



**ADVERSE DRUG REACTIONS REPORTING: A COMPREHENSIVE REVIEW OF
THE PRACTICE AMONG COMMUNITY PHARMACISTS IN NIGERIA**

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Abstract

Adverse drug reactions (ADRs) continue to be a global health concern, causing an enormous impact on treatment outcomes, increased hospital admission rates, morbidity and mortality rates, raised therapy costs, lower quality of life, and lower patient satisfaction with healthcare. The aim of this review was to assess the practice of adverse drug reactions reporting among community pharmacists in Nigeria. The study's objective was to review the practice of adverse drug reaction reporting among community pharmacists in Nigeria. A comprehensive electronic search on published articles, from 2002 to 2024, on adverse drug reactions reporting among community pharmacists and related issues was conducted. Searches were performed on PubMed, Cochrane libraries, Google and Semantic Scholar. Advanced Boolean searches were utilized for focused results, limited to English language articles. Several barriers including but not limited to inadequate knowledge about ADRs, inadequate training and inefficient procedures, have resulted in low ADR reporting rates within this crucial cohort. Community pharmacists in Nigeria play a crucial role in the country's pharmacovigilance efforts by reporting adverse drug reactions, which guarantee the continued safety and effectiveness of drugs used by the populace. It is possible to greatly increase community pharmacists' involvement in adverse drug reactions reporting by eliminating the identified barriers through focused education, streamlining the reporting procedure, improving feedback systems, and creating a supportive regulatory environment.

Keywords: Adverse Drug Reactions, Community Pharmacist, Reporting, Practice, Pharmacovigilance

INTRODUCTION

Adverse Drug Reactions (ADRs) continue to be a global health concern, causing an impact on treatment results, increased hospital admission rates, morbidity and death rates,

increased therapy costs, lower quality of life, and lower patient satisfaction with healthcare.¹ ADRs was defined in the 1980s by the International Conference on Harmonization of Technical Requirements

for Registration of Pharmaceuticals for Human Use, of which the World Health Organization is a member, as 'a response to a drug which is noxious and unintended, and which occurs at doses normally used for prophylaxis, diagnosis, or therapy of disease or the modification of physiologic function'.² ADRs are an important cause of increased health costs, increased morbidity and mortality rates¹. About 10% of outpatients experience adverse drug reactions, ADRs result in 5–10% of hospital admissions, and 10%–20% of hospitalized patients develop ADRs, which lengthens their average hospital stay.³

For every 1,000 patients, there are six Emergency Department visits related to therapeutic and non-therapeutic pharmaceutical hazards; around 38% of these visits result in hospitalization.⁴ ADRs also cause a patient's death in 3 out of every 1000 hospital admissions⁵. In Nigeria, not much is known about ADRs especially with the existing weak post marketing surveillance for monitoring drug use and its effect on the population. However, the incidence rate of ADRs in Nigeria was estimated at 10.7% in 2015.⁶ The reported incidence showed the need for interventions to efficiently report ADRs especially among community health pharmacies in Nigeria.

Community Health Pharmacies (CHPs) are private healthcare establishments run under the direction of licensed pharmacists. Customarily, they offer a range of primary healthcare (PHC) services, such as dispensing over-the-counter (OTC) and prescription drugs, patient counseling and education,⁷ and are often the first point of

contact for patients, particularly for OTC medications. In Nigeria, the provision of primary healthcare services is greatly aided by community pharmacies.⁸ The majority of community pharmacies in Nigeria, more than 90% of them, are small to medium-sized businesses that operate as independent retail establishments.^{8,9}

Medication Post-marketing Surveillance (PMS) is the method used to track marketed drugs for ADRs following clinical trials. Since phase III clinical trials are necessary for most medications to be approved for sale, phase IV investigations are thought to include PMS research.¹⁰ Clinical trials used to assess the safety and efficacy of new medications provide only limited information about uncommon ADRs.¹¹ It is during the PMS that 'rare' (1 in 1000) and 'very rare' (1 in 10,000) ADRs are discovered.¹² The primary cause of this is the small range of conditions, referred to as the 'five toos' (too few, too simple, too narrow, too median-aged, and too brief), which are caused by the low sample size and patient selection criteria along with the short duration of clinical studies.¹¹ This makes it challenging to attain all the required safety data when relying exclusively on such studies. ADRs associated with the use of contrast media, medical equipment, vaccinations, allopathic drugs, and traditional medicines are encouraged to be reported.¹³ ADRs are reported using ADR forms, also known as yellow cards and can be reported by the patient, public or healthcare professional.¹⁴

An essential component of pharmacovigilance (PV) is gathering and examining individual adverse reaction

reports.¹⁵ ADR reporting is important because it contributes to achieving the goals of the PV system which is the promotion of safe and effective use of medicinal products as well as a constant update of the information on the product safety.¹⁶ Previous researches from developed countries have shown that healthcare workers like pharmacists play a vital role in reporting ADRs, particularly in a community pharmacy setting, due to their extensive medication expertise and close proximity to the patients.^{17,18} Thus, this review aims to describe adverse drug reactions reporting among community pharmacists in Nigeria.

METHODS

Search strategy

This was a narrative review. A narrative review was chosen over a systematic review or meta-analysis as it allows for a broad thematic exploration of reporting of adverse drug reactions by community pharmacists, accommodates the heterogeneity of studies that vary in design and outcomes, while integrating emerging research from multiple disciplines. To achieve this, a detailed electronic search of published articles in English language was conducted, with the search period limited to between 2005 and 2025 to ensure the articles' recency. Searches were performed on PubMed, CINAHL, Cochrane libraries, Google, and Semantic Scholar. Advanced Boolean searches were employed to obtain focused results, limited explicitly to English-language articles.

Screening and Study selection

To guide against bias, Cochrane RoB was used to assess the quality of the study. Two reviewers independently reviewed the titles, abstracts, and full articles. Duplicated and incomplete articles were manually removed, and the remaining articles were assessed based on selection criteria.

Theoretical framework

The theoretical underpinning of this paper is significantly the Theory of Planned Behaviour (TPB). The involvement of community pharmacists' in the reporting of adverse drug reactions can be viewed through the lens of the theory of planned behaviour. The three key factors that compose the TPB that can influence the community pharmacists' behaviours include:

Attitude towards the behaviour: refers to the pharmacists' beliefs about the importance and consequences of reporting ADRs. This means that if community pharmacists perceive ADR reporting as beneficial to patient safety and public health, they are more likely to engage in it.

Subjective norms: This involves the influence of peers, professional bodies, and regulatory expectations on pharmacists' intentions to report ADRs. If pharmacists believe that their colleagues or professional organizations expect them to report ADRs, they may be more motivated to do so.

Perceived behavioural controls: This refers to the pharmacists' perception of their ability to report ADRs, considering factors such as time, resources, knowledge, and the simplicity or complexity of the reporting process. If pharmacists feel confident and

capable of reporting ADRs, they are more likely to engage in this behaviour.

Using the TPB as a theoretical framework allows an exploration of how these factors influence the likelihood of community pharmacists in Nigeria participating in ADR reporting, providing a comprehensive understanding of the barriers and facilitators. This approach can also help in designing interventions to enhance ADR reporting practices by targeting these specific factors.

Overview of ADR Reporting

ADR reporting is pharmacovigilance which involves the collection, documentation and evaluation of information about adverse effects in patients taking medications or pharmaceutical products.¹⁹ It involves systematically reporting any unexpected, harmful or unintended reactions in patients that result from using drugs, vaccines, herbal medicines or medical devices.¹⁹ The key objective of ADR reporting is to improve patient safety and enhance safe drug practices. At the core of this framework lies the major goal of patient safety, highlighting the importance of protecting patients from potential medication-related harm.^{20,21}

ADR reporting promotes the early detection of safety issues by monitoring and analyzing adverse effects beyond clinical trials, which are sometimes limited by sample size and short duration of clinical studies.¹⁰ Post-marketing surveillance is ensured through ADR reporting because it extends drug safety surveillance beyond clinical trials to monitor the real-world safety of medications in a larger patient population.¹⁹ ADR reporting also aids in signal detection by identifying

potential safety concerns related to specific drugs based on reported adverse events²¹. Data collected from ADR reports influence regulatory decisions such as updating safety labels, issuing warnings or withdrawing drugs if necessary, through its ability to ensure regulatory decision-making.²² Aggregated ADR data aids public health and epidemiological research which helps to identify trends and patterns in adverse events on a broader scale. Healthcare professionals utilize ADR reports to make informed decisions about drug choices, dosages and patient management thus enhancing healthcare practices.^{19,23}

Global Perspective of ADR Reporting

Worldwide Pharmacovigilance (PV) initiatives are managed by the WHO's Programme for International Drug Monitoring (PIDM). Operationally, the initiative is overseen by the Uppsala Monitoring Centre (UMC) in Sweden,²⁴ which also manages the global database (VigiBase) of ADR reports that National Centers submit.²⁵ The governments, those in possession of marketing authorizations, medical professionals, academics, patients, and the media have all been recognized as essential collaborators in the monitoring of drug safety.²⁶ Healthcare professionals' and market authorization holders' reporting of ADRs have greatly aided in the PV system's ongoing development in both developed and developing nations.^{24,25} Nevertheless, a significant contributing factor remains the global under-reporting of ADR.²⁵⁻²⁷

ADRs Reporting in Africa

The morbidity and mortality rate from ADRs in Africa has not been extensively studied.²⁸ Thirty-five studies from 12 countries were found to have a median under-reporting rate of 94% after a thorough literature search.²⁹ From 1992 to 2015, African nations submitted less than 1% of all ADR reports to the WHO PIDM.²⁹ The following factors contribute to PV activities and under-reporting in Africa: inadequate personnel, inadequate infrastructure, fear of litigation, inadequate training and limited awareness among healthcare workers in PV and pharmacoepidemiology, cultural and social factors, ethnic and racial differences, patient ignorance, poor health-seeking behaviour, self-medication, medication errors, medication quality issues, counterfeit and substandard products, as well as weak policy and legal framework.²⁸⁻³⁰ The early identification and evaluation of medication safety issues are hampered by under-reporting, and in nations where resources are few, it is necessary to adopt appropriate PV techniques to enhance government healthcare policies.

ADR reporting in Nigeria

In Nigeria, PV faces many difficulties in monitoring side effects and guaranteeing medication safety. Research has shown a number of problems with the nation's PV program.

A significant factor that must be addressed for efficient PV is the underreporting of ADRs.³¹ Underreporting is linked to patients' and healthcare workers' ignorance of formal reporting procedures, awareness, and knowledge gaps.³² Effective PV techniques are further hindered by the lack of structured

training programs for healthcare workers.³³ Although they face obstacles like poor reporting procedures and perceived difficulties with implementation, pharmacists, including interns play a crucial role in PV efforts.³⁴ Adisa *et al.*,³⁵ assert that tackling these difficulties requires a proactive response from stakeholders, especially the National Pharmacovigilance Centre (NPC).

Neurological effects like dizziness, headaches, drowsiness, confusion, and tremors, dermatological reactions (itching, urticarial) and the more severe condition known as Stevens-Johnson syndrome, and gastrointestinal disturbances like nausea, vomiting, diarrhea and abdominal pain are the most common ADRs that affect patients in general.³⁵ The healthcare resources of any community are severely strained by these ADRs. The commonly used drug classes that cause ADRs in patients are the anti-inflammatory, gastrointestinal, antibiotics, cardiovascular, anti-diabetes and anticancer drugs.

The National Agency for Food and Drugs Administration and Control (NAFDAC) is home to the National Pharmacovigilance Centre (NPC), which maintains a database of all adverse drug reactions recorded in Nigeria.³⁶ Numerous examples exist of medications that were withdrawn from the Nigerian market due to reports of their ADRs. The rapid withdrawal of hazardous acetaminophen contaminated with diethylene glycol, which killed several newborns and young children in 2008, was made possible by spontaneous reporting of ADRs to the NPC.³⁷ Due to the frequent injection abscesses and mysterious deaths linked to its

use, dipyrone was also prohibited in 2005. Therefore, to ensure patient safety, ongoing post marketing surveillance and signal identification from the NAFDAC Pharmacovigilance database are crucial.^{38,39} Safety of medication assessment requires a review of adverse drug reaction reports to NAFDAC, in order to identify patterns of ADRs signals in NAFDAC pharmacovigilance efforts, and investigate information concerning new and unexpected adverse drug reactions reported.

When reporting ADRs to the NAFDAC, healthcare providers in Nigeria rely on the 'yellow form'. The yellow form usually contains information about the patient's demographics, the name, dose, and mode of administration of the suspected drug, the type of adverse reaction, when it started, and any other pertinent medical history or concurrent drugs.⁴⁰ The Yellow Form can be completed by doctors, pharmacists, nurses, and other healthcare professionals, guaranteeing that a wide spectrum of experts can participate in the PV process. This form provides a crucial feedback loop that aids in the ongoing monitoring of drug safety by making it easier to gather information on the effectiveness and safety of pharmaceuticals after they have been put on the market. This allows NAFDAC to evaluate the risk of a given drug and take appropriate regulatory action, which may include warnings, changing usage guidelines, or even pulling a product off the market. This proactive PV strategy guarantees that the general public is protected from the potential risks associated with the use of pharmaceutical products.¹⁴⁻¹⁶

ADRs Reporting and Community Pharmacists' Practice in Nigeria

Community pharmacies are the first line of defense for the identification and reporting of any drug-related problems, and they are vital to the reporting of ADRs in Nigeria.^{41,42} These pharmacies play a crucial role in the early detection and recording of ADRs because they are frequently the initial point of contact for patients who may have unanticipated or hazardous medication reactions. Community pharmacists are in charge of closely monitoring how well patients are responding to prescription drugs, educating patients on safe drug usage, and reminding patients of the significance of reporting any ADRs.^{42,43} Community pharmacies provide the NAFDAC with important data through active participation in PV.⁴⁴⁻⁴⁶ By assisting in the discovery of patterns or trends in ADRs, this reporting may eventually result in the implementation of regulations that safeguard the public's health.^{47,48}

There are several interconnected factors that contribute to the low participation rate of community pharmacists in ADRs reporting in Nigeria. These factors posed different barriers to the success of PV. Community pharmacists' lack of knowledge and instruction regarding the significance and procedures for reporting ADRs is one of the main problems. It's possible that many community pharmacists lack the pharmacovigilance-focused continuing education or professional development that they need, which leaves a knowledge and engagement gap.⁴² ADR reporting is also frequently neglected by community

pharmacists because to their busy schedules and time constraints, which arise from balancing a variety of duties such as prescription administration and patient consultations. There are also little or no incentives available for taking part in ADR activities, which lowers motivation.⁴³ Pharmacists are discouraged from engaging in the ADR reporting process due to the perceived complexity of the process, which involves filling of the yellow form and uncertainty about the results of these reports. Studies have shown that insufficient feedback from regulatory bodies regarding submitted ADRs complaints might make pharmacists feel discouraged, which lowers their propensity to report in the future.⁴²⁻⁴⁵

The problem is made more difficult for pharmacists to continuously contribute to PV efforts by the lack of a reliable and user-friendly reporting system incorporated into community pharmacists' everyday operations.³⁷ By addressing these obstacles with focused training initiatives, streamlined reporting procedures, and increased regulatory body assistance, community pharmacists' participation in ADR reporting in Nigeria could be greatly enhanced.

Challenges to ADR Reporting in Nigeria

Sustaining an efficient ADR reporting system is still challenging, given Nigeria's weak healthcare standards and growing population. Positive initiatives at PVC by the government continue to be hampered by inadequate staffing, poor remuneration and compensation of healthcare personnel, work environment constraints and ineffective reporting systems,⁴⁶⁻⁴⁸ consequently, ADRs in clinical practice continue to be under-

reported. The lack of access to cutting-edge medical services and technology for the purpose of tracking, reviewing, and reporting ADRs presents a number of difficulties for medical professionals who are responsible for PV among the general population.⁴⁸ The increased rates of ADRs seen in clinical practice in Nigeria can be attributed to a number of factors, including increased rates of polypharmacy, counterfeit drugs, the prevalence of co-morbidities, widespread use of herbal medicines, age-related physiological deterioration, and changes in pharmacodynamics and pharmacokinetics that alter drug metabolism.^{49,50}

Recommendations

Regular and focused training courses to raise community pharmacists' awareness of ADR reporting should be conducted. For healthcare students particularly medical and pharmacy students, pharmacovigilance and drug safety practices modules should be added to the students' curriculum. Healthcare facilities and pharmacies should establish an ADR department or unit, led by a trained staff, in order to enhance reporting practices and establish documentation protocols for ADRs.

Creating user-friendly mobile applications or digital platforms that make it simple and quick for pharmacists to report ADRs can expedite the ADR reporting process. While the NAFDAC have improved its website and provided an ADR e-reporting form online, they have performed poorly in educating the healthcare professionals on ADR reporting and creating adequate awareness to ensure these resources are utilized effectively. Increased efforts should be made to educate

community pharmacists about the vital role that they play in guaranteeing medication safety by reporting adverse drug reactions. To promote more active engagement, implementing incentives like Continuous Professional Development (CPD) credits or recognition rewards will be useful. Professional organizations, such as the Pharmacists Council of Nigeria (PCN) and the Association of Community Pharmacists of Nigeria (ACPN) should collaborate to promote a culture of ADR reporting. Advocacy by NAFDAC and other relevant bodies to create policies that support and facilitate ADR reporting, such as providing resources, offering regular updates on drug safety issues, and ensuring easy access to reporting tools and information should be fostered. Public awareness and education about the importance of reporting ADRs should be increased by involving patients in the PV process which can, in turn, enhance the overall reporting culture.

Conclusion

Community pharmacists in Nigeria play a crucial role in the country's PV efforts by

reporting ADRs, which guarantees the continued safety and effectiveness of pharmaceuticals used by the general population. Certain barriers including inadequate training and knowledge on ADRs reporting, inadequate training, and inefficient procedures, have resulted in low ADRs reporting rates among the community pharmacists. Eliminating these barriers through focused education, streamlining the reporting procedure, improving feedback systems, and creating a supportive regulatory environment with concerted and coordinated efforts by regulatory agencies, healthcare professionals and the general public will improve ADRs reporting.

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Conflicts of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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