Effects of health education on knowledge, attitude and practice of adverse drug reaction reporting among community pharmacists in Anambra state, Nigeria

Abstract

Background: Poor reportage of adverse drug reaction has been linked o. increase in morbidity, mortality and economic burden of diseases and health related conditions.

Objective To determine the effects of health education on knowledge, attitude and practice of adverse drug reaction (ADR) reporting among community pharmacists practicing in Anambra State.

Methods: This interventional study was conducted among Community Pharmacists in Anambra State. Simple random samp\ling technique was used. Pre-tested, semi-structured self-administered questionnaire was used to collect data on respondents' socio-demographics, knowledge of, attitude to and practice of ADR reporting Associations between variables were tested using Chi-square and Binary logistic regression at 5% level of significance. Data obtained were analyzed using SPSS version 23.

Results The mean age of the respondents was 46.5±11.2 years. Post intervention result shows that there was an increase in knowledge of ADR reporting in the intervention group from 52% to 95.3%. There was a decrease in knowledge of ADRs reporting in the control group from 47.3% to44.7%. There was a statistically significant difference between the experimental group and the control group on their attitude towards ADR reporting (p<0.05). Only 26.7% of the test group had filled a spontaneous reporting ADR form prior to this study compared to 18% from the control group and is associated with the effect of health education intervention.

Conclusions: There was underreporting of ADRs, associated with gaps in the knowledge, attitude and practice among the community pharmacists studied. There is need for focused continuous health education interventions on ADR reporting among them

Keywords: *Health education, reporting, adverse drug reaction Nigeria, community pharmacists.*

Introduction

“Adverse Drug Reaction (ADR) is poorly reported globally but more in developing countries with poor participation by health professionals” (1). :Under-reporting of ADR may be associated with poor knowledge of, attitudes towards and practices of Pharmacovigilance: (2).

“The spontaneous reporting of ADRs using yellow cards remains the most effective surveillance system of drugs in clinical practice. Its value is determined by the nature and volume of reports received, factors which themselves are determined by the vigilance and commitment of those involved with the prescribing and dispensing of drugs to patients” (3). “For instance in Nigeria despite the existence of a Nigerian National Pharmacovigilance System (PVS), available data shows that ADRs are under-reported in Nigeria. Poor understanding of the reporting system among Nigerian healthcare professionals and lack of proper education on the side of health care professionals and patients has been documented as the major reasons for under-reporting of ADRs in this country” (4).

“A recent assessment of the Nigerian PVS, as well as those of most of the Sub-Saharan countries, showed that they did not meet their PVS’ capacity and performance indicators” (5). One of the cardinal objectives of the five year Pharmacovigilance Plan for Nigeria (2007 – 2011) (6) is “To ensure that over 80% of healthcare providers are aware and have acceptable level of knowledge on the concept of ADRs and take appropriate measures to control them, notably their documentation and reporting(6). “Similarly, Iran, with a population of over 60 million, was expected to receive at least 12,000 reports per year. Unfortunately this is not so, considering the fact that only 2,330 reports were sent to the Iranian Pharmacovigilance Centre in the year 2006”(7). “The situation is not different in Thailand where despite the fact that it has a good ADRs reporting system, it still suffers from low reporting by health care professionals”(8) “The few studies in Malaysia that have investigated the low reporting rates of ADRs amongst the health professionals indicated that up to 40% of the physicians were unaware of the existence of the ADRs reporting system” (8). “These low

reporting rates are not only restricted to developing nations as studies have also shown that ADRs reporting rate in USA to be as low as 1 - 6%". (9). "In the United Kingdom, since the yellow card spontaneous ADRs reporting scheme was initiated, the number of yellow cards increased to reach a peak in the early 1990s. Since then, the number received annually has fallen and stabilized at about 17,000 with a percentage of 2.4%" (10).

"The community pharmacies provide easy access to patients due to shorter waiting times, availability of wider range of drugs at low cost. Depending on their purchasing power, they can get full or half dose, without any restrictions from the drug sellers".(10). "A large number of the population access medical advice through community pharmacies instead of going to the hospitals as means to avoid consultation charges, hospital bureaucracy and escape from the out stock saga common in government health facilities" (11). "Thus community pharmacies are the first point of contact of most patients with the health care system in many developing countries" (11). Community pharmacists have a unique role in the monitoring and reporting of ADRs due to their ease of access for patients and chances that the patients approach them for the management of symptoms associated with ADRs. Further, they have a major role in preventing ADRs by giving appropriate medication counselling for the patients. It is therefore important to know the attitude of community pharmacists towards their role as members of the health care team in reporting ADRs and the factors that influence ADR reporting. In the light of this, the index study aims is to create awareness of adverse drug reaction reporting among community pharmacists in Anambra State.

"Educational intervention can increase awareness of Pharmacovigilance among the health care professionals and incorporate this gained knowledge of Pharmacovigilance into their everyday clinical practice. In a study carried out in Nigeria to evaluate the change in knowledge, attitudes and practices of healthcare professionals about ADR monitoring and reporting after six months of

interventions. Following the interventions, change in the participants' knowledge of ADR monitoring and Pharmacovigilance increased by over 100% after the training intervention which was statistically significant" (12). "In another educational intervention study carried out in India to assess the knowledge, attitude, practice of Pharmacovigilance among the healthcare professionals who attended educational training program on Pharmacovigilance at the hospital where hospital based ADR reporting and monitoring system exist. The result of the study shows that healthcare professionals who attended theoretical and also practical part of educational intervention on Pharmacovigilance are much satisfied with them and consider them very useful. This educational intervention program on Pharmacovigilance encouraged physician, pharmacist and nurses to enhance the relationship between them for reporting adverse drug reactions" (13). "This finding indicates in the study that health educational intervention increased among physician, pharmacist and nurses' awareness of Pharmacovigilance and able to transfer their gained knowledge into their everyday clinical practice" (13). Although there are 22 post-KAP questionnaires that either encouraged or discouraged physician, pharmacist and nurses to know more about Pharmacovigilance in our study (98.9%) of doctors,(76.5%) of nurses, (93%) of pharmacist have responded correctly to the definition of Pharmacovigilance. This data suggests that continuing educational intervention is an important tool for increasing physician, pharmacist and nurse's awareness to Pharmacovigilance (13). Teaching how to report ADR is a very important task in healthcare. Because knowing the side effects of a specific drug helps to protect a specific patient's health more effectively. A significant part of the side effects of a given drug becomes known during research and development, but some side effects are only known during long-term use, SOME appear when it is taken at the same time as another medicine. Unfortunately, when taking some medicines, it is necessary to take into account what the patient ate or drank. Therefore, this topic is worth writing about This study

was thus designed to determine the knowledge, attitude and practice of ADRs reporting among community pharmacists practicing in Anambra State, Nigeria

Methodology

Description of study area

The index study was carried out in Anambra State, Nigeria. The State comprises three (3) senatorial districts (North, South and Central) 21local government areas with a human population of 4,182032 persons (14). Anambra State has about 393 registered community pharmacists as at 2018 (15). The study was conducted in Anambra State in southeast Nigeria. It is located in the tropical rainforest belt.

Study design: This was an intervention study
Study population: This comprises community pharmacists practicing in Anambra State, Nigeria.
Inclusion criteria: Pharmacists in charge of community pharmacies in Anambra State, duly registered with the Pharmacist Council of Nigeria and must have practiced in the State for at least one year.
Exclusion criteria: Respondents not willing to participate in the study, pharmacist absent during the study period and those who declined full informed consent were excluded from the study.
Sample size determination.

The sample size was determined using the formula for the calculation of sample size for comparing two proportions (16).

$$n = \frac{[Z_{1-\alpha}\sqrt{(2P(1-P)} + Z_{1-\beta}\sqrt{(P_1(1-P_1) + P_2(1-P_2)}]^2}{(P_1 - P_2)^2}$$

n = the estimated minimum sample size required for the study
$Z_{1-\alpha}$ = percentage point of the standard normal deviate corresponding to the two-sided significant level given as 1.96 (for α = 5% or 0.05).
$Z_{1-\beta}$ = one-sided percentage point of the standard normal deviate corresponding to 90% = 1.28
P_1 = Intervention group knowledge of Pharmacovigilance from a previous study = (61.0%). (17); P_2 = Control group knowledge of Pharmacovigilance from a previous study (14.8%)(17); P = Combined intervention rate $\frac{(P_1 + P_2)}{}$.

$P_1 = 0.610, \quad P_2 = 0.148, \quad P = \underline{(0.610 + 0.148)}\ /2 = 0.379$

$$n = \frac{[1.96 \sqrt{(2 \times 0.379\ (1 - 0.379) + 1.28 \sqrt{(0.61\ (1 - 0.61) + 0.148\ (1 - 0.148)\ ]^2}}{(0.462)^2}$$

$n = 21.1$

To minimize errors arising from the likelihood of non-response, sample size was calculated as follows using the formula:(16) $n_s = n/f$, Where n_s = Sample size to compensate for non-response, n = calculated sample size, f = anticipated response rate Assuming 10% non-response (attrition) rate, 90% (0.90) response rate is anticipated $n_s = 21.1/0.90 = 23.4$ rounding off to 24. The final sample size was 24, however a sample size of 150 respondents were recruited per group (experimental and control) in order to increase the power of the research.

Sampling Technique

Simple random sampling was used for subject selection. The community pharmacists were enrolled from attendance register by simple random sampling. This was done at the quarterly annual meeting of the Association of Community Pharmacists in Nigeria (ACPN) Anambra state chapter, held at Five Star and Food Restaurant, Onitsha recorded more than 520 Community Pharmacists from the 21 Local Government Areas of the State. Each pharmacist was given a number (1 to 350) written on small piece of paper. At the back of each paper was written a YES or a NO. There were a total of 320 'YES' and 30 'NO' on the total papers of 350 names of the registered community pharmacists in Anambra State. All the 350 papers were placed in a box and shaken to ensure randomization. After each shaking of the box, a paper was picked and any pharmacist that picked YES was recruited in the study while anyone who picked NO was excluded from the study. They were further divided into experimental and control group comprising of 160 community pharmacists in each group.

Data Collection

Administration of Questionnaire

Data were collected by using pretested, semi-structured self-administered questionnaires adapted from United State Agency for International Development manual for strengthening pharmaceutical systems,(18) and from relevant literatures([4,5.6,19,20,21,22,23,24])The questionnaire comprised of four sections: Section A consisted of eleven questions which covered demographic and continuing health education information. Second B contained ten questions which were used to assess respondents' knowledge of 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 Section C contained six questions which assessed practice of ADRs reporting in terms of adherence to the Guidelines for ADRs monitoring and reporting Section D of the questionnaire consisted of five questions which assessed respondents' attitude towards ADRs reporting.

Pretesting

Prior to the study the questionnaire was self- administered on 20 Community Pharmacists from 20 selected pharmacies in Delta State in order to check for consistencies, possible modifications and corrections, ability to comprehend it as well as time taken to complete the study used.

Data collection procedure

Data were collected from the participants with the help of three research assistants who were all pharmacists and have been trained and intimated on the nature and objectives of the study. The questionnaire was self- administered on each participant (both intervention and control group. The intervention group received a comprehensive health talk on adverse drug reaction reporting including its benefit and how to report adverse drug reactions while the control group was given the questionnaire to fill without any health talk on ADR. The returned questionnaires were checked for completeness, clarity and consistency.

Data management and analysis

There were 10 questions related to knowledge of ADR and each right answer was given the score of '1' and each wrong answer was given the score of '0'. Mean knowledge score was calculated for each individual and on the basis of individual score. Respondent's knowledge was categorised as good and poor knowledge. 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 4 or more questions were categorized as having 'good knowledge' and those who answered less than 4 questions correctly were categorized as having 'poor knowledge. A likert scale was used for assessing attitude level whereby five responses will be used as follows; strongly agree, agree, not sure, disagree and strongly disagree. These responses were grouped into positive attitude and negative attitude whereby strongly agree and agree responses were taken as positive attitude and disagree, strongly disagree and not sure responses were taken as negative attitude.

Pretesting

The data collected from the participants were cleaned, coded, entered and analyzed using 2013 version 22.0 of International Business Machine, Statistical Package for Social Sciences (SPSS).(25). Summary of the Descriptive analysis was presented as simple frequencies and percentages. Test of statistical significance was carried out using Chi square and Binary Logistic Regression for proportions and t-test for mean scores. $p \leq 0.05$ was considered significant.

Period of study

The study was carried out from 1st August 2017 to 30th December 2018 (13 months)

Results

Three hundred and twenty questionnaires were distributed among community pharmacists in Anambra State. Out of 320 questionnaires, 300 were duly filled giving a response rate of 93.8%. Table 1 shows that more than half (59.3%) of the respondents were males. The mean age of all respondents was 46.5±11.2 years. About (5.3%) had additional qualifications (Master's degree and above) More than 50% of the experimental group had between 6 – 10 years of experience compared to 46% of the control group, however this difference was statistically insignificant (p=0.282). There was a statistically significant difference between the two

groups on the duration of consultation (p= 0.003) and number of patients seen daily (p= 0.004). Only 35.3% of the test subjects had attended continuous pharmaceutical education (CPE) compared to 27.3% of the control group. The difference in proportion was not significant (p= 0.135). Also only 14% of the control group had attended CPE more than two times compared to 9.3% 0f the test subjects.

Table 2a shows the overall knowledge of the respondents on adverse drug reporting. There were 10 questions assessing knowledge regarding ADR. All the respondents have heard of ADR. Respondents obtained new information about ADRs to new drugs through the textbooks (58.7%), internet (48.7%). Out of 51 respondents from experimental group that attended CPE, 41(77.4%) have heard of ADR in any CPE session attended while out of 41 respondents from the control group that attended CPE, 78% have heard of ADR in CPE sessions attended. At pre-test, there was no statistically significant difference between the experimental and the control group on their responses as regards correct definition of ADR (p=0.334), types of ADR (p=0.064), professions required to report suspected cases of ADR (p=0.062), where reports of ADR are sent to (p=0.095), WHO online database for reporting of ADR (p=0.131), form used in spontaneous reporting of ADR (p=0.166), how to report ADR (p=0.103) and things to be considered during reporting of ADR (p=0.641). However, after intervention (post-test), the findings shows that there was a statistically significant difference between the experimental and the control group on the overall knowledge of adverse drug reaction reporting (p<0.001).

Result at three (3)-months post intervention shows that out of 137 and 142 respondents in the experimental vs. control group; 134 (97.8%) vs. 119 (83.8%) correctly defined ADR, 132 (96.4%) vs. 87 (61.3%) types of ADR, 129 (94.2%) vs. 98 (69.0%) meaning of Pharmacovigilance, 127 (92.7%) vs. 56 (39.4%) WHO online database for reporting of ADR, 135 (98.5%) vs. 89 (62.7%) form used in spontaneous reporting of ADR and 137 (100%) vs. 97 (68.3%) things to be considered during reporting of ADR. These differences

were statistically significant ($p<0.001$). Table 2c shows the mean scores of the respondents' knowledge of ADR reporting. The mean score of the experimental group vs. control group knowledge of ADR reporting at baseline was 4.79 ± 4.30 vs. 5.13 ± 4.31 compared to 9.79 ± 1.75 vs. 5.21 ± 4.35 after post intervention. T-test finding after intervention shows that there was a statistically significant difference between the experimental and the control group on mean scores of the respondents knowledge of ADR reporting ($p<0.001$). Three month post intervention result also revealed a statistically significant difference on the mean knowledge score of ADR reporting ($p<0.001$) between the experimental (9.64 ± 1.47) and the control group (5.97 ± 4.33).

As shown in figure 1 and 2, 52.0% (n=78) of the experimental and 47.3% (n= 71) of the control group have good knowledge of ADR reporting at baseline while 95.3% (n=143) respondents from test subjects showed good knowledge regarding ADR reporting after intervention compared to 44.7% (n=67) from the control group. After three (3) months, 129 (94.1%) out of the 137 respondents in the experimental group still have good knowledge of ADR reporting compared to 88 (62.0%) out of 142 respondents from the control group.

Table 3a shows the attitude of the respondents towards adverse drug reporting at baseline. There were five questions regarding attitude, the answer of strongly agree was assigned with the score of 4, agree with 3, disagree with 2 and strongly disagreed with 1 for each type of question. Reverse scoring was done for the negatively worded question. Less than 20% of the respondents from both groups strongly agreed that ADRs reporting is part of a professional role, 8.7% of the experimental group strongly agreed that reporting of ADRs is necessary for new drugs compared to 12% of the control group, 18% of the test subjects strongly agreed that reporting of ADR is necessary for serious ADRs compared to 25.3% of the control group, 19.3% respondents from the experimental group think that ADRs reporting is necessary for well recognized ADR compared to 21.3% of the control group and 26.7% of the

experimental group think ADR reporting should be voluntary compared to 38% of the control group. However, these differences between the experimental and the control group was not statistically significant ($p>0.05$). After intervention, there was a statistically significant difference between the experimental group and the control group on their attitude towards adverse drug reaction reporting ($p<0.001$). More than 50% of the experimental group now strongly agreed that adverse drug reaction reporting is part of professional role compared to 38.7% of the control group however, 40% of the experimental group strongly disagreed that reporting of ADR should be voluntary compared to 38% of the control group that strongly agreed that ADR reporting should be voluntary (Table 3a).. Three month post intervention also shows that there was an overall statistically significant difference between the experimental and the control group on their attitude towards adverse drug reaction reporting ($p<0.001$). One hundred and nine (79.6%) out of the 137 respondents in the experimental group still strongly agreed that adverse drug reaction reporting is part of professional role compared to 42 (29.6%) of the control group. However, 70.8% of the experimental group strongly agreed that reporting of ADR is necessary for well recognized ADR compared to 26.8% of the control group (Table 3c).

Table 4 shows the practice of adverse drug reaction reporting between the two groups. Majority of the respondents from the two groups have no system for monitoring and reporting of ADRs in their pharmacies. Less than 50% of the respondents from the two groups have had cases of ADR in their pharmacies prior to the study however, there was a significant difference on the number of cases between the two groups. Forty nine out of 67 test subjects that have had cases of ADR reported to the drug company compared to 30 out of the 49 respondents from the control group. Only 35.3% of the experimental group have forms for spontaneous reporting of ADR available in their pharmacies compared to 25.3% of the control group. More than 50% of the respondents from both groups have

not filled a spontaneous ADR reporting form before. One hundred and nineteen respondents (79.3%) in the intervention group have no reference materials in their pharmacies compared to 127(84.7%) from the control group.

Discussion

This is an interventional study of the effect of health education on adverse drug reaction reporting. . The current study shows a response rate of 93.8% which is similar to the outcome of studies reported from other developing countries(26,27,28,29,30,31,32,33)..

From the results of the index study, all the participants have ever heard of adverse drug reaction. Majority of the participants reports there commonest sources of information as textbooks, internet, journals and health professionals. This is in accordance with findings from studies carried out by several researchers on ADR ($_{27,3034,35,36,37)}$. In this study, more than six in every ten of intervention and of the control group respectively correctly identified the meaning of ADRs and Pharmacovigilance (PV). This finding is in line with the recent study done in Kuwait on pharmacists' knowledge about ADRs, where most participants identified the correct definitions of ADRs, PV and as well as the purpose of undertaking PV activities.(37).· Also, our findings show there were no statistically significant differences on the responses between the interventional and control group on where reports are sent to and what reactions are to be reported. Based on the findings of this study, the participants had no adequate knowledge regarding ADR reporting prior to intervention. The reason for the similarity in inadequate knowledge between the intervention and the control group at baseline could be due to inadequate attention to the subject of ADRs in the clinical pharmacology and therapeutics curricula of medical schools. The inadequate knowledge of ADR reporting by the majority of pharmacists may be related to the fact that community pharmacists are not in direct contact with other health care professionals such as physicians and nurses who are more often involved in the identification

of potential ADRs, thus they are more exposed to situations where there is a need to manage or to report such adverse effects. However, the findings of the index study such as lack of knowledge on ADR reporting by majority of the participants at baseline is in line with similar studies in Nigeria (38,39,40).

Post intervention result shows that there was an increase in knowledge of ADRs reporting in the intervention group from about half to nine in ten however, there was a decrease in knowledge of ADRs reporting in the control group from 47.3% to 44.7%. This is a critical observation which is undoubtedly associated with the effect of health education administered only to the intervention group. This may also be related to inadequate information on ADRs reporting from sources, do not know how to report, uncertain association and being unaware of the existence of a national ADR reporting system. This finding is in tandem with the studies carried out by Bisht *et al*.(17),, Lopez-Gonzalez *et al(38* , Rajesh *et* a*l(42).* and Elkalmi *et al(43).*/ Nevertheless, this finding is not similar with the reports of previous studies conducted among healthcare professionals (37,43).

Three- month post intervention, the current study shows that about nine in every ten participants in the experimental group still possess good knowledge of ADR compared to six in ten participants in the control group. There was a slight increase in knowledge of ADRs reporting in the control group by 14.7%. This may be as result of new knowledge acquired by some members of the control group during the three-month period, also the number of participants in the control group also reduced from 150 to 142 out of 160 participants.

The findings of the present study shows statistically significant difference on the attitude of the participants (intervention and control group) on adverse drug reactions reporting at baseline. This may be as a result of lack of awareness of ADRs reporting among the community pharmacists. This finding is in contrast with the reports generated from other studies (39,44,45,46). From the findings of the current research, less than half of the participants also believed that adverse drug reaction reporting is part of professional role thus may be willing to report it if the reaction is serious and unusual. This observation is supported by similar studies with pharmacists from other countries, who concurred that reporting ADRs is a professional obligation(29,30,47).Also this finding is similar to the results of surveys carried out among pharmacists working in pharmacies in the Turkey and Iran (27,28). More than 50% of the participants (intervention and control group) in the current study also opine that ADR reporting should be optional, which is in line with results from other studies.(27,30,31). This does not show a sense of responsibility on their parts. However, after intervention there were significant differences on the responses between two groups. The effect of health education intervention was observed among the experimental group. This gap in the attitude and reporting suggests that newer methods must be developed so that reporting becomes a reality and not just mere thought process.

From the index study, majority of participants do not have a system of monitoring and reporting ADRs at their pharmacies. This finding is in line with the report by Iffat *et al*., in 2014 (47). This might be as a result of lack of adequate knowledge about ADRs reporting and unavailability of forms at their pharmacies. This could also be linked to the ease of use of the ADR reporting tools by the participants. In the present study about four in ten of the intervention and three in ten of the control group respectively, have had cases of ADR. Out of 67 participants in the intervention group that have had cases of ADR in their pharmacies, about eighty percent

reported such cases. This finding in the index study is dissimilar with the findings in a study elsewhere, which showed that 91.5% of healthcare workers involved in the study never reported any ADR (48). This may be as a result of unavailability of report forms, uncertainty of the reaction and lack of knowledge on how to report and where to report.. Majority of the participants reported of ADR to drug companies instead of agencies responsible for handling cases of ADR. The reason may be because they deal directly with the drug companies and as such feels it is right to report such cases to them first before involving other agencies. Lack of knowledge on ADR might also be one of their reasons for taking such action.

Limitations Some of the questions used in the study questionnaire were dependent on the participants ability to recall information, such as any identified cases of ADRs during their practice years, which may have led to recall bias.In addition, due to the sensitive nature of some of the questions, the study may have been faced with socially desirable responses from the participants leading to over-responding or under-responding, however they were assured of confidentiality and that this research was strictly academic.

Conclusions

The findings of this study shows that all the participants have ever heard of adverse drug reaction, while majority of them reports there commonest source of information as textbooks, internet, journals and health professionals. The knowledge of ADR reporting was inadequate. Post intervention result shows that there was an increase in knowledge of ADRs reporting in the intervention group, while there was a decrease in knowledge of ADRs reporting in the control group. Three- month post intervention, the current study shows that about nine in every ten participants in the experimental group still possess good knowledge of ADR compared to six in ten participants in the control group. There was statistically significant difference on the attitude of the participants (intervention and control group) on adverse drug reactions reporting at baseline. However, after intervention there were significant differences on the

responses between two groups. The effect of health education intervention was observed among the experimental group. Majority of the respondents from the two groups have no system for monitoring and reporting of ADRs in their pharmacies. There was a significant difference on the number of cases between the two groups.

It is recommended that there is need for improved regular training and retraining of the participants on ADR reporting by the government to improve their knowledge. of ADR; With regards to the apparently poor level of attitude to ADR reporting found, there is need for attitudinal change programs such as behavioral change communication to be organized by the government for these participants to achieve positive attitude. With reference to the poor practice seen from the study, the government should make forms for reporting of ADR available and also provision on filling of these forms by relevant stake holders. Generally there is need for periodic and targeted health education program towards improvement of knowledge, attitude and practice of ADR reporting among the participants.

ETHICS APPROVAL AND CONSENT

The study has been examined and approved by the Nnamdi Azikiwe University Teaching Hospital Ethics Committee. Permission to conduct the study was obtained from the State Ministry of Health and the selected Local Government PHC Departments. Written informed consent was obtained from each participant for the conduct and publication of this research study and assurance of confidentiality given. Study participants were free to refuse or withdraw from the study at any time without any penalty. The study's purpose and objectives were explained to each participant prior to interview. All authors hereby declare that the study has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

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Tables and Figure

Table 1: Socio-demographic profiles of the respondents

Variables	Experimental group n(%)	Control Group n(%)	Total n(%)	Test Statistic	*p*-value
Age category (years)					
≤30	14(9.3)	9(6.0)	23(7.3)		
31 – 40	25(16.7)	18(12.0)	43(14.3)	$\chi^2 = 6.61$	0.086
41 – 50	71(47.3)	93(62.0)	164(54.7)		
≥ 51	40(26.7)	30(20)	70(23.3)		
Mean ± SD	46.5±11.2	45.8±11.8	47.3±10.5	t = 1.16	0.248
Sex					
Male	97(64.7)	81(54.0)	178(59.3)	$\chi^2 =3.54$	0.060
Female	53(35.3)	69(46.0)	122(40.7)		
Highest level of Education					
BSc	120(80)	128(85.3)	248(82.7)		
Pharm.D	20(13.3)	16(10.7)	36(12.0)		
Masters	6(4.0)	4(2.7)	10(3.3)	$\chi^2 =1.77$	0.622
PhD	4(2.7)	2(1.3)	6(2.0)		
Years of experience (years)					
< 1	4(2.7)	4(2.7)	8(2.7)		
1 – 5	31(20.7)	20(13.3)	51(17.0)		
6 – 10	69(46.0)	83(55.3)	152(50.7)	$\chi^2 =5.06$	0.282
11 – 15	35(23.3)	28(18.7)	63(21.0)		
> 15	11(7.3)	15(10.0)	26(8.7)		
Duration of consultation (minutes)					
< 5					
6 – 10	11(7.3)	4(2.7)	15(5.0)		
11 – 15	71(47.3)	50(33.3)	121(40.0)	$\chi^2 =15.8$	0.003*
16 – 20	22(14.7)	36(24.0)	58(19.3)		
>20	34(22.7)	53(35.3)	87(29.0)		
	12(8.0)	7(4.7)	19(6.3)		
Number of patients seen					

(per day)					
< 5	3(2.0)	0(0)	3(1.0)		
6 – 10	41(27.3)	57(38.0)	98(32.7)	χ^2 =15.3	0.004*
11 – 15	62(41.3)	40(26.7)	102(34.0)		
16– 20	15(10.0)	29(19.3)	44(14.7)		
>20	29(19.3)	24(16.0)	53(17.7)		
Working hours (per day)					
< 5	21(14.0)	19(12.7)	40(13.3)		
6 – 10	82(54.7)	99(66.0)	181(60.3)		
11 – 15	47(31.3)	32(21.3)	79(26.3)	χ^2 =4.54	0.103
16– 20	0(0)	0(0)	0(0)		
>20	0(0)	0(0)	0(0)		
Attended CPE					
Yes	53(35.3)	41(27.3)	94(31.3)	χ^2 =2.23	0.135
No	97(64.7)	109(72.7)	206(68.7)		
Number of time(s) of attendance of CPE					
None	97(64.7)	109(72.7)	206(68.7)		
Once	4(2.7)	2(1.3)	6(2.0)	χ^2 =8.30	0.081
Twice	7(4.7)	3(2.0)	10(3.3)		
Thrice	14(9.3)	21(14.0)	35(11.7)		
More than three times	28(18.7)	15(10.0)	43(14.3)		

***significant at $p<0.05$**

Table 2 a: Respondents' knowledge of Adverse drug reaction reporting

Questions	Pretest			Posttest			3-month Posttest		
	Experimental n=150	**Control n=150**	***p*- value**	**Experimental n=150**	**Control n=150**	***p*- value**	**Experimental n =137**	**Control n=142**	***p-value***
Heard of Adverse Drug Reaction									
Yes	150(100)	150(100)		-	-	-	-	-	-
Sources of new information about ADRs									
Textbooks	75(50.0)	88(58.7)	0.132						
Internet	81(54.0)	73(48.7)	0.355						
Journals	79(52.7)	63(42.0)	0.064	-	-	-	-	-	-
Seminar/conferences	41(27.3)	32(21.3)	0.226						
Health professionals	57(38.0)	66(44.0)	0.291						
Heard of ADR in any attended CPE									
Yes	41(77.4)	32(78.0)	0.226	-	-	-	-	-	
Meaning of ADR									
Correct	101(67.3)	93(62.0)	0.334	143(95.3)	95(63.3)	<0.001*	134 (97.8)	119 (83.8)	<0.001*
Types of ADR									
Correct	42(28.0)	59(39.3)	0.038*	136(90.7)	60(40.0)	<0.001*	132 (96.4)	87 (61.3)	<0.001*
Meaning of Pharmacovigilance									
Correct	61(40.7)	77(51.3)	0.064	146(97.3)	77(51.3)	<0.001*	129 (94.2)	98 (69.0)	<0.001*
Professions required to report suspected cases of ADR	78(52.0)	94(62.7)	0.062	140(93.3)	94(62.7)	<0.001*	130 (94.9)	105 (73.9)	<0.001*
Correct									
Where are reports for ADR sent to?									
Correct	87(58.0)	101(67.3)	0.095	139(92.7)	103(68.7)	<0.001*	130(94.9)	109 (76.8)	<0.001*
WHO online database for reporting of ADR									
Correct	51(34.0)	39(26.0)	0.131	132(88.0)	41(27.3)	<0.001*	127 (92.7)	56 (39.4)	<0.001*
What reactions should be reported									

Correct	72(48.0)	91(60.7)	0.028*	147(98.0)	(60.7)	<0.001*	129 (94.2)	113 (79.6)	<0.001*

Table 2b: Respondents' knowledge of Adverse drug reaction reporting

Questions	Pretest			Posttest			3-month Posttest		
	Experimental n(%)	**Control n(%)**	***p*- value**	**Experimental n(%)**	**Control n(%)**	***p*-value**	**Experimental n(%)**	**Control n(%)**	***p-value***
Form used in spontaneous reporting of ADR									
Correct	81(54.0)	69(46.0)	0.166	148(98.7)	73(48.7)	<0.001*	135 (98.5)	89 (62.7)	<0.001*
How to report ADR									
Yes	59(39.3)	73(48.7)	0.103	150(100)	74(49.3)	<0.001*	137 (100.0)	100 (70.4)	<0.001*
Things to be considered during reporting of ADR									
Correct	87(58.0)	83(55.3)	0.641	137(91.3)	83(55.3)	<0.001*	137 (100.0)	97 (68.3)	<0.001*

***significant at *p*<0.05**

Table 2c Mean scores of the respondents' knowledge of ADR reporting

	Pretest			Posttest			3-month Posttest		
Variable	**Experimental**	**Control**	***p*-value**	**Experimental**	**Control**	***p*-value**	**Experimental**	**Control**	***p*-value**
	n=150	**n=150**		**n=150**	**n=150**		**n=137**	**n=142**	
Knowledge	4.79 ± 4.30	5.13 ± 4.31	0.503	9.79 ± 1.75	5.21 ± 4.35	<0.001*	9.64 ± 1.47	5.97 ± 4.33	<0.001*

*significant at $p<0.05$

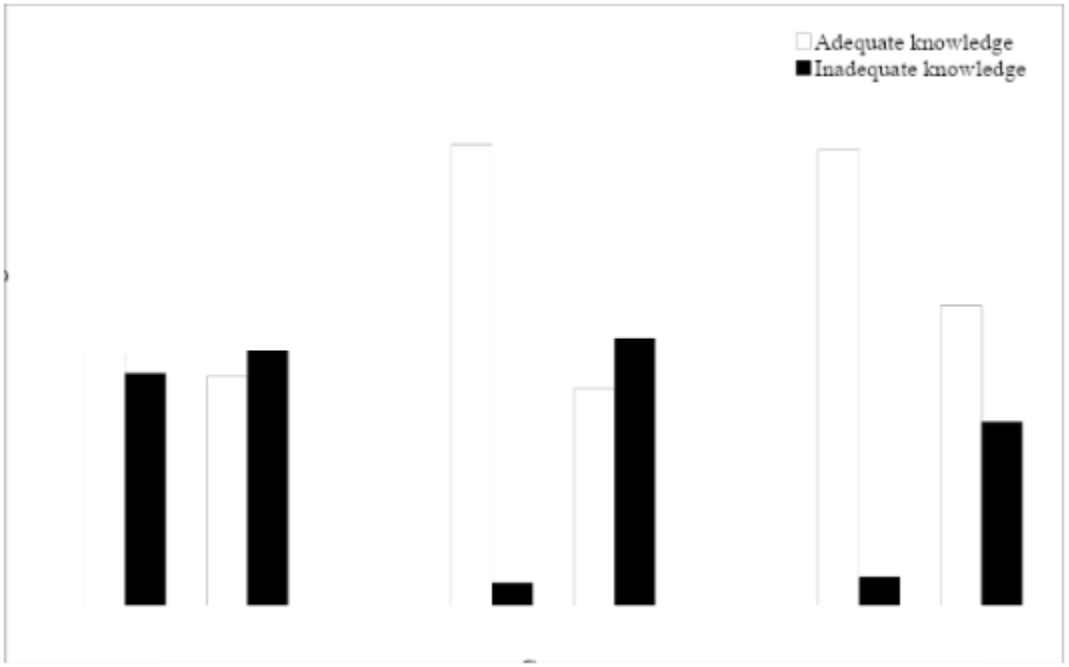

Figure 1: Knowledge of the respondents on adverse drug reporting

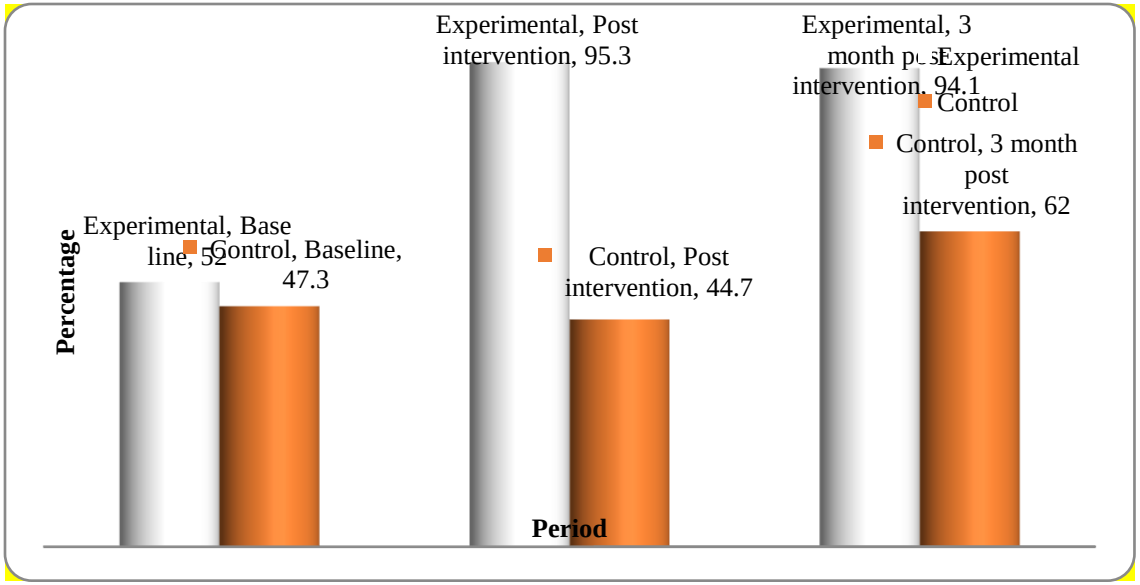

Figure 2: Knowledge of adverse drug reporting

Table 3a: Respondents' attitude towards adverse drug reaction reporting at baseline.

Questions	Experimental group n=150					Control group n=150					*p -value*
	SA (%)	A (%)	NS (%)	D (%)	SD (%)	SA (%)	A (%)	NS (%)	D (%)	SD (%)	
Adverse drug reaction reporting is part of professional role	21 (14.0)	50 (33.3)	48 (32.0)	17 (11.3)	14 (9.3)	19 (12.7)	55 (36.7)	46 (30.7)	25 (16.7)	5 (3.3)	0.187
Reporting of ADRs is necessary	13 (8.7)	62 (41.3)	49 (32.7)	21 (14.0)	5 (3.3)	18 (12.0)	47 (31.3)	46 (30.7)	30 (20.0)	9 (6.0)	0.223
Reporting of ADRs is necessary for serious ADR	34 (22.7)	62 (41.3)	35 (23.3)	19 (12.7)	0 (0)	38 (25.3)	69 (46.0)	33 (22.0)	8 (5.3)	2 (1.3)	0.328
Reporting of ADRs is	29	57	55	8	1	32	53	51	6	8	

necessary for well recognized ADR	(19.3)	(38.0)	(36.7)	(5.3)	(0.7)	(21.3)	(35.3)	(34.0)	(4.0)	(5.3)	0.187
Reporting of ADR should be voluntary	40 (26.7)	62 (41.3)	13 (8.7)	28 (18.7)	7 (4.7)	57 (38.0)	48 (32.0)	10 (6.7)	24 (16.0)	11 (7.3)	0.175

***significant at *p*<0.05, SA= Strongly Agree, A=Agree, N=Not sure, D=Disagree, SD= Strongly Disagree**

Table 3b: Respondents' attitude towards adverse drug reaction reporting post intervention.

Questions	**Experimental group n=150**					**Control group n=150**					***p -value***
	SA (%)	**A (%)**	**NS (%)**	**D (%)**	**SD (%)**	**SA (%)**	**A (%)**	**NS (%)**	**D (%)**	**SD (%)**	
Adverse drug reaction reporting is part of professional role	101 (67.3)	36 (24.0)	4 (2.7)	2 (1.3)	7 (4.7)	20 (13.3)	58 (38.7)	39 (26.0)	29 (19.3)	4 (2.7)	<0.001
Reporting of ADR is necessary for new drugs	81 (54.0)	64 (42.7)	4 (2.7)	0 (0)	1 (0.7)	21 (14.0)	49 (32.7)	41 (27.3)	36 (12.0)	4 (1.3)	<0.001
Reporting of ADR is necessary for serious ADR	93 (62.0)	51 (34.0)	4 (2.7)	0 (0)	2 (1.3)	38 (25.3)	72 (48.0)	33 (22.0)	7 (4.7)	2 (0.7)	<0.001
Reporting of ADR is necessary for well recognized ADR	86 (57.3)	57 (38.0)	7 (4.7)	0 (0)	0 (0)	32 (21.3)	56 (37.3)	40 (26.7)	14 (9.3)	8 (9.3)	<0.001
Reporting of ADR should be voluntary	0 (0)	0 (0)	9 (6.0)	81 (54.0)	60 (40)	59 (39.3)	45 (30.0)	20 (13.3)	12 (8.0)	14 (9.3)	<0.001

***significant at *p*<0.05, SA= Strongly Agree, A=Agree, N=Not sure, D=Disagree, SD= Strongly Disagree**

Table 3c Respondents' attitude towards adverse drug reaction reporting 3-month post intervention.

Questions	Experimental group n=137					Control group n=142					*p -value*
	SA (%)	**A (%)**	**NS (%)**	**D (%)**	**SD (%)**	**SA (%)**	**A (%)**	**NS (%)**	**D (%)**	**SD (%)**	
Adverse drug reaction reporting is part of professional role	109 (79.6)	26 ()	0 (0.0)	2 (1.5)	0 (0.0)	42 (29.6)	53 (37.3)	34 (23.9)	11 (7.7)	2 (1.4)	<0.001
Reporting of ADR is necessary for new drugs	126 (92.0)	11 ()	0 (0.0)	0 (0.0)	0 (0.0)	33 (23.2)	56 (39.4)	30 (21.1)	23 (16.2)	0 (0.0)	<0.001
Reporting of ADR is necessary for serious ADR	120 (87.6)	10 ()	7 (5.1)	0 (0.0)	0 (0.0)	48 (33.8)	62 (43.7)	26 (18.3)	4 (2.8)	2 (1.4)	<0.001
Reporting of ADR is necessary for well recognized ADR	97 (70.8)	31 ()	8 (5.8)	1 (0.7)	0 (0.0)	38 (26.8)	46 (32.4)	48 (33.8)	7 (4.9)	3 (2.1)	<0.001
Reporting of ADR should be voluntary	0 (0.0)	0 (0.0)	4 (2.9)	51 (37.2)	82 (59.9)	50 (35.2)	40 (28.2)	28 (19.7)	18 (12.7)	6 (4.2)	<0.001

***significant at *p*<0.05, SA= Strongly Agree, A=Agree, N=Not sure, D=Disagree, SD= Strongly Disagree**

Table 4 Respondent's practice regarding Adverse Drug Reaction Reporting

Questions	Experimental group	Control group	*p*-value
Is there a system of monitoring and reporting ADRs at your pharmacy?			
Yes	40(26.7)	27(18.0)	
No	110(73.3)	123(82.0)	0.072
Have you ever had ADR cases in your pharmacy?			
Yes	67(44.7)	49(32.7)	
No	83(55.3)	101(67.3)	0.033*
If Yes, where do you report it?			
Ministry of Health	0 (0)	0 (0)	
NAFDAC headquarter offices	0 (0)	0 (0)	
NAFDAC zonal offices	1(1.5)	3(6.1)	
Zonal Pharmcovigilance Centre	3(4.5)	5(10.2)	0.293
Drug company	49(73.1)	30(61.2)	
Do not report	14(20.9)	11(22.4)	
Are the forms for spontaneous reporting of ADR available in your pharmacy			
Yes	53(35.3)	38(25.3)	
No	97(64.7)	112(74.7)	0.060
Have you ever filled a spontaneous reporting ADR form?			
Yes			
No	40(26.7)	27(18.0)	
	110(73.3)	123(82.0)	0.072
Are reference materials available in your pharmacy?			
Yes	31(20.7)	23(15.3)	
No	119(79.3)	127(84.7)	0.229
If Yes, what are they			
Emdex	24(77.4)	19(82.6)	0.640
Bmf	27(87.1)	20(13.0)	0.988
List of registered drugs	20(64.5)	17(73.6)	0.462
Guideline for monitoring and reporting ADRs	18(58.1)	14(60.9)	0.836

**significant at p<0.05*