**Nigerian Journal of Pharmaceutical and Biomedical Research**
**Vol. 9 Issue.1 April, 2025. p-ISSN: 2579-1419 e-ISSN: 2814-1423**

# Assessment of Knowledge, Attitude and Practice of Pharmacovigilance and Adverse Drug Reaction Reporting Among Patients in Federal Neuro-Psychiatric Hospital, Maiduguri.

Abdulazeez R[1,*], Yusuf H[1], Ohieku JD[1], Ahmed A[1]
[1]Department of Clinical Pharmacy and Pharmacy Administration, University of Maiduguri, Maiduguri, Nigeria.
**Correspondence Author**: Email: pharmrashidat500@gmail.com Phone: 07068142813

**Abstract**
*Psychotropic drugs are psychoactive medications used to manage mental illnesses. Despite their usefulness in psychiatric settings, they can be associated with significant level of morbidity and mortality owing to their adverse effects. Practically, no drug can be absolutely devoid of adverse effects, but their use has to be associated with an acceptable risk-benefit ratio. Reporting of adverse drug reactions (ADR) to a relevant authority is one of the methods of enhancing medication safety. This study therefore aimed to assess awareness, knowledge, attitude and practice of ADR reporting among patients in Federal Neuro-psychiatric Hospital Maiduguri.*
*A cross-sectional survey was conducted among outpatients in Federal Neuro-psychiatric Hospital Maiduguri. Three hundred and seventy patients were enrolled from September to November 2022. A semi-structured questionnaire was used. The questionnaire generally comprised open-ended and closed-ended questions that explored general knowledge and awareness of ADRs and pharmacovigilance, while other question-items evaluated attitudes towards ADR reporting and ADR reporting practices. The overall percentage score in the knowledge and attitude domains for the patients was developed into binary categories of > 60% versus ≤60% for "adequate" and "inadequate" knowledge, as well as "positive" and "negative" attitude, respectively. Data were summarized using descriptive statistics, while Chi-square test was used to evaluate categorical variables at $p< 0.05$ only. Only 16 (4.8%) of the patients had heard of pharmacovigilance, 35(9.5%) understood ADR, while 102(27.3%) reported previously experienced ADRs. Most patients cited ignorance of the importance of ADR reporting (35.7%) and how to report it (27.3%) as the common reasons for non-reporting.*
*Patients generally have a low knowledge and awareness of ADR reporting and a poor ADR reporting practice. To enhance ADR reporting, hospital management and other stakeholders should advocate continuous public enlightenment and awareness campaigns on spontaneous reporting of ADRs*

**Keywords:** *Pharmacovigilance, Adverse drug reactions, patients, Federal Neuro-Psychiatric Hospital*

## INTRODUCTION

Psychotropic drugs are psychoactive medications used to manage mental illnesses such as schizophrenia and psychosis among others. Despite their usefulness in psychiatric settings, they can be associated with significant level of morbidity and mortality owing to their adverse effects (Rajkumar and Melvin, 2014). An Adverse drug reaction is 'a response to a drug that is noxious and unintended and which occurs in doses normally used for the treatment, prophylaxis, or diagnosis of disease, or the modification of physiological function' (WHO, 2002). Practically, no drug can be devoid of adverse effects, but their use has to be associated with an acceptable risk-benefit ratio. One component of pharmacovigilance programs that has not gotten much attention is how adverse drug reactions are reported. After drugs are released into the market, they are likely to exhibit unexpected adverse effects (Fmhaca., 2014). The WHO Uppsala Monitoring Centre (UMC) in Sweden maintains the international database of the ADR reports. Nigeria contributes to this database in the form of the national Pharmacovigilance centre (NPC) which has been operational since September 2004. From 2004 to 2018, only 14,062 individual case safety reports (ICSRs) have been reported (Ogar *et al.,* 2019) which is very small compared to our population, to provide any conclusive and meaningful evidence. Assessing the level of knowledge, attitudes and practice of pharmacovigilance and ADR reporting among patients in federal neuro-psychiatric hospital, Maiduguri can help to identify knowledge gap and misconceptions, allowing for feature targeted educational interventions to improve understanding and awareness of ADR reporting. A recent study in the UK shows that from 2011-2013, the number of ADR cases reported by patients and their care givers increased by approximately 24%. In 2014, they reported only 30 % of the total reported cases annually (Sienkiewicz *et al*., 2022). Avery *et al*., (2011) and Rolfes *et al*., (2015) concluded that patient- reported ADRs are more descriptive. A study conducted by Babigumira *et al*. (2014) outlined that PV systems have the potential to improve health outcomes and reduce healthcare expenditures related to drug safety by identifying and reducing medication-related problems. The study showed that a fully developed tool to assess economic value could assist policymakers and donors in evaluating investments required to increase the capacity of national programs to improve the use, safety, quality, cost-effectiveness, and affordability of medicines in low and middle-income countries (LMICs).

From an economical perspective, a country's lack of a functional PV system may lead to greater costs in terms of the resources used to manage and prevent medication related problems (MRPs), poor health outcomes in terms of medicines-related morbidity and mortality as well as reduction of medicine-related quality-of life (QOL). Comparing these impacts in terms of the opportunity cost of the resources used and the adverse health impacts is important in assessing the potential value of starting or strengthening national PV centers. The safety of a drug needs to be followed during its whole life cycle. This life-cycle approach includes

identifying safety signals, designing studies to confirm them, evaluating benefits as well as risks, assessing risk–benefit assessments to integrate study results and communicating key findings to patients and physicians (Awodele *et al*., 2011). This approach to pharmacovigilance has resulted in major decisions about the safety of drugs, including the withdrawal of already approved drugs from the market.A meta-analysis published in June 2004, linked the use of rosiglitazone to an increased risk of myocardial infarction and death from cardiovascular causes (Caldwell *et al*., 2006). These results, initiated a new debate on the safety of the drug, it was later concluded that the benefits of rosiglitazone outweigh its risks within the framework of its approved indications (Solomon and Winkelmayer., 2007). However, constant revision/updating of product information and a continued monitoring of this ADR are necessary. Another safety concern is the association between aprotinin and increased mortality. In 2006, a study based on observational data was published by Mangano *et al*. in which the authors questioned the safety of aprotinin (Mangano *et al*., 2007). On November 21, 2007, aprotinin was withdrawn from the European Union market based on data from the BART clinical trial showing increased mortality for patients receiving aprotinin.

The importance of spontaneous reporting systems cannot be overemphasized in pharmacovigilance practices as a major source of signal detection. Additionally, active surveillance and the role of clinical trials play a vital role as methods of collecting ADR data.

## METHODOLOGY

### Study Site and design

The study was conducted at the Federal Neuropsychiatric Hospital (FNPH), Maiduguri. The 150-bed capacity hospital was established in 1995 by the Federal Government of Nigeria to cover the North–East zone for the treatment and prevention of mental disorders as well as drug abuse and rehabilitation of mentally ill persons. The hospital had previously also established a general clinic to cater for the general health of the surrounding people (Yusuf *et al*., 2019).

This study is a cross-sectional questionnaire-based survey among patients attending the hospital.

### Inclusion and Exclusion Criteria

Included in the study were adult outpatients who attended FNPH who were stable and capable of giving consent. Unstable patients (those who have no clear perception of their situation) were excluded from this study.

### Sample Size and Sampling Technique

Patient sample size was time based. All patients attending the outpatient clinic of Federal Neuro psychiatric Hospital, Maiduguri from 1st September to 30th November, 2022 were conveniently sampled and included in the study. Data were collected from a total of 370 patients who consented to participate in the study.

### Data collection Instrument

A semi-structured questionnaire was adopted from a previous study (Kassa *et al*., 2017; Adisa and Omitogun, 2019). The

questionnaire assessed the patient awareness and knowledge of pharmacovigilance and ADR reporting practice.

The questionnaire has three sections that explore the patients' socio-demographic variables, and variables used to measure knowledge and awareness of pharmacovigilance and ADR reporting practice.

**Data Analysis**

Collected data were sorted and entered into SPSS version 20.0 for analysis. The data were presented using frequency and percentages. The total of scores for the patients in the knowledge and attitude domains were converted into percentage scores and subsequently developed into a binary category. Any patient that defined adverse drug reaction correctly was categorized as score > 60 as having adequate knowledge. Regarding practice about ADR reporting, those who record and report at least one of the encountered ADRs are considered to have good practice while those who are unable to do this are regarded as having poor practice. The Pearson Chi-square test was used to evaluate association between the outcome and independent variables and statistical significance was set at $p < 0.05$.

**Ethical Consideration**

The study proceeded after obtaining ethical approval from the Federal Neuropsychiatric Hospital Ethics and Research Committee (Ethical approval number: FNPH 1052022/REC116).

**RESULT**

**Socio-Demographic characteristics of patients attending FNPH Maiduguri**

Table 1 shows a total of 370 patients out of the 420 eligible patients approached to participate in the study gave consent, giving us a response rate of 88%. Female patients constituted 54.9% of the study population and males were 45.14%. Majority (41.4%) were within the age bracket of 31-40, followed by those within the age of 21-30 (34.9%) and 41-50 years (11.9%). about half (42.2%) of the study population had no formal education, 7.8% had only primary education, 27% went up to secondary and only 22.9% of study population have tertiary education training. Forty nine percent of the study population were artisans, 14% were civil servant, likewise 18.7% were house wives, 7.6% were students and 13.8% were unemployed.

**Table 1 Socio-Demographic characteristics of patients attending FNPH Maiduguri**

| Variable | Frequency | Percentage % |
|---|---|---|
| Sex | | |
| Male | 167 | 45.14 |
| Female | 203 | 54.86 |
| Age(years) | | |
| <20 | 32 | 8.60 |

| | | |
|---|---|---|
| 21-30 | 129 | 34.90 |
| 31-40 | 153 | 41.40 |
| 41-50 | 44 | 11.90 |
| >50 | 12 | 3.30 |
| Education | | |
| No formal education | 156 | 42.20 |
| Primary | 85 | 23.00 |
| Secondary | 100 | 27.00 |
| Tertiary | 29 | 7.80 |
| Work status | | |
| Artisan | 170 | 46.00 |
| Civil servant | 52 | 14.10 |
| House wife | 69 | 18.70 |
| Student | 28 | 7.60 |
| Unemployed | 51 | 13.80 |

**Patients' knowledge and awareness of pharmacovigilance and adverse drug reaction reporting**

Table 2 shows 4.8% of the study population had heard of the term "pharmacovigilance and adverse drug reporting", mostly (37.5%) through social media platforms. 48% of the study population see adverse drug reaction as an expected reaction from drug use, 41.1% defined it as any effect from medications taken, 9.5% of them defined it as an unexpected reaction from drug therapy while 1% of the study population had no self-explanation for ADR. 31% of the study population defined serious adverse drug reaction as a reaction that required another drug treatment, 29.4% see it as a reaction that may lead to hospitalization, 24.8% see it as a reaction that is life threatening while 3.2% of the study population felt that serious ADR resolves on their own. Only (0.27%) respondent had a prior knowledge of the short message service (SMS) alert short code for reporting ADRs and the awareness was gotten through online source.

**Table 2: Patients' knowledge and awareness of pharmacovigilance and adverse drug reaction reporting**

| Question/Variable | Frequency | Percentage |
|---|---|---|
| Have you heard of pharmacovigilance? (n = 370) | | |
| Yes | 16 | 4.8 |
| No | 354 | 95.2 |
| If yes, source of awareness of pharmacovigilance (n = 16) | | |
| Social media platform | 6 | 37.5 |

| | | |
|---|---|---|
| Radio / television | 4 | 25.0 |
| Internet | 3 | 18.8 |
| A close healthcare professional | 3 | 18.8 |
| What is your understanding of adverse drug reaction? (n = 370) | | |
| Any effect from a medication one is taken | 152 | 41.1 |
| Unexpected reaction after taking a medication | 35 | 9.5 |
| Expected reaction | 179 | 48.4 |
| I do not know | 4 | 1.0 |
| A serious adverse drug reaction means: (n=370) | | |
| A reaction that may lead to hospitalisation | 109 | 29.4 |
| A reaction that is life-threatening | 92 | 24.8 |
| A reaction that requires another drug treatment | 116 | 31.5 |
| A reaction that resolves on its own | 12 | 3.2 |
| I do not know | 41 | 11.1 |
| Ever heard of SMS short code for reporting adverse drug reactions (n=370) | | |
| Yes | 1 | 0.27 |
| No | 369 | 99.73 |
| If yes, source of awareness of the SMS alert short code (n=1) | | |
| Online source | 1 | 100 |
| Overall cut-off for knowledge score (%) | Frequency (%) | Remark |
| Score > 60 | 35(9.5) | Adequate |
| Score <60 | 335(90.5) | Inadequate |

**Adverse drug reaction reporting practice among patients in FNPH**

Table 3 shows that 76.5% of patients attending FNPH Maiduguri had experience ADR in one form or the other and common steps taken includes: informing the healthcare professional (27.3%), continue therapy since reaction is tolerable (23.5%) and discontinuation of therapy (21.4%) . Forty three percent of patients that experienced ADR interacted with the pharmacist, 24.2% relate with physician and 21.2% through friends and families and 7.9% obtained their ADR information through the nurses.

Sixty nine percent of the study population preferred reporting ADR directly to the healthcare professionals, 24.5% preferred phone call/ text messages and 2.6% preferred filling online ADR reporting form. Cited reasons for non-reporting of ADRs included ignorance of the importance of ADR reporting (35.7%), as well as unserious nature of ADRs (19.7%)

**Table 3 Adverse drug reaction reporting practice among patients in FNPH**

| Variable | Frequency | Percentage |
|---|---|---|
| **Have you ever experienced an adverse drug reaction? (n=370)** | | |
| Yes | 283 | 76.50 |
| No | 87 | 23.51 |
| **Action taken in the case of adverse effect/reaction (n=374)**** | | |
| Informed a healthcare professional | 102 | 27.30 |
| Stopped the drug(s) | 80 | 21.40 |
| Did nothing because the reaction was tolerable | 85 | 23.50 |
| Did nothing because the reaction resolved on its own | 35 | 9.40 |
| Used another drug to treat symptoms of reaction | 33 | 8.80 |
| Switched to herbal/traditional medicine | 37 | 9.90 |
| Switched to another drug | 2 | 0.50 |
| **Sources of obtaining information about adverse drug reactions (n=458)**** | | |
| Drug leaflet | 14 | 3.06 |
| Pharmacist | 198 | 43.20 |
| Physician | 111 | 24.20 |
| Internet | 2 | 0.40 |
| Nurse | 36 | 7.90 |
| Relative/Friend | 97 | 21.20 |
| **Preferred methods of adverse drug reaction reporting (n=384)**** | | |
| Reporting directly to healthcare professional | 268 | 69.80 |
| Phone call or text messages | 94 | 24.50 |
| Online application designed for adverse drug reaction reporting | 7 | 1.82 |
| Filling a reporting form | 5 | 1.30 |
| Filling an online reporting form | 10 | 2.60 |
| **Suggested reasons why patients do not report experienced adverse drug reactions (n=370)** | | |
| Do not know the importance of reporting adverse drug reaction | 132 | 35.70 |
| Adverse reaction may not be very serious | 73 | 19.70 |
| Do not know how to report such reaction | 101 | 27.30 |
| Not sure if adverse reaction is related to the medication(s) use | 13 | 3.50 |
| Adverse effect/reactions resolved on its own | 51 | 13.80 |

** Multiple options

**4. Association between patient's Socio-demographic Characteristics and Awareness, Knowledge and Practice of Adverse Drug Reaction Reporting**

Table 4 shows a chi-square test of independence performed to examine the relation between respondent socio-demographic characteristics and ADR reporting awareness, knowledge, and practice. The relation between respondent gender and ADR reporting awareness and practice was significant at $X^2$=6.023, *P*=0.014 and $X^2$=7.920, *P*=0.004 respectively. There was also relationship between respondent age categories and ADR knowledge ($X^2$=28.142, *P*<0.05) and ADR reporting practice ($X^2$=6.026, *P*=0.01). the relationship between the respondent educational qualification with ADR reporting awareness and knowledge was also significant at $X^2$=85.995, P<0.05 and $X^2$=35.601, *P*<0.05 respectively. The table also shows a significant relationship between respondent work status and ADR reporting awareness ($X^2$=43.733, *P*<0.05)

**Table 4 Association between patient's Socio-demographic Characteristics and Awareness, Knowledge and Practice of Adverse Drug Reaction Reporting**

| Variable | Awareness | | Knowledge | | Practice | |
|---|---|---|---|---|---|---|
| Gender | Yes | No | adequate | Inadequate | Good | Poor |
| Female | 12(75) | 155(43.8) | 21(60) | 146(43.6) | 34(33.3) | 133(49.6) |
| Male | 4(25) | 199(56.2) | 14(40) | 189()56.4 | 68(66.7) | 135(50.4) |
| | $X^2$=6.023 | *P*=0.014 | $X^2$=3.449 | *P*=0.06 | $X^2$=7.920 | *P*=0.004 |
| Age | | | | | | |
| <40 | 11(68.8) | 303(85.6) | 19(54.3) | 295(88.1) | 79(77.5) | 235(87.7) |
| >41 | 5(31.2) | 51(14.4) | 16(45.7) | 40(11.9) | 23(22.5) | 33(12.3) |
| | $X^2$=3.338 | *P*=0.06 | $X^2$=28.142 | *P*<0.05 | $X^2$=6.026 | *P*=0.014 |
| Education | | | | | | |
| NFE | 2(12.5) | 154(43.5) | 2(5.7) | 154(46) | 55(53.9) | 101(37.7) |
| Primary | 1(6.25) | 84(23.7) | 3(8.6) | 82(24.5) | 20(19.6) | 65(24.3) |
| Secondary | 2(12.5) | 98(27.7) | 10(28.6) | 90(26.8) | 17(16.7) | 83(31) |
| Tertiary | 11(68.8) | 18(5.1) | 20(57.1) | 9(2.7) | 10(9.8) | 19(7.1) |
| | $X^2$=85.995 | *P*<0.05 | $X^2$=35.601 | *P*=0.05 | $X^2$=0.201 | *P*=0.977 |
| Work Status | | | | | | |
| Artisans | 2(12.5) | 168(47.5) | 6(17.1) | 164(49) | 46(45.1) | 124(46.3) |
| CS | 5(31.25) | 47(13.3) | 10(28.6) | 42(12.5) | 14(13.7) | 38(14.2) |
| House wife | 2(12.5) | 67(18.9) | 6(17.1) | 63(18.8) | 18(17.6) | 51(19) |
| Students | 4(25) | 24(6.8) | 11(31.4) | 17(5.1) | 10(9.8) | 18(6.7) |
| Unemployed | 3(18.75) | 48(13.6) | 2(5.7) | 49(14.6) | 14(13.7) | 37(13.8) |
| | $X^2$=14.949 | *P*=0.0048 | $X^2$=43.733 | *P*<0.05 | $X^2$=1.039 | *P*=0.903 |

NFE- No Formal Education CS- Civil Servant

**Table 5 Summary of Awareness, Knowledge and Practice of pharmacovigilance and ADR reporting among patients attending FNPH Maiduguri**

Table 5 Shows that only 16(4.8%) of the patients attending FNPH were aware of PV and ADR reporting, and only 35(9.5%) of the respondent have adequate knowledge ADR. However, up to 102(27.3) of the patients exhibit good ADR reporting practices.

Table 5. **Summary of Awareness, Knowledge and Practice of pharmacovigilance and ADR reporting among patients attending FNPH Maiduguri**

| variable | Awareness | | Knowledge | | Practice | |
|---|---|---|---|---|---|---|
| | Yes | No | Adequate | Inadequate | Good | Poor |
| Score | 16(4.8%) | 354(95.4%) | 35(9.5%) | 335(90.5%) | 102(27.3%) | 268(72.7%) |

## DISCUSSIONS

Pharmacovigilance is an aspect of pharmaceuticals which deals principally with the recognition, management and reporting of ADRs which may result from medicines taken at normal doses for prophylaxis or treatment of a disease. These ADR may vary from a simple reaction to a permanent disability or death. This study assessed awareness and knowledge, attitudes and practice of pharmacovigilance and ADR reporting among patients and factors hindering the reporting in Federal Neuropsychiatric hospital Maiduguri.

It is important to note that, out of the 370 respondents in this study. Less than 5% had heard of the term pharmacovigilance and only 1(0.27%) was aware of the short message service (SMS) alert code for reporting ADR. However, previous studies have also reported low level of awareness of pharmacovigilance activities among patients (Robertson and Newby., 2013; Adisa and Omitogun., 2019). This study also revealed that less than 10% of respondent displayed a good understanding of the term ADR. It is also important to note that 37.5% and 25% of the respondent who have heard of pharmacovigilance became aware through social media and radio/television respectively. Social media and multimedia had long been recognized as a potential means of creating patient awareness (Ishak and Harris., 2016). These platforms and others (internet/online) if utilized properly may be used to sensitize and create awareness on pharmacovigilance activities with subsequent improvement in ADR reporting.

However, majority of the respondents claimed to have experienced ADR. Common measures taken by patients include informing healthcare professionals and neglecting the reaction as it was tolerable. Most of the patients got to know about ADR after interacting with the pharmacist and the physicians. More than half of the respondents preferred reporting ADRs directly to the healthcare professionals and less than half preferred to make phone calls or send text messages to a designated number. This underscores the need to explore a combination of approaches in ensuring

proper and early dissemination of information regarding suspected ADR.

## CONCLUSION

Majority of the patients actually demonstrated a low level of pharmacovigilance awareness and poor level of ADR reporting practice. majority of the patient's cited ignorance of importance of ADR reporting and how to report it as the common reasons for non-reporting.

## Recommendations

1. The hospital management should create policies that encourage patient or healthcare consumers to report ADR.
2. To enhance ADR reporting, hospital management and other stake holders should advocate continuous public enlightenment and awareness campaigns on spontaneous reporting of ADRs.

## REFERENCES


Adisa, R., and Omitogun, I. T. (2019). Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centers in Ibadan, southwestern Nigeria. *Biomed Central Health Services Research,* **19**(1): 92-95.

Avery, A., Anderson, C., Bond, C. and Watson, M. (2011). Evaluation of patient reporting of adverse drug reactions to the UK "Yellow Card Scheme": literature review, descriptive and qualitative analyses, and questionnaire surveys. *Health Technology Assessment*, **15**(20): 231–234.

Awodele, O., Akinyede, A., Adeyemi, O.A. and Awodele, DF. (2011). Pharmacovigilance amongst doctors in private hospitals in Lagos West Senatorial District, Nigeria. *International Journal of Risk and Safety in Medicine*, **23**(4):217–226.

Babigumira, J.B., Stergachis, Andy, Hye Lyn Choi, Alexander Dodoo, Jude Nwokike and Louis P. Garrison Jr. (2014). A framework for assessing the economic value of pharmacovigilance in low- and middle-income countries. *Drug Safety*. DOI 10.1007/s40264-014-0143-1

Caldwell B, Aldington S, Weatherall M, Shirtcliffe P and Beasley R. (2006). Risk of cardiovascular events and celecoxib: a systematic review and meta-analysis. *Journal of the Royal Society of Medicine*, **99**(3):132–40.

Fmhaca, (2014). Guideline for Adverse Drug Events Monitoring (Pharmacovigilance), Fmhaca, Addis Ababa, Ethiopia, 3 editions.

Ishak omar harris elaine. (2016). The use of social media in ADR monitoring and reporting. *Journal of pharmacovigilance*, **04**(06): 223-240

Kassa Belete, Mulu and Andugnaw, Berhanu Geresu. (2017). Healthcare providers knowledge, attitude and experience of adverse drug reaction reporting. *African Journal of Pharmacy and pharmacology*, **11**(31): page 362-367.

Mangano, D.T., Miao, Y., Vuylsteke, A., Tudor, I.C., Juneja, R., Filipescu, D., et al. (2007). Mortality associated with

aprotinin during 5 years following coronary artery bypass graft surgery. *Journal of American Medical Association*. **297**(5):471–479.

Ogar Kunak Comfort, Abiola Abiodun, Yuah Daniel, Ali Ibrahim, Adekunle Ibrahim Oreagba, Amadi C. Emmanuel et al. (2019). Retrospective review of serious adverse drug reaction reporting in Nigeria VigiFlow Database from September 2004 to December 2016. *Pharmaceutical Medicine*, **33**(2): 145-157.

Rajikumar Ravi Philip and Melivin George. (2014). Pharmacovigilance for psychiatrists: An introduction**.** *Indian Journal of Psychiatry,* **56**(2):176-181.

Roberson jane and Newby A. David. (2013). Law awareness of adverse reaction reporting systems: a consumer survey. *Medical Journal of Australia*, **199(**10): 684-686.

Rolfes, L., van Hunsel, F., Wilkes, S., van Grootheest, K. and van Puijenbroek, E. (2015). Adverse drug reaction reports of patients and healthcare professionals-differences in reported information. *Pharmacoepidemiology and Drug Safety*, **24**(2): 152–158.

Sienkiewicz K, Burzyńska M, Rydlewska-Liszkowska I, Sienkiewicz J, Gaszyńska E. (2022). The Importance of Direct Patient Reporting of Adverse Drug Reactions in the Safety Monitoring Process. *International Journal of Environmental Research and Public Health*. **19**(1):413

Solomon D.H and Winkelmayer W.C. (2007). Cardiovascular risk and the thiazolidinediones: déjà vu all over again? JAMA. 298(10):1216-8.

World health organization. (2002). Safety of medicines: A guide to detecting and reporting adverse drug reactions. World health organization. Geneva.

Yusuf, H., Ohieku, J.D., Haruna, W.K., Bello, F.A. and Abdul-Aguye, S. N. (2019). Medication knowledge and beliefs in patients with Major depressive disorder at a tertiary health facility in North East Nigeria. *journal of Pharmaceutical Research*, **15**(2): 143-152.