

Awareness, Attitude and Barriers towards Adverse Drug Reactions among Community Pharmacists in Cross River State, Nigeria.

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Abstract- Spontaneous reporting of adverse drug reactions is the foundation of drug safety evaluation after approval for use in general population. The research was carried out to assess the awareness, attitude, and barriers of community pharmacists in Cross river state towards adverse drug reactions reporting. A cross-sectional study design was conducted on sixty community pharmacists to assess their awareness, attitude and barriers towards adverse drug reactions reporting, using structured questionnaire. There was a follow up survey to assess the possibility of overcoming the barrier of unavailability of reporting forms. The response rate was ninety-five percent; Female and male respondents were fifteen and seventy-five percent respectively. The awareness was high. There was no significant difference between females and males respondents' awareness, no significant relationship between duration of service and awareness but a significant relationship existed between duration of service and attitude of the respondents towards adverse drug reaction reporting. The respondents had low level of attitude. The barriers included non-availability of yellow form, lack of financial incentives and inadequate information from patients. Follow-up survey showed that misplacement of yellow form, forgetfulness and time constraints were the barriers towards adverse drug reaction reporting. The respondents' level of awareness was high but had poor attitude. With training and motivation, their attitude can significantly change.

Index Terms- Cross River, PRASCOR, Adverse drug reactions, pharmacists, pharmacovigilance, report form

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1.0 Introduction

Adverse drug reaction (ADR) is a response to a drug which is noxious and unintended, which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. It is poorly reported globally but more in developing countries. Johnson et al. [1]. Adverse drug reactions (ADRs) occur everywhere and in every health facility setting regardless of geo-political locations. It has no regards to gender, age, race and socio-economic status but may vary in frequency and severity from one person to the other.

The burdens of ADRs continue to present as one of the greatest challenge towards the attainment of the gold standard of quality and safety in healthcare delivery worldwide. Raymond et al. [2]. It is expected that these burdens are higher in developing countries because of ignorance, poverty, self medication and increased prevalence of fake and adulterated medicines. Adedeji et al. [3].

The United States Institute of Medicine reported that more than one million preventable adverse events occur each year in the United States and 44,000 – 98,000 of adverse events are fatal. Ogundele et al.[4] This may be proportionally higher in many developing countries like Nigeria where there are no proper and adequate records

and statistics of adverse drug events. The success of a pharmacovigilance program depends upon the involvement of the healthcare professionals and reporting the ADRs. Assessing the awareness, attitude and barriers of Community pharmacists relating to spontaneous reporting of adverse drug reactions is very important. When pharmacists have sufficient knowledge of the ADR reporting process, they can improve other healthcare professionals' knowledge about ADR reporting. Khali et al. [5]

In many countries the knowledge of pharmacists about pharmacovigilance and ADR reporting is poor and the rate of reporting is low. Oreagba et al. [6] It has been realized that creating awareness on the relevance of ADRs reporting can sustain the objectives of pharmacovigilance (PVG). Currently over 11,000 completed individual case safety report forms (ICSR) have so far been received at the NPC from inception till date, translating to 8.1 reports/million inhabitants year (Oreagba et al. [6] Although WHO reported 200 reports/million inhabitants year, this is still below WHO's recommendation. On this background this research was designed to explore the knowledge, attitude and practice of adverse drug reactions reporting among the community pharmacists in Cross River State, Nigeria.

2.0 Research Elaborations

2.1 Study setting

This study was carried out in Cross River State, Nigeria. Its capital is Calabar, and is made of 18 Local Government Areas. In all the Local Government Areas, pharmacies are sparsely located except in Calabar Municipality and Calabar South.

2.2 Scope of study

This study covered only the practicing Community Pharmacists (CPs) in Cross River State. The CPs must have been practicing in the state before January 2015 and must be duly registered with PCN and ACPN as at year 2015.

2.3 Study Design

A descriptive cross sectional survey was used. Simple convenience sampling method was employed to distribute structured questionnaires to the participants during the survey. This was conducted between the month of March and April 2016 across the State. Three copies in triplicates of ADRs reporting form were provided for each participant. These were retrieved after 6-12 months. The final retrieval was done April 2017. Statistical analyses included Chi-test and Pearson Correlation test.

2.4 The instrument for data collection

The instrument for data collection was structured questionnaire to assess: Community pharmacists' awareness, attitude and barriers towards adverse drug reaction reporting.

2.5 Procedure for data collection

The questionnaires were distributed either directly, in proxy or by email.

2.6 Method for Data Analyses

Each completed questionnaire was checked manually on hard copy to ensure that there was no missing information. Data generated from the questionnaires were analyzed using the Statistical Package for Social Sciences (SPSS version 20) and results presented in tables, percentages, pie chart and. The relationships between the duration of service and awareness, males and females' awareness, and duration of service and attitude toward adverse drug reaction reporting were analyzed using Pearson correlation and 2x2 chi's square tailed tests

4.0 Results

4.1 Socio-demographic characteristics of the respondents (n = 57)

The results on the demographic characteristics are presented in table 1. A total of sixty (60) identified community pharmacists volunteered to participate in this survey. Fifty seven (57) completed the questionnaire and returned them as expected. Thus response rate was 95%. All respondents are community pharmacists in Cross River

State, Nigeria. Majority of the respondents were male 43 (75.4%) while the female respondents were 14 (24.6%). Rank of respondents at place of work varied greatly. Superintendent Pharmacists were 28 (49.0%) while the least were Pharmacist Directors and Resident Pharmacists 8 (14%) each.

Years of service of the respondents were grouped. Thirty-two (56.1%) of the respondents have spent up to five (5) years while the number of respondents who have spent between 26 – 30 years were 3 (5.3%). Universities or institutions attended by the various respondents were eleven (11). Those who attended university of Nsukka were 19 (33.3%), 11(19.2%) attended University of Benin while 1 (1.8%) attended a Pyatigersk, a foreign University in Russia

There were 18 local government areas in the State. Respondents were located across only 5 (27.5%) local government areas. Calabar Municipality had the highest number 34 (59.6%) of resident community pharmacists. Thirteen (22.5%) respondents were located in Calabar south Local Government while 1(1.8%) respondent was located in Akpabuyo local government.

4.2 Community Pharmacists' awareness of adverse drug reactions reporting in Cross River State, Nigeria (n=57)

The results presented in table 2 show the respondents' awareness of adverse drug reactions reporting. This was assessed with twelve different questions. The respondents had low awareness in 4 (33.3%) areas which included the type of ADRs reporting involved as related to community pharmacists. Fifty respondents (87.7%) indicated that Community pharmacists practiced active pharmacovigilance. Forty-three (75.4%) were of the opinion that reporting adverse drug reactions could have legal implication while used 37 respondents (64.7%) indicated that only pharmacovigilance yellow form could be used for ADRs reporting. It was also noted that 48 (84.2%) were not aware of the meaning of the acronym PRASCOR. The respondents' awareness of ADRs reporting in the remaining 8 assessment questions was very high ranging from 64.7 – 100%.

4.3 Community pharmacists' attitude towards ADRs reporting in Cross River State (n=57)

The attitudes of the respondents toward ADRs reporting were assessed and results presented in table 3. Forty three (75.4%) of respondents came across adverse drug reactions in the last three years while 14 (24.6%) did not. Out of the 43 (75.4%) who came across ADRs in the last three years, 17 (39.5%) reported the ADRs encountered, while 26 (60.5%) did not report them. A total of 13 (76.5%) respondents among the 17 who reported ADRs actually submitted the

reports, while 4 (23.5%) did not. Among the 13 respondents, 7 (54%), 2 (15%) and 4 (31%) submitted the ADRs reports in NAFDAC, ACPN and MOH respectively.

4.4 Community pharmacists' awareness of where ADRs reports should be submitted (n=57)

Submission of reported ADRs is very important to adverse drug reaction monitoring. The response to the question on where ADRs reports should be submitted was presented in fig.1 Forty (70.2%) respondents indicated that ADRs report forms should be submitted in NAFDAC office, 7 (12.3%) indicated submission of such forms at ACPN's office while 10 (17.5%) indicated that ADRs report forms should be submitted to the office of the State Ministry of Health.

4.5 Community pharmacists' barriers to ADRs reporting in Cross River State (n=57)

The indicated barriers by the respondents are presented in table 4 Thirty respondents (52.6%) agreed that non-

availability of reporting forms was a barrier. Likewise, 21 (36.9%) agreed that inadequate information from patients was a barrier. Fear of extra work load was indicated as a barrier by 13 (22.8%) of the respondents while 15 (26.3%) of the Community pharmacists in Cross River State agreed that lack of financial incentives was also a barrier. On the other hand, 56 (98.2%) of the respondents disagreed that lack of confidence was a barrier, while 54 (94.8%) disagreed that reporting adverse drug reactions was doctors' responsibility. Most of the respondents 46 (80.8%) also disagreed that time constraint was a barrier while 45 (89%) of the respondents disagreed that lack of ADRs reporting knowledge was a barrier. Also from table 4, it was noted that 54 (94.5%) of the Community pharmacists disagreed that lack of awareness of the need to report was a barrier. The fear of any legal liability for not reporting ADRs was not a barrier to most of the respondents as indicated by 48 (84.3%) of the respondents.

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Table 1 Socio - demographic characteristics of the respondents (n = 57)

Variables	Frequency(n=57)	Percentage (%)
Gender		
Male	43	75.4
Female	14	24.6
Rank at place of work		
Superintendent Pharmacist	28	49
Pharmacist Director	8	14
Managing Pharmacist	8	14
Resident Pharmacist	13	23
Local government area of practice		
Ikom	7	12.3
Ogoja	2	3.5
Akpabuyo	1	1.8
Calabar municipality	34	59.6
Calabar south	13	22.8
Year of service (yr)		
0-5	32	56.1
6-10	14	24.6
11-15	4	7
16-20	3	5.3
21-25	1	1.8
26-30	3	5.3
University attended		
UNN	19	33.3
UniUyo	9	15.8
Uni Ben	11	19.2
Uni Jos	8	14
ABU	2	3.5
OAU	2	3.5
Maddona University	2	3.5
Others	4	7.2
	57	100

Table 3 Community pharmacists' awareness of adverse drug reactions reporting in Cross River State, Nigeria (n=57)

	Response n (%)	
	Yes (%)	No (%)
Familiar with ADRs reporting process	53(91.4)	4 (8.6)
Aware of regulatory body responsible for ADRs report collection	40(70.2)	17(29.8)
ADRs report can be submitted online	50(87.7)	7(12.13)
Aware of the meaning of PRASCOR	9(15.8)	48(84.2)
PRASCOR involves the use of specialized code for reporting via SMS	44(77.2)	13(22.8)
ADRs reporting form must always be submitted in yellow form	37(64.7)	20(35.1)
Filling of ADRs must be properly done to avoid legal action	43(75.4)	14(24.6)
ADRs form should be filled by prescribers only	10(17.5)	47(82.5)
Community pharmacist who reports ADRs practices active reporting	50(87.7)	7(12.3)
ADRs should be reported only if they are new	13(22.8)	44(77.2)
ADRs should be reported only if they are life threatening	8(14.0)	49(86)
ADRs can only occur when one takes expired drugs	0(0.0)	57 (100)

Table 4 Community pharmacists' attitude towards ADRs reporting in Cross River State (n=57)

Variables	Frequency	Percentage %
Came across ADRs in the last 3 years (n=57)		
Yes	43	75.4
No	14	24.6
Reported encountered ADRs (n=43)		
Yes	17	39.5
No	26	60.5
Where ADRs report forms were submitted (n=13)		
ACPN	2	15
NAFDAC	7	53.8
MOH	4	30.8
Submitted reported ADRs (n=17)		
Yes	13	76.5
No	4	23.5

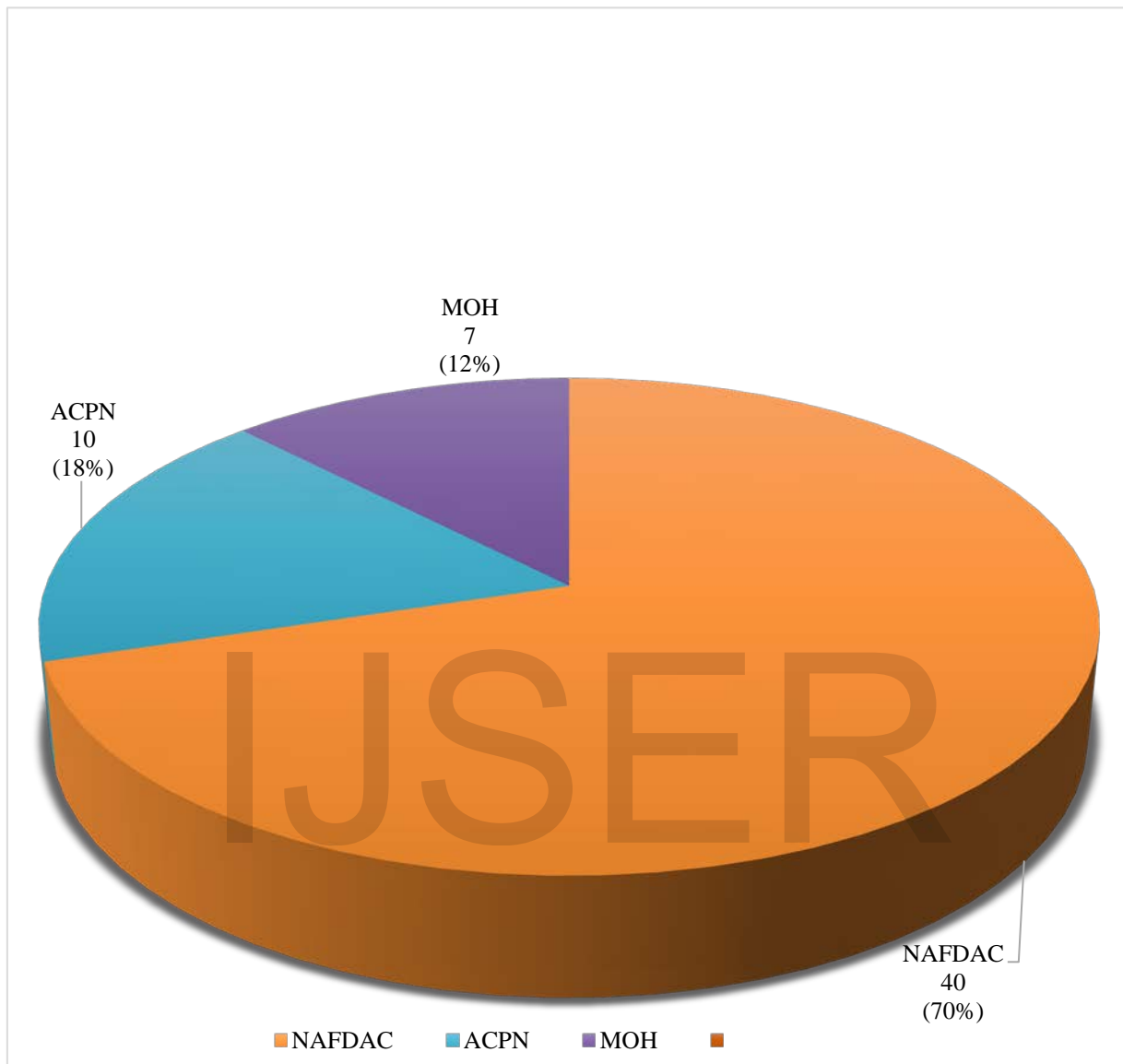


Figure1

Community Pharmacists' awareness of where ADRs report forms should be submitted in Cross River State, Nigeria.

Table 4 Community Pharmacists' barriers toward adverse drug reactions reporting in Cross River State, Nigeria (n=57)

Items	Response n (%)				
	SD	D	NC	A	SA
Unavailability of ADRs form	11(19.3)	12(21.1)	4(7)	28(49.1)	2(3.5)
Inadequate information from patients	6 (10.5)	26(45.6)	4(7)	20(35.1)	1(1.8)
Fears of extra work load	9 (15.8)	29(50.9)	6(10.5)	10(17.5)	3(5.3)
No financial incentives	17(29.8)	14(24.6)	11(19.3)	10(17.5)	5(8.8)
Forgetfulness	11(19.3)	26(45.6)	9 (15.8)	8(14)	3(5.3)
Unawareness of national ADRs reporting system	18(31.6)	24(42.1)	7 (12.3)	4(7)	4(7)
Lack of ADRs reporting knowledge	25(43.9)	20(35.1)	4 (7)	4 (7)	4(7)
Time constraint	23(40.4)	23(40.4)	8(14)	3 (5)	0(0)
Triviality of ADRs	31(54.4)	21(36.8)	3 (5.3)	1 (1.8)	1(1.8)
Fear of legal liability	25(43.9)	23(40.4)	7 (12.3)	2 (3.5)	0(0)
Lack of clear association between drug and ADRs	36(63.2)	19(33.3)	1 (1.8)	1(1.8)	0(0)
Reporting ADRs is a Doctor's responsibility	38(66.7)	16(28.1)	3 (5.3)	0(0)	0(0)
Lack of awareness of the need to report	31(54.4)	23(40.4)	2 (3.5)	1(1.8)	0(0)
Inadequate clinical knowledge of ADRs	40(70.2)	15(26.3)	1 (1.8)	1(1.8)	0(0)
Lack of confidence to discuss ADRs	34(59.6)	22(38.6)	1 (1.8)	0(0)	0(0)

Note: SD-Strongly Disagreed: D=Disagreed: NC=Not Certain:
A=Agreed: SA=Strongly Agreed

5.0 Discussion

This study sought to assess the level of awareness, understand the attitude and determine the barriers towards ADRs reporting among Community Pharmacists in Cross River, Nigeria. The response rate was very high (95%) compared to the response rate of 26% recorded by Emeka et

al. [7], in Enugu among Community Pharmacists. The number of females who participated in the survey was fewer (14, 24%) than males (43,75.4%). This is in agreement with Emeka et al. [7], where he recorded 27.5% and 67.5% females and males' participants respectively in his survey at Nsukka, Nigeria. It is noteworthy that the result was at variance to what Zimmermann et al. [8] reported in Poland where female respondents were pre-dominant, (90.5%). The result obtained in Cross River State therefore shows that more males were into Community pharmacy practice than females in ratio 3:1.

Many local government areas of the state lack pharmacists in the community setting. Five out of eighteen of the local government areas had CPs. This is a reflection of distribution problem of pharmacists in Nigeria either due to migration of pharmacists outside the country or still insufficient graduates of the noble profession on yearly basis. Although the five local government areas where there were presence of CPs, were seen as the most commercial and developed in terms of basic amenities among the eighteen local government areas. There were sixty registered Community Pharmacists as at the time of this survey in a State of more than 2.8 million people. WHO's statistics [9], stated that Nigeria has one (1) pharmacist per 10,000 of the population. The ratio of Community Pharmacists (CPs) to Cross River State population was about 1:40,000 based on this study.

Quick ADRs reporting can be done in Nigeria using PRASCOR scheme. This is Pharmacovigilance Rapid Alert System for Consumer Reporting. It involves sending SMS to the short code 20543 using MTN, GLO and Etisalat network, NAFDAC.[10] Although this is targeted at encouraging consumers in ADRs reporting, Community Pharmacists should be aware to encourage consumers to use this scheme and possibly use it as professionals to overcome time barriers. Forty-eight (84.2%) were not aware of PRASCOR Scheme introduced by National Pharmacovigilance in Nigeria since 2012. Generally, the participants have high level of awareness, but despite this high level of awareness as demonstrated by the respondents, some education during monthly meeting of pharmacists is needed to upgrade their knowledge in areas like the type of ADRs reporting system employed among Community pharmacists, legal basis of ADRs reporting and different ways reports can be submitted without necessarily using yellow form. Out of the twelve questions asked to assess their awareness towards ADRs reporting the participants scored between 65-100% which demonstrated high level of awareness. This was not the case in Lagos as reported by Oreagba et al. [6] that they had poor knowledge about pharmacovigilance. The awareness of

community pharmacists in Saudi Arabia as reported by Mahmoud et al. [11], was very poor. This report is in support of Oreagba but at variance to the situation of Community Pharmacists in Cross River State. The general opinion of the community Pharmacists in Cross River State towards their awareness on ADRs reporting was very high as indicated in their willingness and responses to the questions asked to access their awareness level.

There was no significant difference between females and males respondents' awareness towards ADRs reporting. This report is at variance with the report of Eniojukan et al. [12], in Delta State where gender was strongly correlated with respondents' knowledge of ADRs reporting. This means that female and male respondents in Cross River State are knowledgeable at same level. The correlation between duration of service and awareness is positive. This shows that there is no significant relationship between the respondents' duration of service and awareness. Respondents at all levels have high awareness of ADRs reporting.

The community pharmacists in Cross River State had poor attitude towards ADRs reporting. A significant number of the respondent 43 (75.4%) came across ADRs within the last 3 years but only 17(39.5%) reported the ADRs encountered. Those who submitted the reports were 13 (76.5%).

Oreagba et al. [6], stated that in Lagos 40% of respondents encountered ADRs but only 3% respondents actually reported the ADR to National Pharmacovigilance Centre (NPC). This earlier report is supported by this research. That is, reporting rates were poor in both states (Lagos and Cross River State among Community Pharmacist (CPs). This result is also in line with Mahmoud et al. [11] who stated that 86.5% of community pharmacist had never reported ADRs in Saudi Arabia. A study conducted in Malaysia supported also by this result, where only one (1) community pharmacist submitted ADR report Sandos et al. [13].

The implication of this is obvious, as the purpose of pharmacovigilance to ensure proper monitoring of the usage, development of new risks and benefits of pharmaceutical products after they have been released in the market will not be easily achieved. Although the attitudes of the respondents were low and poor, there is a significant correlation between duration of service and attitude. This shows that attitude of the respondents improved with number of years in service. There was a contrary report from Uganda that health care providers

including pharmacists of ≥ 30 years in service were less likely to report ADRs than their younger counterparts.

Non-availability of ADRs form (30, 52.6%); lack of attached financial incentives (15, 16.3%) and inadequate information from patients (21, 37%) were mostly indicated by respondents as barriers to ADRs reporting. The observation made during 12 months period for the respondents to utilize the ADRs forms given to them showed that only 4 (7%) respondents filled and returned the ADRs forms while 53(93%) did not. When asked why this was so, 17(32%) indicated loss of ADRs forms given to them while 12(22.6%) forgot to report ADRs. Nine (17%) of them also indicated lack of time as the reason why they could not fill the ADR forms. These are negative signs toward adequate reporting. Motivation may be necessary to overcome forgetfulness in reporting. The lack of time as a barrier was corroborated by Christopher et al. [14] in England as stated that lack of time was indicated by the respondents. In Malaysia, Elkalmi et al. [15] reported also that unavailability of report was as a barrier to ADRs reporting.

The possibility of the respondents improving in attitude toward ADRs is in doubt. For example, the respondents were given opportunity to have access to yellow forms for a year and could not overcome the barrier of lack of ADRs reporting forms, even with several calls and reminders.

5.1 Conclusion.

The study looked at Community Pharmacists' awareness, attitude and barriers towards adverse reactions reporting in Cross River State, Nigeria. Their awareness of ADRs reporting was very high without gender difference. The respondents had high opinion that they are fully aware of ADRs reporting. They also showed high interest and willingness towards the survey. Awareness improved with year of service among the Community Pharmacists in Cross River State.

The study also revealed that the Community Pharmacists in Cross River State had poor attitude towards ADRs reporting. One would have expected that high awareness level would translate to high attitude, but this was not the case among the respondents. Relationship between gender and attitude was quite significant with better attitude among males towards ADRs reporting than their female counterparts.

The barriers to adequate reporting among the respondents were observed to be in two folds. Firstly, three major causes of under reporting or poor attitude toward ADRs reporting were revealed from the responses given in the survey. Namely in ascending order: lack of financial incentives,

inadequate information from patient and unavailability of ADRs report forms. Secondly, from the follow up on utilization of ADRs reporting forms distributed to them, it was revealed that, misplacement of the yellow forms, forgetting to reports ADRs encountered and lack of time were the three major causes of not reporting ADRs adequately among those who failed to make use of the forms.

Adverse Drug Reactions (ADRs) reporting level can be improved upon among the Community Pharmacists' (CPs) in Cross River State. The willingness and awareness are factors to this. With little self motivation, their attitude can significantly and positively change.

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