

# A Study on the Knowledge and Barriers Towards ADRs Reporting among Community Pharmacists in Enugu and Nsukka areas, South-Eastern Nigeria.

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## ABSTRACT

**Background:** The unique position of community pharmacist (CP) particularly in the developing economies places them at the forefront of pharmacovigilance. The need of providing an enabling environment is of importance in encouraging them to report cases of adverse drug reactions (ADRs). This is with a view of minimising inherent risks associated with drug use. The study aims at assessing the knowledge, barrier to ADRs reporting and factors that could improve spontaneous reporting. **Methods:** A cross sectional study-survey, using a self-structured questionnaire was adopted. The study consisted of pharmacists in community settings. The sample size was determined using online sample size calculator RaoSoft at a confidence of 95%. Out of 150 pharmacists targeted only 40 responded. **Results:** Majority (92.5%) of the pharmacists had between 1-20 years Community Pharmacy Practice experience. About 40% of them see over 100 patients daily with 17.5% witnessing more than 10 ADR cases. However, 52.5% had not reported encountered ADRs cases, for the past 12 months. Barriers to reporting included, insufficient knowledge of pharmacotherapy in detecting ADRs (57.5%), lack of reporting forms (40%) and lack of adequate professional environment to discuss issues relating to ADRs (75%). Some of the factors adduced that can encourage and enhance spontaneous reporting

were listed as, proper guideline for spontaneous reporting system (SRS) and making reporting obligatory instead of voluntary. In addition, a simple reporting method instituted with regular feedback. **Conclusions:** Despite having huge turnover of patients and seeing ADRs cases, there appeared to be a massive under-reporting in the area of study. Authors observed that majority of the pharmacists were afraid of being incriminated, due to the high level of self-medication practices encouraged by them.

**Key Words:** Community pharmacists, physician, Adverse Drug reactions, spontaneous reporting system, pharmacovigilance, patients.

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## INTRODUCTION

Increasing incidence of adverse drug reactions (ADRs) has become a major concern across the developing world largely due to lack of the will to implement healthcare laws.<sup>1</sup> Drug use is characterised by accepting the attendant risk and usually weighed in favour of its safety, which is a crucial element. Thus, drug safety can be defined as the propensity of a drug not to cause harm under proposed condition and duration for its use.<sup>2</sup> The importance of safety is moreover enshrined in the Hippocratic Oath, which clearly requires physicians to keep patients from harm, emphasising the need for safety. However, the axiom that no drug is safe is a paradox and universally accepted. Based on this, most countries have established rational drug use.<sup>3</sup> Also, the establishment of Pharmacovigilance for the effective reporting of ADRs and adopting its Spontaneous Reporting System (SRS) to curtail the number of ADRs among patients.<sup>4, 5, 6</sup> Reports indicated that ADR is the fourth leading cause of death in Russia,<sup>7</sup> whereas in the USA, it is 6<sup>th</sup> cause of mortality. It is also reported that 35% of all hospital admission experience this phenomenon.<sup>8</sup> In Sweden it is suggested that 12% of hospital patients experience ADR during admission,<sup>9</sup> however, only 6% of these experiences are actually due to ADR. The incorporating of Pharmacovigilance program by some countries has helped in identifying risks factors and that has eventually led to a reduction of harm to patients.<sup>10, 11</sup> However, in order to adequately stem the rising tide of ADRs, there is the need for spontaneous reporting by practitioners and this should be an absolute prerequisite. Healthcare professionals like Community Pharmacists (CP) who are drug experts should play a leading role in this regard. One of the factors negating the progress of pharmacovigilance among Healthcare practitioners is under-

reporting.<sup>12</sup> Cases of under reporting have been described in a number of developing countries like Brazil, Malaysia, India, Jordan and Bosnia Herzegovina by various researchers.<sup>13, 14, 15, 16</sup> The essence of the process of reporting is to provide evidence that will help to regulate drug use management and ensure safety in public healthcare. The entire outcome is aimed at cost effectiveness measures in Healthcare delivery. Although, ADRs reporting in hospitals among in-patients is a key element in disease management in terms of monitoring, assessment and evaluation, this however reporting represents a small percentage (6%) according to Hazell and Shakir.<sup>17</sup> In developing countries where self-medication is rife and uncontrolled due to poverty, easy access of medication and lack of adequate healthcare facilities, Physicians are not in any vintage position to significant report ADRs. In Nigeria, Ezeuko *et al.*<sup>18</sup> had linked a number of factors with low or lack of spontaneous reporting of ADR among Healthcare Practitioners in their report. This includes poor attitude to reporting due to the fact that spontaneous reporting is voluntary, depending on goodwill. Other factors mentioned are lack of knowledge of pharmacovigilance and fear, because of medication errors.<sup>19, 20</sup> Most of the studies on ADRs reporting in Nigeria have been about Healthcare professionals in general and in hospital settings.<sup>18, 19, 20</sup> Giving that majority use pharmacy outlets such as community pharmacies, as treatment option,<sup>21</sup> the importance of community pharmacists in providing ADRs information cannot be over emphasised.

Nigeria is the most populous country in Africa and many studies<sup>22, 23, 24</sup> regarding the extent, consequences of highly prevalent self-medication practices, polypharmacy and sale of drugs by community pharmacies

without prescription have been reported. These consequences include ADRs. There is also the issue of fake and substandard drugs, another factor, which contributes to ADRs. Cases of ADR have been reported even among paediatric patients.<sup>25, 26</sup> Evidence show that there are 10.7 ADRs per 100 persons<sup>26</sup> and these cases are preventable. Information about types of ADRs and occurrence in Nigerian patients is limited.<sup>25</sup> Most of the patients use community pharmacies or patent medicine stores due to lack of functional primary health centre, poverty and availability of over the counter (OTC) drugs. Since ADRs has been identified as a major public healthcare problem, community pharmacists have a role to play and needs to be equipped in performing this function. Therefore, there is need to examine areas that militate against SRS and adequately, address them to encourage ADRs reporting in rural and urban communities of Nigeria. Therefore, this study targets community pharmacists with the aim of assessing their knowledge, barrier to ADRs reporting and factors that can improve spontaneous reporting.

## MATERIALS AND METHODS.

### Study Area.

The study was carried out in Enugu and Nsukka local government areas (LGAs) of Enugu State, Nigeria. The health program in these local government areas conforms to those of the National Health Policy of Nigeria. The communities in these LGAs also have privately run pharmacies with at least one or more qualified practicing pharmacist. However, these areas are known for high level of self-medication use.<sup>21</sup>

### Study Sample size

The study consisted of pharmacists in community settings. The sample size was determined using online sample size calculator Rao Soft at a confidence of 95%. A total of 150 pharmacist were approached for their participation, however, only 40 completed the questionnaire. It was ensured that only Pharmacists who have had at least 1 year or more community pharmacy practice experience participated in the study.

### Study Design

A cross sectional study was carried out amongst pharmacists practicing in the mentioned communities. A self-structured questionnaire was adopted which examined the attitudes, awareness, perception and barriers leading to ADRs reporting. The questionnaire consisted of four parts with various items.

Part 1, covered demographic information of the participants. The educational level, the number of years of practising post-graduation and the number of daily visits to the pharmacy were also covered in this section. In addition, the number of ADR cases encountered and whether or not these had been reported within the past 12 months were included in this section.

Part 2 had 12 items, which explored the knowledge of ADRs and it reporting. This section was made up of a series of statements to which the pharmacist were asked to say whether they agreed (Yes) or Disagreed (No) to, similar to that used by Elkalmi *et al.*<sup>27</sup>

Part 3 of the questionnaire had 10 items. The statements here included probable barriers to ADRs reporting. In this section, pharmacists were asked to indicate their agreement or disagreement to certain statements. A 5 point Likert scale format (1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree and 5 = strongly disagree).

The fourth part of the questionnaire consisted of 7 components aimed at identifying factors which might encourage reporting of ADRs by practitioners. These components were also framed in a 5 – point Likert rating scale.

## Questionnaire Content Validation

The questionnaire used for this study was adopted from the work done by Khan<sup>8</sup>, but the Nigerian scenario was then taken into consideration. The validity of the questionnaire was tested using 15 pharmacists as a pilot, who were not included in the eventual study. Using SPSS 19 software, Cronbach's alpha was calculated as measure of questionnaire reliability scale, giving the internal consistency coefficient value of 0.73.

## Data Analysis.

Data obtained from the questionnaire was analysed using SPSS Statistics version 19.0 software package. Frequencies were measured for categorical variables. Any associations between groups were examined and statistical significance was set at  $p < 0.05$ . By the W2 or Fisher, exact tests as appropriate for categorical variables. Data obtained using Likert scale measurement were treated as nonparametric statistics.

## RESULTS

### Demography

The results on the demographic details of the respondents in the study are presented in table 1. The survey respondents were made up of both males (67.5%) and females (27.5%) within the age range of 20 – 60 years and above. Majority of the respondents (57.5%) were between the ages of 30 – 49 years of age. Only one of them was aged above 60 years. In terms

**Table 1: Demography of the Respondents**

Parameter	Result	
	Number	Percentage
<b>Age (Years).</b>		
Not Given	9	22.5%
20 – 29	3	7.5%
30 – 39	13	30%
40 – 49	11	27.5%
50 – 59	4	10%
60 and above	1	2.5%
<b>Gender:</b>		
Males	27	67.5%
Females	11	27.5%
Not Stipulated.	2	2%
<b>Educational Level</b>		
Bachelor of Pharmacy	15	37.5%
Pharmacy Diploma	6	15%
Masters	13	32.5%
PhD	4	10%
Others	2	5%
<b>Country of Graduation.</b>		
Nigeria	37	92.5%
Unidentified	2	5%
Others	1	2.5%
<b>Community Pharmacy Practice Experience (years).</b>		
1 – 5	19	47.5%
6 – 10	7	17.5%
11 – 19	2	5%
20 or more.	9	22.5%
Unidentified	3	7.5%

of educational background, most (37.5%) of the respondents had a first degree in Pharmacy, 32.5% and 10% had Master's and PhD degrees respectively with majority (92.5%) of them graduating from Nigeria. Post-graduation, 47.5% of them had been in community pharmacy practice for less than 6 years while 22.5% had been practicing for 20 years and above. Those who did not stipulate the number of work years constituted 7.5%. The results are shown in table 1.

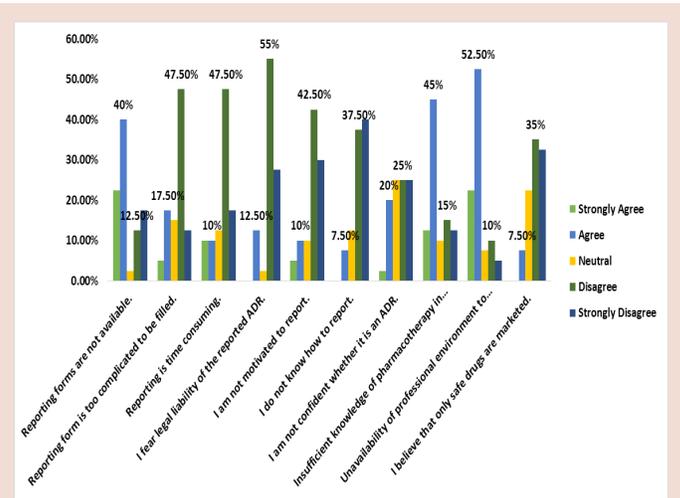
**Patient visits and ADRs encountered.**

The results presented in table 2 shows the number of daily patients visits to the various community pharmacies and the number of ADR cases encountered during the period. The results in the table indicate that 95% of the pharmacists were aware of ADR, as they had affirmed to having encountered cases in the last 12 months. Only 5% of the respondent did not say the number of patients they saw daily, nor if they had encountered or reported any ADR cases.

**Table 2: Number of daily patient visits and ADR cases encountered in one year**

No. of Daily Patients/ Customers Visit	Parameters	Number	Percentage
	Unidentified	2	5%
	less than 50	12	30%
	51-80	7	17.5%
	81-100	3	7.5%
	101 and over	16	40%
No. of ADR Cases Seen	Unidentified	2	5%
Less than 5	19	47.5%	
6 to 10	12	30%	
More than 10	7	17.5%	
Reported ADR in last 12 months?	Unidentified	2	5%
Yes	17	42.5%	
No	21	52.5%	

respondents (92.5%) were affirmative. However, about half (50%) of them did not think that reporting will help in improving the quality of life of their patients. In terms of where to report the encountered cases about 63% of them said they were aware of existence of the on-line ADR reporting system in Nigeria (Significant, P-value 0.018) while 40% did not know about the Pharmacovigilance activity in the country. Again, when asked if they thought that reporting of ADR will contribute to drug safety, most of them (80%) were affirmative. However, 55% of them said they believed that it was necessary to first confirm the particular drug causing the ADR before reporting while others (30%) were of the view that only the names of the suspected drugs needed to be reported. More than half of the survey respondents (57%) did not think there was any need to report an ADR, which had previously been documented by the manufacturers. Majority (72.2%) of them however agreed that preventable ADRs can easily be managed by them and the result was statistically significant, P-value, 0.019. Regarding the reporting of ADRs caused by over the counter drugs, more than half of the participants did not think it was necessary to reporting that (P-value 0.039).



**Figure 1: Showing Pharmacist barriers to ADRs reporting.**

**Pharmacists Knowledge of ADRs and the process of reporting.**

The response to the questions on the knowledge about ADRs and the process of reporting are as presented in Figure 1. Most (75%) of the pharmacists were knowledgeable about ADR and this awareness is shown to be statistically significant with a P-value of 0.046. Also, a higher percentage (85%), were familiar with the signs and symptoms that could be exhibited by a patient suffering from ADR and this response was also significant with a P-value, 0.006. When asked if any patient had reported to their pharmacy in the last 12 months before the survey, most of the

**Pharmacists perceived barriers to ADR reporting.**

The survey also looked into some of the perceived hindrances that were considered as barriers in the reporting of ADRs. About half of the pharmacists, attributed one of these barriers to be the non-availability of reporting forms. The results of these barriers are shown in table 3. The same number of respondents did not however find these forms when available, to be complicated nor did they find them too time consuming

**Table 3: Barriers to ADRs reporting.**

I do not report because?	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1) Reporting forms are not available.	9 (22.5%)	16 (40%)	1 (2.5%)	5 (12.5%)	7 (17.5%)
2) Reporting form is too complicated to be filled.	2 (5%)	7 (17.5%)	6 (15%)	19 (47.5%)	5 (12.5%)
3) Reporting is time consuming.	4 (10%)	4 (10%)	5 (12.5%)	19 (47.5%)	7 (17.5%)
4) I fear legal liability of the reported ADR.	0 (0%)	5 (12.5%)	1 (2.5%)	22 (55%)	11 (27.5%)
5) I am not motivated to report.	2 (5%)	4 (10%)	4 (10%)	17 (42.5%)	12 (30%)
6) I do not know how to report.	0 (0%)	3 (7.5%)	5 (12.5%)	15 (37.5%)	16 (40%)
7) I am not confident whether it is an ADR.	1 (2.5%)	8 (20%)	10 (25%)	10 (25%)	10 (25%)
8) Insufficient knowledge of pharmacotherapy in detecting ADR.	5 (12.5%)	18 (45%)	4 (10%)	6 (15%)	5 (12.5%)
9) Unavailability of professional environment to discuss about ADR.	9 (22.5%)	21 (52.5%)	3 (7.5%)	4 (10%)	2 (5%)
10) I believe that only safe drugs are marketed.	0 (0%)	3 (7.5%)	9 (22.5%)	14 (35%)	13 (32.5%)

**Table 4: Factors encouraging reporting of ADRs by GPs**

I would report if:	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1) There is an obligation to do so.	14 (35%)	20 (50%)	2 (5%)	0 (0%)	0 (0%)
2) Guidelines on reporting and bulletins on ADRs provided regularly.	18 (45%)	18 (45%)	1 (2.5%)	0 (0%)	0 (0%)
3) I receive feedback from relevant authorities.	18 (45%)	18 (45%)	0 (0%)	1 (2.5%)	0 (0%)
4) A simple method of reporting is implemented.	19 (47.5%)	17 (42.5%)	0 (0%)	1 (2.5%)	1 (2.5%)
5) If there is toll free number provided by the relevant authorities.	14 (35%)	17 (42.5%)	5 (12.5%)	0 (0%)	0 (0%)
6) I am willing to report ADR at the request of a patient.	10 (25%)	17 (42.5%)	3 (7.5%)	6 (15%)	1 (2.5%)

to fill. The fear of any legal liability for reporting ADRs was not a barrier either, as was stipulated by 82.5% of the respondents. They are motivated to report but did not know how to. Non-reporting was not due to lack of confidence to do so as was indicated by 50% of the respondents. However, 22.5% of them attributed lack of reporting to not having enough confidence to do so. Other barriers were attributed to insufficient knowledge of pharmacotherapy in detecting ADR as was indicated by 58% of the responding pharmacists. The results of the study presented in table 3, showed that most of the respondents agreed that there was the unavailability of professional environment to discuss ADRs. They did also agree that not only safe drugs were being marketed.

### Factors that could encourage ADRs reporting by community pharmacists.

The results on factors, which could encourage the surveyed community pharmacists to report ADRs, are presented in Table 4. There is affirmation to the obligation to report as indicated by 85% of the respondents. More (90%) of them agreed that the guidelines and bulletins on ADRs should be provided and regularly too, as well as receiving feedback from the relevant authorities, when such reports are filled. Other factors, which the community pharmacists considered encouraging, is the implementation of a simple method of reporting, such as provision of a toll free number provided by the relevant authorities. However, only 67.5% of the agreed to report ADRs at the request of a patient.

## DISCUSSION

The problem of under reporting of ADRs among pharmacist cuts across different countries as reported by various researchers.<sup>28, 29, 30, 31</sup> The region of the present survey, is a region of heavy use of non-prescribed medication.<sup>21</sup> There is a thriving use of over the counter medications. The study was aimed at evaluating the attitudes of these pharmacists towards knowledge, encountering and reporting ADRs. The response rate in the present survey was quite low. Of the one hundred and fifty questionnaires distributed among the community pharmacists, only forty of them were completed upon collection. There was unwillingness on the part of most of these community pharmacists to participate in the survey. They for some reason believed that completing the forms would create problems for their practise thus returning their forms uncompleted. Van Grootheest *et al.*,<sup>32</sup> and Elkalim *et al.*,<sup>27</sup> had reported a low questionnaire response rate among Malaysia community pharmacists. The low response rate in the present survey is contrary to the findings of Ezeulo *et al.*,<sup>18</sup> who reported a high response rate among healthcare workers at Nnewi in Nigeria and attributed this to proper sensitization. Those refusing to participate in the present survey did so out rightly, no amount of motivation was going to change their opinion. It can therefore be considered that this group of practitioners either are not ADR knowledgeable, or are not reporting cases encountered, thus thinking their response to the survey, might jeopardise their practice, refused to participate in the survey.

For the participating pharmacists however, majority of them had en-

countered cases of ADRs. They were also knowledgeable on ADRs as well as on the symptoms exhibited by patients in these cases. These findings are contrary to those of Suyagh *et al.*,<sup>16</sup> who demonstrated that majority of pharmacists in their survey had insufficient knowledge on ADRs. Awareness, they said was better amongst hospital pharmacists than those in the community pharmacies. Toklu and Uysal<sup>28</sup> had also reported similar findings to those of Suyagh *et al.*<sup>16</sup> The obtained survey results in the present investigation showed that the percentage of awareness did not correlate with the percentage of those reporting cases of encountered ADRs. A fewer number of these community pharmacists were found to be reporting ADRs and this is because they did not believe that reporting will contribute to future drug safety, neither did they think there was any need to report an ADRs of a drug which had been previously documented by the manufacturers. Earlier reports<sup>30</sup> had stipulated that there was more reporting by hospital pharmacists, which they said was 20 times more than those of community pharmacists. This they attributed to the fact that the hospital practitioners were better educated and more informed. Suyagh *et al.*,<sup>16</sup> attributed a high reporting among hospital pharmacists to the fact that they were in direct contact with other healthcare professionals who are also involved in identifying ADRs. Education was not an issue amongst the respondents in the present survey as shown from their demography. However, it was not indicated if there had been a prior hospital work experience before becoming community pharmacists. There is therefore the possibility that working in a hospital might have given an added exposure to the reporting of ADRs. The study also showed that though 65% of the respondents were aware of the existence of on-line ADRs reporting system only 40% of them knew of the existence of ADRs regulating body in Nigeria. Ezeuko *et al.*,<sup>18</sup> and Oshikoya & Awobusoji,<sup>19</sup> had noted this poor awareness among healthcare professionals to the National ADR reporting scheme. This might therefore be the reason for insufficient reporting encountered in the results from the present survey. There is therefore an indication that this problem has existed and is persisting as well as cutting across the developing countries of the world as reported by Elnorr *et al.*,<sup>33</sup> for Sudan; Bharathan *et al.*,<sup>34</sup> for India and Aziz *et al.*,<sup>35</sup> for Malaysia. Ezeuko *et al.*,<sup>18</sup> found awareness of ADR reporting scheme was higher among senior categories of practitioners and this they attributed to the longer number of years put into practise. However, contrary to their findings, John *et al.*,<sup>36</sup> and Bartel *et al.*,<sup>37</sup> found that the majority of ADRs reporting clinicians were those with less than 10 years of experience. This can be attributed to regional differences as well as differences in the educational systems and curriculums in the different geographical regions.<sup>27</sup> Some factors considered by respondents in the present survey as barriers in ADRs reporting is the non-availability of reporting forms, insufficient knowledge of pharmacovigilance in detecting ADR as well as the unavailability of a professional environment to encourage discussion about ADRs. The non-availability of reporting forms was also one of the barriers reported.<sup>16</sup> In Turkey, Toklu and Uysal<sup>28</sup> reported the lack of knowledge by pharmacists on how to reach ADRs forms and this was a barrier in the reporting of ADRs.

In Nigeria, community pharmacists play a major role in the healthcare system in the provision of medication to patients. They play a major role in the provision and management of the patient medication process. In some cases, Pharmacists are the first point of consultation by patients, as they are considered cheaper, faster and much easier to have access to. The fact therefore that most of the respondents in the present survey did not think that there was need to report OTC drugs responsible for ADR simply points to that fact that they are trying to protect their businesses.

## CONCLUSION

The study has shown that positive stance on the knowledge of ADRs exhibited by the community pharmacists, has not been reflected in the reporting of daily encountered cases. This could be attributed to insufficient knowledge on the aims and objectives of pharmacovigilance, availability of forms and who to report to. Interventions at solving this problem could be through training and educational curriculum.

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## CONFLICT OF INTEREST

None

## ABBREVIATIONS USED

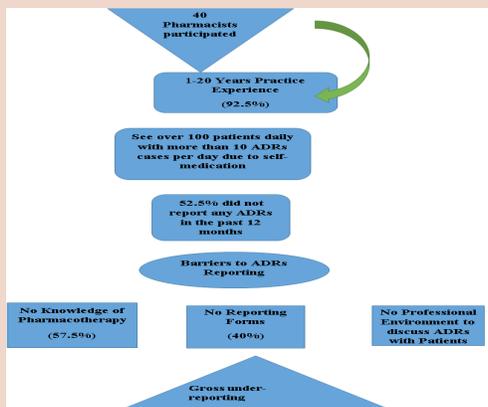
ADRs: Adverse drug reactions; SRS: Spontaneous reporting system; OTC: Over the counter medication; CP: Community Pharmacist; SPSS: Statistical Package for the Social Science; LGAs: Local Government areas.

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### PICTORIAL ABSTRACT



### SUMMARY

- Majority of the population use community pharmacies
- Community Pharmacists are afraid to report ADRs
- 92.5% have 1-20 years practice experience
- 52.5% did not report ADRs seen for fear of prosecution
- Barriers to reporting include, lack of knowledge of pharmacotherapy, no reporting forms
- Massive under reporting found
- Pharmacists want simple reporting method.

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