health care workers cannot get access to up-to-date information about ADRs they may not recognize them and therefore won't report them. This is because most information from drug inserts and textbooks on drugs, which health workers resort to may be outdated and may not reflect the current state of information on ADRs.^[23] When there is unavailability of electronic reporting, it may lead to the high rate of under-reporting which can in turn, delay signal detection and consequently impart negatively on the public health.^[9]

Some respondents stated unavailability of reporting forms as obstacle to reporting. This agrees with the findings of other studies.^[12,22] The importance of availability of these forms was further revealed by previous studies, which showed that distribution and availability of Yellow Cards to the doctors increase ADRs reporting.^[24,25] There is no doubt the distribution and availability of these cards to the other health workers would increase ADRs reporting.

Ignorance of how to report ADR runs through all categories of doctors and nurses/related workers. This tallies, to a large extent, with other reports from Nigeria, China and Malaysia.^[11,26,27] While it is important to note that these studies were carried out among physicians, several other studies involving pharmacists have indeed confirmed that under-reporting of ADRs is common to all health care professionals and the same factors as reported in our study have been implicated.^[28,29]

Its true previous studies on ADRs reporting have been on physicians alone.^[9,11-13] The health workers involved in our study were doctors, pharmacists and nurses/other related cadre of health workers. This is because they are the major groups involved in the process of drug administration. Also, patients are likely to give feedback (including reaction to the administered drugs) to them. The nurse related health workers studied were the CHEWs, and they were so grouped because

they perform nursing services in most health posts and PHCs. So to get a broad view of factors affecting ADR reporting implies that as many health workers involved in reporting as possible should be studied.

Some health workers suggested the use of financial incentives as a tool to stimulate reporting of ADRs.^[30] This proposition has not been widely accepted and practiced, but if not well monitored, may lead to over-reporting by some health care workers in a bid to obtain undeserved financial reward.

Training on ADR was generally poor among the health workers studied. Though about half of pharmacists had an appreciable training on ADR reporting compared to less than one-fifth of nurses and doctors and less than one-fifth of respondents studied have had training on ADR reporting. This is very poor and would exert a serious negative influence on ADR reporting and patient's outcome if no intervention strategies are put in place. Previous studies have documented that ADR reporting improves with educational programs.^[31,32] Oshikoya and Awobusuyi in the perceptions of doctors to ADR reporting in a teaching hospital in Lagos, Nigeria, also reported that education and training were the most recognized means of improving ADR reporting.^[9]

Limitations of the study include; those inherent to questionnaire-based studies such as subjective response and recall bias.

CONCLUSIONS

The key factors associated with ADR reporting include: unavailability of electronic reporting, unavailability of reporting forms and ignorance. In order to address some of the factors affecting reporting found in this study, the NAFDAC should make accessible, available and in an adequate quantity reporting forms as well as reporting guidelines in the form of booklets and posters at conspicuous locations in health care facilities to serve as a constant reminder. This should be in addition to regular sensitization of all health care workers on the importance of pharmacovigilance in the quest to decrease morbidity and mortality among the population through seminars, workshops, conferences and training on ADR reporting. Electronic means of reporting (cell phones, fax and E-mails) should be provided to lesson bureaucratic process of reporting. There should be regular training and retraining of health workers on ADR reporting as well as continuous monitoring of ADR reports by NAFDAC officials at all levels of health care delivery.

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